LAURA XL

Urine Analyzer



USER MANUAL

REF INS00065

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Preface

The User Manual for the fully automated urine analyzer LAURA XL was created as a property of Erba Lachema s.r.o. All the information contained in User Manual may not be edited nor published unless Erba Lachema s.r.o. has given prior written approval.
All the technical information and parameters of the urine analyzer LAURA XL and its application were published by Erba Lachema s.r.o in a good faith, but may contain errors. The User Manual is only intended to help the user with the control of the LAURA XL urine analyzer, therefore Erba Lachema s.r.o is not responsible for any damages or losses of any kind arising from the usage, provided information, data errors or omissions contained in this manual.
Users of LAURA XL urine analyzer shall act in compliance with the warnings and comments which serve as a means of their protection against injury or damage to the device, respectively.
Inappropriate use of LAURA XL urine analyzer and/or failure to act in compliance with the prescribed manner of use and maintenance procedures shall result in a loss of product warranty and may even result in injury.
LAURA XL urine analyzer is designed for urine analysis based on diagnostic strips as well as analysis of urine sediment.

Icons

The following symbols are used on the instrument to aid the user:

	Warning:	Review the section related to installation of the analyzer.
	Information:	Read the instructions carefully before attempting practically.
	Biological Risk:	Certain biological risk is related to this product due to the nature of materials which are used for analyses. Take appropriate pre-cautions in this User manual below.
	High Temperature Hazard:	Certain hazard is associated with dessicators inside the analyzer. The temperature can reach 100 °C.
	Storage Conditions	Store the analyzer at temperatures within the range between 0° C and +40 °C.
	IVD:	This analyzer is covered by the EU Directive governing IVD (In Vitro Diagnostic Products).
	CE:	This product contains CE mark.
	Manufacturer:	This analyzer is manufactured by an appointed producer for Erba Lachema s.r.o.
	Manufacturing Date:	Indication of the date on which a product was manufactured. The symbol is present on a back side label of the analyzer.
	Serial Number:	Denotes the product serial number.



SGHS07

Danger pictogram of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), used as of 2017. Regulated in E.U. as the 'CLP Regulation', and United States 'Occupational Safety and Health Administration' standards. General meanings can be Toxic, irritant, sensitizer, narcotic. It is part of the Health danger class (SGH05 to SGH08)
The logo is accompanied by
Signal word: "Danger" or "Warning" to indicate the relative level of severity of the hazard GHS hazard statement: codes starting with H, translated in Standard phrases assigned to a hazard class and category that describe the nature of the hazard.
GHS precautionary statements: Codes starting with P, translated into standard phrases of measures to minimize or prevent adverse effects.



Waste Disposal:

The symbol depicted on the device means that the device may not be handled as standard household waste. Disposal of the product (analyzer) is to be performed at the location reserved for collection and recycling of power appliances and electronic products. By the means of ensuring due disposal of the product you can prevent possible negative impact on the environment and human health, which might result from inappropriate handling with the product in connection with its disposal. Please consult your competent local authority or distributor of this product.
The used diagnostic strips should be treated as potentially infectious material and disposed of in accordance to local regulations regarding the safe handling of these materials.

The following icons are used throughout the manual to help the user:

	Warning:	Please, pay special attention to the information presented in association with this icon. Safety of the user or device may be endangered.
	Note:	This item is worth noticing.
	Information:	Review the User manual or guides to individual reagents and consumables prior to commencement of measurement.
	Biological Risk:	Perform decontamination of all parts of the analyzer prior to any service work. Act in compliance with the respective security level – in connection with use of the analyzer, handling of analyzed samples or waste; use a laboratory coat, gloves and protective goggles. Consider all human-source material (measured samples, controls) as potentially contagious. Dispose of all liquid waste in accordance with local regulations. Pre-treatment of liquid waste is recommended.

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2. Overview

2.1 General Description

LAURA XL analyzer is designed for in vitro semi-quantitative evaluation of urine analytes using diagnostic test strips PHAN® Auto and evaluation of urine sediment using automatic microscopy. The result evaluation is based on image analysis of the colour change on particular pad of the diagnostic strip as well as the analysis of sediment elements based on learned classifiers and neural networks. Full automation is represented by the intuitive transport system, automatic homogenization and dosing of urine sample, processing and evaluation of the sample and eventually by saving or transferring of the results to LIS. Operation with LAURA XL analyzer is facilitated by user-friendly LCD screen with convenient user interface.



2.2 Intended Use

Urinalysis is intended for use to reveal conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney dysfunction, and urinary tract infections. Diagnostic test results can be evaluated along with other diagnostic information to assess certain disease states and to decide if microscopic analysis is needed.
The Laura XL Urine Analyzer is fully automated integrated urine analyzer, hybrid system combining urine test strip chemistry and urine microscopy, producing microscopic images of urine sediment and automatically classifying and counting urine sediment particles from the images together in a single integrated device.
The test strip chemistry module is an automated urine analyzer intended for the in vitro measurement of the following parameters: specific gravity, leukocytes, nitrite, pH, protein, glucose, ketones, urobilinogen, bilirubin, blood, ascorbic acid, microalbumine and creatinine, (depending on the type of test strips), plus color and turbidity. The chemistry module is intended for use with the 3 types of multi-parameter urine chemistry test strips (DekaPHAN® Auto, UnDekaPHAN® Auto, or DoDekaPHAN® Auto)

The urine microscopy module is an automated urine particle analyzer intended to analyze the following parameters in urine samples: red blood cells, white blood cells, white blood cell clumps, squamous epithelial cells, non-squamous epithelial cells, hyaline casts, pathological casts, sperms, mucus, small crystals, uric acid, calcium oxalate dihydrate, triple phosphate crystals, yeasts and rod or cocci shaped bacteria, and dysmorphic red blood cells (ghost/half lysed and echynocytes/acanthocytes. In addition, from the images, the user can manually identify the following categories: red blood cells clumps, granulated casts, cell casts, waxy casts, red blood cell casts, white blood cell casts, renal epithelia casts, fatty casts, calcium phosphate crystals, leucin crystals, cystine crystals, tyrosine crystals, amorphous crystals, cholesterol crystals, fat droplets and trichomonas

PHAN Auto Urine Test Strips:

- DekaPHAN® Auto Urine Test Strips is a urinalysis test strip with reagent pads for the determination of specific gravity, leukocytes, nitrite, pH, protein, glucose, ketones, urobilinogen, bilirubin, and blood (10 parameters).
- UnDekaPHAN® Auto Urine Test Strips is a urinalysis test strip with reagent pads for the determination of specific gravity, leukocytes, nitrite, pH, ascorbic acid, protein, glucose, ketones, urobilinogen, bilirubin, and blood (11 parameters).
- DoDekaPHAN® Auto Urine Test Strips is a urinalysis test strip with reagent pads for the determination of microalbumin, creatinine, specific gravity, leukocytes, nitrite, pH, protein, glucose, ketones, urobilinogen, bilirubin, blood, (12 parameters).

All PHAN® Auto Urine Test Strips are for use with the Laura XL Urine Analyzer only.
The Laura XL Urine Analyzer and PHAN® AUTO urine test strips are intended for In Vitro Diagnostic use in screening patient populations found in clinical laboratories and for professional use only.

2.3 Scientific principle

LAURA XL is a fully automatic urine analyzer. It comprises two independent modules – a module designed for semi-quantitative evaluation of diagnostic strips for urine analysis and a module designed for microscopic evaluation of urine sediment. Each of the modules may be used separately; therefore, it is possible to perform evaluation of urine strips and/or evaluation of urine sediment. Furthermore, the assessment of color, clarity and specific gravity of the urine is part of the system. The sample reception is carried out by the automatic movement of arm, which ensures the insertion and correct positioning of racks with sample tubes under the dosing pipette. The precise assignment of the sample to corresponding patient is secured by an inbuilt barcode reader. Prior to dosing of analyzed samples of urine onto the diagnostic pads an automatic homogenisation of samples is performed. High precision pipette sampling system with determined volume dosing system is designed to avoid cross-contamination across individual pads and to enhance the result repeatability and accuracy. The diagnostic strips are safely preserved inside a strip feeder. Unique system of drying chambers is connected to this feeder and ensures continous delivery of dry air inside maintaining humidity on very low levels.
Evaluation of diagnostic strips is based on the principle of image analysis. A real snapshot of the whole diagnostic strip is taken showing colours of individual diagnostic pads. Each colour is processed by integrated algorithm and final result is recalculated accordingly.

LAURA XL automatic urine analyzer – in combination with PHAN® Auto diagnostic strips – allows for the determination of following parameters:

Parameter		Analysis method	DekaPHAN	UnDekaPHAN	DoDekaPHAN
Specific gravity	SG	Image analysis	X	X	X
Color correction	CP		X	X	X
Leukocytes	LEU	Image analysis	X	X	X
Nitrites	NIT	Image analysis	X	X	X
pH	pH	Image analysis	X	X	X
Ascorbic Acid	**ASC**	**Image analysis**		X	
Proteins	PRO	Image analysis	X	X	X
Glucose	GLU	Image analysis	X	X	X
Ketones	KET	Image analysis	X	X	X
Urobilinogen	UBG	Image analysis	X	X	X
Bilirubin	BIL	Image analysis	X	X	X
Blood	BLD	Image analysis	X	X	X
Creatinin	**CRE**	**Image analysis**			X
Micro-Albumin	**MA**	**Image analysis**			X
Color		**scattering/absorption**			
Turbidity		**scattering/absorption**			

The automated **evaluation of colour and turbidity** of the analyzed urine sample is performed concurrently with evaluation of the aforementioned parameters. The principle of colour and turbidity evaluation is based on light scattering/absorption inside an inbuilt colorimeter. Once the sample is dispensed on a diagnostic strip, remaining liquid goes inside the colorimeter and following options for the result can be obtained:

METHOD	RESULTS
COLORIMETRY	COLORLESS
	PALE YELLOW
	YELLOW
	DARK YELLOW
	AMBER
	BROWN
	PINK - RED
	ORANGE
	GREEN - BLUE
TURBIDIMETRY	Clear
	Cloudy
	Turbid

Evaluation of urine sediment is based on the principle of automatic microscopy. The homogenised samples are dosed into the system of 14 cuvettes and left 6.5 min for the sedimentation. The total number of 15 snapshots is taken for each analyzed sample, and the recognition and evaluation of present elements is processed by the artificial intelligence technology. LAURA XL offers an insight of whole urine sample composition represented by 20x magnified images which can be further zoomed in facilitating accurate element identification.
LAURA XL analyzer performs an automatic identification of 23 categories of elements of urine sediment:

Parameter name	Parameter codes
Total RBC / Normal Red Blood Cells	RBC /nRBC
'Dysmorphic' Echinocytes RB	dRBCe**
Dysmorphic Ghosts and/or Half Lyzed RBC	dRBCg**
Dysmorphic Acanthocytes RBC	dRBCa**
Other Dysmorphic Red Blood Cells	dRBC
White Blood Cells	WBC
White Blood Cells clumps	WBCc
Squamous Epithelial Cells	SQEP
All other Epithelial Cells	NSE
Hyaline Casts	HYA
All pathological casts	CASTS
Calcium Oxalate di-hydrate	CaOX
Triple Phosphate or Magnesium Phosphate Crystals	TRIP
Uric Acid Phosphates Crystals	UA
Calcium Oxalate Monohydrate	MOX
Amorphous Crystals	AMO
Small unidentified crystals	CRYS
Rod-shaped bacteria	BACR
Cocci bacteria	BACC
Bacteria Clumps	BC
Yeast (single, budding, Hyphae)	YST
Spermatozoids	SPRM
Mucus	MUC
Unclassified Element*	UNCC

**Special category which comprises the so-called unclassified elements such as various deformed elements which may be further identified by the user.*
*** by default these subcategories are grouped under dRBC, and can be either hidden or displayed, see detail in 8.9.7 Sedimentation ranges section of this manual.*

In addition to automatically identified categories of elements, the user disposes of 15 additional categories which may be identified manually. The scope comprises the following categories:

Parameter		Parameter	
Red blood cells clumps	RBCC	Calcium phosphate	CAPH
Granulated casts	GRAN	Leucin crystals	LEU
Cell casts	CELL	Cystine crystal	CYS

Parameter		Parameter	
Waxy casts	WAXY	Tyrosine crystals	TYR
Red blood cell casts	RBCT	Cholesterol crystals	CHOL
White blood cell casts	WBCT	Fat droplets	FAT
Renal epithelia casts	RECT	Trichomonadas	TRICH
Fat casts	FACT		

The user can decide which categories to activated or hide.
These are explained in the *8.9.7 Sedimentation ranges* section of this manual.
On the other hand, the user can define up to 4 custom additional manual categories of elements.
In comparison with visual microscopy, the golden standard of urine sediment analysis, LAURA XL automatic analyzer simplifies the laboratory workflow, eliminates potential risks originating from the human factor and offers to the users considerable time savings as well as the possibility of archiving the measured results (results and microscopic images). Compared to manual method, centrifugation of the sample is not performed - the analyzer works with naturally sedimented urine – thus potential degradation of sediment elements is circumvented.

2.4 Technical Specifications

2.4.1 General Specifications

Overall dimensions	1780 (W) x 675 (D) x 563(H)
Dimensions without LCD	943 (W) x 675 (D) x 563(H)
LCD dimensions	approx. 505 x 336 x 55 mm
Weight approx.	70 kg
Power source Input	100-240 VAC, 50-60Hz
Power consumption	Main unit: 730 W max; LCD: 26 W max
Input voltage range	90-264 V Ac

2.4.2 Operating and Storage Conditions

Operating Environment	
• Placement of analyzer	Stationary work desk
• Temperature	16 – 30 °C
• Humidity	5- 85% RH (non-condensing)
Storage Environment	
• Temperature	0 – 40°C
• Humidity	5 – 90 % (non-condensing)

2.4.3 Controlling PC Specifications

Memory capacity (results)	>500 000 results (chemistry + sediment)
LCD	23” touchscreen
Harddisk capacity	2 TB
Interface	RS232, 4 x USB, Ethernet, DVI
Operating system	Windows 10
LIS	ASTM (RS232 + LAN)
Data export	USB / LIS / Print / LAN

2.4.4 User Interface Specifications

Display type	Capacitive color touch screen
Active display area	23”
Native format	16/9
Resolution	Full HD (1920 x 1080)

2.4.5 Sampling system

Test tubes accepted	Ø 11-16 mm, height: 70 – 110 mm Or 1.5ml microtube on specific adapters
Racks	Rack identification based on barcode
Rack capacity	10 test tubes positions
Rack capacity on board (input bay)	12 racks (120 samples)
Barcodes	Code 128, EAN 8, EAN 13, etc.
Sample Aspiration Volume:	minimum required in a 16 x 100 mm tube is 2 mL, Minimum required in a Eppendorf 1.5mL microtube on a specific adaptor is 0.9 mL aspired volume 0.8 mL
Sampling System:	Sample aspiration probe coupled with a high precision, maintenance free syringe of 2500 µL used for homogenization and aspiration/dispense
Sample type	Fresh urines (ref. to sample preparation)

2.4.6 Analysis Based on Diagnostic Strips

Principle of method	Image analysis
Capacity of strip feeder	150 diagnostic strips
Capacity of waste container	300 diagnostic strips
Maximum throughput	Up to 160 samples per hour
Optically visible area	130 x 40 mm (1200 x 250 pixels)
Camera resolution	1280 x 960 pixels
Tank – Liquid system:	volume: 10 litres
Tank – waste	volume: 10 litres

2.4.7 Analysis of Urine Sediment

Principle of method	Automatic microscopy + image analysis
Maximum throughput	125 samples per hour
Camera resolution	1280 x 960 pixels
Processing	15 snapshots / sample
Tank – Liquid System	volume: 10 litres
Tank – Opti-sol XL	volume: 10 litres
Tank – waste	volume: 10 litres

2.4.8 Hybride Mode

Maximum throughput	125 samples per hour
Principle of method	Automatic microscopy + image analysis

2.4.9 Consumables

Diagnostic strips	See section Test components, Diagnostics strips 4.1.1
Cleaning solution	See Section Test components, Cleaning solution 4.1.2.1
Liquid system	See Section Test components, Liquid system 4.1.2.2
Loading of consumables	RFID tags
Detection of level of liquid consumables	Floating level sensors for liquid system, cleaning solution and waste

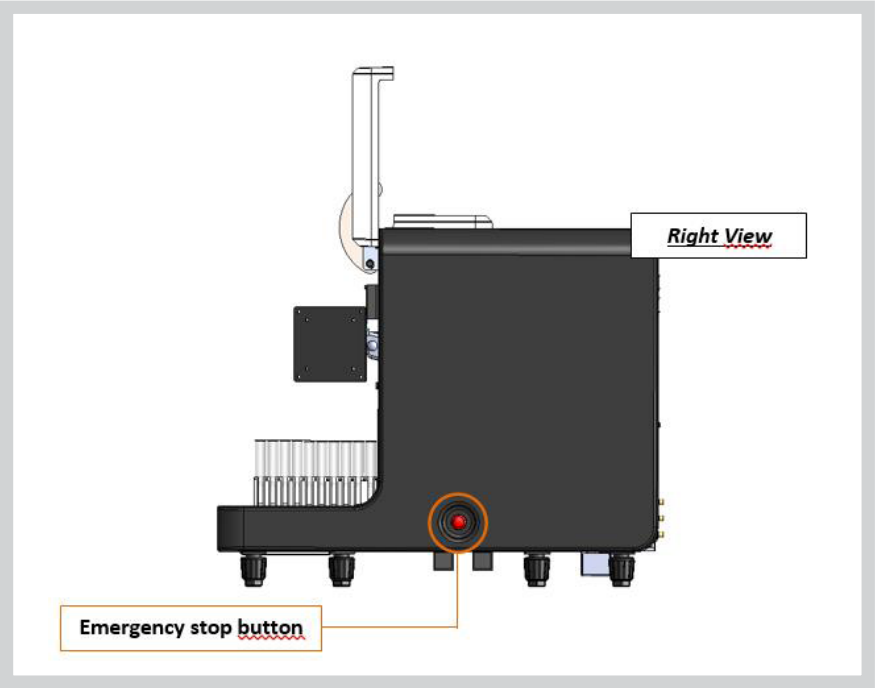
2.5 Instrument Modules Overview

2.5.1 Front View

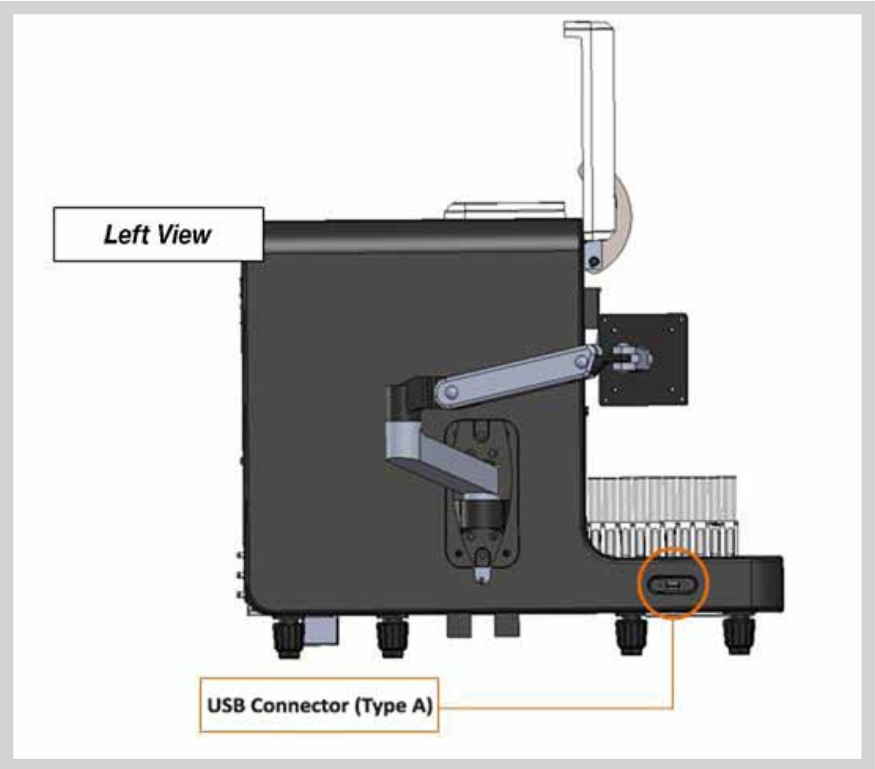


1. *Touch screen*
2. *Power Switch*
3. *Area for placement of racks with sample tubes*
4. *Feeder for diagnostic strips*
5. *Entry for racks with sample tubes*
6. *Waste container for diagnostic strips*
7. *RFID antenna*

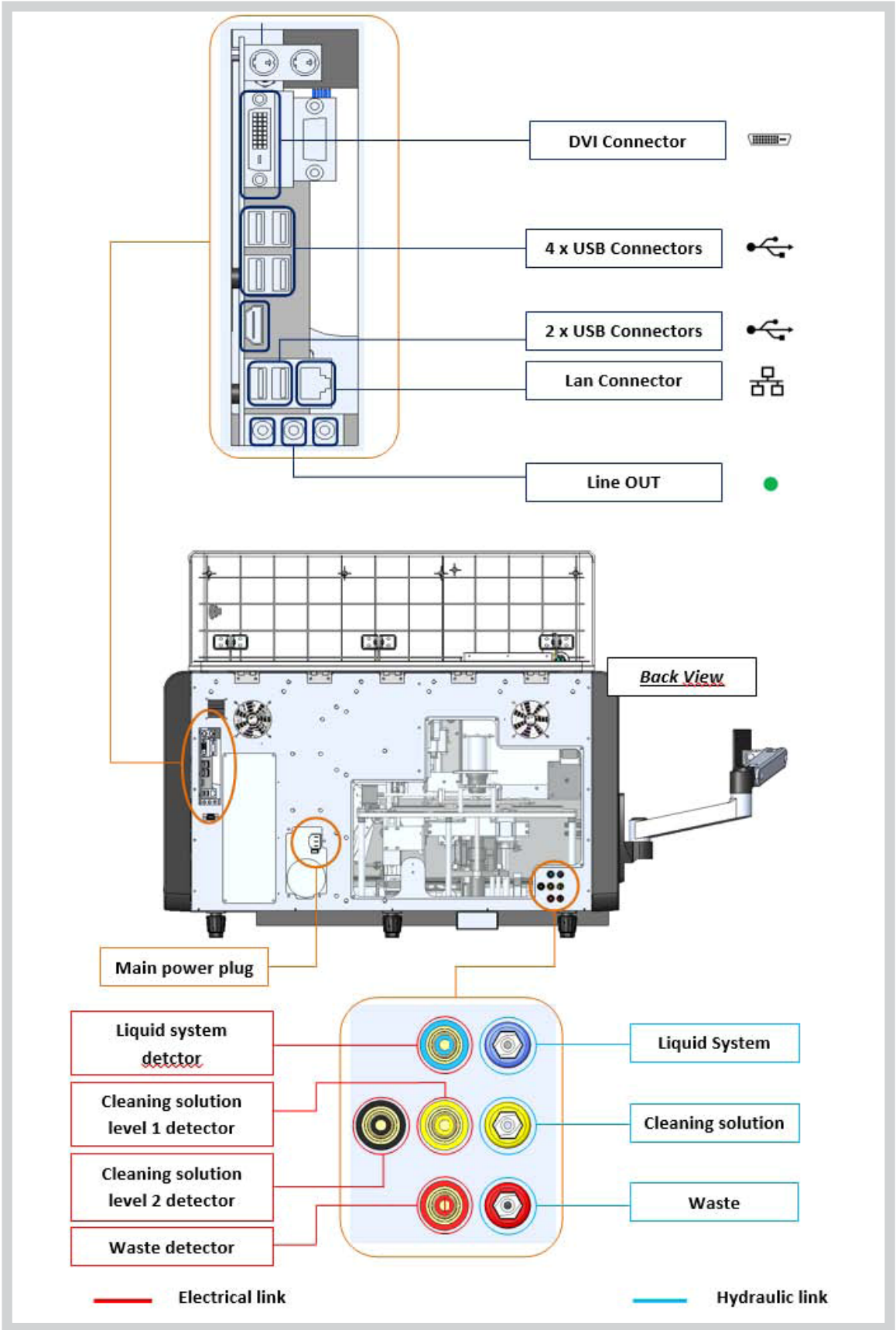
2.5.2 View from the right side of LAURA XL analyzer



2.5.3 View from the left side of LAURA XL analyzer

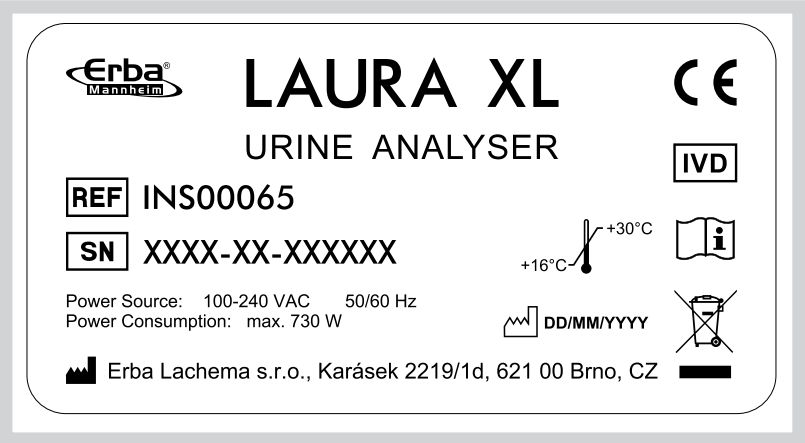


2.5.4 Back View of LAURA XL analyzer – Available ports, Tank connections

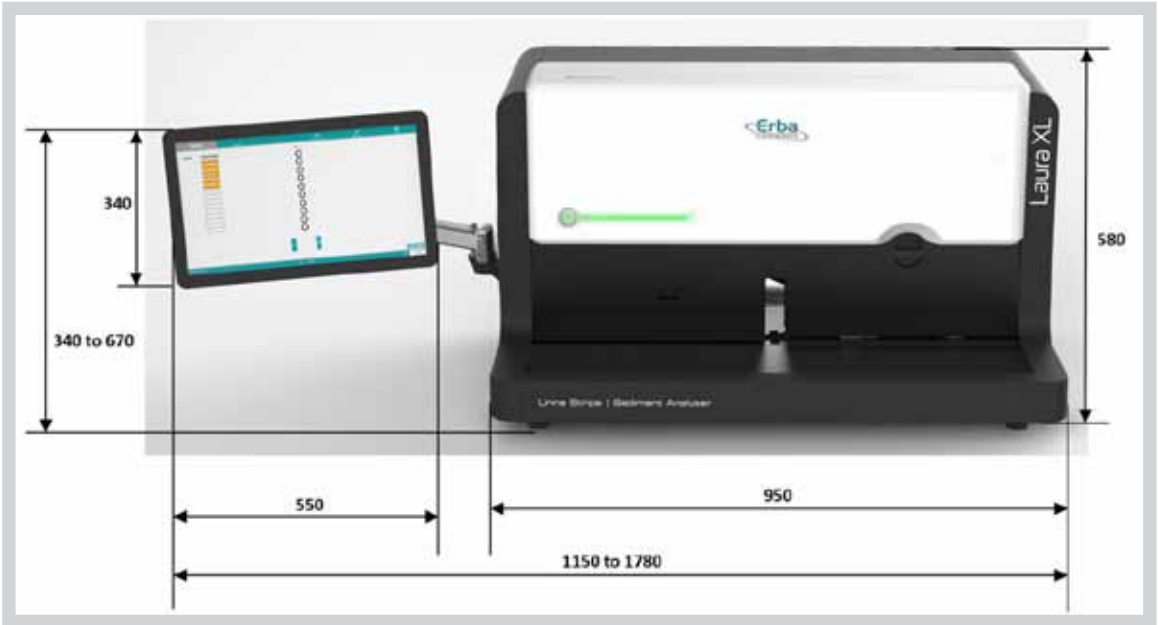


2.6 Model Identification Plate

The device is labelled in accordance with the applicable regulations and standards. The plate contains symbols and the meanings are explained in the List of Used Symbols (*Section 2.1.*).



2.7 Diagram of Analyzer Including Dimensions

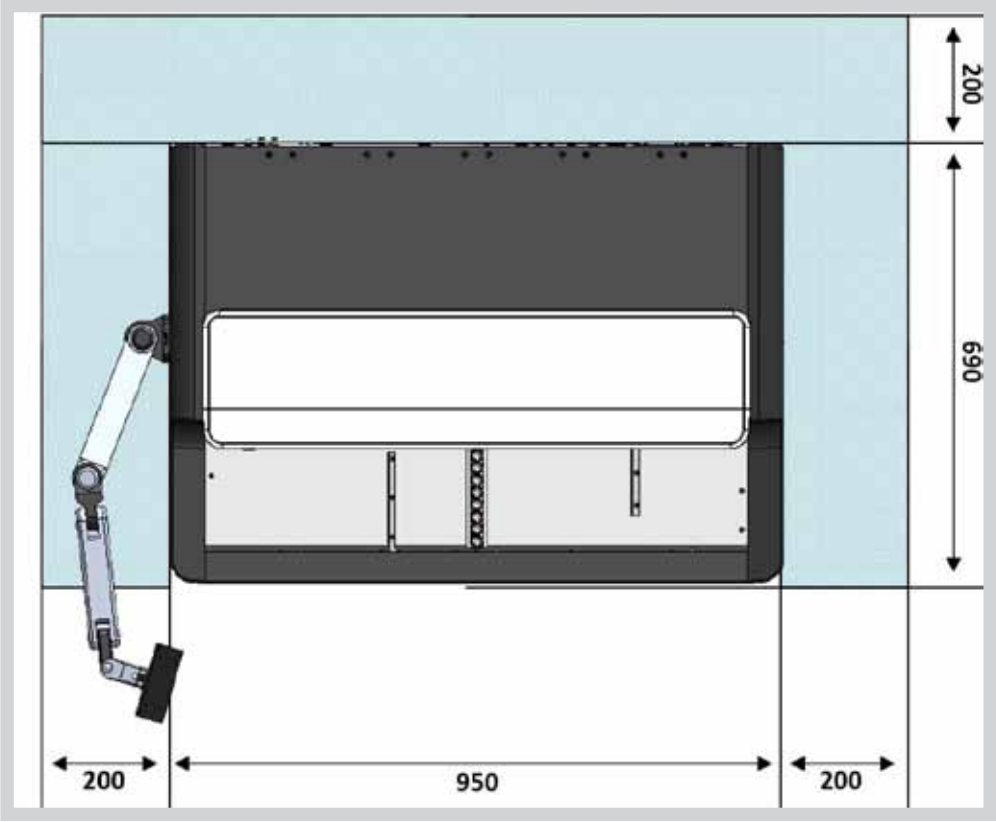


3. Installation

3.1 Site Preparation

Please, ensure that the area reserved for installation of LAURA XL analyzer is:

- Out of direct sunlight; or bright light
- Out of sources of vibrations;
- Clean and without any obstacles;
- Stable, flat and level surface;
- With a load bearing capacity of min. 70 kg;
- Located max. 2 metres far from a power socket;
- Min. 200 mm far (back side of the analyzer) from any objects, in order to ensure proper ventilation and maintenance.



3.2 System Preparation

This section serves as a guide for unboxing and setting up LAURA XL analyzer, however, it is recomended to have a service engineer present during this process. The detailed procedure is described in Service manual.

3.2.1 Unboxing of LAURA XL

Warning: Following unpacking of the device, please check carefully whether the package contains all the components listed below and that no parts are damaged.

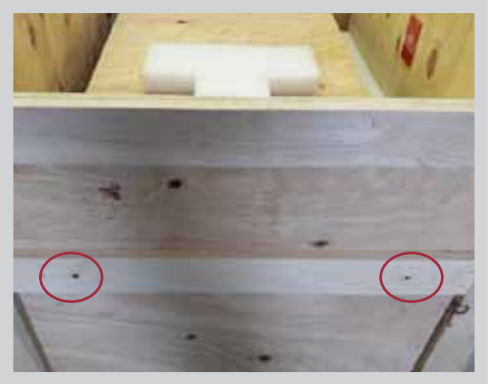
1. Unscrew the upper plate of the box (14 screws)



2. Put out the boxes with LCD and accessories



3. Unscrew the partition on the sides of the box (4 screws) separating the analyzer from accessories




4. Take out the analyzer, remove the protective foils and place it on the working bench.






3.2.2 List of all Components of LAURA XL Analyzer

N°	ID	Description	QTY.	Image
1	80009196	LAURA XL	1	

N°	ID	Description	QTY.	Image
2	**LH15-00-01** **66000658**	Touch Screen, 23”	1	
3	**LH15-00-02** **66000692**	External keyboard (USB, QWERTY – US)	1	
4	**LH15-00-10**	Set of cables for touch screen + audio	1	
5	**LH15-00-03** **66000693**	External mouse (USB)	1	
6	**LH15-00-06** **66000726**	Tank + tube waste	1	
7	**LH15-00-06** **66000727**	Tank + tube water	2	
8	**LH15-00-06** **66000728**	Tank + tube Opti-sol XL	1	

N°	ID	Description	QTY.	Image
9	**LH17-01-42** **LH17-01-43** **LH17-01-44**	Complete set of surface sensors, water waste, Opti-sol XL	3	
10	**LH15-00-04** **66000721**	Rack for test tubes	12	
11	**LH15-00-05** **66000724**	Magnetic Adapters for pediatric tubes	10	
12	**LH15-00-07** **66000696**	Power cable (NEMA 5-15)	1	
13	**LH15-00-08** **66000695**	Power cable (UK, BS 1363)	1	
14	**LH15-00-09** **66000694**	Power cable (EU, CEE 7)	1	
15	**LH15-00-14** **66000291**	CD Windows	1	
16	**LH15-00-11**	User Manual	1	
17	**LH06-02-00**	Strip waste container		
18	**LH06-02-00**	Strip feeder		

3.2.3 Installation of Tanks – Waste, Liquid System, Opti-sol XL

Prior to initiating any routine measurements, it is essential to ensure that LAURA XL analyzer is connected to the 3 tanks containing distilled water + Liquid System concentrate, diluted Opti-sol XL, as well as a tank for the liquid waste. The tanks and their hydraulic tubing used for their connection to the LAURA XL analyzer are part of the components delivered with every analyzer. For each tubing, a matching color socket needs to be plugged for the level sensors (see picture below).



3.2.4 Connecting of Analyzer to Power Source

After connecting all the tanks, plug the cables of analyzer and LCD touch screen to the power supply:



3.2.5 Removing Safety Material

1. Remove the safety tapes on the front panel and on the feeder inside the analyzer.




2. Carefully cut the plastic straps of pipette belts with the splitters.




3.2.6 Switching the Analyzer ON

When LAURA XL analyzer is connected to all the tanks (Liquid System, Opti-sol-XL, waste), connected to the power supply and all safety straps removed, it is possible to switch it ON with the button located on the back side. To start the analyzer up, press the button located on the frontal panel.




3.2.7 Safety Guidelines

Requirements pertaining to hardware of LAURA XL analyzer

Warning: Incorrect grounding of the device circumvents essential security elements and may result in misrepresentation of results or permanent damage caused to the analyzer, which leads to the loss of product warranty. It is essential to ensure due grounding. The electrical netword should be in compliance with the NFC 15100 Standards.

Warning: Installation of LAURA XL analyzer in an area with known power supply problems (such as current impulses or power outages) is not recommended. LAURA XL analyzer uses alternating current in the interval of 100–240 V, frequency: 50–60 Hz (selection of input voltage and frequency does not require user's intervention). It is recommended to use a UPS backup power supply in order to ensure operation of the analyzer during power outages or temporary losses of voltage, thus allowing for proper switching off the analyzer without the risk of loss of measured results.

Warning: Use the power switch located on the rear side of the device for secure powering off LAURA XL analyzer. Please ensure its accessibility.

Warning: Placement of devices which may be a source of vibrations – such as external printers, centrifuges, stirring devices, etc. – on the bench where LAURA XL analyzer is installed is not compatible with proper operations.

Warning: External USB devices should comply with the requirements applicable to the CE mark, thus preventing contingent functional instability.

Warning: Eliminate the possibility of spilling any liquid on the surface of the analyzer, to prevent any possible damage.

Warning: Reliable results can only be achieved from the exclusive use of reagents and consumables provided and validated by Erba Lachema and in strict compliance of instructions for use, including proper maintenance, provided in the Laura XL analyzer user manual and reagents and consumables package inserts.

Requirements related to biological risks

Biological Risk: Act in compliance with the applicable safety guidelines in connection with use of the analyzer, handling of analyzed samples and waste. Use protective devices such as a laboratory coat, protective gloves and goggles.

Biological Risk: All waste material is to be disposed of in accordance with the local regulations. It is recommended to perform inactivation of waste materials by the means of adding disinfectants.

Biological Risk: Perform comprehensive cleaning (decontamination) of all accessible parts of LAURA XL analyzer prior to any service work.

Warning: LAURA XL analyzer is intended to be used only by fully trained professional!

4.1 Test Components

To run LAURA XL, except of urine samples themselves, diagnostic strips, cleaning and Liquid System solutions, and quality control urine are required. The detail of components is listed in this section. Depending on the country, these can be ordered either under a single code, or have to be ordered separately. Please consult your local representative to find out the proper way to order in your case.

4.1.1 Diagnostic Strips

Diagnostic strips PHAN® AUTO are intended to semi-quantitative analysis of urine sample by LAURA XL analyzer. Individual pads of the strip correspond to individual analytes. After dispense of the urine onto the pads and incubation, the pads will develop colors in relation to their respective concentrations. The resulting colors are interpreted through an image analysis and the results are reported.
Three types of diagnostic strips are available for chemistry analysis of urine samples on the Laura XL analyzer:
DekaPHAN® AUTO: 100 diagnostic strips per 1 tube; URPH0030
UndekaPHAN® AUTO: 100 diagnostic strips per 1 tube; URPH0031
DodekaPHAN® AUTO: 100 diagnostic strips per 1 tube (available soon)

Parameter		Analysis method	DekaPHAN	UnDekaPHAN	DoDekaPHAN
Specific gravity	SG	Image analysis	X	X	X
Color correction	CP		X	X	X
Leukocytes	LEU	Image analysis	X	X	X
Nitrites	NIT	Image analysis	X	X	X
pH	pH	Image analysis	X	X	X
Ascorbic Acid	**ASC**	**Image analysis**		**X**	
Proteins	PRO	Image analysis	X	X	X
Glucose	GLU	Image analysis	X	X	X
Ketones	KET	Image analysis	X	X	X
Urobilinogen	UBG	Image analysis	X	X	X
Bilirubin	BIL	Image analysis	X	X	X
Blood	BLD	Image analysis	X	X	X
Creatinin	**CRE**	**Image analysis**			**X**
Micro-Albumin	**MA**	**Image analysis**			**X**

4.1.2 Cleaning and Liquid System solutions

The use of cleaning and proper Liquid System solutions is mandatory to ensure the cleanliness of the system and individual cuvettes used for analysis of urine sediment and to avoid the presence of bubbles which could decrease the quality of sediment images and elements identification.

4.1.2.1 Cleaning solution concentrate

Opti-sol XL 1500 (Cleaner)– 1 x 400 mL package - REG00055
(see preparation in section *4.4.3.1*)

4.1.2.2 Liquid System solution concentrate

Opti-sol XL 750 (Liquid System) REG00054
(see preparation in section *4.4.4.1*)

NOTE This solution is new, and may not be immediately available in your country, due to registration delays.
In the anterim of availability, an alternate solution (composed of Tween 20 and Proclin 950) is advised to ensure acceptable performance of decontamination and carryover. (see *4.4.4.2*)

Warning: Be careful with these 2 solutions, as they should not be confused for one another! The cleaner is a strong alkalin solution and would greatly alter the results of chemistry and sedimentation tests.
The purpose of each solution is added just below the name; Cleaner is added to the Opti-Sol XL 1500, and likewise, the mention of Liquid System is added to the Opti-Sol XL 750. The Liquid system also has a blue cap, which matches the color code of the hydraulic line connectors. The cleaner on the other hand will have a white cap.

4.1.3 Quality Control reagents

Quality control performed on LAURA XL analyzer is associated with examination of control urines URINORM XL manufactured by Erba Mannheim. These control samples represent a two-level system, i.e. normal level (URINORM XL N) and a pathological level (URINORM XL P). URINORM XL urine controls allow verification of correct functionality of LAURA XL system combined with PHAN® AUTO diagnostic strips as well as the part designed for evaluation of urine sediment.

Catalogue number	Name	Description
REG00060	URINORM XL	2 x 120 ml (1x URNORM XL N + 1x URINORM XL P)

URINORM XL urine controls are human urine-based samples containing human and animal origin species as well as purified chemicals that cause both negative and pathological states of diagnostic zones for all parameters, and they also contain artificial latex particles which simulate presence of fundamental particles of urine sediment (WBC, RBC). URINORM XL control urines contain preservatives added to maintain product stability and avoid the microbiological growth. For any and

URINORM XL includes following analytes for chemistry evaluation by PHAN® AUTO diagnostic strips:

- Bilirubin (BIL)
- Blood (BLD)
- Glucose (GLU)
- Ketones (KET)
- Leukocytes (LEU)
- Nitrites (NIT)
- pH
- Proteins (PRO)
- Specific gravity (SG)
- Urobilinogen (UBG)

URINORM XL includes following analytes for sediment examination identified by LAURA XL:

- Red blood cells (RBC)
- White blood cells (WBC)

The target (declared) values applicable for each respective LOT are presented in the instruction for use of URINORM XL control urines. Target values for chemistry examination are presented in both scales (SCALE 1 and SCALE 2) which are applicable for LAURA XL. Please note that used scale is set during the installation of LAURA XL by our service team.

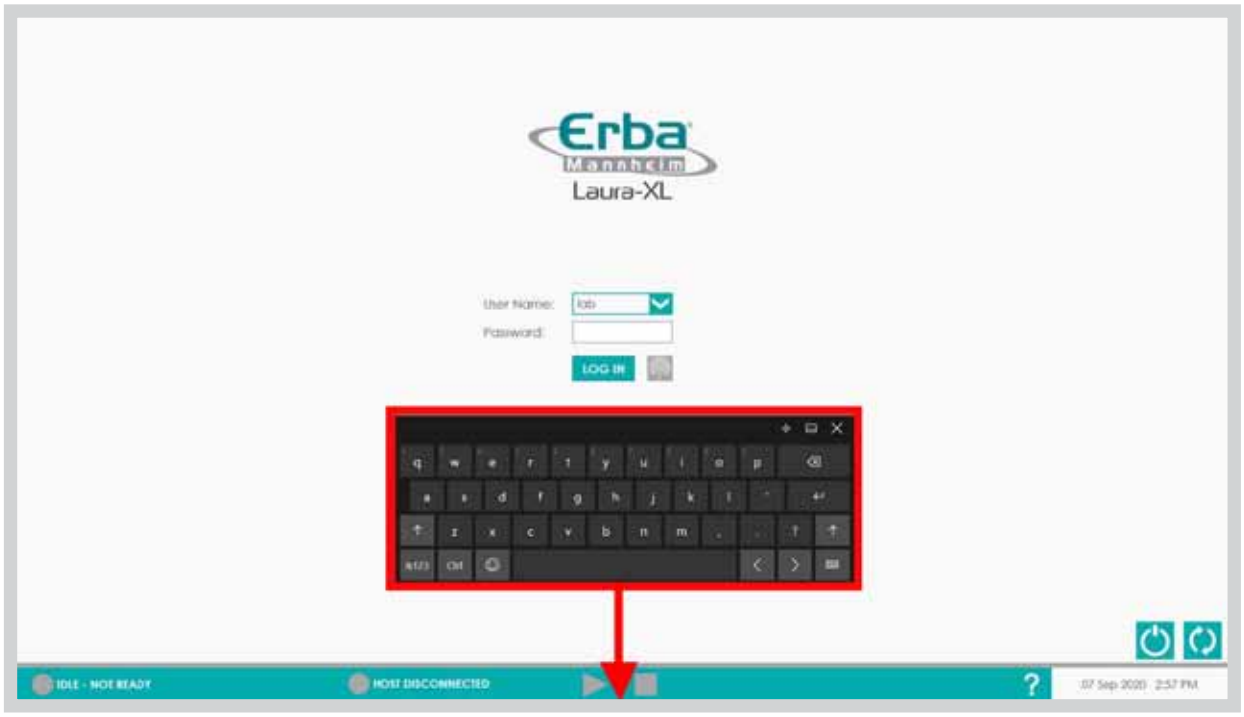
NOTE These 2-level control material come in large vial of 120mL, this quantity can be used over a long period; it is therefore very important to ensure thorough mixing prior to pouring in the testing tube., to ensure consistent results throughout the duration of the full vial.

For users which require using an independent QC material, additional controls for Laura XL from another vendor, Bio-Rad offers products which include Laura XL specific values. See details of kit references in the table below.

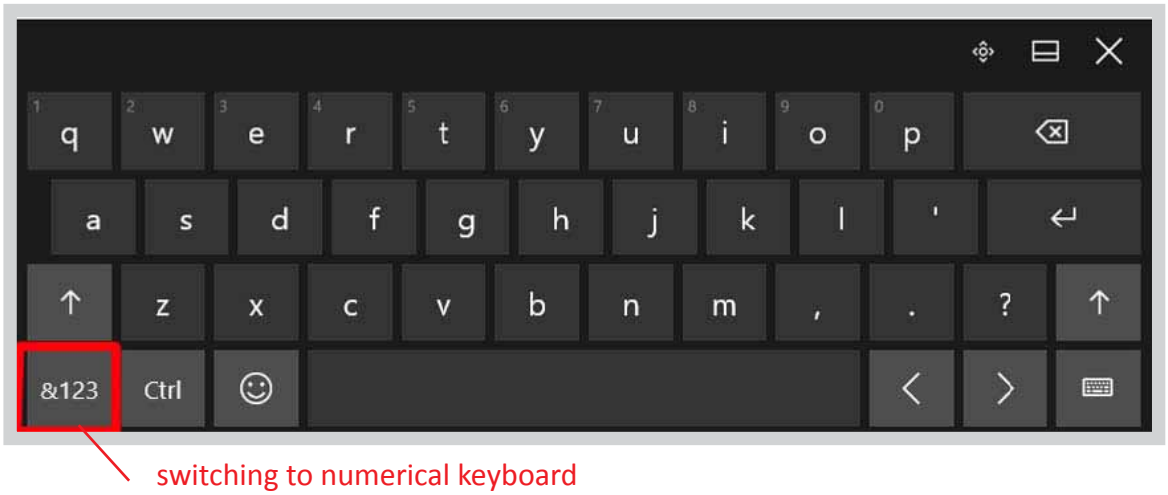
Catalogue number	Name	Description
435	Bilevel	12 x 12 mL (vials / level)
436	Level 1	12 x 12 mL (12 vials Level1)
437	Level 2	12 x 12 mL (12 vials Level2)
435X	Bilevel MiniPak	2 x 12 mL (1 vial / level)

4.2 Log In

Once LAURA XL analyzer is switched on (see section 3.2.6 switching the analyzer ON), the user application (LauraGUI) is started up automatically, following by login window depicted below:



Pressing the blank space next to either ‘User name’ or ‘Password’ a field will display the virtual / on-screen keyboard. Use this to enter your User name and Password.



Login can be also performed by pressing the RFID symbol. Once pressed, the user is prompted to attach the RFID tag to the antenna on the front cover of the analyzer (see Chapter *2.5.1*).

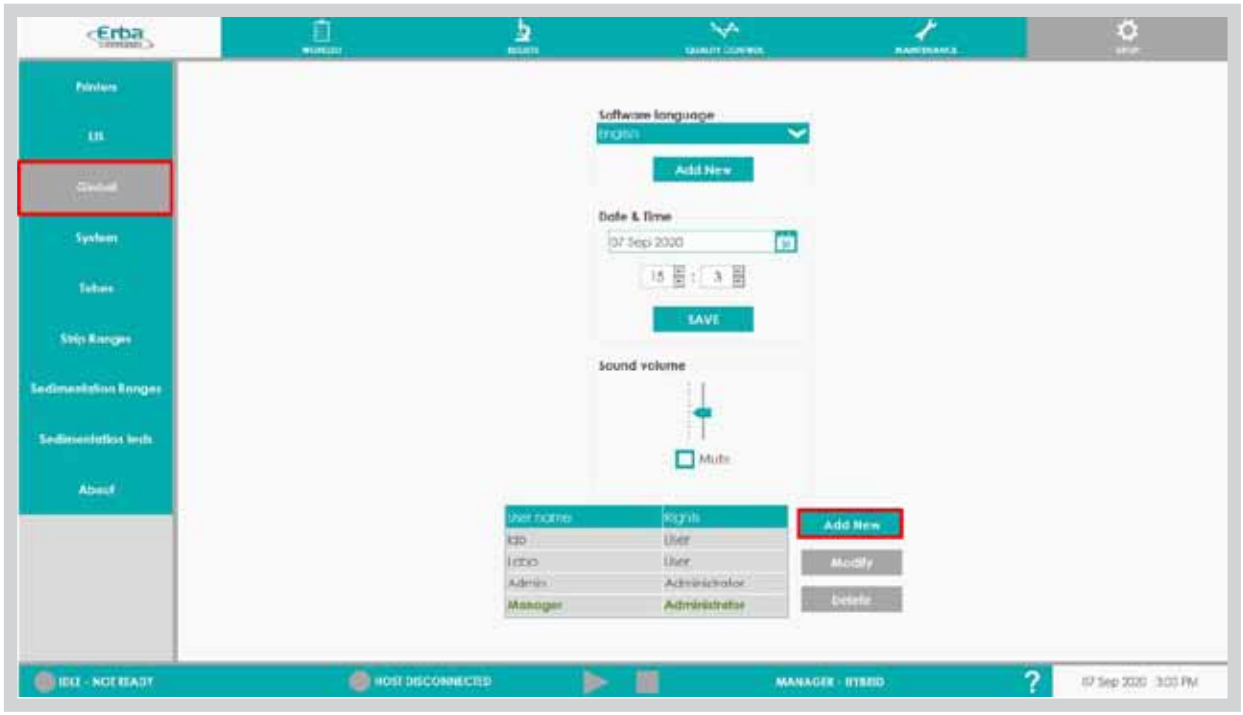


Once you have logged in the Status Screen will be displayed. The Status Screen is used for controlling the device. Details will be described in User Interface section (*8.1*).

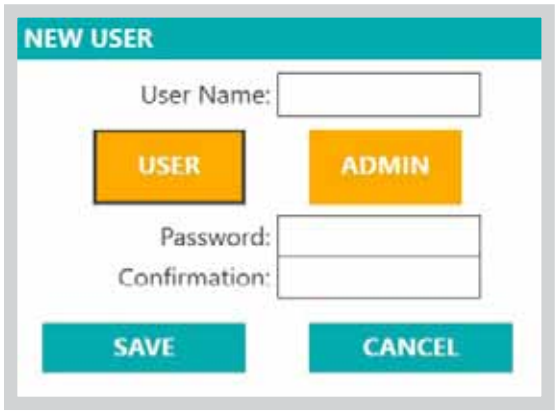
4.2.1 Creation of New User Account

Following installation of LAURA XL analyzer, the system provides one user account offering administrator's rights. This account allows the user to perform changes in the analyzer's setup as well as create additional user accounts related to predefined rights.
Once the user logs in as ADMIN (administrator's account), it is possible to perform creation of additional user accounts in the following manner:

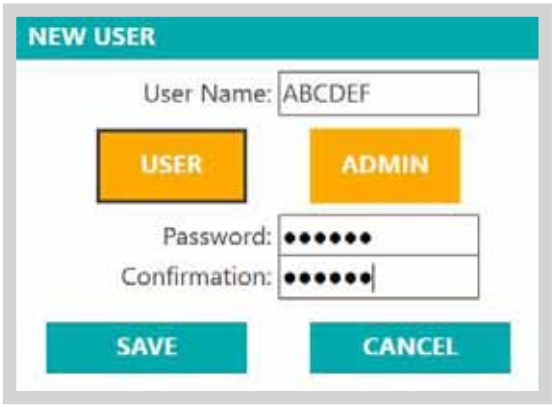
3. In SETUP tab click on GLOBAL



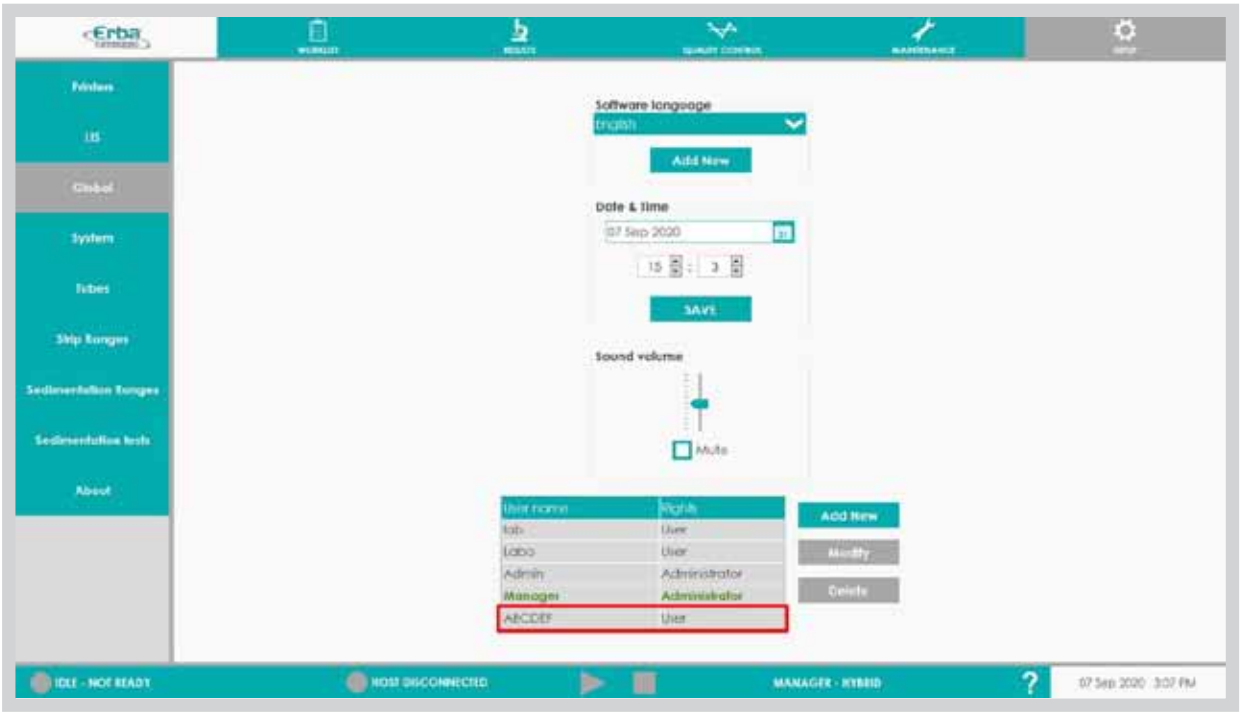
4. Press the 'Add New' button and the following window will be displayed:



5. Enter a new user name (for example ABCDEF), then enter + verify the user's password; choose the type of user's rights (USER or ADMIN)



6. The new user account is created subsequently.

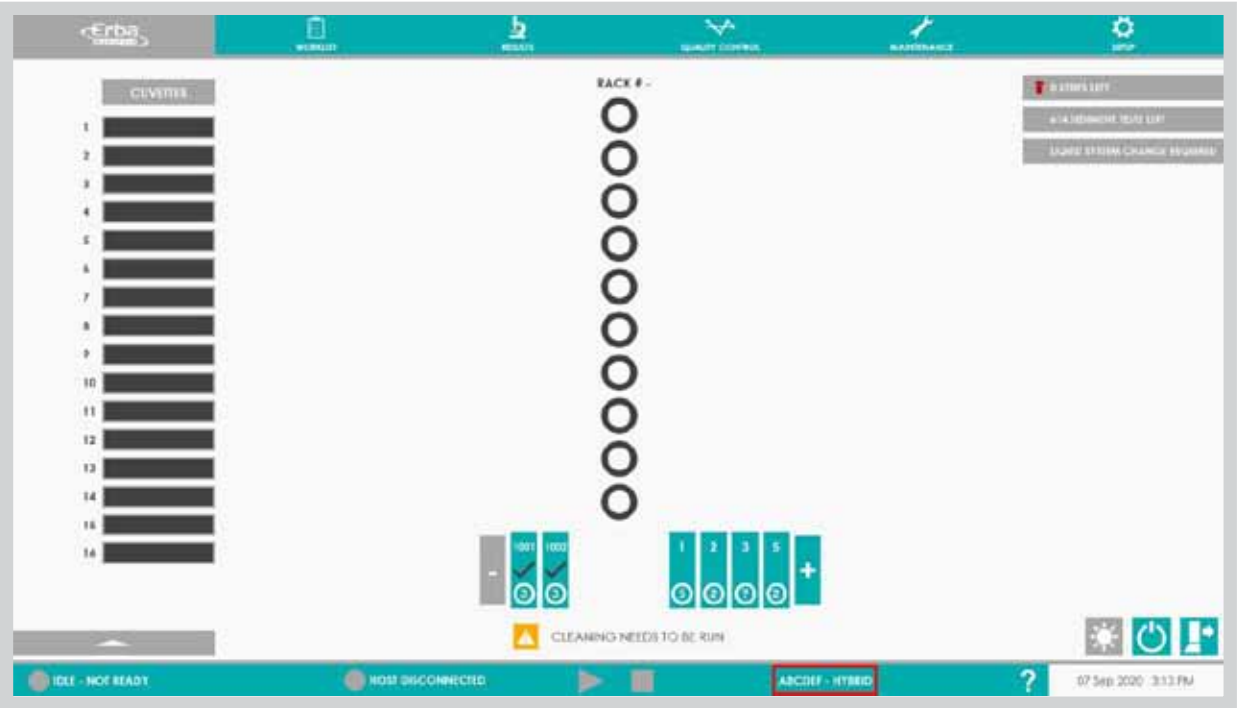


7. Log in the application.



8. Once you log in, the user name is displayed in the right part of the bottom section (ABCDEF – user name, HYBRID – predefined measurement mode)

An unlimited number of user accounts may be created in the manner presented above.



4.3 Software setup

Each laboratory has its specific preferred settings for using, reviewing and reporting Urinalysis.
The Laura XL system allows the user to configure the system to these preferences.
The customization is split in system and analysis setting.

4.3.1 Customer system customization Setting

The system customization corresponds to settings which are general and would likely remain unchanged.
These settings are:

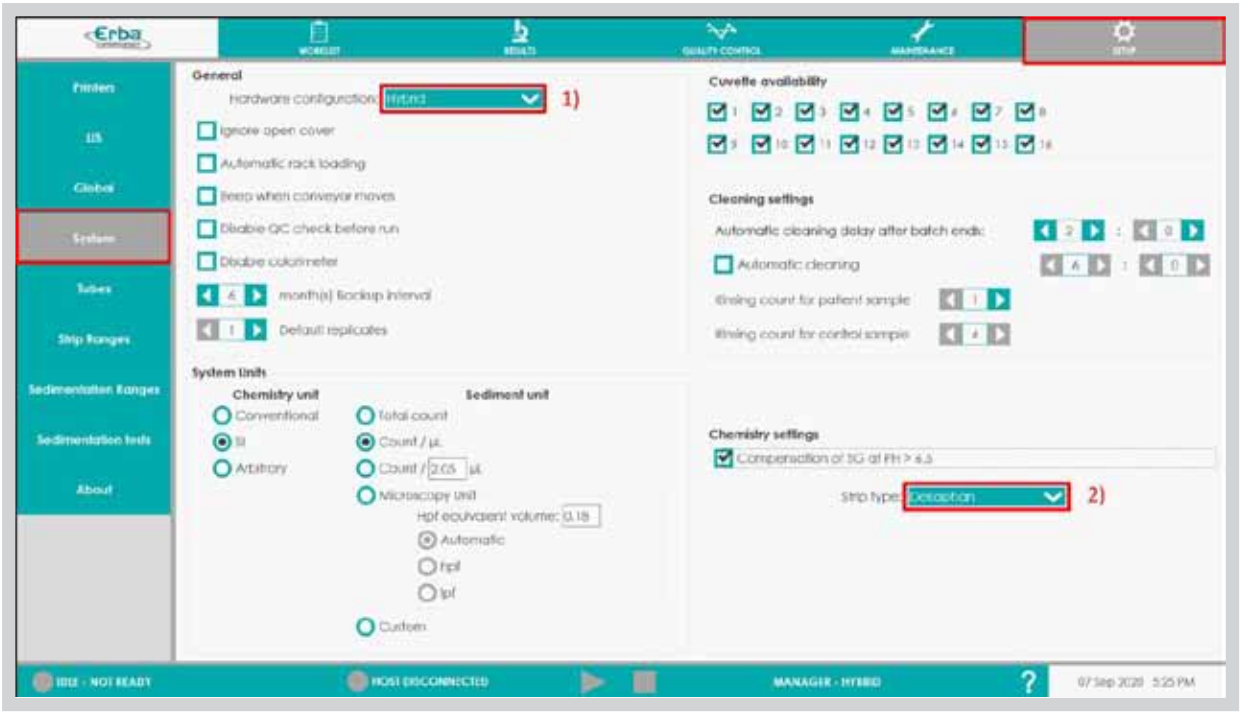
- System language can be selected, so the UI is in the operators' language (see *8.9.3* for details)
- General setting (see *8.9.4.1*) including :
  - Automatic Rack loading or manual programming
  - Disabling the QC check before run (which makes the QC optional)
  - Backup interval reminder
  - Default analysis replicates
- Specific tubes usage (see *8.9.5* Tubes).
- System units (see *8.9.4.2*):
  - For Chemistry (strip) testing (between conventional in mg/dL, or xmol/L or + ranges)
  - For sediment testing (between arbitrary system unit (pictures), microscopic standard units (per LPF and HPF), to standardize it with laboratory manual method)
- Automatic compensation of SG for high pH (see *8.9.4.3*)
- Selecting the Sediment elements optional displays (like RBC dysmorphic subcategories, Crystals subcategories, hiding of showing Cocci shaped bacteria and Unclassified elements (UNCC); (see *8.9.4.5*).

- Setting the cleaning parameters, specifically for the automatic cleaning setting, see *8.9.4.6*
- The sedimentation ranges (see *8.9.7*):
  - Customization of the values to the laboratory practice.
  - Addition of customs cell label
- Setting the Chemistry results which will trigger the sedimentation tests (see *8.9.8*)
- Printer setting, including report header (see *8.9.1*)
- LIS connection setting (see *8.9.2* and section *10* for complete configuration)

4.3.2 Analysis Setting

When the system is Initialised (Chapter *5.4.1*), diagnostic strips are loaded (Chapter *4.4.1*) and racks with sample tubes are placed on board (Chapter *5.3.4*), it is possible to run the actual analysis. The last action involves setting of parameters for the measurement in SETUP > SYSTEM menu: 1. MODE; 2. STRIP TYPE; 3. REPETITION

1. **MODE** – the user is allowed to choose from three different measuring modes:
   - **CHEMISTRY ONLY** – which involves measurement and evaluation of diagnostic strips only
   - **SEDIMENT ONLY** – which involves measurement and evaluation of sediment only
   - **HYBRID** – which involves measurement and evaluation of both diagnostic strips and sediment
2. **STRIP TYPE** – the user is allowed to choose between two types of diagnostic strips – DekaPHAN and UndekaPHAN (see Section *4.1.1*)

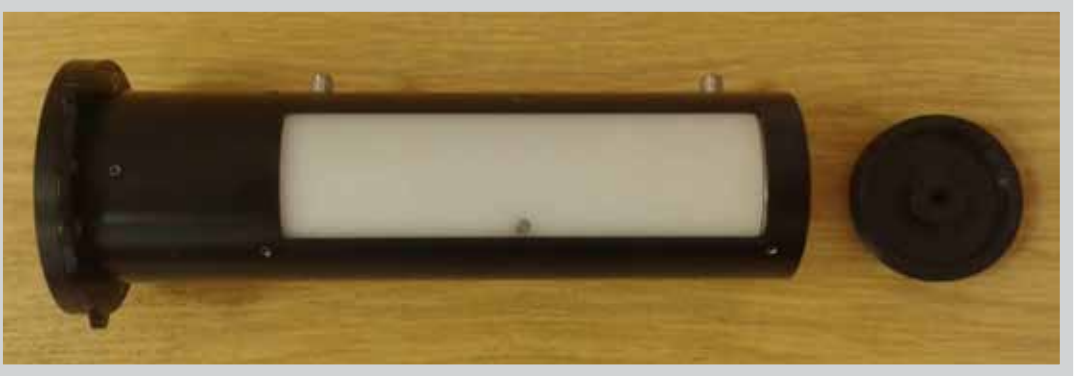


NOTE The System menu will be described in detail in Chapter *8.9.4*

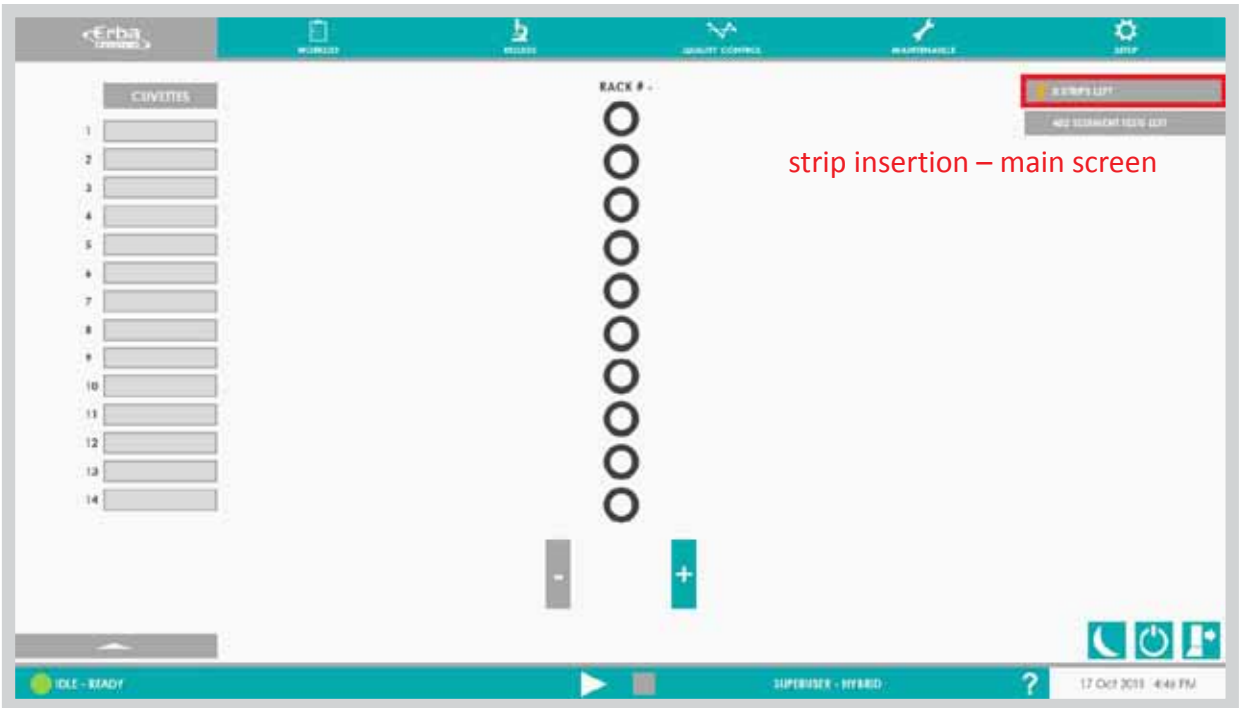
4.4 Loading/unloading of consumables and their preparations

4.4.1 Loading of Diagnostic Strips

Prior to commencement of any measurement, diagnostic strips have to be inserted into the feeder of the analyzer. The transfer of diagnostic strips from the tube into the feeder is realized with help of removable feeder cylinder.



Strip insertion can be performed either from the Main screen by clicking on “STRIPS LEFT” or from the Maintenance menu by clicking on “FEED STRIPS”.





Strip insertion – Maintenance menu

For further strip loading from Main screen or Maintenance menu, please, proceed as follows:

1. After pressing “STRIP LEFT” or “FEED STRIP” the following window will be displayed:



2. Two options are possible:
   - By pressing „FEED REMOVED STRIPS“, it is possible to load the strips, which were unloaded and stored properly in their original tube with properly maintained desiccator(s). These previously removed strips can only be reloaded **within their onboard maximum stability**. *After this delay is exceeded, the option will no longer appear, only Feed New Strips will be available*.



Follow the on-screen instructions

- By pressing „FEED NEW STRIPS“, it is possible to load new strips into the feeder.

3. Open and empty the strip waste container (the sensor will automatically sense the closing action and will automatically activate the first item “EMPTY AND CLEAN THE STRIP WASTE CONTAINER”



4. Press the following button – the removable feeder cylinder is placed into the position allowing pulling it out from the feeder drum.



5. Turn the loading cylinder into “In/Out” position and pull it out.
6. Click on ‘SCAN RFID TAG’ and position the RFID label located at the bottom of the strip tube in front of the RFID logo on the front top cover of the analyzer to scan the RFID tag and fill the loading cylinder with diagnostic strips. The RFID reader/writer will operate and be

Warning: Before opening, shake the tube with the diagnostic strips energically in all directions to prevent sticking of individual strips together.

Warning: Based on the setting by user (see Chapter *8.9.4.3*), only one type of diagnostic strips – DekaPHAN Auto or UndekaPHAN Auto can be loaded into the feeder.

7. Insert the loading cylinder back into the analyzer and turn it into the position “Locked”.
8. Press LOAD STRIPS button.



After the completion of this step the strips located in the feeder drum are ready for use.

NOTE To have 150 strips loaded into the feeder, the first 50 strips of a pack need to be consumed **before** getting access to loading another full tube.

Warning: it is not recommended to load new strips before consuming all the strips already on-board, unless being sure to consume them within the day. The system monitors the strip stability from the first loading time. This time is only reset when the feeder is completely emptied (unloaded or consumed by runs). If the system keeps being loaded with new strips without ever emptying the feeder, then it is possible to reach a situation where the system will refuse working on recently loaded new strips).

4.4.2 Unloading of Diagnostic Strips

The system of drying blocks keeps low humidity inside the strip feeder, thus protects the diagnostic strips. However, when the analyzer is switched off, this protection is not available; therefore, it is necessary to put unused strips back into the original tube. This ensures a long protection of diagnostic strips against the effects of air humidity.

Unload strips from the feeder in the manner specified below:
1. In MAINTENANCE mode press UNLOAD STRIPS button.



2. Press the following button – strips located in the feeder drum are relocated to the removable feeder cylinder.



Warning: The maximum capacity of removable feeder cylinder is **100 strips**. If the number of unloaded strips is higher, the excessive strips are automatically pulled out of the feeder and discarded into waste container.

3. Strips are automatically relocated from the feeder drum to the removable feeder cylinder; place the removable feeder cylinder into In/Out position; remove the cylinder and put unused diagnostic strips back into the tube. **Close the tube properly!**



4. Return the empty removable feeder cylinder into the analyzer and confirm the operation – press INSERT THE FEEDER INSIDE THE SYSTEM.



4.4.3 Preparation and loading of Cleaning solution

4.4.3.1 **Preparation of Cleaning solution**

NOTE Prior to preparing fresh Cleaning (Opti-Sol XL 1500) solution, the remaining solution in the tank must be discarded, and not mixed with the fresh one. Tank should be rinsed prior to preparation

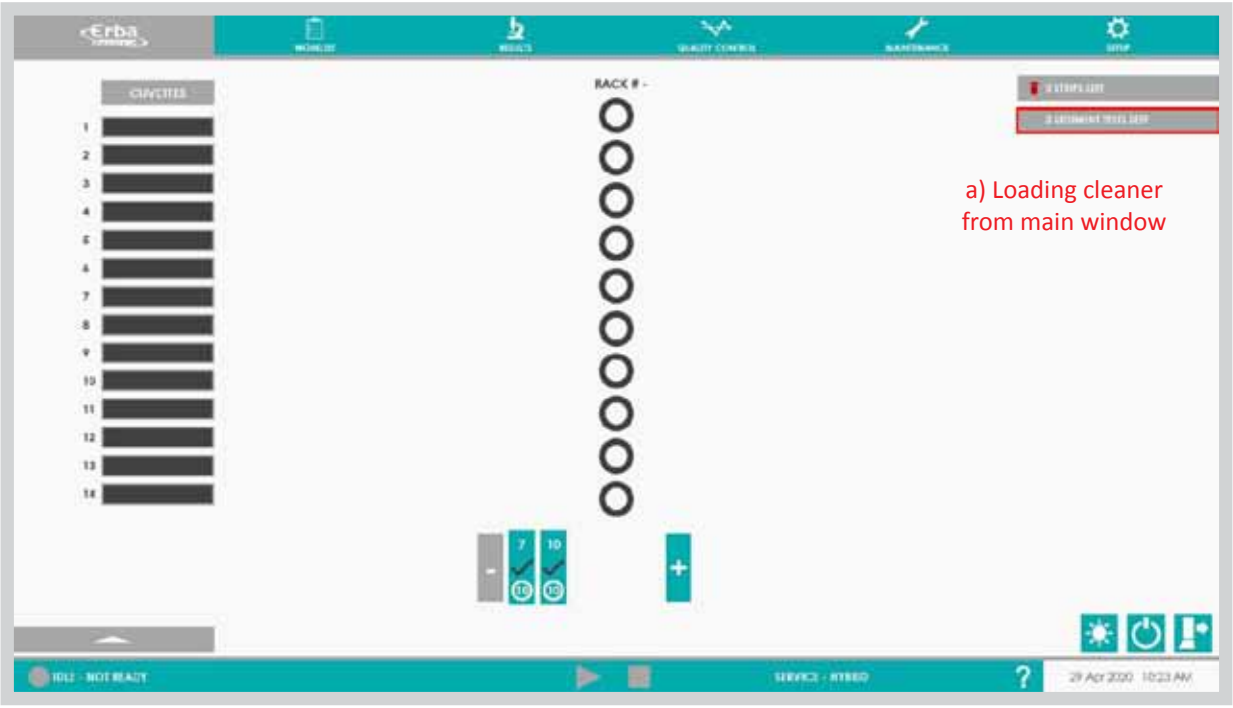
1. Dilute 1 bottle of 400 mL in its 10 L tank with distilled water (instruction included in the package insert)
2. Gently shake with the canister to homogenize and connect the tubing and level sensor

Warning: Opti-sol XL 1500 can cause severe skin burns and eye damage. Act in compliance with the respective security level – use of laboratory coat, gloves and protective goggles is recommended.

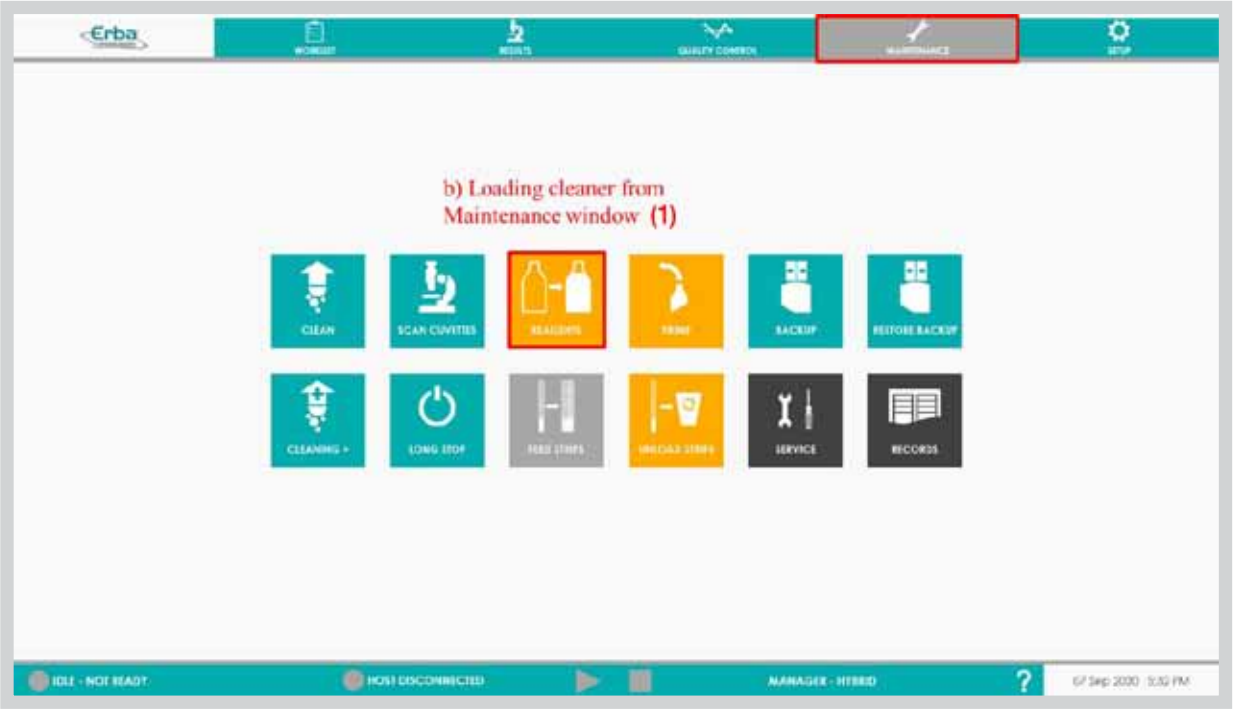
4.4.3.2 Loading of Cleaning solution

Loading of the cleaner consists of connecting the hydraulic lines inside the tank, but also requires a registration in the software. The action of loading a new cleaner reset the possible maximum number of sedimentation tests to 1500. This number is possible for a usual workload around to 200 tests per day. For lower workloads, the number of possible tests will be reduced. For example, 100 tests per day would lead to a maximum of 1000 tests with 1 vial of Opti-Sol XL 1500. The strict respect of executing the cleaning cycles as soon as they are due will also contribute to the maximum number of possible tests. Refusing cleaning cycles will enduce sanitation cycles which consum are more.

The loading can be done from the main window when the level or test count is empty. Or from the Maintenance menu.



1. Open the Loading Cleaner dialog box
   - From the main window, click on the 0 sediment tests left button, the system will open the loading new cleaner window instruction
   - Or From the Maintenance window, click on 'REAGENTS' (1), and then select the 'CLEANER' option (2)







2. Click on SCAN RFID TAG *this will activate the RFID reader of the instrument*
3. Position the RFID label located at the back of the Optisol XL 1500 vial in front of the RFID reader – marked by the RFID logo engraved on the front top door of the instrument.
   The reader will be heard, it is normal; it will load automatically the information of lot number, expiration, number of possible sediment tests. If issues are detected during the loading of the cleaner, the system will display the error in the field as shown in the example below. Correct the issue, close the window, and restart the process.





4. Discard the remaining volume of old cleaner from the tank, and rinse it clean, then click on the 2nd step (DISCARD REMAINING CLEANER FROM TANK)
5. Click on FILL THE CLEANER TANK to confirm the task is done
6. Click on CONFIRM TO RUN PRIMING the system will prime the cleaner line to remove bubbles; and it will end with priming the Liquid System.

NOTE The priming will last 47 seconds
If the priming is not performed and the loading process is interrupted, **it will not be possible to start a sediment or hybrid batch nor run a cleaning cycle**.
If all other steps have been performed and only the priming is missing, priming can be executed from Maintenance, PRIMING, CLEANER (see *8.8.4.1*)

4.4.4 Preparation and loading of Liquid System solution

NOTE Prior to preparing fresh Liquid System solution, the remaining solution in the tank must be discarded, and not mixed with the fresh one. Tank should be rinsed clean prior to preparation.

4.4.4.1 Case of Opti-Sol XL 750 solution (Ref. REG00054)

The Opti-Sol XL 750 comes with a RFID label located at the back side of the bottle which registers the product to the system. The RFID management will have to be activated once by technical service when the solution becomes available for your laboratory.

1 vial of Opti-Sol XL 750 is intended to reconstitute 1 tank of 10 L of Liquid System.
Unlike the cleaning solution, the Liquid System does not load a given number of tests. The number of tests possible with 1 vial is related to the workload, work habits and cleaning regimen. But it is usually around 250 tests for a daily workload of 200 tests.

The software loading dialog box of the software includes both guidance steps as cleaning tank, preparation of solution, loading and priming. But for clarity (detailed information), in the manual, the preparation and loading are separated.

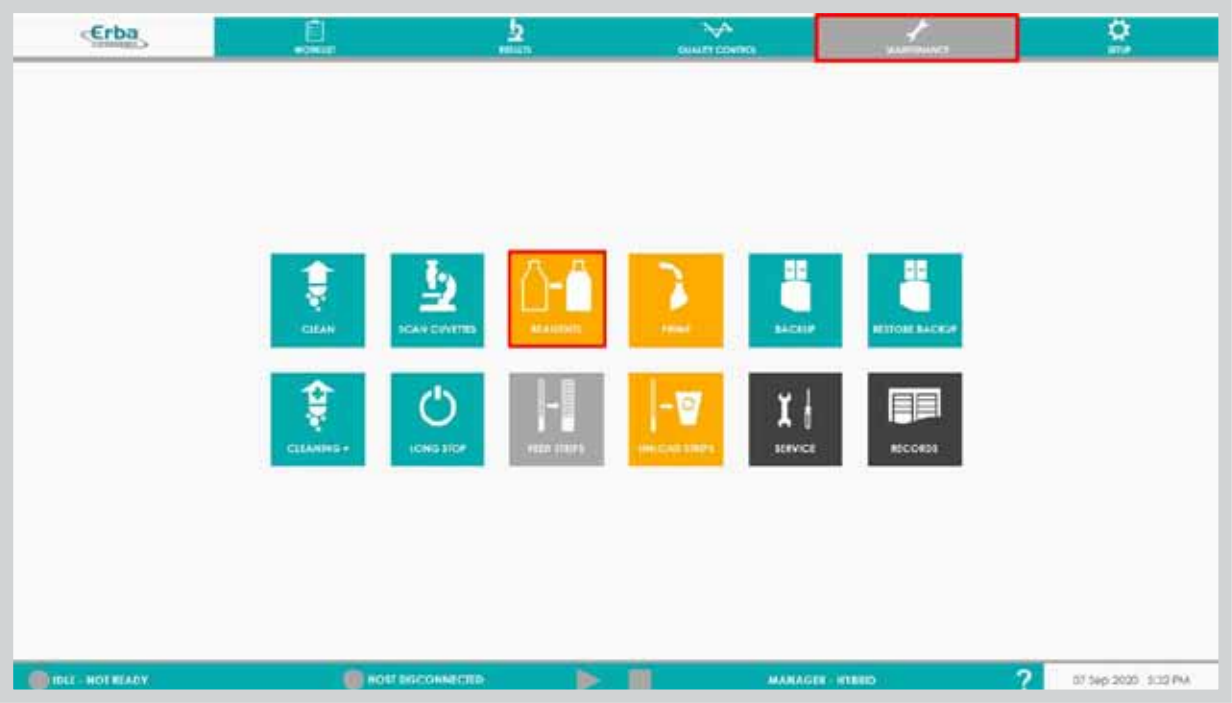
4.4.4.1.1 Preparation of Opti-Sol XL 750 solution

1. Prior to preparing fresh Liquid System (Opti-Sol XL 750) solution, the remaining solution in the tank must be discarded, and not mixed with the fresh one. Tank should be rinsed prior to preparation.
2. Dilute 1 bottle of 50 mL in its 10 L canister with distilled water (instruction included in the package insert)
3. Gently shake with the canister to homogenize and connect the tubing and level sensor
4. Perform the Loading of Opti-Sol XL 750 solution (see *4.4.4.1.2*)

4.4.4.1.2 Loading of Opti-Sol XL 750 solution

The Opti-Sol XL 750 comes with a RFID label which registers the product to the system.

1. Open the Loading Liquid System dialog box
   - **From the Maintenance window**, click on 'REAGENTS'



   - and then select the 'Liquid System option





2. Click on the SCAN LIQUID SYSTEM RFID TAG circle and present the RFID label to RFID antenna of the instrument marked by the RFID logo engraved on the front top door of the instrument.
The reader will be heard, it is normal; it will automatically load the information of lot number, expiration, number of possible sediment tests.
If issues are detected during the loading of the Liquid System (expiration date, incorrect product, incompatibility with instrument, not able to read the label…), the system will display the error in the field as shown in the example below. Correct the issue, close the window, and restart the process.





3. Follow the onscreen instructions and confirm through the check circles:
   - DISCARD REMAINING LIQUID SYSTEM TANK (and rinse the tank with water until clean prior to filling freshly prepared solution)
   - FILL THE LIQUID SYSTEM TANK (and place the hydraulic line and floater level sensor back in)
   - Then click on circle CONFIRM TO RUN PRIMING

The priming will last 13 seconds

- Then click on the X on the top right of the window to exit the dialog box

NOTE The priming will last 13 seconds
If the priming is not performed and the loading process is interrupted, **it will not be possible to start a batch nor run a cleaning cycle**.
If all other steps have been performed and only the priming is missing, priming can be executed from Maintenance, PRIMING, LIQUID SYSTEM (see *8.8.4.2*)

Warning: Loading of the Liquid System consists of placing the hydraulic lines inside the tank. The priming must systematically follow any manipulation of the hydraulic lines (above the level of the liquid, which induces air bubbles to enter in the system.

Opti-sol XL 750 working solution
Warning
Contains: 2-Methyl-2H-isothiazol-3-one
H317 May cause an allergic skin reaction.
P280 Wear protective gloves. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

Warning: Label the canister with the working solution with the appropriate warning symbol according to the applicable local legislation, if required.

4.4.4.2 Preparation and loading of interim Liquid System solution

4.4.4.2.1 Preparation of interim Liquid System solution

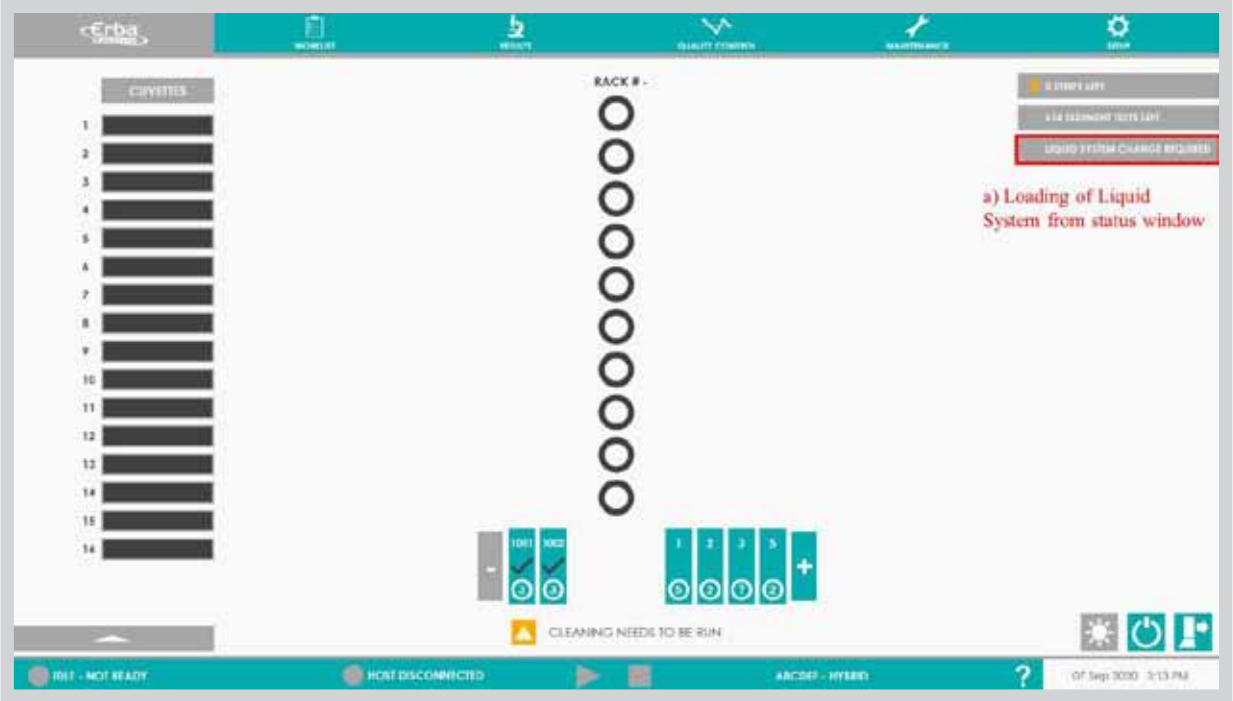
In the interim of availability (registration delays) of the Opti-Sol XL 750, the liquid system needs to be composed of Tween 20 and Proclin 950 and prepared as below:

1. *Tween solubilization* – add 5 mL of **Tween 20** into 500 mL of distilled water and mix thoroughly until complete homogenization - stirring with a weighing spoon, for example, helps make this task easier.
2. *Add Biocide* – add 10 mL of Proclin 950* into the solubilized Tween (*Sigma Proclin™ 950, cat. n.46879-U, 1 bottle of 400 mL)
3. *Dilution* – pour the combined Tween + Proclin solution (prepared in Steps 1 and 2) into a canister and dilute it further with distilled water to 10 L - adding the water on top of the diluted solution helps homogenization)
4. *Homogenization* – connect the canister to instrument and mix by gentle movement to ensure proper homogenization
5. Then go to the *Loading of interim Liquid System solution* see *4.4.4.2.2*

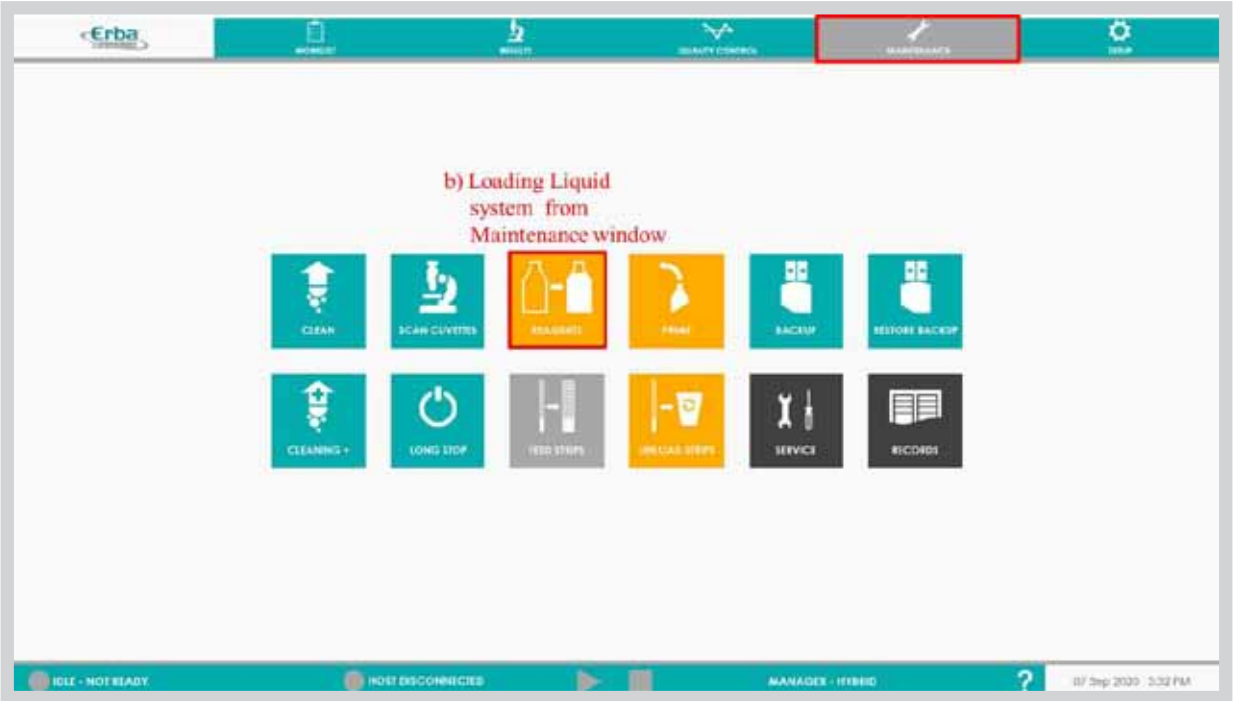
Warning: Refilling/Replacingof the Liquid System involves pulling out the lines out of the liquid. afterwards, it is IMPERATIVE to perform a correct priming to avoid entry of air bubbles in the hydraulic lines during testing, which could impair correct aspiration, dispense and sediment readings. To do so, follow the ‘Loading of interim Liquid System solution’ instructions below.

4.4.4.2.2 Loading of interim Liquid System solution

The loading of the liquid system can be done from the status window when the level is empty, or from the Maintenance menu.



1. Open the Loading of Liquid System dialog box
   - From the Status window (in pause, stop or ready status) by clicking on the LIQUID SYSTEM CHANGE REQUIRED error/button
   - Or from the Maintenance window, REAGENTS; then Liquid System Option





2. Open the Loading of Liquid System dialog box



3. Follow the onscreen instructions and click on the corresponding circle to confirm execution or launch process till the priming



4. Close the dialog box by clicking on the X in the top right of the dialog box.

NOTE The priming will last 13 seconds
If the priming is not performed and the loading process is interrupted, **it will not be possible to start a batch nor run a cleaning cycle**.
If all other steps have been performed and only the priming is missing, priming can be executed from Maintenance, PRIMING, LIQUID SYSTEM (see *8.8.4.2*)

4.4.5 Empyting the waste tank

Even if the instrument will give alerts and alarms when waste tank is full, it is recommended to discard the content of the waste tank and rinse the canister with water, when filling other tanks, to limit run interruptions.



Act in compliance with the respective security level – in connection with use of the analyzer, handling of analyzed samples or waste; use a laboratory coat, gloves and protective goggles.

Consider all human-source material (measured samples, controls) as potentially contagious. Dispose of all liquid waste in accordance with local regulations. Pre-treatment of liquid waste is recommended.

4.4.6 RFID error messages

When scanning RFID the system will check the suitability of the RFID tag against the product, the instrument configuration (distributor, reagent rental status) the current mode/setting (strip type…), the expiration date, the number of tests, the prior usage of the kit.
The Laura XL system uses RFID to load consumables. During this process the system reads from and writes to the tags. These operations take some time, and require the tag to be well aligned with the antenna and to be steady throughout the full process.

In case of RFID error message, it is always recommended to retry the reading, to ensure the error is not consecutive to a partial misalignment with antenna during the process.

Below is the list of possible error messages and their respective meanings.

Error Code	Displayed message	Reason(s)
WrongProduct	Wrong product detected.	The product scan does not correspond to the expected product.
Expired	The product is expired.	Product is already expired or has a defective Tag with no expiry
Over	The product is over, no tests available.	The RFID Tag counter is 0 The tag has already been scanned.
Unknown	Invalid tag detected.	The Tag counter is not matching the expected 100 for strip
		The Tag counter is not matching the allowed range for Cleaner or LS
		No Lot number was found in the RFID Tag (or has a defective tag)
Locked	The product is not valid for this unit.	The tag is not matching the distributor ID and/or the instrument rental status

Error Code	Displayed message	Reason(s)
No kit	No tag detected.	The Tag was not read (no tag, or not able to read tag).
AlreadyUsed	Product already used!	This specific Tag has already been read by this instrument and is disabled
WrongStripType	This kind of strip (name of the kit) cannot be added, (name of onboard strips) already in use.	The Tag is Not matching already loaded strip type

4.5 Registration of Quality Control reagents

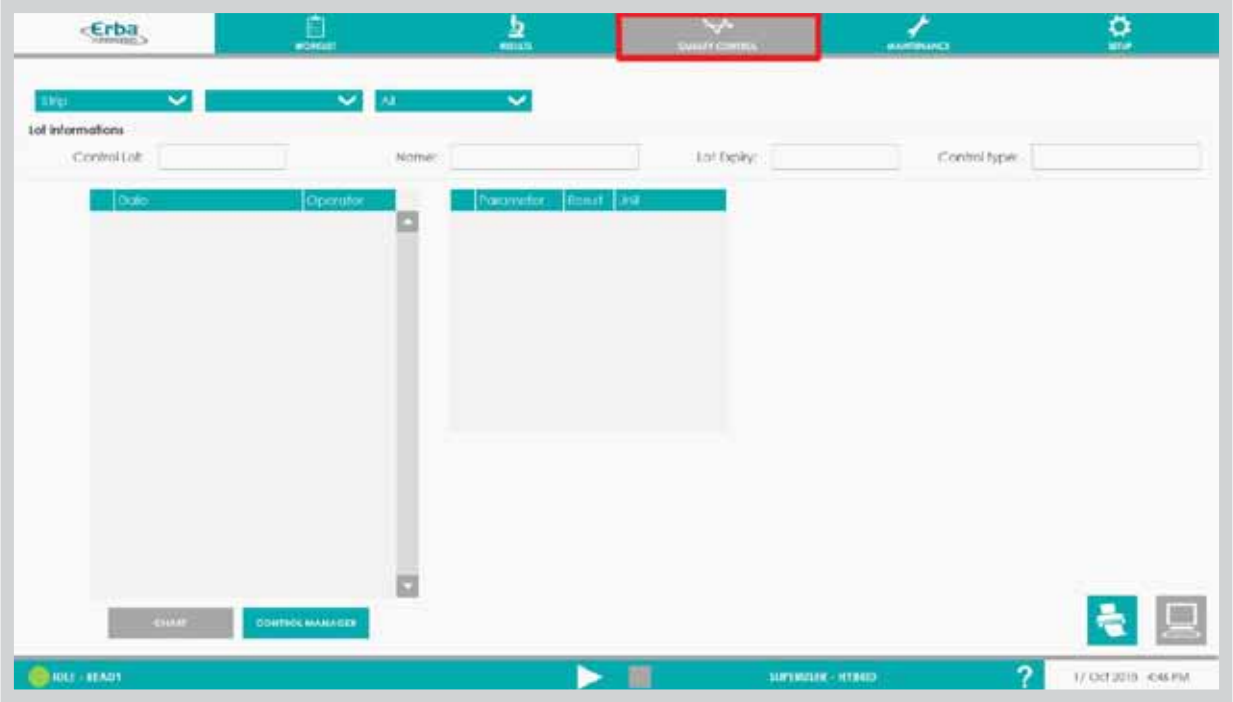
The intention of Quality Control system is to verify the proper calibration and setting of Laura XL components. In case the run does not follow a calibration procedure which includes the Quality Control material, controls should be run on a regular basis. Each laboratory should follow its own protocol for frequency of QC run. It is recommended to run at least 2 levels of QC per 24 hour of activity to check the system performance. QC can also be added any time as felt needed. Once the QC is performed, Laura XL analyzer provides immediate information about conformity of target and evaluated values for chemistry and urine sediment.

NOTE For Administrator account the QC check is optional (see Chapter *8.9.4.1*), however, for User account the QC check is mandatory and has to be performed as a first sample each day. **Further analyses of patient samples are allowed only if the samples pass QC.**

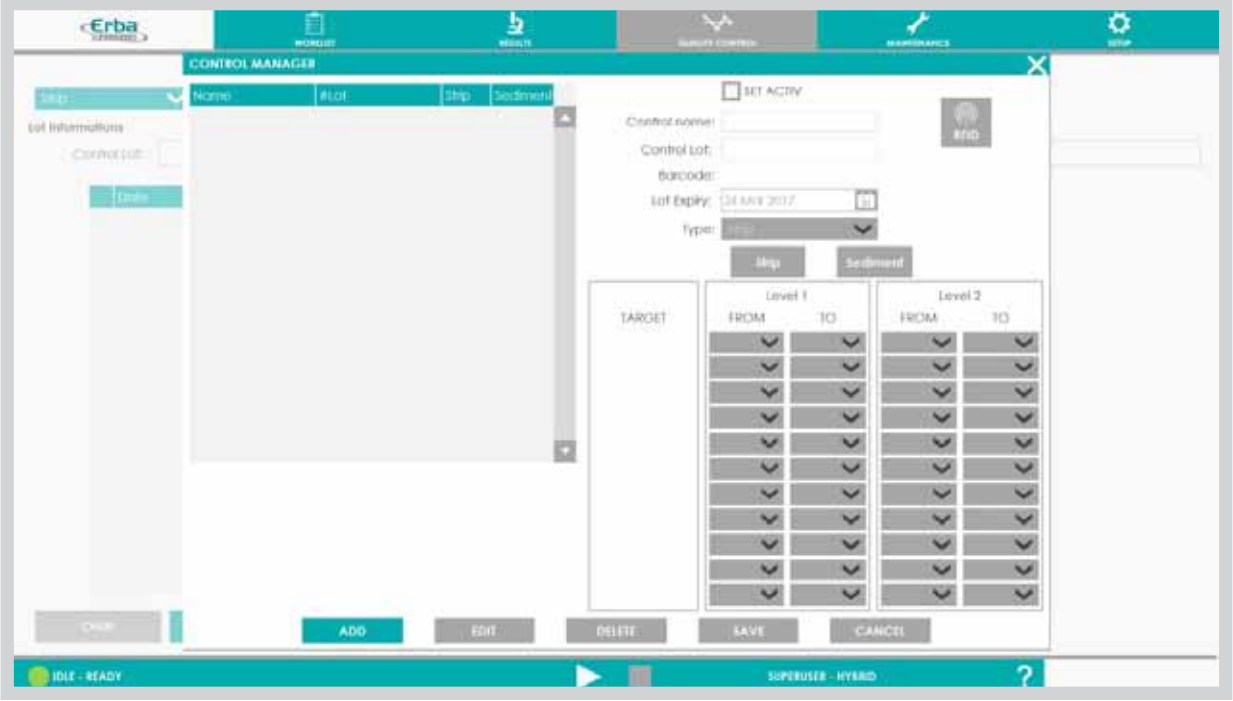
4.5.1 Adding of Control Urine

Before the actual measurement of urine control may be performed, it is necessary to enter the respective values to the QC Menu of LauraGUI. This step includes adding of particular LOT number and its target values from the leaflet (see Chapter *4.1.3*).
The procedure is as follows:

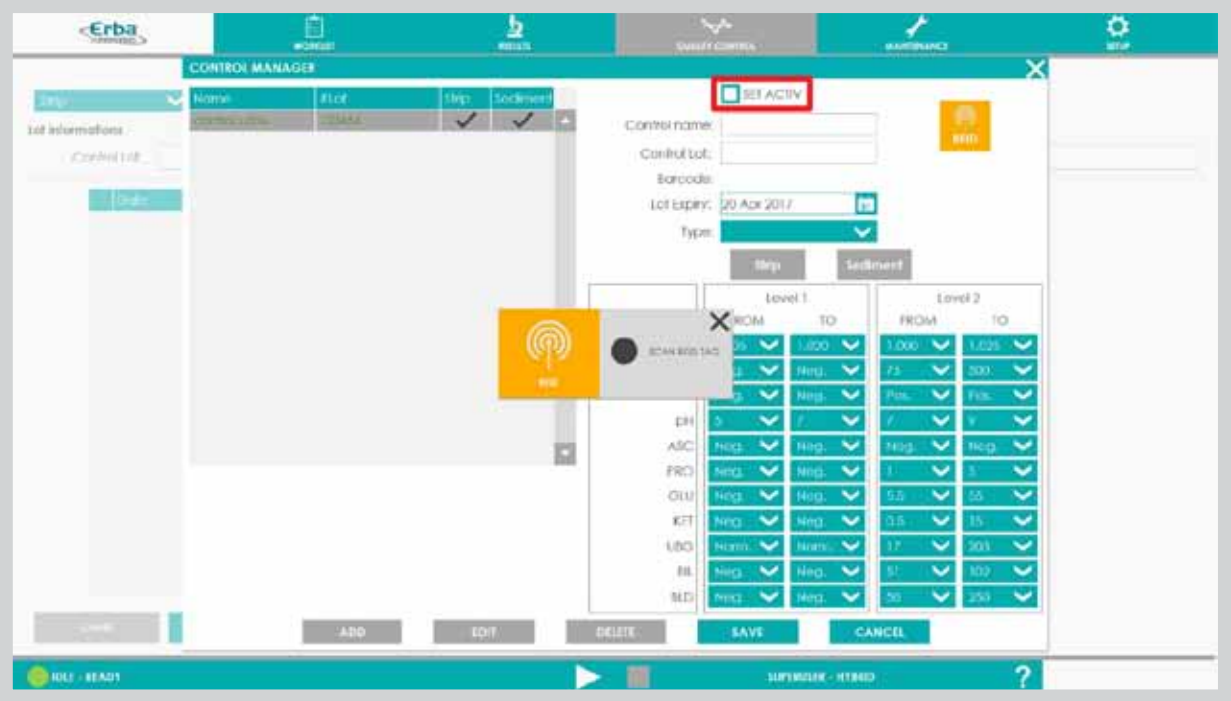
5. Click on “QUALITY CONTROL” menu



6. Click on “CONTROL MANAGER” in order to add, edit or delete already existing control material.



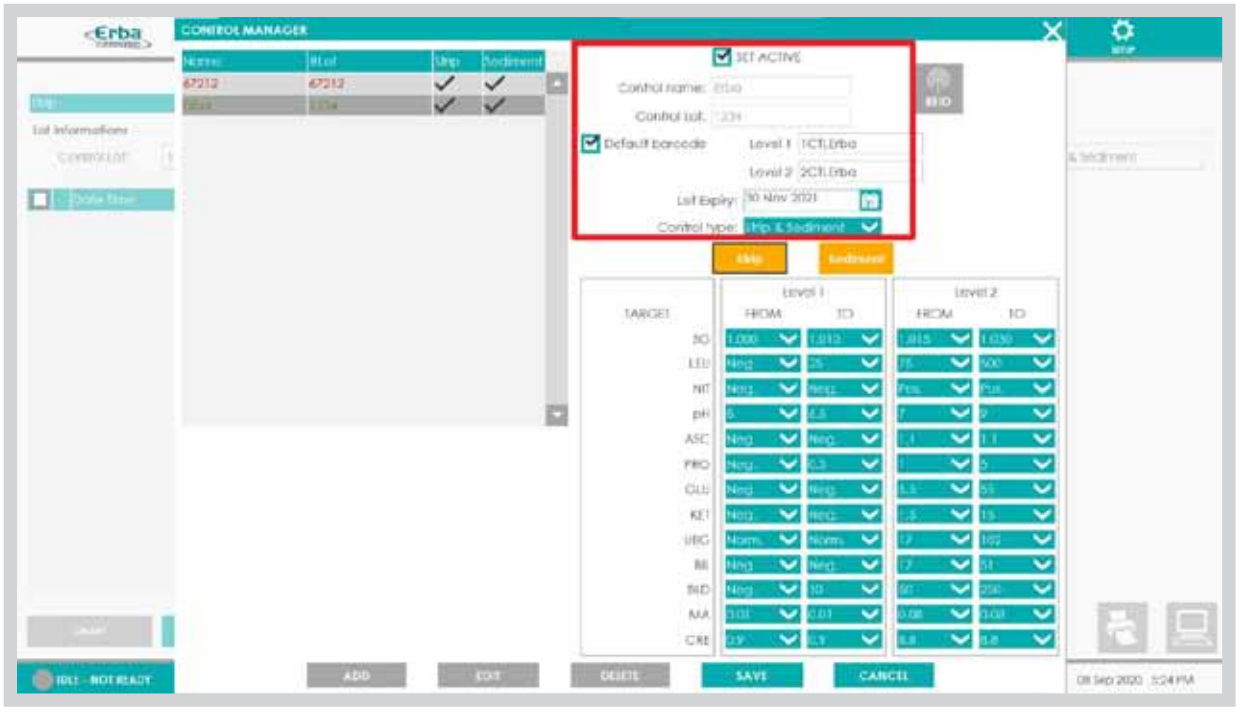
7. The new control material can be added:
   - Automatically:
     - Open “CONTROL MANAGER”
     - Press “ADD” button; right part of the Control manager window becomes active
     - Press “RFID” button and scan RFID tag attached on the bottle



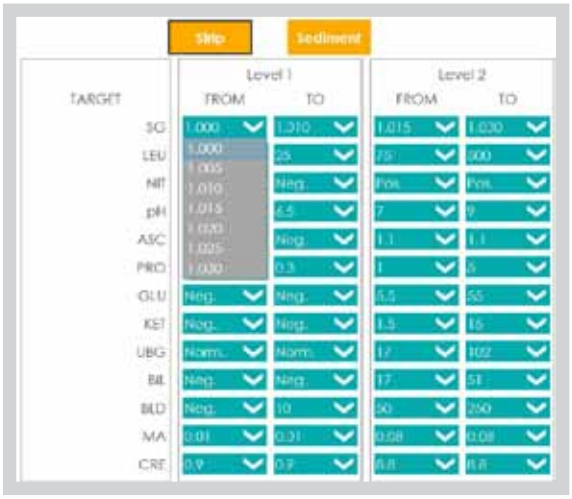
- Click on “SET ACTIVE” in order to use the entered values for evaluation of controls
- Save loaded values by pressing “SAVE” button

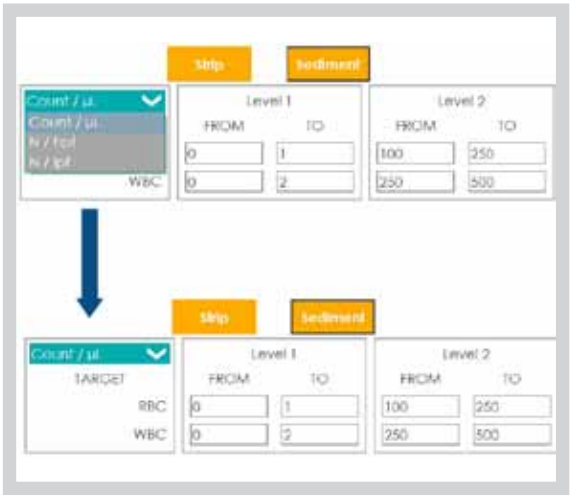
Warning: Only one control material (for each level and type of measurement) can be active at one time.

- Manually
  - Open “CONTROL MANAGER”
  - Press “ADD” button; right part of the Control manager window becomes active.
  - Fill in the Control name, Lot, Expiration and Type (strip, sediment or both)



- Set the target values for strips and/or sediment for Level 1 and Level 2

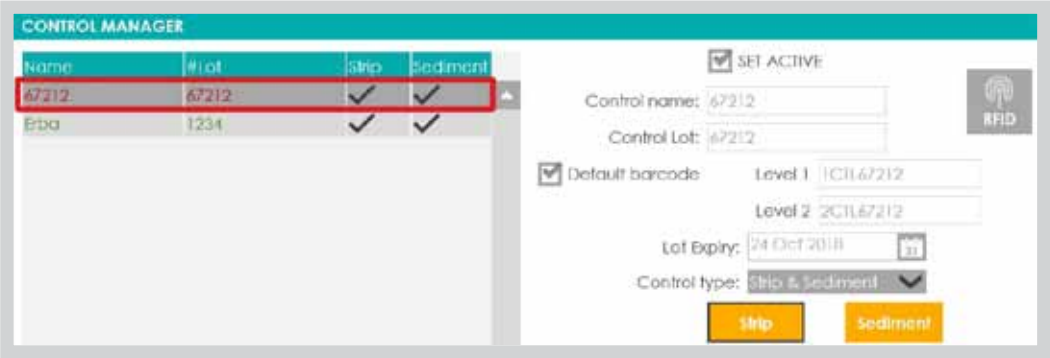




- Click on “SET ACTIVE” in order to use the entered values for evaluation of controls
- Save entered details and values by pressing “SAVE” button

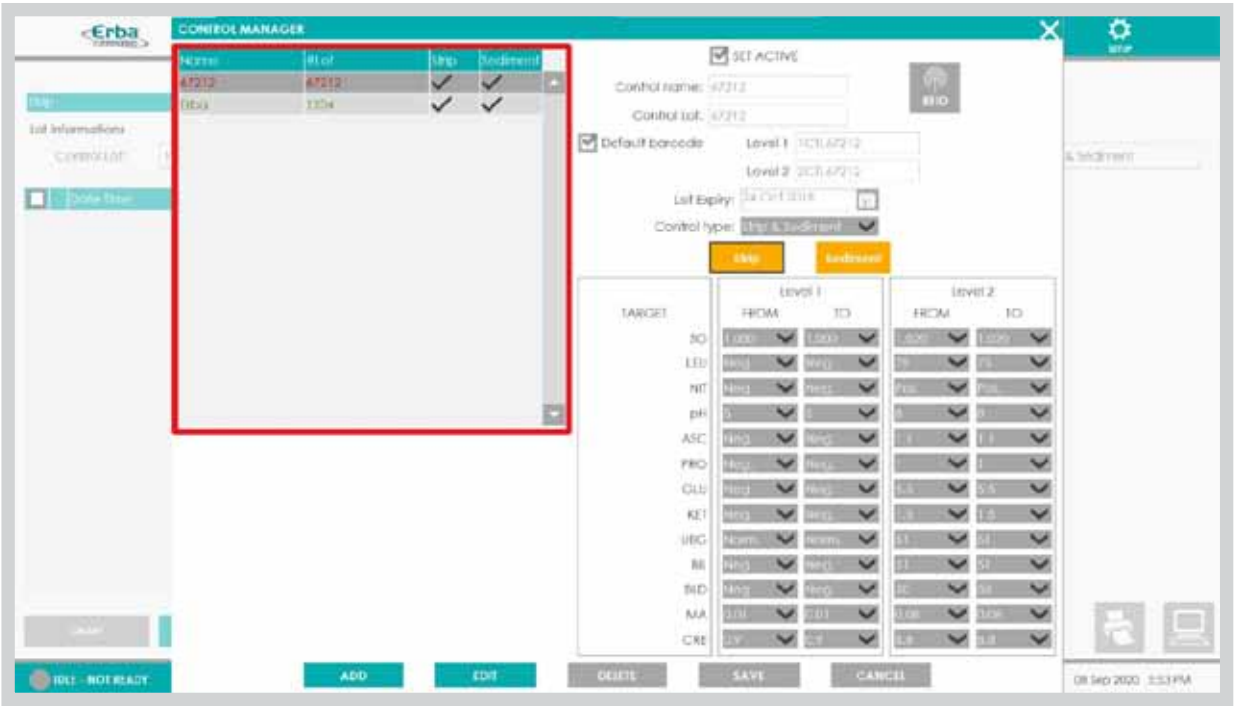
Warning: Only one control material (for each level and type of measurement) can be active at one time.

The newly added control material is displayed on the left part of Control manager window. The “check” sign indicates if the values were assigned for Chemistry (Strip) and/or Sediment.



4.5.2 Editing / Deleting of Control Urines

All the added control urines are listed on the left part of Control manager window. Here, the control urines can be edited or deleted.



Editing of already existing control urines:

- Choose the control urine which needs to be edited
- Press “EDIT” button
- Do the necessary adjustments (change expiration, range values, etc.)
- Save the changes by clicking on the “SAVE” button

Deleting of already existing control urines

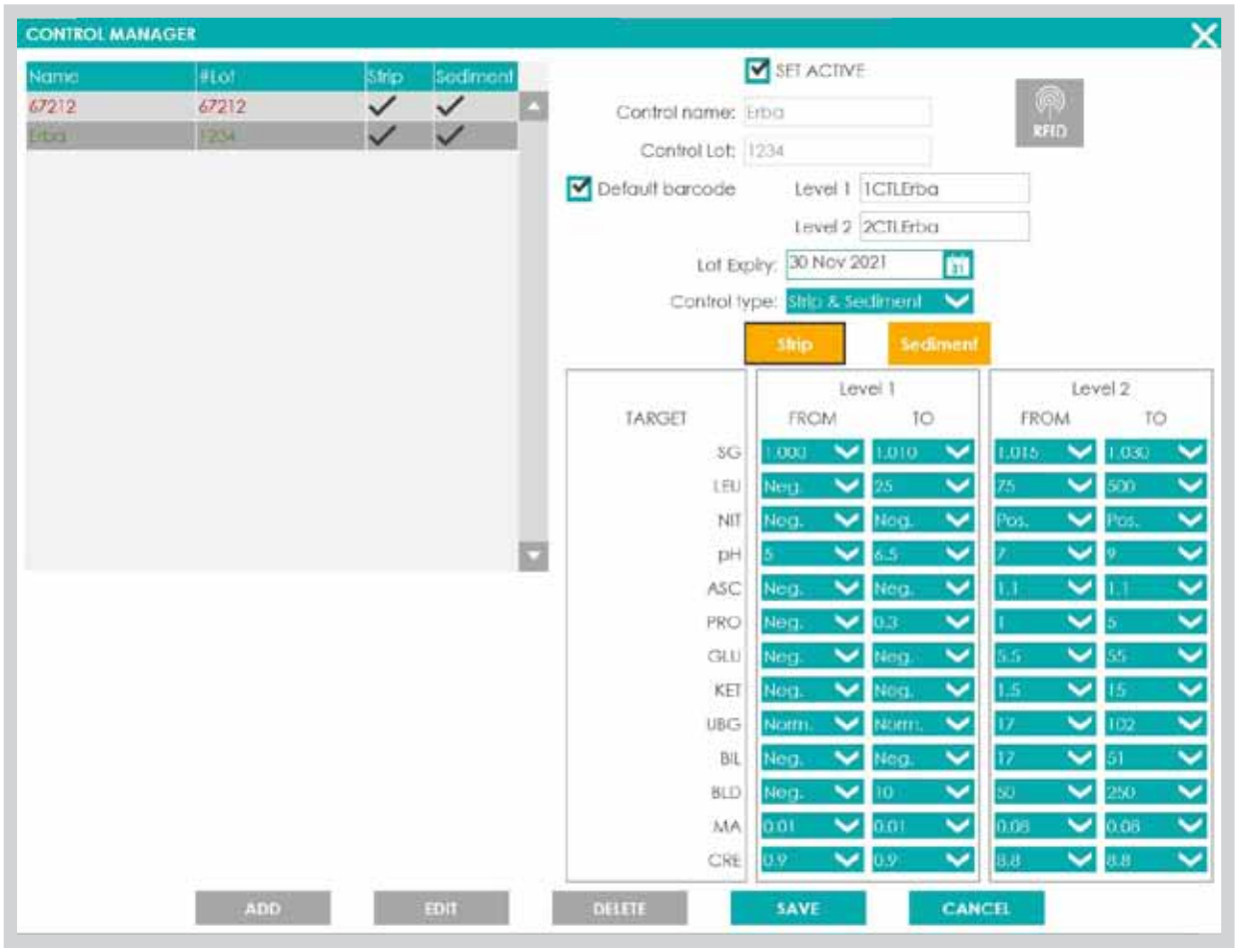
- Choose the control urine which needs to be deleted
- Click on the “DELETE” button

Warning: Once the control was deleted it cannot be restored anymore.

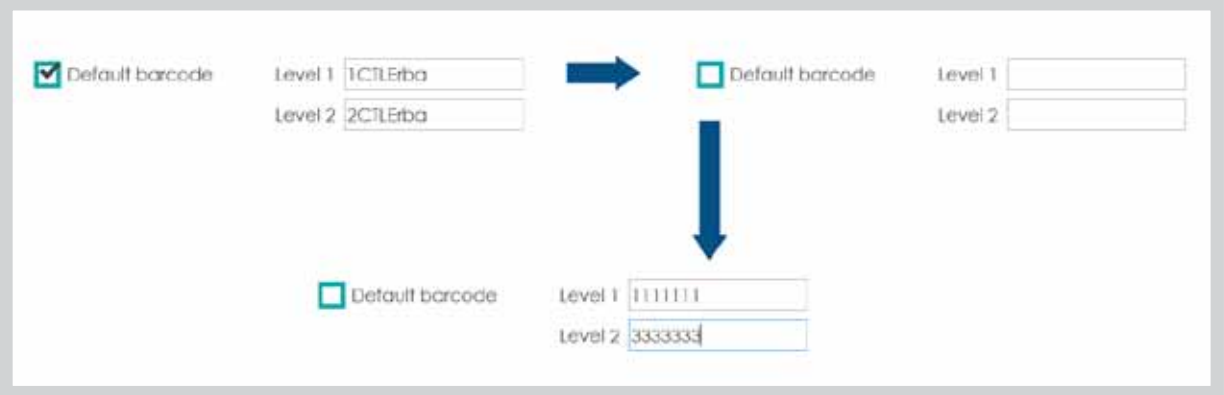
4.5.3 Editing the barcodes of Urine Controls

When defining a control, byt default a barcode is generated which can be produced for the system to automatically recognize the barcode read as being a control material and treating accordingly. It is possible to create customs barcodes for QC.

For that at the time of QC creation or existing from the list of controls, click on the EDIT button



Then untick the Default barcode, the barcode fields clear, then type the desired codes and click on the SAVE button



5. Running

5.1 General information about running samples

LAURA XL can be connected to the LIS, in which case the system will receive the information about sample name, test ordered, etc. from it. But it can also be configured to run one assay by default, in which case when running with barcoded samples, the test request is quite easy and fast.
Running samples on LAURA XL can be achieved in different ways:

1. Loading a rack of barcoded samples and having the system scan for occupied spaces.
   - If the system is connected to the LIS in bidirectional interface, then the requests will be retrieved from the LIS.
   - If the system is NOT connected to the LIS, then the system will propose to run all detected positions with the default assay and inform the user of all the unidentified positions.

NOTE The system detects tubes from rack by either reading their barcode, or just their presence even in the absence (of readable) barcode

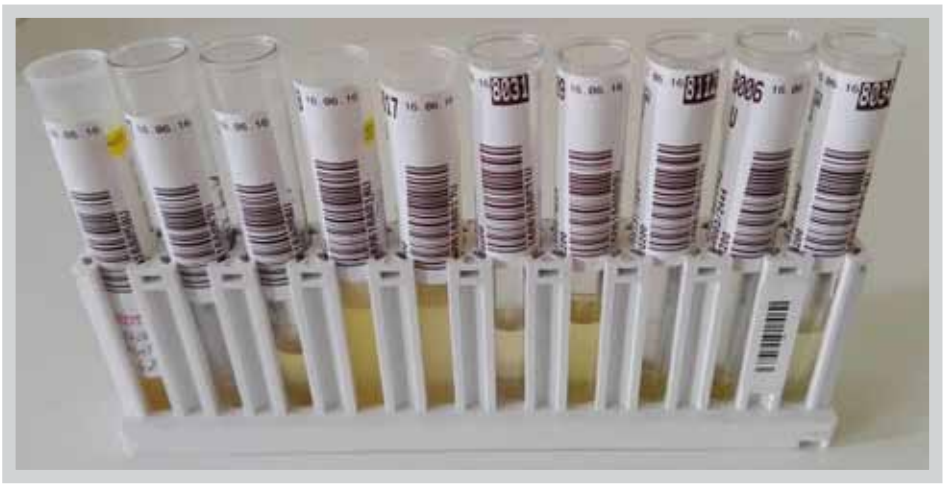
   - The user can decide to let the system run as is
   - Or decide to change manually the orders and / or add new samples where barcodes could not be found.

2. Registering each sample on the system before pressing the Run button and loading the rack into the system. The system will check for obvious differences between the sample information registered and what it detects and highlight discrepancies.

5.2 Samples identification

5.2.1 Barcodes

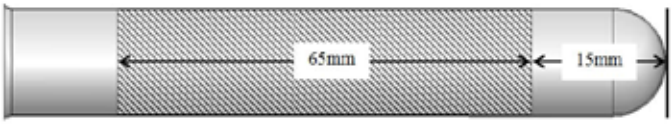
Barcodes can be used on urine samples and controls. The identification of the analyzed urine samples is based on barcodes reading.



List of barcodes which are automatically identified by LAURA XL analyzer:

- Code 128 (A, B, C)
- Codabar
- Code 39
- Code 93
- Interleaved 2/5

Specifications of Barcodes and their Positions

Item	Specification
Barcode Type	128 A, 128B, 128C, Interleaved 2/5, 93, 39, Codabar
Minimum Bar Thickness	Code 128A : 5 mm Code 128B : 5 mm Code 128C : 5 mm Interleaved 2/5 : 7 mm Code 93 : 12 mm Code 39 : 7 mm Codabar : 7 mm
Minimum Bar Length	Test tubes ≥ 15 mm; Micro test tubes ≥ 10 mm
Reading Range	Width of reading range: 65 mm Beginning of reading range: 15 mm from bottom of test tube 
Tag Size	Depends on type of barcode and number of characters Tag size must be smaller than scope of reading range
Number of Characters	1 – 15 for each aforementioned type of barcode Number of characters may be limited – depending on type of barcode, considering its reading range
Position of Barcode Tag	Barcode (tag) must be placed within reading range. Angular deviation: max. ±1°. Tag containing barcode placed on test tube must be turned to face opening of rack.
Printing of Barcodes	White background is mandatory Individual parts of barcode must be printed properly Barcode must be without scratches (decreased efficiency of identification) It is not recommended to print barcode on thermal paper – considering time stability of barcodes

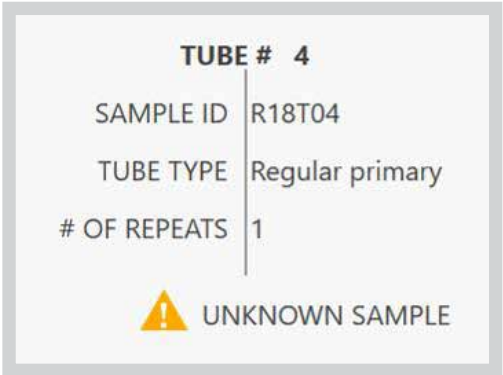
5.2.2 Manual Registration

Identification of urine samples may be performed even in case when the laboratory does not dispose of a system of sample identification based on barcodes. In such case it is possible to perform measurements in mode of sequence numbers. Each rack is equipped by its own identification number which is associated to the barcode located on the side of the rack.



In case of reading the test tube which is placed in position 4 of Rack 018, the resulting identification number is presented in the following format:

R18T04



Warning: While handling the racks, pay special attention to the barcodes located on the side of each rack, thus preventing any possible damage. Any damage caused to the barcode may result in incorrect identification of analyzed samples!

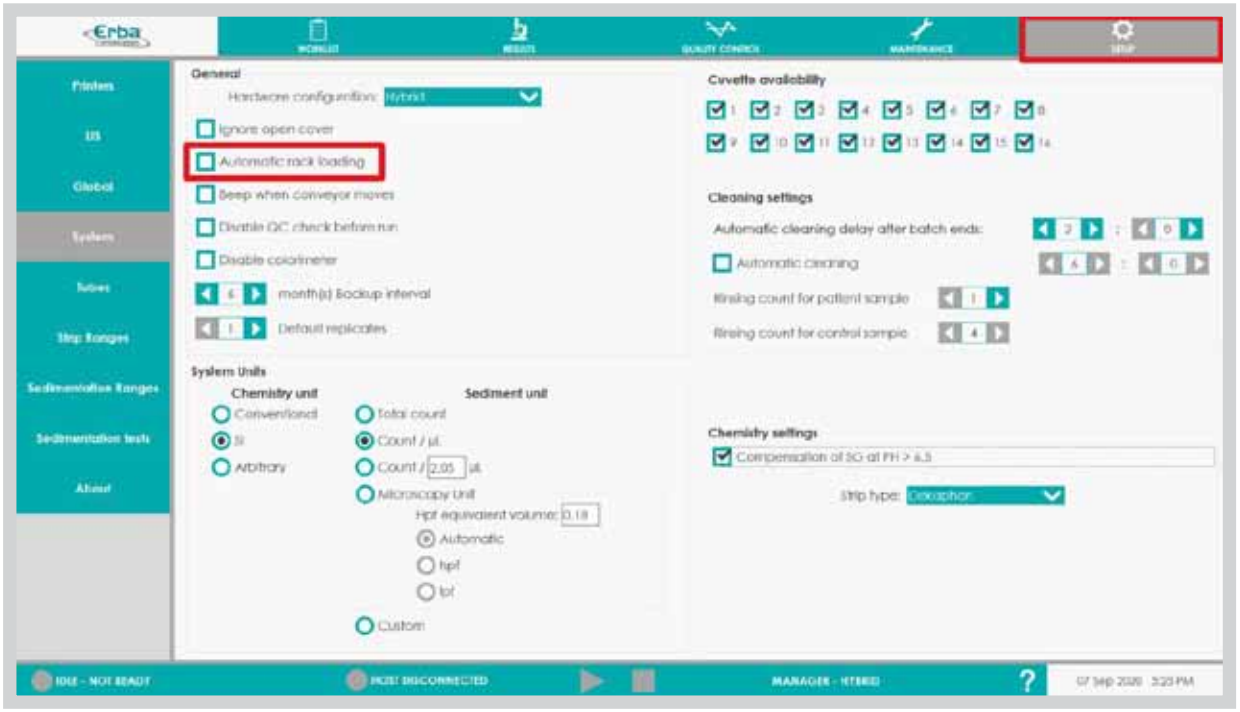
5.2.3 Special Case of Controls

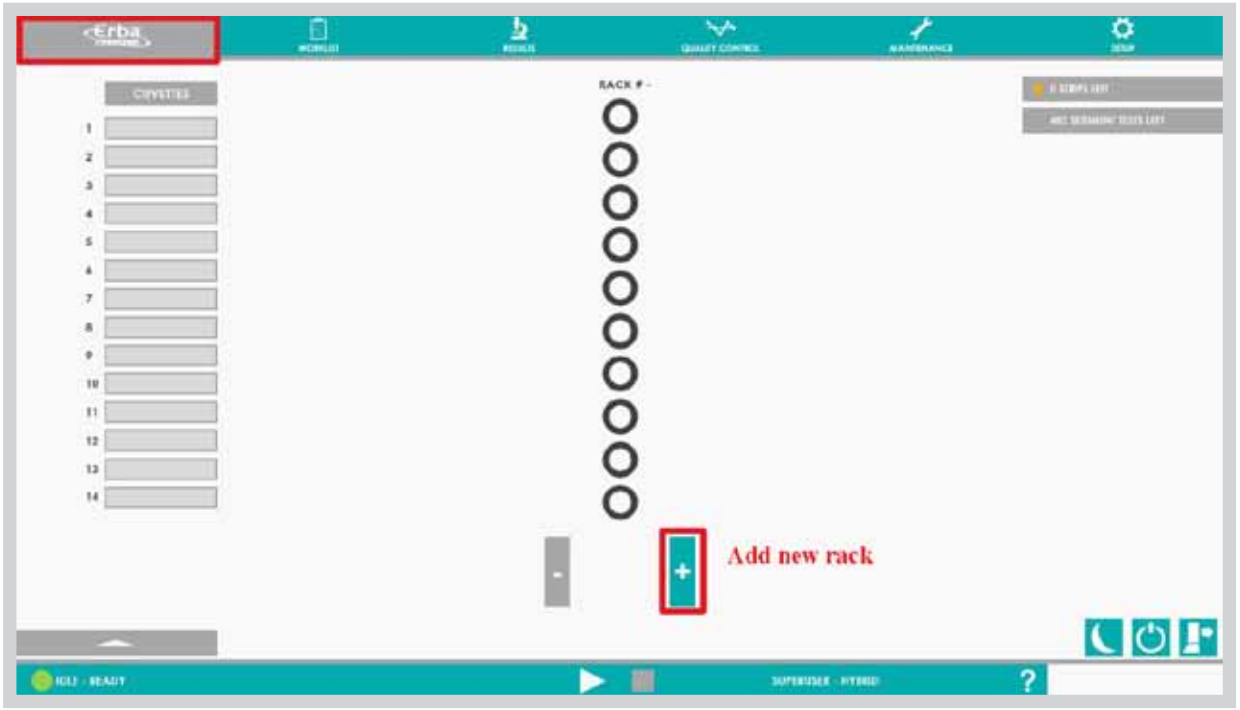
5.2.3.1 Measurement of Urine Control

The controls can be run using barcoded tubes (see barcodes to be generated from section *4.5.3*). If the controls are run with barcodes, they can just be placed on a rack and the rack run like a regular rack with patient samples by automatic mode.

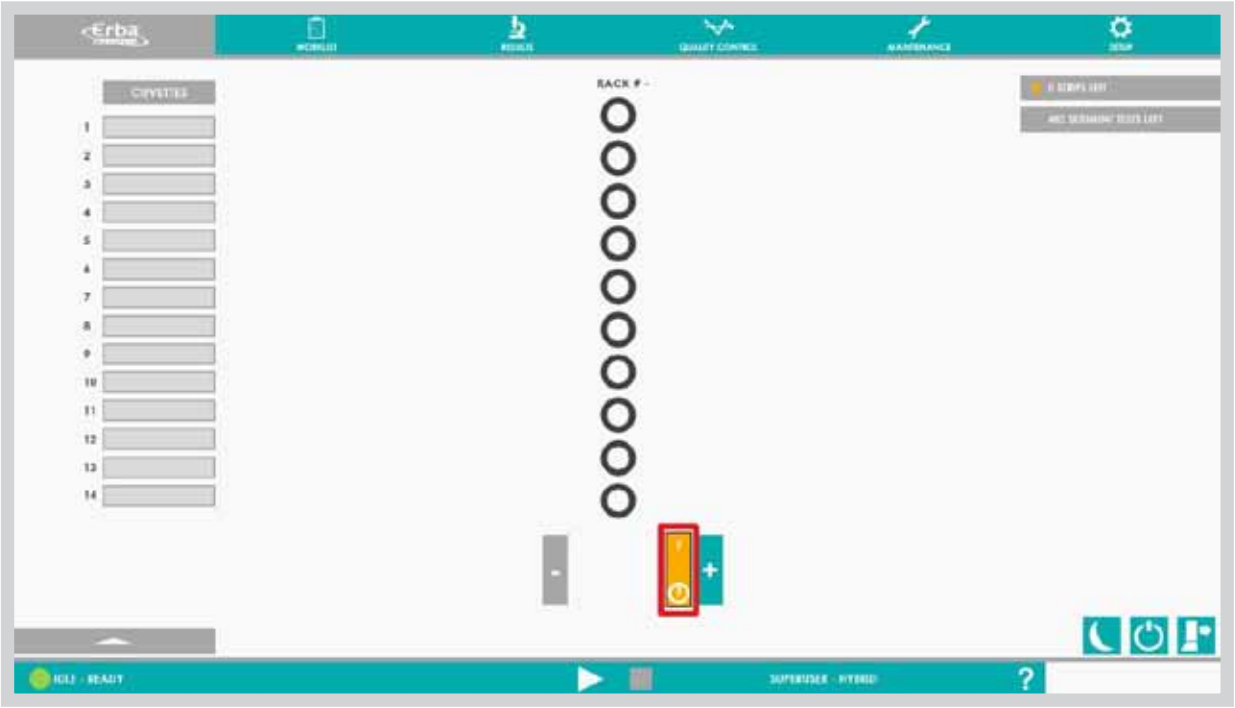
If the controls have to be programmed manually, then before starting any measurement, make sure the system is initialized (according to Chapter *5.4.1*), diagnostic strips and liquid consumables are loaded (according to Chapter *4.4*) and racks with sample tubes are placed on the board (according to Chapter *5.3*).

1. In the “Setup” Menu make sure that option “Automatic rack loading” is disabled

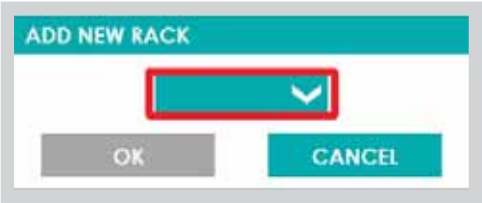




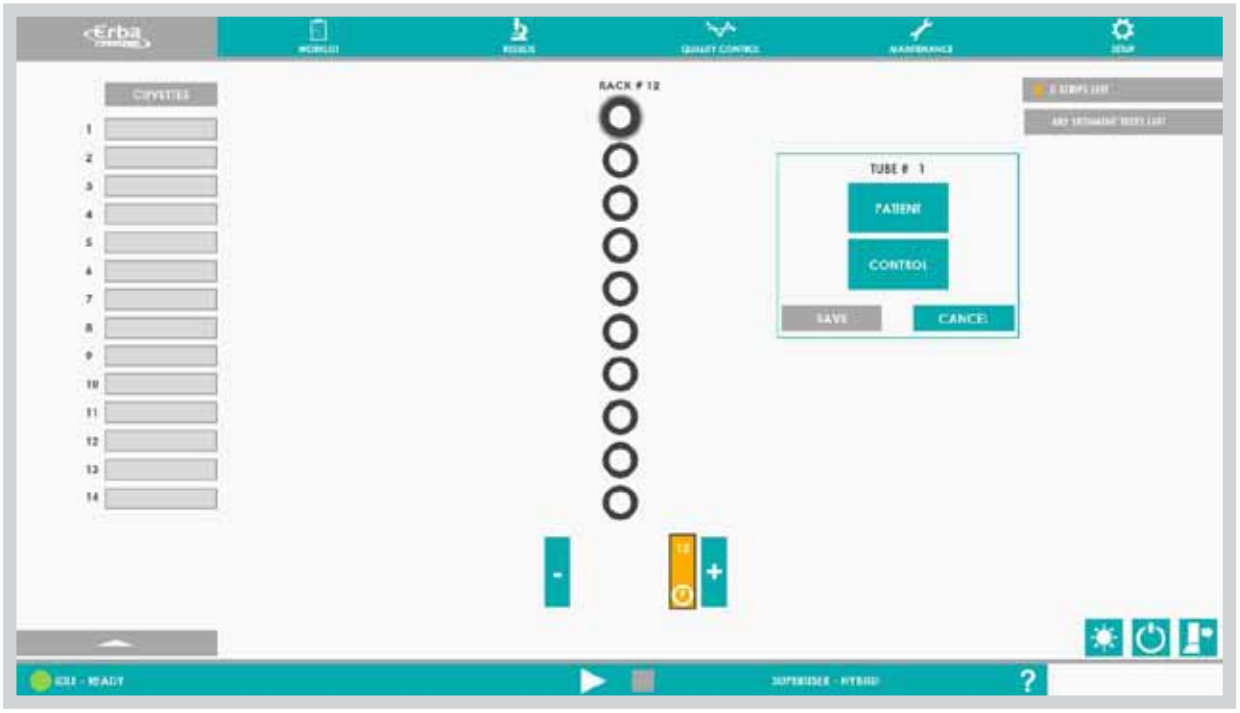
2. Click the button which symbolizes the newly added rack



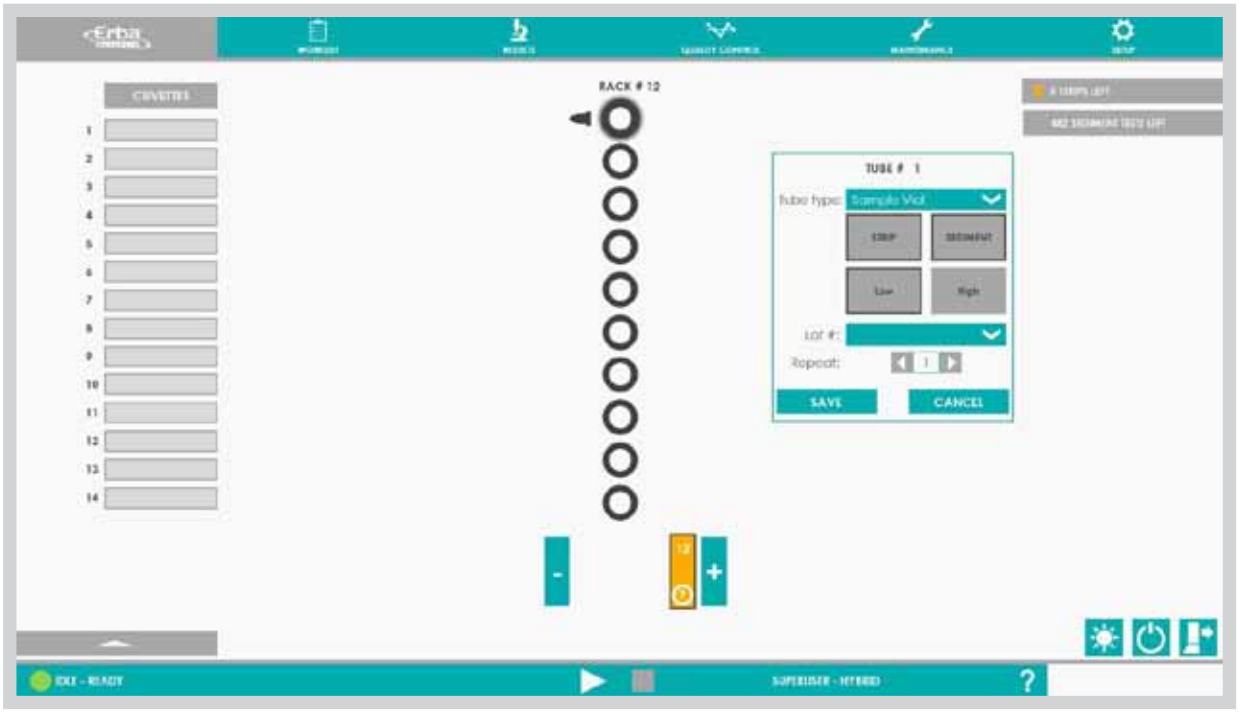
3. Select the rack number



4. Click on the first position of the rack – a window with “CONTROL / PATIENT” sample option for the test tube no. 1 will be displayed:

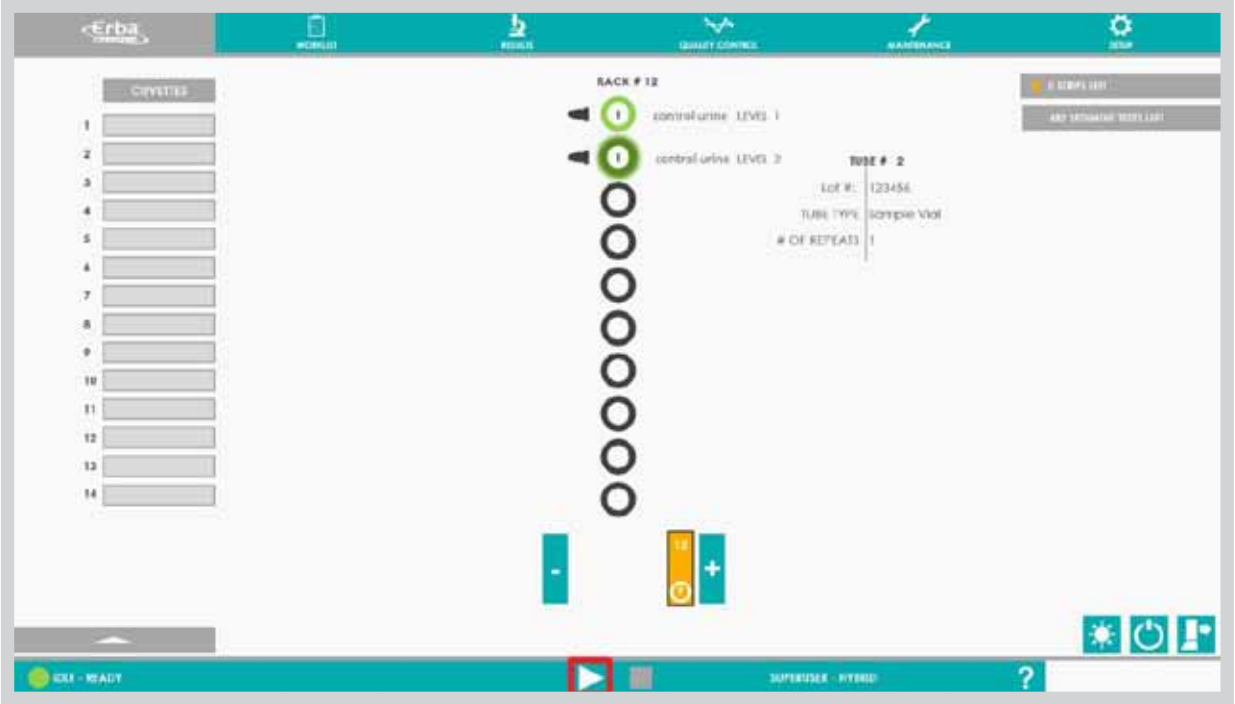


5. Press “CONTROL” button to display further options:



6. Set the parameters for control:
   - **Tube type:** Possibility to select the test tube size – regular primary test tube or sample vial
   - **STRIP:** Measurement using a diagnostic strip will be performed.
   - **SEDIMENT:** Measurement using urine sediment will be performed
   - **Low:** Negative (normal) level
   - **High:** Positive (pathological) level
   - **Lot:** Number of LOT of the control material
   - **Repeat:** Possibility to set number of repeats – only when using primary test tube

7. Press “SAVE” button to save the entered data and repeat the same procedure to set the parameters for the other Level.



5.3 Loading Samples

5.3.1 Urine collections

Although different types of urine collections are required for different analyses purposes, the most common analysis is for the detection of Urine Track Infectio (UTI).
Collecting urine is a key step that determines the quality of the results. It must therefore be done under conditions of rigorous asepsis.
Although this sample can be taken in the laboratory where directions can be strictly given, often urine collection can be done at your home for outpatients.
Collections must be done in a sterile test bottle to store urine (about 20 to 30 ml).
It is best to collect the first morning void, because the sample must be taken **at least 4 hours after the previous micture**; thus the urine has remained sufficiently in the bladder so that, in the event of urinary infection, the bacteria are numerous enough for a culture.

In case of suspicion of UTI, it is also necessary to do the urine collection before starting an antibiotic treatment (or for a control, after at least 48 hours of stopping such treatment) so as not to prevent the growth of bacteria during culture in the laboratory.
Collection of a midstream specimen of urine in a clean/sterile container after cleaning the genital area, retracting the foreskin in boys/men or spreading the labia open in girls/women, is the method recommended, to avoid bacteria on the skin or mucous membranes (especially the anal or vaginal mucosa) to contaminate the urine.
The collected urine must be analyzed within a very short time after collection. They should not be kept for more than 2 hours at room temperature.

5.3.2 Preparation of Samples

Correctly collected and stored urines should be tested within 2 hours of collection.
Generally, it is accepted that after standing two hours at room temperature, the chemical composition of urine changes, and formed elements begin to deteriorate, and bacteria actively proliferate. Urine constituents, such as bilirubin and urobilinogen, are light unstable. Bacteria can consume glucose resulting in pH changes if the urine is allowed to stand. Casts, erythrocytes, and leukocytes are especially susceptible to lysis in urine specimens with a low specific gravity (<1.010) and in urine specimens with an alkaline pH (>7.0). While refrigerated, keep in mind that precipitates of amorphous urates or phosphates can be formed.
Generally, chemical preservatives should be avoided. If commercially available “urine preservation” systems are used, they should first be evaluated by the laboratory. Such systems, while perhaps useful for some analytes, may have limitations for specific urine tests.
The urine sample should be well-mixed, to rehomogenize the sediment elements (visually visible or not) uncentrifuged, before transferring them if required into a tube compatible with the Laura XL analyzer.
If the urine is already in a compatible tube for the analyzer, the tube should still be homogenized before placing it into a rack for testing. The mixing of the sample prior to analysis performed by the analyzer is designed to ensure rehomogenization of **2 hours sedimentation, not more**.

5.3.3 Test Tubes & adapters

Various types of test tubes may be used for the purpose of urine samples analysis. It is recommended to use the test tubes made of glass or plastic. The analyzer is able to detect both barcode labeled or unlabeled tube.
Ther system is designed for two types of test tubes, which can be used for the analysis:

- REGULAR PRIMARY – for regular routine patient samples
    - diameter: up to 16 mm
    - height: up to 110 mm
    - volume: approx. 10–12 mL
    - material: glass or plastic
    - shape: round or conic bottom

- SAMPLE VIAL (with adapter) – for paediatric or low volume samples (marked as Eppendorf vials)
  - diameter: 10 mm
  - height: 40 mm
  - volume: 1.5 mL
  - material: plastic

Labelling	Description
	REGULAR PRIMARY
	SAMPLE VIAL

In addition to these 2 types, the system also allows using specific tubes which have different characteristics than the regular one (typically different bottom height – like Sarstedt for example). These tubes need to match the rack characteristic to position and secure them correctly. These specific tubes have to be defined initially by a service engineer to determine the bottom of the tube to ensure proper mixing and aspiration, then the user needs to configure the rack(s) on which these specific tubes will be used. The definition of specific tubes racks are described in section *8.9.5*, and as part of the system customization.

The maximum outer diameter of the test tube is 16 mm. It is also possible to use test tubes with a smaller outer diameter (mainly in case of paediatric samples). The correct gripping and positioning of the tubes are secured by metallic clamps implanted inside each rack.

Warning: Use only original Laura XL racks for positioning the test tubes with urine samples on the analyzer. If a different type is used, the device may be damaged (incorrect position of test tubes can result in pipette hit).

Warning: The sample vials can be used only when placed into the specific Laura XL adapters with magnetic sensors (LH15-00-05, see Chapter *3.2.2*) which ensure their correct recognition. Placing the vials into the primary test tube or directly into the rack will result in incorrect identification and may lead to destruction of dosing pipette or other parts of the instrument.

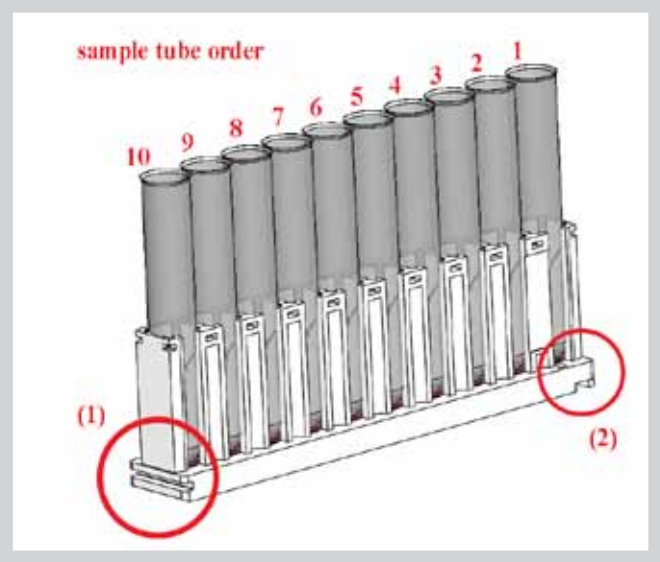
Warning: In case of exceeding the determined height of the tube – 110 mm – the pipette can hit the tube and cause a severe damage. Always use the type of test tubes which corresponds to the technical specifications.

Warning: Prior to start a run, or placing racks onto the input bay of a running instrument, **ensure that no caps are present on any of the tubes**. If the caps are not removed the dosing pipette may be destroyed.

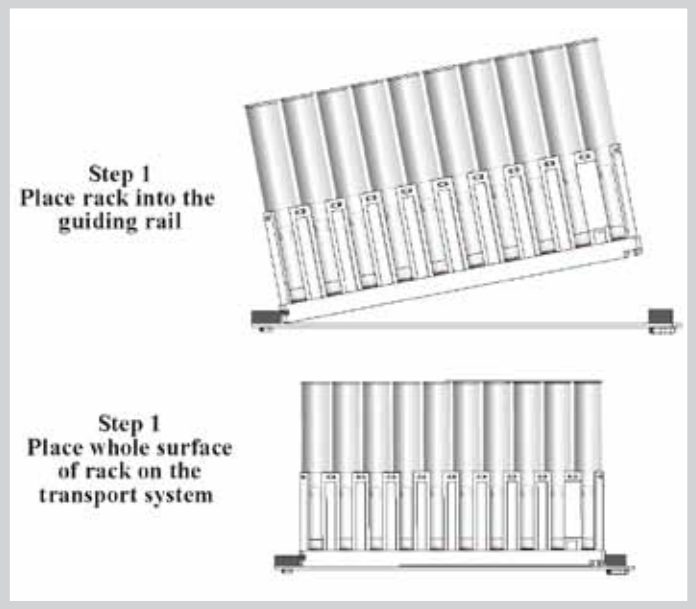
5.3.4 Rack

The rack for test tubes is not symmetrical and must be positioned on the analyzer in the proper side orientation. There are two types of grooves which ensure the correct movement of the rack:

1. **Guiding groove** – which supposes to be on the frontal side of the rack when placed on the board. It protects the samples to be spilled off.
2. **Catching groove** – which serves for the catching by rack hook and subsequent insertion of the rack into the analyzer as well as correct positioning for the pipette

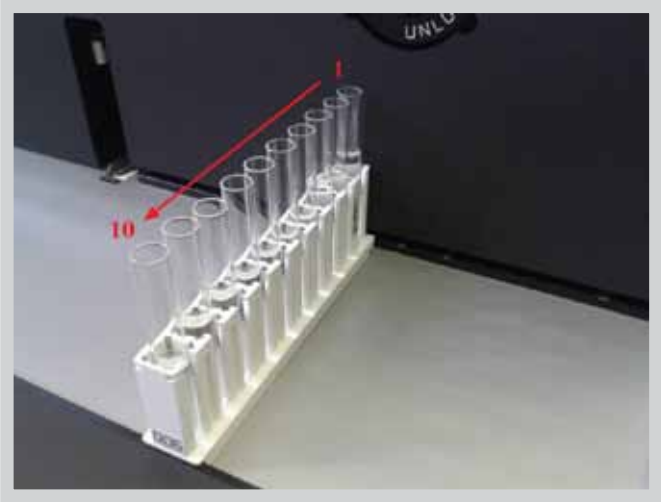


The first sample tube which undergoes the analysis is the one close to catching groove (2), on the contrary, the last sample tube which undergoes the analysis is close to guiding groove (1).
The following picture shows the correct placement of the rack containing samples:





Correct position of the rack is show in picture below:



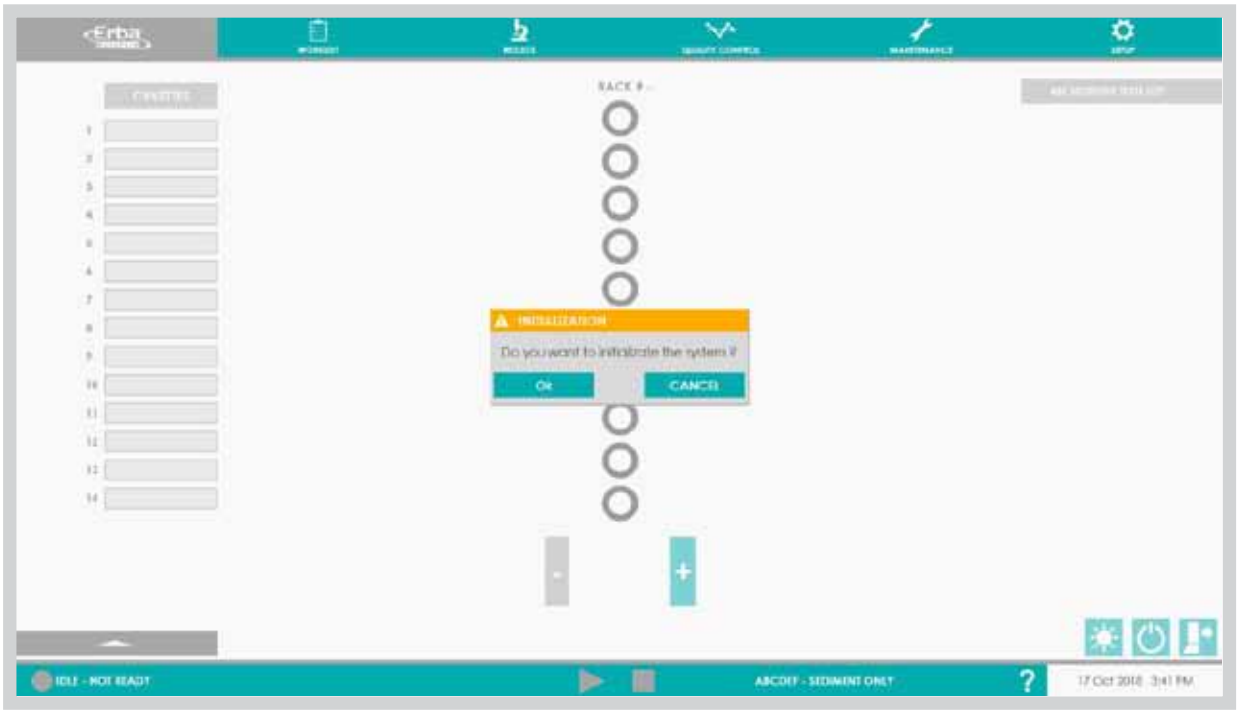
NOTE The Rack number should also be readable once placed on the system

For information on how to program racks for specific tubes, refer to section *8.9.5*

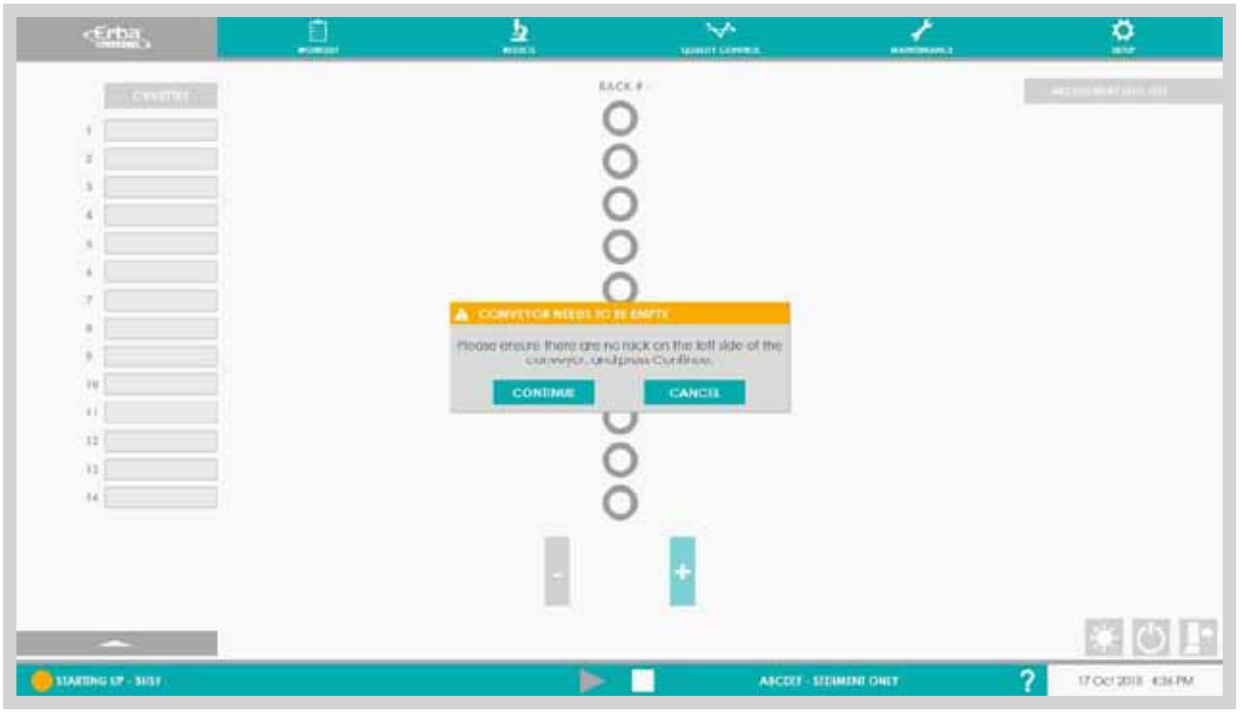
5.4 Start device

5.4.1 Initialization

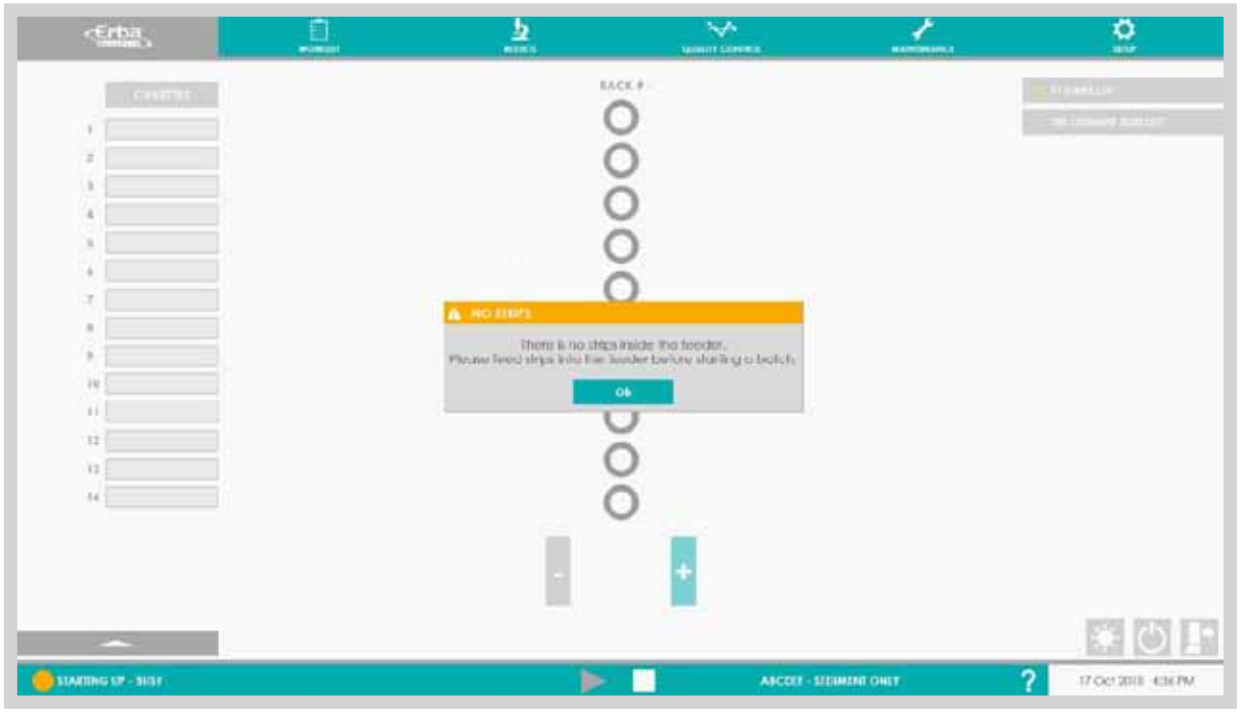
Initialization is a process of preparation of the whole system including movement test of all the motors and pipette flushing. It is mandatory to perform Initialization when coming back in the software before beginning measurements – within the start up / when switching between measuring modes / every time the measurement was stopped forcely by user. The window for Initialization is displayed automatically after Log in or can be manually initiated by pressing the “Sun” symbol (see Chapter *8.2.5* for further details).



As soon as OK button is pressed, the user is notified about the necessity of checking the left side of the transport system which is reserved for the racks with already measured urine samples. If a rack is present, it is necessary to remove it. Only then user can continue with the initialization process by pressing CONTINUE button.



If there are no diagnostic strips displayed in the strip counter field, user is notified by the following window:



As soon as start up of the process of initialisation is confirmed, the system icon changes from “IDLE NOT – READY” to “STARTING UP – BUSY”. At the same time, the colour of STOP button changes from grey to white, thus becomes active. If it’s necessary, the initialization can be interrupted by pressing STOP button.



Initialisation completion is notified by the change of status icon from “STARTING UP – BUSY” to “IDLE – READY”.



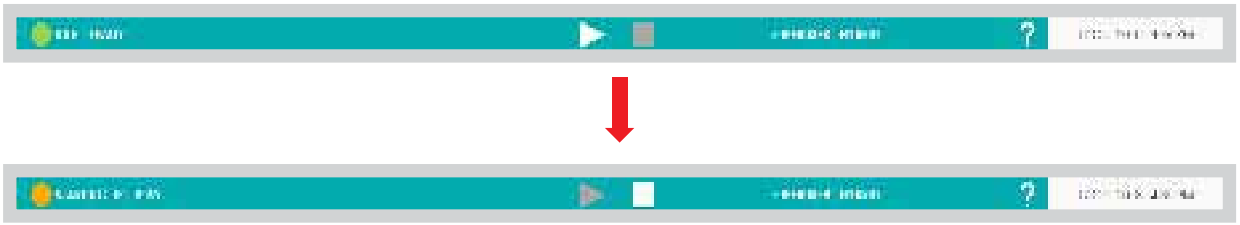
Once the process of initialisation is completed, LAURA XL analyzer is ready for analysing of urine samples.

5.4.2 Run Settings

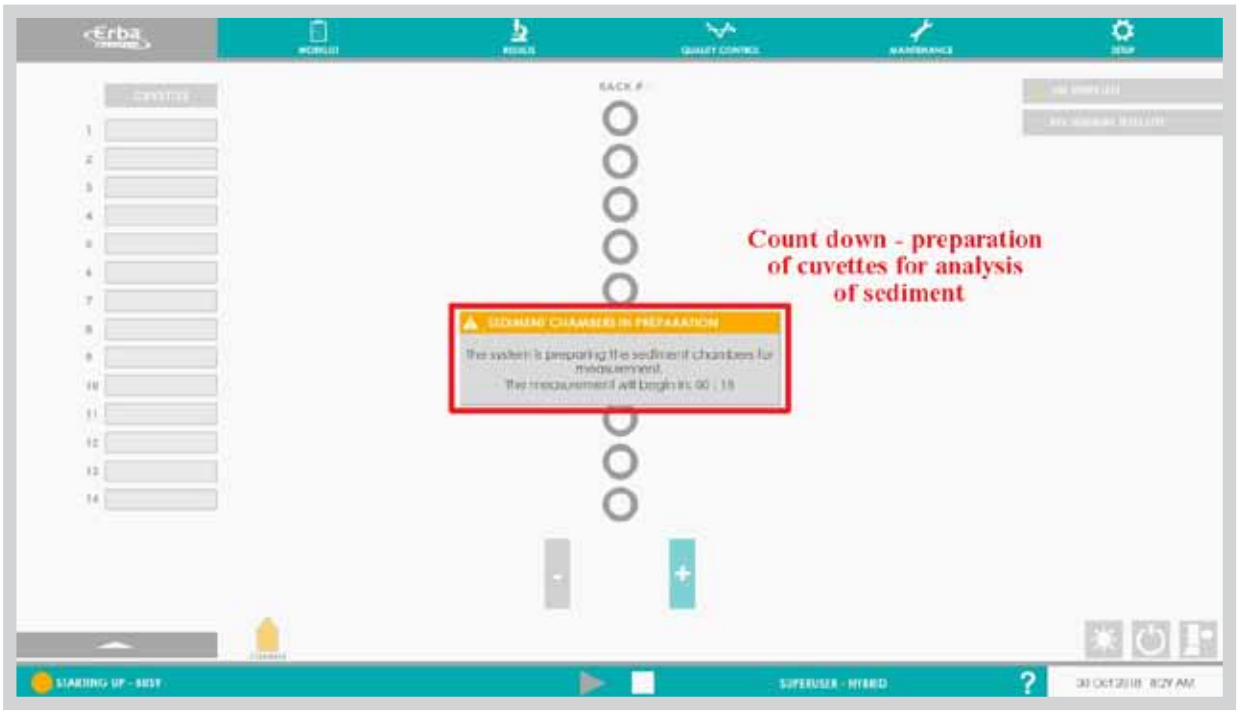
See start up section for software and customization.
The racks and samples can be programmed ahead of starting the run (see *8.4.7* registering samples), or racks can be loaded directly to run the default replicates on detected tubes.

5.4.3 Start run

The measurement can be started by pressing “PLAY” ▶ button, which becomes active after completion of above mentioned steps. At the same time the status in bottom bar is changed from “IDLE – READY” to “STARTING UP – BUSY”.

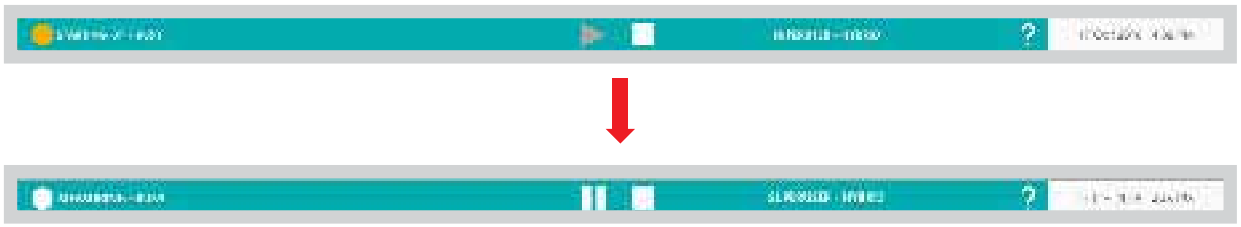


When ▶ button is pressed, if Hybrid or Sediment mode is selected, the system performs inspection of individual cuvettes to be ready for analysis of urine sediment. The process lasts approx. 1 min and 45 seconds and is accompanied by a countdown presented on the screen of LauraGUI.

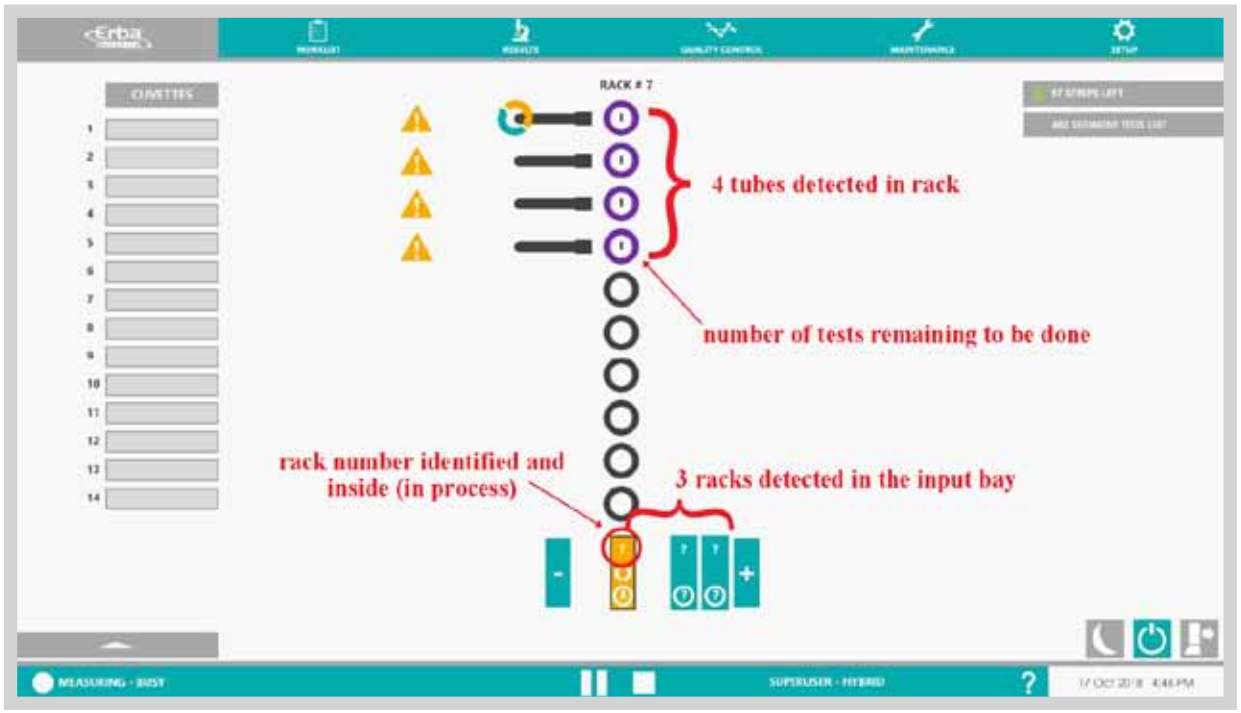


Warning: Once the measurement is started, manipulation with individual racks is not allowed anymore! If the manipulation is required, the analysis must be stopped first by ”STOP” button ☐.

When the countdown for cuvettes preparation is finished, the status is changed from “STARTING UP – BUSY” to “MEASURING – BUSY“



and following screen is displayed:



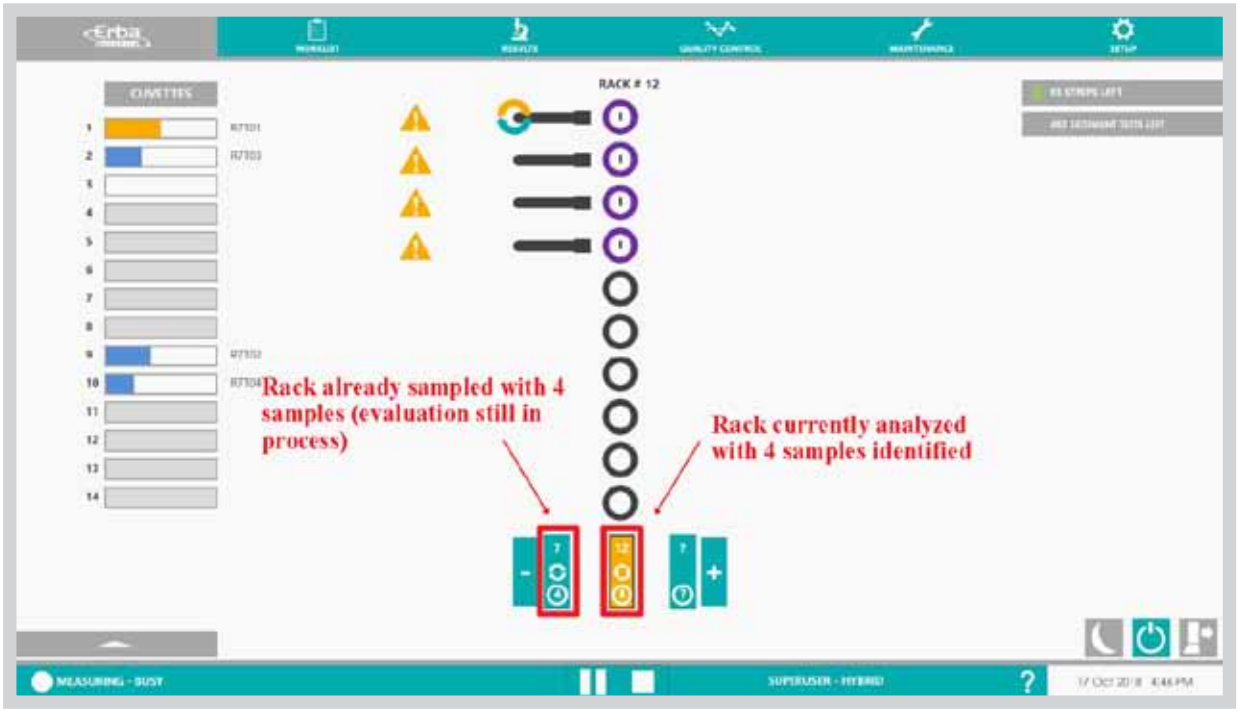
This screen serves as an example.

5.4.4 Events Walkthrough

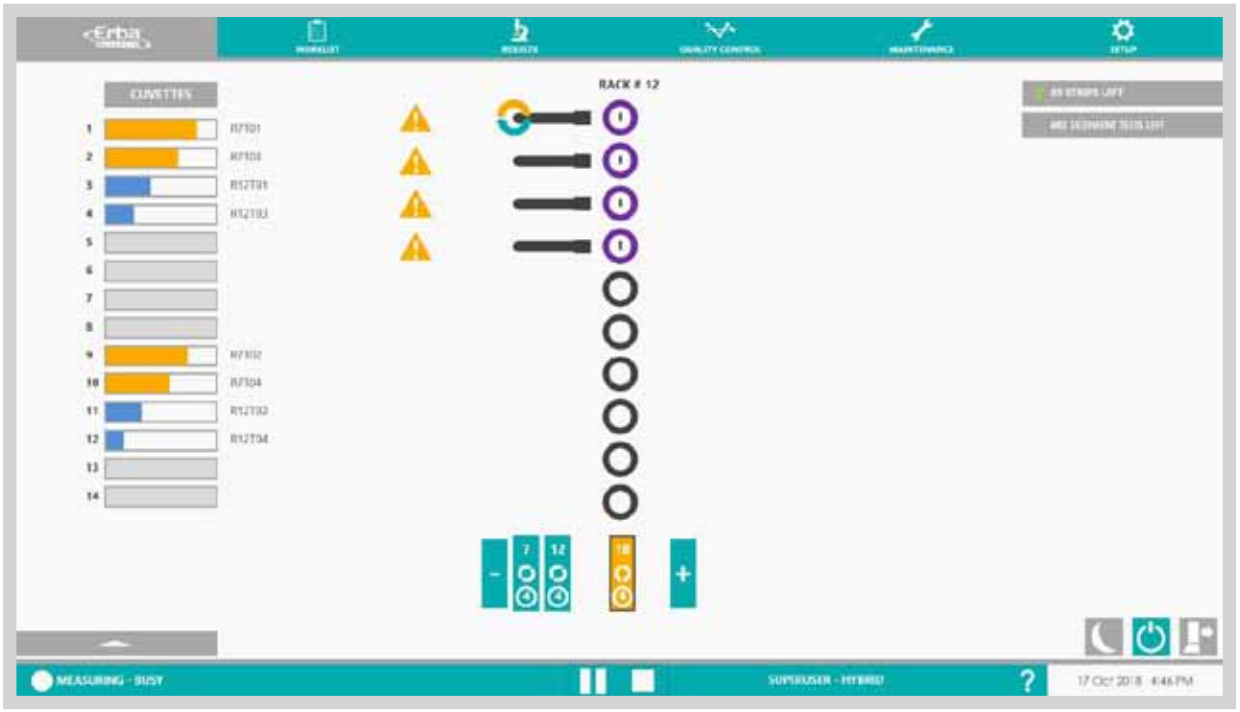
The exact procedure – measurement cycle – will be described using the following example:

1. The number detected racks on the board is 3, each rack contains the total number of 4 analyzed urine samples (in total, the number of analyzed samples is 12).
2. The number of analyses (repetitions, or still to be done) per sample is 1 – each sample is measured (evaluated) once.
3. The first rack is automatically inserted into the inner part of the analyzer, where the process of identification (of racks, tubes, barcodes) is performed. The remaining 2 racks keep their positions on the right side of conveyor.
4. The first rack was identified specifically (the identification number of the rack as well as number of samples in the rack are known).
5. Once the measurement of the first rack is finished, measurement of the second rack starts automatically – the first rack is moved to the left part of the transport board for completed samples; the second rack enters the analyzer, and the third rack maintains its position on the

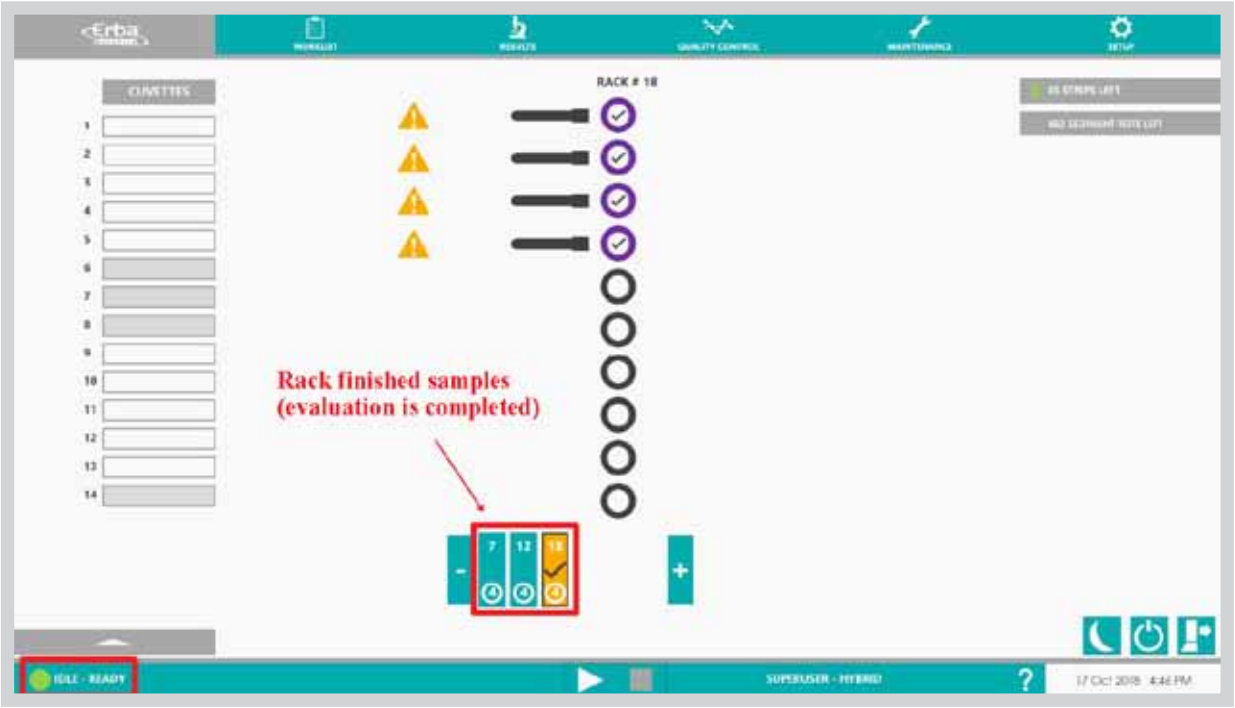
right side of the transport board.



6. As soon as the measurement of the second rack is finished, measurement of the third rack starts automatically – it enters the inner part of the analyzer.

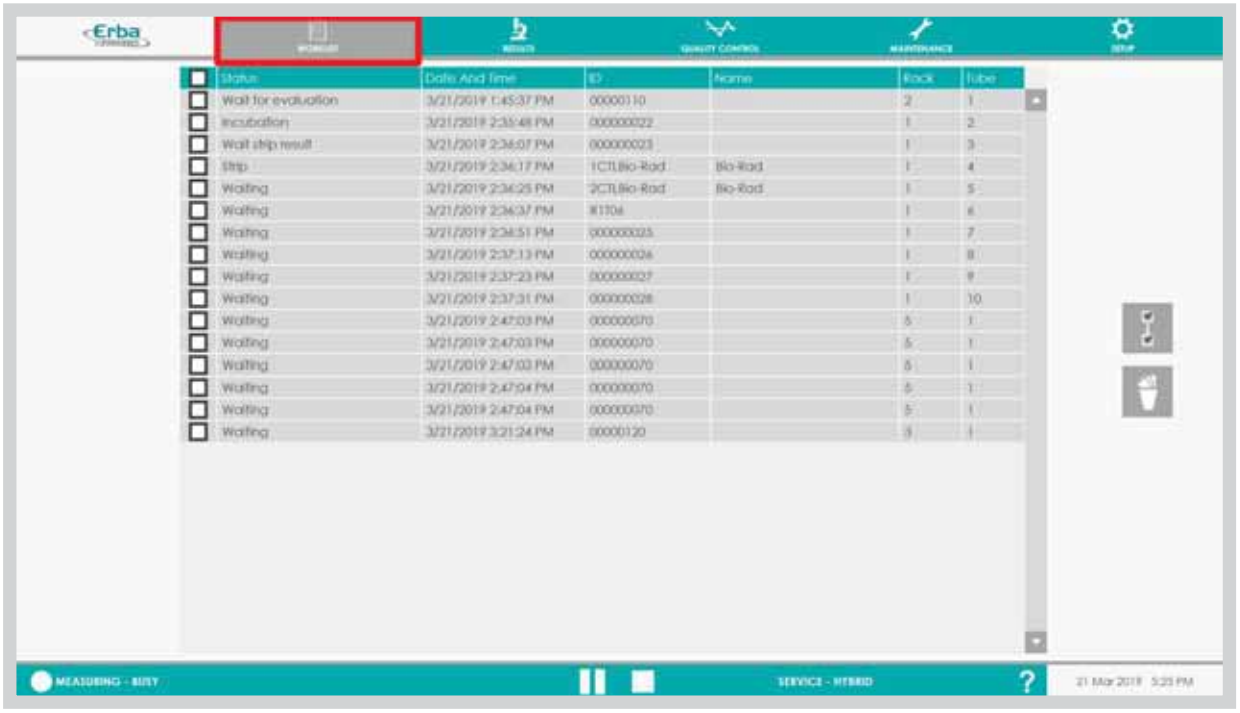


7. When the measurement is completed, all three racks are located in the left part of the conveyor (the output bay) and the status in the bottom bar is changed to “IDLE – READY”.



NOTE Further details of individual options / colors / symbols / flags will be described in User Interface (Chapter *8.4)*.

The status of individual samples during the measurement as well as error appearance can be followed in “WORKLIST” menu:



5.5 Options during run

5.5.1 Manual edition of sample ID

The system automatically assigns ID of detected tubes (tube presence sensor), if the tube was not previously preprogrammed on that rack or if the barcode reader was not able to read a barcode (uncompatible, bad quality, damaged or wrong positioning…). Only in this case, the barcode can be manually edited. All other manually assigned ID and barcode read, the ID is final and cannot be changed.
Likewise, the sample ID can only be changed once, from the automatically generated code, to a manually modified one. Once it is done, it becomes final.

5.5.1.1 Editing of ID During the Analysis (before results)

There are 2 places where this can be done during the analysis BEFORE results are available:

1. From worklist
2. From Status window (limited access)

5.5.1.1.1 Procedure of ID editing during the measurementfrom Worklist:

The simplest way to modify a sample ID before the results become available, is to do it from the Worklist, once the sample becomes available in the worklist (once the rack has been inserted and tubes detected).

If the rack shows a alert triangle next to the tube position from Status worklist,



1. Go to to Worklist



2. Double click on the sample to be modified (for example R4T02)

The EDIT PATIENT ID dialog box opens



3. Change the Sample ID (and complete if necessary, the First and/or Last Name, Date Of Birth and gender, but it is not mandatory), in our example to 98765



4. Click SAVE

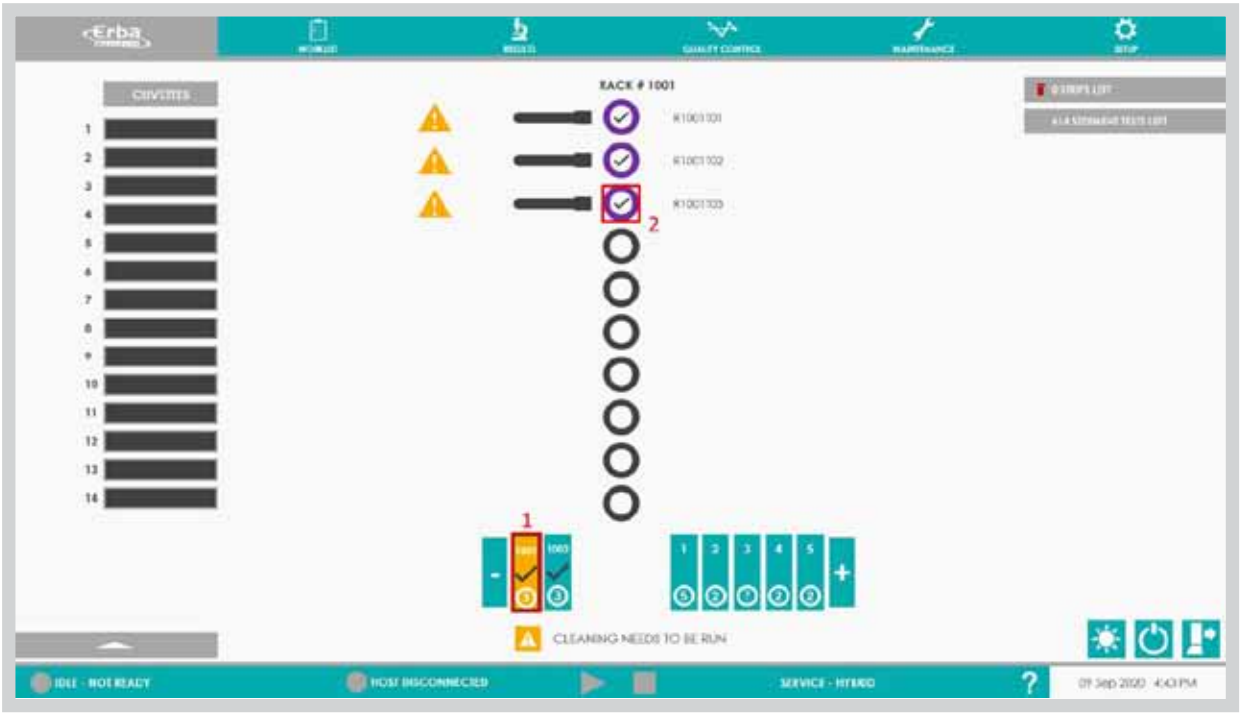
The sample ID in the worklist updates, as well as in the status window.

NOTE This operation can be done at anytime during the testing, including during the active aspiration of the sample. As long as it is present in the worklist, it is possible to edit it.

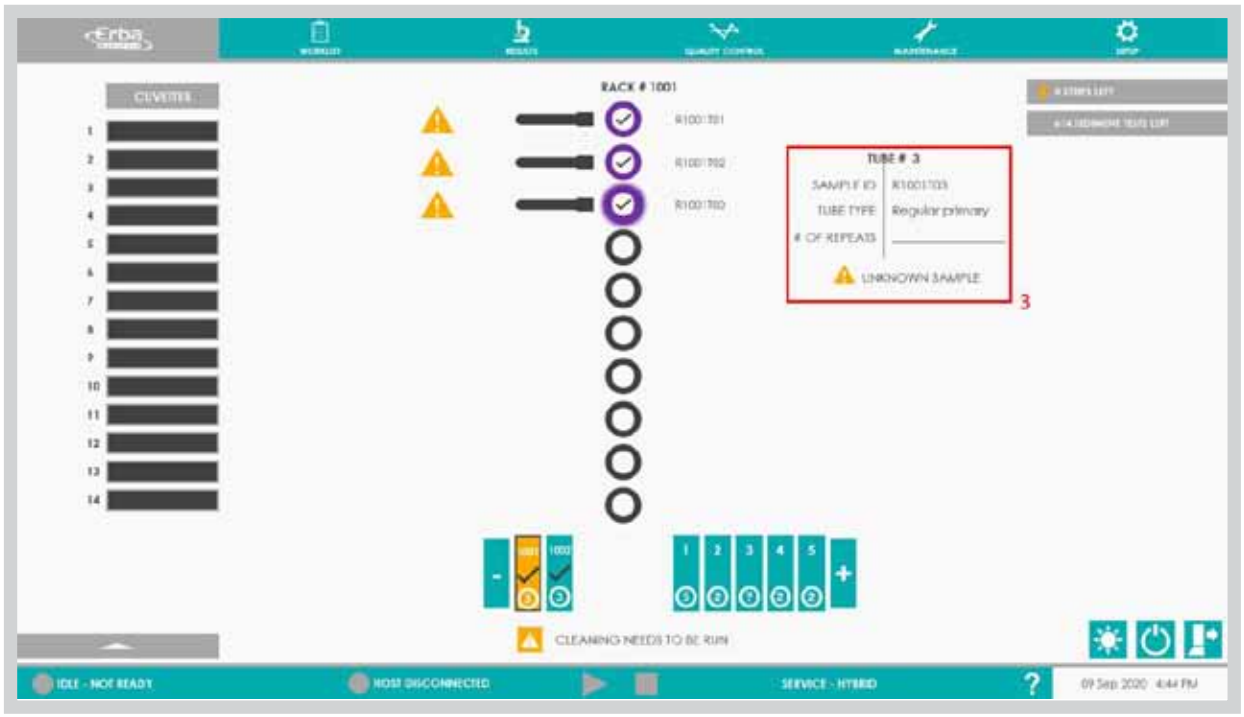
5.5.1.1.2 Procedure of ID editing from Status Window:

With some limitations, it is possible to edit sample ID from the Status window:
Keeping in mind that only automatically assigned ID can be modified once, It cannot be done Only from the output bay (not when the rack is actively inside the instrument), and before results become available. (it can also still be done once results are available, until the racks are removed from the output bay, and become unaccessible in the user interface.

1. Select the rack you wish to modify from the output bay, by clicking on the rack image (1) from Figure below

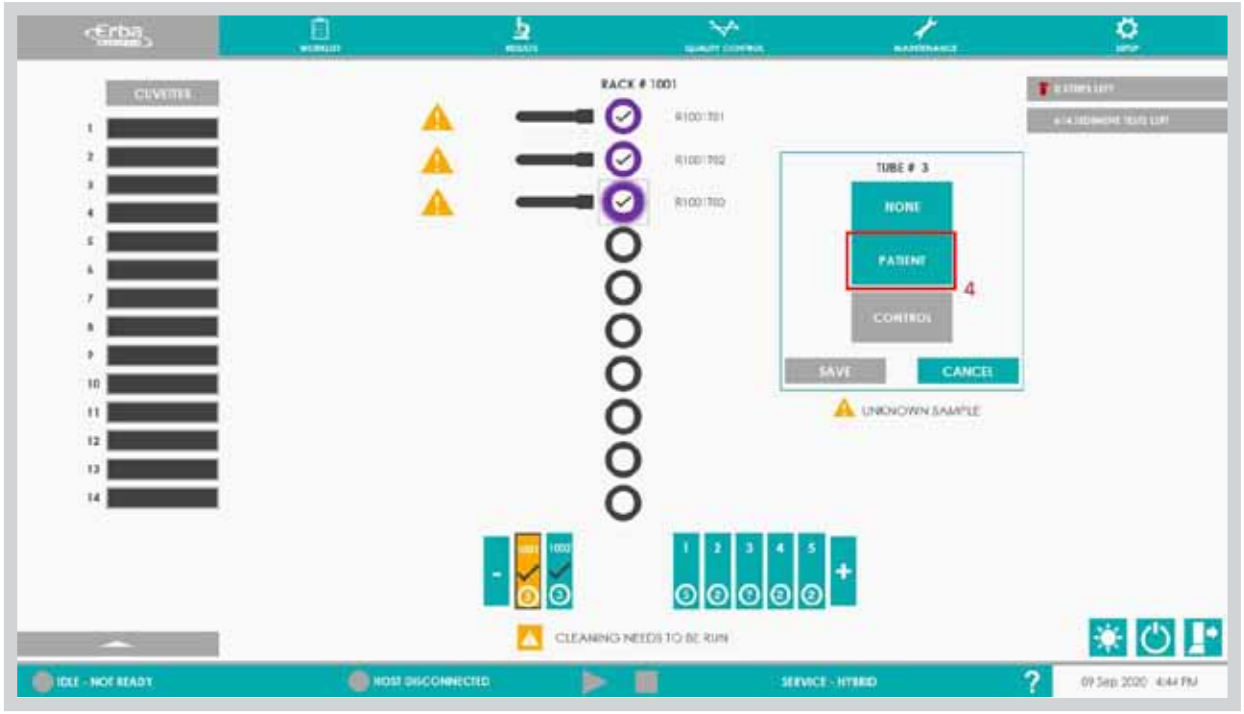


2. Then click on the tube you wish to change ID (2) from Figure above

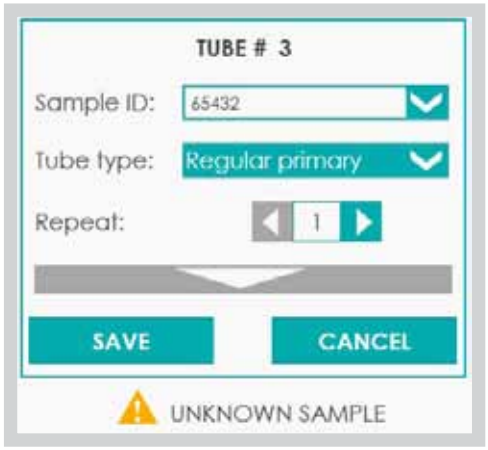


The display as above appears

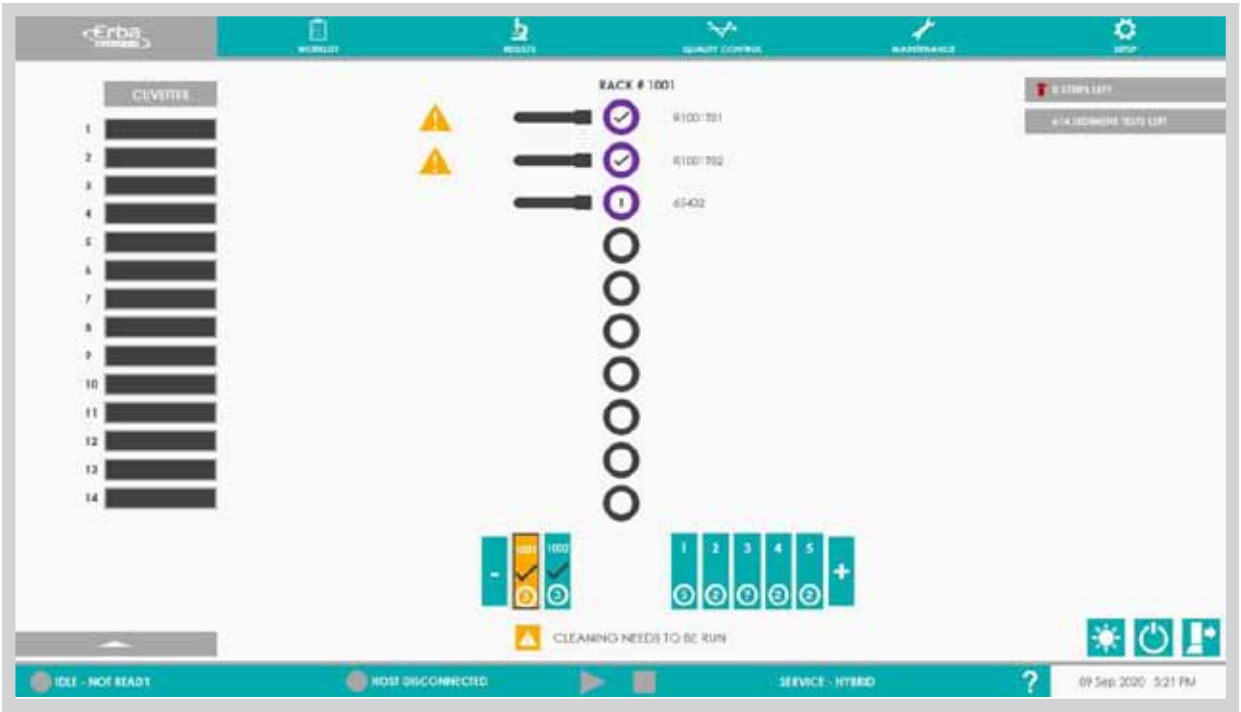
3. Click on the Tube information area
4. Click on PATIENT button to reopen the patient information



5. Type the new sample ID in the Sample ID field



6. Then click on the SAVE button



5.5.1.2 Editing of ID after Completion of the Analysis

Editing of ID of sample may be performed even after completion of the analysis, i.e. at the moment when the result related to the respective sample is displayed in the RESULTS menu.

Procedure of ID Editing After the Measurement:

1. In RESULTS menu choose the sample of which you intend to edit its ID (here the sample R18T04 is selected).



2. Click on the corresponding ID to display the following menu:



3. ID of the sample may be edited using the keyboard on the touch screen as well as by an external keyboard (for example, change from R18T04 to 1234567890).



4. Click OK button to save the new ID and the analyzed sample will be further recorded under the new (edited) ID number.



5.5.2 Loading of New Racks with Samples

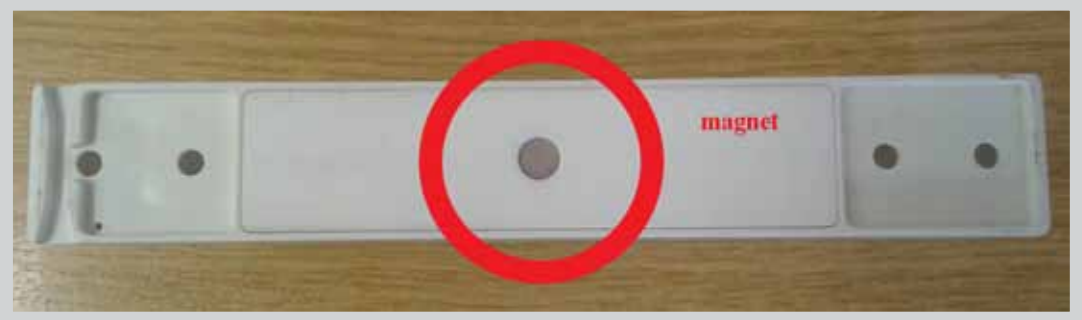
In case new samples come and need to be run as the instrument is already analyzing, it is possible to load new racks with samples onto the input bay of the analyzer at any time (if the maximum capacity is not exceeded). Loading of new racks is possible in the middle of measurement as well as after analysis of all racks, when the sedimentation or evaluation is still in progress.

Warning: Do not load any racks while the arm is moving! Movement of the arm ensures movement of racks and it is accompanied with a sound signal. Do not load any racks into the right-hand part of the transport system at that time! Samples of urine might be spilled!



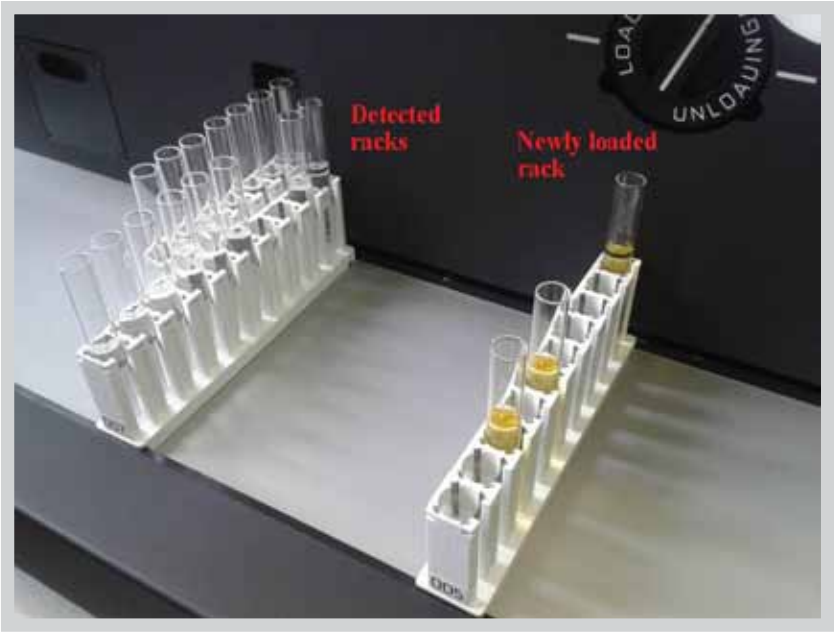
5.5.2.1 Loading of Samples During Measurement

Presence of racks is detected on the basis of magnetic sensors. They are located under the transport system plate. The racks contain magnets and, thanks to their presence, they are detected.



Warning: In case that a rack is damaged – e.g. the magnet fell off – put the respective rack out of operation. Unless a magnet is present, the rack is not detected by the transport system and samples placed in this rack will not be analyzed!

When measurements are in progress and the right-hand side of the transport system still contains racks which have not been measured yet, a new rack may be added simply – by the means of putting it onto the input bay:



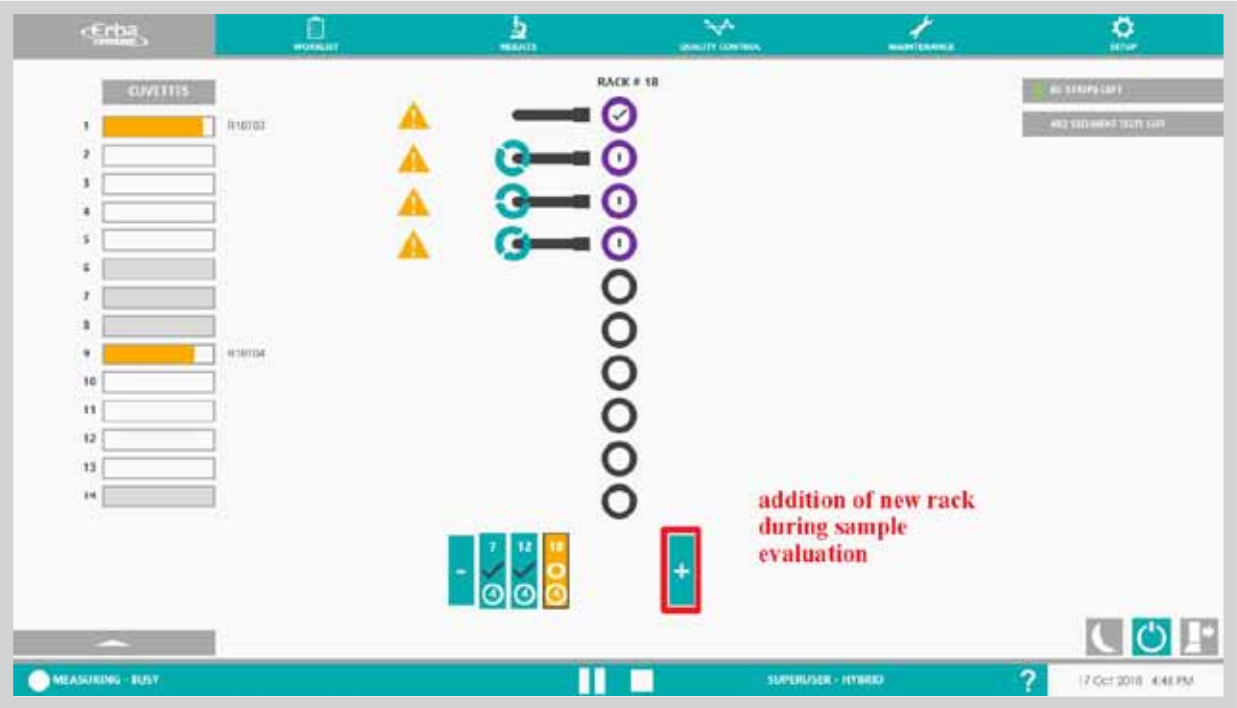
As soon as the automatic movement of the right arm starts, the newly added rack is automatically detected and loaded.

5.5.2.1.1 Loading of STAT Samples During Measurement

STAT sample(s) can be loaded as the instrument is already running.
Proceed as in 5.5.2.1, but position the STAT sample in the position 1 of the next rack to be pulled in the analyzer, or alternately, push the racks from the input bay toward to right, and insert a new rack loaded with STAT sample(s) on the left, so it becomes the next rack to be processed.
Proceed as usual for ordering by autosensing or programming it prior to placing it onboard.
The STAT sample(s) will be processed as soon as the running rack is ejected after completion of last sample aspiration.

5.5.2.2 Loading after Completed sampling

Racks may be placed on the input bay. Once the aspiration of all the samples is completed (the racks are positioned on the left part in the output bay) and the sedimentation or evaluation of remaining samples is still in progress, new rack can be added by pressing “+” button in Measurement screen. The rack is automatically detected and the right arm will move it inside the analyzer.
In order to allow the process of automatic addition of new samples during sample evaluation, item “Automatic rack loading” has to be enabled in Setup menu (see Chapter *8.9.4.1*).



Example: Rack numbers 7, 12 and 18 are located on the left side of the transport system. The device is in PAUSE mode and another rack may be added either after completion of the measurement (the device is in READY mode), or by pressing "+" button. The analyzer will respond to the user's command and the arm starts its movement.

5.5.3 Running out of Components

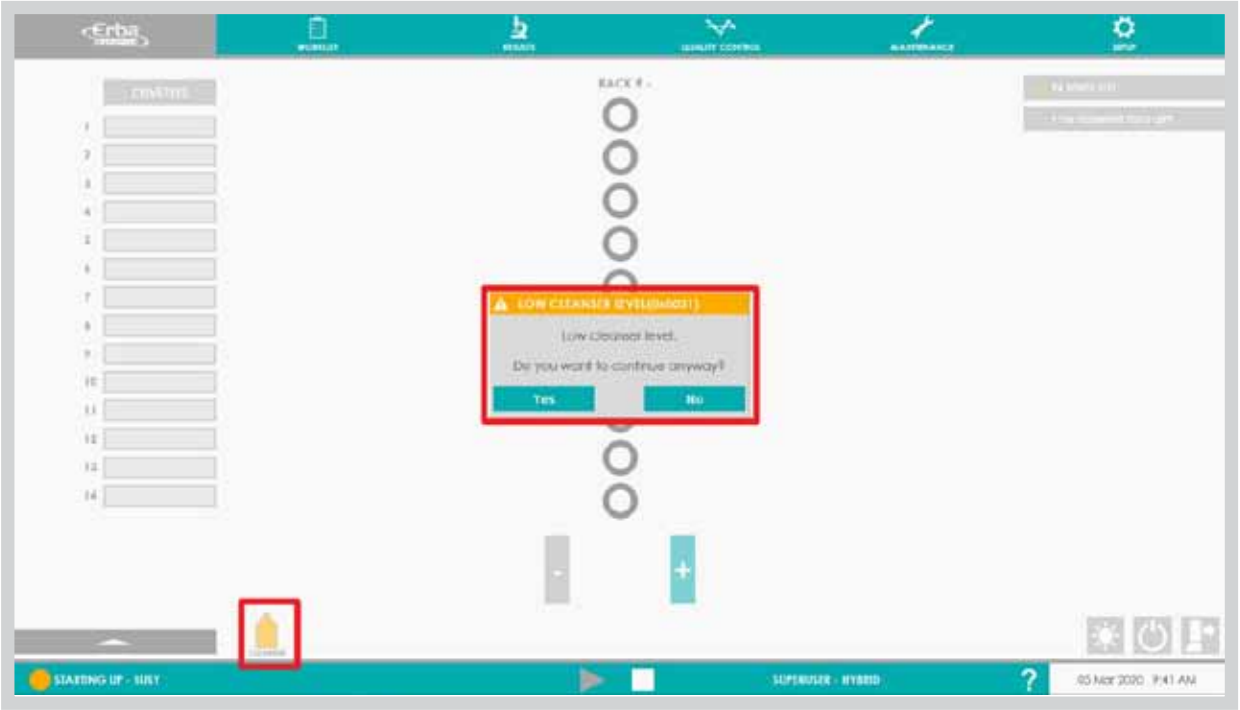
During a run, it is possible to run out of the different components or have alerts and/or alarms:

1. Tank alerts of cleanser low level
2. Tank alarm of cleanser empty or Cleanser count reached
3. Tank alarm of Liquid System empty
4. Tank alarm of waste full
5. Strips empty and/or strip expired, or strip onboard stability exceeded

The Laura XL system is equipped with level sensors on its 3 tanks (Liquid system, Cleanser, and Waste). Thus, it continuously monitors the volumes of liquids inside the canisters. Before or during a run, it is possible that the number of possible tests is lower than the requested tests. The system will display alerts or alarms depending on the liquids.
For the strips, it may be necessary to reload more strips to complete testing.
Below are steps to continue the run as soon as possible.

5.5.3.1 Low Cleanser Level

First level is symbolized by an orange canister in the left bottom corner of the screen and informs the user that there's a low level of Cleanser but allows continuing in measurement or commencement of a new one. Following pop-up window is displayed:



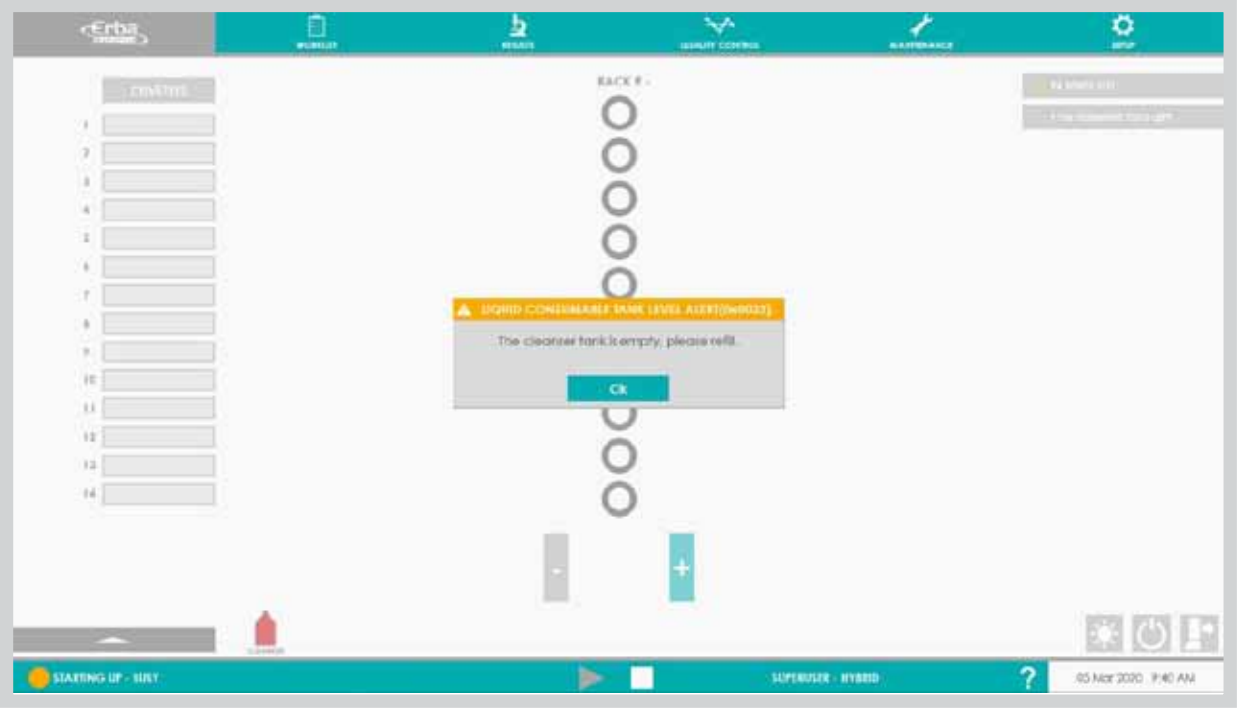
The user can decide to continue analysis by pressing "YES". In this case, the system will run all possible samples until the level reaches the empty state (or 1500 tests completed from last Cleanser loading).

When the level reaches empty, the system will no longer initiate new sample, but will complete and report the aspirated samples. Once the system turns into "IDLE – READY" status, user can re-fill Cleanser by .

It is also possible that the level of Liquid system or Cleaner is too low to continue testing, and is then displayed in Red bottle. Then, the instrument will stop initiated any new test until the bottle is refilled and the test count reset to 1500 by the RFID.

5.5.3.2 Tank alarm of cleanser empty or Cleanser count reached

Once the tank floater alarm reaches the lower limit, the Cleaner is considered too low to continue testing, the bottle is then displayed in flashing between Red and Orange.



The same situation arises from a sediment test counter reaching 0 from the 1500 loaded tests from the last Cleaner loading by the RFID.
To correct the situation:

1. Remove the cleaner hydraulic line and floater from the cleaner container
2. Empty and rinse it
3. Then proceed to preparation and loading of cleaner as described in section 4.4.3.

5.5.3.3 Tank alarm of Liquid System empty

Once the Liquid System tank floater alarm reaches the lower limit, the Liquid System is considered too low to continue testing, the bottle is then displayed flashing between Red and Orange.

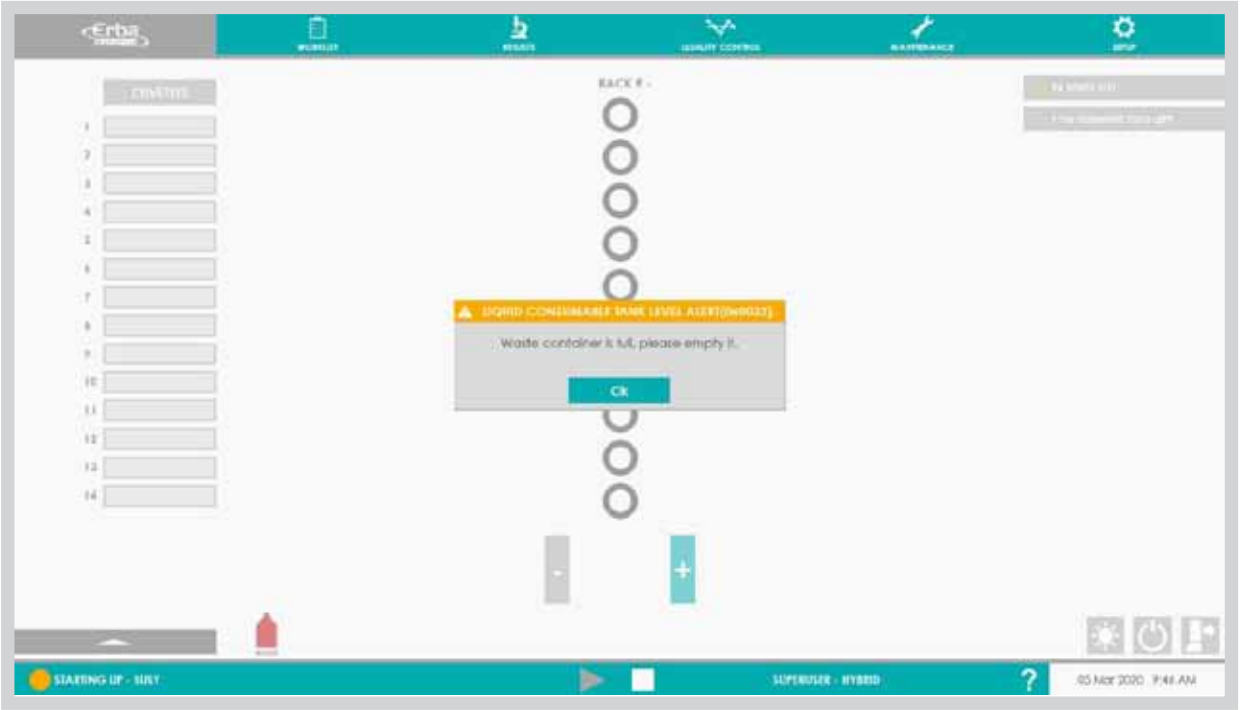
To correct the situation:

1. Remove the Liquid System hydraulic line and floater from the Liquid System container
2. Empty and rinse it
3. Then proceed to preparation and loading of Liquid System as described in section *4.4.4.* (search the appropriate solution Opti-sol XL 750 or interim solution)
4. Use the **Loading of liquid system** function from the status window or the maintenance menu (REAGENTS, Liquid System, and follow the on-screen instructions)

Make sure to perform the procedure until the complete prime to remove the bubbles before they reach the critical hydraulic path which could affect precision of aspiration, impair of optical measurements of color & clarity and/or impair the recognition of sediment elements.

5.5.3.4 Tank alarm of waste full

When the waste tank is full the screen will display an alert and the bottle representation will display in flashing between orange and red color in left bottom of the screen to inform the user that there is no longer enough space for more liquid waste to initiate new tests.



During run, last tests will be finished, afterwards the user must empty the canister.
To correct the situation:

1. Remove the waste hydraulic line and floater from the waste container
2. Empty the waste container and dispose of the waste
3. Rinse the waste container regularly to avoid microbic proliferation
4. Then reinstall the hydraulic line and floater in the empty container

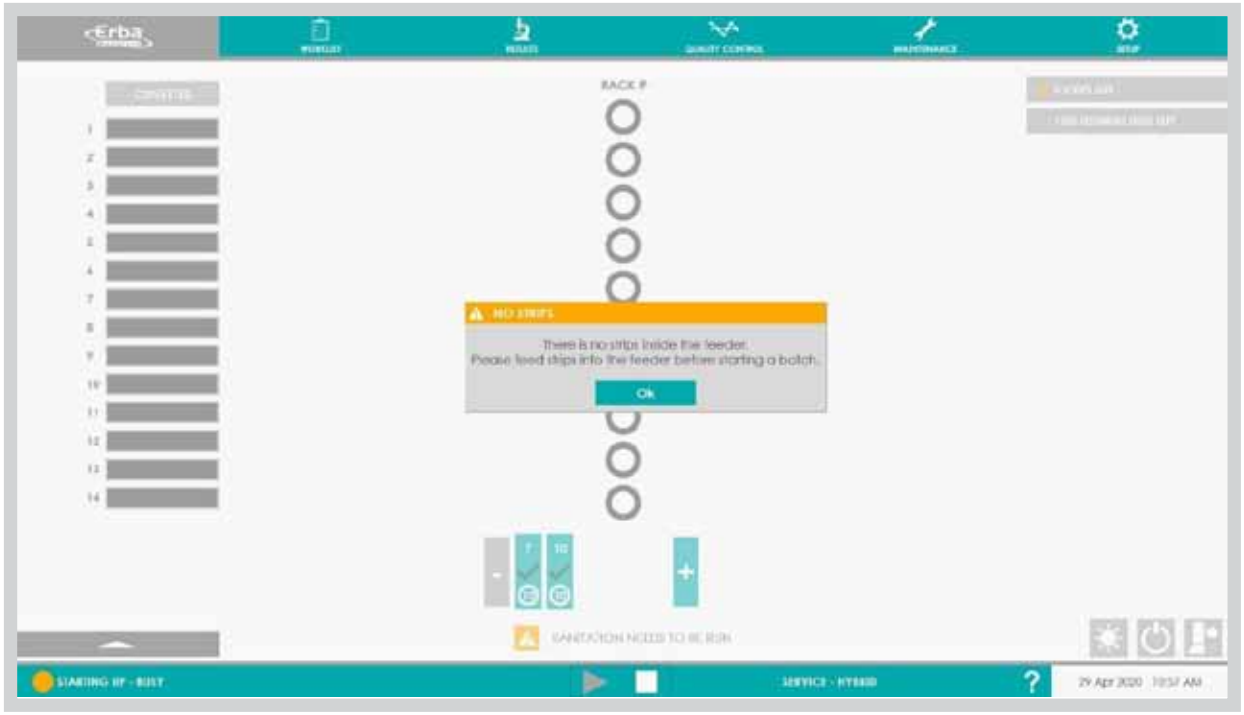
Act in compliance with the respective security level – in connection with use of the analyzer, handling of analyzed samples or waste; use a laboratory coat, gloves and protective goggles.

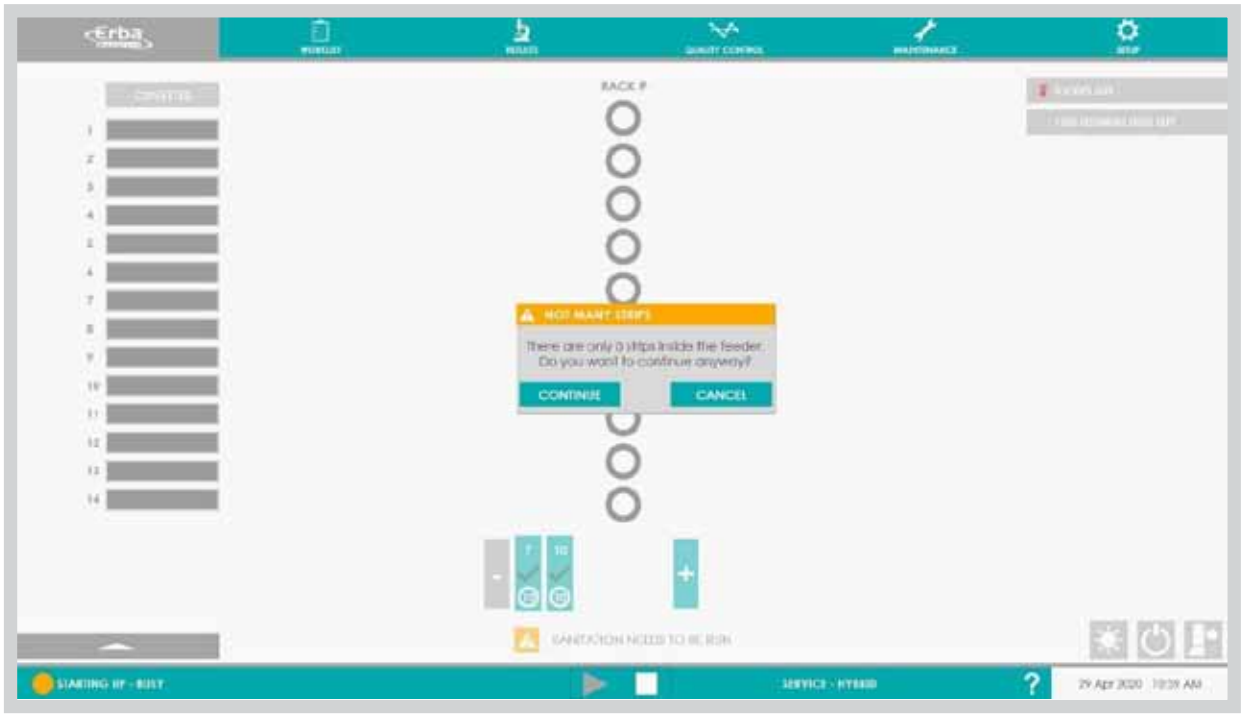
Consider all human-source material (measured samples, controls) as potentially contagious. Dispose of all liquid waste in accordance with local regulations. Pre-treatment of liquid waste is recommended.

5.5.3.5 Strips replacement during a run

5.5.3.5.1 Strips consumed

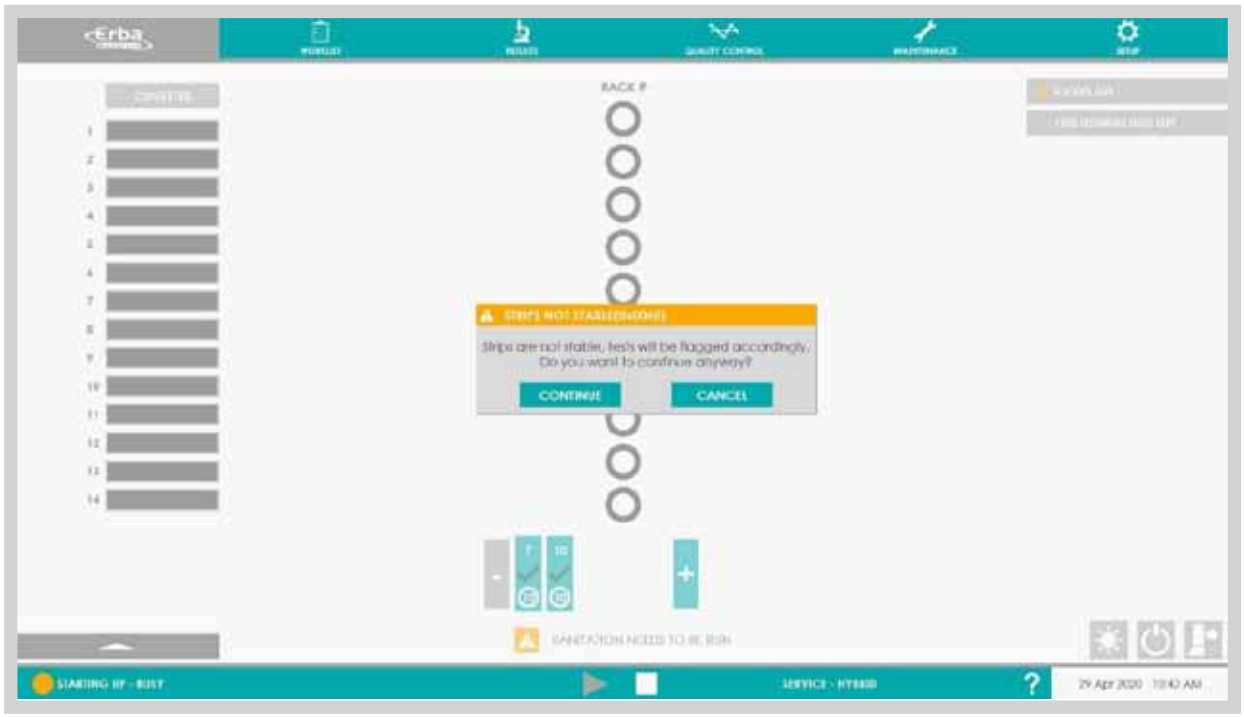
When the strips are all consumed and/or the feeder can no longer find strips to load onto the belt, the following messages appear on the screen.





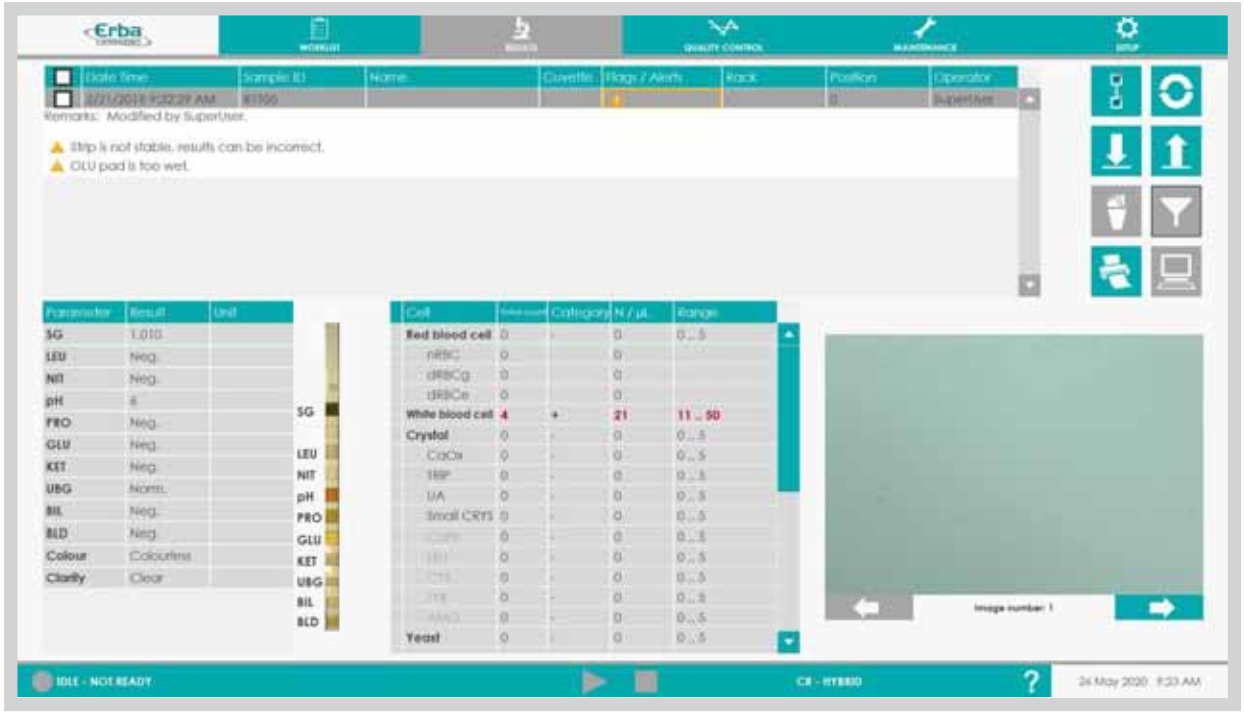
The user then need to reload more strips.
Refer to section *4.4.1* loading of Diagnostic strips.

5.5.3.5.2 Strips expired or onboard stability exceeded



Upon appearance of the “strips not stable” message, the user has the choice to :

- Continue testing, but the results will be flagged for expired strips (see image below).



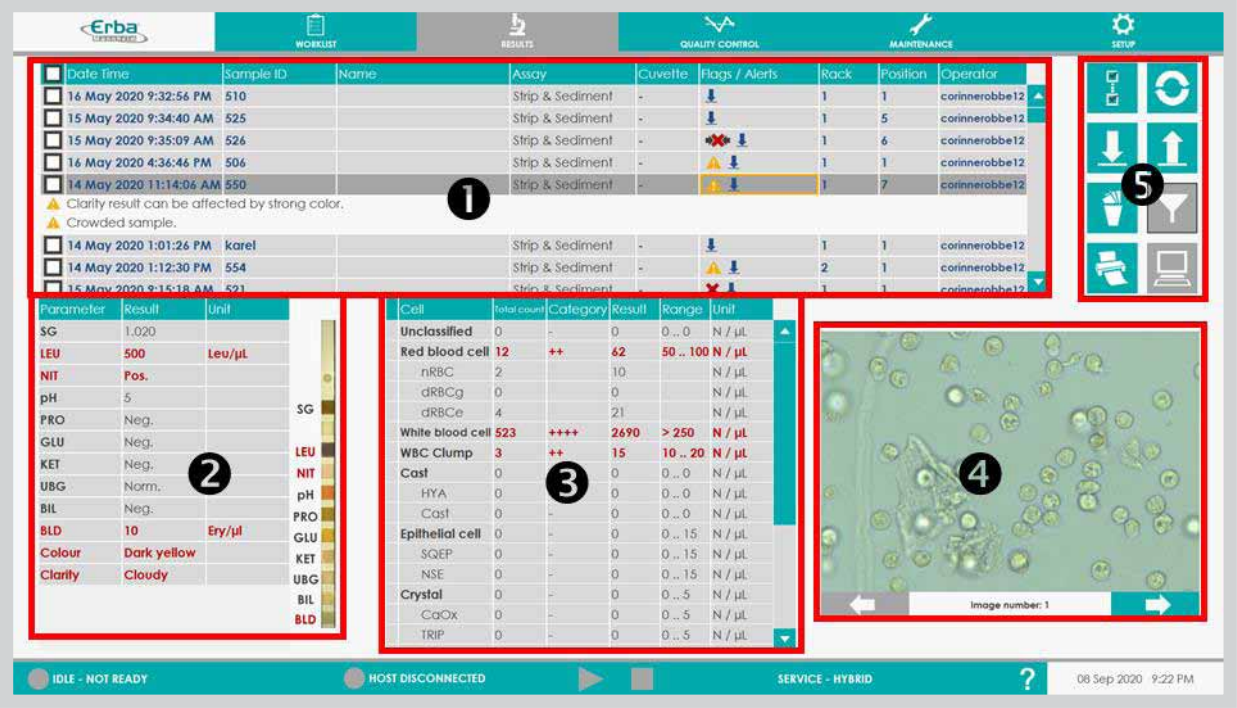
- Or user can opt for removal (unloading) of all strips from the feeder, then load fresh strips. (see *4.4.2* Unloading of Diagnostic Strips for more details on procedure)

6. Reviewing sample results

The results are presented in “RESULT” menu and their availability depends on the measurement mode chosen by user:

- **HYBRID** – both results for diagnostic strips and sediment are available
- **CHEMISTRY ONLY** – only results for diagnostic strips are available
- **SEDIMENT ONLY** – only results for sediment are available

When clicked on the “RESULT” button, following screen is displayed:

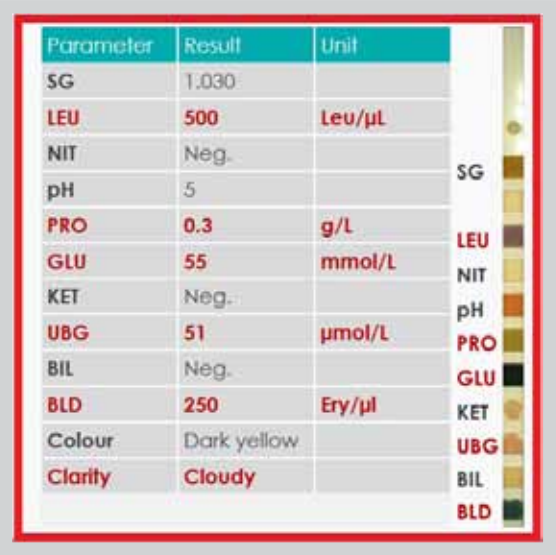


It is devided into 5 parts:

❶ Overview of measured and evaluated samples
❷ Chemistry results + photo of diagnostic strip
❸ Results for urine sediment
❹ Snapshots of urine sediment of analyzed sample
❺ Result management (filtering, print, export, import, delete…)

6.1 Evaluation of Chemistry Results

Results of analyses based on diagnostic strips are shown in the bottom left-hand corner of the screen. They provide information about 10 or 11 measured parameters as well as the respective colour and turbidity. Individual parameters are accompanied with information about measured concentrations including units (user selected from “SETUP – SYSTEM – System Units (Section *8.9.4.2*)”. Positive results are marked in red colour. Photo of corresponding strip is attached to the result table. These results cannot be modified by the user.



NOTE The ranges for particular parameter are accessible in “SETUP – STRIP RANGES” menu.

6.2 Evaluation of Urine Sediment Results

Evaluation of individual snapshots is performed automatically. 15 snapshots are analyzed for each sample. The success rate of element identification depends on individual samples. In case of samples which contain floods of certain elements, automatic identification is deteriorated. Similarly, for the elements which overlap or occur on the edge of picture the success rate of automatic identification decreases. Therefore, the user is always required to perform a visual check of measured results in order to avoid their misrepresentation. Editing of results leads to automatic recalculation of the final concentration.

6.2.1 Result View

Results related to urine sediment are presented in windows located in the bottom section of the screen – in its central part (results table) and right part (snapshots). Individual elements are accompanied with information about: Total count (N), Level (-/+/++/+++/++++), Selected units (N/µL; N/hpf, N/lpf; N/chosen volume, or arbitrary) and Range (specific for each element). Positive results are marked in red colour. User can browse between pictures by the arrows.



Sediment results can be manually edited (see Chapter *8.6.3*).

6.2.2 Picture View

By clicking on the sediment picture a window with more details about every picture is opened. This menu allows the user to manually edit the sample element tagging – either those which were not recognized, misidentified and CUSTOM and/or manual categories.

Warning: Always perform a check of measured data! Review individual snapshots and perform their correction, if required. Once the changes are saved, results for urine sediment shall be recalculated automatically!

7. Reviewing Quality Control

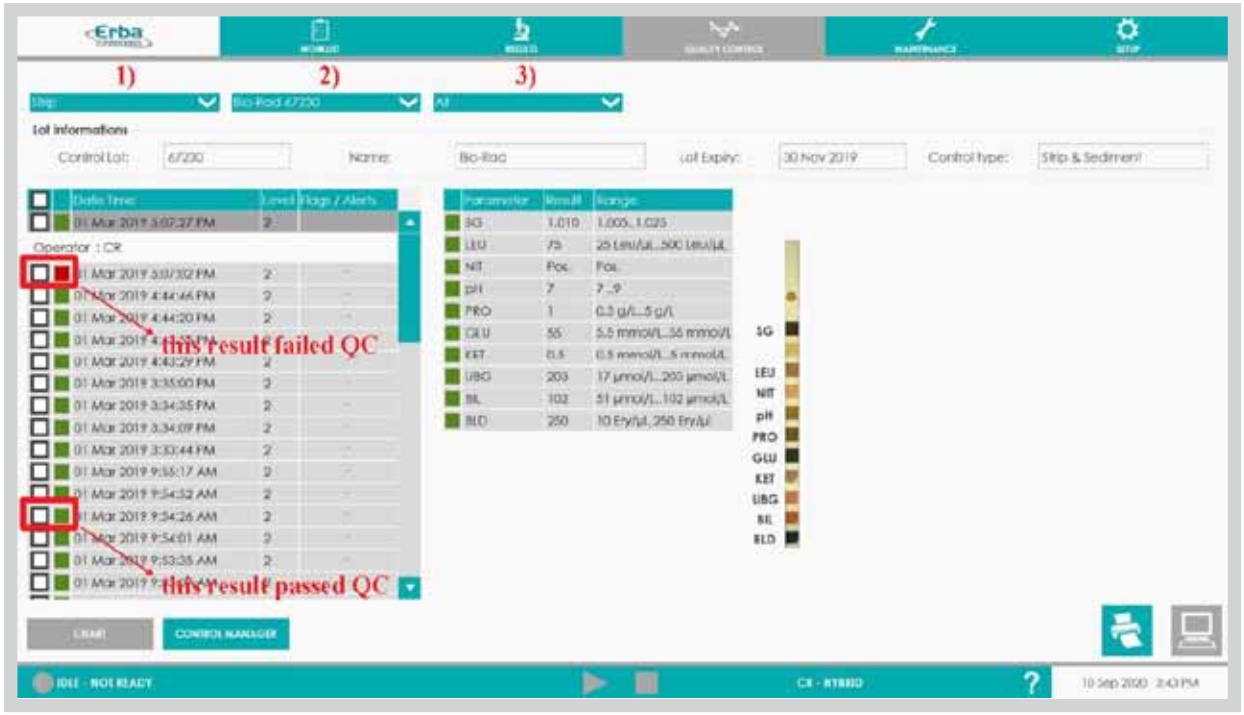
After completion of analysis the results are saved in “QUALITY CONTROL” menu. Control results are visible:

- In table form, which include. Pictures (-of diagnostic strip for chemistry and the 15 pictures for sediment)
- In Levy Jennings graphs
- Comments can be added for any QC run.

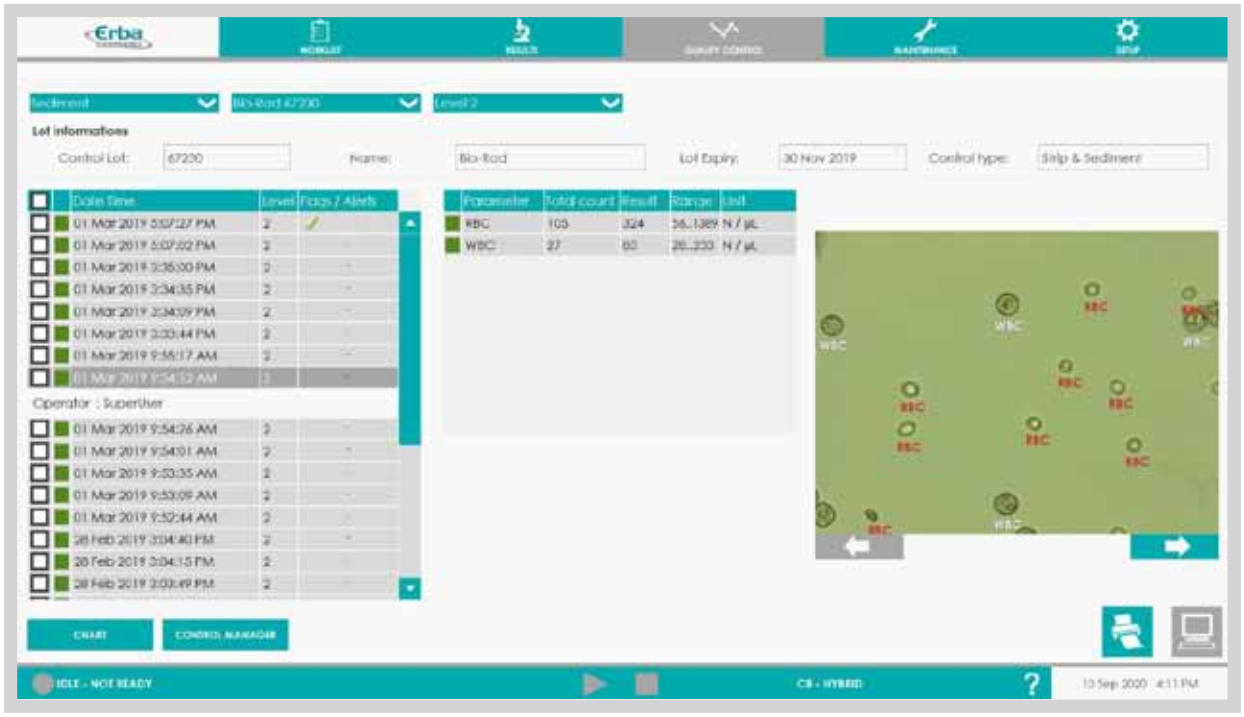
7.1 Review from Table window

Upon opening the QUALITY CONTROL menu, the table view is accessible.
By default, the Strip resul category is selected and the most recent lot number selected for ALL levels, displaying the corresponding results in the table, with the most recent run selected displaing the detailed results on the right table and the strip image.
For sorting the results, there are several options:

1. Strip / Sediment results
2. Urine Control LOT
3. Level – Level 1 / Level 2 / All



The Pass/Fail status of measurement is symbolized by “green square” (passed QC) or “red square (failed QC):

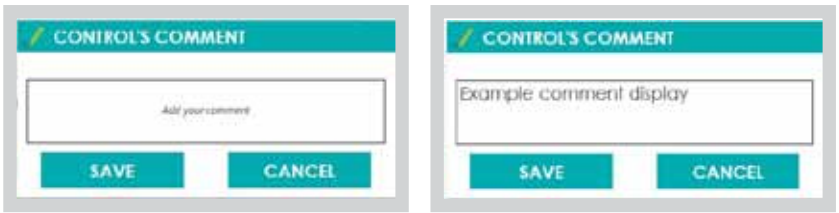


The operator who was running the instrument at the time of measurement is recorded and visible upon clicking on the result line.
Flags and alerts are visible through small icons in the Flags/Alerts column. Clicking on them or the result line, will display the full list of flags and alerts.
The images of sediment can be scrolled through by the right and left arrow below the images. But unlike for patient samples, **control tagging cannot be modified** (correction nor addition).

7.2 Add comments

For any determination, it is possible to add comments, most important for traceability of failures and corrective actions. To do so:

1. Double click on a result line
   The comment dialog box opens



2. Type the text in the add your comment field
3. Then click on SAVE

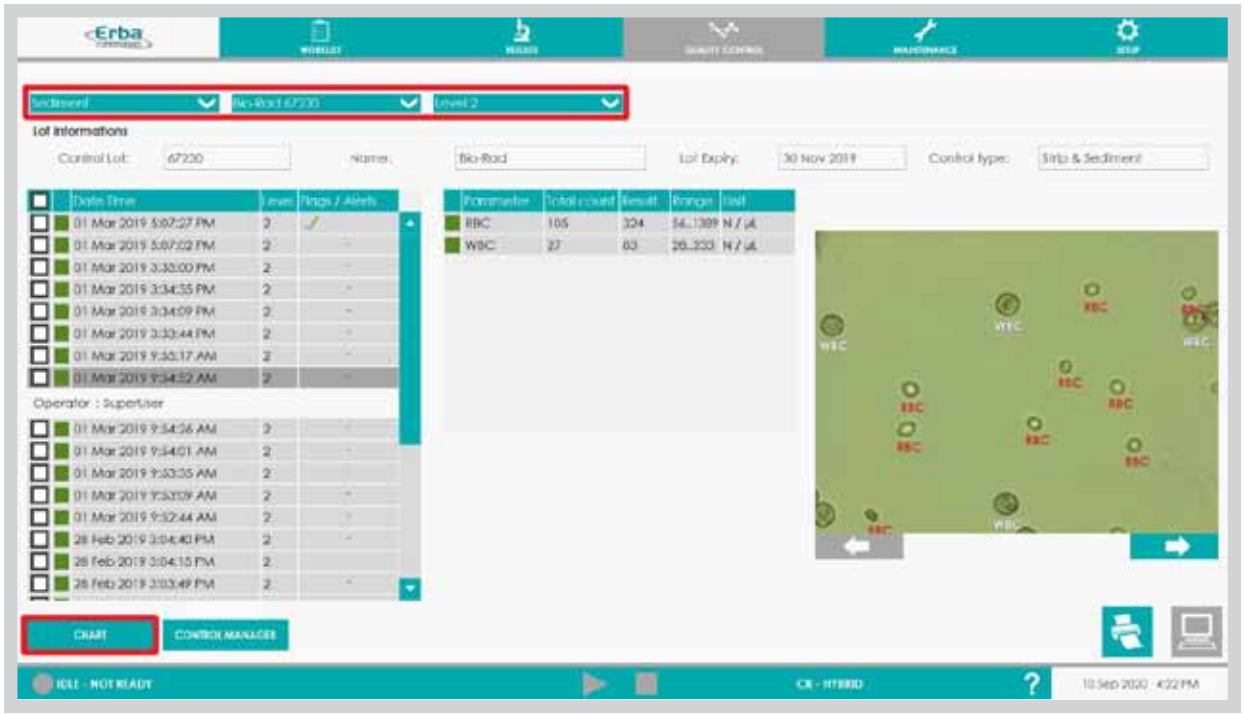
The content of the comment is visible by clicking on the result line, and the presence of a comment is indicated by a green writing pen in the Flags/alerts column



7.3 Review in Levey Jennings charts

The results are also interpreted in form of Levey-Jennings (LJ) control charts.
The successive values are displayed for each type (strip/sediment) and level of control
Displaying of LJ chart:

1. Choose type (strip/sediment), Lot and level of control you want to display
2. Click on “CHART” button

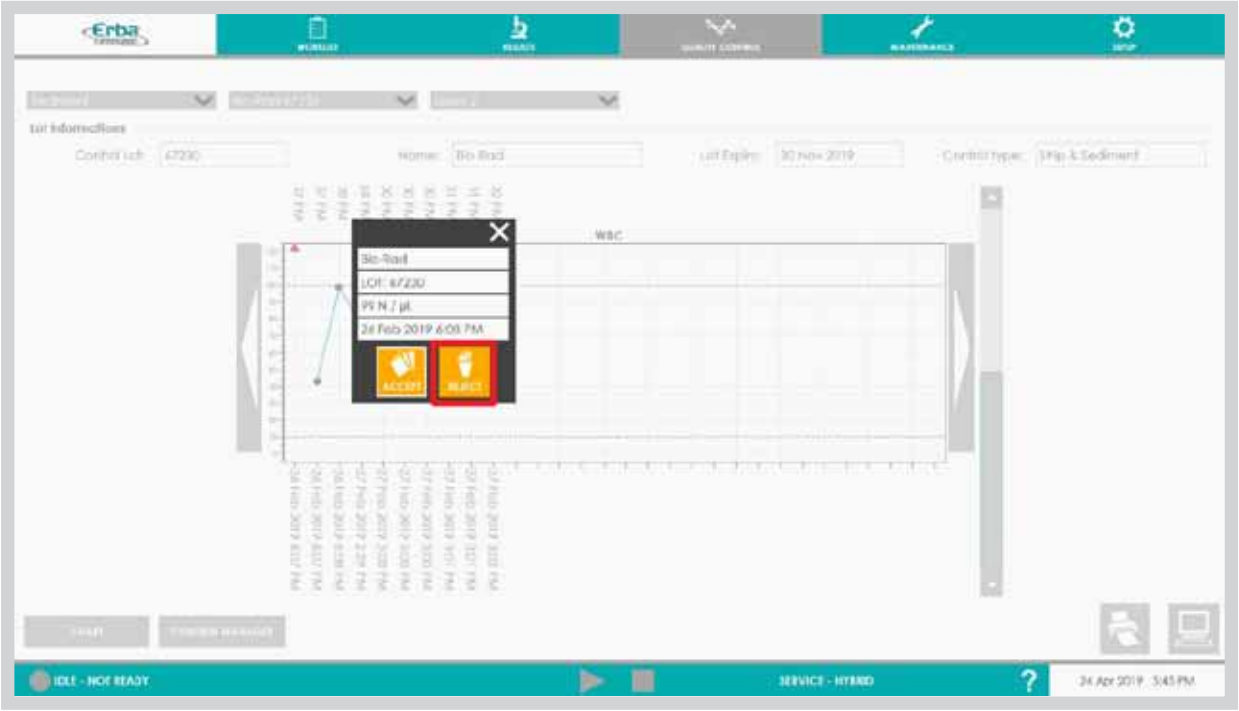


3. Following window is displayed for strip / sediment results. Browsing of the results of individual parameters is allowed by scrolling up/down on the righ side of the screen.
   Results which fall within the set range are illustrated by “black dot”.
   Results, which are out of the range, are illustrated by either “red dot” (out of limit within the graph) or “red triangle” (outside the graph):





Results which are out of the range can be excluded or accepted back. Once excluded the LJ curve will no longer go through the excluded points. By clicking on the given point in LJ chart, it is possible to display its details - control name, LOT, number of particles/µL, date and time of measurement - and there's also option to REJECT/ACCEPT this point



4. To go back to the list of already measured controls, click on the “CHART” button again to unselect it.

7.4 Managing results

Results of QC can be printed, and sent to LIS by clicking on the corresponding button *LIS button is only active is / LIS connection is active*
The printing or sending selection works similarly, by printing selected (higlighted lines), checked (by ticking the box(es) in front of the result line, or the unprinted or unsent automatically detected items.

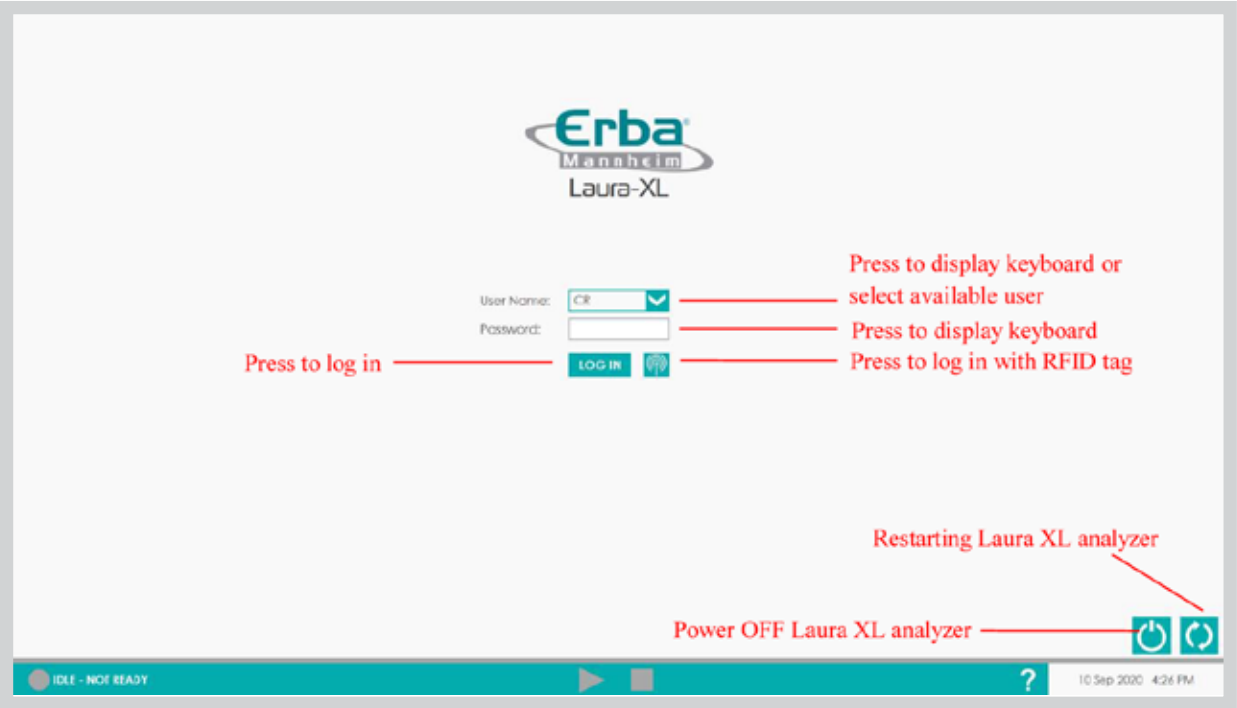


8. User Interface

This section presents a comprehensive overview of all screens available in the user interface (hereinafter referred to as UI) of LAURA XL analyzer.

Please review this section carefully prior to any further handling of LAURA XL analyzer!

8.1 Login Screen



8.1.1 User Name Field

User name field is a combo box, it is either a dropdown list or a text box; it corresponds either to individual users, a group of users (laboratory operators or supervisors).
Any access level users can see the full list of standard and Administrators usernames. Anyone can also type directly their user name in the field.
New user names may be added in SETUP menu – by a user with appropriate administrator's rights (see Chapter *4.2.2*). By clicking on "User name" bar the on-screen keyboard is displayed, which allows for entering the User name. The User name may also be entered by an external keyboard.

8.1.2 Password Field

The password field is a text box. The entered password must match with the corresponding User name. By click on “Password” bar the virtual keyboard opens. A Password may also be entered by an external keyboard.

8.1.3 LOG IN Button

Once a User name and a corresponding Password have been entered, it is possible to perform log in by pressing “LOG IN” button. The user name and password are subsequently verified and if both match access to system functions is granted, and the Status window opens.

8.1.4 RFID Button

It is possible facilitate the login without necessity of entering the User name and Password by pressing the RFID symbol and presenting a special RFID code/card to the front cover of the analyzer.

8.1.5 Analyzer Power OFF

By pressing the “Power OFF” button the PC part of the system is properly shutdown. To power off completely and disconnect LAURA XL analyzer from the electricity after proper power off, use the main ON/OFF switch button located on the back side of the analyzer. Perform this procedure only if you intend to switch off LAURA XL analyzer for a longer time period. (see *8.8.8* Long stop process from maintenance)

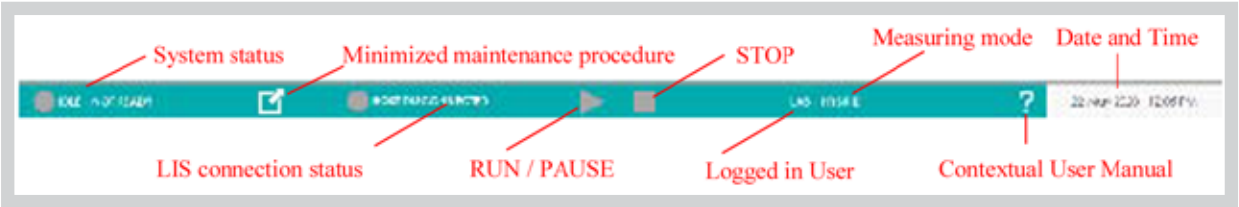
Warning: Never use the main switch on the back side of the analyzer for powering off the analyzer prior to using Power Off button in the User Interface!

8.1.6 Restart Button

Restart button should be used only when a system reboot (PC part) is required.

8.2 Bottom Bar

The bottom bar is visible on all available screens of User Interface. It provides real time information about the current time and date, informs the user about current status of the analyzer and offers access to key controls.



8.2.1 Date and Time

The date and time are shown in relation of the current setup and may be changed by a user who disposes of appropriate administrator's rights.

Field	Status	Description / Use	Format
Date/Time	17 Oct 2018 3:09 PM	This field shows the date and time corresponding to the setup of the integrated computer. Names of months are presented in the abbreviated format from regional setting	Information field updated in real time

8.2.2 System Status Icons

These icons inform the user about the current status of the system. Information about the current status is available on any screen of the User Interface. The colour of these icons changes along with the description. The list of all statuses and its colors are mentioned below:

Icon	Status	Action	Description	Format
	IDLE	NOT READY	It is necessary to perform initialisation of the analyzer – the analyzer is not ready for measuring of urine samples.	Information
	STARTING UP	BUSY	Preparation of the analyzer is in progress: Initialisation cycle is active.	Information
	SHUTTING DOWN	NOT READY	The shut down process has been started.	Information
	IDLE	READY	LAURA XL analyzer is ready for analysis of urine samples (the process of initialisation has been completed successfully).	Information
	MEASURING	BUSY	Measurement is in progress.	Information
	PAUSING	BUSY	The analyzer is in PAUSE mode. This status is shown from the moment the Pause button was pressed. Initiated and unfinished samples are processed and the analyzer is switched to STOP mode subsequently.	Information

8.2.3 RUN / PAUSE

Depending on the current status of LAURA XL analyzer, this button is pictured either as a white triangle (– PLAY) or two vertical strips (– PAUSE). RUN / PAUSE status informs the user whether it is possible to load additional samples. In case the PLAY ( ), button is active, it is possible to place racks with samples onto the transport system and run the analysis. The PAUSE ( ) button stops the system from running any further samples from ongoing measurement but allows to finish currently analyzed samples.

Button	Active status	Inactive status	Description	Format
PLAY			Press PLAY button to start the measurement. Once PLAY button is pressed it is toggled to PAUSE button. The PLAY button is inactive when instrument is NOT READY	The button switches between PLAY and PAUSE depending on status of the analyzer
PAUSE			Press PAUSE button to prevent measuring of new samples (already started tests will be completed until results reporting). At the time of finishing evaluation of samples in progress the device is in BUSY / PAUSING mode.	The button switches between PLAY and PAUSE depending on status of the analyzer.

8.2.4 STOP

STOP button is displayed as a white square ( ) and it is visible during initialization of the system or during run of the analysis. This button serves for stopping of particular run.

Button	Active status	Inactive status	Description	Format
STOP			STOP button is present during initialization or run of analysis. Once the cycle is completed the button toggles automatically to PLAY button	Button is toggling between STOP and PLAY buttons

8.2.5 HELP

The button with a question mark symbol ( ) opens the contextional User manual, meaning at a specific section with a brief description of the window from which the Help button was clicked. The User manual is available in electronic format and it is presented directly on the touchscreen. Access to the User manual is available from all screens of the User Interface.

Button	Active status	Inactive status	Description	Format
HELP		Always active	Press the button to open the User manual for LAURA XL analyzer.	Button

8.2.6 Logged-in User and Measuring Mode

In the right area of the bottom bar, the logged in user is displayed, followed by the indication of the current operating mode of the analyzer, separated by an hyphen, as shown below with User logged-in= Lab, and Hybrid mode run.

Field	Status	Description / Use	Format
LIS connection status		This field shows the color-coded dot and text of LIS connection status	Information field up-dated in real time

8.2.7 LIS connection Status

On the left side of the bottom bar, right of the system status, the LIS connection status is displayed (only if LIS connection is activated), otherwise this area remains empty.

Field	Status	Description / Use	Format
LIS connection status		This field shows the color-coded dot and text of LIS connection status	Information field up-dated in real time

Icon	Status	Description	Format
	HOST DISCONNECTED	When Host is disconnected	Information
	CONNECTING TO THE HOST…		Information
	HOST CONNECTION ERROR		Information
	HOST CONNECTED	When Host is connected	Information
			Information

8.2.8 Minimized Maintenance processing icon/ Maximize button

The Maximize button will restore the full view of the maintenance window that has been moved away from the view. During some maintenance (cleaning) procedures the window can be moved away to access the other menus of the software. Then, (and only then) the icon displays in the bottom bar.

Button	Default / active status	Selected / inactive status	Description / use	Format
MAXIMIZE		ABSENT	This button is only visible when a mainte-nance procedure has been minimized, click on it to restore the normal view of the maintenance procedure window	button

8.3 Top Bar

The Top Bar is visible on all available screens of User Interface. It comprises several different Menus:

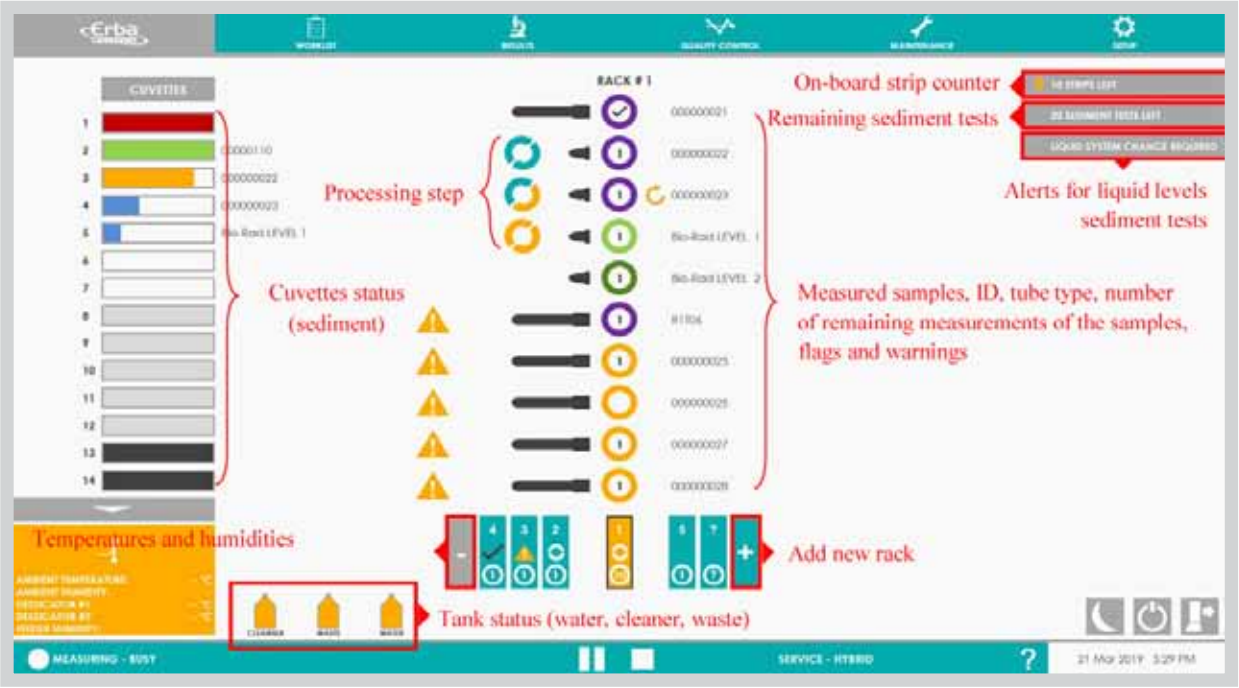


1. STATUS WINDOW
2. WORKLIST
3. RESULTS
4. QUALITY CONTROL
5. MAINTENANCE
6. SETUP

8.4 Status window

The status window displays all the important information about the measurement being currently in progress. This screen provides information about the rack with samples, number of analyzed samples in the rack, number of repeated measurements per sample, number of racks which are waiting for analysis, number of diagnostic strips available in the feeder, number of sediment tests left (before refilling of new Opti-sol XL bottle) and about individual measuring cuvettes designed for analysis of urine sediment. This screen displays important flags and warnings regarding specific sample and the status of canisters (water, cleaner, waste). Eventually, current temperature and humidity can be read here.

Button	Active status	Inactive / Selected status	Description	Format
STATUS			Programming racks and samples, Information about system status, measuring samples, editing of sample IDs, possibility to perform initialisation, start/stop measurements, shut down.	Button



8.4.1 Tube status from rack display

In the center of the window, the selected rack displays the status of the 10 positions with color-coded images.

8.4.1.1 Test tube with a sample

In case that the rack contains test tubes with urine samples and their analysis has already started, following symbol is shown in the Status window (in various colours depending on the measurement status). The number inside symbolizes remaining tests to be analyzed:



Icon	Color	Description
	DARK GREY	Empty position
	HALO OF MATCHING TUBE COLOR	Selected position
	PURPLE	Standard sample – patient's urine

Icon	Color	Description
	ORANGE	Marking of analyzed sample which features the same ID as a sample which has already been analyzed min. once that day
	LIGHT GREEN	Control urine sample – LEVEL 1
	DARK GREEN	Control urine sample – LEVEL 2
	DARK GREY	Number of remaining tests to be done from tube
	DARK GREY	Completed sample tube

8.4.1.2 Tube type

Graphic	Meaning	Information	Action	Result
	Regular primary and/or specific tubes (see *8.9.5* for details)	16 W x 100 mm Height	From selection of Regular primary from the sample definition popup window	The “Regular primary” icon displays to the left of the sample position
	Sample vial	Eppendorf 1.5ml type This tube type is positioned into a specific Laura XL magnetic adaptor on the sample tray.	From selection of sample vial from the sample definition popup window.	The “Sample vial” icon displays to the left of the sample position

8.4.1.3 Test tube measuring Status:

Following icons symbolizes that the measurement for a specific tube is currently in progress and the colour is related to measuring mode which was selected for particular analysis:

Colour	Description
	SEDIMENT ONLY – measurement of the sample is in progress – sedimentation / picture taking / result evaluation
	STRIP ONLY – measurement of the sample is in progress – dosing / incubation on strip / photo taking / result evaluation
	HYBRID – measurement of the sample is in progress – dosing / incubation on strip / strip photo taking / sedimentation / sediment picture taking / result evaluation

8.4.1.4 Flags & Warnings

Following flags or warnings can appear during or after the analysis:

	Unknown sample – the barcode was not used or recognized
	The sample (000000025) is already placed on the rack – was measured **Warning** that the same barcode is used for another sample
	The sample (000000025) is already placed on the rack – was not measured
	Barcode mismatch: Manual entry: 000000027; Auto entry: 000000029 **Warning** that manually added barcode is not in conformity with automatic recognition
	Tube is missing – the tube was not present or recognized by the analyzer
	The sample with same barcode was already measured the same day

8.4.2 Cuvette (analysis) status

LAURA XL contains a total number of 14 cuvettes. The cuvette panel and running actions are displayed in various colours on the left part of the screen of Status window.



Colour	Description
WHITE	Clean cuvette prepared for a sample
BLUE	Sample dosed on a strip is in phase of incubation (1 min)
ORANGE	Sedimentation of sample in progress, chemistry part is finished
GREEN	Sediment evaluation – taking pictures of sediment in progress
DARK GREY	Cuvette is about to be cleaned and prepared for a next sample
RED	The result was evaluated, the cuvette is in process of cleaning
BLACK	Cuvette is disabled

8.4.3 Rack status

Several symbols may appear in the rack section depending on current status:



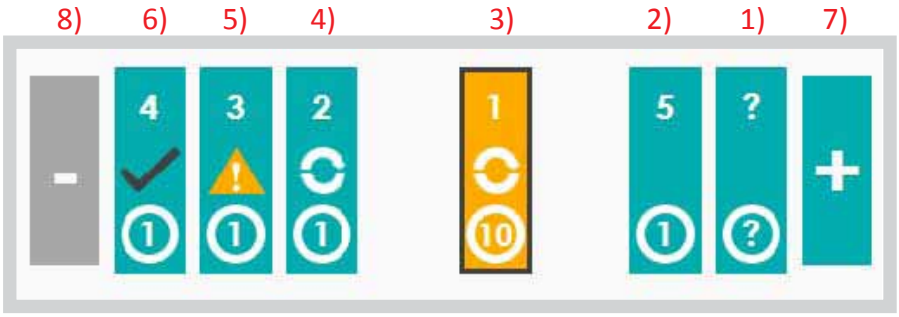
Rack number

From left to right

- All samples were processed correctly
- at least one sample not processed
- Analysis in process

Number of tubes in the rack

Here are examples of all the possible situations which can happen during the analysis:



1. Rack programmed or in input bay (right part) waiting for analysis – unknown status of rack number and number of tubes in rack
2. Rack programmed or in input bay (right part) waiting for analysis – manually assigned rack number and number of tubes in rack
3. Selected rack (orange color) and in process of analyses (center position just below the aligned circles – Rack number – 1; Number of tubes in the rack – 10
4. Rack on board in output bay (left part) – samples are already aspirated, however, some samples are still in phase of incubation / sedimentation / evaluation; Rack number – 2; Number of tubes in the rack – 1
5. Rack on board in output bay (left part) – evaluation is finished; at least one of the samples was not processed correctly (the tube remains with a number in its center); Rack number – 3; Number of tubes in the rack – 1
6. Rack on board in output bay (left part) – evaluation is finished, all the samples were processed correctly; Rack number – 3; Number of tubes in the rack – 1
7. + sign is used to add new rack to program or to load automatically
8. – sign is used to remove programmed or run racks from the display

8.4.4 Tank status (top right corner)

There are two possible statuses of consumables displayed in different colors:

9. ORANGE – Low level of consumables – it is possible to run further analyses, but the liquids will be soon consumed



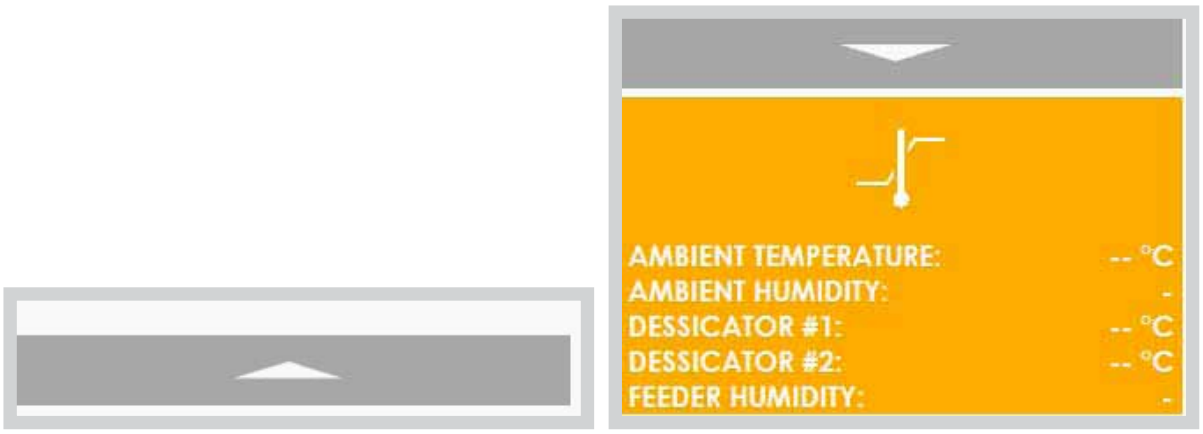
10. RED / ORANGE flashing– Not enough consumables to start further analyses – canisters have to be re-filled



In case of **WASTE** there is only one detectable level when the canister is full and needs to be emptied. User is informed by the canister symbol blinking in ORANGE-RED colour.

8.4.5 Sensor status (bottom left corner)

In the left bottom corner of Status window information about temperatures and humidities can be obtained. By default, it is not expanded and just shows the grey arrow up. The user can click on the arrow to expand and view the details, or it will automatically expand in case of sensor values issues.



It displays the ambient Temperature and humidity, as well as temperature and strip feeder humidity to control the humidity of the onboard strips.
This monitoring is a crucial element of performance of the Laura XL chemistry, of the control and correction of humidity in the strip feeder.
If operating temperature or humidity limits are exceeded, the display will expand, and warning messages will display.



In case this message displays, it is most likely an issue with instrument hardware and should be reported to your local techical service.

8.4.6 StartUp/Standby, Logging, Power buttons

8.4.6.1 Initialization / Sleep

By pressing the “Sun” button ( ) the analyzer can be manually initialized. The initialization is automatically proposed to user upon login to UI. If the analysis is stopped or if the measuring mode or strip type is switched, the analyzer needs to be initialized manually by pressing the “Sun” button.
By pressing the “Moon” button ( ), it is possible to switch the analyzer into “Sleep” status, which is the status before initialization – user is not allowed to start the measurement.

Button	Active status	Inactive status	Description	Format
INITIALIZATION			By pressing the “Sun” button the analyzer is manually initialized. During initialization or run of analysis the “Sun” button is inactive	The button is switching between “Sun” and “Moon”
SLEEP			By pressing the “Moon” button the analyzer is switched to “Sleep” status. During initialization or run of analysis the “Moon” button is inactive	The button is switching between “Moon” and “Sun”

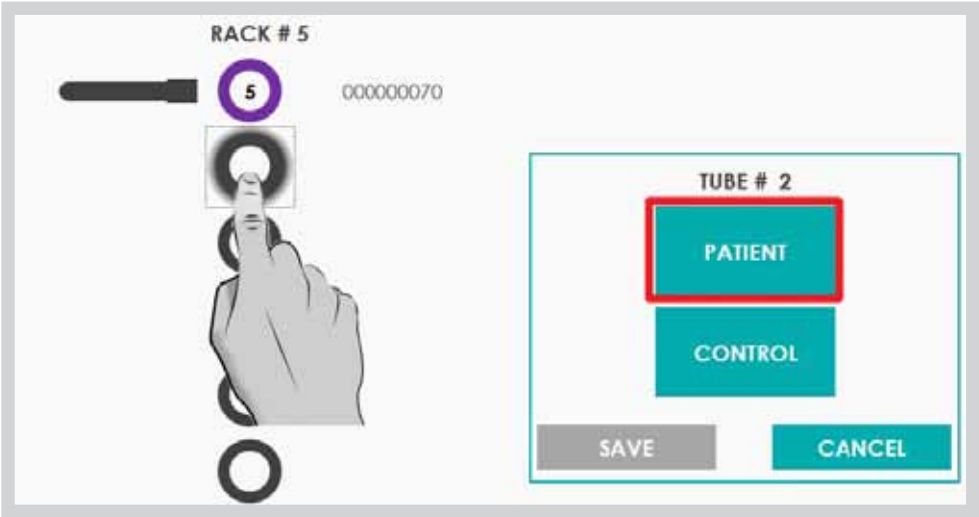
8.4.6.2 Power Off / Log Out

By pressing this sybmol the analyzer is powered off (see Chapter *8.1.5*). By pressing this symbol user is logged out and can be logged in with different account. Both buttons are inactive during the analysis. If it is necessary to power off the analyzer or log out the user, the STOP button has to be pressed first.

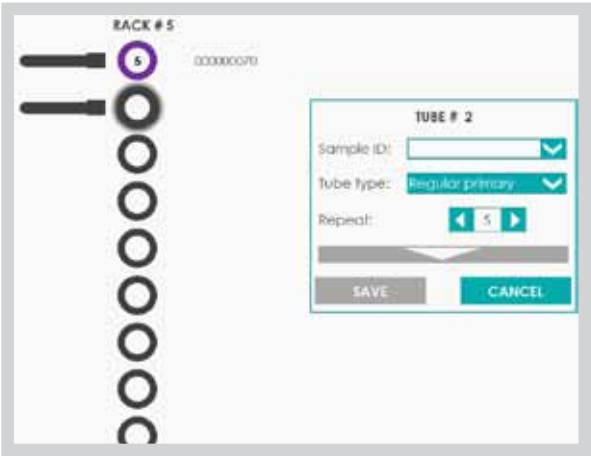
Button	Active status	Inactive status	Description	Format
POWER OFF			By pressing this button the analyzer is powered off. During initialization or run of analysis the “Power Off” button is inactive	The button is switching between active/ inactive form
LOG OUT			By pressing this button the user is logged out. During initialization or run of analysis the “Power Off” button is inactive	The button is switching between active/ inactive form

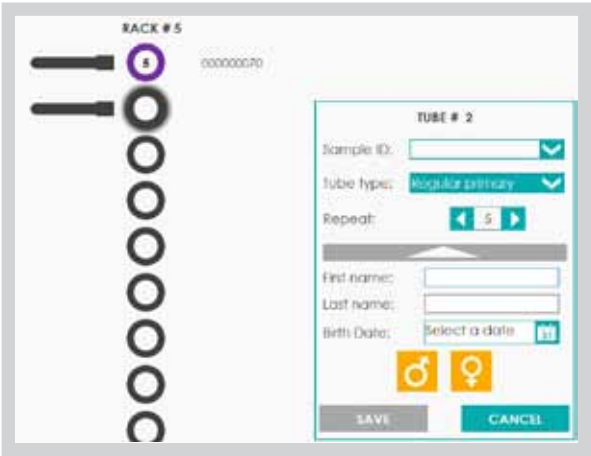
8.4.7 Registering samples (click on tube)

By clicking on an empty circle, it is possible to manually register and edit new patient sample. Adding of control samples was already mentioned in Chapter *4.4*.



1. Press “PATIENT” button to open option for setting parameters





NOTE The dialog box opens as its smallest mandatory input version., Aadditional information including patient first, last name, DOB and gender can be accessed upon clicking on the large down arrow.

2. Type Sample ID, choose the tube type, and select number of repeats per sample. Registering of Name, Birth date and Gender are optional.

   There are two types of tubes which can be used for patient sample analysis:

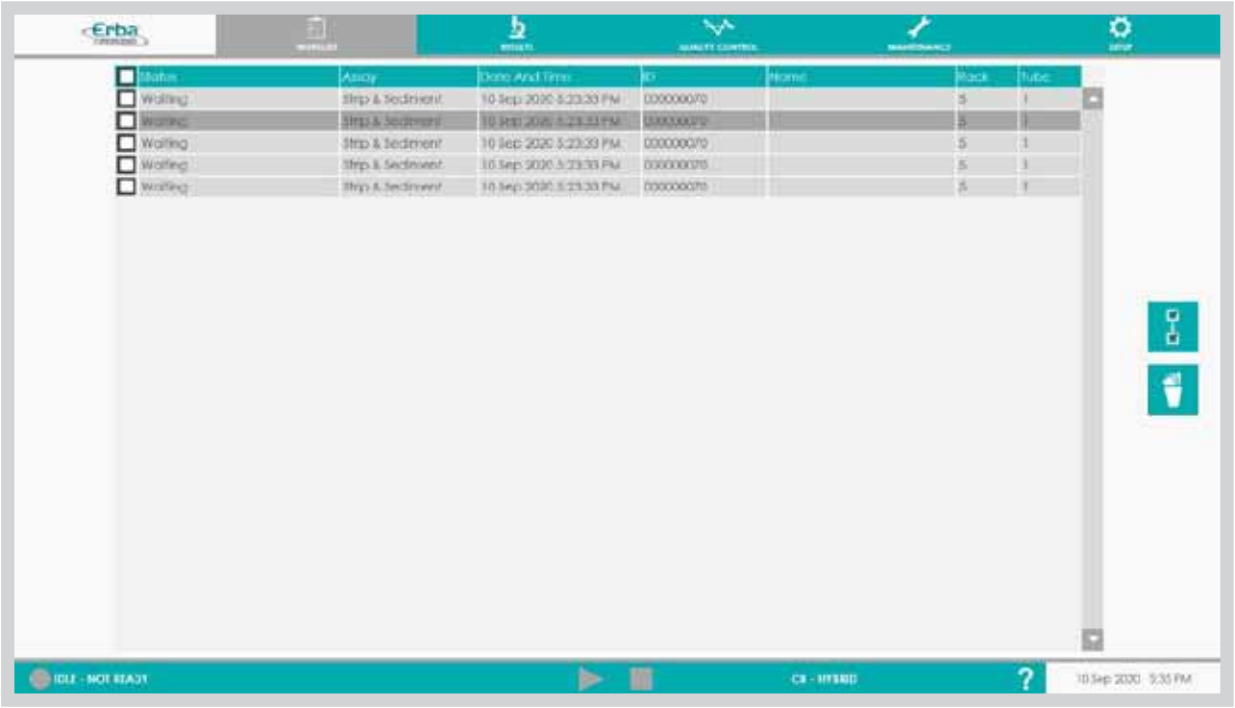
Labelling	Description
	REGULAR PRIMARY (volume range: 2 – 10 mL)
	SAMPLE VIAL (volume range: 0.9 – 2 mL)

NOTE The magnetic sensor detection will prevail on the manual programming. The detection of a magnetic adaptor will auatomatically modify the manual programming of a regular primary into a Sample vial AND will also reduce the replicate value to 1.

8.5 Worklist window

Worklist menu provides information to user running and programmed samples. Information include Status, assay requested, Date and Time of request/measurement, sample ID, Name, Rack number and Tube position.
Once a rack containing 10 samples (each sample is measured once) is loaded, user obtains information about operations being currently performed with each individual sample. When the sample is evaluated it is removed from the Worklist. If no errors, at the end of the analysis of all samples, the Worklist should be empty.
2 buttons are present to perform range selections, or delete from worklist
From this window, it is possible to modify automatically assigned ID, or add names, DOB, gender information to any sample.

Button	Active status	Inactive/ Selected status	Description	Format
WORKLIST			Press Worklist button to display the screen which provides information to user about measured samples considering their processing, dosing, evaluating and processing of results.	Button



The window displays all possible status for analyzed sample:

Displayed Status	Meaning
Waiting	The sample has not been aspired yet
Strip	Strip only mode: the sample is dispensed and incubation with individual pads ongoing
Wait strip result	Hybrid mode: Strip has been dispensed, incubation running. Sample is also injected into cuvette, incubation ongoing
Incubation	Sediment mode: Sample was injected in the cuvette, sedimentation is in process Hybrid mode: Strip results available, sediment incubation continues
Evaluation (%X/15)	camera is evaluating sediment pictures, result will be available soon
Wait for evaluation	Sediment pictures have been taken but are not yet evaluated
Complete	Test is complete, and results available
Delayed - No tube	Sample are not on-board
Delayed - Conflict	Sample appears in 2 positions, user must resolve conflict
Delayed - System mode does not match	Test has been requested in a different mode, and cannot be executed under the current mode
Error - Bubbles detected	Too many bubbles have been detected, sediment evaluation cannot complete
Error - Unknown	Unknown error occurs, no result available
Error - Strip issue	Strip cannot be evaluated (no strip, no drop, many strip, strip upside down issue detected)
Error - Picture missing	Sediment picture is missing, sediment cannot be evaluated
Error - Focus failed	Cuvette focusing fails (low signal / time out / picture missing)

8.6 Result window

Press “RESULTS” button of the Top Bar to display the window in which all the measured results may be reviewed, edited, re-evaluated or printed. Flags and Alerts are present in the Results section informing the user about issues or discrepancies between chemistry and sediment part of individual sample.

Button	Active status	Selected / Inactive status	Description	Format
RESULTS			It displays results for individual samples – for chemical and sediment part.	Button

When clicked on the “RESULTS” button, following screen is displayed:



It is devided into 5 sections:

1. Overview of measured and evaluated samples
2. Chemistry results + photo of diagnostic strip
3. Results for urine sediment
4. Snapshots of urine sediment
5. Result management (filtering, print, export, import, delete…)

8.6.1 Section 1: Overview of Measured and Evaluated Samples

8.6.1.1 Overview

In this section, all the information about measured samples are presented:

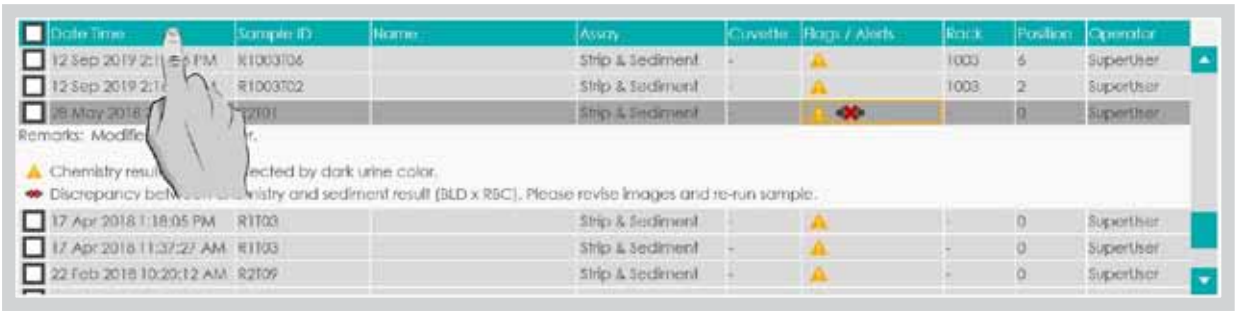
- **Date and Time** of the measurement
- **Sample ID** – either identified by barcode or automatically marked by a rack number and tube position
- **Name** – of the patient either automatically assigned by barcode or manually edited by user
- **Cuvette** – number of cuvette, in which the sample was analyzed
- **Flags / Alerts** – for corresponding sample represented by various symbols



- **Rack** – number of used rack
- **Position** - tube position in the rack
- **Operator** – username logged in during the analysis

It is possible to sort the data according to above mentioned characterictics by clicking on respective table titles.

Sorting by Date and Time



8.6.1.2 Font color coding

The results may be represented by various colours with different meaning:

Colour	Description
BLACK	Standardly measured sample
ORANGE	**Result for a sample which was already measured at least once that day** – the measurement and evaluation are performed, and the user is informed that at least 2 results for a single sample are available
BLUE	**Imported data** – data imported to LauraGUI from external drive
RED	**Result of a measurement which was modified by the user** - after manual identification of elements in urine sediment which were not recognized automatically
PURPLE	**Re-evaluation of samples in process** – temporary colour for a result; the original colour of this result is restored once the re-evaluation process is completed

8.6.1.3 Flag and Alerts

1. Chemistry

Chemistry flags/alerts are depicted by the warning symbol:



Here is the list of possible issues flagged by the warning symbol:

Issue	symbol	Description	Consequence
Detected strip does not match awaited strip		Detection of pads not matching the defined strip type - of UndekaPHAN for DekaPHAN or vice versa. or other strips not matching settings	No chemistry results available
Several strips detected		Traffic jam under the camera caused by mispositioned strip	No chemistry results available
Dispense issue detected		The pipette position check detected a possible issue with dispense on strip	No chemistry results available
Unknown rack		System configuration includes programming of specific tubes. The sample was aspirated from an unknown rack from a primary tube type. As system cannot know if the tube was standard or specific. In such case, the instrument aspirates from the higher bottom to protect the pipette. If the rack was a specific rack, the aspiration was correctly done, but if the rack was standard, the aspiration might be partial, and homogeneisation of the sample may not be optimum.	Chemistry result could be affected
Not enough sample on chemistry pad		Dispension on some of the pads was not sufficient – usually not enough sample and/or foaming low volume urine sample, or inexact position of pipette Z axis	No chemistry results available
Chemistry pad is too wet		The sample is not fully absorbed into the pad causing a drop reflection under the camera	Chemistry result could be affected
Whole strip seems to be dry		Indicates a problem with sample aspiration – either not enough sample or problem with syringe	No chemistry results available
No drop detected before first pad		Dispense or not enough sample in tube. There is a risk that negative sediment could be due to insufficient sample. However, the results are given for sediment to acknowledge possible pathological results on samples for which there may not be excess volume to rerun.	No chemistry results available and Not enough sample, sediment results can be affected.
There are too many brights on the % pad.		Pad is overdosed	No chemistry results available

Issue	symbol	Description	Consequence
No strip detected		Strip fallen down or mispositioned	No chemistry results available
Strip is reversed		Wrongly inserted strip into the feeder	No chemistry results available
Strip is upside down		The strip was placed upside down on the transporting belt.	No chemistry results available
Strip is not stable, results can be incorrect			Chemistry result could be affected
Sample color can affect result		Strongly colored samples can affect the color of the pad reaction.	Chemistry result could be affected
Result threshold has changed since strip evaluation			No chemistry results available
Color result can be affected by turbidity		Sample turbidity can change urine color interpretation	Color results could be affected
Too turbid sample to assess color		The high level of turbidity impairs the urine color measuring	No Color results reported
Clarity result can be affected by color		Strongly coloured samples can affect evaluation of clarity	

2. Sediment

In case of sediment, the user may encounter a warning symbol or symbol for discrepancy which indicates a collision between the chemical results and urine sediment:



Discrepancies between

- blood (BLD) and red blood cells (RBC),
- leukocyte esterase (LEU) and white blood cells (WBC),
- nitrite (NIT) and bacteria (BAC)

are the most frequent observation owing to different limitations of urine test strip and microscopic examination. The pre-analytic phase including sample collection and handling can highly affect the stability and lifetime of the sediment elements as well as the time delay between sample reception and measurement. Hence, lysis of cells may appear resulting in no presence on the sediment pictures. However, the hemoglobin (of RBC) or esterase (of WBC) remains in the solution and reacts with the corresponding pads on the test strip. In the other direction, not all WBC produce esterase, thus Negative LEU can still result in presence of WBC.

The presence of bacteria is detected by NIT pad on the test strip. The pad can detect only bacteria which are able to reduce nitrates to nitrites, i.e. primarily gram-negative bacteria. In the urine sediment plenty of other bacteria which are unable to produce nitrites can be present causing the discrepancy between chemistry and sediment. Furthermore, urines with very low concentration of nitrates can be positive on the sediment result while negative on the test strip.
For these reasons, the discrepancy flags for the 3 main categories listed are only triggered for unexpected cases.
Additional discrepancy flags are seeable with unmatching pH versus type of automatically identified crystals.

NOTE The discrepancy can be caused by insufficient automatic recognition. In that case, please perform a manual identification of elements in concern.

All the possible flags/alerts and result discrepancies are listed below:

Issue / Discrepancy	Symbol	Description
Crowded sample		Floods of certain elements, especially RBC, WBC and BAC can result in deteriorated automatic recognition. In this case it is recommended to perform manual identification or re-measurement of sample using microscope.
Too many bubbles detected		Bubbles may be present in cuvette, if the Liquid system was not mixed with water properly, if the priming of tubing after canister refilling was not performed correctly or in case of leakage in hydraulics presence. Bubbles are represented by dark shadows on the sediment picture which impair the automatic element recognition. In case of a large number of bubbles, there's no sediment result available
Unknown rack		System configuration includes programming of specific tubes. The sample was aspirated from an unknown rack from a primary tube type. As system cannot know if the tube was standard or specific. In such case, the instrument aspirates from the higher bottom to protect the pipette. If the rack was a specific rack, the aspiration was correctly done, but if the rack was standard, the aspiration might be partial, and homogeneisation of the sample may not be optimum.
Focus issue		The sediment camera had a problem with focus on a cuvette. The result of sediment is not available.
BLD / RBC discrepancy		Indicates a difference between results of Blood (chemistry) and Red Blood Cells (sediment) in the following cases: BLD = 0 & RBC >= 10 /µL or BLD = 1+ & RBC >= 50 /µL or BLD = 2+ & RBC >= 250 /µL Check the pictures of urine sediment and perform manual identification of RBCs if required.

Issue / Discrepancy	Symbol	Description
LEU / WBC discrepancy		Indicates a difference between results of Blood (chemistry) and Red Blood Cells (sediment) in the following cases: LEU = 1+ & WBC <=5 /µL or LEU = 2+ & WBC <=25 /µL or LEU = 3+ & WBC <=75 /µL Please check the pictures of urine sediment and if required, repeat the analysis of the sample!
NIT / BAC discrepancy		Difference between results of chemical testing and urine sediment (NIT x BAC/BACR) when NIT = 1+ & BACC+BACR <= 39 /µL and no BC Please check the snapshots of urine sediment and if required, repeat the analysis of the sample! *Note: Bacteria Clumps (BC) are considered Positive for Bacteria presence, even if only 1 BC in the 15 images*
pH_vs_TRIP		Crystals of Triple Phosphate identified in sediment in a non-matching pH (low pH) Please check the images of urine sediment and if required, repeat the analysis of the sample or review manual sediment slide
pH_vs_UA_CaOX		Crystals of Calcium Oxalate identified in sediment in a non-matching pH (High pH) Please check the images of urine sediment and if required, repeat the analysis of the sample or review manual sediment slide
Mucus bias		This message is related to the specific case of imported data, which if reavaluated may be biased for MUCUS, due to slight differences in camera calibration between devices or time of measurements



Warning: If the warning symbol is displayed, always perform a thorough review of measured results.

8.6.2 Section 2: Chemistry results

8.6.2.1 Overview of chemistry results

Chemistry results are available for 10 or 11 parameters of DekaPHAN Auto and UndekaPHAN AUTO, respectively. Results are displayed in selected units from Setup menu (Section…). For each result there are three types of available units, which can be chosen by the user - SI, conventional or arbitrary. Picture of the strip is present for each sample in case that the result correctness needs to be double-checked by eye.

To better suit customers' habits and demands for strip testing, the results can be reported using two different scales. Still results are obtained using PHAN strips produced by Erba Lachema.



For each pad of the test strip there are specific concentration ranges (except of SG and pH) as printed on the PHAN® Auto strip tube label for Scale 1. Evaluation of chemistry by Laura XL analyzer and diagnostic strips PHAN® Auto represents a semi-quantitative method meaning that certain deviations from the real analytical value might occur. Furthermore, user needs to take into account results which are on the borderline of particular Ranges. In this case, both results from two Ranges (lying next to each other) can be obtained if the sample is measured in replicates. The borders are usually represented by concentration of value = (Range X + Range Y)/2, e.g. the border between Range 1 and Range 2 of PRO zone = (30 + 100)/2 = 65 mg/dL.

Warning: If the results of several replicates occur in two Ranges not lying next to each other e.g. in Range 1 and 3, check the flags/alerts and photo of the strips of concern. If no flags/alerts are present and sample was dispensed well on the test strip, please, contact a local service.

8.6.2.2 Available Scales and ranges details

All the available ranges are listed in table below:

Scale 1			
PAD	**SI**	**Conventional**	**Arbitrary**
SG	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
LEU	Neg.	Neg.	Neg.
	25	20	+
	75	75	++
	500	500	+++
NIT	Neg.	Neg.	Neg.
	Pos.	Pos.	Pos.
pH	5	5	5
	6	6	6
	6.5	6.5	6.5
	7	7	7
	8	8	8
	9	9	9
PRO	Neg.	Neg.	Neg.
	0.3 g/L	30 mg/dL	+
	1 g/L	100 mg/dL	++
	5 g/L	500 mg/dL	+++
GLU	Neg.	Neg.	Neg.
	2.8 mmol/L	50 mg/dL	+
	5.5 mmol/L	100 mg/dL	++
	17 mmol/L	300 mg/dL	+++
	55 mmol/L	1000 mg/dL	++++
KET	Neg.	Neg.	Neg.
	0.5 mmol/L	5.2 mg/dL	+
	1.5 mmol/L	16 mg/dL	++
	5 mmol/L	52 mg/dL	+++
	15 mmol/L	156 mg/dL	++++
UBG	Norm.	Norm.	Norm.
	17 µmol/L	1 mg/dL	+
	51 µmol/L	3 mg/dL	++
	102 µmol/L	6 mg/dL	+++
	203 µmol/L	12 mg/dL	++++
BIL	Neg.	Neg.	Neg.
	17 µmol/L	1 mg/dL	+
	51 µmol/L	3 mg/dL	++
	102 µmol/L	6 mg/dL	+++
BLD	Neg.	Neg.	Neg.
	10	10	+
	50	50	++
	250	250	+++
ASCA	Neg.	Neg.	Neg.
	0.6	10	+
	1.1	20	++
	2.3	40	+++
	3.4	60	+++

Scale 2			
PAD	**SI**	**Conventional**	**Arbitrary**
SG	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
LEU	Neg.	Neg.	Neg.
	Traces (15)	Traces (15)	Trace
	70	70	+
	125	125	++
	500	500	+++
NIT	Neg.	Neg.	Neg.
	Pos.	Pos.	Pos.
pH	5	5	5
	6	6	6
	6.5	6.5	6.5
	7	7	7
	7.5	7.5	7.5
	8	8	8
	8.5	8.5	8.5

Scale 2			
PAD	**SI**	**Conventional**	**Arbitrary**
PRO	Neg.	Neg.	Neg.
	Traces (0.15 g/L)	Traces (15 mg/dL)	Traces
	0.3 g/L	30 mg/dL	+
	1 g/L	100 mg/dL	++
	3 g/L	300 mg/dL	+++
	20 g/L	2000 mg/dL	++++
GLU	Neg.	Neg.	Neg.
	Traces (5.5 mmol/L)	Traces (100 mg/dL)	Traces
	14mmol/L	250 mg/dL	+
	28 mmol/L	500 mg/dL	++
	55 mmol/L	1000 mg/dL	+++
KET	Neg.	Neg.	Neg.
	Traces (0.5 mmol/L)	Traces (5.2 mg/dL)	Traces
	1.5 mmol/L	16 mg/dL	+
	4 mmol/L	42 mg/dL	++
	8 mmol/L	83 mg/dL	+++
	>16 mmol/L	>166 mg/dL	++++

PAD	SI	Conventional	Arbitrary
UBG	Norm.	Norm.	Norm.
	33 µmol/L	2 mg/dL	+
	66 µmol/L	4mg/dL	++
	>131 µmol/L	>8 mg/dL	+++
BIL	Neg.	Neg.	Neg.
	17 µmol/L	1 mg/dL	+
	51 µmol/L	3 mg/dL	++
	102 µmol/L	6 mg/dL	+++
BLD	Neg.	Neg.	Neg.
	Traces (10)	Traces (10)	traces
	25	25	+
	80	80	++
	200	200	+++

8.6.2.3 Editing of chemistry results

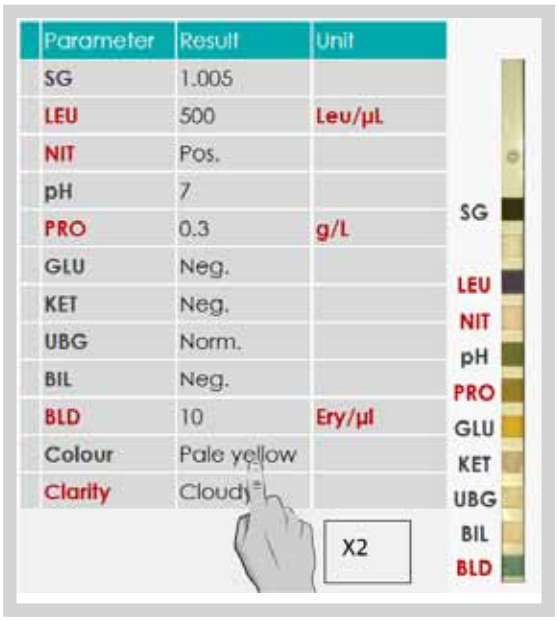
8.6.2.3.1 General information on Editing chemistry results

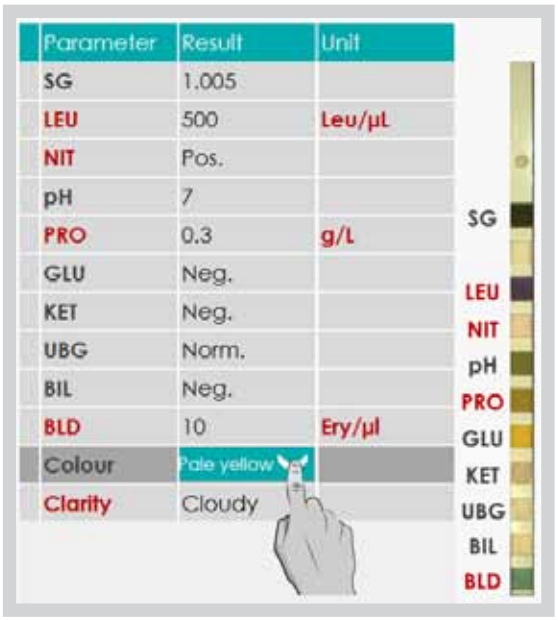
The results displayed in the chemistry table are automatically calculated by the system based on the color developed on the strip pads, compensated with urine color.
If the user would find a conflicting confirmatory result for a chemistry, and wants to modify some chemistry results, it is possible to do so.

Warning: Discrepancies between chemistry and sediment results may not necessarily mean that one of the results is inaccurate. There are circumstances where this would happen without system malfunction. For example, a positive BLD pad is not always correlated by positive RBC. The RBC could have been lysed in-vivo due to intravascular hemolysis or other disorders. They also could have been lysed in-vitro, due to a variety of reasons like dilute or alkaline samples or delayed processing. Same apply for other parameters.
Therefore, changing the results should be done with caution, ensuring not to hide a relevant and clinically significant discrepancy, that would hinder the clinician decision.

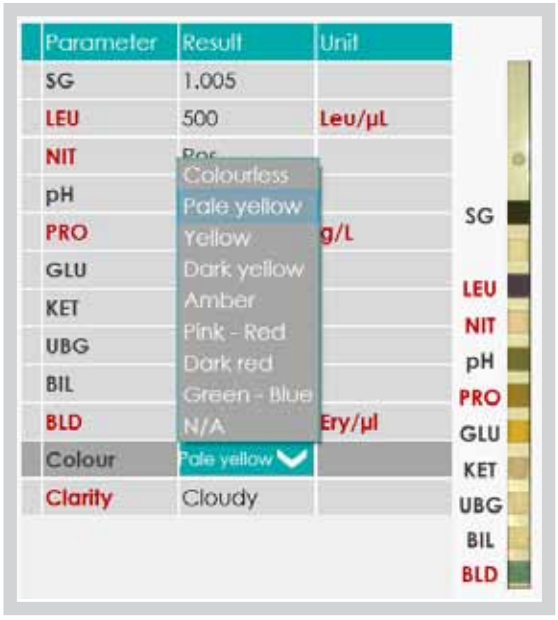
8.6.2.3.1.1 Procedure of Editing chemistry results

Any of the chemistry parameters can be edited. This means from Strip pads or color and turbidity. From the Chemistry result table





Double click on the result of the parameter you wish to modify (for example colour)
Then Click on the arrow to develop the drop down list of options to select from



This list corresponds to all the options available from the scale the system is configured to work with.

Select the value you want to change it to



- The result is changed to the new value
- When applicable, if a result is changed from Negative to a value, the Unit will automatically be displayed in the Unit column. And vice versa, a positive result with Unit mentioned, once changed to a negative result will remove the unit from the Unit column
- The result line in the chemistry table is preceded by the sign “!” to indicate the result was manually edited
- The sample result line indicates the manual result edition by a Red bold font, a ! in the Flag / Alerts column, and the user name of the user logged in at the time of last edition is written under Remarks: Modified by …



When reviewing other samples, and going back to an edited sample:

- The modified sample appears bold; red, with the ! and comment of who last modified the result(s).
- The specific result no longer displays as a drop-down list but as a regular text field.

NOTE 1- The printed report shows the modification as a YES mentioned in the 'Modified' column as seen below

Patient Report

Patient name: - **Gender:** -

Sample ID: R10T04 **Birth date:** - **Result date:** 3/16/2022 7:12:24PM

Parameter	Result	Unit	Range	Modified	Normal range
SG	1.005				
LEU	500	Leu/µL			
NIT	Pos.				
pH	7				
PRO	0.3	g/L			
GLU	Neg.				
KET	Neg.				
UBG	Norm.				
BIL	Neg.				
BLD	10	Ery/µl			
Colour	Yellow			Yes	
Clarity	Cloudy				
Red blood cell	3	N / µL	- (≤ 5)		< 50
nRBC	0	N / µL			
dRBC	3	N / µL			
White blood cell	1105	N / µL	++++ (> 250)		< 50
WBC Clump	15	N / µL	++ (10 - 20)		< 50
Epithelial cell	28	N / µL	++++ (> 20)		≤ 0
SQEP	28	N / µL	+ (15 - 50)		< 50
NSE	0	N / µL	- (≤ 15)		< 50
Crystal	22	N / µL	+ (5 - 69)		≤ 0
CaOx	0	N / µL	- (≤ 5)		< 50
mCaOx	0	N / µL	- (≤ 1)		< 1
TRIP	0	N / µL	- (≤ 5)		< 50
UA	0	N / µL	- (≤ 5)		< 50
Small CRYS	0	N / µL	- (≤ 5)		≤ 0
AMO	22	N / µL	+ (5 - 69)		≤ 0
Bacteria Clump	56	N / µL	++++ (> 30)		≤ 0
Bacteria	2651	N / µL	++++ (> 400)		< 40
BACC	932	N / µL	++++ (> 400)		< 50
BACR	1719	N / µL	++++ (> 400)		< 50
Cast	3	N / µL	+ (0 - 4)		≤ 0
HYA	0	N / µL	- (≤ 0)		< 50
CAST	3	N / µL	+ (0 - 4)		< 50
Yeast	0	N / µL	- (≤ 5)		< 50
Mucus	3	N / µL	- (≤ 5)		< 50

Page 1 of 1

2- Results sent Results sent to L.I.S. are as well transferred with 'EDIT' flag as indication of manual modification. This flag is present for any manual result change (chemistry or sediment).
3- To restore original system calculated results, the user can reevaluate using the icon. This action is not specific and will re-evaluate both chemistry interpretation and sedimentation automatic recognition.

8.6.3 Section 3: Sediment results

8.6.3.1 Overview of sediment results

Window with sediment results contains:

ELEMENT – *information about element type of urine sediment. They are sorted as per defined in in sediment ranges setting, and under their main category name. The category name is written in bold and aligned left, the subcategories are below, in normal lettering and indented. Some elements are both category name and element themselves ie White blood cell.*

TOTAL COUNT – number of automatically identified elements from the 15 pictures. *Or manually retagged or corrected elements numbers.*

LEVEL – results of urine sediment displayed in arbitrary unit as - / +/ ++ / +++ / ++++

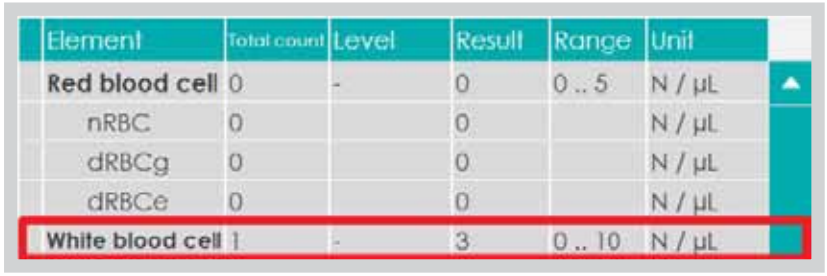
SELECTED UNITS – results of urine sediment displayed as N / N/µL / hpf / lpf/ arbitrary…

RANGE – range associated to particular level of results (see Section…)

Element	Total count	Level	Result	Range	Unit
Red blood cell	0	-	0	0 .. 0	N / hpf
nRBC	0		0		N / hpf
dRBCg	0		0		N / hpf
dRBCe	0		0		N / hpf
White blood cell	**40**	**+++**	**12**	**10 .. 25**	**N / hpf**
WBC Clump	**1**	**+**	**5**	**2 .. 16**	**N / lpf**
Crystal	**22**	**+**	**109**	**8 .. 110**	**N / lpf**
CaOx	0	-	0	0 .. 8	N / lpf
TRIP	0	-	0	0 .. 8	N / lpf
UA	1	-	5	0 .. 8	N / lpf
Small CRYS	**10**	**+**	**49**	**8 .. 110**	**N / lpf**
AMO	0	-	0	0 .. 8	N / lpf
Epithelial cell	**24**	**++**	**119**	**80 .. 160**	**N / lpf**
SQEP	**22**	**++**	**109**	**80 .. 160**	**N / lpf**
NSE	2	-	10	0 .. 24	N / lpf
Casts	**1**	**+**	**5**	**0 .. 6**	**N / lpf**

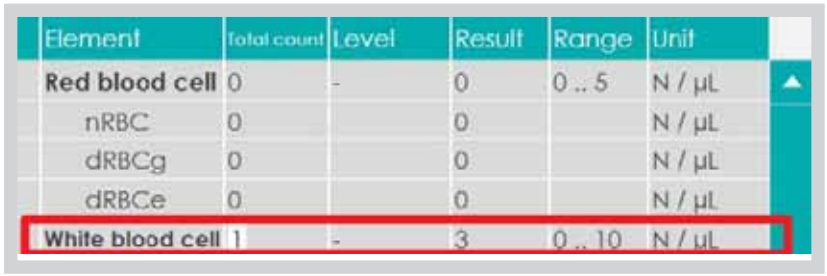
8.6.3.2 Editing of Sediment Results in Result View

It is possible to edit the Total count of any element:



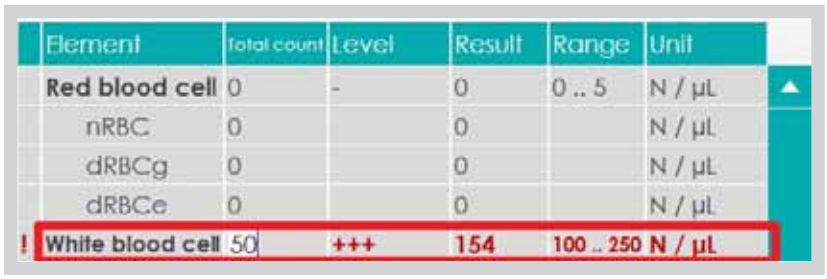
Element	Total count	Level	Result	Range	Unit
Red blood cell	0	-	0	0 .. 5	N / µL
nRBC	0		0		N / µL
dRBCg	0		0		N / µL
dRBCe	0		0		N / µL
White blood cell	1	-	3	0 .. 10	N / µL

Once the number is entered, the system automatically converts it to level and selected unites.



Element	Total count	Level	Result	Range	Unit
Red blood cell	0	-	0	0 .. 5	N / µL
nRBC	0		0		N / µL
dRBCg	0		0		N / µL
dRBCe	0		0		N / µL
White blood cell	1	-	3	0 .. 10	N / µL

The example shows that initial number of WBC = 1 was changed to 50 and level was automatically converted from "–" to "+++" and selected units result from "0" to "154", and its range accordingly.



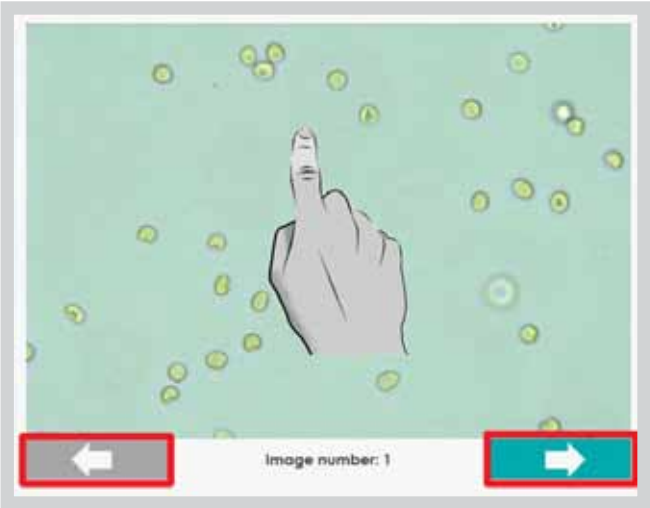
Element	Total count	Level	Result	Range	Unit
Red blood cell	0	-	0	0 .. 5	N / µL
nRBC	0		0		N / µL
dRBCg	0		0		N / µL
dRBCe	0		0		N / µL
! White blood cell	50	+++	154	100 .. 250	N / µL

The manual edit of Total count with subsequent unit conversion is indicated by red exclamation mark ! in the first column.

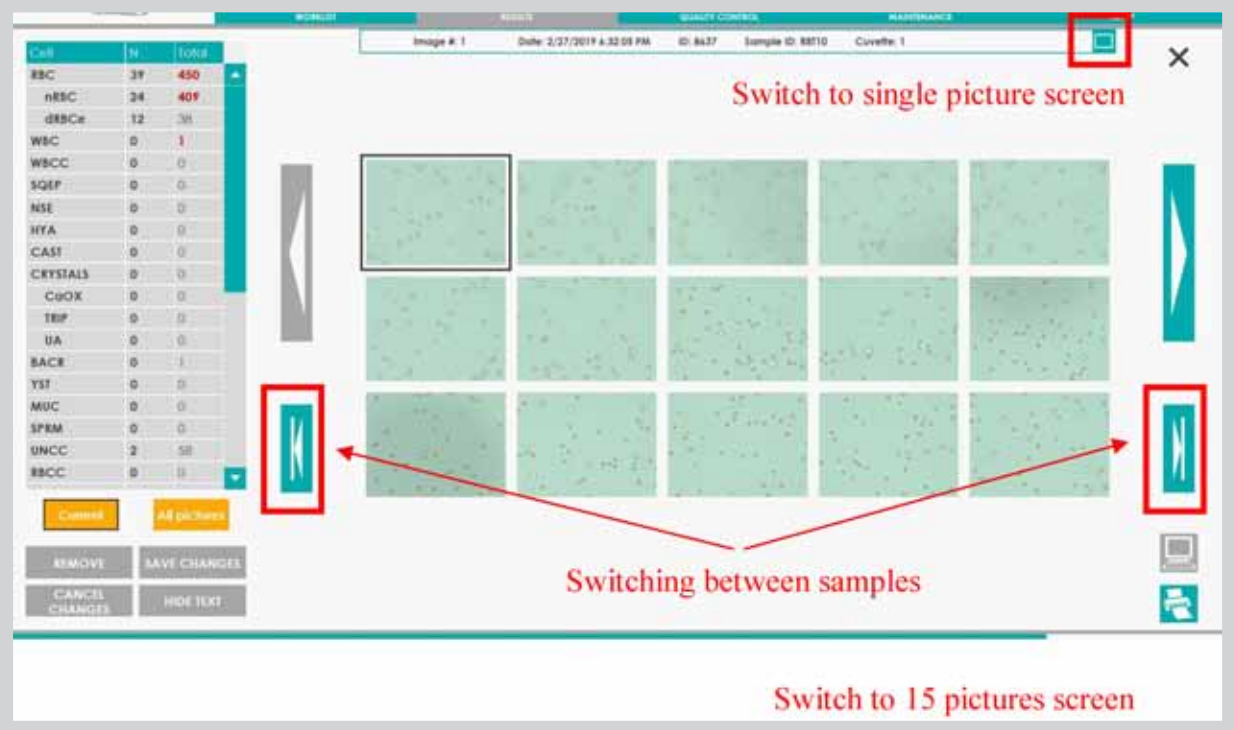
8.6.4 Section 4 : Sediment snapshots

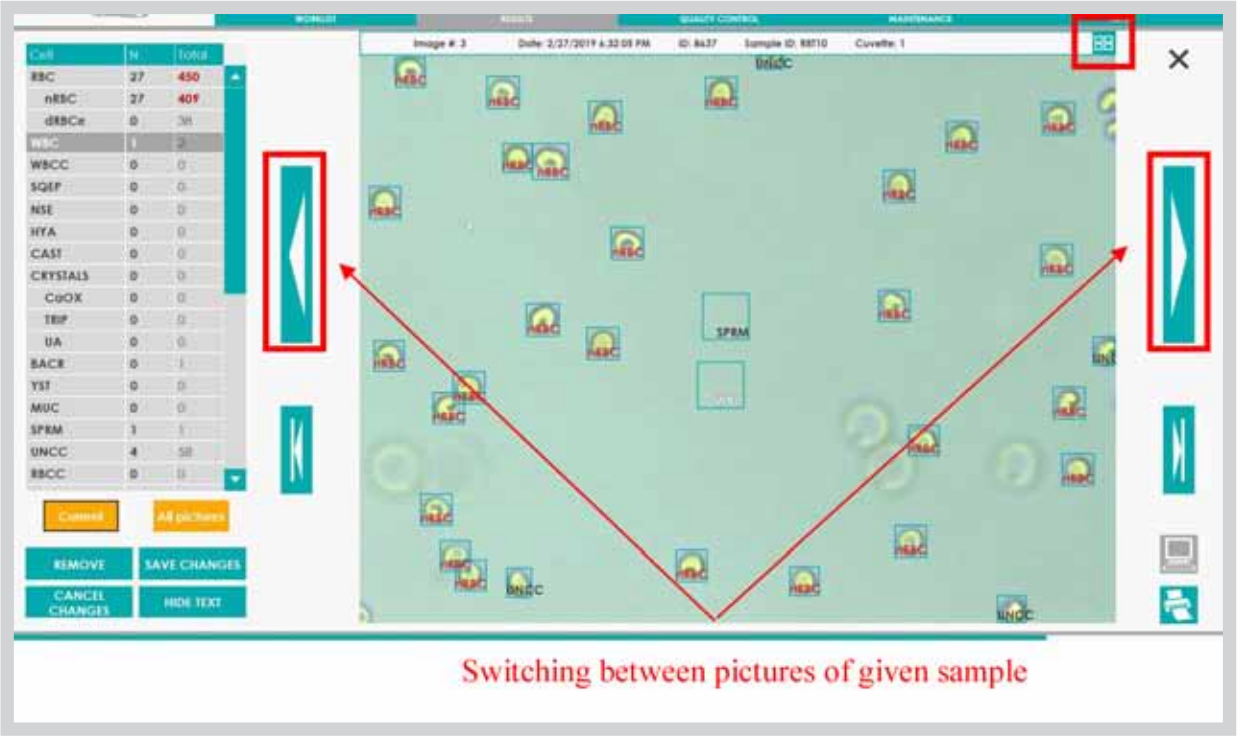
8.6.4.1 Sediment results – screens overview

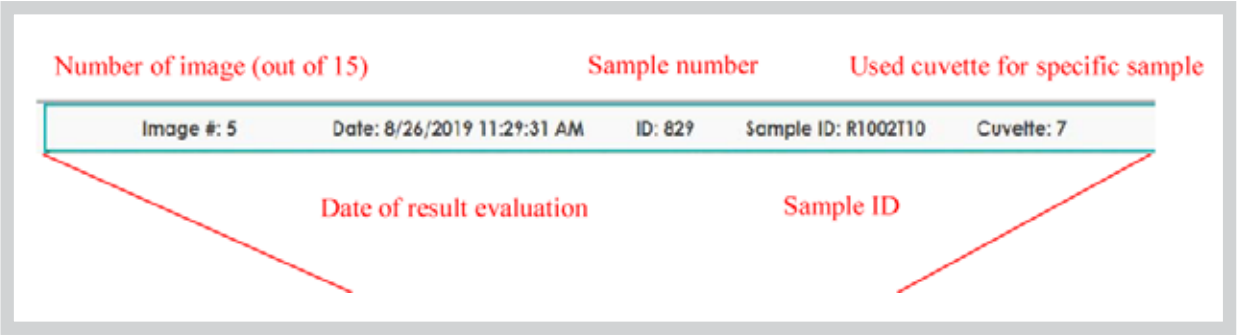
Individual photos of urine sediment corresponding to particular sample can be viewed in Result menu by pressing left/right arrows:

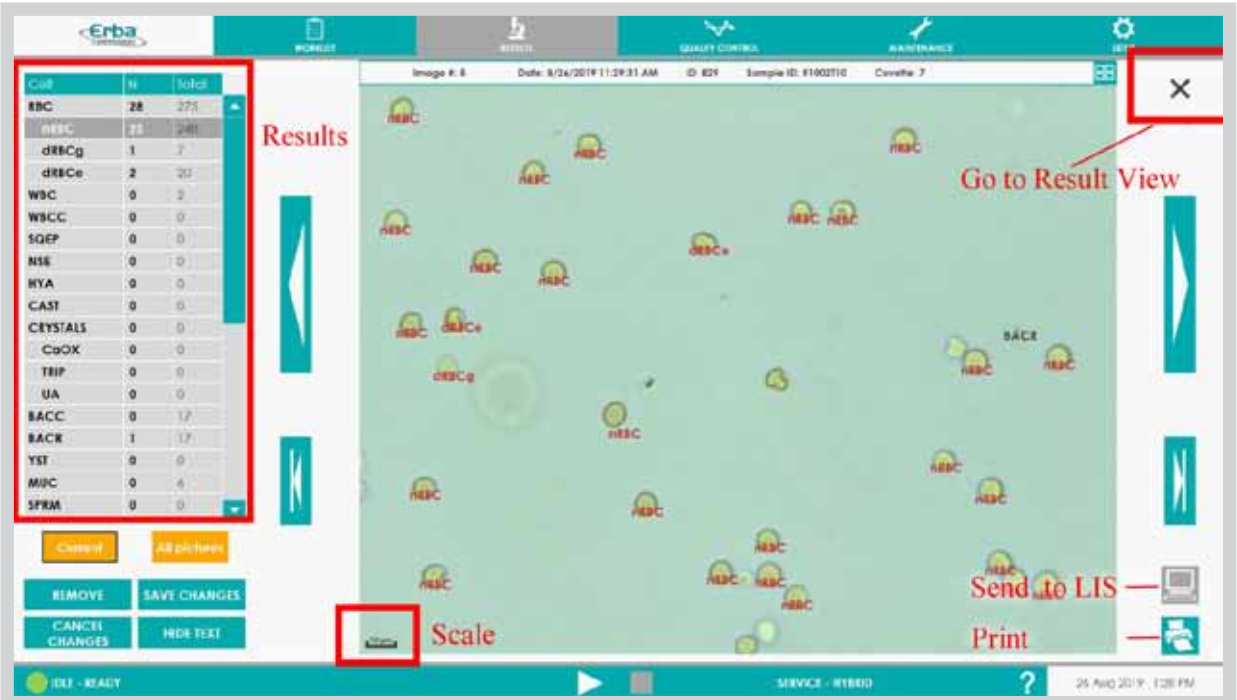


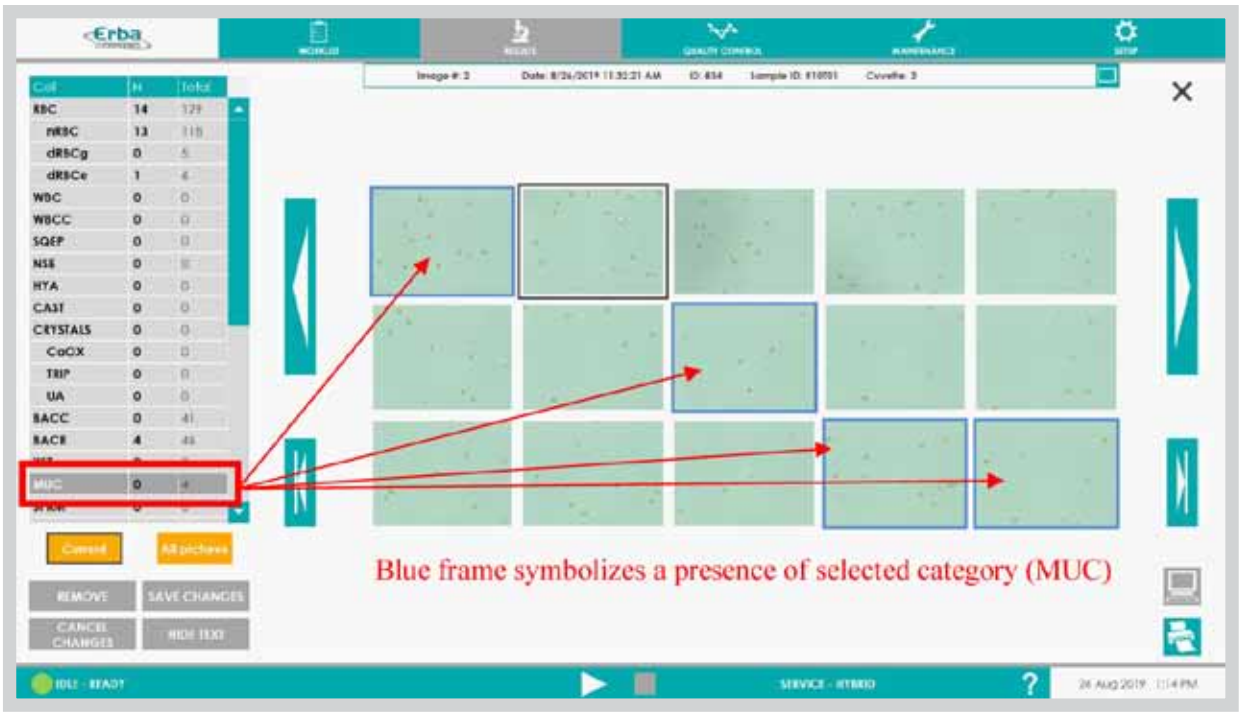
However, more comprehensive menu and possibility to review and manually edit the sediment results will be displayed by clicking on the photo. In Picture View user can switch between screens with all 15 pictures or single zoomed picture. Switching between individual pictures or samples is allowed by left/right arrows on the sides. Besides providing overview of whole sample, the 15 pictures screen allows to find particular element. On the contrary, single picture screen allows to investigate each photo in details.




Switching between pictures of given sample


Number of image (out of 15)
Sample number
Used cuvette for specific sample
Image #: 5
Date: 8/26/2019 11:29:31 AM
ID: 829
Sample ID: R1002T10
Cuvette: 7
Date of result evaluation
Sample ID


Results
Go to Result View
Send to LIS
Scale
Print



8.6.4.2 Procedure for Sample Editing in Picture View:

1. Select the category of interest
2. Double click on the unidentified element



3. The title will be displayed close to the element and the result will be recalculated. If it's necessary to mark other elements from another category, choose the required category from the left column and follow the same procedure.



4. The deletion of wrongly identified element is a reverse process and can be done by:
   A) Double clicking on the title of interest – only one title will be deleted
   B) Pressing “REMOVE” button – all the titles of selected category will be deleted and the result will be recalculated



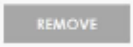
Furthermore, the User can delete all the titles of selected category either from single picture or all the 15 pictures of concerned sample by pressing “CURRENT” or “ALL PICTURES” buttons.

5. In order to keep the values of modified sample it is necessary to save it by pressing “SAVE CHANGES” button once the editing of all the pictures is finished. If this action is forgotten while going back to Result View, the User is asked by the pop up window to either save or cancel the changes:

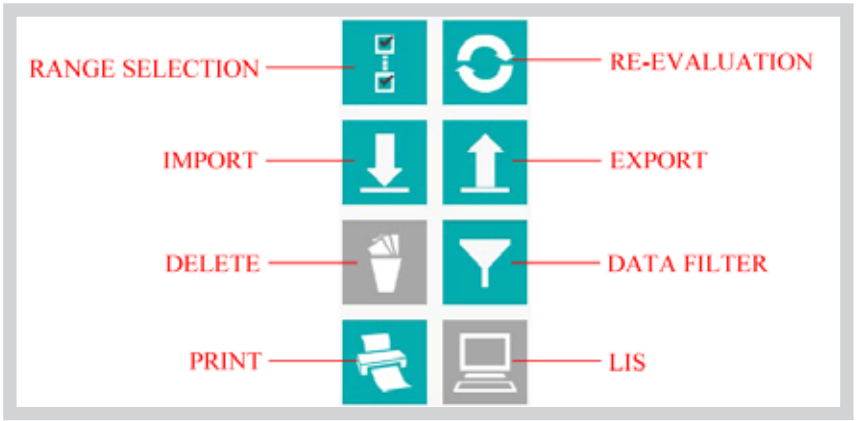


6. Going back to Result View the sample of interest turns to red colour symbolizing a modification by User, furthermore, black exclamation mark is present in first column of sediment results corresponding to manual changes done by User in Picture View.

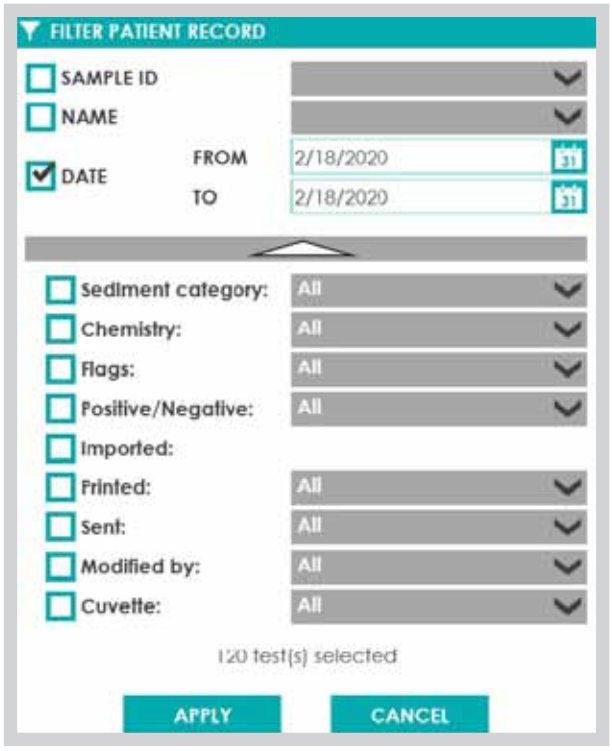


Button	Active status	Inactive status	Description	Format
REMOVE			Press “REMOVE” button to delete all the titles of selected category in urine sediment picture	Active formate in single picture screen / Passive formate in 15 pictures screen
SAVE CHANGES			Press “SAVE CHANGES” button to save all the performed modifications – title adding / deleting	Active formate in single picture screen / Passive formate in 15 pictures screen
CANCEL CHANGES			Press “CANCEL CHANGES” button to cancel all the performed modifications – title adding / deleting	Active formate in single picture screen / Passive formate in 15 pictures screen
HIDE TEXT			Press “HIDE TEXT” button to hide all the present titles on the picture	Active formate in single picture screen / Passive formate in 15 pictures screen. The button is switching between “HIDE TEXT” and “DISPLAY TEXT”
DISPLAY TEXT			Press “DISPLAY TEXT” button to display hidden titles back	Only inactive formate. The button is switching between “DISPLAY TEXT” and “HIDE TEXT”
CURRENT			Press “CURRENT” button to remove all the titles of selected category from currently displayed picture	Only active formate
ALL PICTURES			Press “ALL PICTURES” button to remove all the titles of selected category from all 15 pictures of particular sample.	Only active formate

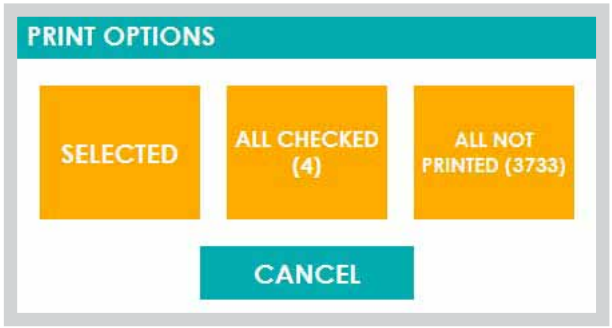
8.6.5 Section 5 : Additional Functions



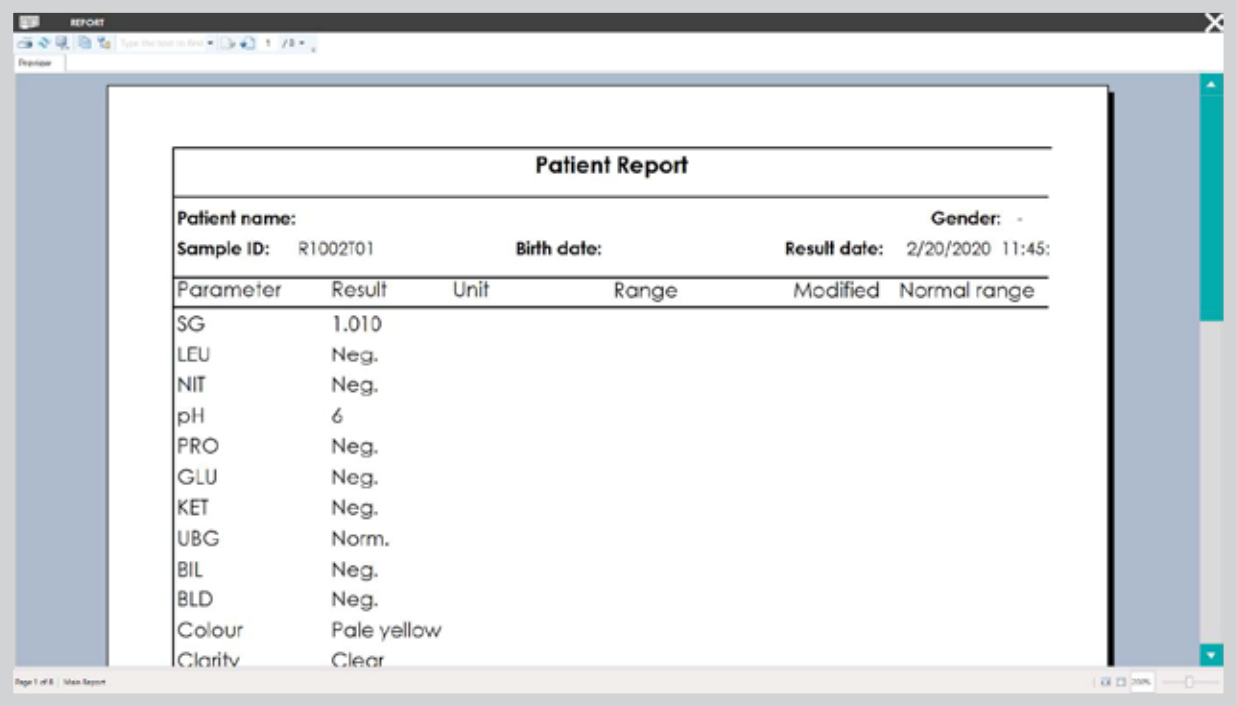
- **RANGE SELECTION** – by clicking on the first and last result (the boxes in the first column) user is allowed to select the range for further manipulation (export, deletion, print) instead of clicking on every single result
- **RE-EVALUATION** - once the results were manually edited, recalculated and saved, they can put back to the original state by clicking on this button. The process of re-evaluation of one sample takes several seconds (depending on the amount of elements in sediment). Results which are in process of re-evaluation or waiting for re-evaluation are colored in purple.
- **IMPORT** – the results can be imported in .lxl formate from one analyzer to another via USB key
- **EXPORT** – the results can be exported to USB key in .lxl formate. If the .lxl formate is renamed to .zip, it can be extracted. A folder with results (pictures of sediment and strip) and .xml file (which can be opened in Excel) is created subsequently
- **DELETE** – if necessary the results can be deleted from the database by pressing "Delete" button
- **DATA FILTER** – results can be filterd by sample ID, name, date and others



- **PRINT** – by clicking the "Print" button, results can be either printed or saved as PDF (or other) file



Patient report is created allowing comprehensive browsing of both chemistry and sediment results:



Patient Report

Patient name: Gender: -

Sample ID: R1002T01 Birth date: Result date: 2/20/2020 11:45:

Parameter	Result	Unit	Range	Modified	Normal range
SG	1.010				
LEU	Neg.				
NIT	Neg.				
pH	6				
PRO	Neg.				
GLU	Neg.				
KET	Neg.				
UBG	Norm.				
BIL	Neg.				
BLD	Neg.				
Colour	Pale yellow				
Clarity	Clear				

- **LIS** – allows sending the data the host PC (LIS)

Button	**Active status**	**Inactive status or *selected***	**Description**	**Format**
RANGE SELECTION		*Selected* 	Selection of all the results for further actions is allowed by clicking just on first and last result.	Button
RE-EVALUATION			Re-evaluation of selected results is allowed by pressing this button. Re-evaluation can be useful if default results need to be obtaineed, e.g. after manual edit / deletion or SW update.	Button
IMPORT		N/A	Import of selected results is possible by pressing this button. User is asked for insertion of external drive with results. Only files with .lxl format can be imported.	Button
EXPORT		N/A	Export of selected results is possible by pressing this button. User is asked for insertion of external drive. Selected results are exported in .lxl format.	Button
DELETE			Deletion of unwanted results is possible by pressing this button.	Button

Button	Active status	Inactive status or *selected*	Description	Format
DATA FILTER		*selected* 	By pressing this button results can be filterd by sample ID, name, date and others	Button
PRINT			By clicking the “Print” button, results can be either printed or saved as PDF (or other) file	Button
LIS			Sending the data the host PC (LIS) is allowed by pressing this button. The button is inactive when LIS is not connected.	Button

AUTO VALIDATION The LIS can be configured to send AUTOMATICALLY the normal samples and retain the others for manual sending. The LIS can be configured to send:

- EVERYTHING automatically
- Only Normals automatically
- Everything manually, see *8.9.2 LIS section* for more details

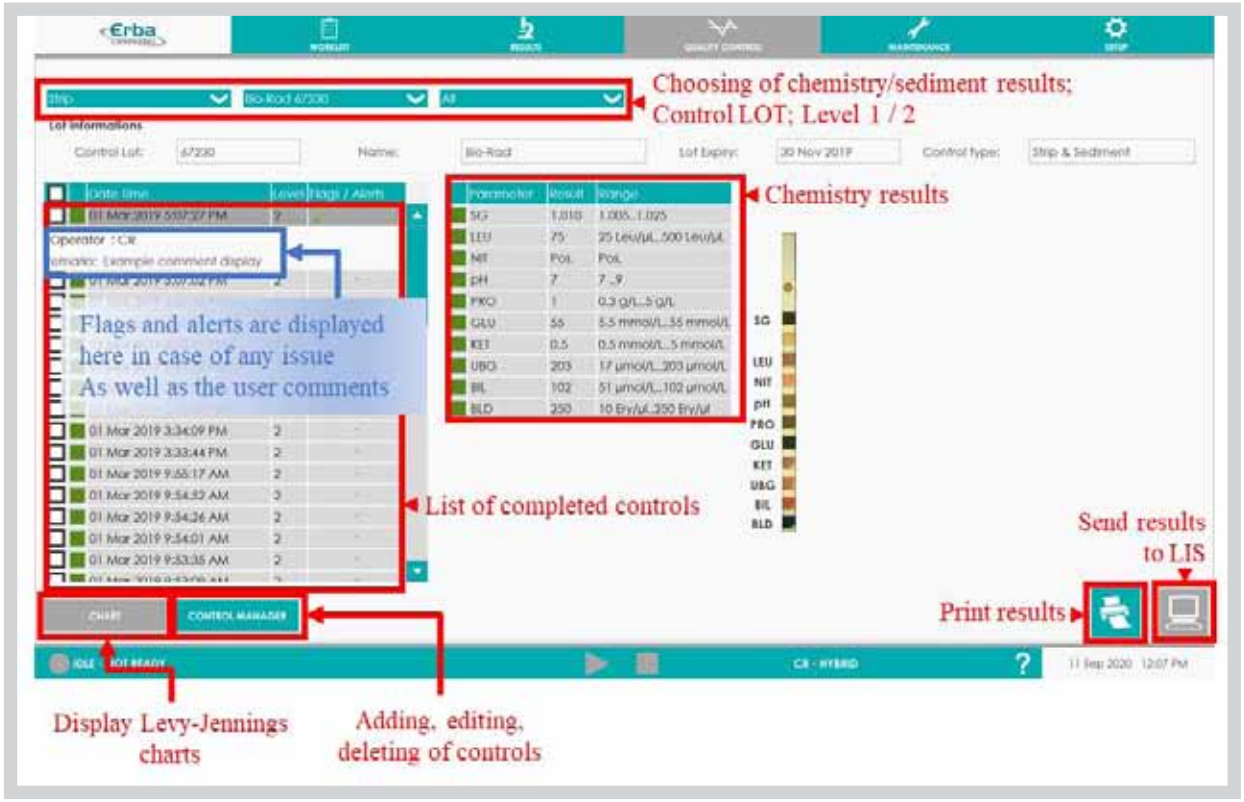
STAT TESTING: STAT samples should be placed in the first position of the sample rack. When the sample rack is placed onto the analyzer, the system will aspirate from this position first. (see section *5.5.2.1.1 loading of STAT samples during measurement* for more details)

8.7 Quality Control window

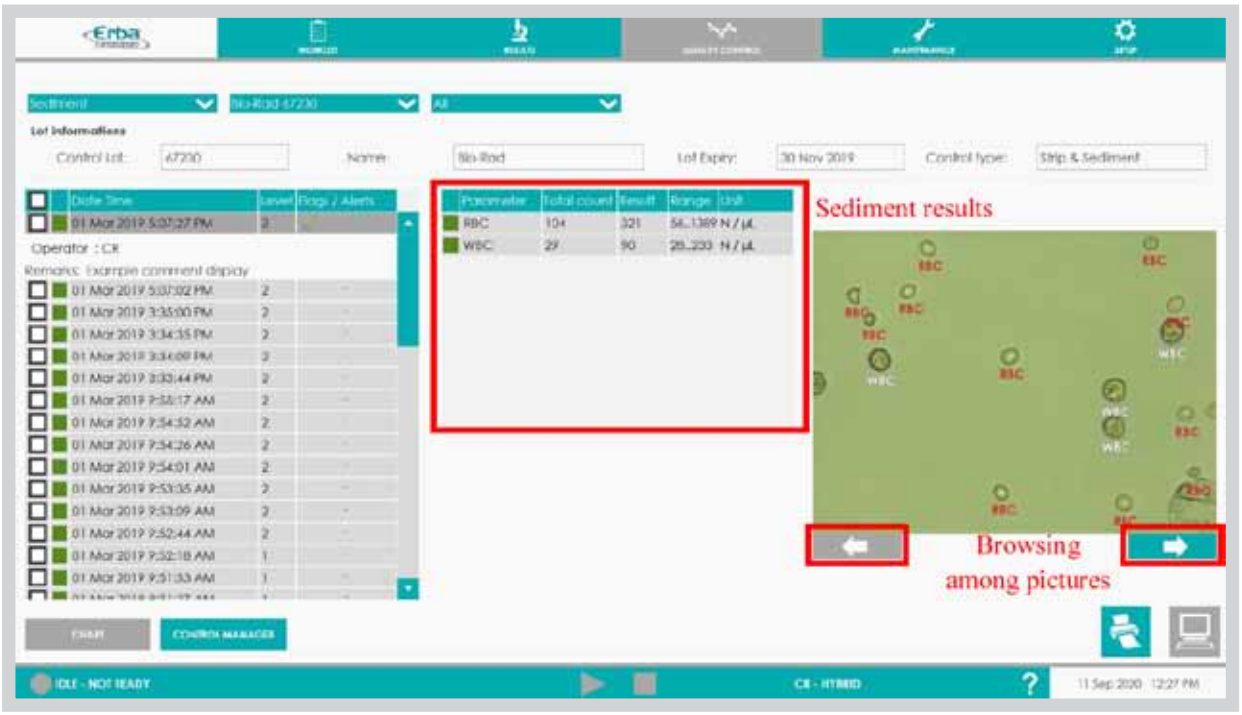
Quality control button presents the screen for checking and evaluation of both chemistry and sediment results, adding and setting new control LOT and displaying Levey-Jennings charts.

Button	Active status	Selected/ Inactive status	Description	Format
QC			Press this button to display the QC menu for browsing the QC results, displaying Levey-Jennings charts or adding new control or new lots	Button

Chemistry result screen



Sediment result screen



Images of the QC sediment are visible, user can scroll through the 15 images by the right and left arrows, but the tagging cannot be edited on controls.

8.8 Maintenance window

Press MAINTENANCE button to enter the extended menu allowing for technical maintenance of LAURA XL analyzer – in the form of simple automatic or semi-automatic diagnostics.

Button	Active status	Inactive status	Description	Format
MAINTENANCE			Press this button to access several automatic or semi-automatic functions related to diagnostics of the device (cleaning, data backup, loading or unloading of diagnostic strips...).	Button



Button	Active status	Inactive status	Description	Format
CLEAN			Press this button to request a manual routine cleaning	Button
SCAN CUVETTES			Perform cuvette scanning to examine their cleanliness.	Button
REAGENTS			Loading of new container of cleaner or Liquid System	Button
PRIME			Perform “prime” everytime the lines are moved above the liquid level in the canisters, to remove bubbles from lines, and prevent them from entering the analytical path. Prime is accessible for cleaner and Liquid System	Button
BACKUP			Press this button to create a data backup on USB key	Button
RESTORE BACKUP			Press this button to restore data from USB key	Button
CLEANING +			Press this button to request a long cleaning (14H procedure in case of system contamination)	Button

Button	Active status	Inactive status	Description	Format
LONG STOP			Press this button to perform a long procedure for drying the system before shutting	Button
FEED STRIPS			Press this button everytime there's a need to load new strips inside the analyzer. This button is inactive once the number of strips inside is above 50.	Button
UNLOAD STRIPS			Press this button everytime the strips need to be unloaded. It is recommended to unload the strips and put them back to the tube at the end of the analysis of the day.	Button
SERVICE		N/A	Service button provides the opportunity to upgrade software version or to go to Service adjustment software (for service technicians only!).	Button
RECORDS		N/A	Any action / process on Laura XL can be followed in Records menu.	Button

8.8.1 Clean

Click on the Clean button



The dialog box opens



Click in the circle to confirm the cleaning cycle start. *It includes a scan of all the active cuvettes. The full cycle lasts about 20 minutes if all cuvettes are found clean.*

Case 1: If all cuvettes are clean, the window states completeness of the procedure, and the window can be closed by the X on top right of the window. All active cuvettes are enabled for testing.

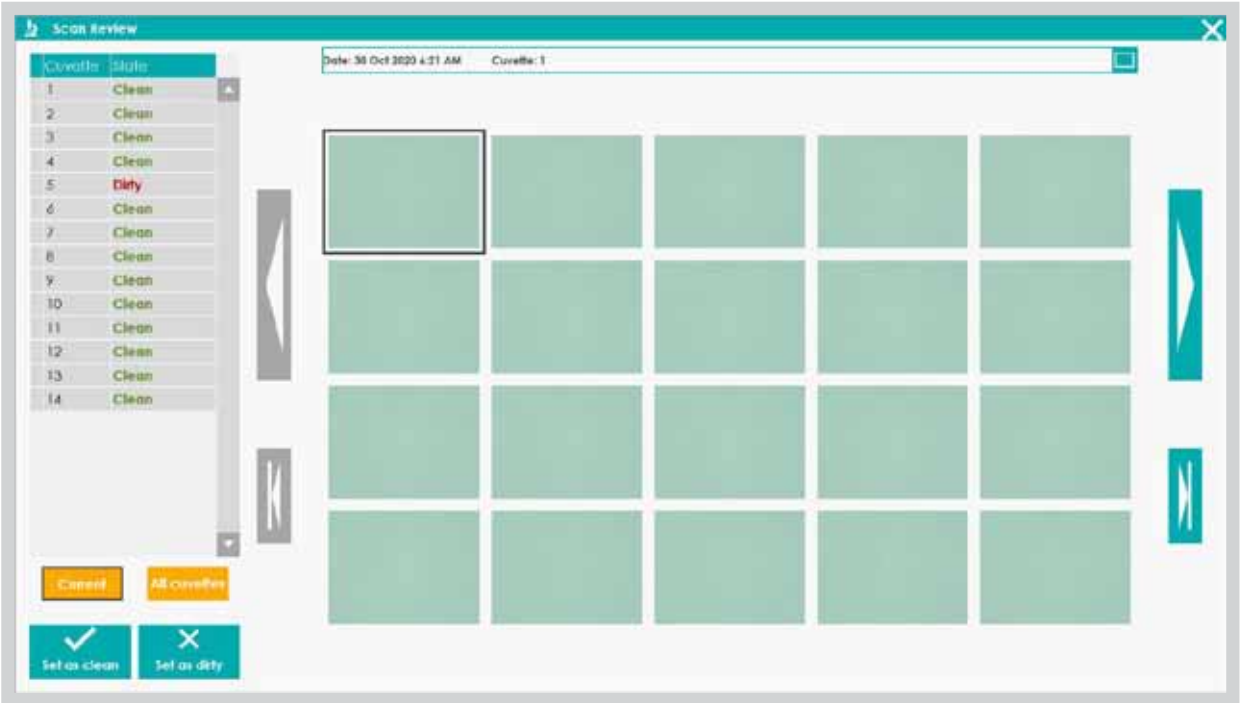
Case 2: If some cuvettes are found dirty, an additional Second pass is automatically done on the dirty cuvettes only, if the option is ticked in Setup/System/cleaning settings. Otherwise it immediately reports the dirty cuvette(s) status and 2 buttons appear (Close / Review Scan)



Clicking on Close will accept the disabled status
Clicking on Scan Review opens the Scan Review window.
See section 9 maintenance for more details

8.8.1.1 Scan Review

Upon clicking on the SCAN REVIEW button from the cleaning with resulting dirty cuvettes or from Scan cuvettes (before or after the cleaning), the following window opens



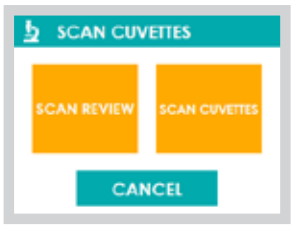
The window displays the table of cuvette numbers and their status (as color coded information)
The user can select a cuvette line number and visualize the images like in routine testing either the 20 pictures or 1 by 1.
The user can decide to Set as clean or Set as dirty individual cuvettes (the selected one, and selecting Current), or all cuvettes then pressing the corresponding button (Set as Clean or Set as dirty).
Once the cuvettes are set as clean, they are automatically reactivated and can be used for testing.
The system traces the reactivations, loging date, time and logged-in user.

8.8.2 Scan Cuvettes

This option allows a check of cuvettes cleanliness.

Click on the Scan cuvettes button 

to perform this check
Then select the sub option between SCAN REVIEW and SCAN CUVETTES



Clicking on the scan review button, opens the last scan done (by scan cuvettes or by cleaning), see *8.8.1.1* for details on the window.
Clicking on SCAN CUVETTES sub menu button opens the scan cuvettes dialog box



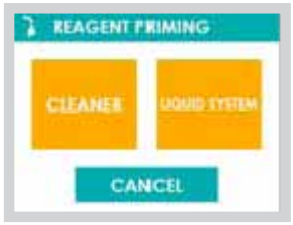
Then click on the circle to start the procedure
At the end of the procedure, 2 buttons appear OK to close the window, or Scan Review to open the Scan review window (see *8.8.1.1*)

8.8.3 Reagents

Once the liquid consummables are exhausted, they need to be replaced.
For the Cleaner either when the level detection from the container detects empty or the count from 1500 tests has reached 0, then the Cleaner needs to be replaced.

For the Liquid system the replacement will be required when the level detection from the container is detecting empty.

To load new Reagents (liquid consumables): use the REAGENTS button 
A submenu will open



8.8.3.1 Load cleaner
Click on Cleaner button,
The dialog box opens



Follow the on-screen instructions
See 4.4.3.2 Loading of Cleaning solution

8.8.3.2 Load Liquid System
Select the 'Liquid System' option



The dialog box opens



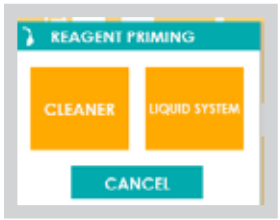
Follow the onscreen instructions
See 4.4.4.1.2 Loading of Liquid System (OptiSol XL 750) or 4.4.4.2.2 (Interim Liquid system)

8.8.4 Prime

Priming is possible for both liquid Consumables: Cleaner and Liquid System

Click on Maintenance menu, then 

A submenu opens



8.8.4.1 Prime Cleaner

Click on the Cleaner button
The Dialog box opens



Click on the circle to initiate the process of priming the Liquid System. *It lasts 47 seconds*

NOTE This process is very important to ensure correct removal of bubbles from the hydraulic system before it reaches measuring and precision aspiration dispense sections, risking altering accuracy of instrument.

The priming is required whenever the containers tubing are manipulated and move above the liquid level.
The prining of cleaner includes a priming of the liquid system at the end

8.8.4.2 Prime Liquid System

Click on the Liquid System button
The Dialog box opens



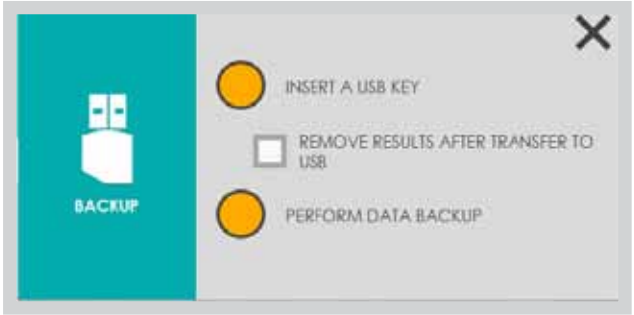
Click on the circle to initiate the process of priming the Liquid System. *It lasts 13 seconds*

NOTE This process is very important to ensure correct removal of bubbles from the hydraulic system before it reaches measuring and precision aspiration dispense sections, risking altering accuracy of instrument.

The priming is required whenever the containers tubing are manipulated and move above the liquid level.

8.8.5 Backup

Click on Maintenance menu, then 
The Dialog box opens



Insert the USB first, then click on the sircle and follow the steps to perform the backup

8.8.6 Restore from backup

To restore system from backup, click on Restore backup and follow on screen instructions.

8.8.7 Cleaning +

Once in a while, it might be required to perform a stronger cleaning of the full hydraulic system, in case of contamination for example.

For this purpose, click on the Cleaning + button



Follow the onscreen instructions.
This procedure is very long and consists in a long soaking into the cleaning solution,
The procedure requires FRESH solutions, so any remaining volume of cleaner has to be discarded.
If contamination is present, the system requires freshly prepared solutions so that contamination can be resolved.
This procedure requires the use of the new cleaner Opti-Sol XL 1500 in package of 400mL bottle.
The procedure requires initial hand-on for the cleaning of the containers, and preparation of fresh solution. Afterwards the long duration of about 14H is due to very long soaking, followed by harsh flushing, then scanning to check cuvettes cleanliness. If the procedure finds that the cuvettes are dirty after the initita scan, it will reflush the columns some more then rescan to check.

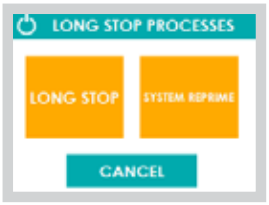
8.8.8 Long Stop

The Long stop is a procedure to perform in case the system needs to remain unfunctional from prolonged durations. It also gives the prossiblity to reprime an empty system, or reprime a system with bubbles further in the hydraulic path than the pipette external cleaning tubings.

8.8.8.1 Long Stop procedure

For this, click on the Long Stop button 

The submenu opens between Long stop and System Reprime



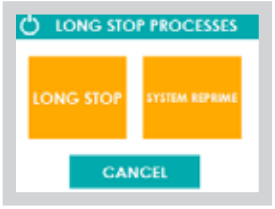
Click on Long Stop button
The dialog box opens.



8.8.8.2 System Reprime

For this, click on the Long Stop button 

The submenu opens between Long stop and System Reprime



Click on System Reprime button. The dialog box opens,



Click on the circle to start the procedure

8.8.9 Feed strips

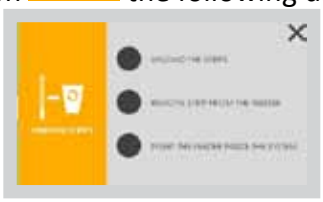
Upon pressing the Feed strips button  the following dialog box opens



Follow the on-screen Instructions. See *4.4.1 Loading of diagnostic strips* for more details

8.8.10 Unload strips

Upon pressing the Feed strips button  the following dialog box opens



Follow the on-screen instructions; See *4.4.2 Unloading of diagnostic strips* for more details.

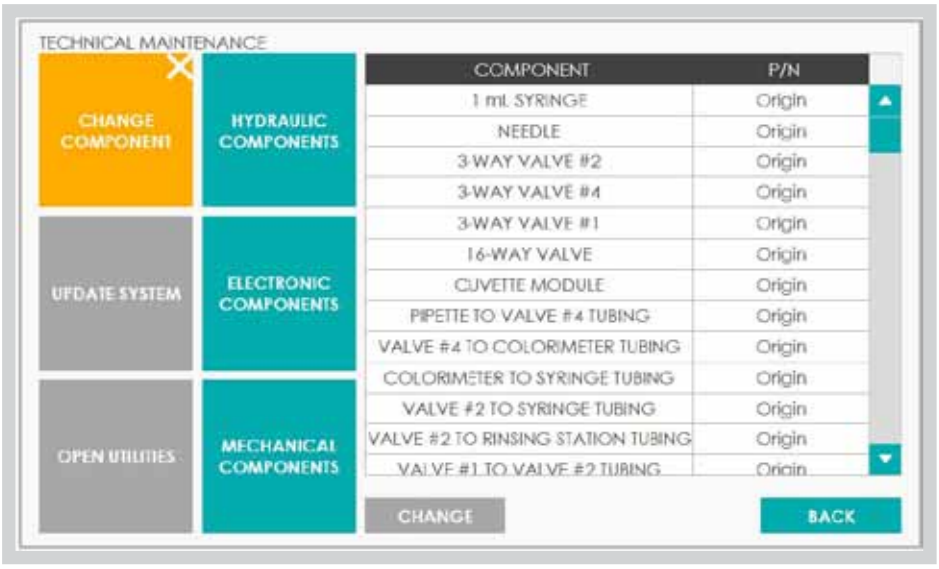
8.8.11 Service



Left is access for a Standard user, right is the access for an Admin user; Open Utilities option is only accessible for Technical Service personnel.

8.8.11.1 Change Component

It is recommended that any part replacement be logged into the change component tracking system by service personnel.
For logging part replacement, click on Service from the maintenance menu, then change component. User can visualize the status of parts between origin or replaced serial part number.
The following window opens

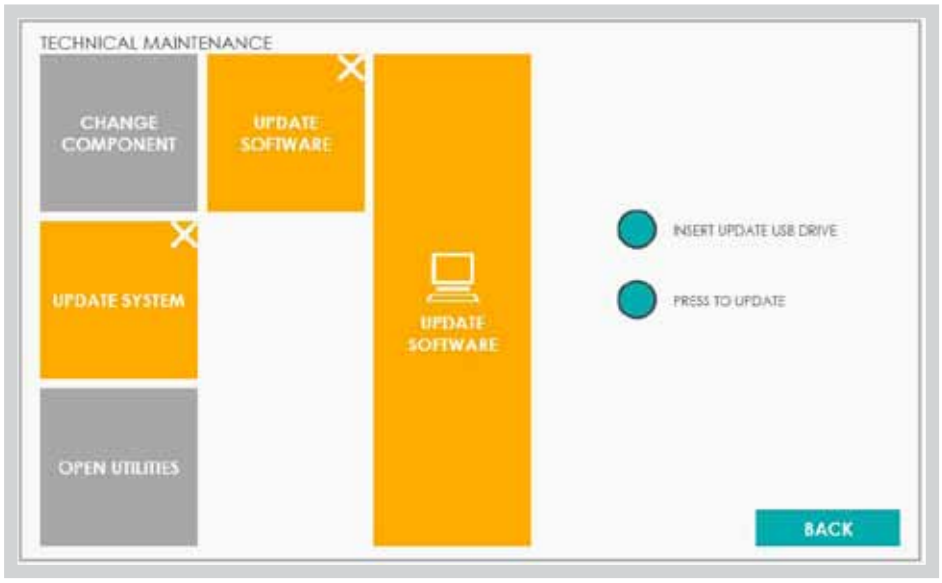


Clicking on components types narrows down the list of parts listed in the table on the right.



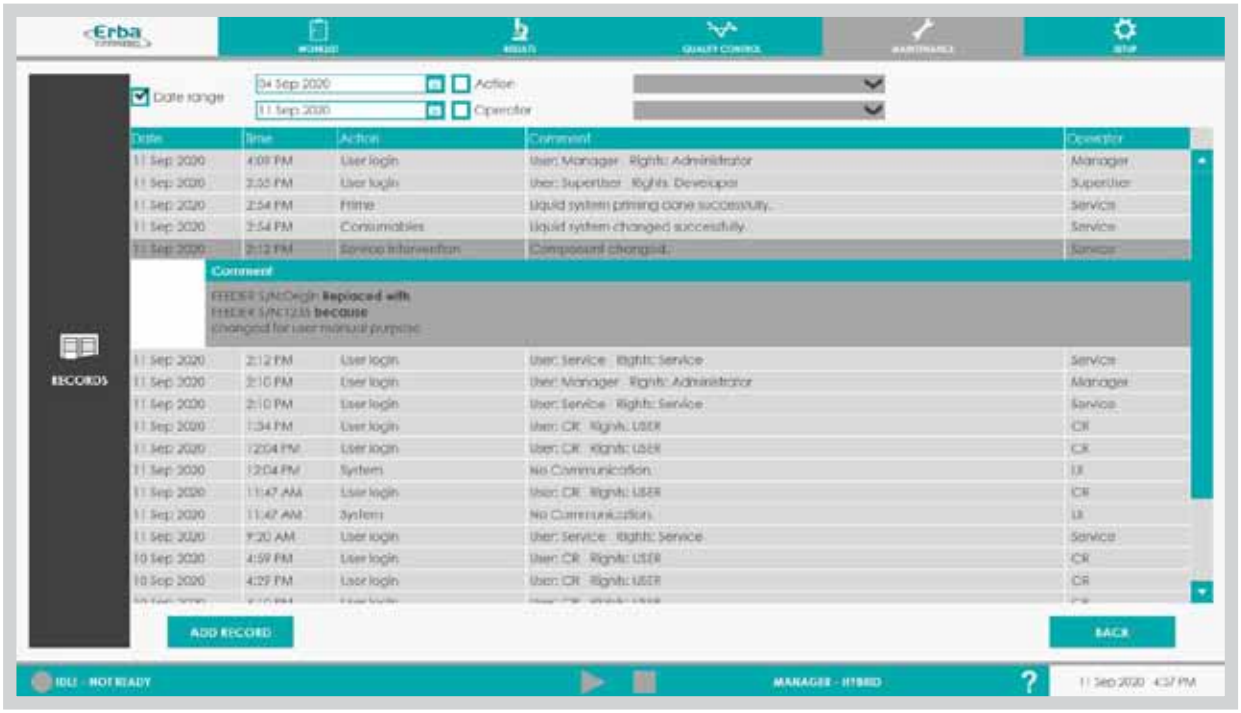
8.8.11.2 Update system

An admin User can perform a software upgrade from USB key.
To perform a software upgrade, connect the USB key containing the UI update, then click on Maintenance, Service, Update system, Update software and follow on-screen instructions



8.8.12 Records

All operations and activities are recorded in Records, and can be viewed later
To review records, click on the Records button form Maintenance menu



Filtering is possible by date range, Action type, or Operator.
It is possible to add records, like manual maintenance or important notes which user wants to keep as records.
To exit the window, click on the Back button.

8.9 Setup window

Press SETUP button to enter the window which enables authorized users to perform changes of the system setup such as the format of date and time, setup of measuring mode, strip type, repeatability of tests, setup of units for results etc.

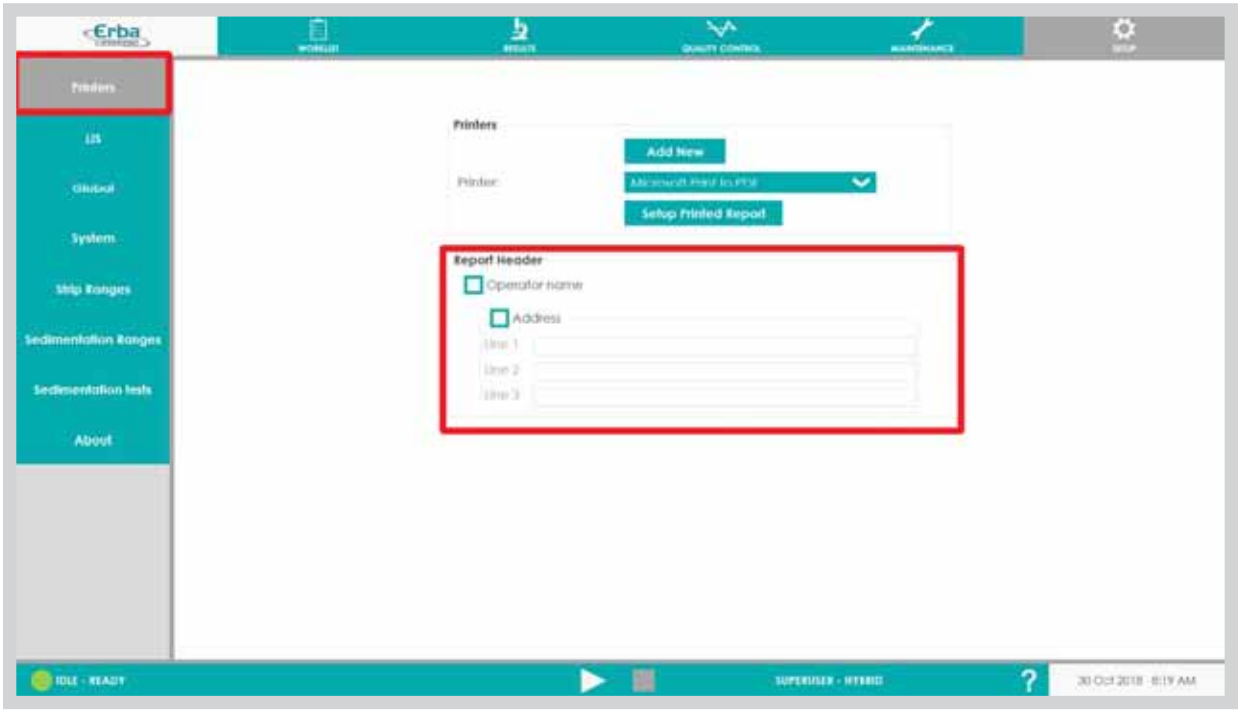
Button	Active status	Inactive status	Description	Format
SETUP			Access to setting parameters for LAURA XL analyzer	Button

Some of the functions of the Setup menu are accessiable only for users with appropriate rights (service/administrator/user).

8.9.1 Printers

Printers menu is accessible to any user and used for setting up of an external printer. LAURA XL analyzer does not include bult-in printer, so printing of results is available only with external printer. In clinical practice, it is anticipated that the device will be connected to LIS and results will be processed in electronic format. However, an external printer may be connected and set up through Printers menu.

The printer setup also allows defining the addition of the username who ran the sample to be printed on the reports, as well as 3 additional lines of text in which the name of the workplace and its address may be specified. This additional information will become an integral part of the printed results of measurements.



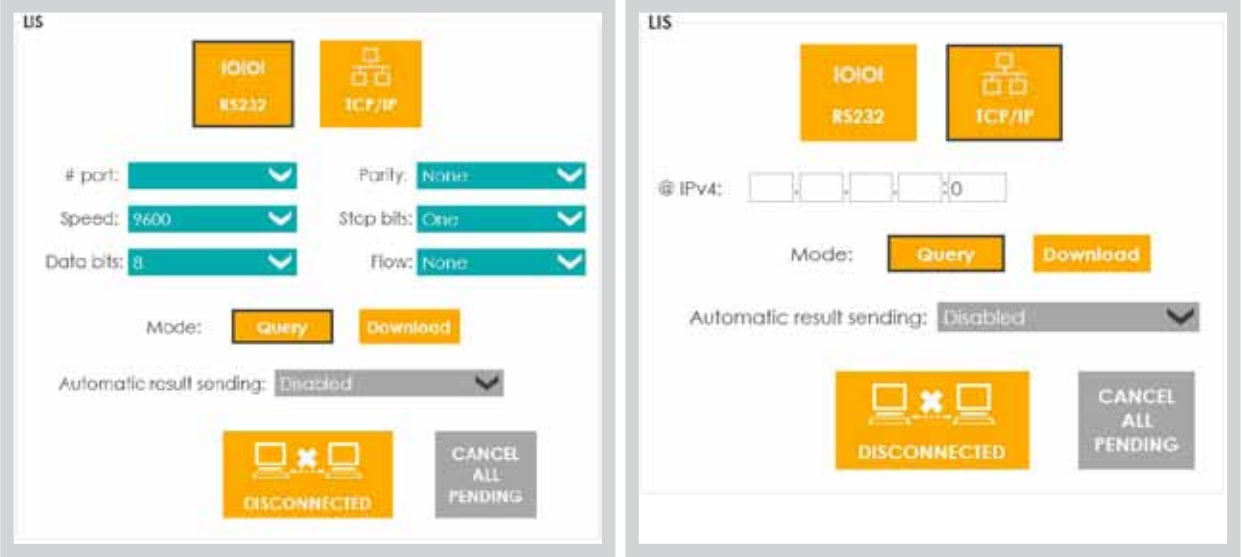
8.9.2 LIS

For detailed specifications of connection to LIS see *Section 10*.
Connection to LIS is possible through RS232 port or via LAN connection.

Warning: Once you perform the activation of connection to LIS, LAURA XL analyzer will behave as if it was connected to LIS! It will wait for information from LIS and measurements will not start until the information, how the respective sample should be handled, is delivered to the analyzer!



Depending on the connection type, the window expands to different setting options.



See chapter *10* and section*10.5* for details instructions on setting up LIS connection
Different options are possible for sending results out to the LIS:



Through the Automatic result sending:

- Disabled (which means Manual result sending)
- Enabled (which means all results are sent as soon as they become available)
- Negative Only (which means **Auto Validation**, sending automatically normal samples and retaining the others for manual sending).

8.9.3 Global

Global menu provides:

- Selection of the User Interface language displayed, *click on the list and select language, system will automatically reboot to the new language*
- It can also import new languages, or update existing languages (see *8.9.3.1* below)
- setting of the date and time *click on the calendar and change hour and minutes with arrows*
- adjustment of the sound (Mute or volume); tick mute or cahnge volume by cursor
- creation/deletion of individual user accounts and chage of user passwords. See *4.2.1* for details



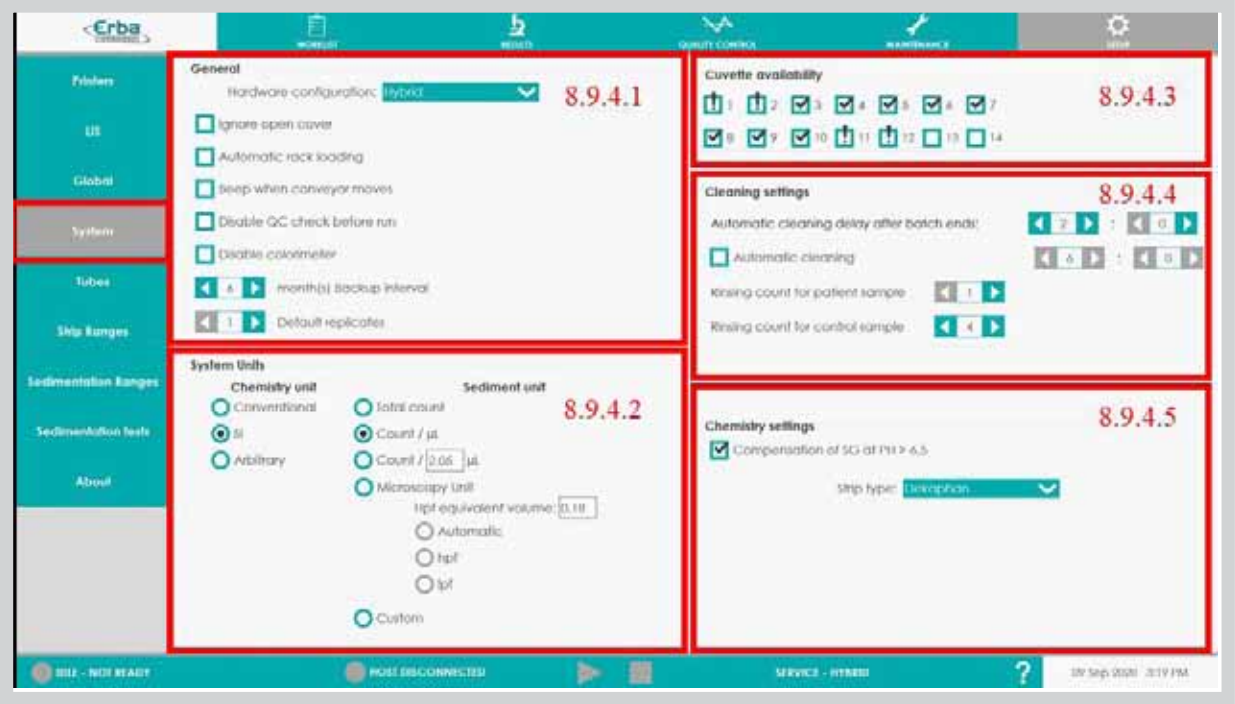
8.9.3.1 Add or update languages

Click on the Add New button under Software language
The dialog box opens
Tick the language(s) you wish to add / update
Then click on press to install new language
The system will automatically reboot for update of the current language, or will only reboot when the new language is selected from the updated list of software languages.



8.9.4 System

System menu contains numerous functions which may be set up for LAURA XL analyzer. Some of the parameters can be modified only by the service technician.



8.9.4.1 General

1. **HW configuration** – Setting of the measuring mode – Hybrid, Chemistry only, Sediment only can be performed here. Switching of measuring mode is always associated with necessity of manual initialization of system by clicking on the "Sun" button (see Chapter *5.4.1*). This selection is accessible to any user.
2. **Ignore open cover** – by default the system should be detecting the opening of the cover, as it can disturb the normal functioning of the system and the cover also protects user from moving parts. Normal setting is unticked 'ignore open cover'. If the front cover is opened during a run, all the running activities will be terminated Exceptionally, for troubleshooting for example, it is possible to be willong to open the cover without any warning. For this purpose, the option should be ticked. This function can only be modified by service technician.
3. **Automatic rack loading** – Once enabled, new racks with samples can be loaded on the board. If the "+" button in Measurement screen (Chapter *8.4*) is pressed, the rack will be processed by the system and analysis of samples will be initiated. If this function is enabled, manual addition of both patient and control samples is not allowed. This is accessible to any user.
4. **Beep when conveyor moves** – In order to prevent spilling of analyzed samples, movement of the arms is accompanied by an acoustic signal which may be deactivated (by administrator/user).
5. **Disable QC check before run** – When the check box is NOT ticked, the system requires measurement of controls in the beginning of each day. If the QC fails, the system does not allow user to start measuring of patient samples. In that case, the control check needs to be re-done. If it fails again, troubleshoot between control and instrument, then contact your customer service in case of impossibility to resolve the issue.

If the box is ticked, then the QC is not mandatory, but can still be run manually and evaluated, but without locking running sample in case of QC failure.
This option is only accessible to administrator users.

NOTE It is recommended to run QC each day and monitor proper performance of the system.

6. **Disable colorimeter** - If a colorimeter issues are repeatedly reported and cannot be solved by priming, it is possible to disable it and continue testing (without reporting urine color and clarity). Accessible to any user.

NOTE Problems with colorimeter may appear if "Prime" is not performed when refilling water canisters, or in case of presence of bubbles in the colorimeter. Performing another prime before renewing the initialisation request usually fixes the issue.

7. **Data backup** – Determines the interval during which all the results are stored in the application (6 months in default); this does not regard the data stored on the hard drive. Accessible to Admin users.
8. **Default replicates** - Repetitions for one urine samples can be set here (max. 10).

NOTE When running a sample from Eppendorf tube, the default replicate will be ignored and only 1 replicate will be applied for the sample when magnetic adaptor is detected.

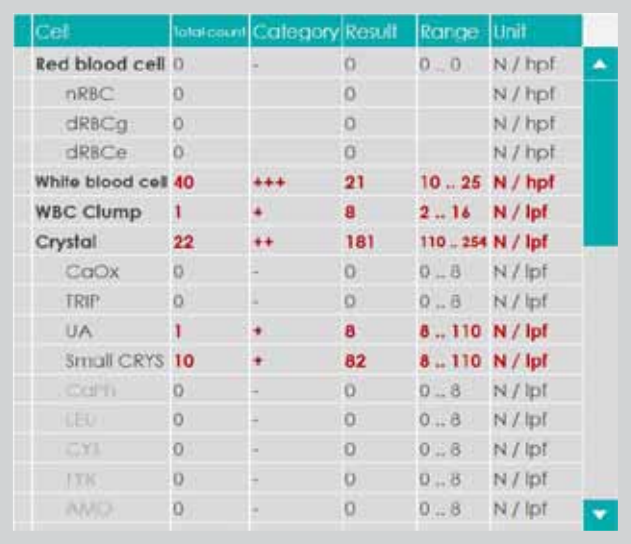
8.9.4.2 System units

Results which will be displayed in the result menu can be setup here

1. **Chemistry unit**:
   - **conventional** (mg/dL, LEU and BLD are in x/µL),
   - **SI** (xmol/L, except for PRO in g/L; LEU and BLD are in x/µL),
   - and **arbitrary** (Neg or Norm versus 1+ to 3 or 4+)
2. **Sediment unit**:
   - **Total count** = System specific unit representing the number of identified elements on the LAURA XL 15 pictures
   - **Count / µL** = number of identified elements on 15 pics / volume of 15 pics ~ 0.19 µL
   - **Microscopy Unit** = Count / µL * VH (~0.18 µL), this volume can be changed to match the volume of the user manual microscopy chamber volume.

   There are 3 possibilities for microscopy unit:
   - automatic

   The microscopy unit reports some elements in High Power Field (HPF), and some others in Low Power Field (LPF); see below image for details



Cell	total count	Category	Result	Range	Unit
Red blood cell	0	-	0	0 .. 0	N / hpf
nRBC	0		0		N / hpf
dRBCg	0		0		N / hpf
dRBCe	0		0		N / hpf
White blood cell	40	+++	21	10 .. 25	N / hpf
WBC Clump	1	+	8	2 .. 16	N / lpf
Crystal	22	++	181	110 .. 254	N / lpf
CaOx	0	-	0	0 .. 8	N / lpf
TRIP	0	-	0	0 .. 8	N / lpf
UA	1	+	8	8 .. 110	N / lpf
Small CRYS	10	+	82	8 .. 110	N / lpf
CaPh	0	-	0	0 .. 8	N / lpf
LEU	0	-	0	0 .. 8	N / lpf
CYL	0	-	0	0 .. 8	N / lpf
TTK	0	-	0	0 .. 8	N / lpf
AMO	0	-	0	0 .. 8	N / lpf

- hpf everything is reported in High Power Field
- lpf everything is reported in Low Power Field

- **Custom** = User can set any of the above unit independently to any sediment element. The user selects this unit, then the detail of each element is to be configured in the Sedimentation ranges tab *8.9.6*

8.9.4.3 Cuvette availability

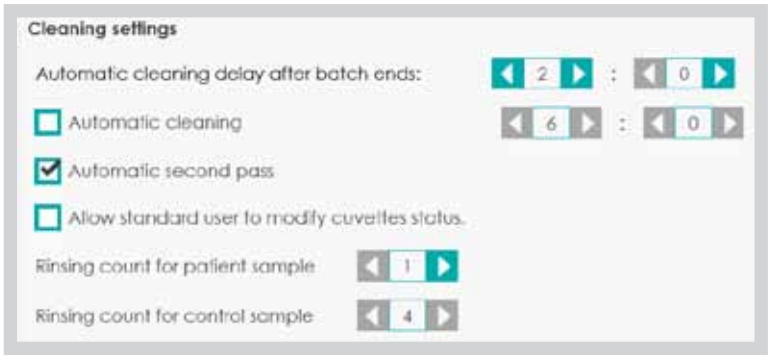
LAURA XL analyzer uses its 14 cuvettes; their activation is confirmed by „✓“ symbol ☑; the picture shows activation of all 14 cuvettes. Any cuvette can be manually disabled from any reason, by unticking it, by unticking it (only Admin users can do it) ☐. It is also possible that cuvettes be skipped due to failure cleanliness check (manual cuvette scanning or automatic check after Clean or Cleaning + procedures. In the latter case, the cuvette(s) will be marked by a ❗



Warning: Deactivation of cuvettes should be performed based on the agreement with service engineer! A contingent deactivation of a cuvette affects the overall measuring throughput of the analyzer.

8.9.4.4 Cleaning and rinsing settings

These settings were established based on the validation of the system (set at 2 hours delay after batch ends). It should not be modified to extend the delay of cleaning. But it can be shortened. Some options can only be changed by service engineers, some can be accessed by Admin users. Standard users cannot modify any of these parameters.
The setting may be altered according to special requirement of the laboratory only once consulted with customer service/R&D department.



1. **Automatic cleaning delay after batch ends** – The cleaning cycle is automatically launched after the established time interval after the last measurement - after 2 hours of inactivity by default
2. **Automatic cleaning** – this option sets the time of day when the cleaning cycle can be incorporated in the routine, especially once there is frequent idle time in utilization of the instrument (days/weekends). The time of cleaning start can be set optionally. The cleaning is then performed each day only if the device is switched ON and initialized (IDLE / READY). This function can only be set by Admin right users and higher.
3. **Automatic second pass** – this option is selected by default. It applies to all the cleaning procedures whether they are launched automatically or manually. If the first cleaning finds dirty cuvettes, then those are cleaned a second time and scanned to check cleanliness again. It increases the timing of cleaning, but unless all cuvettes are found dirty, it does not double it.
4. **Allow standard user to modify cuvette status** – This option is for a standard user to be able to review and reactivate cuvettes which have been automatically disabled after a cleaning or scan procedure. This box can be ticked only by Admin users; if this box is not ticked, only Admin rights users can reactivate cuvettes.
5. **Rinsing count after patient sample** – by default 1 rinsing between each sample aspiration is done. This number can be increased for specific very dirty samples for example. Increasing this number will impair the system throughput.
6. **Rinsing count after control sample** – by default 4 rinsing are required after any control sample aspiration is done. This number can only be changed by service.

8.9.4.5 Chemistry setting

1. **Compensation of SG at pH > 6.5** – Alkaline urines can affect the indicator system of the SG pad. By selecting the compensation option, the system will automatically apply a correction to the measured SG result for urine with pH greater than 7. By default, this function is disabled.
2. **Strip type** – Any user can choose the strip type here – DekaPHAN, UndekaPHAN, DodekaPHAN Auto (available soon)

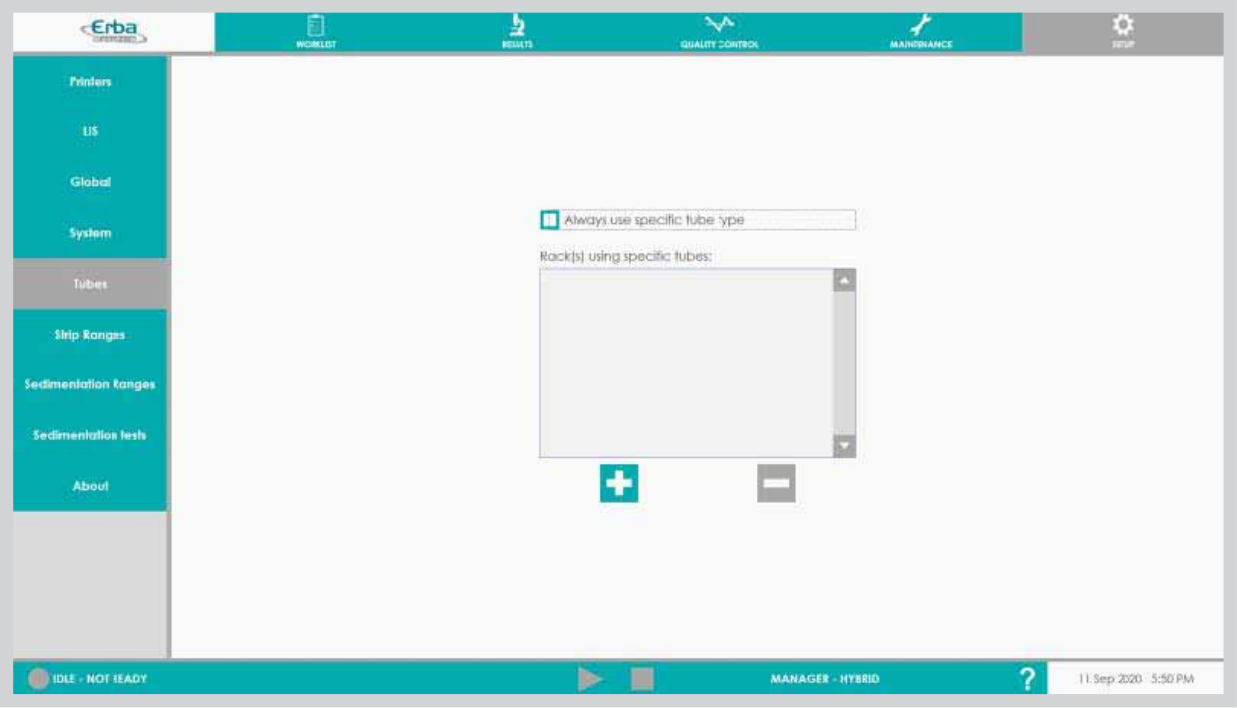
Warning: Anytime the type of strips (either 10, 11 or 12 parameters) is changed, unloading of strips has to be carried out (as described in Section *4.3.2.*).

8.9.5 (Specific) Tubes

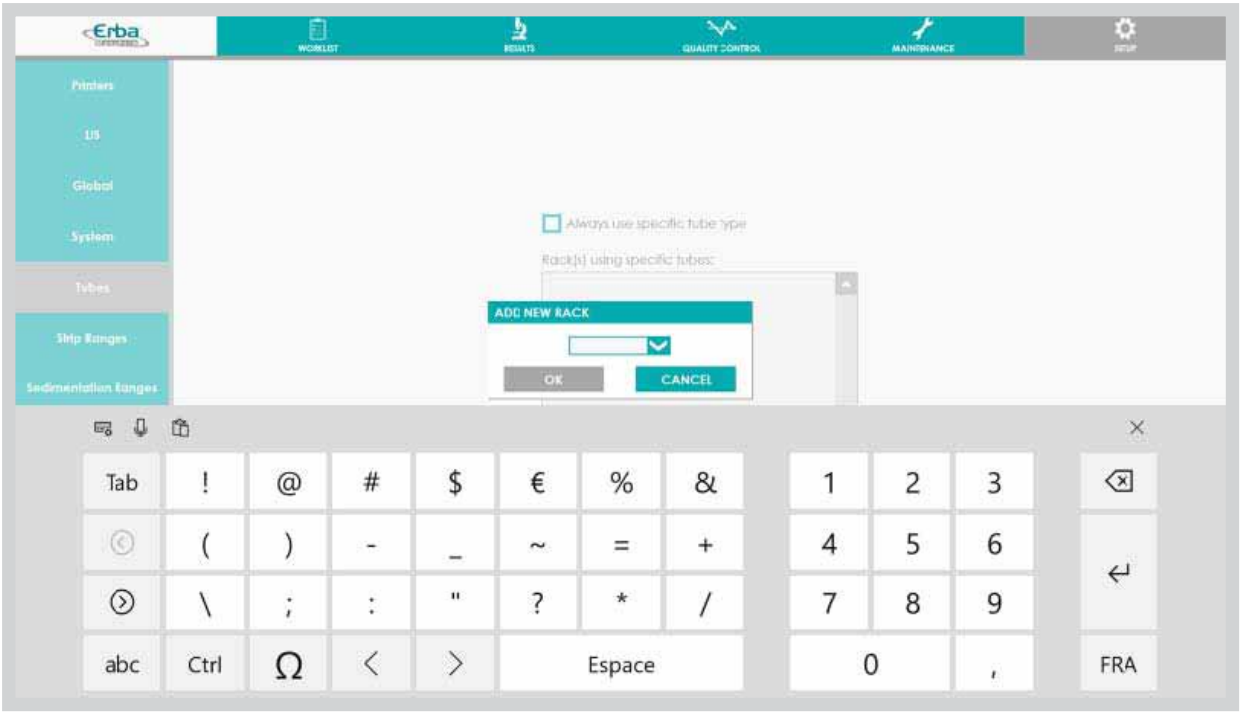
The system was designed to accommodate standard tubes of 10–12mL 16 W x 100 mm height, as well as 1.5 mL Eppendorf tubes using magnetic adaptors.
In some laboratories, there are other types of primary tubes which do not have the same depth, which buttom is higher than the standard 10 mL tubes. For example, Sarstedt tubes have higher bottom and cannot be used as a simple standard primary tube.
To accommodate this type of specific tubes, the tab Tubes allows the user to program some specific racks which will be dedicated for such specific tubes.
The setting of bottom is to be defined by a service engineer.

To program racks for specific tubes:

Click on the Tubes tab



If all racks are to use specific tubes, and never any of the standard design tubes, then tick the Always use specific tube type box
Otherwise, add racks using the + button



Add the racks you wish to use only specific tubes one by one, by keyboard or rack list, and label them to be sure they will not be confused and mixed with standard racks.

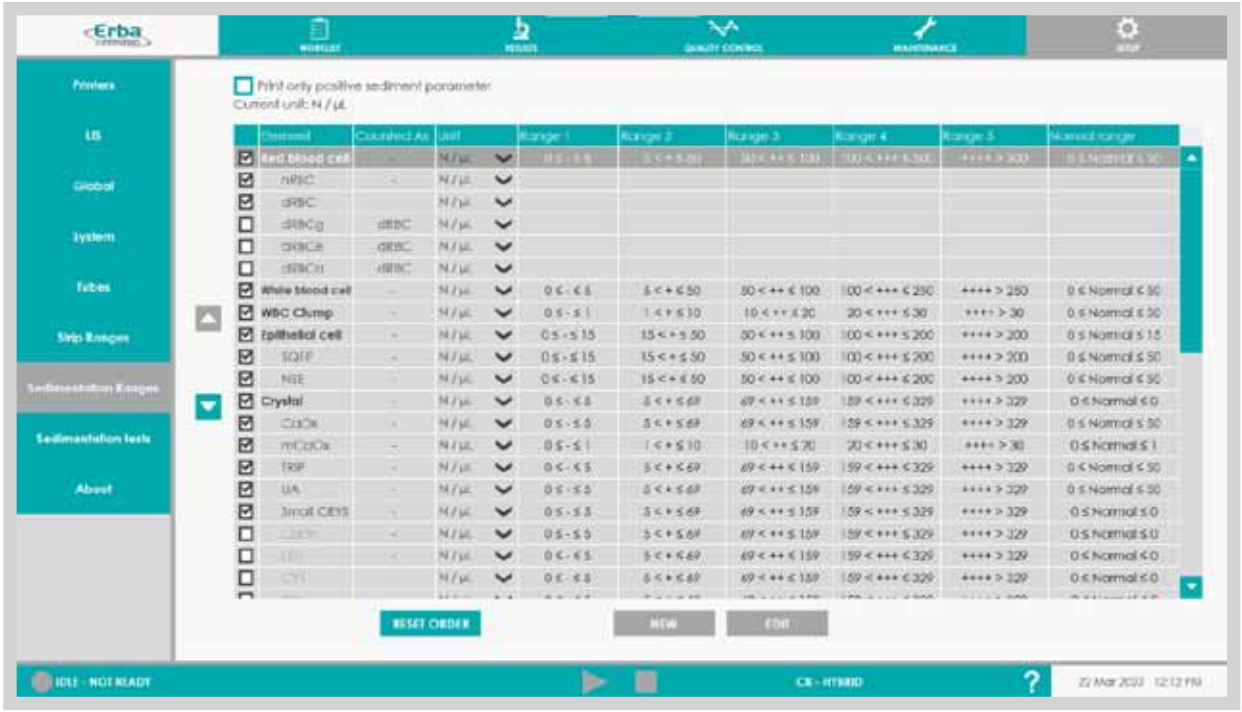
NOTE Eppendorf can also be used on these special racks. The magnetic adaptors will be detected, and correct aspiration will be executed from the Eppendorf bottom.

8.9.6 Diagnostic Strips – Strip Ranges

Strip Ranges menu offers information about all available concentration ranges for individual parameters. These ranges cannot be modified as they contain values which correspond to the setup made by Erba Lachema.
Service engineer can configure the „Range Type“ for the customer during installation, between range1 (scale1) and range2 (scale2) see details *8.6.2*. **PHAN range** is set as default and corresponds to concentration thresholds printed on the label of PHAN® diagnostic strips. The second option which differs in several parameters compared to PHAN.

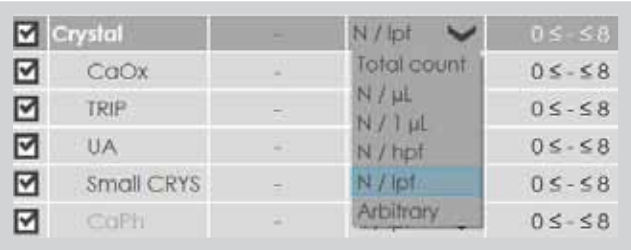


8.9.7 Sedimentation Ranges

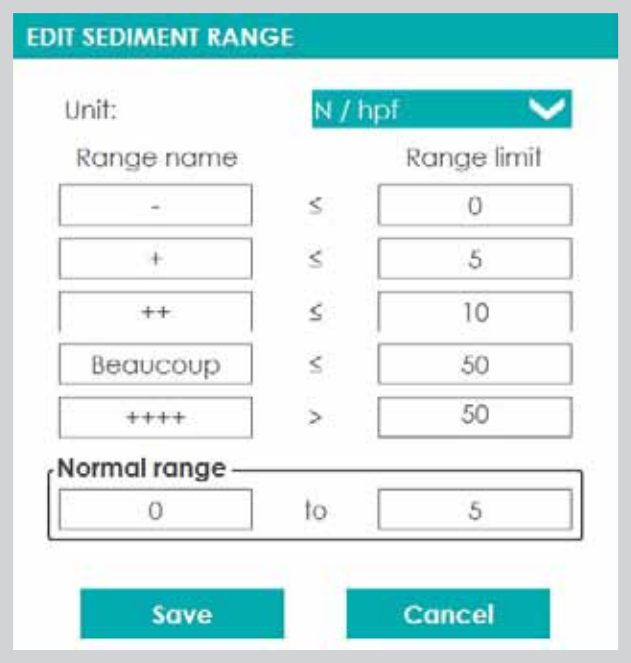


Based on the recommendations presented in individual countries, or different practices, it is possible to customize the **Sedimentation Ranges**, and define the following:

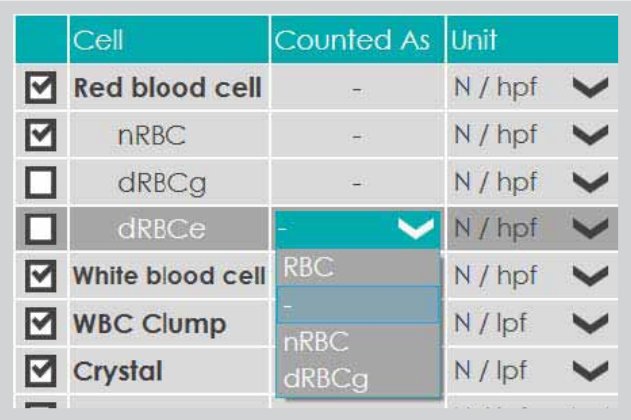
- Printing only the positive sediment parameters on the reports, tick the box
- Definition of the unit for every single element individually by clicking on the unit drop down list and selecting a different unit



- Define the customs limits of each level for each element and their arbitrary labeling, *select an element line, click the EDIT button, modify and Save*



- Define the active and inactive elements or categories, *tick or untick the box in front of element name and define if the element needs to be counted in another sub or main of its own category or not counted.*



- Define the order of display of the elements in the results window and report, *by clicking on the element name and the arrow up or down*
- Reset order of elements by clicking on the RESET ORDER button
- Define up to 4 customs elements

Customs elements can also be created. If a user wishes to report an element which is not already proposed, even in the manual categories, it is possible to create UP TO 4 new element names. Once they are created, they cannot be removed, so the limit of 4 is strict. This element name will ONLY be available for manual tagging.

To create a Customs element name:

1. Click on the NEW button

It opens the dialog box below:



2. Enter the Cell name, and the ranges of positivity, as well as the values for normal range
3. Then save by clicking on the **Save** button.

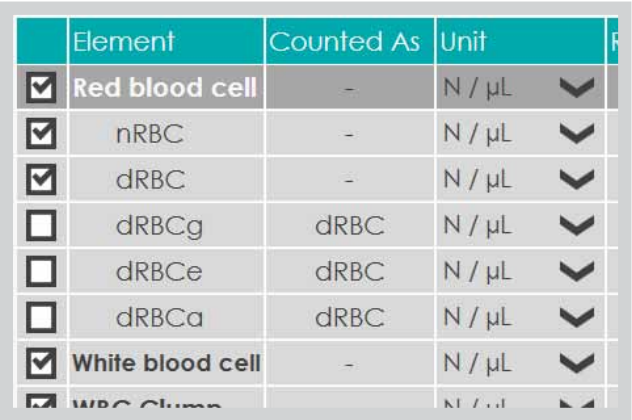
8.9.7.1 Default settings of RBC display

In the Laura XL system, the automatic recognition can point to normal and other aspects of RBC. The system was programmed to point any unusual form as dysmorphic to facilitate reviewing abnormal samples, and not risk missing important biological findings.

By default, the system will therefore show these under the generic denomination dRBC, the most generic dysmorphic subcategory.

These unusual and abnormal forms are echinocytes, ghost and half lyzed RBC, plus acanthocytes, humped spherocytes and all other unusual RBC aspects, even if some can be considered isomorphic.

In the setup by default, the sedimentation ranges for the RBC element is showing as in the image below.

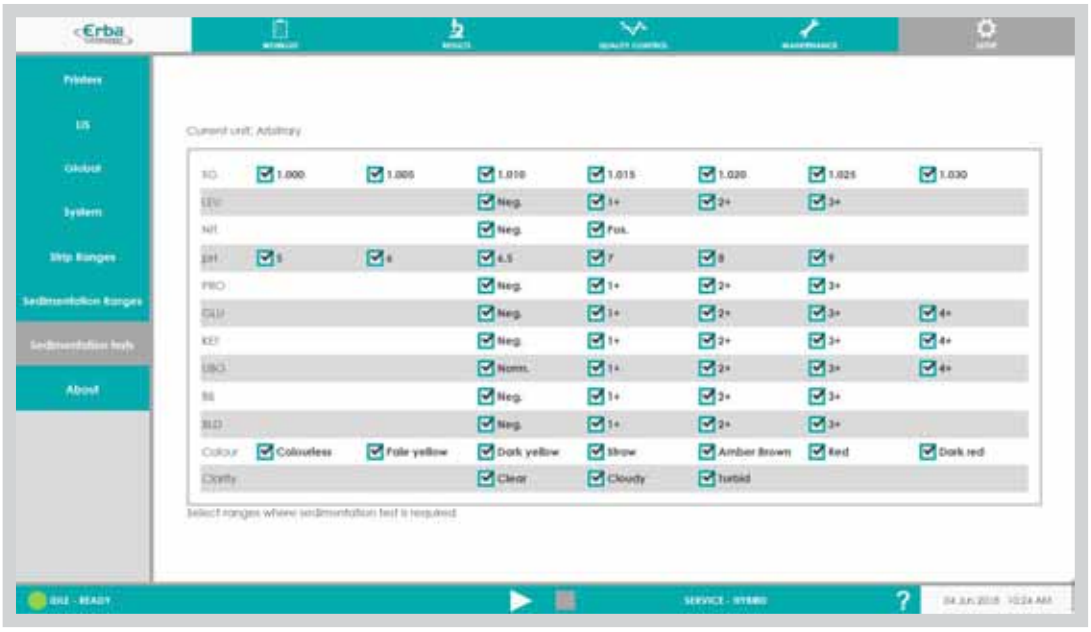


	Element	Counted As	Unit
☑	Red blood cell	-	N / µL
☑	nRBC	-	N / µL
☑	dRBC	-	N / µL
☐	dRBCg	dRBC	N / µL
☐	dRBCe	dRBC	N / µL
☐	dRBCa	dRBC	N / µL
☑	White blood cell	-	N / µL
☑	WBC Clump		

Only these 2 subcategories of RBC (nRBC and dRBC) will display in the results window and print-outs as the initial settings.
Not all laboratories, nor clinicians are trained or interested in pointing to dysmorphic RBC, so it is up to the laboratory to determine with experience the best setting for their practice.
The user can choose to display some or all RBC subcategories by ticking the respective subcategories name(s). He can on the opposite also opt for a unique RBC display and disregard dysmorphic, by hiding by unticking the dRBC subcategory, and choose to count as RBC.

8.9.8 Sedimentation Tests

In this menu, the user can select chemistry criteria for which the sediment results will be displayed in case Hybrid mode was set for the measurement. By default, all the chemistry parameters are selected; therefore, the sediment tests are performed systematically. But the user can elect to run sediment tests ONLY on certain conditions. By deselecting conditions, results which fall in this range will not trigger the sediment testing.
If there are ticked e.g. only positive LEU, NIT, PRO, BLD boxes, the sediment results will be displayed only in case of dg. strips positive for these parameters.



8.9.9 About

This menu informs the user about currently installed software/firmware version. Also statistics about measured samples and consumed strips and Optisol XL bottles number can be found here.



It is also where the collection of data to report a bug is located.
For that, click on the REPORT A BUG button, and follow the onscreen instructions of the dialog box



9. Maintenance

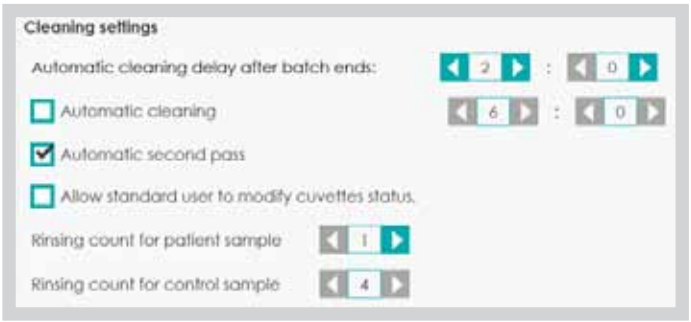
Maintenance of LAURA XL analyzer is important for cleaning the analyzer and preventing potential contamination inside the tubing and cuvettes.
The cleanliness of the cuvettes is checked automatically.
There are several ways sto keep the instrument clean and operational.

Warning: Insufficient maintenance of LAURA XL can be harmful to the device and can contribute to incorrect results.

9.1 Clean

Daily, the system needs to be thoroughly cleaned to prevent contamination of the system and ensure system performance.
In Setup, under System tab, in the Cleaning settings area are located the parameters managing the frequency of cleaning, its process customization or its automatic execution.





Preferably, the cleaning should be performed as soon as the last tests are completed. Cleaning lasts approx. 20 minutes and is automatically performed X hours after the last measurement, as defined in the setup. It can also be requested from Maintenance manually as soon as required. Once a cleaning is performed, it will no longer be requested if no new tests are initiated.
The cleaning comprises cleaning of hydraulic paths and all of the active cuvettes, it ends the process with an automatic cuvette cleanliness check and automatically can repeat the cleaning on all cuvettes identified as dirty only if the option 'automatic second pass' is activated, otherwise, it will directly report the dirty cuvettes at the end of the cleaning/scan process. The 2nd pass will add time to the 20 minute-procedure.

If the cleaning process ends finding all cuvettes clean, the system can be used with all cuvettes.
If the end of the cleaning process (1 or 2 passes depending on the setup) finds some cuvettes dirty, they will be reported and automatically deactivated. The user has the choice to accept the deactivation or review the scans to decide to use some or all the cuvettes anyway. The reactivation of dirty cuvettes is possible for Admin users or Standard users if the Laboratory management allows this function for them by ticking the option 'Allow standard user to modify cuvette status'. (see *8.9.4.4*), for details on how to review the scans after cleaning refer to *8.8.1.*
If the system requires Cleaning, and the cleaning could not be automatically started, the user is informed in Measurement window that cleaning has to be initiated manually by following warning symbol:



See 8.8.1 for details

User can also choose to perform an automatic cleaning at a given time of the day (for example before the laboratory daily routine by entering the time of day when the procedure needs to start automatically. (see chapter *8.9.4.4*), the preventive cleaning will be initiated every day.



NOTE This automatic process will execute if the instrument is ON and in IDLE READY mode.

9.2 Liquid system Canister Cleaning

The package of LAURA XL analyzer contains two canisters for Liquid System solution. To prevent bacteria contamination of the canister which can be transferred into the hydraulic system of the device, it is recommended to regularly clean the canister by any accessible disinfection solution.

9.3 Cleaning +

Cleaning + is a curative cleaning which can be launched by the user in case of issues with cuvette cleanliness and/or suspicion of hydraulic system contamination.
See section 8.8.7 for detailed instructions

9.4 Long stop

If the system will not be used for a prolonged duration, it is important to perform a proper procedure to empty the system and dry it thoroughly to avoid formation of biofilm in the system.
See 8.8.8 for detailed instructions

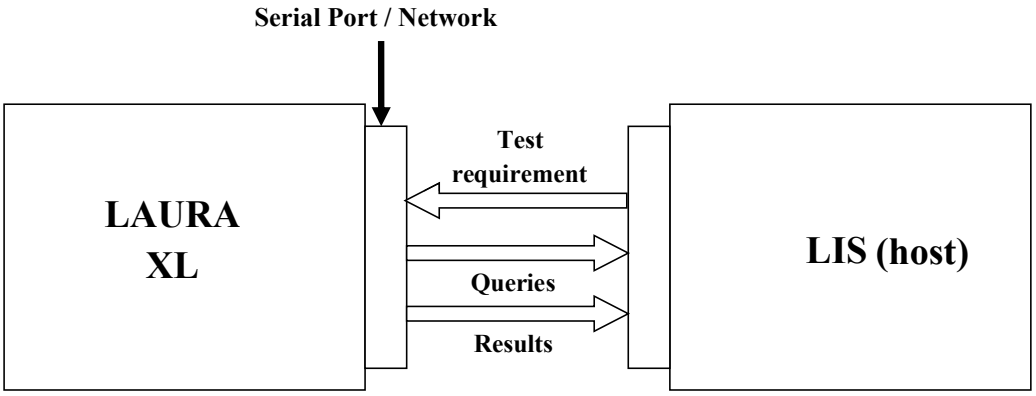
10. LIS Setup

10.1 General

The Laura XL System is linkable to a LIS (Laboratory Information System). For that you will need to:

- Physically connect the Laura XL to the laboratory system
- Configure the Laura XL

Connection may be done either by serial port or network connection.

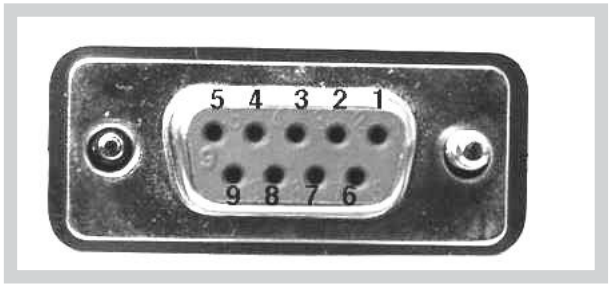


10.2 Hardware configuration

10.2.1. Serial communication

The connection uses a RS232 serial interface with DB-9 connector between the Laura XL and the Host computer.





RS232 Pin Assignments (DB9 PC signal set)	
Pin 1	Received Line Signal Detector (Data Carrier Detect) (DCD)
Pin 2	Received Data (RD)
Pin 3	Transmit Data (TD)
Pin 4	Data Terminal Ready (DTR)
Pin 5	Signal Ground
Pin 6	Data Set Ready (DSR)
Pin 7	Request To Send (RTS)
Pin 8	Clear To Send (CTS)
Pin 9	Ring Indicator

Data:

Low level:
+5 ⇒ +20 V

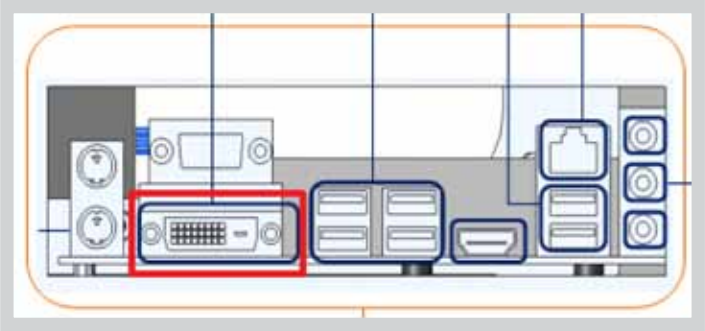
High level:
-5 ⇒ -20 V

Control :

OFF:
+5 ⇒ +20 V

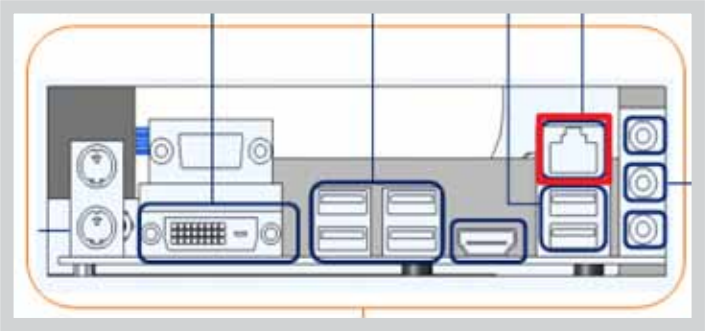
ON:
-5 ⇒ -20 V

The serial cable must be plugged to the standard DB9 connectors of the Laura XL.



10.2.2. TCP-IP communication

The network connection is done by plugging an Ethernet RJ 45 Category 5 cable connector at the rear of Laura XL.



10.2.3. Work modes

« Download » mode
In this mode, the LIS sends all the requests to the automate. The Laura XL delays the analysis for samples that are not on board. It executes possible analysis then sends the results.

« Query » mode
Once a sample has been identified on the Laura XL (with the internal barcode reader, with a handy barcode reader, or with manual test request), the system sends to the LIS a Query for the sample. Then, the LIS sends only the requests concerning this sample.
Once tests are executed, results are sent by the Laura XL.

NOTE Laura XL doesn't check matching between queries sent and request received, and does not re-query automatically (to ask again requests for tube where no analysis has been received, for example)): so, rerun requested from the LIS must be sent directly by the LIS without waiting a new query.

10.3. Protocols

When using serial port, the Laura XL works with 2 standard protocols:

- ASTM 1381 for « physical » communication: this protocol describes the mechanisms of data send.
- ASTM E 1394 for « logical » communication: this protocol describes the mechanism of data coding (test requests, queries, results)

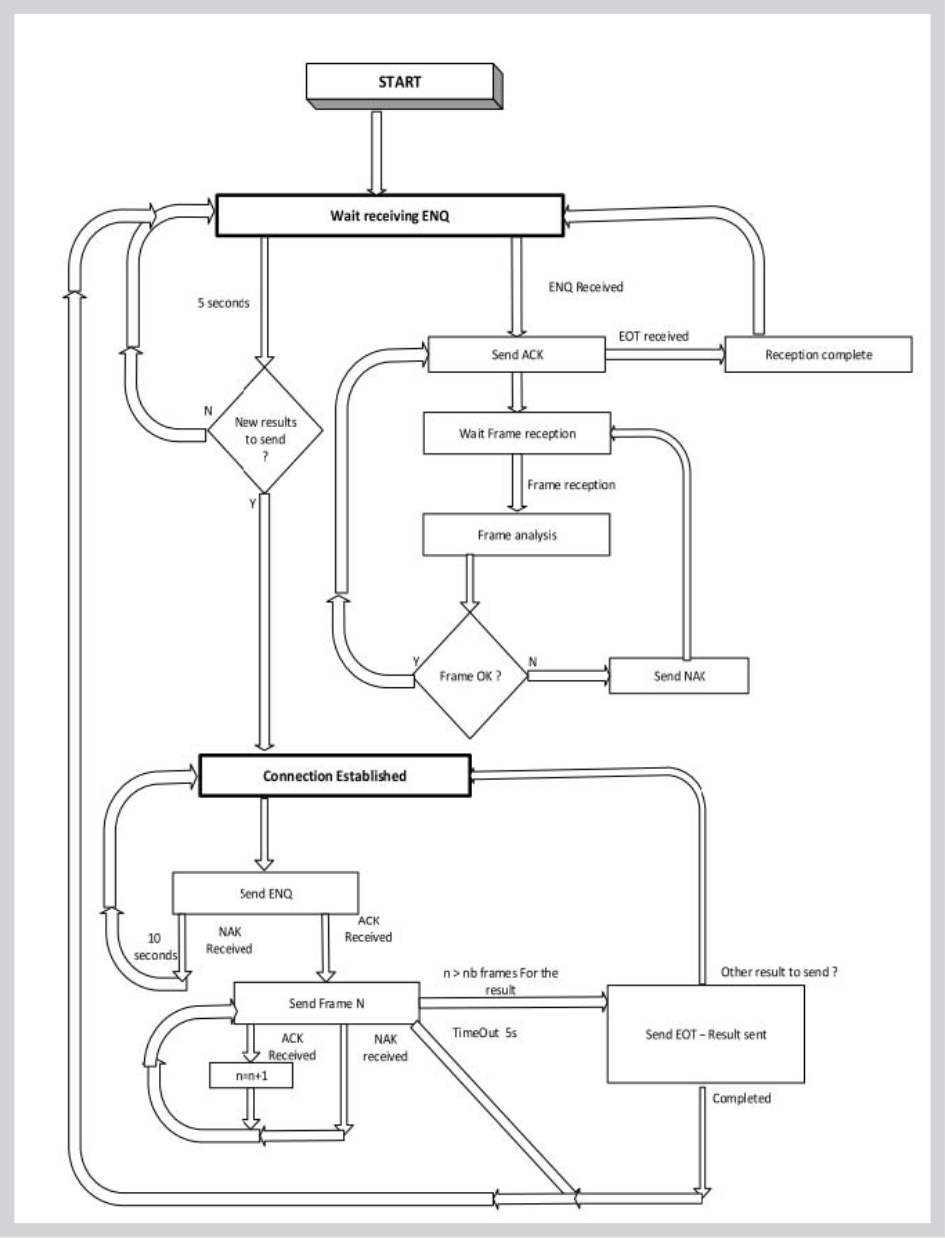
NOTE With TCP-IP communication, only ASTM E 1384 protocol is used: the physical protocol is TCP-IP.

10.3.1. Physical protocol: ASTM 1381

The purpose of this protocol is to send the Queries, (i.e. transform queries in frames exploitable by the LIS), to receive tests requests (i.e. transform frames received from the LIS in test requests), and finally return the results (i.e. transform results in frames exploitable by the LIS).
The frame format is:

<STX><Frame #><Data><ETX><Checksum><CR><LF>

(For more information about this protocol, visit *www.astm.org*)
The working schema is resumed in the next page.



10.3.2. Logical protocol: ASTM E 1394

The Logical protocol ASTM E 1394 allows communication between LIS and Laura XL System:

- In Query mode, send the queries for sample identified onboard
- Receive Sample Ids and analysis to execute
- Send the results

(For more information about this protocol, visit *www.astm.org*)

10.3.2.1 Query

The query message is sent by the Laura XL to request tests for a sample ID.

A query message is always made by:

- A « H » line (header)
- A « Q » line (query)
- A « L » (end of message1)

Example of query sent by the Laura XL for sample 05203002:

H|\^&||| Laura XL |||||||P|E 1394-97|20150106142536
Q|1|05203002|||S|||||||O
L|1

Field table:

	Field	Content	Value or remarks
H Line			
	Field n°1 :	Header ID	H
	2	Field delimiter	generally : |
		Repetition delimiter	generally : \
		Component delimiter	generally : ^
		Escape character	generally : & but unused
	3	Unused Field	
	4	Unused Field	
	5	Automate ID	LAURA XL
	6 => 11	Unused Field	
	12	Processing ID	P (Patient) or Q(CQ)
	13	Version N°	E 1394-97
	14	Date & time of message	YYYYMMDDHHMMSS
Q Line			
	1	Q	
	2	sequence number	1
	3	Sample ID	
	4	unused	
	5	range	ALL
	6	Nature of request	S (specimen collect date), R (result test date)
	7 => 12	Unused Fields	
	13	Request information status code	Generally: O
L Line			
	1	L	
	2	Sequence number	1

10.3.2.2 Test request

The test request message is sent by the LIS, either as an answer to a query when query mode is active, or when the sample and its analysis are recorded on the LIS.

It's mandatory that a test request message contains analysis for 1 patient only.

If it's not the case, the request is analyzed and integrated, but an overload can result for the automate (if, for example, the programs tries to integrate 150 analysis for 20 patients during routine work …)

A test request message is composed by:

- H line (header)
- P line (patient)
- O line (order)
- L line (end of message)

Example:

H|\^&||| P|1|00010032|||CLAUDE^DOMINIQUE|||
O|1|00010032||^^^HYBRID||||||||||
L|1

To configure codes and analysis matching, see paragraph 3.

Action code:

Action code is used to cancel an analysis.
If a «C » is received in the 12th field of the O line, the analysis is canceled on the Laura XL.

This line:

O|1|00010032||^^^HYBRID|||||||C||||
Will cancel a request on the tube 00010032 (if this analysis is not already running).

Fields table:

	Field#	Detail	Value or remarks
H Line	Field n°1 :	Header ID	H
	2	Field delimiter	generally : |
		Repetition delimiter	generally : \
		Component delimiter	generally : ^
		Escape character	generally : & but unused
	3	Unused Field	
	4	Unused Field	
	5	Automate ID	LAURA XL
	6 => 11	Unused Field	
	12	Processing ID	P (Patient) or Q(CQ)
	13	Version N°	E 1394-97
	14	Date & time of message	YYYYMMDDHHMMSS
P Line	1	P	
	2	Sequence number	
	3	Sample ID	
	4	Laboratory Patient ID	(optional)
	5	Patient ID	(optional)
	6	Patient Name	(optional)
	7	Unused Field	
	8	Patient birth date (YYYYMMDD)	(optional)
	9	Sex (M, F, or U)	(optional)
O Line	1	O	
	2	Sequence number	
	3	Sample ID	
	4	unused	
	5	Analysis parameters :	
		component # 1,2,3 : unused	
		component # 4 : Analysis parameters	CHEMESTRY or SEDIMENT
	6 => 9	Unused Field	
	10	Unused Field	
	11	Unused Field	
	12	Code action	(optional) A to add new specimen with test C to cancel a test N for new request P for pending specimen
	13 => 15	Unused Fields	
	16	Unused Fields	
L Line	1	L	
	2	Sequence number	

10.3.2.3 Results

Once tests are completed, the Laura XL sends the results.
A result message contains only data for one sample, but a message may contain one or more result for one or more analysis.

A result message is composed of:

- H line (header)
- P line (patient)
- One O line or more (order)
- for every O line , one R line (result) or more
- L line (end of message)

Example:

H|\^&||| Laura XL |||||||P|E 1394-97|20150106142536
P|1|00010032|||CLAUDE^DOMINIQUE|||
O|1|00010032^12^2||^^^CHEMESTRY|R||||Regular Primary||||||
R|1|^^^SG|1.020||||N|F||||20150106112502||
R|2|^^^LEU|Neg.|Leu/µL|||N|F||||20150106112933||
…
L|1

Results list:

- Chemistry results depending of selected unit and selected threshold on the Laura-XL:

Threshold 1:

Selected unit = Conventional										
Chemistry	Range -2	Range -1	Range 0	Range 1	Range 2	Range 3	Range 4	Range 5	Range 6	Unit
SG	1.000	1.005	1.010	1.015	1.020	1.025	1.030	N/A	N/A	-
LEU	N/A	N/A	Neg.	25	75	500	N/A	N/A	N/A	Leu/µL
NIT	N/A	N/A	Neg.	Pos.	N/A	N/A	N/A	N/A	N/A	-
PH	5	6	6.5	7	8	9	N/A	N/A	N/A	-
ASC	N/A	N/A	Neg.	0.6	1.1	2.3	3.4	N/A	N/A	mmol/L
PRO	N/A	N/A	Neg.	30	100	500	N/A	N/A	N/A	g/L
GLU	N/A	N/A	Neg.	50	100	300	1000	N/A	N/A	mmol/L
KET	N/A	N/A	Neg.	5.2	16	52	156	N/A	N/A	mmol/L
UBG	N/A	N/A	Norm.	1	3	6	12	N/A	N/A	µmol/L
BIL	N/A	N/A	Neg.	1	3	6	N/A	N/A	N/A	µmol/L
BLD	N/A	N/A	Neg.	10	50	250	N/A	N/A	N/A	Ery/µL
COLOR	Colour-less	Pale yellow	Yellow	Dark yellow	Amber	Pink - Red	Dark red	Green - Blue	Brown	-
CLARITY	N/A	N/A	Clear	Cloudy	Turbid	N/A	N/A	N/A	N/A	-
CRE	N/A	N/A	0.1	0.25	1	2	> 3	N/A	N/A	g/L
MA	N/A	N/A	10	30	80	150	N/A	N/A	N/A	mg/L
ACR	N/A	N/A	N/A	Norm.	Micro-Albumi-nuria	Proteinu-ria	N/A	N/A	N/A	-

Selected unit = SI										
Chemistry	Range -2	Range -1	Range 0	Range 1	Range 2	Range 3	Range 4	Range 5	Range 6	Unit
SG	1.000	1.005	1.010	1.015	1.020	1.025	1.030	N/A	N/A	-
LEU	N/A	N/A	Neg.	25	75	500	N/A	N/A	N/A	Leu/µL
NIT	N/A	N/A	Neg.	Pos.	N/A	N/A	N/A	N/A	N/A	-
PH	5	6	6.5	7	8	9	N/A	N/A	N/A	-
ASC	N/A	N/A	Neg.	0.6	1.1	2.3	3.4	N/A	N/A	mg/dL
PRO	N/A	N/A	Neg.	30	100	500	N/A	N/A	N/A	mg/dL
GLU	N/A	N/A	Neg.	50	100	300	1000	N/A	N/A	mg/dL
KET	N/A	N/A	Neg.	5.2	16	52	156	N/A	N/A	mg/dL
UBG	N/A	N/A	Norm.	1	3	6	12	N/A	N/A	mg/dL
BIL	N/A	N/A	Neg.	1	3	6	N/A	N/A	N/A	mg/dL
BLD	N/A	N/A	Neg.	10	50	250	N/A	N/A	N/A	Ery/µL
COLOR	Colour-less	Pale yellow	Yellow	Dark yellow	Amber	Pink - Red	Dark red	Green - Blue	Brown	-
CLARITY	N/A	N/A	Clear	Cloudy	Turbid	N/A	N/A	N/A	N/A	-
CRE	N/A	N/A	0.1	0.25	1	2	> 3	N/A	N/A	mmol/L
MA	N/A	N/A	10	30	80	150	N/A	N/A	N/A	mmol/L
ACR	N/A	N/A	N/A	Norm.	Micro-Albumi-nuria	Proteinu-ria	N/A	N/A	N/A	-

Selected unit = Arbitrary										
Chemistry	Range -2	Range -1	Range 0	Range 1	Range 2	Range 3	Range 4	Range 5	Range 6	Unit
SG	1.000	1.005	1.010	1.015	1.020	1.025	1.030	N/A	N/A	-
LEU	N/A	N/A	Neg.	1+	2+	3+	N/A	N/A	N/A	-
NIT	N/A	N/A	Neg.	Pos.	N/A	N/A	N/A	N/A	N/A	-
PH	5	6	6.5	7	8	9	N/A	N/A	N/A	-
ASC	N/A	N/A	Neg.	1+	2+	3+	4+	N/A	N/A	-
PRO	N/A	N/A	Neg.	1+	2+	3+	N/A	N/A	N/A	-
GLU	N/A	N/A	Neg.	1+	2+	3+	4+	N/A	N/A	-
KET	N/A	N/A	Neg.	1+	2+	3+	4+	N/A	N/A	-
UBG	N/A	N/A	Norm.	1+	2+	3+	4+	N/A	N/A	-
BIL	N/A	N/A	Neg.	1+	2+	3+	N/A	N/A	N/A	-
BLD	N/A	N/A	Neg.	1+	2+	3+	N/A	N/A	N/A	Ery/µL
COLOR	Colour-less	Pale yel-low	Yellow	Dark yel-low	Amber	Pink - Red	Dark red	Green - Blue	Brown	-
CLARITY	N/A	N/A	Clear	Cloudy	Turbid	N/A	N/A	N/A	N/A	-
CRE	N/A	N/A	0.1	0.25	1	2	> 3	N/A	N/A	g/L
MA	N/A	N/A	10	30	80	150	N/A	N/A	N/A	mg/L
ACR	N/A	N/A	N/A	Norm.	Micro-Albumi-nuria	Proteinu-ria	N/A	N/A	N/A	-

Threshold 2:

Selected unit = Conventional										
Chemistry	Range -2	Range -1	Range 0	Range 1	Range 2	Range 3	Range 4	Range 5	Range 6	Unit
SG	1.000	1.005	1.010	1.015	1.020	1.025	1.030	N/A	N/A	-
LEU	N/A	Neg.	Traces (15)	70	125	500	N/A	N/A	N/A	Leu/µL
NIT	N/A	N/A	Neg.	Pos.	N/A	N/A	N/A	N/A	N/A	-
PH	5	6	6.5	7	7.5	8	8.5	N/A	N/A	-
ASC	N/A	N/A	Neg.	0.6	1.1	2.3	3.4	N/A	N/A	mmol/L
PRO	N/A	Neg.	Traces (15)	30	100	300	2000	N/A	N/A	g/L
GLU	N/A	Neg.	Traces (100)	250	500	1000	2000	N/A	N/A	mmol/L
KET	N/A	Neg.	Traces (5.2)	16	42	83	166	N/A	N/A	mmol/L
UBG	N/A	N/A	Norm.	2	4	8	N/A	N/A	N/A	µmol/L
BIL	N/A	N/A	Neg.	1	3	6	N/A	N/A	N/A	µmol/L
BLD	N/A	N/A	Neg.	10	25	80	200	N/A	N/A	Ery/µL
COLOR	Colour-less	Pale yel-low	Yellow	Dark yel-low	Amber	Pink - Red	Dark red	Green - Blue	Brown	-
CLARITY	N/A	N/A	Clear	Cloudy	Turbid	N/A	N/A	N/A	N/A	-
CRE	N/A	N/A	0.1	0.25	1	2	> 3	N/A	N/A	g/L
MA	N/A	N/A	10	30	80	150	N/A	N/A	N/A	mg/L
ACR	N/A	N/A	N/A	Norm.	Micro-Albumi-nuria	Proteinu-ria	N/A	N/A	N/A	-

Selected unit = SI										
Chemistry	Range -2	Range -1	Range 0	Range 1	Range 2	Range 3	Range 4	Range 5	Range 6	Unit
SG	1.000	1.005	1.010	1.015	1.020	1.025	1.030	N/A	N/A	-
LEU	N/A	Neg.	Traces (15)	70	125	500	N/A	N/A	N/A	Leu/µL
NIT	N/A	N/A	Neg.	Pos.	N/A	N/A	N/A	N/A	N/A	-
PH	5	6	6.5	7	7.5	8	8.5	N/A	N/A	-
ASC	N/A	N/A	Neg.	10	20	40	60	N/A	N/A	mg/dL
PRO	N/A	Neg.	Traces (0.15)	0.3	1	3	20	N/A	N/A	mg/dL
GLU	N/A	Neg.	Traces (5.5)	14	28	55	110	N/A	N/A	mg/dL
KET	N/A	Neg.	Traces (0.5)	1.5	4	8	16	N/A	N/A	mg/dL
UBG	N/A	N/A	Norm.	33	66	131	N/A	N/A	N/A	mg/dL
BIL	N/A	N/A	Neg.	17	51	103	N/A	N/A	N/A	mg/dL
BLD	N/A	Neg.	10	10	25	80	200	N/A	N/A	Ery/µL
COLOR	Colour-less	Yellow	Dark yel-low	Dark yel-low	Amber	Pink - Red	Dark red	Green - Blue	Brown	-
CLARITY	N/A	Clear	Cloudy	Cloudy	Turbid	N/A	N/A	N/A	N/A	-
CRE	N/A	0.9	2.2	2.2	8.8	17.7	> 26.5	N/A	N/A	mmol/L
MA	N/A	0.01	0.03	0.03	0.08	0.15	N/A	N/A	N/A	mmol/L
ACR	N/A	N/A	Norm.	Norm.	Micro-Albumi-nuria	Proteinu-ria	N/A	N/A	N/A	-

Selected unit = Arbitrary										
Chemistry	Range -2	Range -1	Range 0	Range 1	Range 2	Range 3	Range 4	Range 5	Range 6	Unit
SG	1.000	1.005	1.010	1.015	1.020	1.025	1.030	N/A	N/A	-
LEU	N/A	Neg.	Traces	1+	2+	3+	N/A	N/A	N/A	-
NIT	N/A	N/A	Neg.	Pos.	N/A	N/A	N/A	N/A	N/A	-
PH	5	6	6.5	7	7.5	8	8.5	N/A	N/A	-
ASC	N/A	N/A	Neg.	1+	2+	3+	4+	N/A	N/A	-
PRO	N/A	Neg.	Traces	1+	2+	3+	4+	N/A	N/A	-
GLU	N/A	Neg.	Traces	1+	2+	3+	4+	N/A	N/A	-
KET	N/A	Neg.	Traces	1+	2+	3+	4+	N/A	N/A	-
UBG	N/A	N/A	Norm.	1+	2+	3+	4+	N/A	N/A	-
BIL	N/A	N/A	Neg.	1+	2+	3+	N/A	N/A	N/A	-
BLD	N/A	N/A	Neg.	1+	2+	3+	N/A	N/A	N/A	Ery/µL
COLOR	Colour-less	Pale yel-low	Yellow	Dark yel-low	Amber	Pink - Red	Dark red	Green - Blue	Brown	-
CLARITY	N/A	N/A	Clear	Cloudy	Turbid	N/A	N/A	N/A	N/A	-
CRE	N/A	N/A	0.1	0.25	1	2	> 3	N/A	N/A	g/L
MA	N/A	N/A	10	30	80	150	N/A	N/A	N/A	mg/L
ACR	N/A	N/A	N/A	Norm.	Micro-Albumi-nuria	Proteinu-ria	N/A	N/A	N/A	-

Sediment: RBC, nRBC, dRBCg, dRBCe, WBC, HYA, SPRM, NSE, CaOX, BACC, YST, TRIP, SQEP, CAST, UA, MUC, WBCC, BACR, UNCC, GRAN, CELL, WAXY, RBCT, WBCT, RECT, FACT, CAP, LEUK, CYS, TYR, RBCC, CHOL, AMO, FAT, TRICH, CRYS, CRYSTALS, Bacteria, Cast, EPC, CUSTOM1, CUSTOM2, CUSTOM3, CUSTOM4.

NOTE User can rename CUSTOM1, CUSTOM2, CUSTOM3 and CUSTOM4 to fit he's needs. Name received by host will be like this: CUSTOM1\'UserNamedCell'.

- Sediment units (sent along with result value):
  N / Total count
  N / µL
  N / X µL (where X is a number defined by user on the instrument)
  N/ hpf or N / lpf (depending of the element)
- Error codes:
- Global flags:
  RACK: Unknown rack detected, not possible to determine tube type, results can be affected.
  EDIT: Result has been modified by an operator.
- Sediment flags:
  BLD/RBC: Discrepancy between BLD chemistry result and RBC sediment
  LEU/WBC: Discrepancy between LEU chemistry result and WBC sediment
  NIT/BAC: Discrepancy between NIT chemistry result and BACC/BACR sediment
  FLOOD: Sediment flood detected
  BUBBLE: Too much bubble detected, no sediment result available
  FOCUS: Focus issue, no sediment result available

MUCBIAS: MUC result may be erroneous due to re-evaluation
NOTENOUGH: Sediment result may be erroneous due to not enough sample.

- Chemistry flags
  BAD: Detected strip does not match awaited strip, no chemistry result available
  M2S: Several strip detected, no chemistry result available
  NODROP: Dispense issue detected, no chemistry result available
  QNS: not enough sample on chemistry pad, chemistry result not available.
  2WET: chemistry pad is overdosed, pad result can be affected
  DRY: whole strip seems to be dry.
  NOSTRIP: No strip detected, no chemistry result available
  REVERSED: Strip is reversed,, no chemistry result available
  2BRIGHT: chemistry pad is overdosed, pad result not available
  WSIDE: Strip is upside down, no chemistry result available
  NOTSTABLE: used strip not stable at all, chemistry results could be affected
  COLOR: sample color can affect result
  THRESH: result threshold has changed since strip evaluation, chemistry result not available.
  TURBBIAS: Color result can be affected by turbidity
  2TURB: Too turbid sample to assess color
  COLORBIAS: Clarity result can be affected by color
  DISP: Dispense issue
- Chemistry flags (only for DODEKAPHAN AUTO)
  LOW: Sample is too diluted to determine ACR result
  MALBU: Micro albuminuria detected
  PROT: proteinuria detected

Date/Time of execution:
The 13th Field contains date and time when test has been completed on the Laura XL. This date format is YYYYMMDDHHMMSS

Fields Table:

	Field#	Detail	Value or remarks
H Line	Field n°1 :	Header ID	H
	2	Field delimiter	generally : |
		Repetition delimiter	generally : \
		Component delimiter	generally : ^
		Escape character	generally : & but unused
	3	Unused Field	
	4	Unused Field	
	5	Automate ID	LAURA XL
	6 => 11	Unused Field	
	12	Processing ID	P (Patient) or Q(CQ)
	13	Version N°	E 1394-97
	14	Date & time of message	YYYYMMDDHHMMSS
P line	1	P	
	2	Sequence number	
	3	Sample ID	
	4	Laboratory Patient ID	(optional)
	5	Patient ID	(optional)
	6	Patient Name	(optional)
	7	Unused Field	
	8	Patient birthdate (YYYYMMDD)	(optional)
	9	Sex (M, F, or U)	(optional)
O line	1	O	
	2	Sequence number	
	3	Sample ID	Barcode^RackNb^TubePosition
	4	unused	
	5	Analysis parameters :	
		component # 1,2,3 : unused	
		component # 4 : Analysis parameters	CHEMISTRY or SEDIMENT
	6 => 9	Unused Field	
	10	Tube Type	(optional)
	11	Unused Field	
	12	Code action	(optional) A to add new specimen with test C to cancel a test N for new request P for pending specimen
	13 => 15	Unused Fields	
	16	Specimen descriptor	

	Field#	Detail	Value or remarks
R line	1	O	
	2	Sequence number	
	3	Analysis parameters :	
		component # 1,2,3 : unused	
		component # 4 : Analysis parameters	See list of results
	4	result	Result^RangeName^StartRange-StopRange
	5	unit	
	6	Unused Filed	
	7	Error codes	Each error code is separated by ^
	8	Nature of abnormality	Generally: N
	9	Result status	Generally: F (Final)
	10 => 12	unused	
	13	Date/time completion	Format YYYYMMDDHHMMSS
L Line	1	L	
	2	Sequence number	

10.4. System Configuration

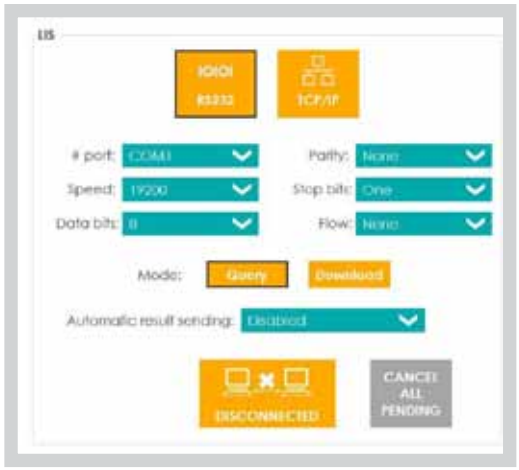
10.4.1. Configuration

In the « Setup »menu, the connection parameters are in the « LIS » tab.



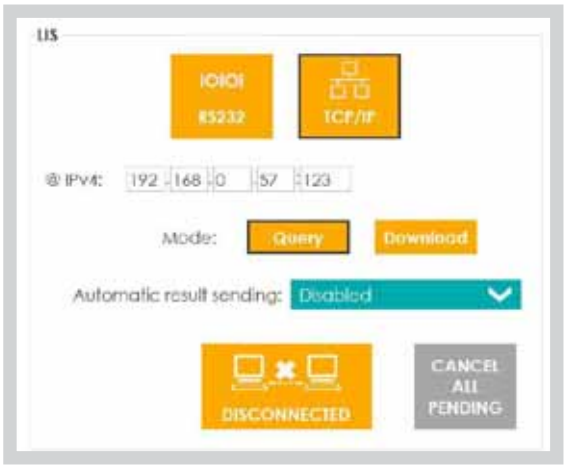
RS232

To configure a serial communication (RS232) click on RS232 button:



 # Port: Specify in this field which COM port is used for the connection with the (Normally it is COM1).
Speed: Specify in this field the connection speed (Generally it is 9600 bauds).
Data bits: Specify in this field the data bits parameter (Generally it is 8).
Parity: Specify in this field the parity (Generally there are no parity, so select None).
Stop bits: Specify in this field the number of stop bits (Generally it is One).
Flow: Specify in this field the flow control (Generally it is None).

Ethernet:
To configure an Ethernet communication (TCP-IP) click on TCP-IP button:



@IPv4: Specify in this field the host IP address and the socket number to establish the communication with the host.

For each kind of communication (RS232 or TCP-IP) you can choose to work in Query or Download mode.

- Query: The Laura XL will send a query to the host for every read barcodes.
- Download: The host will send all information once the connection is establish. The Laura XL will never send queries, and it will run all tests where information are already in its database.

You can also select when results will be sent to host:

- Disabled: No results will be sent. User needs to select which result must be sent (usually after result review)
- Enabled: Results will be sent automatically when test is complete
- Negative only: Only negative result will be sent automatically once the test is complete.

The LIS settings can be set or change at every moment but the connection is establish automatically (if the RS232 or TCP-IP is selected) only when the system is initialized. If the connection needs to be activated manually after an initialization, click on this button:



When the communication will be established, the button will change from:



Once the communication with the host is established, it is possible to send manually results for a test from Result window or Quality Control Window.
Once the LIS connection has been set, Laura XL establish the communication during the initialization, and keep it active till the instrument is powered off or instrument status become 'Not ready' (Emergency stop, user press stop, sleep, user stop manually the LIS connection)

11. Packaging

11.1 Transport Conditions

Limit values of ambient environment during transportation:

- Temperature: 0 – 40 °C
- Humidity: 5 – 90 % (non-condensing)

11.2 Labels

Labels used on the external packaging specify the conditions applicable to transportation and storage of the analyzer and its accessories.
It is essential to use the labels to specify the correct manner of handling of the cargo in the course of its transportation, i.e. inform about its fragility, placement, etc.

12. Sediment Atlas

This section of the manual is intended to help the user to get familiar with the images captured by Laura XL analyzer, compared to the more usual aspect of unstained elements under manual microscopy.
The aspect of the different elements is not limited to these pictures, but this selection represents the most frequent forms of the different automatic categories.
Images of the most common elements on Laura XL analyzer, versus Manual Microscopy

12.1. Red Blood Cells (RBC)

12.1.1. RBC in Laura XL

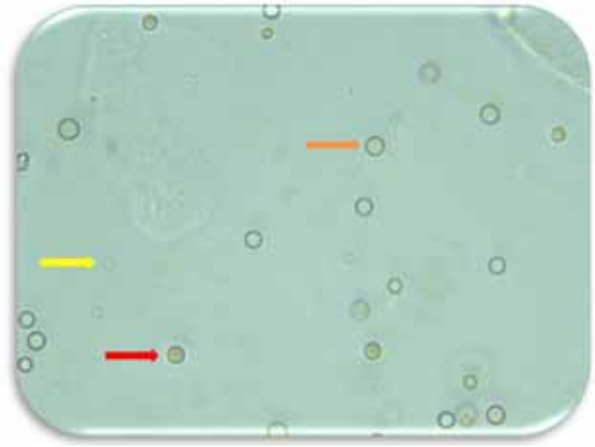


Figure 1: Different RBC morphologies normal RBC nRBC, half-lysed / lysed dRBCg

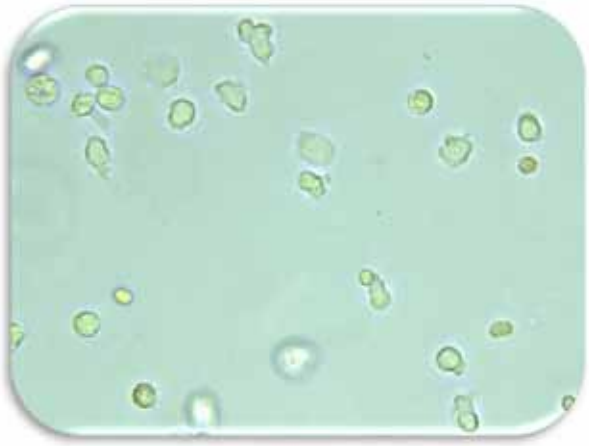


Figure 2: Samples with Echinocytes (dRBCe) and WBC

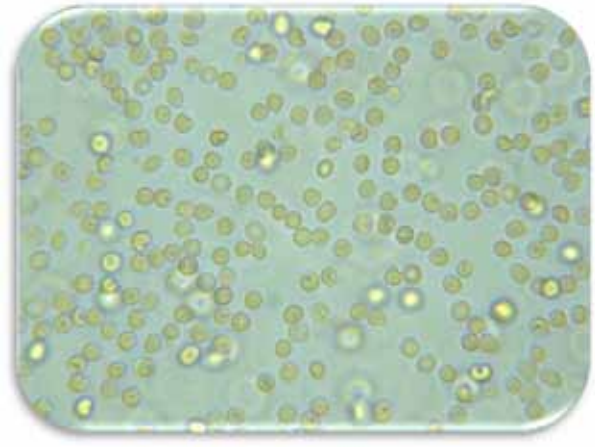


Figure 3: RBC (Erythrocytes) Normal (nRBC), shiny shapes are not sedimented

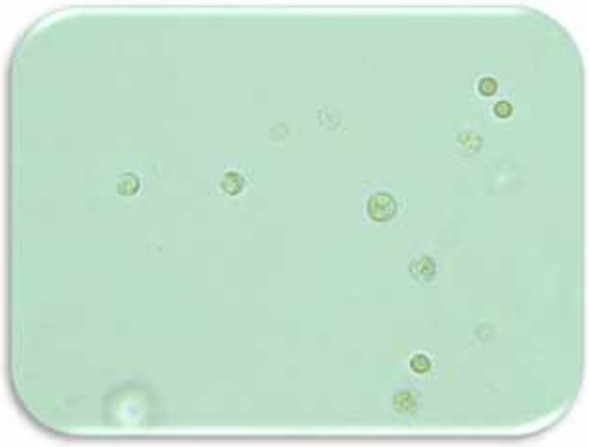


Figure 4: 6 RBC (3 nRBC + 3 dRBCg) and 6 WBC

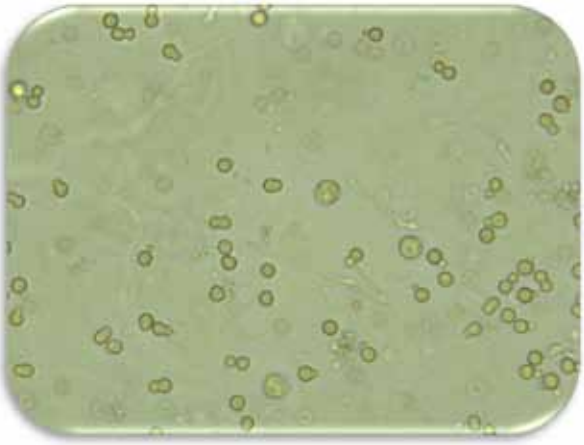


Figure 5: nRBC and dysmorphic RBC (humped spherocytes) with 'budding' RBC and Dysmorphic Ghost RBC (dRBCg), plus MUC, Bacteria

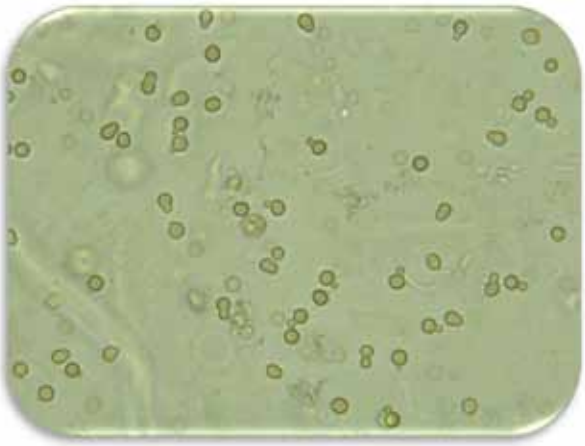


Figure 6: nRBC and dysmorphic RBC (Acanthocytes) with 'budding' RBC and Dysmorphic Ghost RBC (dRBCg), plus MUC, Bacteria

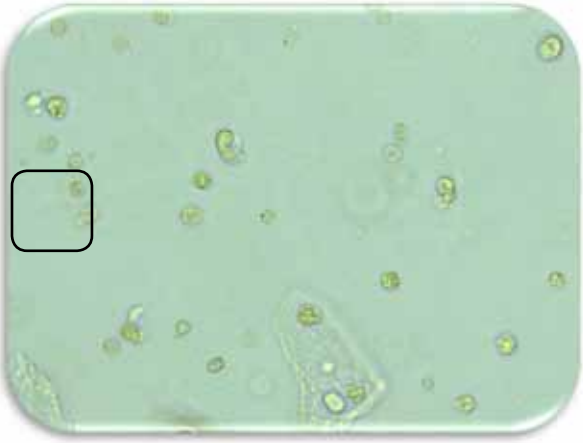


Figure 7: Some Dysmorphic Ghost RBC (dRBCg) and dysmorphic RBC (Acanthocytes dRBCa, framed), and WBC, SQEP

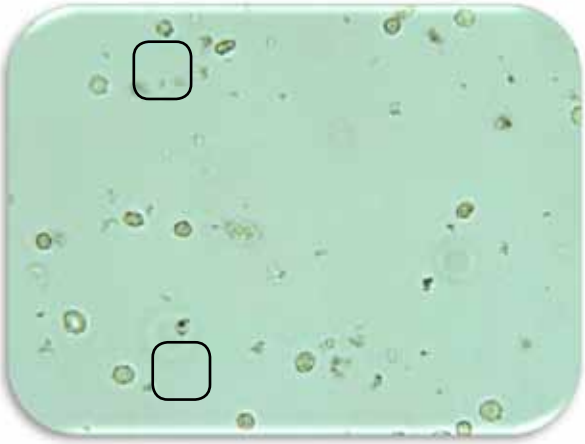


Figure 8: Some Dysmorphic Acanthocytes (dRBCa framed), with other RBC suspected acanthocytes



Figure 9: Acanthocyte dRBCa



Figure 10: 2 Acanthocytes dRBCa

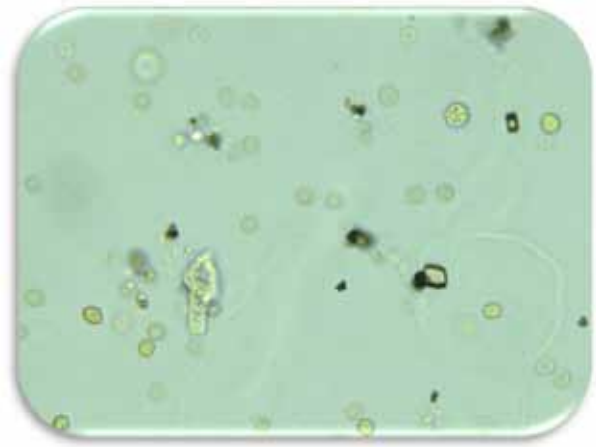


Figure 11: Acanthocyte and various dysmorphic RBC, with Normal RBC, 1 WBC, 1 renal NSE, a few UA crystals and some MUC

12.1.2. RBC in Manual Microscopy



Figure 12: RBC including nRBC and dRBCg and WBC

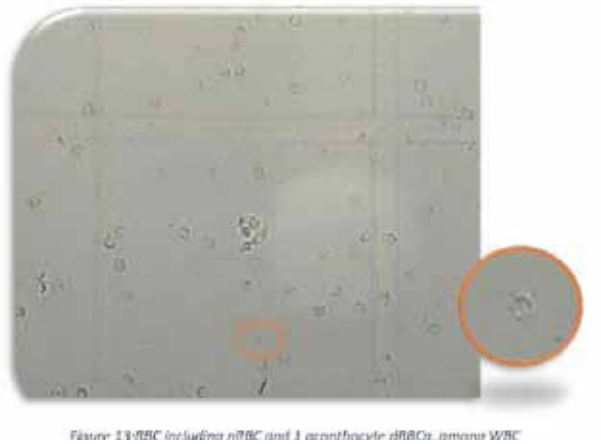


Figure 13: RBC including nRBC and 1 acanthocyte dRBCa, among WBC

12.2. White Blood Cells and White Blood Clumps (WBC and WBCC)

12.2.1. WBC and WBCC in Laura XL

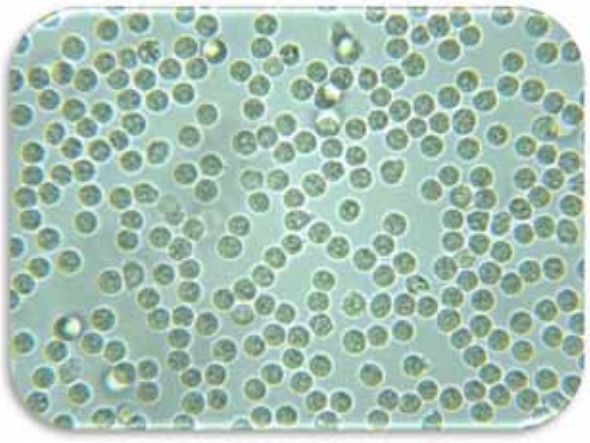


Figure 14: Numerous WBC, some non-sedimented elements (shiny)

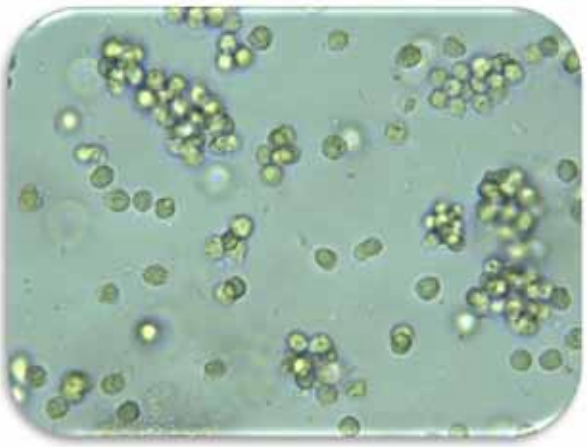


Figure 15: Numerous WBC, and WBC clumps + Bacilli (BACR); blurry shapes are non-sedimented elements

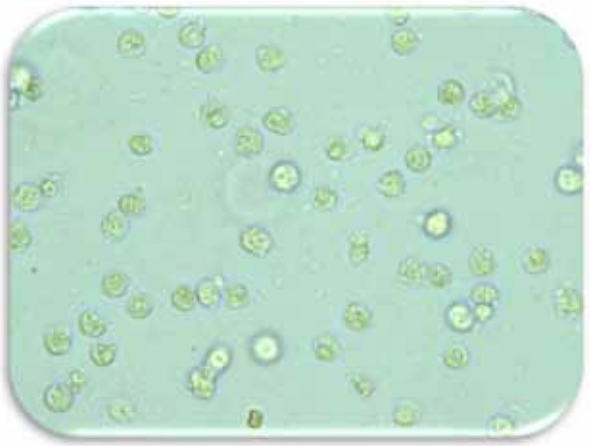


Figure 16: Numerous WBC, 1 nRBC and Bacilli

12.2.2. WBC and WBCC in Manual Microscopy

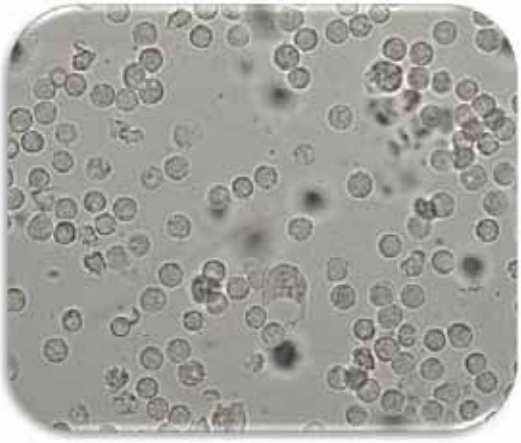


Figure 17: Numerous WBC, non-focused elements



Figure 18: WBC clumps and WBC and bacilli

12.3. Hyaline Casts and Pathological Casts (HYA and CAST)

12.3.1. HYA in Laura XL



Figure 19: Numerous Hyaline casts, plus a cell which is difficult to identify (likely NSE), a few cocci (BACC)



Figure 20: Hyaline cast and convoluted hyaline cast, 1 WBC, 1 RBC and a few BACR

12.3.2. CAST in Laura XL



Figure 21 : granular and cellular (WBC) pathological casts



Figure 22: Pathological CAST (likely waxy), with HYA, WBC and SQEP



Figure 23: Pathological bacteria Casts (CAST)



Figure 24: Pathological waxy Cast (CAST)



Figure 25: Pathological Cast (CAST)



Figure 26: Pathological waxy Cast (CAST)

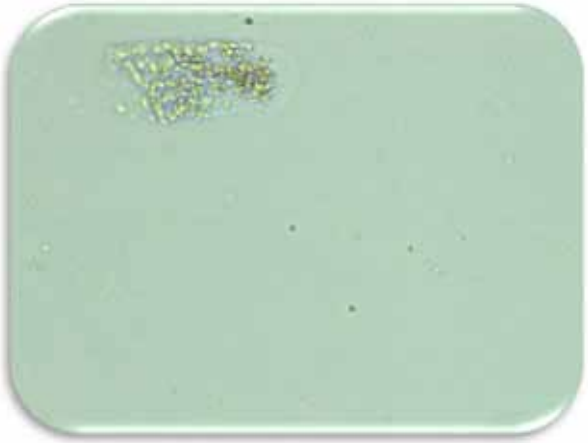


Figure 27: Pathological granular Cast (CAST), with more than 1/3 of granular content

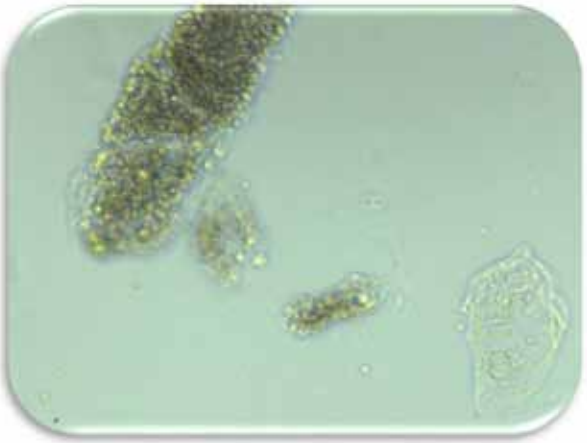


Figure 28: Pathological granular Cast (CAST)



Figure 29: Pathological cast (CAST) and Squamous Epithelial cells (SQEP)



Figure 30: Pathological cast CASTS; with NSE, WBC and RBC

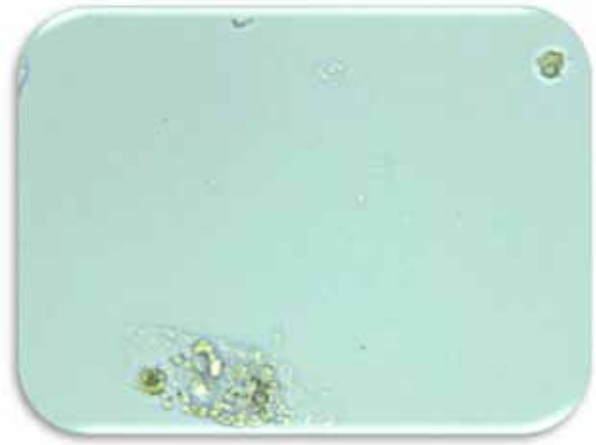


Figure 31: Pathological element cast (more than 3 elements)

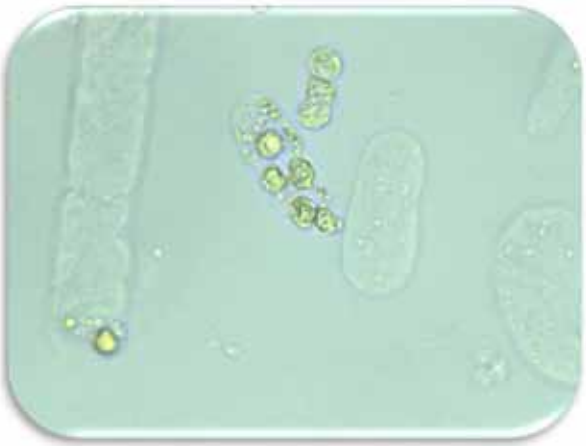


Figure 32: Pathological element CAST with more than 3 elements inside, and 4 HYA casts

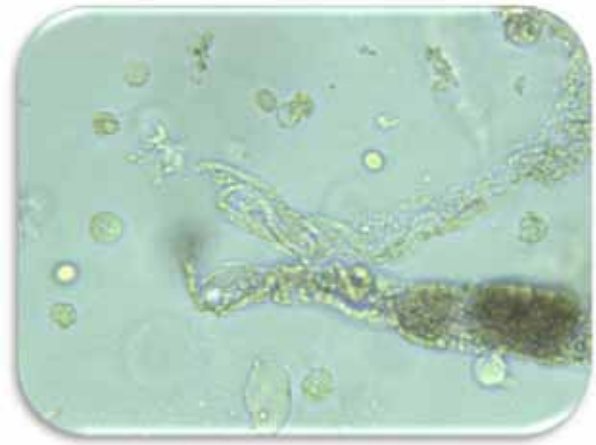


Figure 33: Granular pathological cast (CAST) with WBC and RBC – the shiny element on the left is not fully sedimented, impossible to identify with certainty

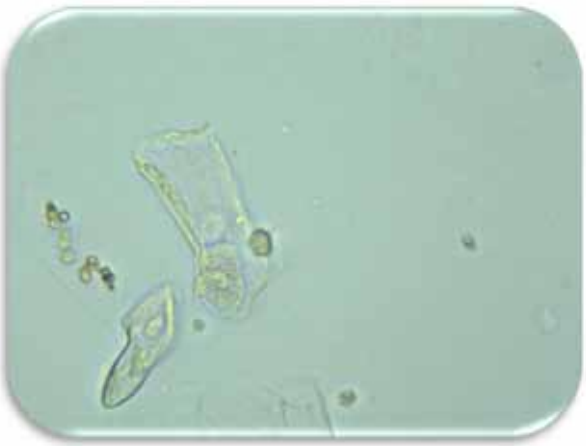


Figure 34: Pathological RBC cast (CAST) with more than 3 RBC inside, with Epithelial cells and a WBC

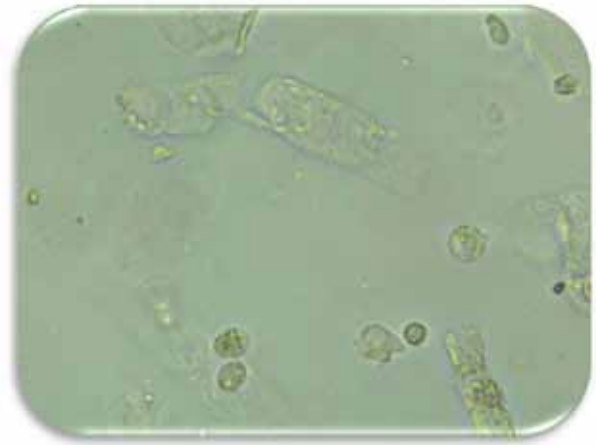


Figure 35: HYA and CAST (pathological)



Figure 36: CAST (more than 1/3 of content) with SQEP and WBC

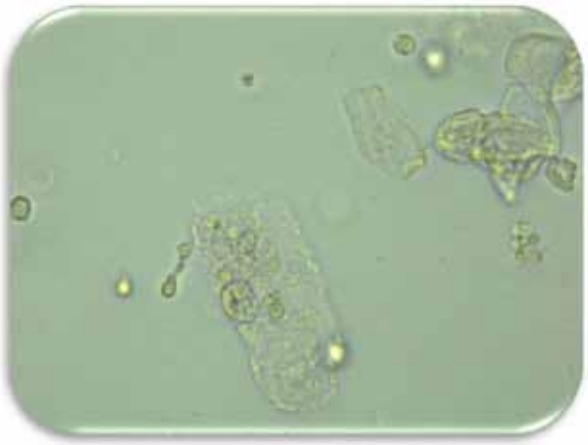


Figure 37: Pathological cast (CAST) with SQEP and WBC



Figure 38: Granular pathological cast, with WBC and Dysmorphic RBC and yeast (YST)

12.3.3. HYA in Manual Microscopy



Figure 39: Hyaline cast



Figure 40: Hyaline (convoluted) cast

12.3.4. CAST in Manual Microscopy

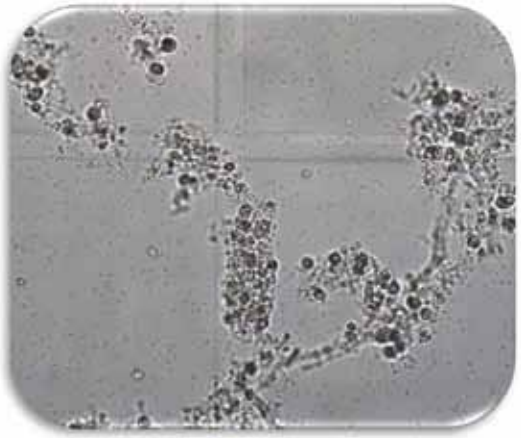


Figure 41: Cellular pathological cast (CAST)



Figure 42: Granular Pathological cast

12.4. Epithelial cells (SQEP and NSE)

12.4.1. SQEP and NSE in Laura XL

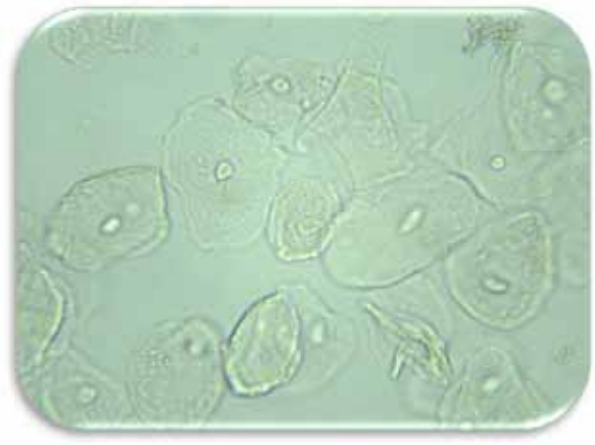


Figure 43: SQEP: Epithelial cells (Squamous)



Figure 44: 3 SQEP, 1 WBC, and crystals



Figure 45: 3 NSE: Non-Squamous Epithelial and 4 SQEP (partially truncated), 1 WBC

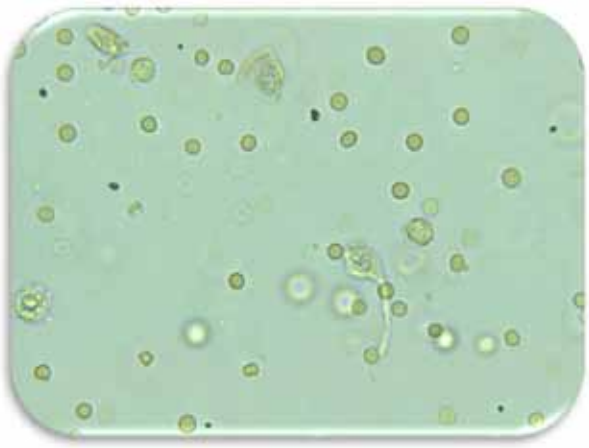


Figure 46: 3 NSE of different shapes, 3 WBC and lots of RBC (Normal and ghosts)

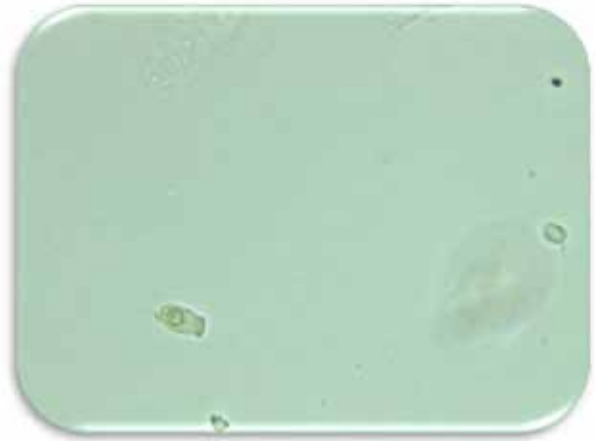


Figure 47: 1 NSE and a discrete HYA (top left)



Figure 48: Group of NSE attached

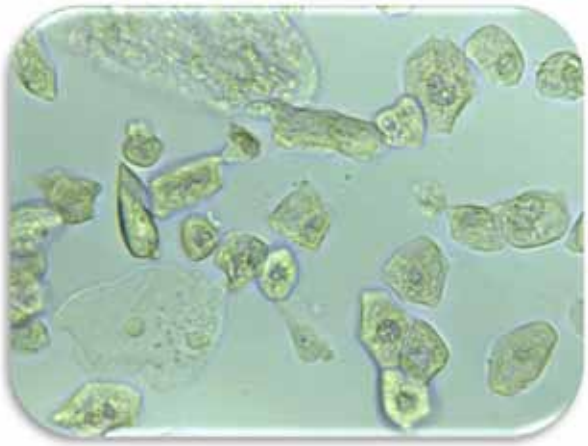


Figure 49: Numerous NSE and some SQEP

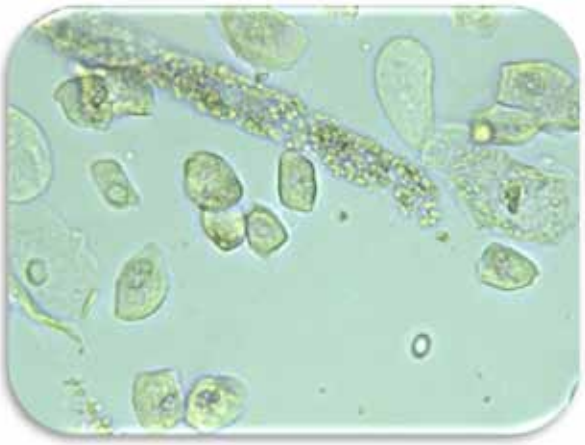


Figure 50: Numerous NSE and some SQEP and a Granular CAST

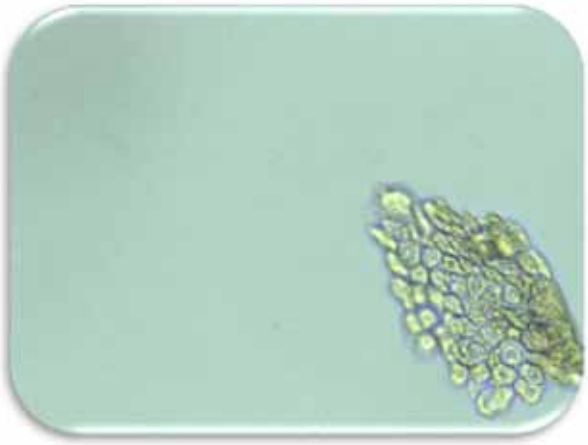


Figure 51: wall of NSE

12.4.2. SQEP and NSE in Manual Microscopy



Figure 52: Squamous Epithelial



Figure 53: Non-Squamous epithelial

12.5. Crystals

12.5.1. Uric Acid (UA) in Laura XL

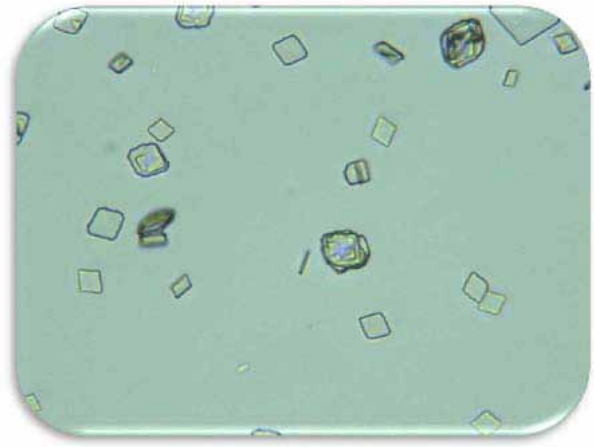


Figure 54: UA = Uric Acid crystals

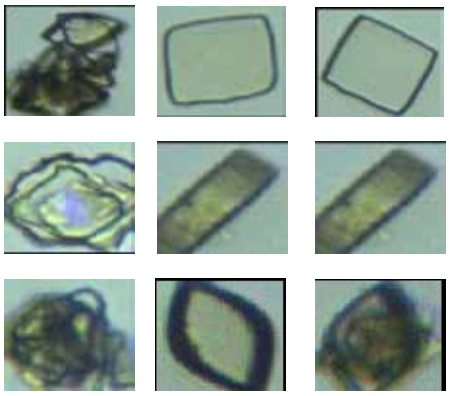


Figure 55: UA crystals of different forms and shapes

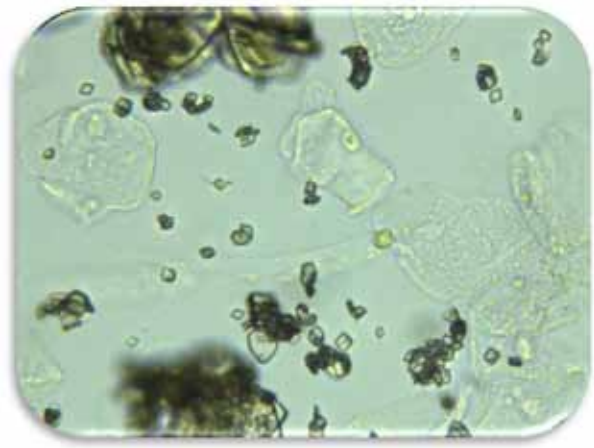


Figure 56: Lots of UA crystals of different shapes plus several SQEP and 1 HYA

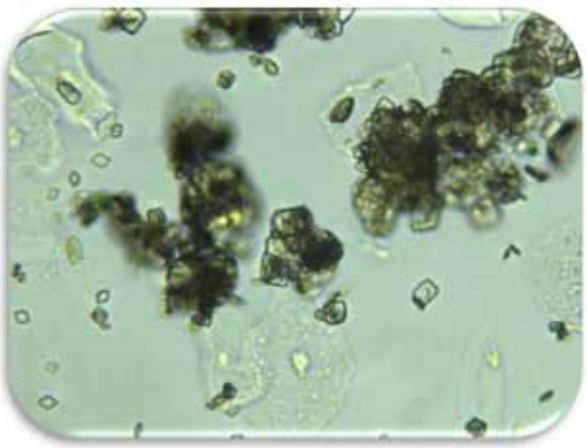


Figure 57: Lots of UA crystals of different shapes plus several SQEP and 1 HYA

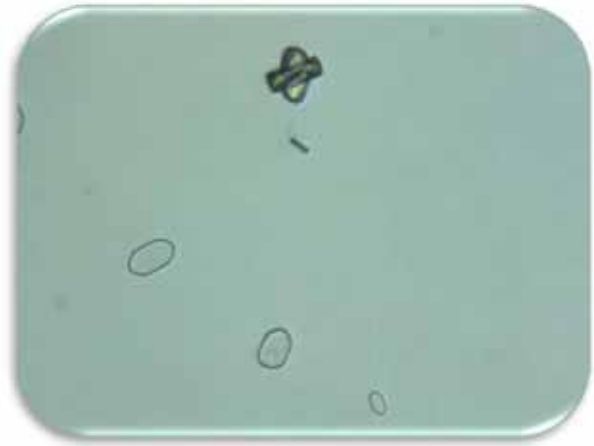


Figure 58: all elements on the image are UA crystals (of different forms)

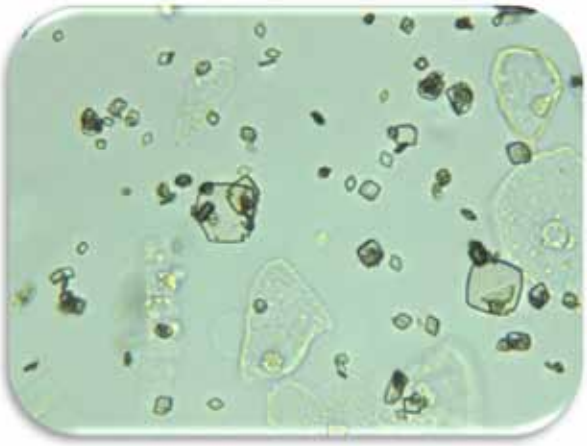


Figure 59: UA crystals, Casts and SQEP

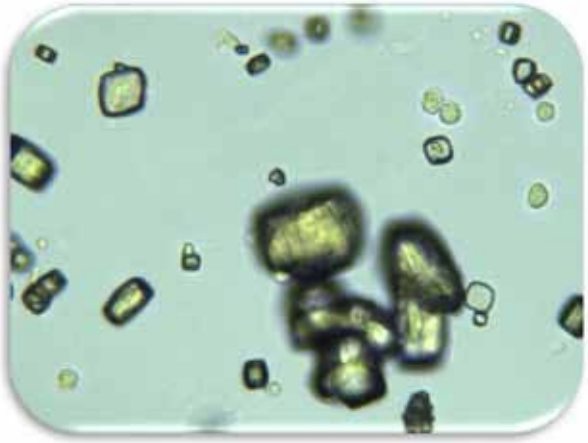


Figure 59: UA crystals, Casts and SQEP

12.5.2. Calcium Oxalate (CaOX and mCaOX) in Laura XL

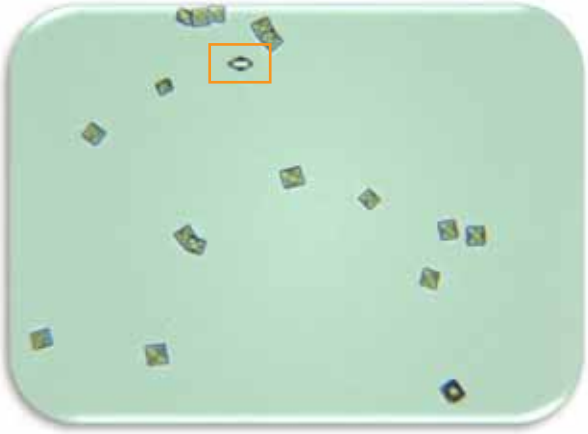


Figure 61: CaOX: numerous crystals of Calcium Oxalate (dihydrate), including the surrounded element



Figure 62: cluster of Calcium Oxalate crystals, numerous bacilli and 1 WBC, and in small image, different angle view of Ca OX (dihydrate)

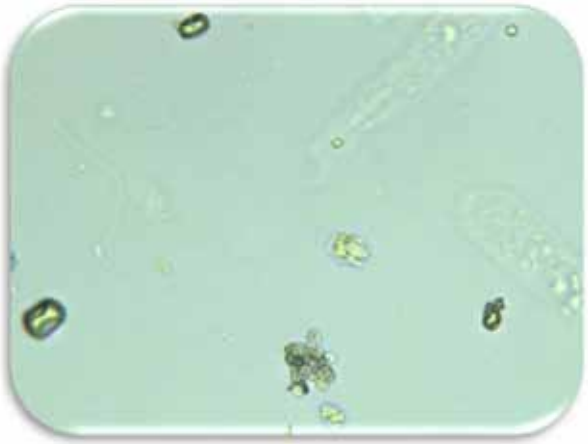


Figure 63: CaOX Monohydrate and some RBC, HYA and MUC

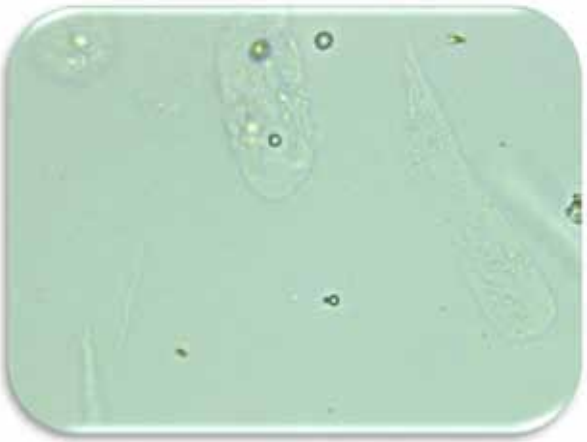


Figure 64: Confirmed CaOX Monohydrate crystal (mCaOX), (upper part of image), and 2 HYA

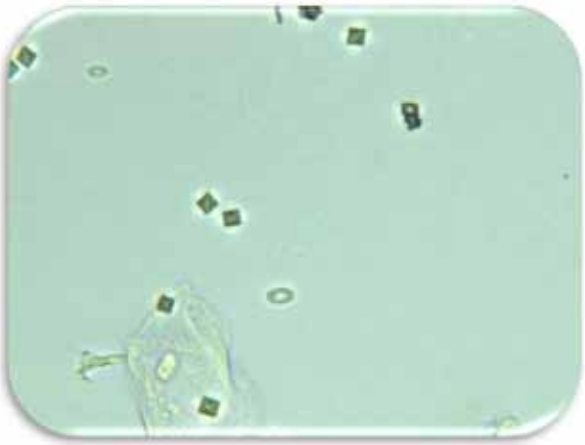


Figure 65: Several CaOX dihydrate and 2 CaOX monohydrate (elliptic shape)

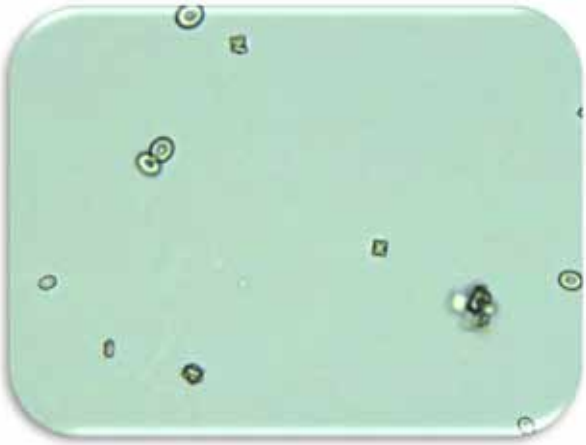


Figure 66: Different sizes of monohydrate Calcium Oxalate (mCaOX) crystals and some dihydrate CaOX

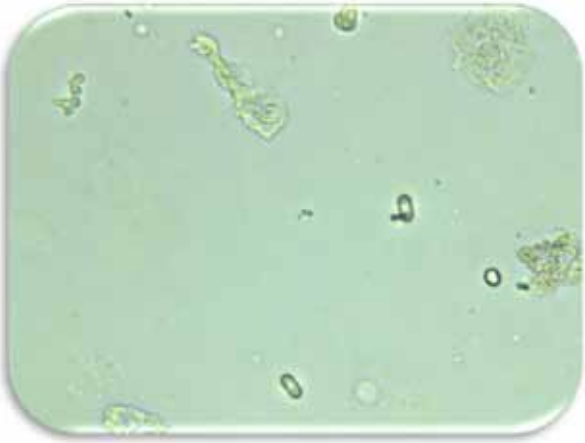


Figure 67: mCaOX in a urine with SQEP, and Yeasts (YST)

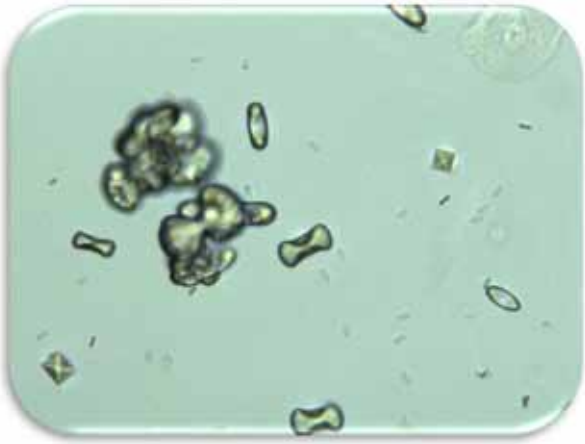


Figure 68: Many forms of mCaOX calcium oxalate (monohydrate), from dumbbell shape, ovoid (large and thin small ones) and 2 CaOX (dihydrate)



Figure 69: Other forms of mCaOX (Calcium monohydrate)

12.5.3. Triple Phosphate (TRIP) in Laura XL

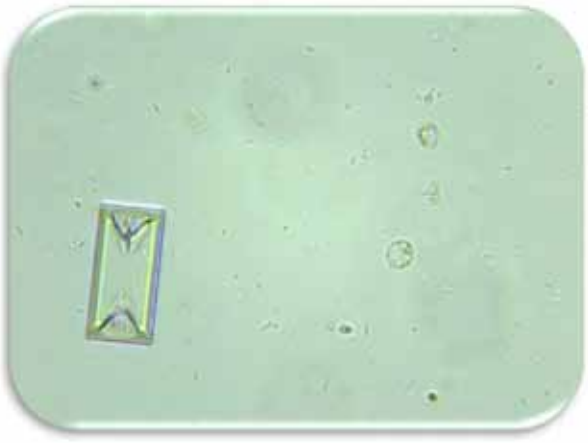


Figure 70: Dissolving TRIP (Triple Phosphate crystals); Lysed WBC and BACR

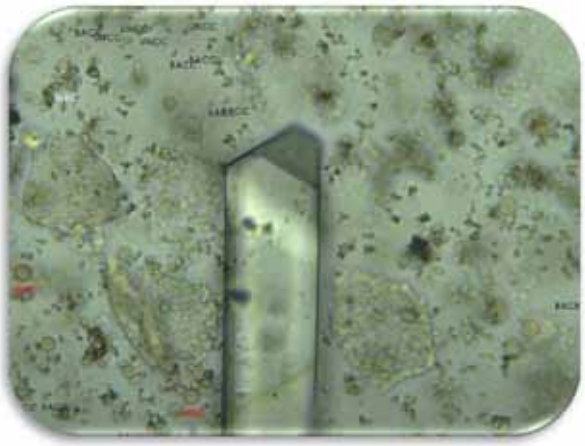


Figure 71: 1 large TRIP crystal with lots of Amorphous crystals, SQEP and RBC

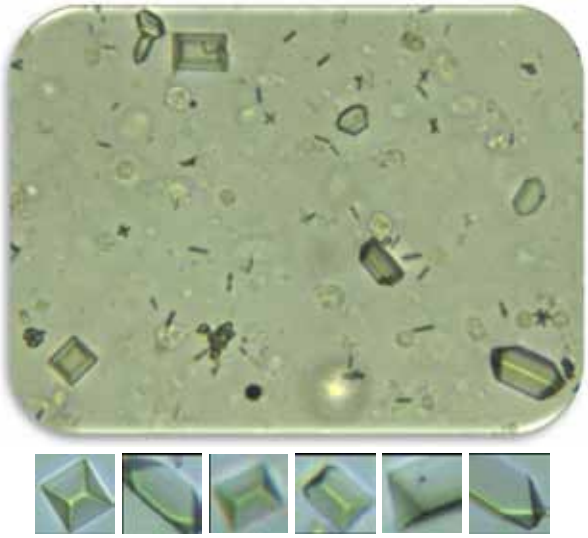


Figure 72: TRIP crystals, WBC and RBC

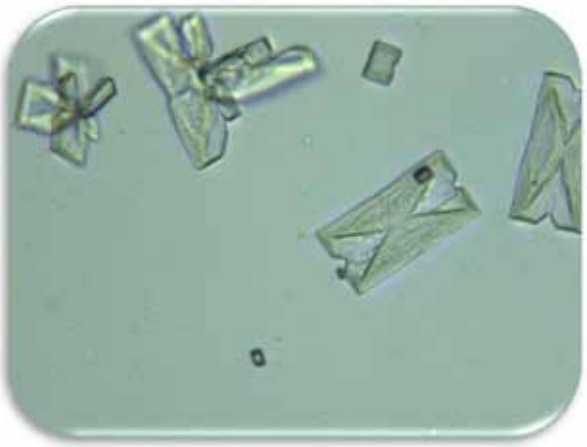


Figure 73: Different shapes and texture of TRIP crystals

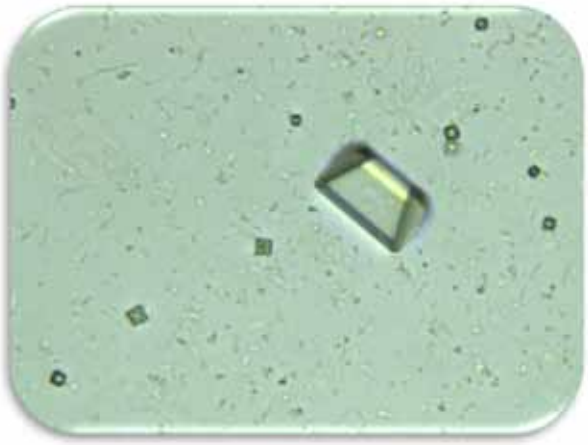


Figure 74: Triple Phosphate crystal in the middle of CaOX Crystals (CaOX can be seen in pH from Acid to Alcalin)

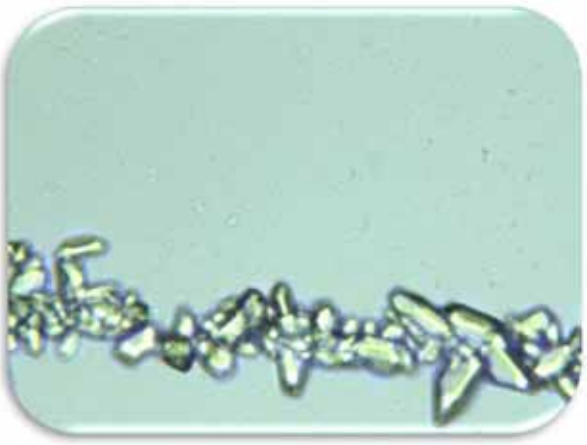


Figure 75: Chain of attached TRIP crystals

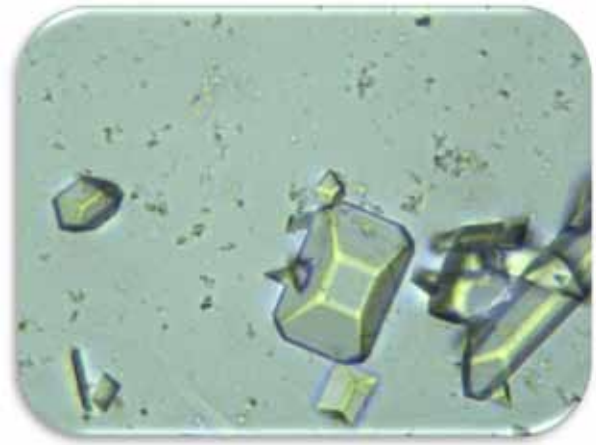


Figure 76: Large and smaller TRIP crystals

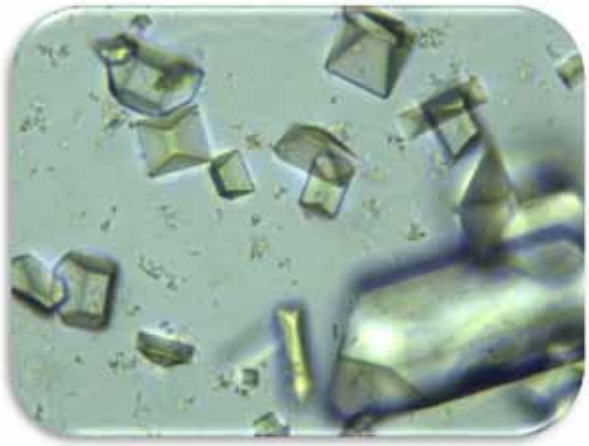


Figure 77: Large and smaller TRIP crystals

12.5.4. Small crystals (CRYS) and other crystals in Laura XL



Figure 78: Small Crystals (CRYS), 3 SQEP and Bacilli



Figure 79:1 Crystal which can be manually changed to CaPH Calcium Phosphate, 1 CaOX, 1 SQEP, Amorphous crystals crystals (AMO)

12.5.5. Amorphous crystals (AMO) in Laura XL

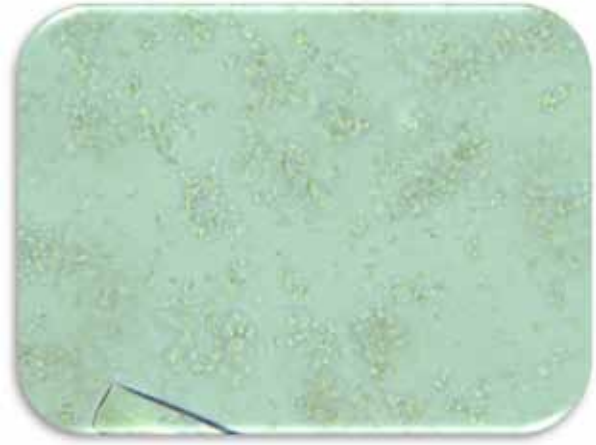


Figure 80: Large hidden crystal and Amorphous crystals

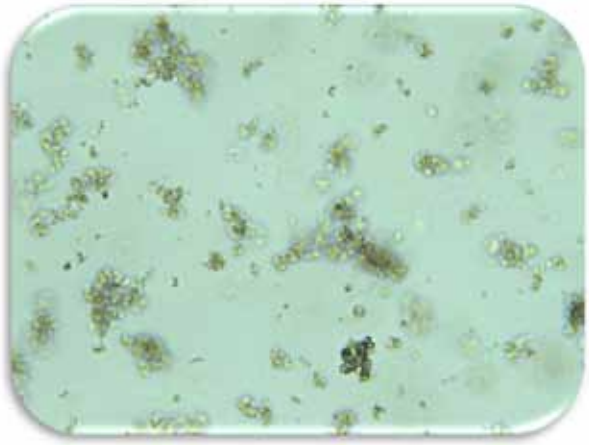


Figure 81: Amorphous crystals

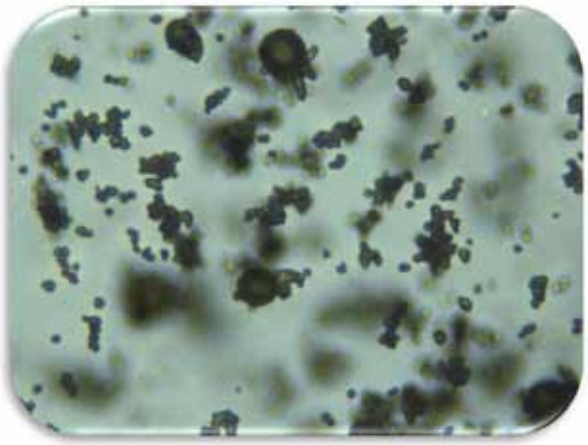


Figure 82: Amorphous crystals and Ammonium urate crystals

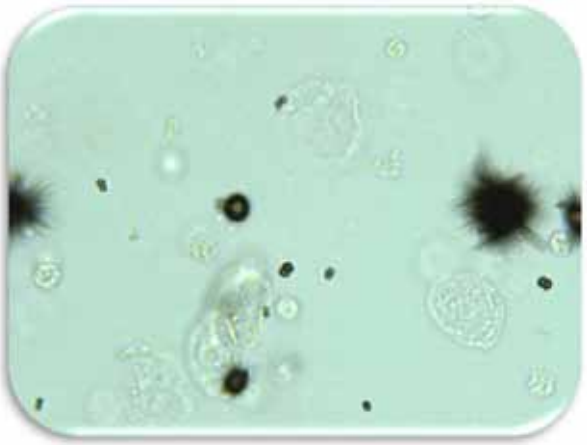


Figure 83: Ammonium urate crystals with Epithelial cells and WBC

12.5.6. Crystals in Manual Microscopy

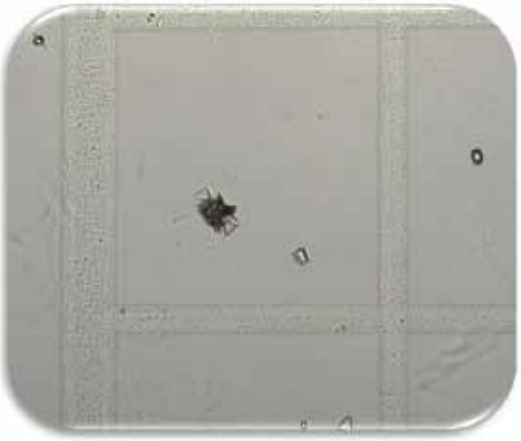


Figure 84: different forms of Uric Acid crystals



Figure 85: 4 crystals of Calcium Oxalate, Mucus and bacilli

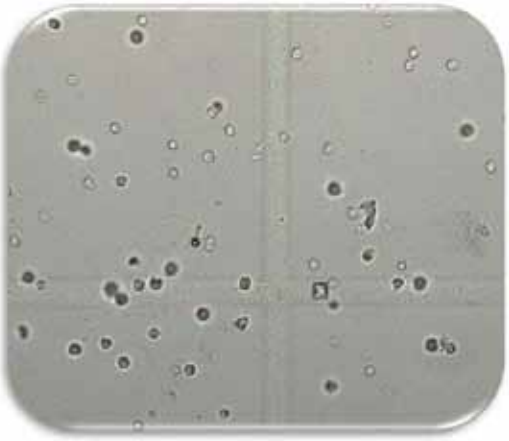


Figure 86: 1 Calcium Oxalate crystal, numerous WBC and bacilli

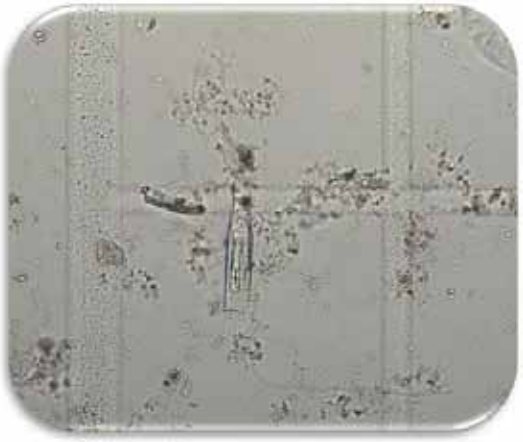


Figure 87: crystal of Calcium Phosphate, Amorphous crystals and Hyaline cast and an epithelial cell



Figure 88: lots of Amorphous crystals with CaPH crystals



Figure 89: Amorphous crystals

12.6. Bacteria (BACC, BACR and BC)

12.6.1. BACC, BACR and BC in Laura XL

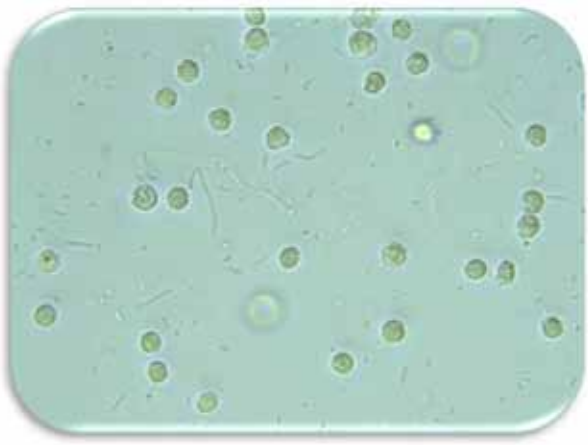


Figure 90: BACR Rod shapes bacteria (Bacilli) long and short ones, and WBC

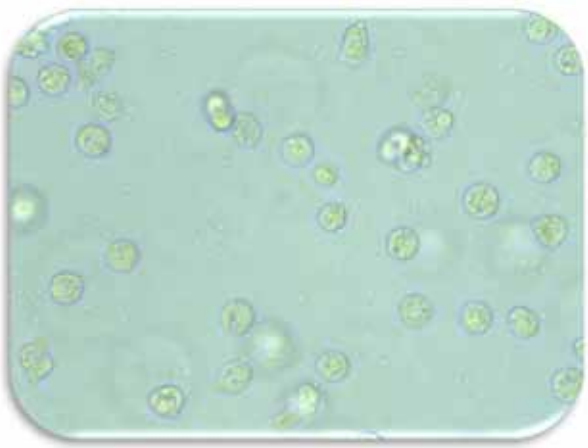


Figure 91: BACC: cocci shape bacteria and WBC

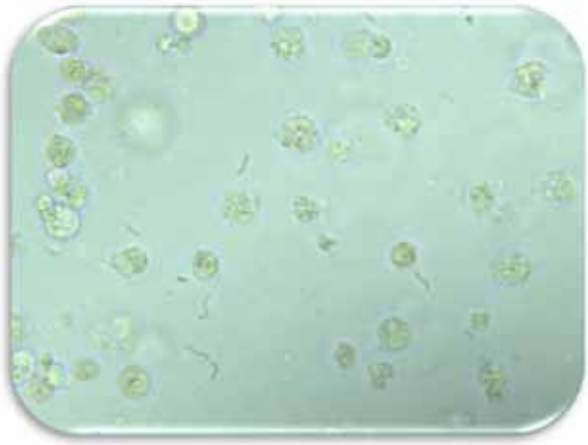


Figure 92: BACC in chains, and lots of WBC

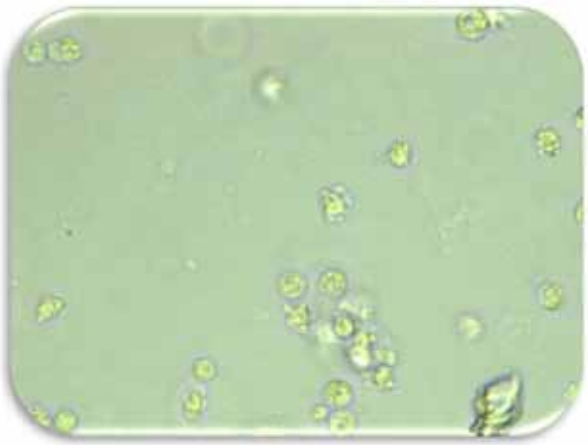


Figure 93: BACC with WBC

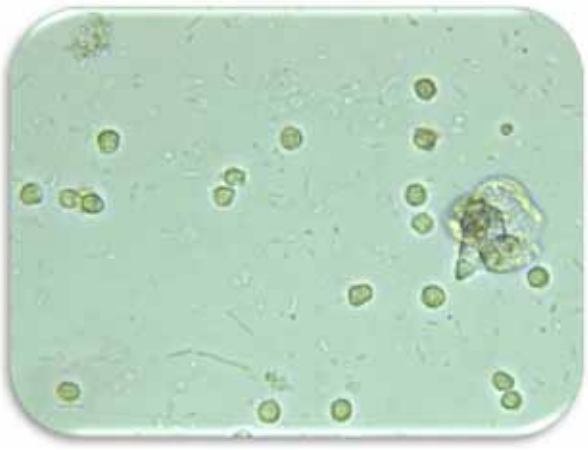


Figure 94: BACR and some very long ones

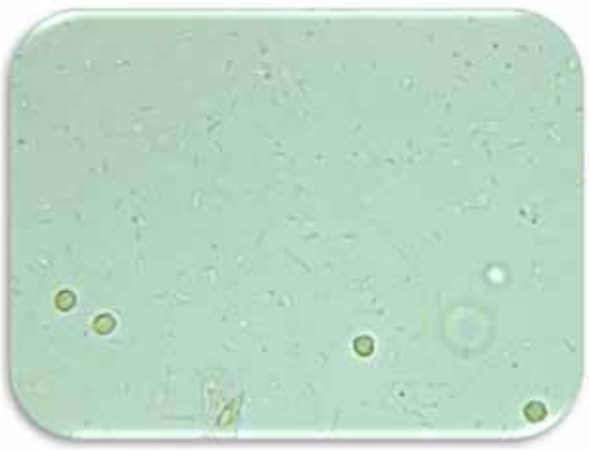


Figure 95: BACR and some very long ones

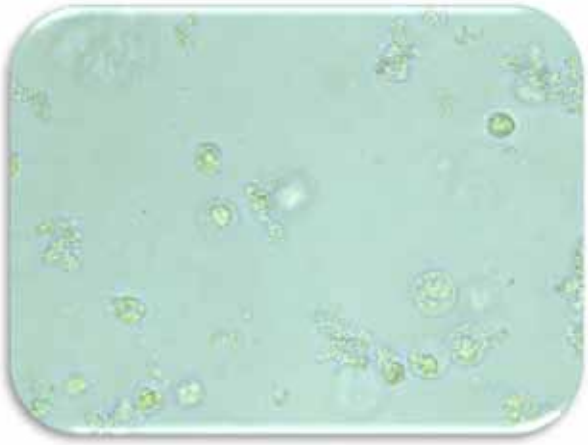


Figure 96: Large number of BACR and Bacteria clumps (BC) attaching together and to other elements

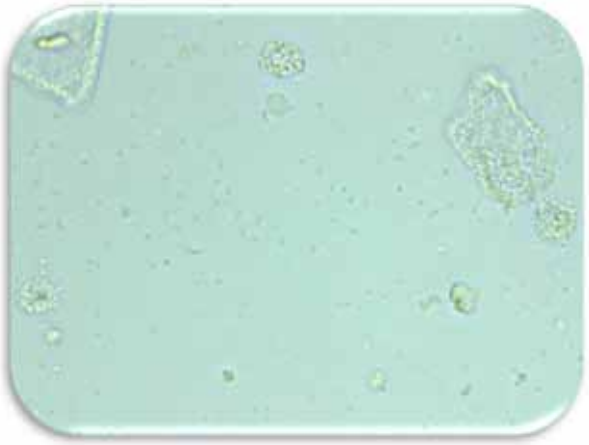


Figure 97: BACR and BC adhering to all other elements (SQEP, WBC)

12.7. Yeast (YST)

12.7.1. YST in Laura XL

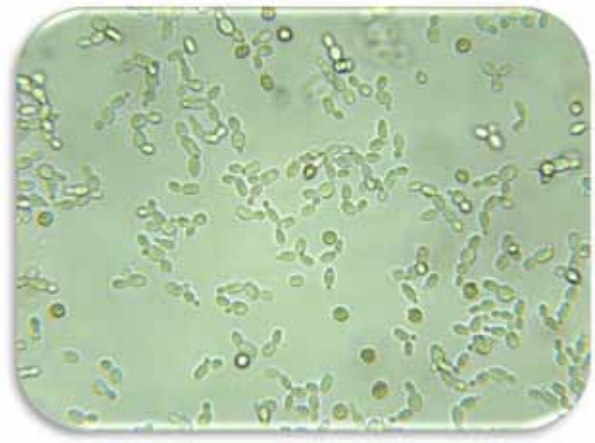


Figure 98: Numerous Yeasts

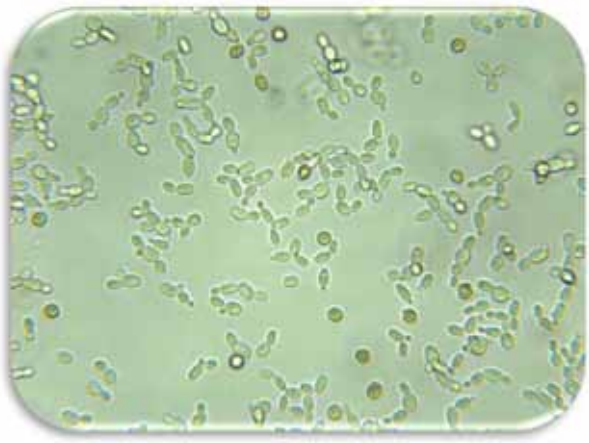


Figure 99: Smaller Budding yeasts, along CaOX Crystals and 1 HYA and MUC

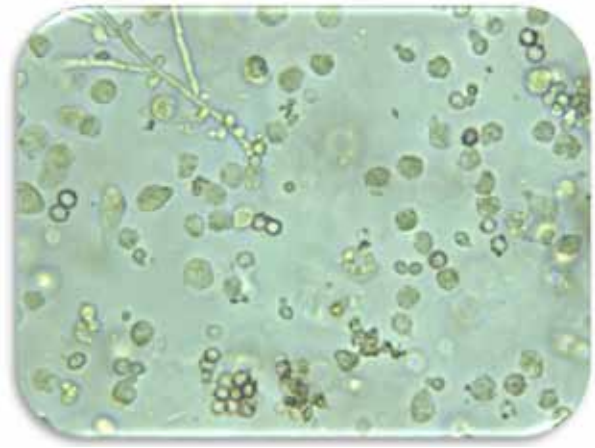


Figure 100: Yeasts forming mycelium (left) and Budding (right), along with Numerous WBC and Dysmorphic RBC (dRBCg, dRBCa – Acanthocytes)



Figure 101: Budding yeasts of different shape, along walls of epithelial cells

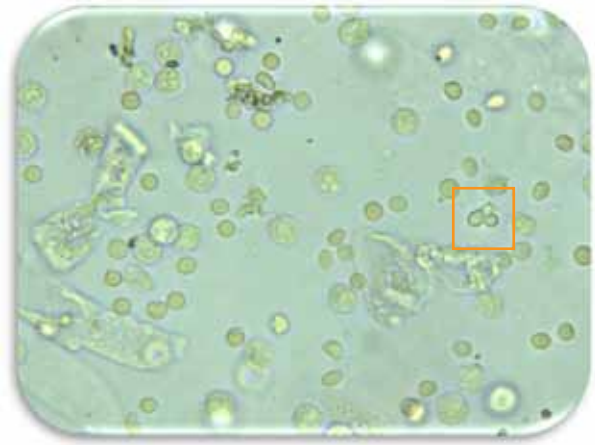


Figure 102: Budding yeasts and RBC, SQEP, NSE, WBC

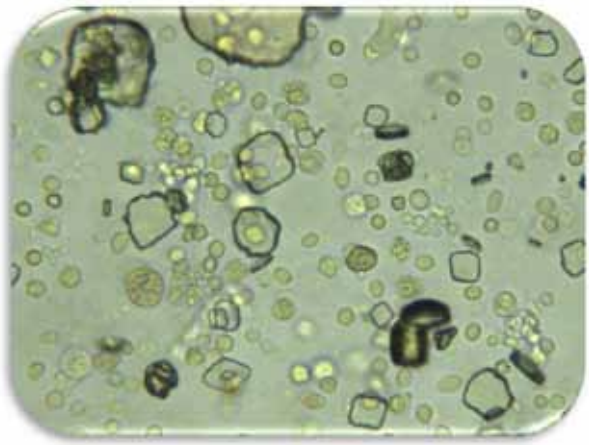


Figure 103: lots of Budding yeasts in the middle of RBC, WBC and UA crystals

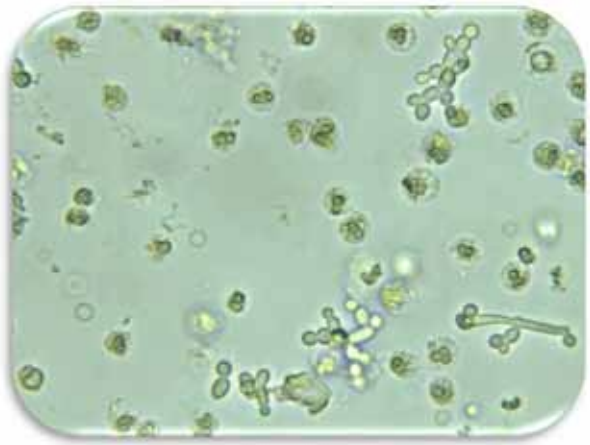


Figure 104: Budding and Pseudohyphae forming yeasts, with WBC and dysmorphic Ghost RBC

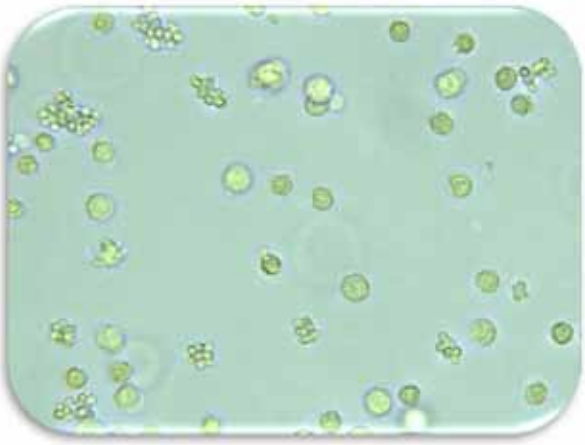


Figure 105: clusters of budding yeasts with WBC



Figure 106: Budding yeasts, 1 RBC and Granular Pathological CAST

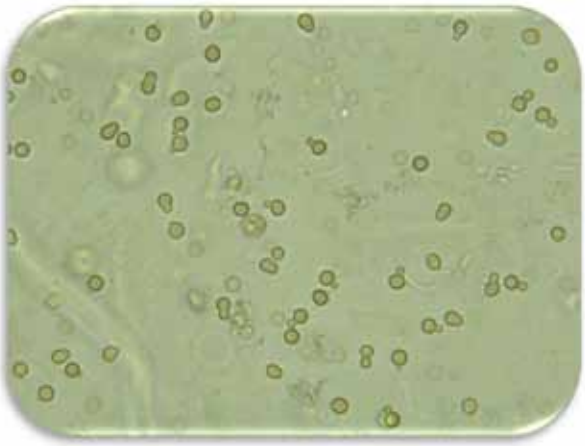


Figure 6: nRBC and dysmorphic RBC (Acanthocytes) with 'budding' RBC and Dysmorphic Ghost RBC (dRBCg), plus MUC, Bacteria

12.7.2. YST in Manual Microscopy



Figure 107: Rare Yeasts



Figure 108: rare yeasts with casts and dysmorphic RBC

12.8. Mucus (MUC)

12.8.1. MUC in Laura XL



Figure 109: MUC: Mucus strand (and bacilli and WBC)



Figure 110: Mucus and a conglomerate of amorphous crystals

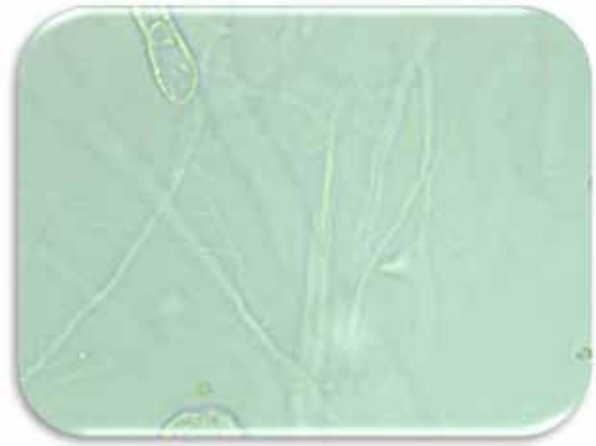


Figure 111: Large amount of MUC

12.8.2. MUC in Manual Microscopy



Figure 112: Mucus and a conglomerate or cast of Amorphous crystals

12.9. Spermatozoids (SPRM)

12.9.1. SPRM in Laura XL

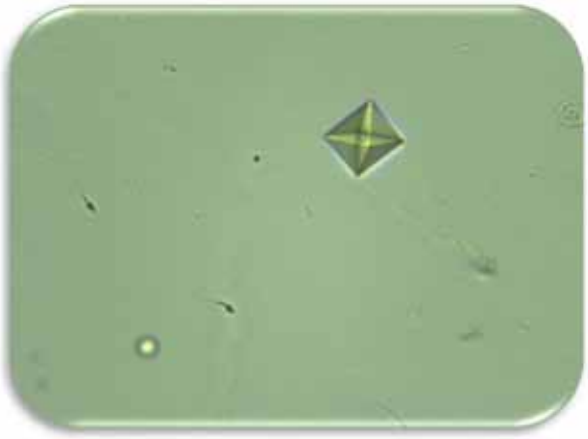


Figure 113: 2 Sperm and 1 large Calcium Oxalate crystal and 1 WBC

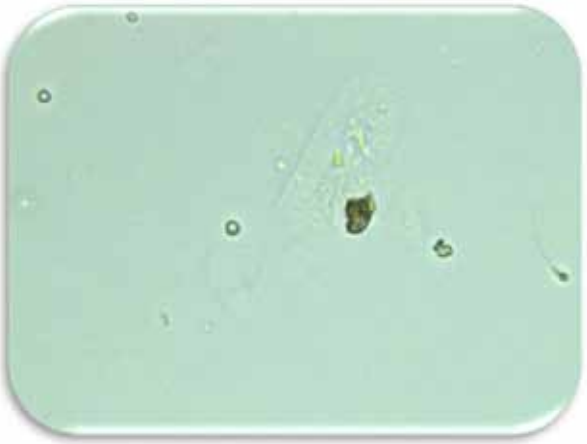


Figure 114: SPRM with 1 HYA and suspicion of CaOX Monohydrate

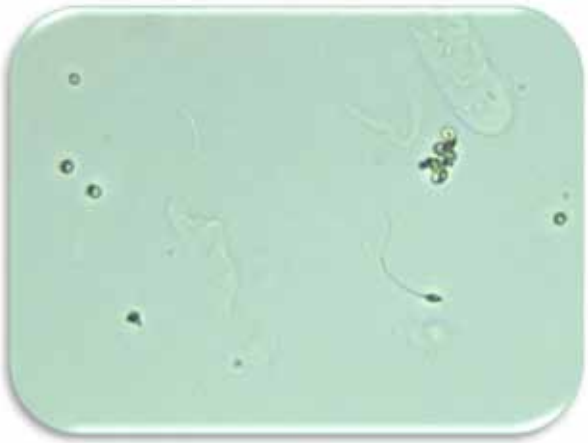


Figure 115: 1 SPRM, with HYA and suspicious agglomerate of CaOX Monohydrate

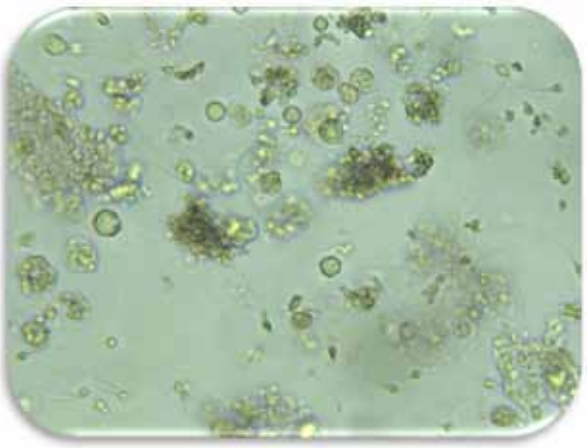


Figure 116: Numerous Sperm with WBC, RBC and suspicion of Granular CAST

12.9.2. SPRM in Manual Microscopy

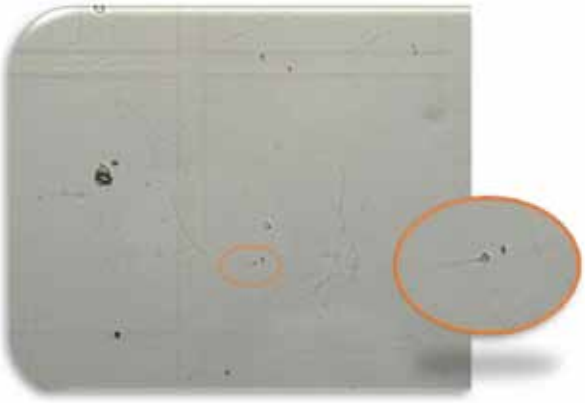


Figure 117: 1 sperm, crystals and a WBC

12.10. Other insights about sediment elements

Like on manual microscopy, not all elements are in the same focal plane. Below are examples of how elements may appear when they are not
focused. These elements should not be attempted to be identified, as depending on their focal plane distance, they may be confused for others.

12.10.1. Non-sedimented elements in Laura XL

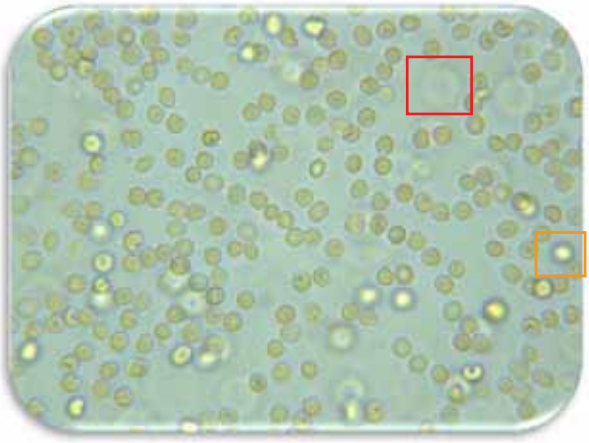


Figure 118: non-sedimented or not focused elements are blurred or shiny; blurred cannot be identified and shiny cannot be identified with certainty

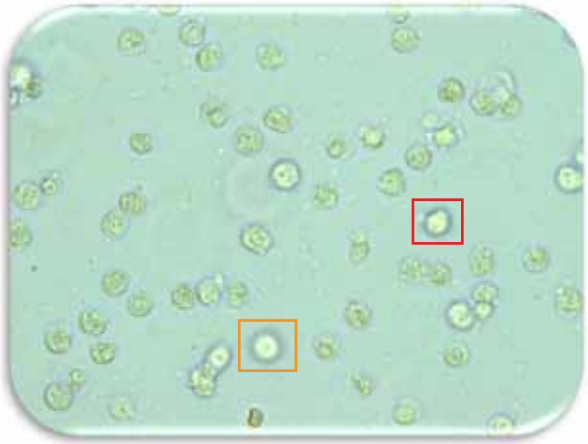


Figure 119: Blurred/shiny shapes are not identifiable elements

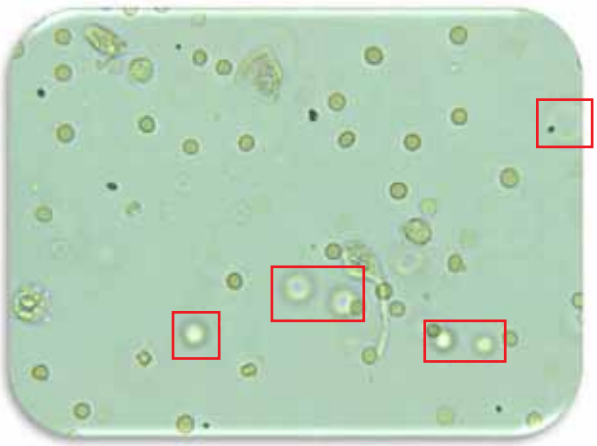


Figure 120: non-sedimented or not focused elements, cannot be identified with certainty

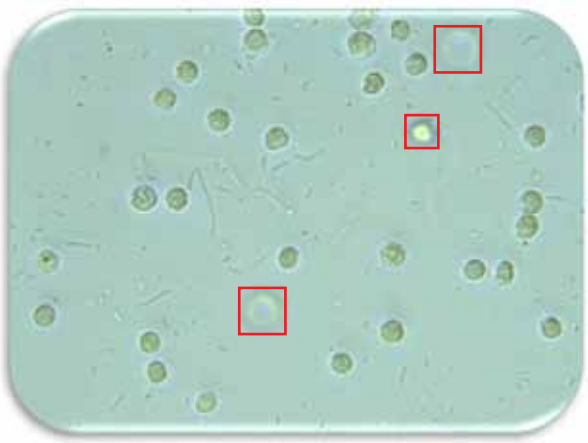


Figure 121: non-sedimented or not focused elements, cannot be identified with certainty

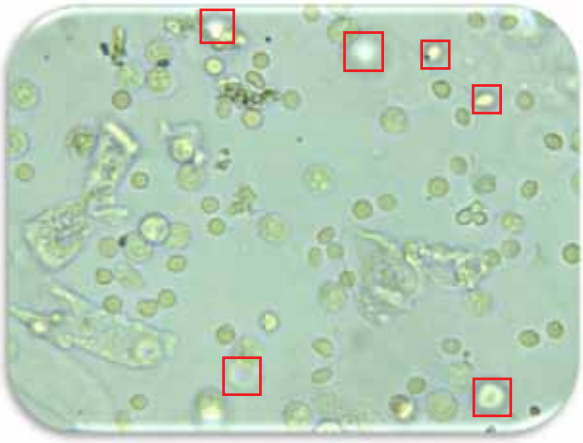


Figure 122: non-sedimented or not focused elements, cannot be identified with certainty



Figure 123: non-sedimented or not focused elements, cannot be identified with certainty

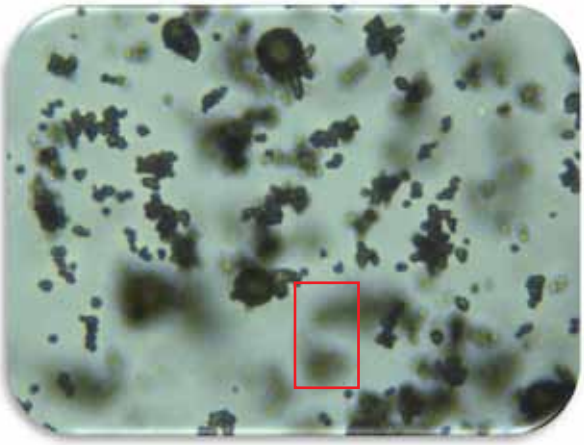


Figure 124: elements not focused, cannot be recognized

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