FUS-360 NEW

Urine Sediment Analyzer

Technical Specification

Test principle	Flow type image technology
Test items	Normal red blood cell, microcyte, acanthoid erythrocyte, erythrocyte ghost, other poikilocytes,
	WBC, white bloodcell cluster, non-squamous epithelial cell, renal tubular epithelial cell, transi-
	tional epithelial cell, hyaline cast, granular cast, waxy cast, broad cast, other casts, lactobacillus,
	suspected coccus, pseudohypha, microzyme, calcium oxalate, uric acid crystal, magnesium
	ammonium phosphate crystal, other crystals, sperm and mucous strands
Throughput	120 T/H
Abnormal RBC prompt	The test results shall have the isomorphic red blood cell and mixed red blood cell prompt function
Sample type	Urine
Sample capacity	60 samples
	The volume can be extended to 320 samples if pre-storage tray and reclaiming tray modules are
	installed
STAT	Special STAT position
LIS	Network interface LIS and serial port LIS
	Bidirectional communication with LIS system is supported
Test results storage capacity	Not less than 150,000 pieces of data
Computer	Standard accessory
Weight	72kg
	107kg if pre-storage tray and reclaiming tray modules are installed
Power	200VA; computer power 800VA
Size (L×W×H)	680 mm×830 mm×680 mm
	1360 mm×900 mm×680 mm if pre-storage trayand reclaiming tray modules are installed
Ambient temperature	10℃~30℃
Relative humidity	Below 70%
Atmospheric pressure	75kPa~ 106kPa
Supply voltage	100-240V~ 50/60Hz

DIRUI

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CE

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·Specifications subject to change without notice.

20210910

FUS-360 NEW

Urine Sediment Analyzer

63d., poz. 1

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- Throughput: 120T/H;
- 25 formed element parameters and 3 prompts;

63d., poz. 3

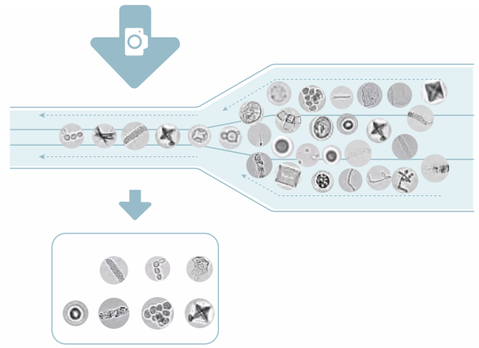
Considerate Improvement

***DIRUI** always focus on what the laboratorians really need*

Inherit DIRUI Classical Principle

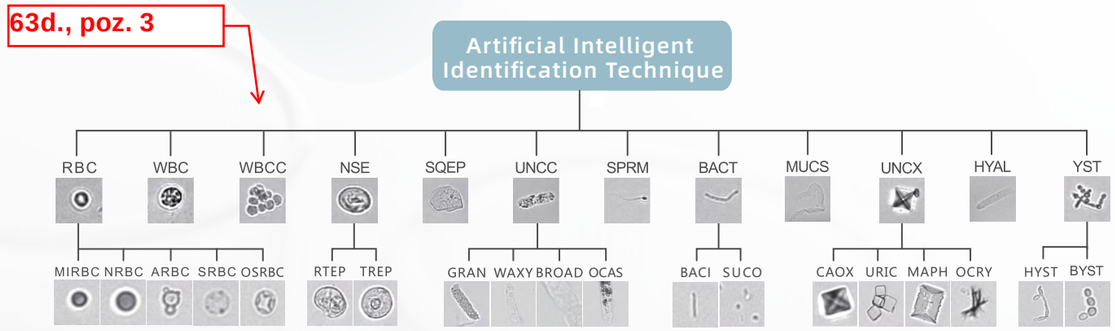
Real images *Trustworthy*

No gather
No overlap



Sheath flow technology
+
High Speed Photography Technology
+
Artificial Intelligence Identification Technology (AII)

63d., poz. 3



Dalinis dokumento <FUS-360 User Manual.pdf> vertimas iš anglų kalbos

63 d., poz. 2
Šlapimo sedimentų analizatoriumi (modelis: FUS-360) galima atlikti šlapimo sedimentų analizę ir suskaičiuoti šlapime susidariusius elementus naudojant vieną mėginį.

63 d., poz. 2
Mėginio tipas – šlapimas.

63 d., poz. 2, poz. , poz. 5, poz. 6
Forminių elementų analizė:
minimalus tūris: 2,6 ml necentrifuguoto šlapimo; įsiurbimo tūris: apie 1,6 ml.

63 d., poz. 7
Tiriamų mėginių kiekis – 60 mėginių.

63 d., poz. 13, poz. 14
Mėginio brūkšninio kodo identifikavimas
Integruotas brūkšninių kodų skaitytuvas (lazerinis). Mėginio brūkšninis kodas gali būti nuskaitomas automatiškai.

63 d., poz. 3
Normalūs raudonieji kraujo kūneliai - NRBC
Mikrocitai - MIRBC
Akantoidiniai eritrocitai - ARBC
Kiti poikilocitai - OSRBC
Baltieji kraujo kūneliai - WBC
Baltųjų kraujo kūnelių sankaupos - WBCC
Plokščiojo epitelio ląstelės - SQEP
Inkstų kanalėlių epitelio ląstelės - RTEP
Pereinamojo epitelio ląstelė - TREP
Hialininiai cilindrai - HYAL
Grūdėti cilindrai - GRAN
Vaškiniai cilindrai - WAXY
Kiti cilindrai - OCAS
Bakterijos - BACI
Įtariami kokai - SUCO
Pseudohifai - HYST
Mielės - BYST
Kalcio oksalato kristalai - CAOX
Šlapimo rūgšties kristalai - URIC
Magnio amonio fosfato kristalai - MAPH
Gleivių gijos - MUCS

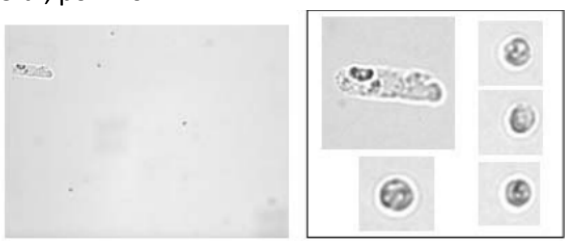
63 d., poz. 7
Mėginių padavimo įrenginys.

63 d., poz. 2

Taikant srauto citometriją galima užtikrinti, kad visi susiformavę elementai pateks prieš mikroskopo objektyvą ir greitaeigę kamerą mikroskopo objektyvo fokuse ir bus užfiksuoti.

63 d., poz. 10
Per tam tikrą laiko tarpą greitaeigė kamera užfiksuos daugybę vaizdų su forminiais visų mėginių elementais.

63 d., poz. 10

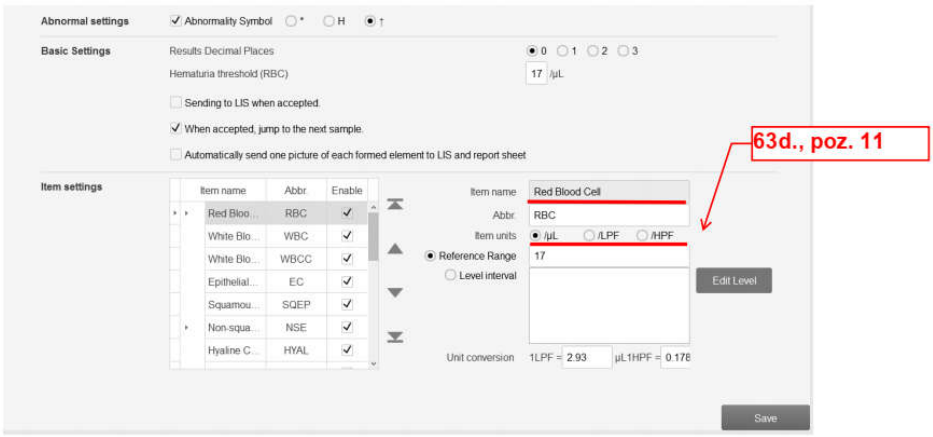


63 d., poz. 2, poz. 3
Automatinė forminių elementų atpažinimo programinė įranga ir gerai parengta išmanioji atpažinimo technologija gali greitai išgauti forminių elementų dalelių atvaizdus ir identifikuoti bei klasifikuoti juos pagal formą, tekstūrą ir charakteristikas dažnių diapazone. Analitinė sistema gali klasifikuoti daleles pagal daugelį kategorijų.

63 d., poz. 4
Prijunkite ekraną, pelę, klaviatūrą ir kompiuterio maitinimo kabelį.

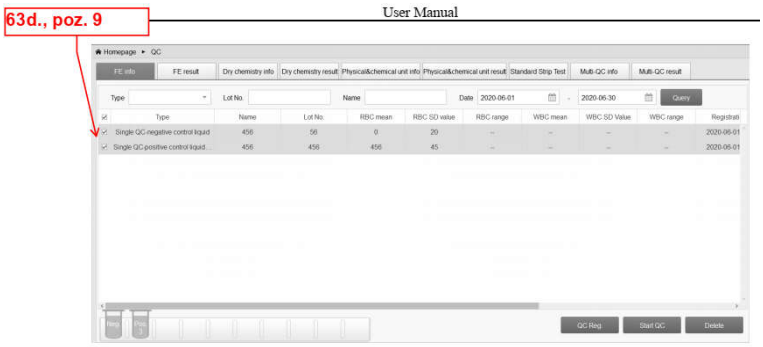
63 d., poz. 4
Analizatoriaus internetinę programinę įrangą įdiegia profesionalūs kompanijos darbuotojai, o naudotojui neleidžiama pašalinti programinės įrangos įprastomis sąlygomis. Jei reikia įdiegti programinę įrangą, atlikite toliau nurodytus veiksmus.
Patalpinkite "Analyzer" taikomosios programinės įrangos diegimo paketą ant kompiuterio darbalaukio ir dukart spustelėkite diegimo paketą. Sąsaja bus tokia, kaip parodyta iliustracijoje.

63 d., poz. 13
Mėginio numerio režimas. Jei pasirinktas šis režimas, prieš išsiunčiant tyrimą, kiekvieną kartą reikia nustatyti kitą mėginio numerį. Šiame režime brūkšninio kodo skaitytuvu nuskaitytas brūkšninio kodo numeris automatiškai užpildomas brūkšninio kodo numerio laukelyje.



63 d., poz. 8
Analizatoriaus kalibravimo dažnis
Analizatorius turi būti kalibruojamas ne rečiau kaip kartą per mėnesį, o prieš kalibravimą turi būti atliekamas fokusavimas.

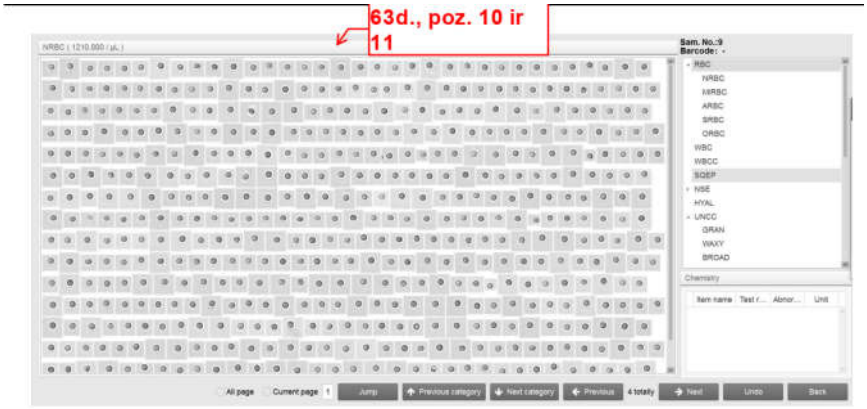
63 d., poz. 9
FE teigiama kontrolė - tai tirpalas su nustatytu kiekiu eritrocitų jonų ekvilibrio skystyje. Ląstelių kiekis yra teigiamos kontrolės etiketėje nurodytas dalelių skaičius.
FE neigiama kontrolė yra tirpalas, kuriame nėra granulių.



63 d., poz. 9
Apie QC (kokybės kontrolės) diagramą
KK (kokybės kontrolės) diagramos rodymo režimai: „Visi KK taškai“ ir „Vienas taškas per dieną“.
KK diagramos abscisė visų KK taškų režime rodo KK datą, o ordinatė - KK liniją. KK diagramos abscisė vieno taško per dieną režimu rodo KK datą, o ordinatė - KK liniją.

63 d., poz. 9
KK diagramos tikrinimas ir spausdinimas.

63 d., poz. 10, poz. 11
Tiriamųjų elementų vaizdų peržiūra
Dukart spustelėkite FE rezultatą su ląstelės ženklu, ir granulių vaizdas bus priartintas ir rodomas ekrane.
Dukart spustelėjus „WBC“, bus rodomas toliau pateiktas vaizdas.



63 d., poz. 12

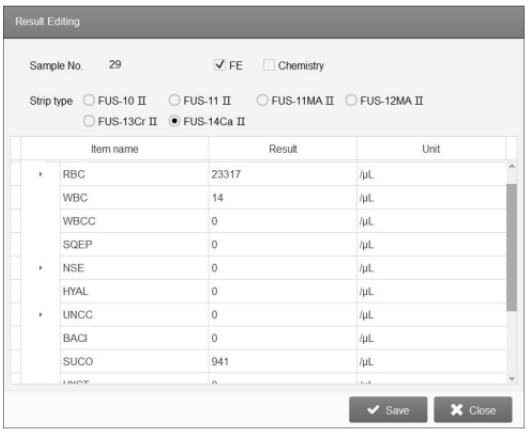
Klaidingo atpažinimo atveju vaizdus galima perklasifikuoti, o operacijos atliekamos kaip aprašyta toliau. Pasirinkite vaizdą, neatitinkantį sąsajoje forminių elementų pavadinimo, spustelėkite atitinkamos kategorijos mygtuką dešinėje ekrano pusėje, kad perklasifikuotumėte, spustelėkite [Back], kad grįžtumėte į sąsają, kaip parodyta 8-5-1 iliustracijoje, tada spustelėkite [Save], kad patvirtintumėte ir išsaugotumėte pirmiau nurodytus pakeitimus.

Iliustracija 8-5-1

63 d., poz. 12

Jei tyrimo rezultatai nesutampa su mikroskopinio tyrimo rezultatais, jie gali būti keičiami taip, kaip nurodyta toliau.

Dukart spustelėkite eilutę, kurioje yra forminių elementų stulpelis „Rezultatas“ rezultatų informacijoje dešinėje sąsajos pusėje, kad būtų rodoma rezultatų redagavimo sąsaja, kaip parodyta iliustracijoje:



63 d., poz. 11
RBCPer - Nenormalus eritrocitų procentas.

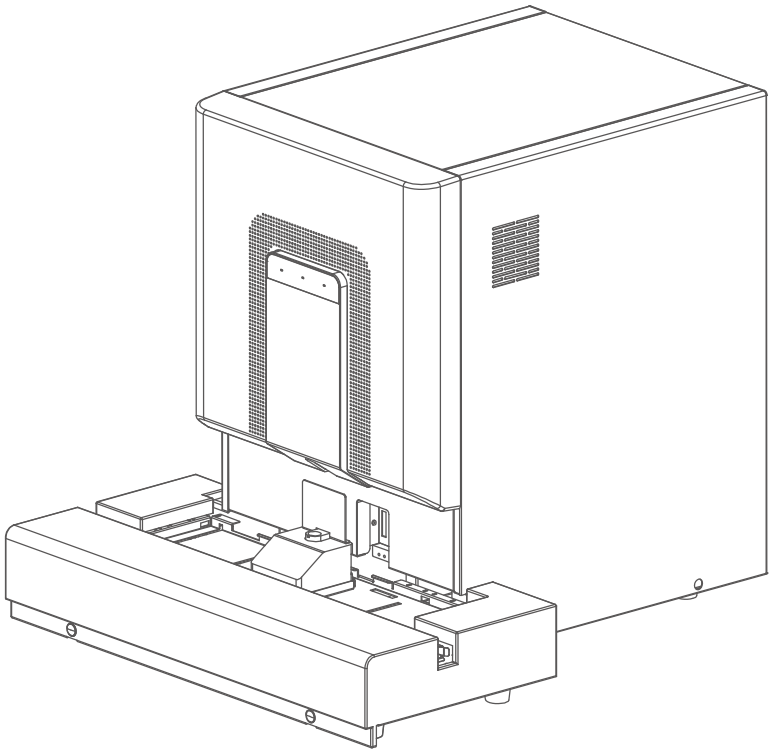
63 d., poz. 3
Analizatorius turi atlikti fokusavimą vieną kartą per dieną, o tada ištirti mėginį, kad galėtų tiksliai klasifikuoti šlapime susidariusius elementus pagal dalelių dydį, morfologiją, kontrasto santykį ir tekstūrą.

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2024-04-19
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

DIRUI

Urine Sediment Analyzer

(FUS-360)



User Manual

DIRUI INDUSTRIAL CO.,LTD.

Chapter 1 Introduction

1.1 Overview

63d., poz. 2

The Urine Sediment Analyzer (model: FUS-360) can finish the analysis and counting of urine formed elements through one-time sampling.

The Analyzer can count 25 types of formed elements in urine (such as cell, cast and crystal).

Scope of application: The identification and analysis of formed elements in urine.

1.2 Parameters of the Analyzer

Items		Indicators
Basic characteristics	Test principle	Test principle of formed element analysis: Flow type image technology; Test principle of physical and chemical items: Refraction method, transmittance absorbance.
	Formed element analysis test items	Normal red blood cell, microcyte, acanthoid erythrocyte, erythrocyte ghost, other poikilocytes, WBC, white blood cell cluster, non-squamous epithelial cell, renal tubular epithelial cell, transitional epithelial cell, hyaline cast, granular cast, waxy cast, broad cast, other casts, lactobacillus, suspected coccus, pseudohypha, microzyme, calcium oxalate, uric acid crystal, magnesium ammonium phosphate crystal, other crystals, sperm and mucous strands.
	Physical and chemical test items	Specific gravity (optional), turbidity (optional), color (optional) and conductivity (optional).
	Test speed	120 samples/ hour;
	Abnormal red blood cell prompt function	The test results shall have the isomorphic red blood cell and mixed red blood cell prompt function.
Sample system	Sample type	Urine
	Sample volume	Formed element analysis item: Min. volume: 2.6mL non-centrifuged urine; aspiration volume: about 1.6mL; Formed element analysis item + physical and chemical item: Min. volume: 3.5mL non-centrifuged urine; aspiration volume: about 2.5mL;
	Volume of sample to be tested	60 samples. The volume can be extended to 320 samples if pre-storage tray and reclaiming tray modules are installed.
	STAT function	Special STAT position, available for sample test at any time
	Sample barcode identification	Built-in barcode reader (laser), sample barcode can be read automatically An external barcode reader (red light), manual scanning of barcode (optional).
Formed element optical system	Light source	High-speed light source
	Camera type	High-speed camera
	Resolution ratio of optical system	40× objective lens shall be used.
Data system	LIS port	Network interface LIS and serial port LIS
	Connection with LIS system	Bidirectional communication with LIS system is supported
	Test results storage capacity	Not less than 150,000 pieces of data
Whole machine	Weight	72kg; 107kg if pre-storage tray and reclaiming tray modules are installed.
	Power	200VA; computer power (optional) 800VA
	Size (L×W×H)	680 mm×830 mm×680 mm 1360 mm×900 mm×680 mm if pre-storage tray and reclaiming tray modules are installed.

63d., poz. 5
63d., poz.2
63d., poz. 2
63d., poz.6
63d. poz. 7
63d., poz. 14
63d., poz. 13

Normal operating conditions

(1) Ambient temperature: 10℃~30℃;

(2) Relative humidity: below 70%;

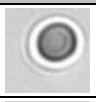
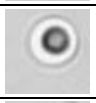
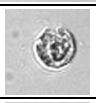
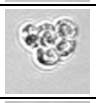
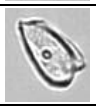
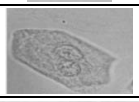
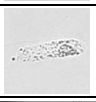
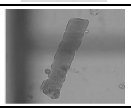
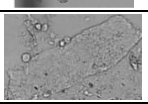
(3) Atmospheric pressure: 75kPa~106kPa;

(4) Supply voltage: 100-240V~ 50/60Hz;

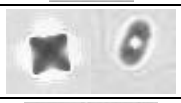
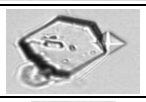
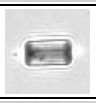
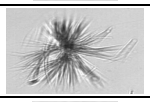
(5) Intensity of light: prevent direct sunlight

63d., poz. 3

Test items and picture of examples:

Category	Abbreviation	Picture of example
Normal red blood cell	NRBC	
Microcyte	MIRBC	
Acanthoid erythrocyte	ARBC	
Erythrocyte ghost	SRBC	
Other poikilocytes	OSRBC	
White blood cells	WBC	
White blood cell cluster	WBCC	
Squamous epithelial cell	SQEP	
Renal tubular epithelial cell	RTEP	
Transitional epithelial cell	TREP	
Hyaline cast	HYAL	
Granular cast	GRAN	
Waxy cast	WAXY	
Broad cast	BROAD	

63d., poz. 3

Category	Abbreviation	Picture of example
Other cast	OCAS	
Bacillus	BACI	
Suspected coccus	SUCO	
Pseudohypha	HYST	
Yeast	BYST	
Calcium oxalate crystal	CAOX	
Uric acid crystal	URIC	
Magnesium ammonium phosphate crystal	MAPH	
Other crystals	OCRY	
Sperm	SPRM	
Mucous strands	MUCS	

Note:

● Single particles not in the 25 categories above are regarded as particles not classified.

● To distinguish and identify the types of crystals and pathologic casts not classified, the operator shall re-check the image picture, identify the image and confirm the classification manually by operating the software.

1.3 Composition of the Analyzer

Composition of the Analyzer: sample processing module, optical counting cell module, microcamera module, data processing module, pre-storage tray and reclaiming tray module (optional) and software system.

1.3.1 Front view of the Analyzer

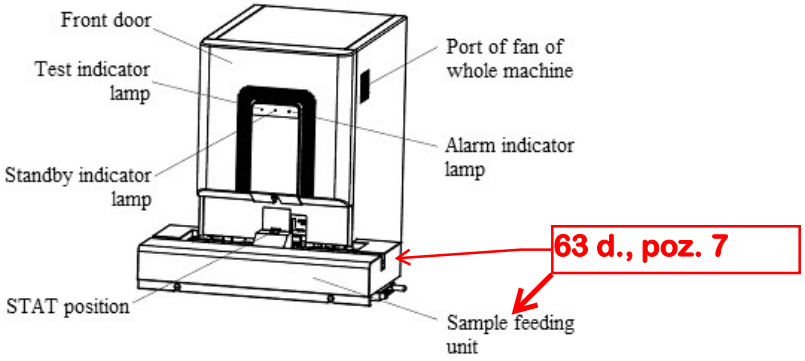


Fig. 1-3-1 Front view of the Analyzer

1.3.2 Rear view of the Analyzer

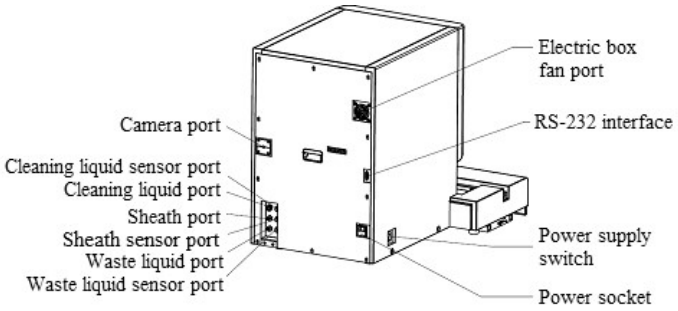


Fig. 1-3-2 Rear view of the Analyzer

1.4 Test principle

1.4.1 Urine formed element test principle

The analytical system applies flow-type micro-imaging technology for urine formed element analysis. The fluid mechanics system of the analytical system consists of a specially made flow cell with thin layer structure. After sampling, the sample will be sent to the flow cell and the syringe pump will promote the sheath liquid used for formed element analysis to enter flow cell, making the sample wrapped by the sheath liquid used for formed element analysis enter the thin layer structure of flow cell. Wrapped by the sheath liquid used for formed element analysis, the sample will flow through the thin layer structure of flow cell at a thickness of a monolayer cell and taken with pictures with a high-speed camera. The urine sample will be drained to a waste liquid container, as shown in figure below.

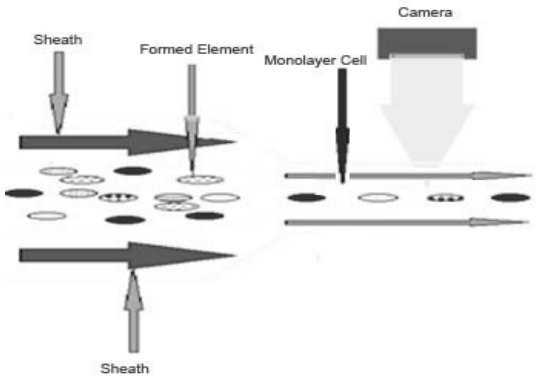


Fig. 1-4-1

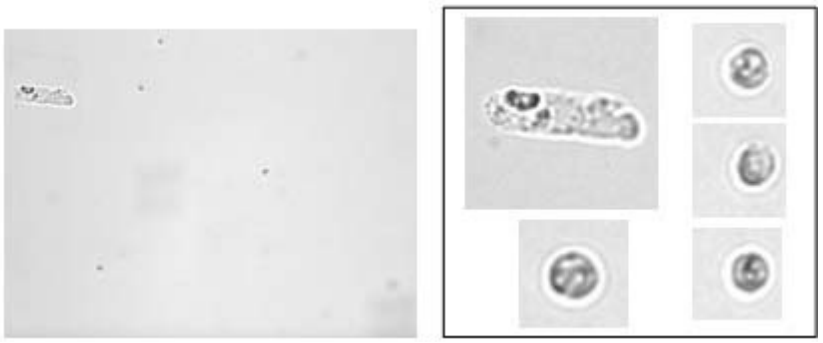
The sheath flow technology, high-speed photography technology and artificial intelligent recognition technology used for the analytical system are described as below.

63d., poz. 2

(1)Sheath flow technology: The sheath liquid, used by the analytical system for formed element analysis in the testing process, is isotonic, a granular solution with buffer function. The sheath liquid used for formed element analysis can ensure the formed element in urine sample solution always flows independently as a single layer. As flow cytometry is applied, it can be ensured that all formed elements will flow in front of the microscope lens and high-speed camera within the focus of microscope lens and be taken with pictures. Besides, as the urine flows in diffusion, aggregation of formed elements can be effectively prevented.

(2)High-speed photography technology: The urine sample wrapped in the sheath flows to the flow cell and passes the microscope lens in a form of flat laminar flow. Its thickness and position are just within the focus of microscope lens. According to the sheath flow type imaging principle, all particles will directly align to the lens in its maximum section area when they pass the lens. When the field of the microscope is lighted up by light source, all passing formed element will be instantly shot. In a certain time period, the high-speed camera will take many images with formed elements of all samples. As shown in the figure:

63d., poz. 10



63d., poz. 10

63d., poz. 3

Fig. 1-4-2

63d., poz. 2

(3)Artificial intelligent recognition technology: The automatic formed element recognition software and highly trained intelligent recognition technology can extract the images of formed element particles quickly and identify and classify them according to the shape, texture and characteristics in frequency domain of the shot particles. The analytical system can classify the particles into many classifications

(4)After the automatic formed element recognition software makes classification, the quantity of images of shot particles and the volume of scanned urine sample will be used to calculate the concentration of formed elements. The result can be represented by the number contained in per microliter or the number contained in per high power field/ low power field.

1.4.2 Turbidity test principle

The light emitted by the luminotron on turbidimeter will pass through the sample and forms an angle of 90 degrees with the incident light to detect how much light is scattered by the particles in the sample. This method used to measure the scattered light is called scattering method. The urine turbidity can be divided into four grades, clear, slightly turbid, turbid and seriously turbid.

The formula used for turbidity testing with the scattering method is as follows:

$$T = \frac{(S_s / T_s - S_w / T_w)}{K}$$

Wherein:

T: Turbidity grade

S_s: Urine sample scattered light intensity grade

T_s: Urine sample emitted light intensity grade

S_w: Detergent scattered light intensity grade

T_w: Detergent emitted light intensity grade

K: Coefficient factor

Chapter 3 Software installation

3.1 Software installation

⚠

- **Firebird-2.5.8 database shall be installed first before application software of the Analyzer.**
- **Users are advised to use the genuine Firebird-2.5.8 database. The company will not provide a database.**

(1) Cancel the system "Fast Start-up" function (only applicable to Win 10 system)

In the "Start" menu, select "Control Panel"-> "Power Options"-> "Select the power button function", and the interface is as shown in the figure:

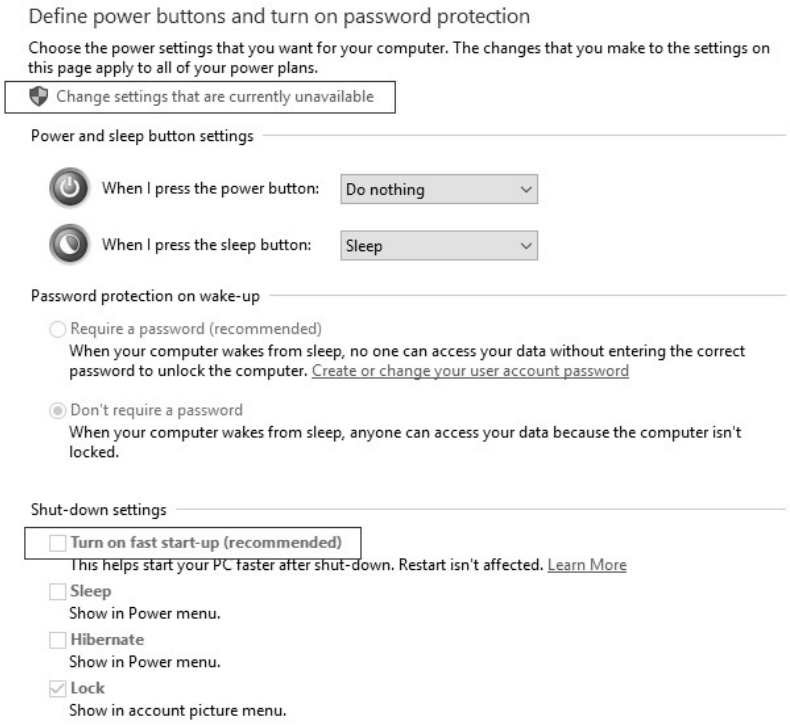


Fig. 3-1-1

Click "Change settings that are currently unavailable" and click to uncheck the "Turn on fast start-up (recommended)" function.

(2) Software installation

63d., poz. 4

The online software of the Analyzer shall be installed by professional personnel of the company and the user is not allowed to uninstall the software under normal conditions. If installation is required, operate as per the following steps:

Place the Analyzer application software installation package on the desktop of the computer, and double-click the installation package, and the interface is as shown in the figure:

Chapter 4 System setting

4.1 Overview

Via "Setup", some general settings of the software system can be realized, including instrument settings, FE settings, QC settings, automatic audit settings, one-key test settings, LIS settings, printing settings, data dictionary settings, basic settings and user settings.

Click 

in the main key area and the interface is as shown below:

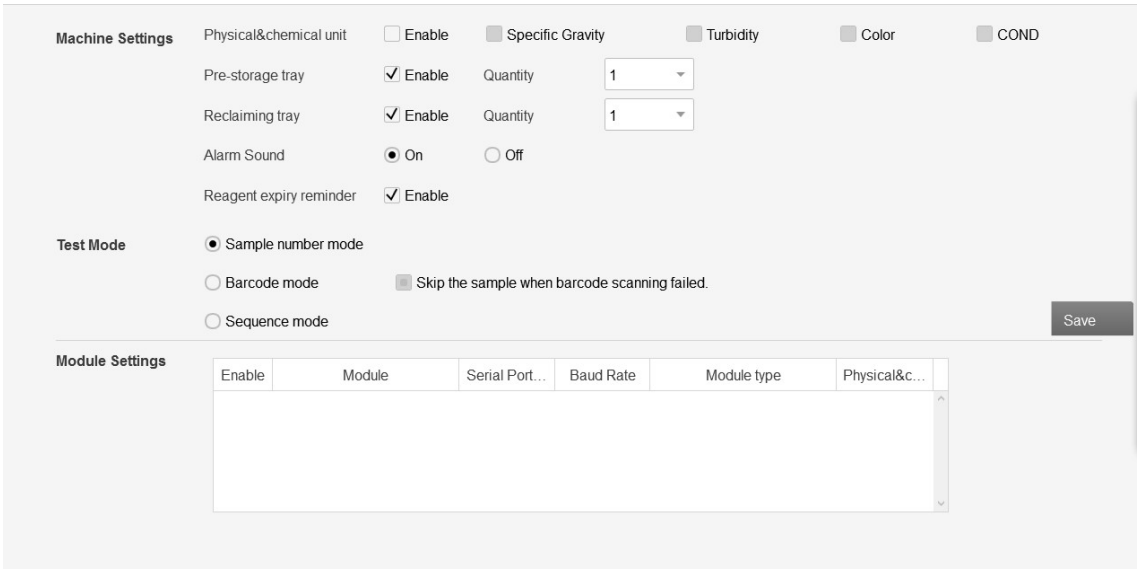
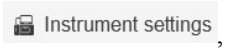


Fig. 4-1-1

4.2 Instrument settings

Click 

in the main key area and then 

, and the interface is as shown below:

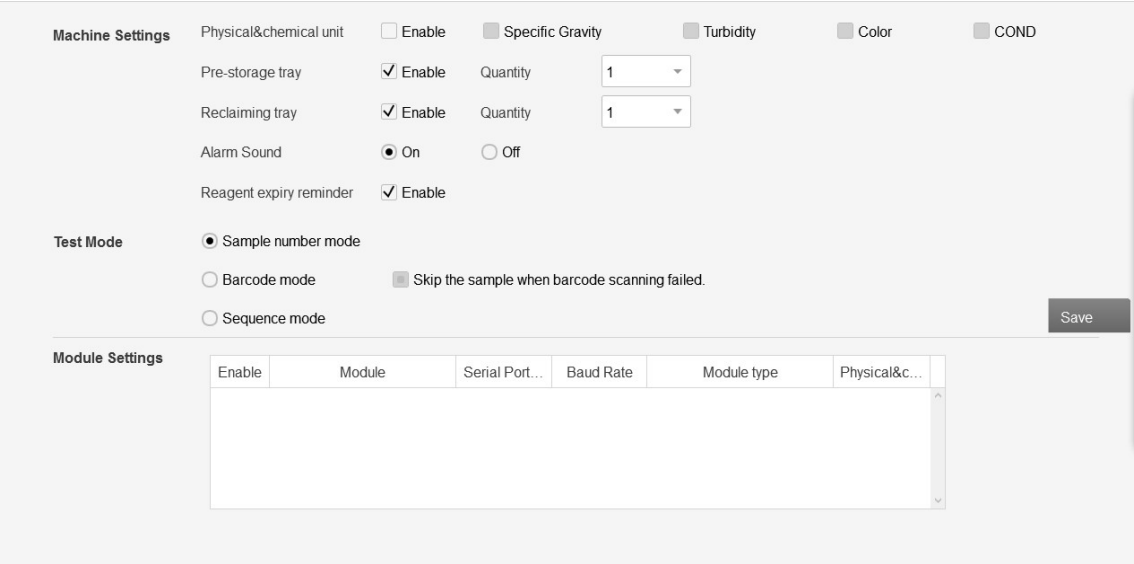


Fig. 4-2-1

Machine settings

(1) Alarm sound

In case of an alarm at the Analyzer, alarm icon "  " flickers. If an alarm sound is also needed to be given by the buzzer, select radio button "On" of alarm sound in the interface (Fig. 4-2-1). Thus double tips will be given in case of an alarm at the Analyzer.

(2) Reagent expiry reminder

If "Enable" is ticked and if the reagent is expired, an icon of reagent expiry will be displayed on the status bar at the bottom of the instrument, and a window reminding reagent expiry will pop up each time when the software is started. If "Enable" is not ticked, no prompt will be given.

63d., poz. 13

Test setting

(1) Sample number mode: If this mode is selected, the next sample number needs to be set each time before the test is sent. In this mode, the barcode number scanned by the barcode reader will be automatically filled in the barcode number box.

(2) Barcode mode: If this mode is selected, whether to skip the sample after a barcode scanning failure needs to be confirmed.

(3) Sequence mode: If this mode is selected, it only needs to send the test, without confirming the sample number.

Instrument settings

Display the current module information.

4.3 FE settings

Click 

in the main key area and then 

, and the interface is as shown below:

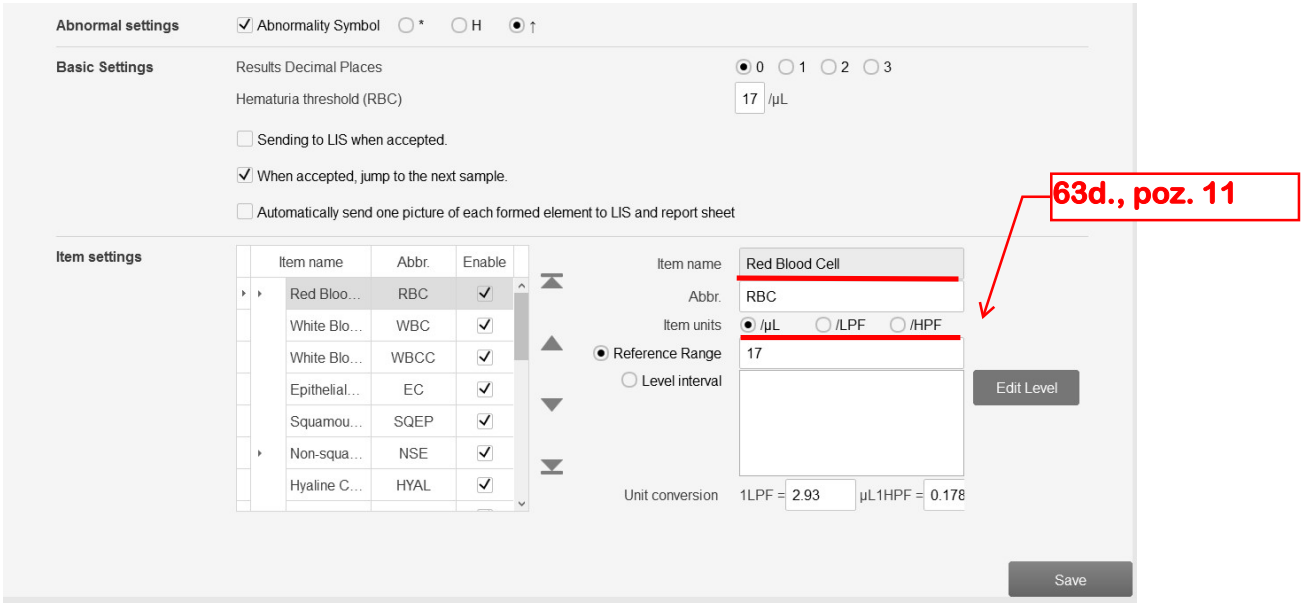


Fig. 4-3-1

(1) Abnormal settings:

If "Abnormality Symbol" is checked, when the formed element results of a certain item exceed the set critical value, the item will be marked with the abnormality symbol "*", "H" or "↑" according to the set value.

(2) Basic settings:

a) Results decimal places

Click to select the decimal places for the test results.

b) Hematuria threshold (RBC)

The hematuria threshold can be set, based on which if the red blood cells exceed the set value, it needs to set the value of red blood cells.

c) Sending to LIS when accepted

If "Sending to LIS when accepted" is chosen, click [Save] on the FE results interface, and the result will be sent to the LIS.

d) When accepted, jump to the next sample

If "When accepted, jump to the next sample" is chosen, click [Save] on the FE results interface, and it will automatically jump to the FE results of the next sample.

e) Automatically send one picture of each formed element to LIS and report

If "Automatically send one picture of each formed element to LIS and report sheet" is chosen, after the test is completed, a picture will be automatically sent to the LIS and the report sheet.

(3) Item settings

Select the item from the list on the left to edit the information of the corresponding test item.

a) Input the name (it can be either text or figures) of the item in the input box following "Item name".

b) Input the abbreviation (it can be either text or figures) of the item in the printed report in the input box following "Abbr.".

c) Select common unit from radio buttons following the "Item Units".

d) If the item is graded, select the radio buttons in front of "Level", and the interface is as shown below:

Chapter 6 Calibration management

6.1 FE focusing

To photograph and image the urine formed elements passing through the focusing plane of the microscope, the Analyzer should start focusing once a day and then test the sample, so that it can accurately classify the urine formed elements based on the particle size, morphology, contrast ratio and texture.

63d., poz. 3

(1) Preparation before focusing

a) Fill about 8mL of well-mixed FE Focus B (level 2) to a plastic test tube.

FE Focus B (level 2) shall be forcibly shaken for 1min~3min.

b) Place the test tube at the front end of the test tube rack.

(2) Precautions for focusing

a) The plastic test tubes in the accessory case shall be used for the focusing test.

b) To ensure the photographed image is clear, the focusing solution designated by Dirui shall be used.

c) Focusing should be executed after the Analyzer is started up for the first time every day.

(3) Focusing test

a) Click [Focus Reg.] to register the focusing solution.

b) Place the test tube rack on the right side of the sample feeding unit, click Calibration in the main key area of the software, and the interface is as shown below:

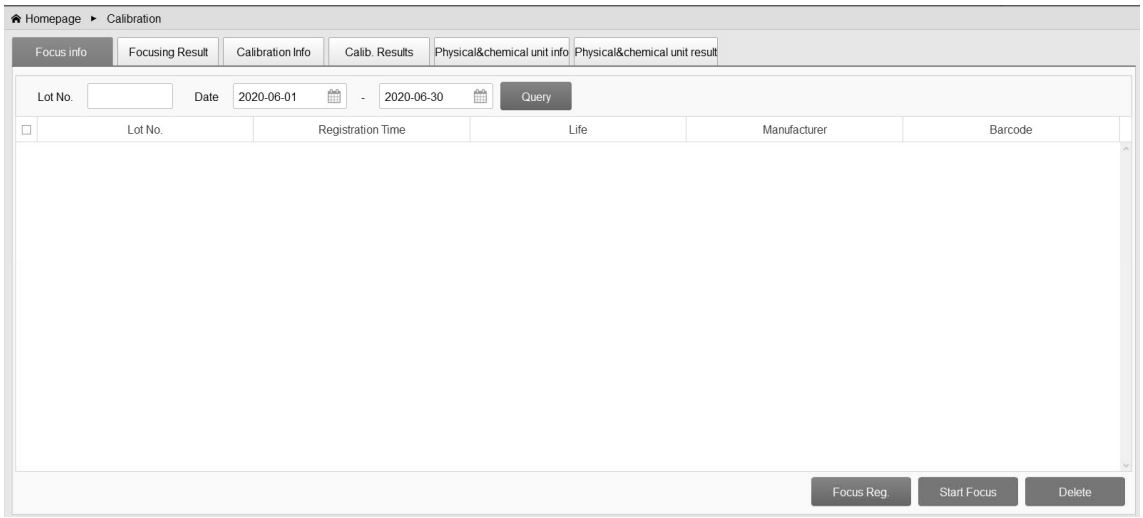


Fig. 6-1-1

c) Click to select the registered focusing solution information from the list, then click [Start Focus], and the sample suction probe will start aspirating samples automatically. After focusing succeeds, the Analyzer will automatically test the blanks, and then enter the standby state.

d) In case of focusing failure, "focusing failed" will be prompted on the screen. At this time, do not conduct sample test and restart focusing. If the focusing still fails, please contact Customer Service Department or agent of Dirui Company.

(4) Printing of focusing records

Click Focusing Result, and then click [Print] below the focusing result list, a print preview report sheet will pop up.

6.2 FE calibration

(1) Storage of calibrators

a) The calibrator is a solution containing aldehydated erythrocytes and the number of cells is the number of particles on the label of the reagent bottle.

b) The calibrator shall be stored at 2℃~8℃ and be balanced to room temperature before use.

c) The calibrator shall not be used once frozen.

(2) Use of calibrators

a) Shake well before use: turn the calibrator bottle upside down and shake it vigorously for 1min~3min.

FE Calibrator II shall be shaken vigorously for 1min~3min before use.

b) The calibrator shall be immediately used after being uncapped. It can only be used once and the remaining amount cannot be used. Calibrators of different lots cannot be used in a mixed manner.

(3) Analyzer calibration frequency

63d., poz. 8

The Analyzer shall at least be calibrated once a month and start focus once before the calibration.

(4) Preparations for calibration

a) FE Calibrator II in the same bottle shall be mixed and then poured into 3 test tubes (≥4mL for each tube), and each test tube shall be tested twice.

b) The three test tubes shall be placed in turn on the test tube rack.

(5) Precautions for calibration

a) The plastic test tubes in the accessory case should be used for the calibration test.

b) To ensure the calibration effect, please use the calibrator designated by Dirui Company.

(6) Calibration test

a) Click [Calib. Reg.] to conduct calibration registration in accordance with the user manual of calibrator.

b) Place the test tube rack on the right side of the sample feeding unit, click Calibration Info, and the interface is as shown below:

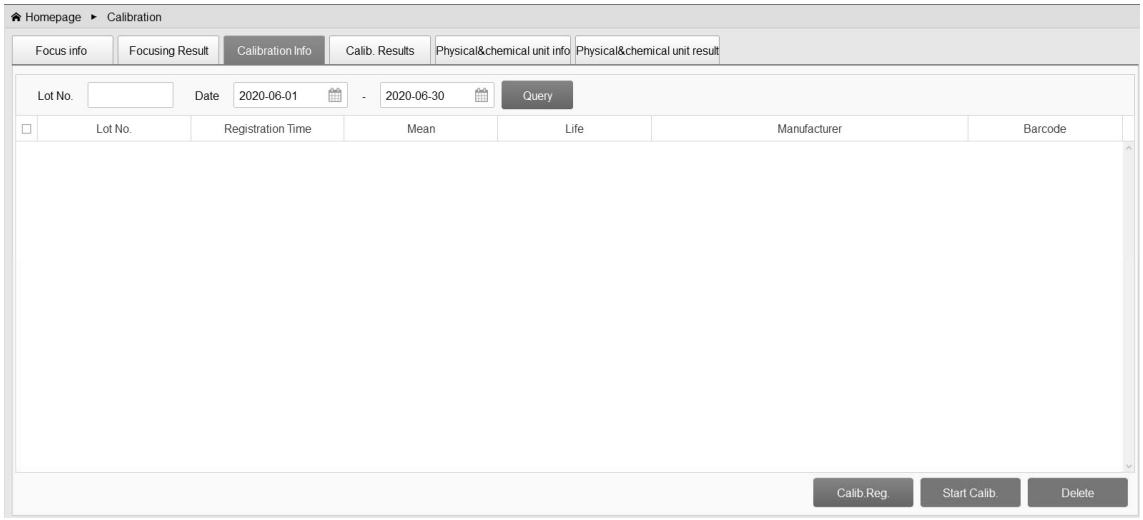


Fig. 6-2-1

Chapter 7 QC Management

7.1 Overview

The quality control (QC) program is designed to verify and test the analytical correctness of Analyzer by testing the urine requiring quality control and collecting the QC data.

The purpose of QC is to ensure the accuracy and repeatability of test results.

7.1.1 About QC

$\bar{x}$ (mean): the arithmetic mean of a set of figures calculated as per the formula below:

$$\overline{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

SD (standard deviation): a statistical method describing the dispersion degree of a group of measured values calculated as per the formula below:

$$SD = \sqrt{\frac{\sum_{i=1}^{n} (X_i - \overline{X})^2}{n-1}}$$

Where: n is the number of tests, and X_i is the measured value of each time.

CV value (variable coefficient): the ratio between standard deviation and mean, another statistical figure reflecting the variation degree of the measured values, which is calculated as per the formula below:

$$CV = \frac{SD}{\overline{X}} \times 100\%$$

7.1.2 QC rules

The judgment should be made according to the QC range type and QC judgment rule set in Setup - QC settings - FE.

(1) When the QC range type is "Upper limit and lower limit", if the test result exceeds the upper limit or lower limit, QC fails.

(2) When the QC range type is "Mean SD value", the judgment rule of QC result is described as follows:

1-1S: when this judgment rule of QC results is selected, the test results exceeding $\overline{X}$ ±1SD mean failure.

1-2S: when this judgment rule of QC results is selected, the test results exceeding $\overline{X}$ ±2SD mean failure.

1-3S: when this judgment rule of QC results is selected, the test results exceeding $\overline{X}$ ±3SD mean failure.

7.2 QC solution

(1) QC solution of the Analyzer

a) QC solution is used for the quality control of measurement results of the Analyzer; positive control, as an abnormal QC type and negative control, as a normal QC type, are both used to verify if the Analyzer can correctly measure or count values.

63d., poz. 9

b) FE positive control is a solution with fixed quantity of RBC in ionic-equilibrium liquid. The quantity of cells is the particle number noted on the label of positive control.

c) The FE negative control is a solution that does not contain granules.

d) The QC solution must be stored at a cold place but it cannot be frozen. It must be balanced to room

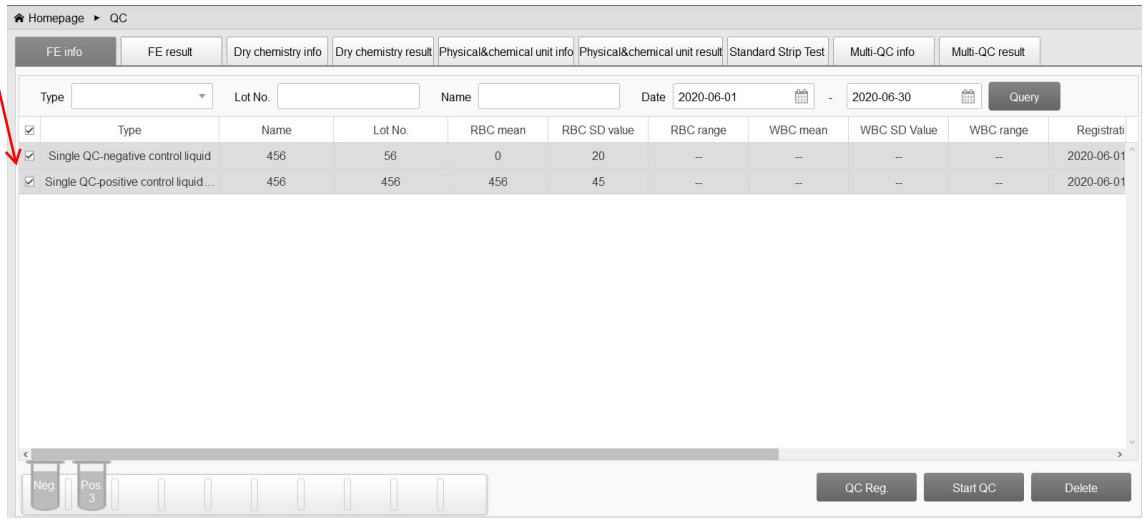


Fig. 7-4-1

7.4.1 FE QC registration

In Fig. (7-4-1), click [QC Reg.], as shown in the following figure:

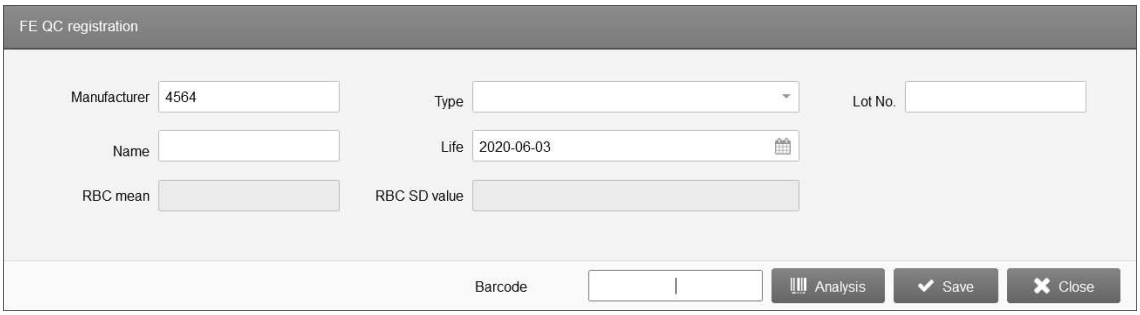


Fig. 7-4-2

(1) Manual addition of QC items

a) Input the name of manufacturer in the input box of "Manufacturer".

b) Select the correct QC type from the pull-down list of "Type".

c) Input the corresponding parameters in the input boxes of "Lot No." and "Name".

d) Click the pull-down list following "Life" and a dialog box as shown below will pop up:

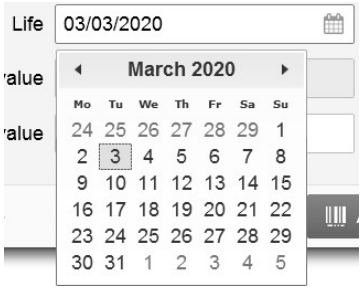


Fig. 7-4-3

Correctly select the date according to the validity period noted on QC manual.

e) Input the corresponding parameters in the input boxes following "RBC mean", "RBC SD value", "WBC mean" and "WBC SD value".

(3) LIS transmission

Click [LIS Trans.] to transmit the selected QC results manually to LIS server. If open LIS, and select bidirectional LIS test to send. After the QC is finished, the results will be sent to LIS server automatically.

(4) FE QC Diagram

Click [QC diagram] at the lower right corner on the interface, and the display is as shown below:

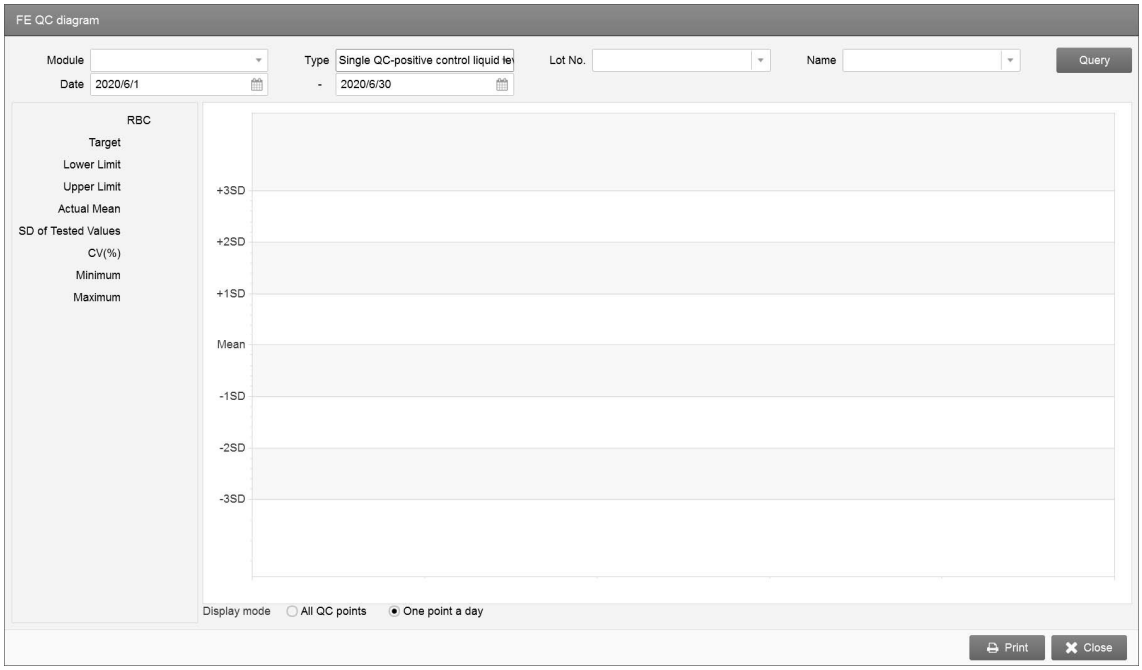


Fig. 7-4-7 (QC diagram of single-QC)

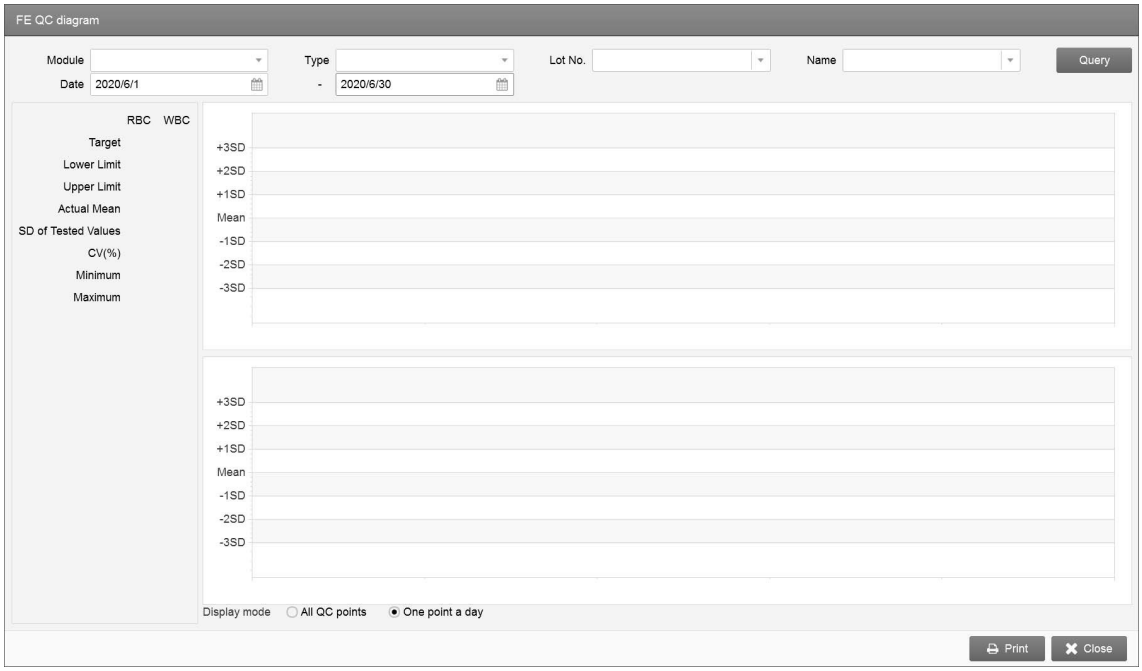


Fig. 7-4-8 (QC diagram of multi-QC)

(1) About QC diagram

63d., poz. 9

a) The display modes of the QC diagram include "All QC points" and "One point a day".

b) The abscissa of the QC diagram in the mode of all QC points represents the date of the QC, and the ordinate represents the QC line. The abscissa of the QC diagram in the mode of one point a day represents the QC date and the ordinate represents the QC line.

c) Each point in the QC diagram corresponds to a QC result and the points are connected by line sections.

(2) Check and print QC diagram

63d., poz. 9

a) Select the QC type to be queried from the pull-down list after "Type", select the QC lot No. to be queried from the pull-down list after "Lot No.", select the QC name to be queried from the pull-down list after "Name", click the control after "Date" to select the start date and end date to be queried, and the query results will be displayed on the QC diagram.

b) Click [Print] to complete the printing of the QC diagram.

⚠

- **Only the results of current day can be rechecked.**
- **Samples having failed to be tested will be automatically added to the recheck list.**

8.5 Test results

On the list of test information on the interface "Samples", click the line where the test results are located in the list box on the left, and the corresponding right side will be displayed as two tabs, sample info and result info. Select the tab of result info, and the corresponding test results will be displayed on the right side of the screen.

Double-click to select the sample information that the test has completed to view the test results, as shown in the figure below:

Fig. 8-5-1

(1) The FE results are displayed on the left where the FE results and threshold range can be checked. Results within normal range are green and results within abnormal range are red and displayed in red in exceeding display area.

(2) The sample information section in the upper right corner displays the sample number, test date, rack number, tube number, barcode number, granule sum and red blood cell information.

(3) The explanation of composition indicators is shown in the upper right corner. Possible reasons for yellow alarm: if the sample is marked in yellow, the possible reasons for causing the yellow alarm can be displayed in the right box, such as "conform to mixed red blood or non-isomorphic red blood cells", "conform to microscopic examination condition", and "conform to urine culture prompt condition".

(4) Click [Previous] or [Next] to review other sample test results.

(5) After FE manual classification, if there is no need to save, click [Restore] to restore the original test results.

(6) After classifying the formed elements, click [Save] to save them, and a prompt box indicating "Sample review succeeded" will pop up, and the review mark will appear in the review column of the sample list.

(7) Click [Panorama View], move the mouse over the cell image on the interface to display an image with cells being three times larger. Double-click the color mark box in front of a test item (such as white blood cells) on the right of the panorama view window, and the color selection window will pop up, where the mark color (such as red) can be set or modified. Click [OK], and all white blood cells will be marked with red borders on the panorama view interface.

8.5.1 Preview test item images

63d., poz. 10 ir 11

Double click the FE result with cell mark, and the image of granules will be zoomed in and display on the screen. Double check "WBC" and the figure below will display:

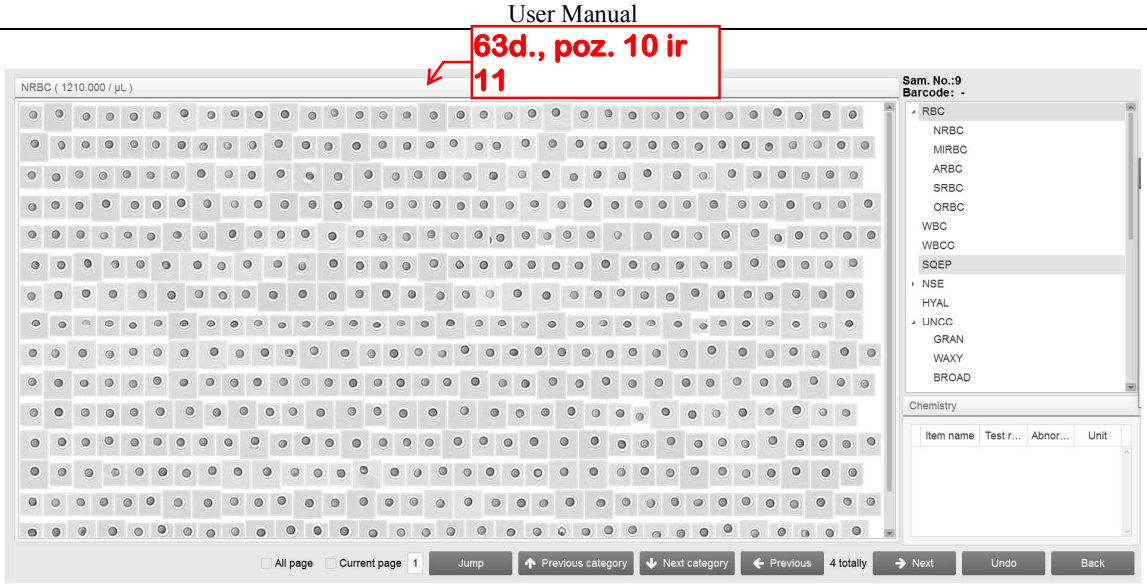


Fig. 8-5-2

(1) Add images in the report

Select the images of the typical test item, right click, and 

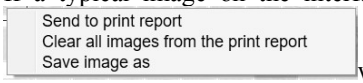
will pop up, then select "Send to print report", and left click to send the images to the remark column in the report list.

(2) Clear images from the report

If the typical images of all items sent to the print report are mis-operated, choose "Clear all images from the print report" from the 

menu having popped up, and images sent to the print report can be deleted and then new images can be added again.

(3) Save typical images

If a typical image on the interface needs to be saved, select the image, click the right mouse button, and 

will pop up, and then select "Save image as", and select the storage path to save the image to the selected location.

8.5.2 Manual classification of images

63d., poz. 12

In case of false identification, the images can be reclassified and the operations are as follows:

Select the image inconsistent with the name of formed elements on the interface, click the corresponding category button on the right side of the screen to reclassify, click [Back] to go back to interface as shown in Fig. 8-5-1, then click [Save] to confirm and save the above changes.

• If "When accepted, jump to the next sample" is selected from "Setup"→"FE settings", after the operation above is completed, jump to the next sample and carry out manual classification of the next sample.

• If "Sending to LIS when accepted" is selected from "Setup" → "FE settings", and the result will be sent to LIS at the same time after completing the operation above.

In above steps, if an option has been dragged but with an operation error, such operation can be canceled by pressing [Restore] in the interface (Fig. 8-5-1) before [Save] is clicked.

The following items can be automatically identified:

Normal red blood cell, microcyte, acanthoid erythrocyte, erythrocyte ghost, other poikilocytes, WBC, white blood

OBX|1|NM|123|Name|10||9-12|Pass|11||F||Sediment|2012-05-30 15:50:49<CR>

Acknowledgement response from LIS to Urine Sediment Analyzer:

MSH|^~\&|LIS|^Sediment^^|FUS-360||20120601155123||ACK|ACK0000002|P|2.3<CR>

MSA|AA|QC0000000<CR>

7.4 Transmission of multi-QC results

Multi-QC result message from Urine Sediment Analyzer to LIS:

MSH|^~\&|FUS-360|^Sediment^^|LIS||20120601161014|| ORU^R01|QC0000000|P|2.3<CR>

OBR||||FUS-360|||20120601161014<CR>

OBX|1|NM|123|Name|34|Manufacturer|10-50-100||34|RBC|F|MultiQC|Sediment|2012-05-23 16:09:50<CR>

OBX|3|NM|123|Name|67|Manufacturer|10-50-100||67|WBC|F|MultiQC|Sediment|2012-05-23 16:09:50<CR>

OBX|5|NM|123|Name|23|Manufacturer|10-50-100||23|UNCX|F|MultiQC|Sediment|2012-05-23 16:09:50<CR>

OBX|7|NM|123|Name|75|Manufacturer|10-50-100||75|CAST|F|MultiQC|Sediment|2012-05-23 16:09:50<CR>

Acknowledgement response from LIS to Urine Sediment Analyzer:

MSH|^~\&|LIS|^Sediment^^|FUS-360||20120601161014||ACK|ACK0000007|P|2.3<CR>

MSA|AA|QC0000000<CR>

7.5 Transmission of chemistry QC results

Chemistry QC result message from Urine Sediment Analyzer to LIS:

MSH|^~\&|FUS-360|^^Chemistry^|LIS|neg|20120601161654|| ORU^R01|QC0000001|P|2.3<CR>

PID|||1||||M<CR>

OBX|1|NM|Date:||^^^2012-05-26 09:55 27^^-1^|||||||Chemistry|20120601161654|||<CR>

OBX|2|NM|No.||^^^1^^-1^|||||||Chemistry|20120601161654|||<CR>

OBX|3|NM|ID||^^^^^-1^|||||||Chemistry|20120601161654|||<CR>

OBX|4|NM|RackTubeNO.||^^^1- 1^^-1^|||||||Chemistry|20120601161654|||<CR>

OBX|5|NM|UBG||^^^Normal 3.4^umol/L^0^|||||||Chemistry|20120601161654|||<CR>

OBX|6|NM|BIL||^^^Neg^^0^|||||||Chemistry|20120601161654|||<CR>

……

Acknowledgement response from LIS to Urine Sediment Analyzer:

MSH|^~\&|LIS|^^Chemistry^|FUS-360|neg|20120601161654||ACK|ACK0000008|P|2.3<CR>

MSA|AA|QC0000001<CR>

8. Test results from Urine Sediment Analyzer to LIS

8.1 Sediment test result

Note: items without results are not transmitted.

Test items	Description of test items
RBC	Red blood cells
NRBC	Normal red blood cell
MIRBC	Microcyte
ARBC	Acanthoid erythrocyte
SRBC	Erythrocyte ghost
ORBC	Other poikilocytes
WBC	White blood cells
WBCC	White blood cell cluster

Test items	Description of test items
SQEP	Squamous epithelial cell
NSE	Non-squamous epithelial cells
RTEP	Renal tubular epithelial cell
TREP	Transitional epithelial cell
STEP	Superficial transitional epithelial cells (big-round epithelial cells)
CAEP	Middle transitional epithelial cells (tail-shape epithelial cells)
UTEP	Underlying transitional epithelial cells (small-round epithelial cells)
BACI	Bacillus
SUCO	Suspected coccus
XTAC	Crystal
CAOX	Calcium oxalate crystal
URIC	Uric acid crystal
OCRY	Other crystals
CACB	Calcium carbonate crystal
CAPH	Calcium phosphate crystal
CYST	Cystine crystal
LEUC	Leucine crystal
TYRO	Tyrosine crystal
MAPH	Magnesium ammonium phosphate crystal
BILI	Bilirubin crystal
CHOL	Cholesterol crystal
DRUG	Drug crystal
HYAL	Hyaline cast
RBCT	Red blood cell cast
GRAN	Granular cast
WBCT	White blood cell cast
RTEPT	Renal tubular epithelial cell cast
MIXT	Mixed cell cast
HEMT	Hemoglobin cast
BILT	Bilirubin cast
BACTT	Bacterial cast
WAXY	Waxy cast
FATC	Fatty cast
BROAD	Broad cast
UNCC	Pathological cast
OCAS	Other cast
HYST	Pseudohypha
BYST	Yeast

Test items	Description of test items
MUCS	Mucus
SPRM	Sperm
RBCInfo	Red blood cell information (empty, isomorphic, mixed or non-isomorphic red blood cells)
RBCPer	Abnormal red blood cell percentage

63d., poz. 11

8.2 Chemistry test result

Note: items without results are not transmitted.

Test items	Description of test items
UBG	Urobilinogen
BIL	Bilirubin
KET	Ketone body
BLD	Occult blood
PRO	Protein
NIT	Nitrites
LEU	White blood cells
GLU	Dextrose
SG	Specific Gracity
pH	pH
VC	Ascorbic acid
MALB	Microalbumin
TURB	Turbidity
COLOR	Color
CRE	Creatinine
Ca	Urinary calcium
A:C	Microalbumin/creatinine ratio
COND	Conducibility

8.3 Single QC result

Test items	Description of test items
Total particles	Total aldehyde cock red cell particles

8.4 Multi-QC result

Note: items without results are not transmitted.

Test items	Description of test items
RBC	Red blood cells
WBC	White blood cells
UNCX	Crystal
CAST	Casts

cell cluster, non-squamous epithelial cell, renal tubular epithelial cell, transitional epithelial cell, hyaline cast, granular cast, waxy cast, broad cast, other casts, lactobacillus, suspected coccus, pseudohypha, microzyme, calcium oxalate, uric acid crystal, magnesium ammonium phosphate crystal, other crystals, sperm and mucous strands.

The following items can be manually identified:

Other crystals	Casts
Calcium phosphate crystal	Hemoglobin cast
Calcium carbonate crystal	Mixed cell cast
Cystine crystal	Bacterial cast
Leucine crystal	Fatty cast
Tyrosine crystal	Red blood cell cast
Bilirubin crystal	White blood cell cast
Cholesterol crystal	Renal tubular epithelial cell cast
Drug crystal	Bilirubin cast

8.5.3 Descriptions of test result alarms

Description of RBC alarm in test result:

Isomorphic RBC: the number of NRBC ≥80% or the type of RBC =1

Mixed RBC: the number of NRBC ≥20% and < 80% and the type of abnormal RBC ≥2.

Non-isomorphic RBC: the number of NRBC < 20% and the type of abnormal RBC ≥2.

8.5.4 Modification of test results

63d., poz.12

If test results are not consistent with the microscopic examination results, they can be modified as below:

(1) Modification of FE results:

Double-click the row where the "Result" column of formed elements is located in the result information on the right side of the interface to display the result editing interface, as shown in the figure:

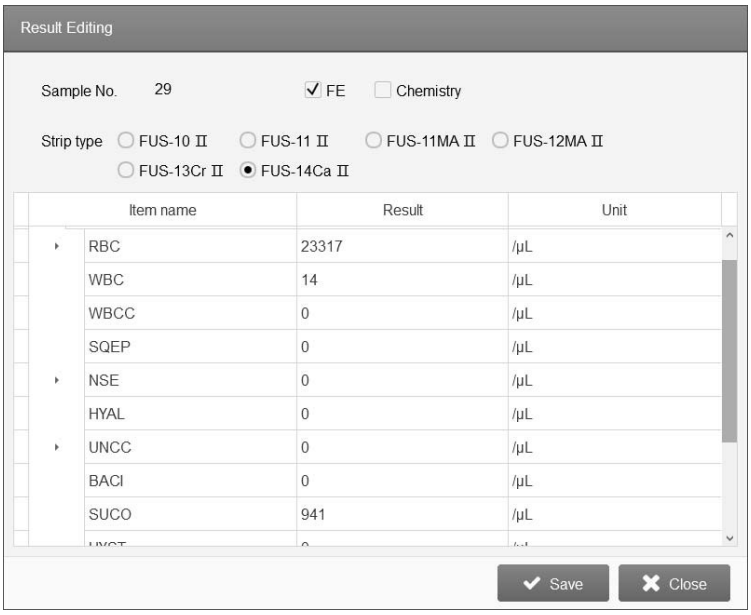


Fig. 8-5-3