6. Reagents Specifications

In order for the instrument to operate correctly, high-quality reagents must be used.

HORIBA Medical provides a full range of reagents.

These reagents are used for *in vitro* diagnostic.

All these reagents are manufactured by **HORIBA ABX SAS**.

Refer to the reagent notices and material safety data sheets for Yumizen H550E available online at www.horiba-abx.com/documentation.

The reagents specified for this instrument have been approved in accordance with the applicable *in vitro* medical devices European legislation in force.

HORIBA Medical manufactures and markets reagents, calibrators and controls specially designed for use with this analyzer. The use of products not recommended may give erroneous results or cause instrument operation problems. For all information regarding the recommended products, please contact your local representative.

6.1. Reagents Location

Risk of erroneous results if the diluent container is not at the same level as the instrument. The diluent container must be installed at the same level as the instrument (on the bench).

- **Diluent input tubing:** tygon 3x6 / 1 meter (40 in.) maximum
- **Waste output tubing:** cristal 4x6 / 2 meters (80 in.) maximum.

1.4. Samples Management

- Autonomy: 40 tubes (four racks with a ten tubes capacity)
- Loading: continuous loading
- Mixing: automatic mixing of racks
- Tube identification: positive identification of tubes

1.5. Computer Characteristics

- Color LCD touch screen: 12.1 in.
- Operating System: Linux™
- Processor: Qseven module based on NXP i.MX 6QuadPlus
- RAM (Random Access Memory): 2 GB
- Storage Technology: 16 GB MicroSD + 4 GB eMMC Flash
- RS232, Ethernet, USB connections
- Capacity: 10000 results

1.6. Tube Identification

Tube identification can be done by using either:

- an external USB keyboard (optional)
- the virtual keyboard
- the integrated barcode reader
- an external barcode reader (optional)

Risk of erroneous diagnosis due to patient misidentification if tubes are not barcoded.
Use barcoded tubes only.

HORIBA Medical recommends that barcodes with integrated check digit be used with the Yumizen H550E.

2. Connection

2.1. Serial Connection (RS232)

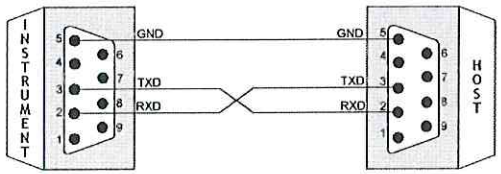
2.1.1. RS232 Connection Overview

The RS232 connection mode is available only for the ASTM format on the Yumizen H550 / Yumizen H550E.

Communications can use the RS232 communication protocol, based on the Electronics Industries Association (EIA) standard RS232-C. As part of the conformance to this standard, the Yumizen H550 / Yumizen H550E Data Management System is configured as Data Terminal Equipment (DTE).

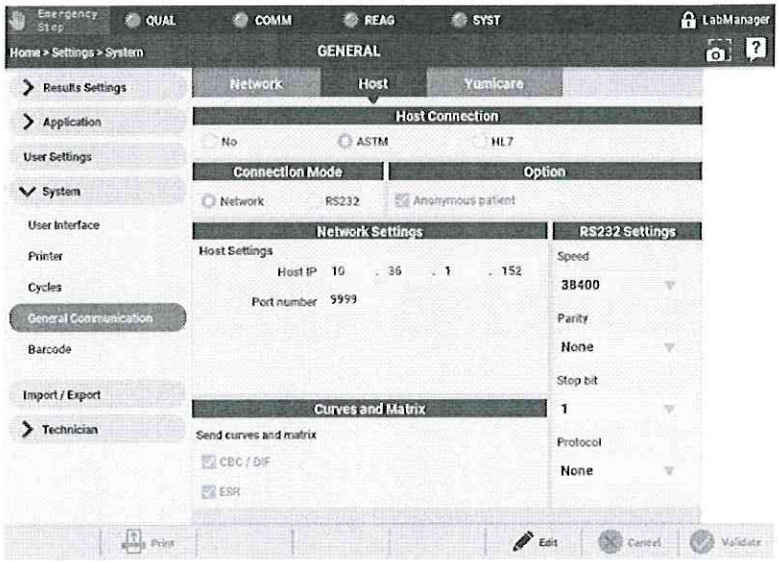
The Yumizen H550 / Yumizen H550E should be connected to the Host via the DB-9 connector of the instrument computer connection.

Pin (DB-9) data management	Host port configuration	Host cable must provide
2	RXD	TXD
3	TXD	RXD
5	Ground	Ground



2.1.2. To Configure the RS232 Connection Mode

*Access: **Home** > **Settings** > **System** > **General Communication** > **Host***



1. Press **Edit** in the contextual toolbar.
2. Select the **ASTM** connection format and select the **RS232** connection mode.
3. Configure the instrument communication port in the ***RS232 Settings*** area.

Option	Function	Default value
Speed	Speed transmission selection	38400
Parity	Parity selection	None

CBC Parameters	LOINC Code	Definition
MCV	787-2	Mean Corpuscular Volume
MCH	785-6	Mean Corpuscular Hemoglobin
MCHC	786-4	Mean Corpuscular Hemoglobin Concentration
RDW-SD	21000-5	Red Distribution Width Standard Deviation
RDW-CV	788-0	Red Distribution Width
MIC	X-MIC	Microcytic Red Blood Cells percentage (versus RBC)
MAC	X-MAC	Macrocytic Red Blood Cells percentage (versus RBC)
PLT	777-3	Platelets
PCT	51637-7	Plateletcrit
PDW	51631-0	Platelets Distribution Width
MPV	32623-1	Mean Platelet Volume
P-LCC	96354-6	Platelets - Large Cell Count
P-LCR	48386-7	Platelets - Large Cell Ratio
WBC	6690-2	White Blood Cells

DIFF Parameters	LOINC Code	Definition
LYM#	731-0	Lymphocytes absolute value
LYM%	736-9	Lymphocytes percentage
MON#	742-7	Monocytes absolute value
MON%	5905-5	Monocytes percentage
NEU#	751-8	Neutrophils absolute value
NEU%	770-8	Neutrophils percentage
EOS#	711-2	Eosinophils absolute value
EOS%	713-8	Eosinophils percentage
BAS#	704-7	Basophils absolute value
BAS%	706-2	Basophils percentage
IMG#	53115-2	Immature Granulocytic cells absolute value
IMG%	71695-1	Immature Granulocytic cells percentage
IMM#	X-IMM#	Immature Monocytic cells absolute value
IMM%	X-IMM%	Immature Monocytic cells percentage
IML#	X-IML#	Immature Lymphocytic cells absolute value
IML%	X-IML%	Immature Lymphocytic cells percentage
ALY#	43743-4	Atypical Lymphocytes absolute value
ALY%	42250-1	Atypical Lymphocytes percentage
LIC#	55432-9	Large Immature Cells absolute value
LIC%	55433-7	Large Immature Cells percentage

ESR Parameters	LOINC Code	Definition
ESR	82477-1	Erythrocyte Sedimentation Rate

1.3. Throughput Analyses

The rate of analysis for the Yumizen H550E is 60 +/- 3 samples per hour.

1. Technical Specifications

1.1. Intended Use

Yumizen H550E classifies and enumerates the following parameters in whole blood:

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC, PLT, MPV, PCT, PDW, P-LCC, P-LCR, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, ALY#, ALY%, LIC#, LIC%, IML#, IML%, IMM#, IMM%, IMG#, IMG%, ESR.

Yumizen H550E provides information for *in vitro* diagnostic use in clinical laboratories.

Yumizen H550E analyzer is used for screening a physiological state (quantitative or qualitative hematology abnormality detection) or a pathological state of patient populations found in clinical laboratories.

Yumizen H550E analyzer is quantitative for parameters measurement and qualitative for alarms detection.

Yumizen H550E analyzer is intended to perform tests on the following specimens:

- venous blood (CBC / DIFF / ESR)
- capillary blood (CBC / DIFF)

collected in K2-EDTA and K3-EDTA anticoagulants.

Yumizen H550E analyzer is intended to perform tests on the following specimens:

Pediatric

- New born: from birth to 28 days (only: CBC / DIFF)
- Infant: from 29 days to 2 years (only: CBC / DIFF)
- Children: from 2 years to 12 years (CBC / DIFF / ESR)
- Adolescent: from 12 years to 18 years (CBC / DIFF / ESR)

Adult population

- Above 18 years (CBC / DIFF / ESR)

1.2. Parameters

LOINC Code: Logical Observation Identifiers Names & Codes

CBC Parameters	LOINC Code	Definition
RBC	789-8	Red Blood Cells
HGB	718-7	Hemoglobin Concentration
HCT	4544-3	Hematocrit

1 = ABX Minoclair

2 = ABX Cleaner

3 = Whitediff 1L

4 = ABX Diluent

5 = Waste tank

6.2. Reagents Description

- You must verify the period of stability mentioned in the reagent notices and dispose of them when they exceed the expiration date to ensure correct results.
- Make sure that your new reagents return to the operating conditions temperature before use.
- Always close your reagent container during use. Use the appropriate operational caps provided with the instrument. Put the original caps back when you remove the reagents from the machine.
- Never pour reagents into the laboratory waste water drainage system. Follow local/ national regulations for chemical waste disposal.

Yumizen H550E

Our company recommends that you use the following reagents on your Yumizen H550E:

Reagent name	Volume	Use
ABX Diluent	10 L[a] 20 L	Dilution, sleeving and rinsing: RBC/PLT Blank measurement: ESR
ABX Cleaner	1 L (integrated)	Cleaning
Whitediff 1L (cyanide free)	1 L (integrated)	Measurement: HGB Differentiation: WBC
ABX Minoclair	0.5 L (non-integrated)	Concentrated cleaning procedure

[a]: If you want to use this reagent volume, contact your HORIBA Medical technical representative.

1. Quality Control

Quality Control allows the user to monitor a set of analyses based on known sample values and ranges over a period of several months. Statistical computations performed on these populations allow the extraction of qualitative information related to the stability of the instrument.

The following control type(s) should be used:

Name	Levels	Parameters
ABX Difftrol	3	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, LYM, MON, NEU, EOS, BAS, IMG
ESRtrol	2	ESR

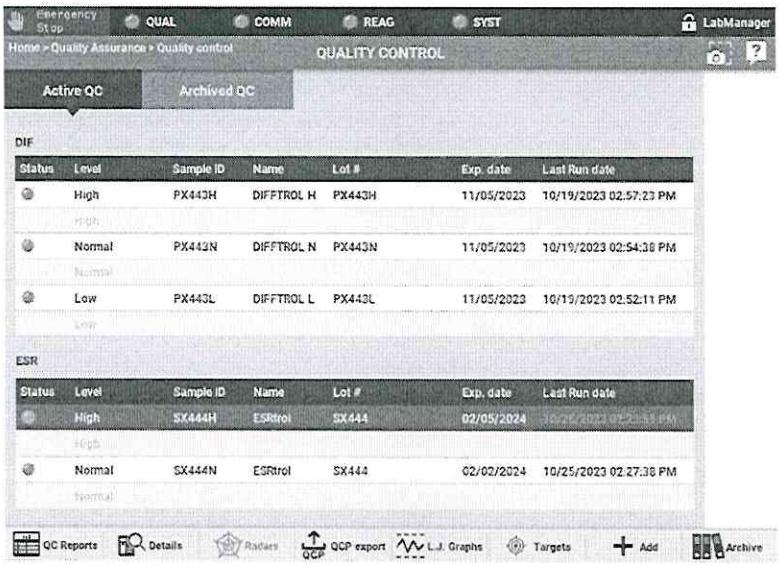
All control levels can be simultaneously active allowing QC on all levels.

Quality control overlap allows you to configure two active control lots on the instrument.

1.1. Quality Control Overview

*Access: **Home** > **Quality Assurance** > **Quality control***

The ***Quality control*** menu is made of two tabs: one for active control blood samples, another for archived control blood samples.



In the ***Active QC*** screen, each control is displayed with a circle in front of it. This circle gives you information about the status of the control:

PASSED: Control blood sample results are within the tolerance range. Analyses can be run if all three levels have passed.

ACCEPTED: Control blood sample results were manually validated by the user. Analyses can be run if a level is accepted but the results are flagged.

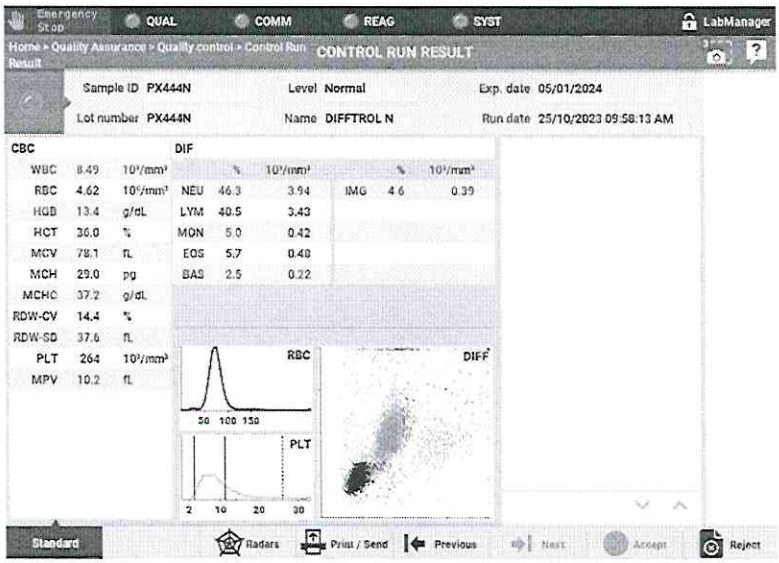
FAILED: Control blood sample results are not within the tolerance range. Analyses cannot be run if at least one of the levels has failed. You can manually validate a failed control result so that it appears as accepted.

Control Run Result

Pressing **Details** displays the ***Control Run Result*** screen.

The ***Control Run Result*** screen shows you the results of the control blood sample run.

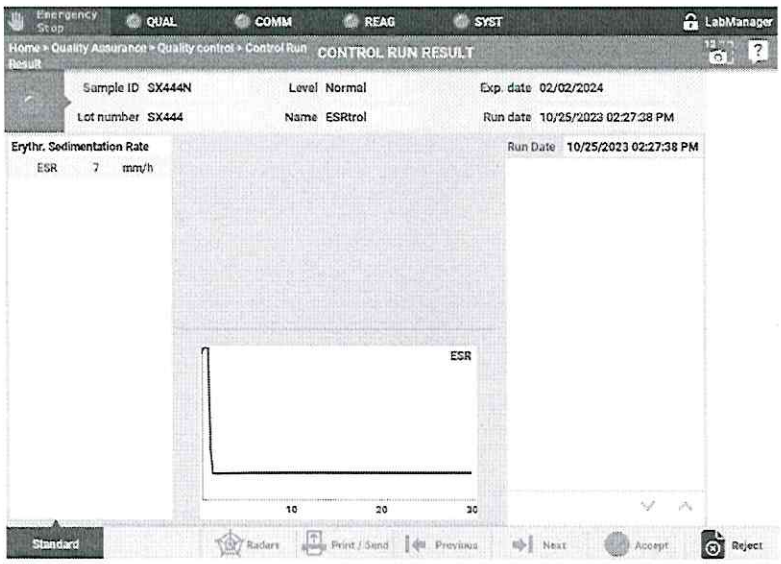
CBC / DIFF



This screen contains the following information:

- Information about the control blood sample.
- Results and matrices (RBC / PLT).
- Results (WBC) and 5 DIFF matrix.
- Alarms.

ESR



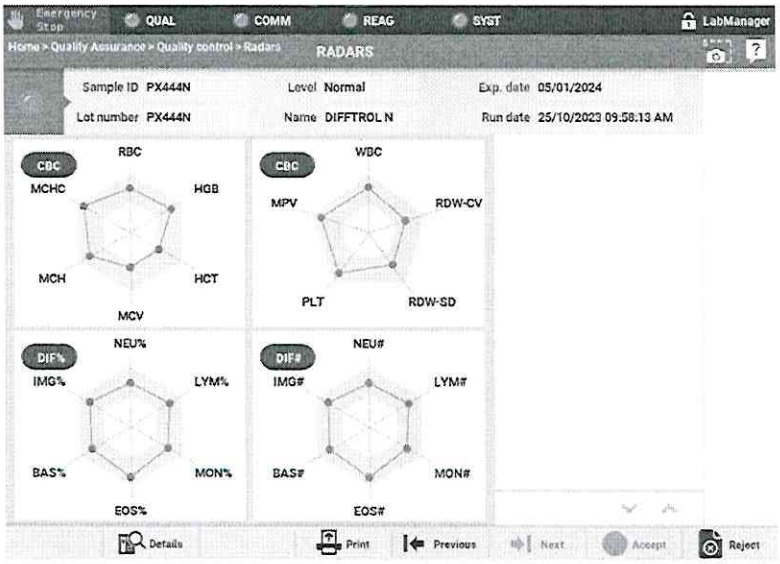
This screen contains the following information:

- Information about the control blood sample.
- Result and syllectogram (ESR).
- Alarms.

Radars

Pressing **Radars** displays the ***Radars*** screen.

The ***Radars*** screen displays the radar graphs corresponding to the control blood sample.

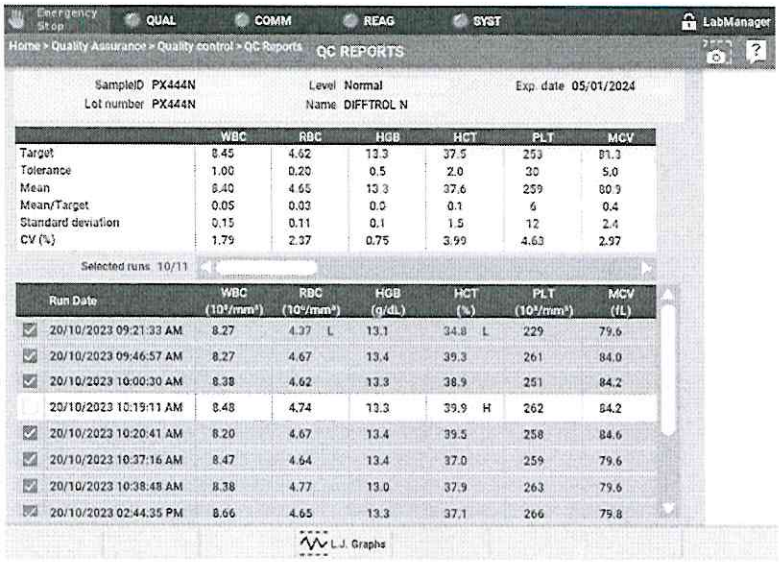


This screen contains the following information:

- Information about the control blood sample.
- Radar graphs showing which parameters are within range or out of range.
- Alarms.

QC Reports

Pressing **QC Reports** displays the results table of the selected control level.



This screen contains the following information:

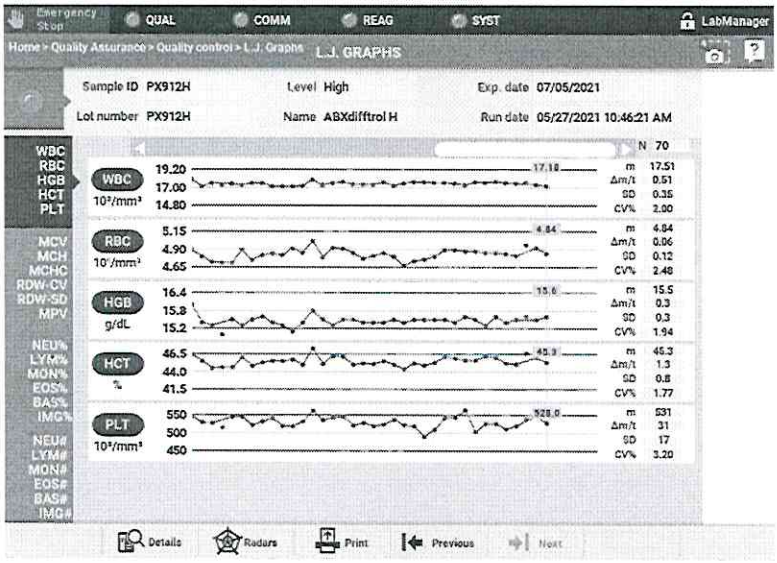
- Information about the control blood sample.
- Control blood results details for each parameter.

You can discard one or several results from the list.

L.J. Graphs

Pressing **L.J. Graphs** displays the ***L.J. Graphs*** screen.

The ***L.J. Graphs*** screen displays the history of the control blood sample.



This screen contains the following information:

- Information about the control blood sample.
- Levey-Jennings graphs showing the history of each parameter.

Control results are displayed in red when they are out of limits.

Control results which are unselected in the ***QC Reports*** table are not linked with the other selected results.

Related information:
- Controls Management, p.88
- Quality Control Results Management, p.91

1.2. Controls Management

1.2.1. To Create a Control Lot Manually

*Access: **Home** > **Quality Assurance** > **Quality control***

Control blood samples have their own target values and their own ranges, defined in the leaflet. They always have an expiration date and a maximum number of samplings.

All the target values are available online at www.horiba-abx.com/documentation. Click **Hematology** and then **quality control target**.

1. Select the control level you want to create.
2. Press **Add** in the contextual toolbar.
3. Select the control type.
4. Press **OK**.
5. Enter the control blood sample ID.
   You can use the virtual keyboard, the optional keyboard or the optional barcode reader.

1.3.2. To Manually Validate Control Results

*Access: **Home** > **Quality Assurance** > **Quality control***

You can manually validate a failed control blood result.

1. Select the control result you want to validate from the ***Active QC*** list.
2. Press **Details** or **Radars** in the contextual toolbar.
3. Press **Accept** in the contextual toolbar.
   The control result is now validated and appears in orange in the ***Active QC*** list.

1.3.3. To Delete Control Results

*Access: **Home** > **Quality Assurance** > **Quality control***

1. Select the control result you want to delete from the ***Active QC*** list.
2. Press **Details** or **Radars** in the contextual toolbar.
3. Press **Reject** in the contextual toolbar.
   The control result is now deleted and the control status is re-evaluated without this control result.

1.3.4. To Print QC Results

*Access: **Home** > **Quality Assurance** > **Quality control***

You can print QC results from ***Control Run Result***, ***Radars*** and ***L.J. Graphs*** screens.

1. To print control run results:
   a. Select the data you want to print from ***Active QC*** or ***Archived QC*** areas.
   b. Press **Details** in the contextual toolbar.
   c. Press **Print / Send** in the contextual toolbar.
   d. Press **Validate**.
2. To print control radar graphs:
   a. Select the data you want to print from ***Active QC*** or ***Archived QC*** areas.
   b. Press **Radars** in the contextual toolbar.
   c. Press **Print** in the contextual toolbar.
   d. Press **Confirm**.
3. To print quality control reports:
   a. Select the data you want to print from ***Active QC*** or ***Archived QC*** areas.
   b. Press **L.J. Graphs** in the contextual toolbar.
   c. Press **Print** in the contextual toolbar.
   d. Press **Confirm**.

1.3.5. To Send QC Results to the Host

*Access: **Home** > **Quality Assurance** > **Quality control***

Results are automatically sent to the Host (LIS or Yumizen P8000) at the end of an analysis if the option is selected.