

HORIBA
Medical

**Installation Qualification,
Operational Qualification
and
Performance Qualification**

YUMIZEN H550
(Serial no: **909YAXH02625**)
Fully Automated Hematology Analyzer

For

**LUPIN HEALTHCARE LTD,
LATUR**

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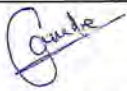
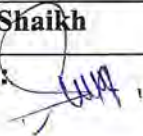
- I. Performance Qualification.
- II. Performance Certificate.

Section 5 Attachments

General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H550, Fully 6 Part Automated Hematology Analyzer, at LUPIN HEALTHCARE, LATUR as per the attached protocol.
- An authorized HORIBA India Pvt. Ltd., representative will physically check the system and proceed for the installation.
- This installation protocol will be followed as specified by the manufacturer.
- Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- After the installation of the system, Instrument calibration & QC will be performed by the authorized HORIBA India Pvt. Ltd. representative.
- An authorized HORIBA India Pvt. Ltd. representative will also perform the precision check on the system to check if it is as per the claim of the manufacturer.
- The results obtained for Calibration, QC & Precision checks will be verified by the qualified trained employee of LUPIN HEALTHCARE, LATUR along with an authorized HORIBA India Pvt. Ltd., representative.
- On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- An authorized HORIBA India Pvt. Ltd., representative will verify the documents of the system checks and approve the same.
- Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.

Report Sign Off

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Yogesh Gawade		
Title: Application Specialist	Sign: 	Date: 14/07/2022	
Approved by:	LUPIN HEALTHCARE, LATUR		
Name:	Mr. Mustkim Shaikh		
Title: Head of Department	Sign: 	Date: 14/07/2022	

YUMIZEN H550
(Serial no: **909YAXH02625**)
Fully Automated Hematology Analyzer

Installation Qualification

For

LUPIN HEALTHCARE LTD,
LATUR

A. Installation Qualification**1. Installation Requirement :**

Sr. No.	Description	Compliance (Yes/No)
1.	Environmental conditions: Indoor Location not exposed to sunlight, water and vibration free platform. Temperature of 16°C to 34°C and maximum relative humidity of 80%.	Yes
2.	Physical Space Requirement: 53(W) x 66.8(D) x 62.1(H)cm with at least 20 cm space at the back of the instrument from the wall.	Yes
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.	Yes
4.	UPS connection available.	Yes

2. The instrument has been checked for the following:

Sr. No.	Verification	Provided (Yes/No)
1.	Instrument is identified Instrument Serial No. : 909YAXH02625	Yes
2.	Manufacturer's specifications: Technical and Physical Requirement	Yes
3.	Accessories / consumables are listed as per checklist (Provided along)	Yes
4.	System checked for any External / physical damage.	Yes
5.	Instrument User Manual (Soft Copy)	Yes

3. Equipment Description :

YUMIZEN H550, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No
Equipment Type : Hematology Analyzer	Yes
Model : YUMIZEN H550	Yes
Manufacturer : HORIBA Medical, France	Yes
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	Yes
Equipment # : One	Yes
Serial Number : 909YAXH02625	Yes
Dimensions : 53(W) x 66.8(D) x 62.1(H)	Yes
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz	Yes
Power Consumption: 165 VA	Yes

4. Accessories/Consumables :

The accessories were supplied with the instrument as per the check list. Check &verified in case they are found to be in order.

5. Preventive Maintenance :

The routine preventive maintenance of the system will be carried out by an authorized HORIBA India Pvt. Ltd., engineer at a specified time interval as recommended by the manufacturer.

6. Spare Parts :

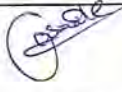
HORIBA India Pvt. Ltd strongly recommends the end user to maintain a basic consumable parts onsite to minimize down time due to minor failures. Spare parts as provided in the installation kit.

B. Installation Procedure:

1. Putting the system at the predefined and pre inspected location (Having suitable Working Conditions).
2. Removal of the internal packing material of the system.
3. Place the Instrument on the bench top (Vibration free).
4. Connect the Power cord to the YUMIZEN H550.
6. Turn on the external Printer.
7. All the operating software has been loaded in to YUMIZEN H550.
8. Now from back side of the instrument turn the power switch ON, YUMIZEN H550 goes through its power up and self-test sequence.
9. The YUMIZEN H550 login menu is displayed after the Start up cycle is completed. Enter the credentials.

C. INSTALLATION CERTIFICATE:

Instrument Name : YUMIZEN H550
Serial Number : 909YAXH02625
Customer Details with complete address : LUPIN HEALTHCARE, LATUR
Barmade Hospital And Life Advanced Test Tube Baby
Centre, Opposite Datta Mandir, Adarsh Colony, AUSA Road,
Latur, Maharashtra 413531.
Installation Date : 14/07/2022
Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Yogesh Gawade		
Title: Application Specialist	Sign: 	Date:14/07/2022	
Approved by:	LUPIN HEALTHCARE, LATUR		
Name:	Mr. Mustkim Shaikh		
Title: Head of Department	Sign: 	Date:14/07/2022	

Deviation: NO

Conclusion: Instrument has been qualified for Installation. Hence it has been taken for Operational Qualification.

HORIBA
Medical

YUMIZEN H550
(Serial no: **909YAXH02625**)
Fully Automated Hematology Analyzer

Operational Qualification

For

**LUPIN HEALTHCARE LTD,
LATUR**

A. Operational Qualification**1. Instrument Identification:**

Instrument Name : YUMIZEN H550

Serial Number : 909YAXH02625

2. Following is the list of actions performed and verified for running the system routinely.

Sr. No.	Test Name	Test Purpose	Method	Observation
1.	SYSTEM SWITCH ON	TO CHECK THE ERROR FREE POWER UP.	Switch on the main, switch on the system. Login into yumizen Application software. Startup cycle is performed .Login in as User and check for the Screen Errors.	Ok
2.	STARTUP CYCLE	TO CHECK THE BACK GROUND IS OK.	Run a startup cycle from the main menu; check if the background is in the acceptable range.	Ok
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	Ok
4.	REAGENT STATUS	TO CHECK ADEQUATE REAGENT IS AVAILABLE FOR ANALYSIS	Manually check in the reagent bottles or else change the reagent from the Status Menu.	Ok

5.	SAMPLE ANALYSIS	TO CHECK PROPER FUNCTIONING OF SAMPLE ANALYSIS	1. To run Stat/ Manual sample, press on sample identification and enter the sample ID and press on validate.	Ok
6.	ARCHIVE AND CURRENT REPORTS	TO RECOVER THE SAMPLE RESULT FROM ARCHIVE AND CURRENT REPORTS	Press on Results History icon and view the current results. To view archived reports, Select Archive results and select the date of the reports and view the report.	Ok
7.	QUALITY CONTROL DATA	TO RECOVER QUALITY CONTROL DATA AND LJ GRAPH	Press on QC Icon from the Main Menu and select the Lot No. To view on QC Runs , Click on Dates .	Ok
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	Ok

B. Operational Training Record


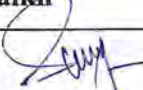
Operator Training: The users responsible for the operation of this instrument will be trained on the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filled as indicated on training sheet:

C. Operator Maintenance Protocol

Maintenance and Troubleshooting: Perform Concentration Cleaning as advised by the HORIBA Medical Representative. Run a Shutdown cycle before switching off the analyzer.

D. OPERATIONAL CERTIFICATE:

Instrument Name : YUMIZEN H550.
Serial Number : 909YAXH02625
Customer Details with complete address : LUPIN HEALTHCARE, LATUR
Barmade Hospital And Life Advanced Test Tube Baby Centre,
Opposite Datta Mandir, Adarsh Colony, Ausa Road, Latur,
Maharashtra 413531.
Installation Date : 14/07/2022
Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Yogesh Gawade		
Title: Application Specialist	Sign: 	Date: 14/07/2022	
Approved by:	LUPIN HEALTHCARE, LATUR		
Name:	Mr. Mustkim Shaikh		
Title: Head of Department	Sign: 	Date: 14/07/2022	

Deviation: NO

Conclusion: Instrument has been qualified for Operational. Hence it has been taken for Performance Qualification.

HORIBA
Medical

YUMIZEN H550
(Serial no:909**YAXH02625**)
Fully Automated Hematology Analyzer

Performance Qualification

For

**LUPIN HEALTHCARE LTD,
LATUR**

A. Performance Qualification**A. Instrument Identification:**

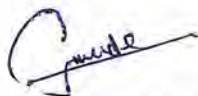
Instrument Name : YUMIZEN H550
Serial Number : 909YAXH02625

B. Following is the list of test to be performed and verified

- Blank Reference cycle: To verify the Startup Cycle of the instrument.

Serial No: 909YAXH02625

Parameters	Acceptable Range	Observed Value
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.07
RBC $10^6/\text{mm}^3$	$\leq 0.02 \times 10^6/\text{mm}^3$	0.00
HGB g/Dl	$\leq 0.3 \text{ g/dl}$	0.0
PLT $10^3/\text{mm}^3$	$\leq 5 \times 10^3/\text{mm}^3$	0



Conducted By:

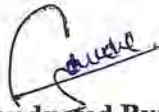


Verified By:

- **Precision Study:** Precision is checked by running blood sample in 10 replicates & getting CV% in within acceptance.

Serial No: 909YAXH02625

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.78	Ok
HGB g/dL	< 1.5	0.37	Ok
HCT %	< 2.0	0.88	Ok
PLT $10^3/\text{mm}^3$	< 5.0	2.32	Ok
WBC $10^3/\text{mm}^3$	< 2.5	2.14	Ok


Conducted By:


Verified By:

- **Calibration:** To calibrate the Instrument using calibrator (ABX Minocal) and verify the same.

Procedure: Go to Quality Assurance icon on main screen and then Calibration icon. Run Calibrator (ABX Minocal) 10 times, without taking the values of first run, calibrate the instrument using average of the last 10 runs. Run Calibrator as a sample to verify the calibration.
Lot: CX471; Expiry: 05/08/2022.

Serial No: 909YAXH02625

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	8.90	8.82	1.12	<2%	PASSED
RBC	4.57	3.98	0.44	<2%	PASSED
HGB	13.2	13.2	0.37	<1.5%	PASSED
HCT	38.6	33.7	0.48	<2%	PASSED
PLT	256	215	3.04	<5%	PASSED
MPV	10.9	10.8	1.73	<3%	PASSED



Conducted By:

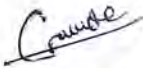


Verified By:

- **Control Runs:** The quality of the analyzer is checked by running three levels of Controls & getting the values in the range as per the kit insert.
 - **Lot:** ABX Difftrol PX436; **Exp:** 05/09/2022.

Serial No: 909YAXH02625

LEVEL	STATUS
LOW (PX436L)	PASSED
NORMAL (PX436N)	PASSED
HIGH (PX436H)	PASSED



Conducted By:

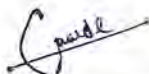


Verified By:

- **Carryover Study:** Carry over is checked by running quality controls /samples (high & low) in 3 replicates & getting CV% in within acceptance.
 - **Carry Over % = $(L1-L3)*100/(H3-L3)$.**

Serial No: 909YAXH02625

Parameters	WBC $10^3/\text{mm}^3$	RBC $10^6/\text{mm}^3$	HGB g/dL	HCT %	PLT $10^3/\text{mm}^3$
Carry Over (%)	0.69	0.97	0	0.91	0.89
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed



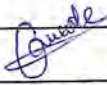

Conducted By:



Verified By:

B. PERFORMANCE CERTIFICATE:

Instrument Name : YUMIZEN H550
Serial Number : 909YAXH02625
Customer Details with complete address : LUPIN HEALTHCARE, LATUR
Barmade Hospital And Life Advanced Test Tube Baby
Centre, Opposite Datta Mandir, Adarsh Colony, AUSA Road,
Latur, Maharashtra 413531.
Installation Date :14/07/2022
Warranty expires on : RR (Reagent Rental) - 5yrs

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Yogesh Gawade		
Title: Application Specialist	Sign: 	Date:14/07/2022	
Approved by:	LUPIN HEALTHCARE, LATUR		
Name:	Mr. Mustkim Shaikh		
Title: Head of Department	Sign: 	Date:14/07/2022	

Deviation: No

Conclusion: Instrument has been qualified for Performance.



HORIBA India Private Ltd.

246, Okhla Industrial

Estate, Phase - III 110

020 New Delhi, India

Tel: +91 (11) 4646 5000 / 4669 5001

Fax: +91 (11) 4669 5010 / 4646 5020

HIN/MED/2023-2024/0299

07th November 2023.

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **ABX Yumizen H550** bearing serial number: **909YAXH02625** installed **LUPIN DIAGNOSTICS, Latur** was Calibrated on **07th November 2023.**

Calibrator : ABX MINOCAL
Lot No. : CX488
Expiry Date : 05th December 2023.

The reports of Blank Cycle, Repeatability and Calibration Values were all found in acceptable range.

Next calibration cycle is due on 06th November 2024.



Shrish Dixit
(Head- Products & Marketing)
For **Horiba India Pvt. Ltd.**

Control Run Result

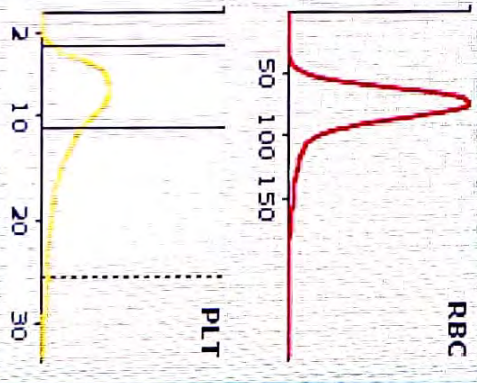


Sample ID: PX4444N
 Lot number: PX4444N

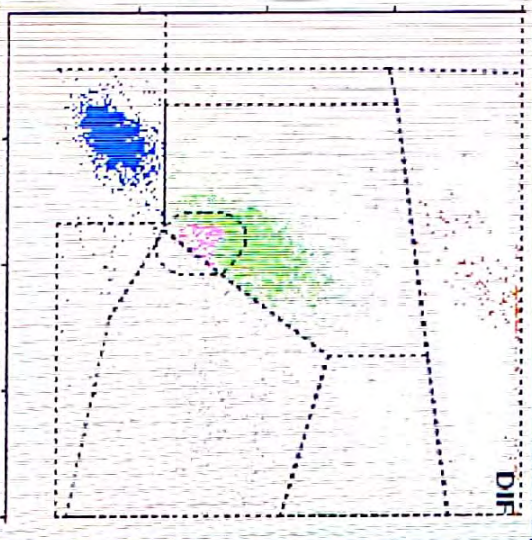
Level: Normal
 Name: ABXdiffrol N

Exp. date: 05/01/2024
 Run date: 07/11/2023 08:41:51 PM

RBC	4.66	10 ⁶ /μL	PLT	234	10 ³ /μL
HGB	13.2	g/dL			
HCT	40.7	%	MPV	9.5	μm ³
MCV	87.3	μm ³			
MCH	28.3	pg			
MCHC	32.4	g/dL			
RDW-CV	13.7	%			



WBC	8.62	10 ³ /μL			
	#				%
NEU	4.00				46.3
LYM	3.39				39.4
MON	0.55				6.4
EOS	0.30				3.5
EAS	0.38				4.4



QUAL COMM REAG SYST

v L2.L1.4 technician

READY

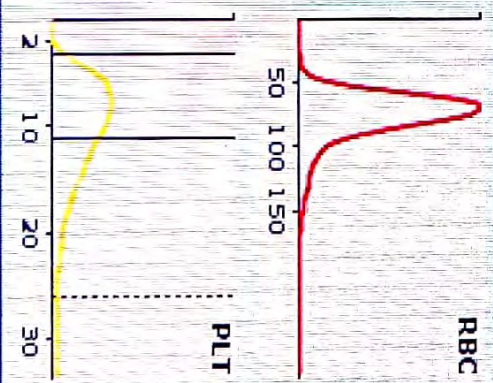


07/11/2023 08:55 PM

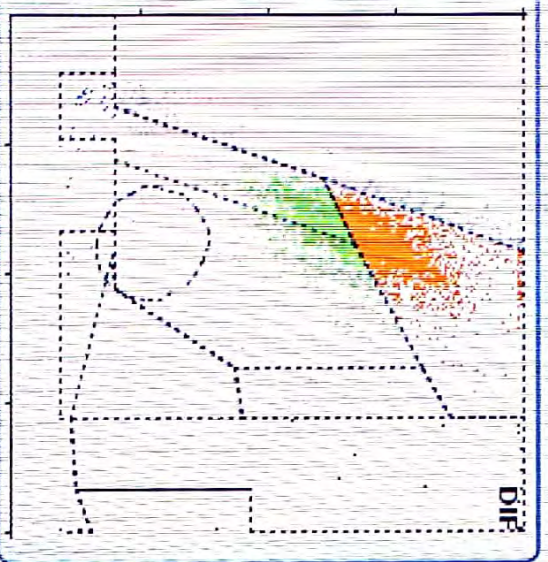
Sample ID **CX488**
 Last Name

Rack/Pos
 First Name

RBC	4.54	10 ⁶ /μL	PLT	244	10 ³ /μL
HGB	12.8	g/dL	PCT	0.24	%
HCT	38.2	%	MPV	10.0	μm ³
MCV	84.2	μm ³	PDW	18.6	μm ³
MCH	28.3	pg	P-LCC	93	%
MCHC	33.6	g/dL	P-LCR	38.2	%
RDW-CV	16.1	%			
RDW-SD	46.2	μm ³			



WBC	8.68	*	10 ³ /μL	%
NEU	3.46	*	40.1	*
LYM	0.06	L*	0.7	L*
MDN	0.00	L*	0.0	L*
EOS	5.09	H*	59.0	h*
BAS	0.02	*	0.2	*
LIC	0.05	*	0.5	*



Run Date
 07/11/2023 07:56:55 PM

Recommended Actions

Slide review
Alarms

- Technician
- WBC
- Background Noise
- Abnormal Differentiation
- Suspected Pathologies**
- Lymphopenia
- Eosinophilia

NLR : 57.67

QUAL COMM REAG SYST

v 1.2.1.4

technician

READY

07/11/2023 07:59 PM

Calibrator Information

Sample ID **CX488**
 Lot number **CX488**

Name **CAL WHITDIFF**

Exp. date **05/12/2023**
 Modified on

Coefficients	WBC	RBC	HGB	HCT	PLT	MPV
	New	1.167	1.009	1.008	1.092	1.068
Current	1.150	1.030	1.000	1.090	1.050	1.039
Target	8.95	4.41	12.7	37.0	239	10.2
Mean	8.82	4.50	12.6	37.7	235	10.6
CV(%)	1.65	0.67	0.28	0.74	1.95	1.76

Selected runs (5 minimum) **6/7**

Run Date & Time	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MPV (μm ³)
07/11/2023 07:33:52 PM	8.78	4.50 h	12.6	37.9	238	10.4
07/11/2023 07:37:14 PM	8.08	4.52 h	12.7	37.8	235	10.4
07/11/2023 07:39:10 PM	8.80	4.51 h	12.6	37.9	231	10.3
07/11/2023 07:40:42 PM	8.99	4.46	12.6	37.2	236	10.8
07/11/2023 07:45:21 PM	8.58	4.50 h	12.7	37.9	231	10.7
07/11/2023 07:46:52 PM	8.95	4.51 h	12.7	37.7	232	10.4

QUAL COMM REAG SYST

Calibrator Information

Sample ID **CX488** Name **CAL WHITDIFF** Exp. date **05/12/2023**
 Lot number **CX488** Modified on

Coefficients	WBC	RBC	HGB	HCT	PLT	MPV
	New	1.194	1.005	1.000	1.093	1.063
Current	1.150	1.030	1.000	1.090	1.050	1.039
Target	8.95	4.41	12.7	37.0	239	10.2
Mean	8.62	4.52	12.7	37.8	236	10.4
CV(%)	4.18 H	0.54	0.45	0.19	2.09	1.06

Selected runs (5 minimum) **4/4**

Run Date & Time	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	HCT (%)	PLT (10 ³ /μL)	MPV (μm ³)
<input checked="" type="checkbox"/> 07/11/2023 07:33:52 PM	8.78	4.50 h	12.6	37.9	238	10.4
<input checked="" type="checkbox"/> 07/11/2023 07:35:41 PM	8.08	4.52 h	12.7	37.8	235	10.4
<input checked="" type="checkbox"/> 07/11/2023 07:37:14 PM	8.82	4.55 h	12.7	37.8	243	10.6
<input checked="" type="checkbox"/> 07/11/2023 07:39:10 PM	8.80	4.51 h	12.6	37.9	231	10.3

QUAL COMM REAG SYST

Repeatability

Min	LYM%	MON%	EOS%	BAS%	LIC%
30.9	30.9	4.4	0.9	0.7	0.4
Max	32.6	5.6	1.4	1.1	0.7
Mean	31.6	5.1	1.2	0.8	0.5
Difference	1.7	1.2	0.5	0.4	0.3
2 SD	1.2	0.8	0.3	0.3	0.2
CV(%)	1.94	8.32	13.60	17.05	21.52

10/11

Run Date & Time	LYM%	MON%	EOS%	BAS%	LIC%	Operator
<input type="checkbox"/> 07/11/2023 06:43:39 PM	31.6	4.3	1.5	0.6	0.6	technician
<input checked="" type="checkbox"/> 07/11/2023 06:43:39 PM	30.9	5.4	1.3	0.9	0.7	technician
<input checked="" type="checkbox"/> 07/11/2023 06:45:49 PM	31.5	5.2	0.9	1.0	0.5	technician
<input checked="" type="checkbox"/> 07/11/2023 06:47:32 PM	32.6	5.2	1.3	0.7	0.4	technician
<input checked="" type="checkbox"/> 07/11/2023 06:49:56 PM	31.6	5.1	1.1	0.7	0.4	technician
<input checked="" type="checkbox"/> 07/11/2023 06:51:54 PM	32.3	5.0	1.4	0.8	0.6	technician
<input checked="" type="checkbox"/> 07/11/2023 07:02:35 PM	32.0	5.6	1.1	0.7	0.4	technician
<input checked="" type="checkbox"/> 07/11/2023 07:04:23 PM	30.9	5.6	1.1	1.1	0.5	technician
<input checked="" type="checkbox"/> 07/11/2023 07:05:55 PM	32.0	4.6	1.0	0.7	0.4	technician

QUAL
 COMM
 REAG
 SYST



v 12.1.4

technician

READY

07/11/2023 07:24 PM

Repeatability

LYM%	MON%	EOS%	BAS%	LIC%
30.9	4.3	0.9	0.6	0.4
32.6	5.6	1.5	1.1	0.7
Mean	5.0	1.2	0.8	0.5
Difference	1.7	0.6	0.5	0.3
2 SD	1.2	0.4	0.3	0.2
CV(%)	1.84	9.25	15.23	18.54
				21.28

11/11

Run Date & Time	LYM%	MON%	EOS%	BAS%	LIC%	Operator
07/11/2023 06:43:39 PM	31.6	4.3	1.5	0.6	0.6	technician
07/11/2023 06:45:49 PM	30.9	5.4	1.3	0.9	0.7	technician
07/11/2023 06:47:32 PM	31.5	5.2	0.9	1.0	0.5	technician
07/11/2023 06:49:56 PM	32.6	5.2	1.3	0.7	0.4	technician
07/11/2023 06:49:56 PM	31.6	5.1	1.1	0.7	0.4	technician
07/11/2023 06:51:54 PM	32.3	5.0	1.4	0.8	0.6	technician
07/11/2023 07:02:35 PM	32.0	5.6	1.1	0.7	0.4	technician
07/11/2023 07:04:23 PM	30.9	5.6	1.1	1.1	0.5	technician
07/11/2023 07:05:55 PM	32.0	4.6	1.0	0.7	0.4	technician

QUAL
 COMM
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 SYST



12:14

technician

READY

07/11/2023 07:14 PM

Repeatability

	MCV	RDW-CV	RDW-SD	P-LCR	NEU%	LYM%
Min	83.5	11.6	37.0	21.8	60.2	30.9
Max	84.0	12.3	38.6	25.5	62.6	32.6
Mean	83.8	11.9	37.7	23.9	61.4	31.6
Difference	0.5	0.7	1.7	3.7	2.4	1.7
2 SD	0.3	0.4	1.0	2.0	1.5	1.2
CV(%)	0.19	1.63	1.26	4.22	1.24	1.94

10/11

Run Date & Time	MCV μm^3	RDW-CV %	RDW-SD μm^3	P-LCR %	NEU% %	LYM% %
07/11/2023 06:43:39 PM	83.8	11.8	37.8	23.0	61.5	30.9
07/11/2023 06:45:49 PM	83.5	11.6	37.0	24.6	61.4	31.5
07/11/2023 06:47:32 PM	83.7	11.7	37.0	21.8	60.2	32.6
07/11/2023 06:49:56 PM	83.7	12.0	37.8	23.7	61.5	31.6
07/11/2023 06:51:54 PM	83.9	11.8	37.8	23.5	60.5	32.3
07/11/2023 07:02:35 PM	84.0	12.3	38.6	24.0	60.6	32.0
07/11/2023 07:04:23 PM	84.0	11.8	37.8	24.1	61.3	30.9
07/11/2023 07:05:55 PM	84.0	11.8	37.8	24.7	61.7	32.0

QUAL
 COMM
 REAG
 SYST

v 12.1.4

technician

READY

07/11/2023 07:24 PM



Repeatability

	MCV	RDW-CV	RDW-SD	P-LCR	NEU%	LYM%
Min	83.5	11.6	37.0	21.8	60.2	30.9
Max	84.0	12.3	38.6	25.5	62.6	32.6
Mean	83.8	11.9	37.7	23.9	61.4	31.6
Difference	0.5	0.7	1.7	3.7	2.4	1.7
2 SD	0.3	0.4	0.9	1.9	1.5	1.2
CV(%)	0.19	1.55	1.20	4.00	1.21	1.84

11/11

Run Date & Time	MCV μm^3	RDW-CV %	RDW-SD μm^3	P-LCR %	NEU% %	LYM% %
07/11/2023 06:43:39 PM	83.8	11.8	37.8	23.0	61.5	30.9
07/11/2023 06:45:49 PM	83.5	11.6	37.0	24.6	61.4	31.5
07/11/2023 06:47:32 PM	83.7	11.7	37.0	21.8	60.2	32.6
07/11/2023 06:49:56 PM	83.7	12.0	37.8	23.7	61.5	31.6
07/11/2023 06:51:54 PM	83.9	11.8	37.8	23.5	60.5	32.3
07/11/2023 07:02:35 PM	84.0	12.3	38.6	24.0	60.6	32.0
07/11/2023 07:04:23 PM	84.0	11.8	37.8	24.1	61.3	30.9
07/11/2023 07:05:55 PM	84.0	11.8	37.8	24.7	61.7	32.0

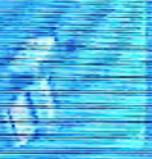
QUAL COMM REAG SYST

v 1.2.1.4

technician

READY

07/11/2023 07:24 PM



Repeatability

	WBC	RBC	HGB	HCT	PLT	MCV
Min	7.34	4.74	13.1	39.7	277	83.5
Max	7.66	4.84	13.3	40.6	299	84.0
Mean	7.52	4.79	13.2	40.2	289	83.8
Difference	0.32	0.10	0.2	1.0	22	0.5
2 SD	0.20	0.06	0.1	0.6	14	0.3
CV(%)	1.34	0.66	0.50	0.73	2.46	0.19

10/11

Run Date & Time	WBC 10 ³ /μL	RBC 10 ⁶ /μL	HGB g/dL	HCT %	PLT 10 ³ /μL	MCV μm ³
<input type="checkbox"/> 07/11/2023 06:43:39 PM	7.69	4.90	13.3	41.1	290	83.9
<input checked="" type="checkbox"/> 07/11/2023 06:43:39 PM	7.66	4.75	13.1	39.9	299	83.8
<input checked="" type="checkbox"/> 07/11/2023 06:45:49 PM	7.60	4.82	13.3	40.2	293	83.5
<input checked="" type="checkbox"/> 07/11/2023 06:47:32 PM	7.60	4.79	13.3	40.1	294	83.7
<input checked="" type="checkbox"/> 07/11/2023 06:49:56 PM	7.56	4.80	13.3	40.2	281	83.7
<input checked="" type="checkbox"/> 07/11/2023 06:51:54 PM	7.58	4.80	13.2	40.3	277	83.9
<input checked="" type="checkbox"/> 07/11/2023 07:02:35 PM	7.34	4.84	13.2	40.6	287	84.0
<input checked="" type="checkbox"/> 07/11/2023 07:04:23 PM	7.40	4.82	13.2	40.5	286	84.0
<input checked="" type="checkbox"/> 07/11/2023 07:05:55 PM	7.53	4.78	13.2	40.2	283	84.0

QUAL
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 SYST



v 1.2.1.4

technician

READY

07/11/2023 07:10 PM

Repeatability

	WBC	RBC	HGB	HCT	PLT	MCV
Min	7.34	4.74	13.1	39.7	277	83.5
Max	7.69	4.90	13.3	41.1	299	84.0
Mean	7.54	4.80	13.2	40.2	289	83.8
Difference	0.34	0.17	0.2	1.5	22	0.5
2 SD	0.22	0.09	0.1	0.8	13	0.3
CV(%)	1.43	0.94	0.50	1.01	2.33	0.19

11/11

Run Date & Time	WBC 10 ³ /μL	RBC 10 ⁶ /μL	HGB g/dL	HCT %	PLT 10 ³ /μL	MCV μm ³
07/11/2023 06:43:39 PM	7.69	4.90	13.3	41.1	290	83.9
07/11/2023 06:45:49 PM	7.60	4.82	13.3	40.2	293	83.5
07/11/2023 06:47:32 PM	7.60	4.79	13.3	40.1	294	83.7
07/11/2023 06:49:56 PM	7.56	4.80	13.3	40.2	281	83.7
07/11/2023 06:51:54 PM	7.58	4.80	13.2	40.3	277	83.9
07/11/2023 07:02:35 PM	7.34	4.84	13.2	40.6	287	84.0
07/11/2023 07:04:23 PM	7.40	4.82	13.2	40.5	286	84.0
07/11/2023 07:05:55 PM	7.53	4.78	13.2	40.2	283	84.0

QUAL COMM REAG SYST

v L2.L4

technician

READY

07/11/2023 07:10 PM

Calibration coefficients

Results Settings

- Normal Ranges
- CV / Limits

Calibration Coefficients

- Alarms

- Age Limits

Application

- General
- Print / Transmit
- Departments & Physicians

User Settings

System

- User Interface
- Printer
- Cycles

- General Communication
- Barcode

Import / Export

Technician

- General
- Reagents / Racks

QUAL COMM REAG SYST

v 12.1.1.4 technician

Automatic

Manual

WBC 1.150

RDW-CV 1.200

1.030

1.000

HGB 1.000

PDW 1.000

1.090

PLT 1.050

1.039




READY

07.11.2023 06:54 PM

Repeatability

	WBC	RBC	HGB	HCT	PLT	MCV
Min	7.56	4.75	13.1	39.9	277	83.5
Max	7.69	4.90	13.3	41.1	299	83.9
Mean	7.61	4.81	13.3	40.3	289	83.8
Difference	0.13	0.15	0.2	1.3	22	0.4
2 SD	0.10	0.10	0.2	0.9	17	0.3
CV(%)	0.65	1.04	0.58	1.10	2.92	0.18

6/6

Run Date & Time	WBC 10 ³ /μL	RBC 10 ⁶ /μL	HGB g/dL	HCT %	PLT 10 ³ /μL	MCV μm ³
<input checked="" type="checkbox"/> 07/11/2023 06:41:24 PM	7.69	4.90	13.3	41.1	290	83.9
<input checked="" type="checkbox"/> 07/11/2023 06:43:39 PM	7.66	4.75	13.1	39.9	299	83.8
<input checked="" type="checkbox"/> 07/11/2023 06:45:49 PM	7.60	4.82	13.3	40.2	293	83.5
<input checked="" type="checkbox"/> 07/11/2023 06:47:32 PM	7.60	4.79	13.3	40.1	294	83.7
<input checked="" type="checkbox"/> 07/11/2023 06:49:56 PM	7.56	4.80	13.3	40.2	281	83.7
<input checked="" type="checkbox"/> 07/11/2023 06:51:54 PM	7.58	4.80	13.2	40.3	277	83.9

QUAL
 COMM
 REAG
 SYST

v12.1.4

technician

READY

07/11/2023 06:54 PM



Repeatability

	WBC	RBC	HGB	HCT	PLT	MCV
Min	7.56	4.75	13.1	39.9	277	83.5
Max	7.69	4.90	13.3	41.1	299	83.9
Mean	7.61	4.81	13.3	40.3	289	83.8
Difference	0.13	0.15	0.2	1.3	22	0.4
2 SD	0.10	0.10	0.2	0.9	17	0.3
CV(%)	0.65	1.04	0.58	1.10	2.92	0.18

6/6

Run Date & Time	WBC 10 ³ /μL	RBC 10 ⁶ /μL	HGB g/dL	HCT %	PLT 10 ³ /μL	MCV μm ³
07/11/2023 06:41:24 PM	7.69	4.90	13.3	41.1	290	83.9
07/11/2023 06:43:39 PM	7.66	4.75	13.1	39.9	299	83.8
07/11/2023 06:45:49 PM	7.60	4.82	13.3	40.2	293	83.5
07/11/2023 06:47:32 PM	7.60	4.79	13.3	40.1	294	83.7
07/11/2023 06:49:56 PM	7.56	4.80	13.3	40.2	281	83.7
07/11/2023 06:51:54 PM	7.58	4.80	13.2	40.3	277	83.9

QUAL
 COMM
 REAG
 SYST

v L2.L4

technician

READY

07/11/2023 06:54 PM

	WBC	RBC	HGB	HCT	PLT	MCV
Min	6.49	4.92	11.7	36.3	329	73.6
Max	6.88	5.02	11.8	37.2	345	74.2
Mean	6.74	4.96	11.8	36.7	337	73.9
Difference	0.38	0.10	0.1	0.9	16	0.6
2 SD	0.24	0.08	0.1	0.7	12	0.4
CV(%)	1.80	0.81	0.34	0.96	1.80	0.28

717

Run Date & Time	WBC 10 ³ /μL	RBC 10 ⁵ /μL	HGB g/dL	HCT %	PLT 10 ³ /μL	MCV μm ³
<input checked="" type="checkbox"/> 27/10/2023 10:06:03 AM	6.88	5.01	11.8	37.1	329	74.0
<input checked="" type="checkbox"/> 27/10/2023 10:07:36 AM	6.82	5.02	11.8	37.2	338	74.0
<input checked="" type="checkbox"/> 27/10/2023 10:09:08 AM	6.72	4.96	11.8	36.6	333	73.7
<input checked="" type="checkbox"/> 27/10/2023 10:10:41 AM	6.75	4.93	11.8	36.3	344	73.6
<input checked="" type="checkbox"/> 27/10/2023 10:12:14 AM	6.71	4.93	11.8	36.5	345	74.2
<input checked="" type="checkbox"/> 27/10/2023 10:13:45 AM	6.49	4.92	11.7	36.3	332	73.8
<input checked="" type="checkbox"/> 27/10/2023 10:15:19 AM	6.77	4.97	11.7	36.8	337	74.0

QUAL COMM REAG SYST



v 1.2.1.4

technician

READY

07/11/2023 06:40 PM



	WBC	RBC	HGB	HCT	PLT	MCV
Min	6.49	4.92	11.7	36.3	329	73.6
Max	6.88	5.02	11.8	37.2	345	74.2
Mean	6.74	4.96	11.8	36.7	337	73.9
Difference	0.38	0.10	0.1	0.9	16	0.6
2 SD	0.24	0.08	0.1	0.7	12	0.4
CV(%)	1.80	0.81	0.34	0.96	1.80	0.28

7/7

Run Date & Time	WBC 10 ³ /μL	RBC 10 ⁵ /μL	HGB g/dL	HCT %	PLT 10 ³ /μL	MCV μm ³
<input checked="" type="checkbox"/> 27/10/2023 10:06:03 AM	6.88	5.01	11.8	37.1	329	74.0
<input checked="" type="checkbox"/> 27/10/2023 10:07:36 AM	6.82	5.02	11.8	37.2	338	74.0
<input checked="" type="checkbox"/> 27/10/2023 10:09:08 AM	6.72	4.96	11.8	36.6	333	73.7
<input checked="" type="checkbox"/> 27/10/2023 10:10:41 AM	6.75	4.93	11.8	36.3	344	73.6
<input checked="" type="checkbox"/> 27/10/2023 10:12:14 AM	6.71	4.93	11.8	36.5	345	74.2
<input checked="" type="checkbox"/> 27/10/2023 10:13:45 AM	6.49	4.92	11.7	36.3	332	73.8
<input checked="" type="checkbox"/> 27/10/2023 10:15:19 AM	6.77	4.97	11.7	36.8	337	74.0

QUAL COMM REAG SYST



v 12.14

technician

READY

07/11/2023 06:40 PM



Date/Time	Operator	Status	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	PLT (10 ³ /μL)
02/11/2023 08:51:51 AM	LUPIN		0.02	0.01	0.0	1
02/11/2023 11:56:39 AM	LUPIN		0.01	0.00	0.0	3
03/11/2023 07:17:15 AM	LUPIN		0.01	0.01	0.0	0
03/11/2023 12:28:07 PM	LUPIN		0.04	0.00	0.0	1
04/11/2023 07:29:16 AM	LUPIN		0.02	0.01	0.0	0
05/11/2023 07:15:19 AM	LUPIN		0.00	0.00	0.0	3
06/11/2023 07:07:37 AM	LUPIN		0.01	0.00	0.0	1
06/11/2023 03:15:55 PM	LUPIN		0.01	0.00	0.0	1
06/11/2023 03:32:31 PM	LUPIN		0.02	0.00	0.0	1
07/11/2023 08:07:20 AM	LUPIN		0.00	0.01	0.0	0
07/11/2023 06:33:47 PM	technician		0.01	0.00	0.0	1

Parameters 0.01, 0.00, 0.0, 1

Status PASSED

Comment

Add Comments

QUAL COMM REAG SYST

v 12.1.4

technician

READY

07/11/2023 06:36 PM

Logs - Blank

Date/Time	Operator	Status	WBC (10 ³ /μL)	RBC (10 ⁶ /μL)	HGB (g/dL)	PLT (10 ³ /μL)
02/11/2023 08:51:51 AM	LUPIN		0.02	0.01	0.0	1
02/11/2023 11:56:39 AM	LUPIN		0.01	0.00	0.0	3
03/11/2023 07:17:15 AM	LUPIN		0.01	0.01	0.0	0
03/11/2023 12:28:07 PM	LUPIN		0.04	0.00	0.0	1
04/11/2023 07:29:16 AM	LUPIN		0.02	0.01	0.0	0
05/11/2023 07:15:19 AM	LUPIN		0.00	0.00	0.0	3
06/11/2023 07:07:37 AM	LUPIN		0.01	0.00	0.0	1
06/11/2023 03:15:55 PM	LUPIN		0.01	0.00	0.0	1
06/11/2023 03:32:31 PM	LUPIN		0.02	0.00	0.0	1
07/11/2023 08:07:20 AM	LUPIN		0.00	0.01	0.0	0
07/11/2023 06:33:47 PM	technician		0.01	0.00	0.0	1

Parameters 0.01, 0.00, 0.0, 0.1

Status PASSED

Comment

Add Comments

QUAL
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DATA ENTRY
 DATA ENTRY
 DATA ENTRY

v 1.2.1.4

technician

READY

07/11/2023 06:36 PM

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