

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 /mm ³	< 2.0	0.78	Ok
HGB g/dL	< 1.5	0.37	Ok
HCT %	< 2.0	0.88	Ok
PLT 10 ³ /mm ³	< 5.0	2.32	Ok
WBC 10 ³ /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 /mm ³	RBC 10 ⁶ /mm ³	HGB g/dL	HCT %	PLT 10 ³ /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:


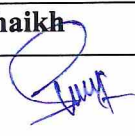
Instrument Name : YUMIZEN H550

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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.

