

HORIBA

HORIBA India Private Limited

246 Okhla Industrial Estate Phase-II,
New Delhi 110020, India
Tel : +91 (11) 4646 5000 / 4689 5001
Fax : +91 (11) 4646 5020
http : //www.horiba.com
CIN : U73100DL2006PTC153232

HIN/MED/2021-2022/100596
10th Sep 2021

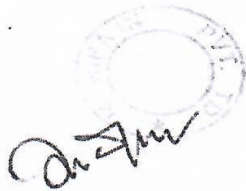
CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **PENTRA ES60** bearing serial number: **901PES15172** installed at **HOUSE OF PATHOLOGY LABS,PVT LTD . DELHI** as calibrated on 10th Sep 2021.

Calibrator : ABX MINOCAL
Lot No. : CX462
Expiry Date : 05th Oct 2021

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

Next calibration cycle is due on 09th Sep 2022.



Shrish Dixit

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

HOUSE OF PATHOLOGY
901PES15172

Patient Name : BLANK		Collect Date :	
Patient Number :		Operator : ABX	Department :
Seq.# : 3	Sample ID :	Physician :	
Birthdate :	Age :	Gender :	Running Date : 09/10/2021 02:20:51 PM Blood Type : Standard
Comment :			

WBC 0.0 * 10 ³ /mm ³
--

RBC 0.00 * 10 ⁶ /mm ³	Suspected Pathology
HGB 0.0 g/dl	
PLT 1 * 10 ³ /mm ³	

Morphology Flags	Analyzer Alarms
Leuko : L1	Analytic : LMNE-

Microscopic Examination

	+ ++ +++		
Anisocytosis	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Neutrophils	_____
Hypochromia	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Band Cells	_____
Polychromasia	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Lymphocytes	_____
Poikilocytosis	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Monocytes	_____
Microcytosis	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Eosinophils	_____
Macrocytosis	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Basophils	_____
Plts Aggregates	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Metamyelocytes	_____
		Myelocytes	_____
		Promyelocytes	_____
		Blasts	_____
		Atypical	_____
		NRBC's	_____

Comment :

HOUSE OF PATHOLOGY PVT LTD
901PES15172

Analyzer : Pentra ES60 Operator : ABX

Repeatability

Seq#	Operator	Running Date	WBC	RBC	HGB	HCT	MCV	PLT	MCH	MCHC	RDW	MPV	NEU%	LYM%	MON%	EOS%	BAS%	NEU#	LYM#	MON#	EOS#	BAS#
2	ABX	09/10/2021 03:22:10 PM	6.1	3.99	12.2	34.7	87	161	30.7	35.2	13.5	11.0	69.0	28.6	1.4	0.9	0.1	4.24	1.76	0.09	0.06	0.01
3	ABX	09/10/2021 03:23:19 PM	6.2	4.02	12.2	35.1	87	153	30.3	34.7	13.8	11.1	65.9	30.7	2.0	1.3	0.1	4.10	1.91	0.12	0.08	0.01
4	ABX	09/10/2021 03:24:29 PM	6.3	4.13	12.2	36.3	88	153	29.6	33.7	14.1	11.0	66.2	29.8	2.3	1.5	0.2	4.14	1.86	0.14	0.09	0.01
5	ABX	09/10/2021 03:25:43 PM	6.2	4.03	12.3	35.4	88	163	30.6	34.8	13.7	11.1	67.8	28.9	2.2	1.0	0.1	4.19	1.79	0.14	0.06	0.01
6	ABX	09/10/2021 03:26:54 PM	6.2	4.05	12.2	35.4	87	165	30.2	34.5	14.5	11.3	66.4	29.6	2.6	1.3	0.1	4.14	1.84	0.16	0.08	0.01
7	ABX	09/10/2021 03:28:06 PM	6.3	4.09	12.3	36.1	88	167	30.0	34.0	14.0	10.9	66.4	29.8	2.5	1.1	0.2	4.21	1.89	0.16	0.07	0.01
8	ABX	09/10/2021 03:30:33 PM	6.3	4.03	12.2	35.1	87	159	30.4	34.9	14.1	11.3	65.8	30.3	2.7	1.1	0.1	4.16	1.92	0.17	0.07	0.01
9	ABX	09/10/2021 03:31:46 PM	6.1	4.15	12.3	36.4	88	160	29.6	33.8	14.1	11.0	67.4	28.5	2.5	1.4	0.2	4.12	1.74	0.15	0.09	0.01
10	ABX	09/10/2021 03:32:57 PM	6.3	4.04	12.3	35.5	88	167	30.4	34.7	14.2	10.6	67.3	28.9	2.4	1.3	0.1	4.25	1.82	0.15	0.08	0.01
11	ABX	09/10/2021 03:35:25 PM	6.4	4.04	12.3	35.3	87	156	30.5	34.8	13.9	11.3	67.5	29.0	2.3	1.0	0.2	4.32	1.85	0.15	0.06	0.01
12	ABX	09/10/2021 03:36:33 PM	6.4	4.04	12.4	35.5	88	164	30.6	34.8	13.6	10.9	66.0	29.9	2.6	1.3	0.2	4.20	1.90	0.17	0.08	0.01
Intermediate Values			WBC	RBC	HGB	HCT	MCV	PLT	MCH	MCHC	RDW	MPV	NEU%	LYM%	MON%	EOS%	BAS%	NEU#	LYM#	MON#	EOS#	BAS#
Mean			6.3	4.06	12.3	35.6	88	161	30.2	34.5	14.0	11.0	66.7	29.5	2.4	1.2	0.1	4.18	1.85	0.15	0.08	0.01
Standard deviation			0.09	0.05	0.06	0.48	0.33	5.33	0.36	0.47	0.26	0.21	0.75	0.70	0.21	0.17	0.05	0.07	0.06	0.01	0.01	0.00
Variation Coef.			1.43	1.15	0.45	1.36	0.38	3.32	1.20	1.35	1.87	1.90	1.12	2.36	8.85	13.85	35.14	1.58	3.06	9.28	13.36	35.48

> Higher Limit

Calibration

Seq#	Sel	Operator	Running Date	WBC	RBC	HGB	HCT	PLT
1	<input type="checkbox"/>	ABX	09/10/2021 03:43:26 PM	9.0	4.59	14.0	36.9	261
2	<input checked="" type="checkbox"/>	ABX	09/10/2021 03:44:37 PM	9.0	4.51	13.9	36.3	259
3	<input checked="" type="checkbox"/>	ABX	09/10/2021 03:45:49 PM	9.0	4.55	14.0	36.7	261
4	<input checked="" type="checkbox"/>	ABX	09/10/2021 03:47:01 PM	9.0	4.56	13.9	36.7	255
5	<input checked="" type="checkbox"/>	ABX	09/10/2021 03:48:21 PM	9.1	4.59	14.1	37.0	254
6	<input checked="" type="checkbox"/>	ABX	09/10/2021 03:49:32 PM	9.0	4.53	13.9	36.6	247

CALI 1

Test CBC	WBC	9.2	10 ⁹ /mm ³
Selected Results 5 / 6	RBC	4.55	10 ⁶ /mm ³
Ident. CX462	HGB	13.7	g/dl
Barcode CX462	HCT	37.8	%
Expiration Date 10/05/2021	PLT	248	10 ⁹ /mm ³
Modified On 09/10/2021 03:40:10 PM			
By ABX			

Intermediate Values	WBC	RBC	HGB	HCT	PLT
Target values	9.2	4.55	13.7	37.8	248
Actual coeff.	136.7	217	42.2	235.7	287
New coeff.	136.7	217	42.2	235.7	287
Mean	9.0	4.55	14.0	36.6	255
Variation Coeff.	0.44	0.64	0.51	0.70	2.11

> Higher Limit XXXXXXXXXX

< Lower Limit XXXXXXXXXX

HOUSE OF PATHOLOGY PVT LTD
901PES15172

QC Control

Analyzer : Pentra ES60

Operator : ABX

Seq#	Sel.	Operator	Running Date	WBC	RBC	HGB	HCT	MCV	PLT	MCH	MCHC	RDW	MPV	NEU%	LYM%	MON%	EOS%	BAS%	NEU#	LYM#	MON#	EOS#	BAS#
1	<input checked="" type="checkbox"/>	ABX	09/10/2021 04:07:34 PM	2.4	2.32	6.6	18.8	81	63	28.4	35.1	13.2	9.2	60.8	24.3	4.2	7.5	3.2	1.46	0.58	0.10	0.18	0.08
2	<input checked="" type="checkbox"/>	ABX	09/10/2021 04:10:48 PM	2.4	2.26	6.5	18.3	81	70	28.8	35.7	12.8	9.0	63.3	22.8	3.4	7.4	3.1	1.54	0.56	0.08	0.18	0.08

CONTROL 8

Test DIF
Selected Results 2 / 2
Ident. PX431L
Barcode PX431L
Expiration Date 11/05/2021
Modified On 09/10/2021 03:58:15 PM
By ABX

Intermediate Values	WBC	RBC	HGB	HCT	MCV	PLT	MCH	MCHC	RDW	MPV	NEU%	LYM%	MON%	EOS%	BAS%	NEU#	LYM#	MON#	EOS#	BAS#
Upper limits	2.9	2.47	6.9	20.0	85	89	30.1	38.2	17.0	11.8	64.2	42.1	9.2	12.9	5.9	1.71	1.08	0.22	0.31	0.15
Target values	2.5	2.31	6.5	18.5	80	69	28.1	35.2	13.0	9.8	54.2	30.1	5.7	6.9	3.1	1.36	0.75	0.14	0.17	0.08
Lower limits	2.1	2.15	6.1	17.0	75	49	26.1	32.2	9.0	7.8	44.2	18.1	2.2	0.9	0.3	1.01	0.42	0.06	0.03	0.01
Mean	2.4	2.29	6.6	18.5	81	67	28.6	35.4	13.0	9.1	62.0	23.5	3.8	7.5	3.1	1.50	0.57	0.09	0.18	0.08
Mean/target diff.	0.1	0.02	0.1	0.0	1	2	0.5	0.2	0.0	0.7	7.8	6.6	1.9	0.6	0.1	0.14	0.18	0.05	0.01	0.00
Standard deviation	0.03	0.04	0.05	0.37	0.20	5.01	0.28	0.43	0.25	0.18	1.77	1.06	0.57	0.07	0.07	0.06	0.02	0.01	---	---
Variation Coeff.	1.17	1.74	0.77	1.98	0.25	7.50	0.97	1.21	1.94	1.99	2.85	4.50	14.89	0.95	2.24	4.01	3.34	13.73	---	---

> Higher Limit



< Lower Limit

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

Pentra ES 60

(Serial no: 901PES15172)

Fully Automated Hematology Analyzer

For

House of Pathology Labs Pvt LTD

NEW DELHI

HORIBA
Medical

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646
5000. Visit us: <http://www.horiba.com/in>

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Section 4 Design Qualifications

- Design Qualification.
- Design Certificate.

Section 5 Performance Qualifications

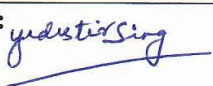

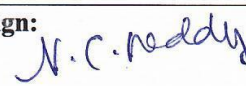
- Performance Qualification.
- Performance Certificate.

Section 6 Attachments

General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of Pentra ES60, Fully Five Part Automated Hematology Analyzer, at HOUSE OF PATHOLOGY LABS PVT LTD, New Delhi 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 HOUSE OF PATHOLOGY LABS PVT LTD, New Delhi 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:	Yudister Singh		
Title: Application Specialist	Sign: 	Date: 10/09/21	
Reviewed by:	HOUSE OF PATHOLOGY LABS PVT LTD, New Delhi		
Name:	Mr. Manzar Alam		
Title: Lab In charge	Sign: 	Date: 10/09/21	
Approved by:	HOUSE OF PATHOLOGY LABS PVT LTD, New Delhi		
Name:	Dr. V.C Reddy		
Title: Pathologist	Sign: 	Date: 10/09/21	

HORIBA
Medical

Pentra ES 60

(Serial no: 901PES15172)

Fully Automated Hematology Analyzer

Installation Qualification

For

House of Pathology Labs Pvt LTD
NEW DELHI

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646
5000. Visit us: <http://www.horiba.com/in/>

- **Installation Qualification**

- **Installation Requirement :**

Sr. No.	Description	Compliance (Yes/No)	Verified by & Date
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	10/09/21
2.	Physical Space Requirement: 44.5 x 48 x 51.5 cm with at least 20 cm space at the back of the instrument from the wall.	YES	10/09/21
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 200W with earth less than 3 V.	YES	10/09/21
4.	UPS connection available.	YES	10/09/21

- **The instrument has been checked for the following:**

Sr. No.	Verification	Provided (Yes/No)	Verified by & Date
1.	Instrument is identified Instrument Serial No. : 901PES15172	YES	10/09/21
2.	Manufacturer's specifications: Technical and Physical Requirement	YES	10/09/21
3.	Accessories / consumables are listed as per checklist (Provided along)	YES	10/09/21
4.	System checked for any External / physical damage.	YES	10/09/21
5.	Instrument User Manual (Soft Copy)	YES	10/09/21

- **Equipment Description :**

Pentra ES60, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No	Verified by / Date
Equipment Type: Hematology Analyzer	YES	10/09/21
Model : Pentra ES 60	YES	10/09/21
Manufacturer : HORIBA Medical, France	YES	10/09/21
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	YES	10/09/21
Equipment # : One	YES	10/09/21
Serial Number: 901PES15172	YES	10/09/21
Dimensions : h87 x w57 x d54 cm	YES	10/09/21
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 230 VA	YES	10/09/21

- **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.

- **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.




- **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 Pentra ES 60.
6. Connect the instrument to the Printer.
7. All the operating software has been loaded in to Pentra ES 60.
8. Switch ON the Printer. Now from back side of the instrument turn the power switch ON. Pentra ES60 goes through its power up and self-test sequence.
9. The Pentra ES60 login menu is displayed after the windows launch is completed. Enter the credentials and select the following. Create a New Work list from the File option.

• **INSTALLATION CERTIFICATE:**

Instrument Name : PENTRA ES60.
Serial Number : 901PES15172
Customer Details : HOUSE of Pathology LABS pvt LTD
With complete address : L-113, Lajpat Nagar-2, New DELHI 110024

Installation Date : 10/09/2021
Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Yudister Singh		
Title: Application Specialist	Sign: 	Date: 10/09/2021	
Reviewed by:	HOUSE of Pathology LABS pvt LTD		
Name:	Mr. Manzar Alam		
Title: Lab in charge	Sign: 	Date: 10/09/2021	
Approved by:	HOUSE of Pathology LABS pvt LTD		
Name:	Dr. V.C Reddy		
Title: Pathologist	Sign: 	Date: 10/09/2021	

Deviation:

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

HORIBA
Medical

Pentra ES 60

(Serial no: 901PES15172)

Fully Automated Hematology Analyzer

Operational Qualification

For

HOUSE of Pathology LABS Pvt LTD

NEW DELHI

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646
5000. Visit us: <http://www.horiba.com/in/>

• Operational Qualification

1. Instrument Identification:

Instrument Name : **Pentra ES60.**
 Serial Number : 901PES15172

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

Sr. No.	Test Name	Test Purpose	Method	Observation	Verified Sign/Date
1.	SYSTEM SWITCH ON	TO CHECK THE ERROR FREE POWER UP.	Switch on the main, switch on the system. Login into Pentra Application software. Pentra ES60 MAIN MENU is displayed after login. Check for any errors on the screen.	Done	10/09/2021
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.	Done	10/09/21
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	Done	10/09/21
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.	Done	10/09/21

5.	SAMPLE ANALYSIS	TO CHECK PROPER FUNCTIONING OF SAMPLE ANALYSIS	1. To run Stat/ Manual sample, press on stat icon and enter the sample ID and press on validate.	Done	10/09/21
6.	ARCHIVE AND CURRENT REPORTS	TO RECOVER THE SAMPLE RESULT FROM ARCHIVE AND CURRENT REPORTS	Press on Reports Icon and view the current results. To view archived reports, Select Archives from File menu and select the date of the reports and view the report.	Done	10/09/21
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. and press on Print Icon to print LJ graph. To view the raw data click on Zoom icon and view the data.	Done	10/09/21
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	Done	10/09/21

- **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 below:

Sr. No.	Operators	Designation	Name & Sign of the Trainer.	Date
1.	Dr. V.C Reddy	Pathologist	Yudister Singh	10/09/21
2.	Manzar Alam	Technician	Yudister Singh	10/09/21
3.	Ashwani kumar	Technician	Yudister Singh	10/09/21
4.	Pramod Kumar	Technician	Yudister Singh	10/09/21

- **Operator Maintenance Protocol**

Maintenance and Troubleshooting: Run Cytometer rinsing during shutdown and cleaning whenever required. Run Concentrated Cleaning Procedure once in a week or whenever required.

- **OPERATIONAL CERTIFICATE:**




Instrument Name : Pentra ES60.

Serial Number : 991PES15172

Customer Details : HOUSE of Pathology LABS Pvt LTD
With complete address L-113, Lajpat Nagar-2, New Delhi 110024

Installation Date : 10/09/21

Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Yudister Singh		
Title: Application Specialist	Sign: 	Date:	10/09/21
Reviewed by:	HOUSE of Pathology LABS Pvt LTD		
Name:	Mr. Manzar Alam		
Title: Lab In charge	Sign: 	Date:	10/09/21
Approved by:	HOUSE of Pathology LABS Pvt LTD		
Name:	Dr. V.C Reddy		
Title: Pathologist	Sign: 	Date:	10/09/21

Deviation:

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

HORIBA
Medical

Pentra ES60

(Serial no: 901PES15172)

Fully Automated Hematology Analyzer

Design Qualification

For

HOUSE of Pathology LABS Pvt LTD
NEW DELHI

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646
5000. Visit us: <http://www.horiba.com/in/>

- Design Qualification

This is to certify that Hematology analyzer specially designed for perform the following parameters.

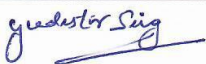

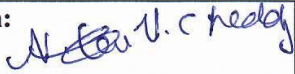
- WBC = White Blood Cell Count
- RBC = Red Blood Cell Count
- HGB = Hemoglobin Concentration
- HCT = Hematocrit
- MCV = Mean Corpuscular Volume
- MCH = Mean Corpuscular Hemoglobin
- MCHC = Mean Cellular Hemoglobin Concentration
- PLT = Platelet Count
- RDW-CV = Red Cell Distribution Width (Coefficient Of Variation)
- PDW = Platelet Distribution Width
- MPV = Mean Platelet Volume
- PCT = Plateletcrit
- NEUT# = Neutrophil Count
- LYMPH# = Lymphocyte Count
- MONO# = Monocyte Count
- EO# = Eosinophil Count
- BASO# = Basophil Count
- LIC# = Large Immature Cell Count
- ALY# = Atypical Lymphocytes Count
- NEUT% = Neutrophil Percent
- LYMPH% = Lymphocyte Percent
- MONO% = Monocyte Percent
- EO% = Eosinophil Percent
- BASO% = Basophil Percent
- LIC% = Large Immature Cell Percent

• **DESIGN CERTIFICATE:**

Instrument Name : Pentra ES60.
Serial Number : 901PES15172
Customer Details : HOUSE of Pathology LABS Pvt LTD
With complete address L-113 Lajpat Nagar-2, New Delhi 110024

Installation Date : 10/09/21

Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Yudister Singh		
Title: Application Specialist	Sign: 	Date: 10/09/21	
Reviewed by:	HOUSE of Pathology LABS Pvt LTD		
Name:	Mr. MANZAR ALAM		
Title: Lab in charge	Sign: 	Date: 10/09/21	
Approved by:	HOUSE of Pathology LABS Pvt LTD		
Name:	Dr. V.C Reddy		
Title: Pathologist	Sign: 	Date: 10/09/21	

Deviation:

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

HORIBA
Medical

Pentra ES60

(Serial no: 901PES15172)

Fully Automated Hematology Analyzer

Performance Qualification

For

HOUSE of Pathology LABS Pvt LTD
NEW DELHI

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646
5000. Visit us: <http://www.horiba.com/in/>

- Performance Qualification

A. Instrument Identification:

Instrument Name : Pentra ES60.
Serial Number : 901PES15172

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:810PES15046

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0	10/09/21
RBC $10^6/\text{mm}^3$	$\leq 0.03 \times 10^6/\text{mm}^3$	0	10/09/21
HGB g/dL	$\leq 0.3 \text{ g/dl}$	0	10/09/21
PLT $10^3/\text{mm}^3$	$\leq 7 \times 10^3/\text{mm}^3$	1	10/09/21
LMNE	$< 0.30 \#$	0.07	10/09/21

Conducted By: *Godastes Singh*

Verified By: *N.C. Neadly*

- 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) 6 times, without taking the values of first run, calibrates the instrument using average of the last 5 runs. Run Calibrator as a sample to verify the calibration.

Lot: CX462; Expiry: 05/10/2021

Serial No: 901PES15172

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	9.2	9.0	0.44	<2%	PASSED
RBC	4.55	4.55	0.64	<2%	PASSED
HGB	13.7	14.0	0.51	<1%	PASSED
HCT	37.8	36.6	0.79	<2%	PASSED
PLT	248	255	2.11	<5%	PASSED

Conducted By: *Yudhakar Singh*

Verified By: *N.C. Neddly*

- **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 PX431; Exp: 05/11/2021

Serial No: 901PES15172

Level I: Low Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 13/12/18	Comments
RBC $10^6/mm^3$	2.15 – 2.47	2.26	Passed
HGB g/dl	6.1– 6.9	6.5	Passed
HCT %	17– 20.0	18.3	Passed
MCV μm^3	75 – 85	81	Passed
MCH pg	26.1 – 30.1	28.8	Passed
MCHC g/dL	32.2 – 38.2	35.7	Passed
RDW %	9.0– 17.0	12.8	Passed
PLT $10^3/mm^3$	49 – 89	70	Passed
MPV μm^3	7.8 – 11.8	9.0	Passed
WBC $10^3/mm^3$	2.1– 2.9	2.4	Passed
NEU %	44.2 – 64.2	63.3	Passed
NEU #	1.01 – 1.71	1.54	Passed
LYM %	18.1– 42.1	22.8	Passed
LYM #	0.42– 1.08	0.56	Passed
MON %	2.2 – 9.2	3.4	Passed
MON #	0.06 – 0.22	0.08	Passed
EOS %	0.9– 12.9	7.4	Passed
EOS #	0.03 – 0.31	0.18	Passed
BAS %	0.3– 5.9	3.2	Passed
BAS #	0.01– 0.15	0.08	Passed

Conducted By: *gudatir Singh*

Verified *N.C. Reddy*

Level II: Normal Control

Parameters	Range (As per Kit Insert)	Observed Value Dated 13/12/18	Comments
RBC 10 ⁶ /mm ³	4.28 – 4.68	4.49	Passed
HGB g/dL	13.0 – 14.0	13.6	Passed
HCT %	35.2– 39.2	37.6	Passed
MCV µm ³	78 – 88	84	Passed
MCH pg	28.1 – 32.1	30.4	Passed
MCHC g/dL	33.3 – 39.3	36.3	Passed
RDW %	8.5 – 16.5	12.7	Passed
PLT 10 ³ /mm ³	216 – 276	250	Passed
MPV µm ³	7.3 – 11.3	8.6	Passed
WBC 10 ³ /mm ³	6.8– 8.8	8.0	Passed
NEU %	47.5 – 67.5	62.1	Passed
NEU #	3.59– 5.39	4.99	Passed
LYM %	20.8– 36.8	23.3	Passed
LYM #	1.55– 2.95	1.87	Passed
MON %	2.4 – 10.0	6.2	Passed
MON #	0.18 – 0.78	0.50	Passed
EOS %	0.7 – 7.7	4.9	Passed
EOS #	0.06– 0.60	0.39	Passed
BAS %	0.1 – 6.5	3.5	Passed
BAS#	0.01-0.51	0.28	Passed

Conducted By: *Juditha Singh*

Verified By: *N.C. Reddy*

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

Serial No: 901PES15172

Parameters	CV % Acceptance	CV % Observed	Comments
RBC 10 ⁶ /mm ³	< 2.0	1.15	PASSED
HGB g/dL	< 1.0	0.45	PASSED
HCT %	< 2.0	1.36	PASSED
PLT 10 ³ /mm ³	< 5.0	3.32	PASSED
WBC 10 ³ /mm ³	< 2.0	1.43	PASSED

Conducted By: *yoder Singh*

Verified By: *N.C. Nedy*

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

Serial No: 901PES15172

Parameters	WBC 10 ³ /mm ³	RBC 10 ⁶ /mm ³	HGB g/dL	HCT %	PLT 10 ³ /mm ³
Carry Over (%)	0.0	-1.10	0.0	-0.77	0.71
Manufacturer acceptable CV%	<2%	<2%	<2%	<2%	<2%
Status	Passed	Passed	Passed	Passed	Passed

Conducted By:



Verified By: *N.C. Reddy*

• PERFORMANCE CERTIFICATE:



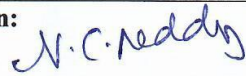
Instrument Name : Pentra ES60.
Serial Number : 901PES15172

Customer Details
With complete address

: HOUSE of Pathology LABS Pvt LTD
L-113 Lajpat Nagar-2 New DELHI 110024

Installation Date : 10/09/21

Warranty expires on : RR (Reagent Rental).

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Yudister Singh		
Title: Application Specialist	Sign: 	Date:- 10/09/21	
Reviewed by:	HOUSE of Pathology LABS Pvt LTD		
Name:	Mr. Manzar Alam		
Title: Lab In charge	Sign: 	Date: 10/09/21	
Approved by:	HOUSE of Pathology LABS Pvt LTD		
Name:	Dr. V.C Reddy		
Title: Pathologist	Sign: 	Date: 10/09/21	

Deviation:

Conclusion: Instrument has been qualified for Performance.

ATTACHMENTS

