

HORIBA

Medical

HORIBA India Private Limited

246, Okhla Industrial Estate Phase-III,

New Delhi 110020, India

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http : //www.horiba.com

CIN : U73100DL2006PTC153232

HIN/MED/2022-2023/100555

03rd March 2022

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **MICROS ES60** bearing serial number: **703ESOH11121** installed at **PATHKIND DIAGNOSTICS, BIJNOR** as calibrated on 03rd March 2022.

Calibrator : ABX MINOCAL

Lot No. : CX467

Expiry Date : 05th March 2022

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

Next calibration cycle is due on **02nd March 2023**.



Shrish Dixit

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

Date : 22/03/2022 12:09:55
User : labtech

BLANK REPORT

WBC	0.0	$10^3/\text{mm}^3$
RBC	0.00	$10^6/\text{mm}^3$
HGB	0.0	g/dl
PLT	0	$10^3/\text{mm}^3$

Date : 22/03/2022 12:19:42
User : labtech

QC RESULT REPORT

PID : MX433H
Name : MX433

Complete: 22/03/2022 12:19:
38
Operator : labtech

RESULT

Analyser Alarms Analysis Alarms

WBC	20.6	$10^3/\text{mm}^3$
LYM%	17.2	%
MON%	3.9	%
GRA%	78.9	%
LYM#	3.50	$10^3/\text{mm}^3$
MON#	0.80	$10^3/\text{mm}^3$
GRA#	16.30	$10^3/\text{mm}^3$

RBC	5.67	$10^6/\text{mm}^3$
HGB	19.0	g/dl
HCT	51.6	%
MCV	91	μm^3
MCH	33.5	pg
MCHC	36.8	g/dl
RDW-CV	12.0	%

PLT	497	$10^3/\text{mm}^3$
MPV	8.5	μm^3

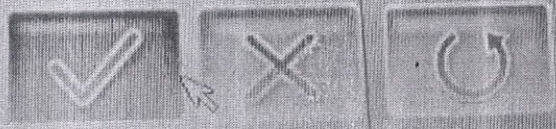


PRECISION CALCULATOR

SR NO	WBC	RBC	HGB	HCT	PLT	RDW	LYM%	MON%	GRA%
1	8.8	4.37	13.4	38.0	207				
2	8.9	4.45	13.7	38.7	201				
3	9.1	4.44	13.9	38.2	216				
4	9.0	4.42	13.7	37.9	214				
5	9.2	4.41	13.7	37.9	199				
6	9.1	4.45	13.8	38.2	212				
7	9.0	4.37	13.6	37.5	211				
8									
9									
10									
MEAN SD	9.01428571 0.10488088	4.41571429 0.03076795	13.6857143 0.10327956	38.0571429 0.40331956	208.571429 7.08284312	#DIV/0! #DIV/0!	#DIV/0! #DIV/0!	#DIV/0! #DIV/0!	#DIV/0! #DIV/0!
% CV	1.16349635	0.69678305	0.75465229	1.05977362	3.39588369	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
TARGET%CV	<=3	<=2	<=1	<=2	<=5	<=2	<=10	<=20	<=4
PASS/FAIL	PASS	PASS	PASS	PASS	PASS	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
MIN	8.8	4.37	13.4	37.5	199	0	0	0	0
MAX	9.2	4.45	13.9	38.7	216	0	0	0	0
DIFF	0.4	0.08	0.5	1.2	17	0	0	0	0

Yudhan S

	WBC	RBC	HGB	HCT	PLT	MPV
	10 ³ /mm ³	10 ⁶ /mm ³	g/dL	%	10 ³ /mm ³	µm ³
Average	9.1	4.42	13.7	38.1	209	8.0
%BAL	18	0.63	1.8	0.7	13	3.0
CV	1.0	0.61	0.7	1.0	3	1.1
New Coef	1.00	0.82	1.28	1.01	1.15	0.96
Old Coef	1.02	0.81	1.30	1.02	1.00	0.93
Target	8.9	4.45	13.5	37.8	240	8.2
A1	8.8	4.37	13.4	38.0	207	8.0
2	8.9	4.45	13.7	38.7	201	8.0
3	9.1	4.44	13.9	38.2	216	8.0
4	9.0	4.42	13.7	37.9	214	7.9
5	9.2	4.41	13.7	37.9	199	8.1
6	9.1	4.45	13.8	38.2	212	7.9
7	9.0	4.37	13.6	37.5	211	7.9
8						
9						
10						
11						



Yashwanth S

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

ABX Micros ES60

(Serial no:**703ESOH11121**)

Fully Automated Hematology Analyzer

For

PATHKIND DIAGNOSTICS PVT LTD

(Bijnor)

UTTER PARDESH

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

Table of Contents:

Section 1 General Instructions

Section 2 Installation Qualification

- I. Installation Qualification.
- II. Installation Procedure.
- III. Installation Certificate.

Section 3 Operational Qualification

- I. Operational Qualification.
- II. Operational Training Record.
- III. Operator Maintenance Protocol.
- IV. Operational Certificate.



Section 4 Performance Qualifications

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

General Instructions:

- HORIBA India Pvt.Ltd. is responsible for installation of Micros ES60, Fully Three Part Automated Hematology Analyzer, at Pathkind diagnostics Pvt Ltd at Bijnor 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 PATHKIND DIAGNOSTICS PVT LTD, BINOR 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:	Mr. Pinnu		
Title: Engineer- Service	Sign: 	Date: 27/07/2017	
Approved by:	PATHKIND DIAGNOSTICS PVT LTD, Bijnor		
Name:	Mr. Neeraj Pratap		
Title: Scientific Officer	Sign: 	Date: 27/07/2017	

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ABXMicros ES60
(Serial no: **703ESOH11121**)
Fully Automated Hematology Analyzer

Installation Qualification

For

PATHKIND DIAGNOSTICS PVT LTD
(BIJNOR)
UTTER PARDESH

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

A. Installation Qualification

1. 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%.	Y	PS. 27/07/17
2.	Physical Space Requirement: 36(W) x 36(D) x 53(H) with at least 20 cm space at the back of the instrument from the wall.	Y	PS. 27/07/17
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.	Y	B. 27/07/17
4.	UPS connection available.	Y	B. 27/7/17

2. The instrument has been checked for the following:

Sr. No.	Verification	Provided (Yes/No)	Verified by & Date
1.	Instrument is identified Instrument Serial No. : 703ESOH11121	Y	B. 27/7/17
2.	Manufacturer's specifications: Technical and Physical Requirement	Y	PS. 27/7/17
3.	Accessories / consumables are listed as per checklist(Provided along)	Y	B. 27/7/17
4.	System checked for any External / physical damage.	Y	B. 27/7/17
5.	Instrument User Manual (Soft Copy)	Y	B. 27/7/17

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:

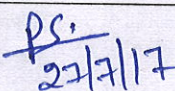

HORIBA India Pvt. Ltd strongly recommends the end user to maintain a basic consumable parts onsite to minimize down time due to minor failures. Spare parts as provided in the installation kit.

A. Installation Procedure:

1. Putting the system at the predefined and preinspected location (Having suitable Working Conditions).
2. Removal of the internal packing material of the system.
3. Place the Instrument on the benchtop (Vibration free).
4. Connect the Power cord to the Micros ES60.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to Micros ES60.
8. Now from back side of the instrument turn the power switch ON. Micros ES60 goes through its power up and self-test sequence.
9. The Micros ES60 login menus displayed after the Start up cycle is completed. Enter the credentials.

B. INSTALLATION CERTIFICATE:

Instrument Name : MICROS ES60.
Serial Number : 703ESOH11121
Customer Details : PATHKIND DIAGNOSTICS PVT LTD, BIJNOR,
With address Main Civil Line, Sai Hotel, Opp. Mamchand Petrol Pump
Binor 246701
Installation Date : 27/07/2017

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Pinnu		
Title: Engineer- Service	Sign: 	Date: 27/7/17	
Approved by:	PATHKIND DIAGNOSTICS PVT LTD, BIJNOR		
Name:	Mr. Neeraj Pratap		
Title: Scientific Officer	Sign: 	Date: 27/7/2017	

Deviation:

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

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ABX Micros ES60
(Serial no: **703ESOH11121**)
Fully Automated Hematology Analyzer

Operational Qualification

For

PATHKIND DIAGNOSTICS PVT LTD
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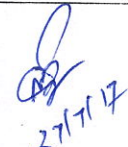

A. Operational Qualification



1. Instrument Identification:

Instrument Name : MICROS ES60

Serial Number : 703ESOH11121


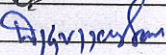
2. Following is the list of actions performed and verified for running the system routinely.

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. Start up cycle is performed. Login in as User and check for the Screen Errors.	ok	 27/7/17
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	 27/7/17
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	ok	 27/7/17
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	 27/7/17
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	 27/7/17
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	 27/7/17

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 on QC Runs ,Click on Datas .	OK	 27/11/17
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	OK	 27/11/17

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 below:

Sr. No.	Operators	Designation	Name & Sign of the Trainer.	Date
1.	Mr. Neeraj Pratap	Scientific Officer		27/11/2017
2.	Mr. Digvijay Singh	Scientific Officer		27/11/17

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.



C. OPERATIONAL CERTIFICATE:

Instrument Name : MICROS ES60.

Serial Number : 703ESOH11121

**Customer Details
with complete address** : PATHKIND DIAGNOSTICS PVT LTD, BIJNOR
Main Civil Line, Sai Hotel, Opp. Mamchand Petrol Pump
Binor 246701

Installation Date : 27/07/2017

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Pinnu		
Title: Engineer- Service	Sign: 	Date: 27/7/17	
Approved by:	PATHKIND DIAGNOSTICS PVT LTD, BIJNOR		
Name:	Mr. Neeraj Pratap		
Title: Scientific Officer	Sign: 	Date: 27/07/2017	

Deviation:

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

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ABXMicros ES60

(Serial no: **703ESOH11121**)

Fully Automated Hematology Analyzer

Performance Qualification

For

PATHKIND DIAGNOSTICS PVT LTD
(BIJNOR)
UTTER PRADESH

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

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

Instrument Name : MICROS ES60.

Serial Number: 703ESOH11121.

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: 703ESOH11121.

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	
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 $10^3/\text{mm}^3$	$\leq 10 \times 10^3/\text{mm}^3$	0	

Conducted by:

P/mny

Verified by:

PS.
27/07/17

- **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) 11 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: CX026; Expiry: 05/08/2017.

Serial No: 703ESOH11121

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	9.1	9.4	1.8	<2%	PASSED
RBC	4.59	4.62	1.05	<2%	PASSED
HGB	13.8	13.9	0.3	<1%	PASSED
HCT	39.2	39.4	1.1	<2%	PASSED
PLT	254	250	3	<5%	PASSED

Conducted By:

Pinny

Verified By:

PS.
27/7/17

- **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 Minotrol MX016; **Exp:** 05/08/2017.

Serial No: 703ESOH11121
Level I: Low Control

Parameters	Target value as per kit	Tolerance limit as per kit (±)	Observed Value Dated 27/07/2017	Comments
RBC 10 ⁶ /mm ³	2.44	0.15	2.41	Passed
HGB g/dL	6.1	0.4	6.0	Passed
HCT %	17.1	2.0	16.6	Passed
MCV μm ³	70	4	69	Passed
MCH pg	25.0	2	24.6	Passed
MCHC g/dL	35.7	3	35.7	Passed
RDW %	14.0	3	13.8	Passed
PLT 10 ³ /mm ³	76	20	75	Passed
MPV μm ³	8.8	2	9.1	Passed
WBC 10 ³ /mm ³	2.0	0.4	2.0	Passed
GRA %	26.0	7	25.2	Passed
GRA#	0.52	0.40	0.70	Passed
LYM%	66.0	8	66.3	Passed
LYM #	1.32	0.40	1.20	Passed
MON %	8.0	6	8.5	Passed
MON #	0.20	0.20	0.10	Passed

Level II: Normal Control

Parameters	Target value as per kit	Tolerance limit as per kit (±)	Observed Value Dated 27/07/2017	Comments
RBC 10 ⁶ /mm ³	4.50	0.2	4.76	Passed
HGB g/dL	13.4	0.5	13.8	Passed
HCT %	36.5	5	37.5	Passed
MCV μm ³	81	4	79	Passed
MCH pg	29.8	2	29.0	Passed
MCHC g/dL	36.8	3	36.7	Passed
RDW %	13.5	3	13.2	Passed
PLT 10 ³ /mm ³	255	40	270	Passed
MPV μm ³	8	2	7.7	Passed

WBC 10 ³ /mm ³	7.7	0.8	7.6	Passed
GRA %	59	6	60.6	Passed
GRA #	4.54	0.6	4.70	Passed
LYM %	33.5	5	32.7	Passed
LYM #	2.58	0.40	2.40	Passed
MON %	7.5	4	6.7	Passed
MON #	0.58	0.30	0.50	Passed

Level III: High Control

Parameters	Target value as per kit	Tolerance limit as per kit (±)	Observed Value Dated 27/07/2017	Comments
RBC 10 ⁶ /mm ³	5.80	0.30	5.85	Passed
HGB g/dL	18.4	0.6	18.2	Passed
HCT %	51.6	6	50.6	Passed
MCV μm ³	89	4	86	Passed
MCH pg	31.7	2.0	31.1	Passed
MCHC g/dL	35.6	3	36.0	Passed
RDW %	13.5	3	12.7	Passed
PLT 10 ³ /mm ³	501	45	536	Passed
MPV μm ³	7.5	3.0	7.4	Passed
WBC 10 ³ /mm ³	20.0	1.6	20.2	Passed
GRA %	79.0	7.0	77.4	Passed
GRA #	15.8	1.40	15.7	Passed
LYM %	16.5	5	16.0	Passed
LYM #	3.3	1.0	3.20	Passed
MON %	4.5	4.0	4.6	Passed
MON #	0.90	0.80	0.90	Passed

Conducted By:

Pinny

Verified By:

PS.

- **Precision Study:** Precision is checked by running blood sample in 07 replicates & getting CV% in within acceptance.

Serial No: 703ESOH11121

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	1	PASS
HGB g/Dl	< 1.5	0.8	PASS
HCT %	< 2.0	1.0	PASS
PLT $10^3/\text{mm}^3$	< 5.0	2.8	PASS
WBC $10^3/\text{mm}^3$	< 2.5	1.2	PASS
GRA %	<4	0.35	PASS
LYM%	<10	1.7	PASS
MON%	<20	3.3	PASS

Conducted By:

Pinnu

Verified By:

PS.
27/7/17

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

Serial No: 703ESOH11121

Parameters	WBC 10 ³ /mm ³	RBC 10 ⁶ /mm ³	HGB g/dL	HCT %	PLT 10 ³ /mm ³
Carry Over (%)	0.6	0.3	0	0.3	0.8
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<2%
Status	Passed	Passed	Passed	Passed	Passed

Conducted By:

Pinnu

Verified By:

B.
27/7/17



B. PERFORMANCE CERTIFICATE:

Instrument Name : MICROS ES60.

Serial Number : 703ESOH11121.

Customer Details : PATHKIND DIAGNOSTICS PVT LTD.
with complete address Main Civil Line, Sai Hotel, Opp. Mamchand Petrol Pump
Binor 246701

Installation Date : 27/07/2017

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Pinnu		
Title: Engineer- Service	Sign:		Date:
			27/7/17
Approved by:	PATHKIND DIAGNOSTICS PVT LTD, BIJNOR		
Name:	Mr. Neeraj Pratap		
Title:	Sign:		Date:
Scientific Officer			27/7/2017