

**HORIBA**

Medical

**HORIBA India Private Limited**

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CIN : U73100DL2006PTC153232

HIN/MED/2021-2022/100517  
3<sup>RD</sup> FEB 2022

## **CALIBRATION CERTIFICATE**

This is to certify that the Hematology Analyzer MICROS ES60 bearing serial number: **703ESOH11096** installed at **PATHKIND BULANSAHAR** as calibrated on **1<sup>ST</sup> FEB 2022**.

Calibrator : ABX MINOCAL  
Lot No. : CX467  
Expiry Date : 05<sup>th</sup> MARCH 2022

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

Next calibration cycle is due on **31<sup>ST</sup> Jan 2023**.

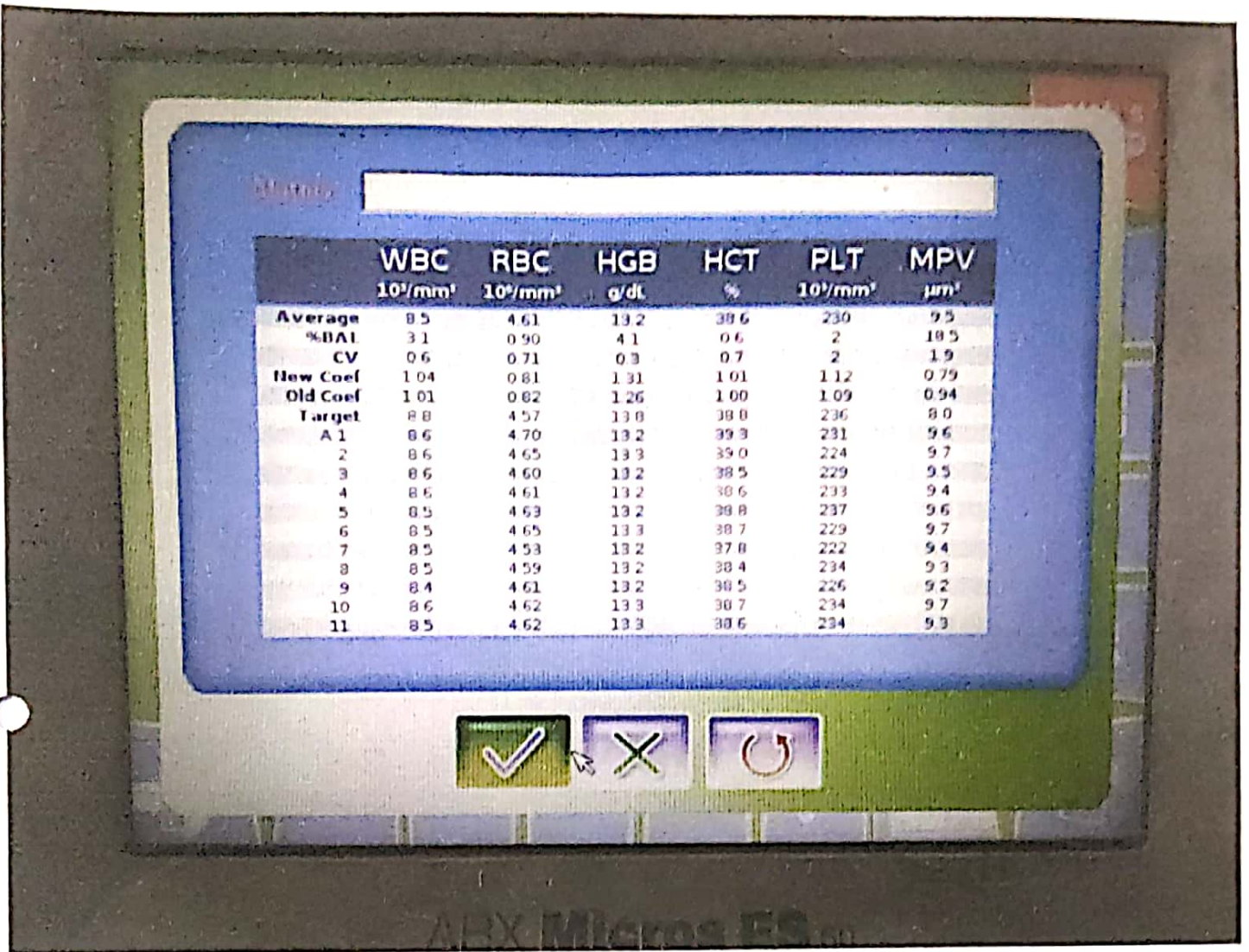


Shrish Dixit

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

# Reference blank counting

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 : 01/02/2022 11:47:27  
User : labtech

### PATIENT RESULT REPORT

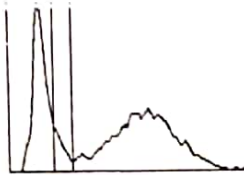
SID : R1  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 11:47:13  
Operator : labtech

### RESULT

Analyser Alarms  
Analysis Alarms

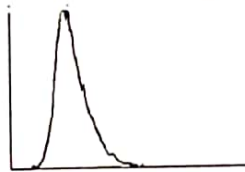
WBC 7.2  $10^3/mm^3$   
LYM% 34.8 %  
MON% 5.3 %  
GRA% 59.9 %  
LYM# 2.50  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.40  $10^3/mm^3$

WBC



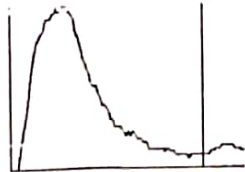
RBC 4.60  $10^6/mm^3$   
HGB 10.0 L g/dl  
HCT 33.1 L %  
MCV 72 L  $\mu m^3$   
MCH 21.7 L pg  
MCHC 30.0 L g/dl  
RDW-CV 17.6 H %  
RDW-SD 45  $\mu m^3$

RBC



PLT 327  $10^3/mm^3$   
MPV 9.3  $\mu m^3$   
PCT 0.304 %  
PDW 16.5 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 11:50:46  
User : tech

### PATIENT RESULT REPORT

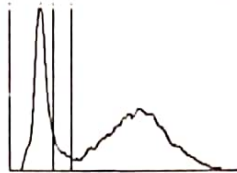
SID : R2  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 11:47:54  
Operator : tech

### RESULT

Analyser Alarms  
Analysis Alarms

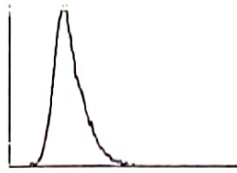
WBC 7.5  $10^3/mm^3$   
LYM% 33.5 %  
MON% 4.4 %  
GRA% 62.1 %  
LYM# 2.50  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.70  $10^3/mm^3$

WBC



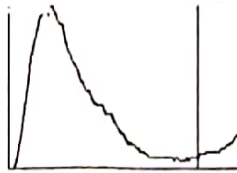
RBC 4.53  $10^6/mm^3$   
HGB 9.9 L g/dl  
HCT 32.6 L %  
MCV 72 L  $\mu m^3$   
MCH 21.9 L pg  
MCHC 30.3 L g/dl  
RDW-CV 17.1 H %  
RDW-SD 44  $\mu m^3$

RBC



PLT 341  $10^3/mm^3$   
MPV 8.9  $\mu m^3$   
PCT 0.305 %  
PDW 16.4 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 11:49:40  
User : labtech

### PATIENT RESULT REPORT

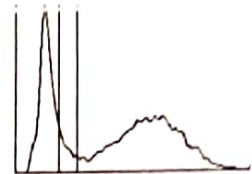
SID : R3  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 11:49:31  
Operator : labtech

### RESULT

Analyser Alarms  
Analysis Alarms

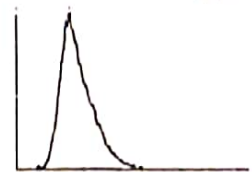
WBC 7.1  $10^3/mm^3$   
LYM% 35.2 %  
MON% 5.4 %  
GRA% 59.4 %  
LYM# 2.40  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.40  $10^3/mm^3$

WBC



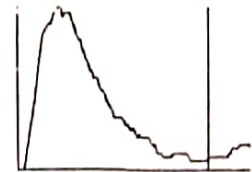
RBC 4.53  $10^6/mm^3$   
HGB 10.1 L g/dl  
HCT 33.1 L %  
MCV 73 L  $\mu m^3$   
MCH 22.3 L pg  
MCHC 30.6 L g/dl  
RDW-CV 17.8 H %  
RDW-SD 47  $\mu m^3$

RBC



PLT 332  $10^3/mm^3$   
MPV 9.2  $\mu m^3$   
PCT 0.306 %  
PDW 16.2 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 11:57:20  
User : tech

### PATIENT RESULT REPORT

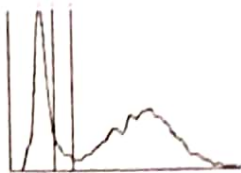
SID : R4  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 11:56:42  
Operator : tech

### RESULT

Analyser Alarms  
Analysis Alarms

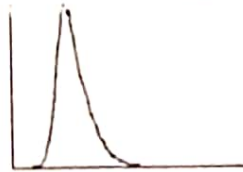
WBC 7.4  $10^3/mm^3$   
LYM% 33.1 %  
MON% 4.3 %  
GRA% 62.6 %  
LYM# 2.40  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.70  $10^3/mm^3$

WBC



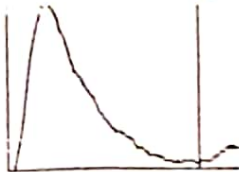
RBC 4.52  $10^6/mm^3$   
HGB 9.9 L g/dl  
HCT 32.4 L %  
MCV 72 L  $\mu m^3$   
MCH 21.8 L pg  
MCHC 30.4 L g/dl  
RDW-CV 17.4 H %  
RDW-SD 45  $\mu m^2$

RBC



PLT 362  $10^3/mm^3$   
MPV 8.9  $\mu m^3$   
PCT 0.324 %  
PDW 15.1 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 11:03:25  
User : labtech

### PATIENT RESULT REPORT

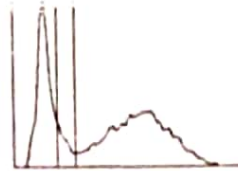
SID : R5  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 12:01:25  
Operator : labtech

### RESULT

Analyser Alarms  
Analysis Alarms

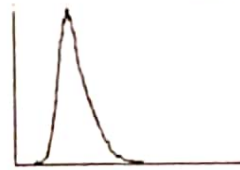
WBC 7.1  $10^3/mm^3$   
LYM% 35.3 %  
MON% 5.6 %  
GRA% 59.1 %  
LYM# 2.50  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.30  $10^3/mm^3$

WBC



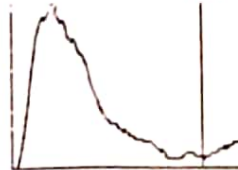
RBC 4.52  $10^6/mm^3$   
HGB 10.0 L g/dl  
HCT 32.9 L %  
MCV 73 L  $\mu m^3$   
MCH 22.0 L pg  
MCHC 30.3 L g/dl  
RDW-CV 18.0 H %  
RDW-SD 47  $\mu m^2$

RBC



PLT 331  $10^3/mm^3$   
MPV 9.1  $\mu m^3$   
PCT 0.301 %  
PDW 16.2 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 12:00:38  
User : tech

### PATIENT RESULT REPORT

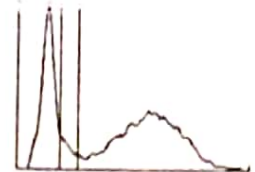
SID : R6  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 12:00:30  
Operator : tech

### RESULT

Analyser Alarms  
Analysis Alarms

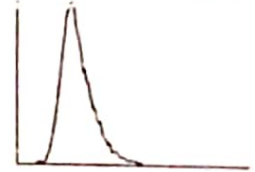
WBC 7.5  $10^3/mm^3$   
LYM% 34.1 %  
MON% 5.1 %  
GRA% 60.8 %  
LYM# 2.50  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.70  $10^3/mm^3$

WBC



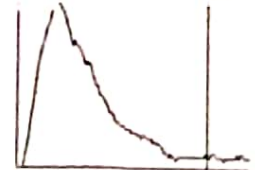
RBC 4.52  $10^6/mm^3$   
HGB 9.9 L g/dl  
HCT 32.7 L %  
MCV 72 L  $\mu m^3$   
MCH 21.9 L pg  
MCHC 30.2 L g/dl  
RDW-CV 17.4 H %  
RDW-SD 45  $\mu m^2$

RBC



PLT 354  $10^3/mm^3$   
MPV 9.2  $\mu m^3$   
PCT 0.325 %  
PDW 13.7 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 12:05:44  
User : tech

### PATIENT RESULT REPORT

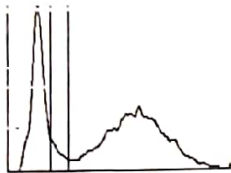
SID : R7  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 12:02:06  
Operator : tech

### RESULT

Analyser Alarms  
Analysis Alarms

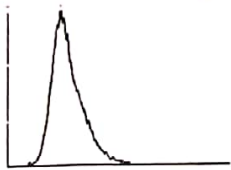
WBC 7.6  $10^3/mm^3$   
LYM% 33.6 %  
MON% 4.4 %  
GRA% 62.0 %  
LYM# 2.50  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.80  $10^3/mm^3$

WBC



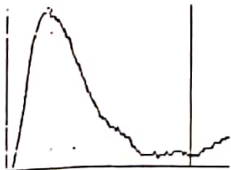
RBC 4.50  $10^6/mm^3$   
HGB 9.9 L g/dl  
HCT 32.7 L %  
MCV 73 L  $\mu m^3$   
MCH 22.1 L pg  
MCHC 30.3 L g/dl  
RDW-CV 17.2 H %  
RDW-SD 45  $\mu m^3$

RBC



PLT 345  $10^3/mm^3$   
MPV 9.0  $\mu m^3$   
PCT 0.311 %  
PDW 15.9 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 12:06:23  
User : tech

### PATIENT RESULT REPORT

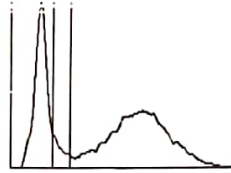
SID : R8  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 12:03:42  
Operator : tech

### RESULT

Analyser Alarms  
Analysis Alarms

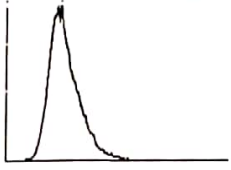
WBC 7.4  $10^3/mm^3$   
LYM% 34.4 %  
MON% 4.6 %  
GRA% 61.0 %  
LYM# 2.50  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.60  $10^3/mm^3$

WBC



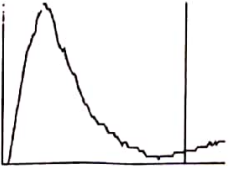
RBC 4.47  $10^6/mm^3$   
HGB 9.9 L g/dl  
HCT 32.4 L %  
MCV 72 L  $\mu m^3$   
MCH 22.2 L pg  
MCHC 30.6 L g/dl  
RDW-CV 17.7 H %  
RDW-SD 46  $\mu m^3$

RBC



PLT 342  $10^3/mm^3$   
MPV 8.8  $\mu m^3$   
PCT 0.301 %  
PDW 14.6 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 12:07:01  
User : tech

### PATIENT RESULT REPORT

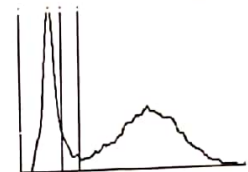
SID : R9  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 12:05:11  
Operator : tech

### RESULT

Analyser Alarms  
Analysis Alarms

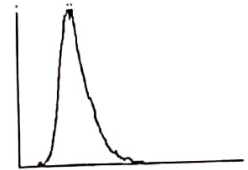
WBC 7.4  $10^3/mm^3$   
LYM% 33.4 %  
MON% 4.6 %  
GRA% 62.0 %  
LYM# 2.40  $10^3/mm^3$   
MON# 0.30  $10^3/mm^3$   
GRA# 4.70  $10^3/mm^3$

WBC



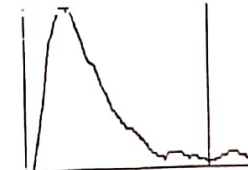
RBC 4.48  $10^6/mm^3$   
HGB 9.9 L g/dl  
HCT 32.4 L %  
MCV 72 L  $\mu m^3$   
MCH 22.0 L pg  
MCHC 30.5 L g/dl  
RDW-CV 17.5 H %  
RDW-SD 45  $\mu m^3$

RBC



PLT 357  $10^3/mm^3$   
MPV 9.2  $\mu m^3$   
PCT 0.330 %  
PDW 16.1 %

PLT



RUO Parameters for Research Use Only

Date : 01/02/2022 12:07:52  
User : labtech

### PATIENT RESULT REPORT

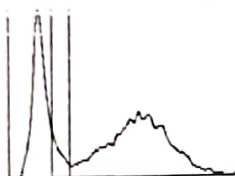
SID : R10  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 12:07:37  
Operator : labtech

### RESULT

Analyser Alarms  
Analysis Alarms

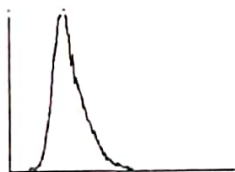
WBC	7.0	$10^3/mm^3$
LVM%	34.6	%
MON%	5.2	%
GRA%	60.2	%
LVM#	2.40	$10^3/mm^3$
MON#	0.30	$10^3/mm^3$
GRA#	4.30	$10^3/mm^3$

WBC



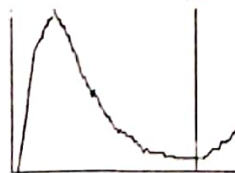
RBC	4.51	$10^6/mm^3$
HGB	10.0 L	g/dl
HCT	32.9 L	%
MCV	73 L	$\mu m^3$
MCH	22.2 L	pg
MCHC	30.4 L	g/dl
RDW-CV	17.7 H	%
RDW-SD	46	$\mu m^3$

RBC



PLT	329	$10^3/mm^3$
MPV	9.3	$\mu m^3$
PCT	0.305	%
PDW	16.4	%

PLT



RUC Parameters for  
Research Use Only

Date : 01/02/2022 12:09:19  
User : labtech

### PATIENT RESULT REPORT

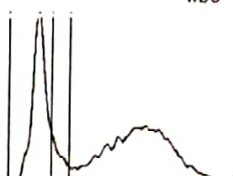
SID : R11  
PID :  
Name :  
Firstname :  
Type : Man  
Department :  
Local :  
Complete: 01/02/2022 12:09:11  
Operator : labtech

### RESULT

Analyser Alarms  
Analysis Alarms

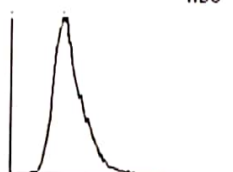
WBC	7.0	$10^3/mm^3$
LVM%	35.1	%
MON%	5.6	%
GRA%	59.3	%
LVM#	2.40	$10^3/mm^3$
MON#	0.30	$10^3/mm^3$
GRA#	4.30	$10^3/mm^3$

WBC



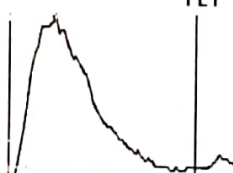
RBC	4.54	$10^6/mm^3$
HGB	10.0 L	g/dl
HCT	32.9 L	%
MCV	72 L	$\mu m^3$
MCH	22.1 L	pg
MCHC	30.6 L	g/dl
RDW-CV	17.3 H	%
RDW-SD	45	$\mu m^3$

RBC



PLT	329	$10^3/mm^3$
MPV	9.2	$\mu m^3$
PCT	0.305	%
PDW	16.6	%

PLT



RUC Parameters for  
Research Use Only

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

**ABX Micros 60/ ES60**  
(Serial no: **703ESOH11096**)  
Fully Automated Hematology Analyzer

For

**PATHKIND DIAGNOSTICS**  
BULANSAHAR

**HORIBA**  
Medical



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#246, Okhla Industrial Estate, Phase III, New BULANSAHAR 110020, India, Tel: 011  
4646 5000.

Visit us: <http://www.horiba.com/in/>

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

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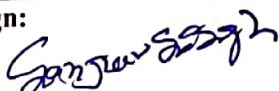

- I. Performance Qualification.
- II. Performance Certificate.

### **Section 5 Attachments**

**General Instructions:**

- HORIBA India Pvt. Ltd. is responsible for installation of Micros ES60, Fully Five Part Automated Hematology Analyzer, at PATHKIND Diagnostic Center, BULANSAHAR 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 PATHKIND Diagnostic Center, BULANSAHAR 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**

<b>Prepared by:</b>	<b>HORIBA Medical - HORIBA India Pvt. Ltd.</b>		
<b>Name:</b>	<b>SANJEEV SINGH</b>		
<b>Title:</b> Application Specialist	<b>Sign:</b> 	<b>Date:</b> 27/7/2017	
<b>Reviewed by:</b>	<b>PATHKIND Diagnostic , BULANSAHAR</b>		
<b>Name:</b>	<b>DR. FAHEEM JAVED</b>		
<b>Title: PATHOLOGIST</b>	<b>Sign:</b> 	<b>Date:</b> 27/7/2017	
<b>Approved by:</b>	<b>PATHKIND Diagnostic , BULANSAHAR</b>		
<b>Name:</b>	<b>DR. FAHEEM JAVED</b>		

**HORIBA**  
Medical

HORIBA India Private Limited

Title: PATHOLOGIST

Sign:

Date:

**HORIBA**  
Medical

**ABX Micros 60/ ES60**  
(Serial no: 703ES0H11096)  
Fully Automated Hematology Analyzer

**Installation Qualification**

For

**PATHKIND DIAGNOSTICS**  
BULANSAHAR

#246, Okhla Industrial Estate, Phase III, New BULANSAHAR 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%.	YES	27/7/2017
2.	Physical Space Requirement: 36(W) x 36(D) x 53(H)cm with at least 20 cm space at the back of the instrument from the wall.	YES	27/7/2017
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.	YES	27/7/2017
4.	UPS connection available.	YES	27/7/2017

### 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. : 404 PNDF 0332	YES	27/7/2017
2.	Manufacturer's specifications: Technical and Physical Requirement	YES	27/7/2017
3.	Accessories / consumables are listed as per checklist ( Provided along)	YES	27/7/2017
4.	System checked for any External / physical damage.	YES	27/7/2017
5.	Instrument User Manual (Soft Copy)	YES	27/7/2017

**3. Equipment Description :**

Micros ES60, Fully Automated Hematology Analyzer

<b>Instrument Identification</b>	<b>Verified Yes/No</b>	<b>Verified by / Date</b>
Equipment Type : Hematology Analyzer	YES	27/7/2017
Model : Micros ES60	YES	27/7/2017
Manufacturer : HORIBA Medical, France	YES	27/7/2017
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	YES	27/7/2017
Equipment # : One	YES	27/7/2017
Serial Number :	YES	27/7/2017
Dimensions : 36(W) x 36(D) x 53(H)	YES	27/7/2017
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 150 VA	YES	27/7/2017

**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.

<b>Qualified Trained employee name</b>	<b>Verified By</b>	<b>Date</b>
SANJEEV SINGH	DR. FAHEEM JAVED	27/7/2017


**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 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 menu is displayed after the Start up cycle is completed. Enter the credentials.

**C. INSTALLATION CERTIFICATE:**

Instrument Name : MICROS ES60.  
Serial Number : 703ES0H11096  
Customer Details with complete address : PATHKIND Diagnostic  
BULANSAHAR  
Installation Date : 27/7/2017  
Warranty expires on : 27/7/2017

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:			
Title:	Sign:	Date:	
Application Specialist		27/7/2017	
Reviewed by:	PATHKIND Diagnostic Center, BULANSAHAR		
Name:	DR. FAHEEM JAVED		
Title: PATHOLOGIST	Sign:	Date:	
		27/7/2017	
Approved by:	PATHKIND Diagnostic Center, BULANSAHAR		
Name:	DR. FAHEEM JAVED		
Title: PATHOLOGIST	Sign:	Date:	
		27/7/2017	

**Deviation:**

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

# **HORIBA**

Medical

**ABX Micros 60/ ES60**

(Serial no: 703ES0H11096)

Fully Automated Hematology Analyzer

**Operational Qualification**

For

**PATHKIND DIAGNOSTICS**



**BULANSAHAR**

#246, Okhla Industrial Estate, Phase III, New BULANSAHAR 110020, India, Tel: 011  
4646 5000.

Visit us: <http://www.horiba.com/in/>

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

Instrument Name : MICROS ES60

Serial Number : 703ES01H1096

**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	27/7/2017
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	27/7/2017
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	OK	27/7/2017
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	27/7/2017
5.	SAMPLE	TO CHECK	1. To run Stat/ Manual sample,	OK	27/7/2017

	ANALYSIS	PROPER FUNCTIONING OF SAMPLE ANALYSIS	press on sample identification and enter the sample ID and press on validate.		
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	27/7/2017
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	27/7/2017
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	OK	27/7/2017

## 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. GIRDHAR KUMAR	SSO	SANJEEV	27/7/2017
2.	MR. KAUSHAL KUMAR	SO	SANJEEV	27/7/2017
3.	MR. OSHO BHARDWAJ	JSO	SANJEEV	27/7/2017
4.	DR FAHEEM JAVED	PATHOLOGIS T	SANJEEV	27/7/2017
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				

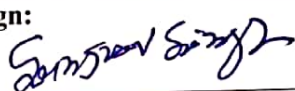
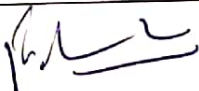

14.				
15.				
16.				

**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 : MICROS ES60.  
 Serial Number : 703ES0H11096  
 Customer Details with complete address : PATHKIND Diagnostic BULANSAHAR  
 Installation Date : 27/7/2017  
 Warranty expires on :27/7/2017

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:			
Title:	Sign:	Date:	
Application Specialist		27/7/2017	
Reviewed by:	PATHKIND Diagnostic Center, BULANSAHAR		
Name:	DR. FAHEEM JAVED		
Title: PATHOLOGIST	Sign:	Date:	
		27/7/2017	
Approved by:	PATHKIND diagnostic Center, BULANSAHAR		
Name:	DR. FAHEEM JAVED		
Title: PATHOLOGIST	Sign:	Date:	
		27/7/2017	

**Deviation:**

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

**HORIBA**  
Medical

**ABX Micros 60/ ES60**  
(Serial no: 703ES0H11096)  
Fully Automated Hematology Analyzer

**Performance Qualification**

For

**PATHKIND DIAGNOSTICS**

**BULANSAHAR**

#246, Okhla Industrial Estate, Phase III, New BULANSAHAR 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 : 703ES0H11096.

**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: 703ES0H11096

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC 10 <sup>3</sup> /mm <sup>3</sup>	$\leq 0.3 \times 10^3 / \text{mm}^3$	0	27/7/2017
RBC 10 <sup>6</sup> /mm <sup>3</sup>	$\leq 0.02 \times 10^6 / \text{mm}^3$	0	27/7/2017
HGB g/dl	$\leq 0.3 \text{ g/dl}$	0	27/7/2017
PLT 10 <sup>3</sup> /mm <sup>3</sup>	$\leq 10 \times 10^3 / \text{mm}^3$	0	27/7/2017

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) 6 times, without taking the values of first run, calibrate the instrument using average of the last 5 runs. Run Calibrator as a sample to verify the calibration.  
**Lot: CX413; Expiry: 05/09/2017**

Serial No: 703ES0H11096

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	9.6	9.8	1.30	<2%	PASSED
RBC	4.60	4.60	0.84	<2%	PASSED
HGB	13.7	13.5	0.67	<1%	PASSED
HCT	38.3	38.4	1.17	<2%	PASSED
PLT	252	243	2.55	<5%	PASSED

Conducted By:

Verified By:

ALL TRILEVEL QC & PRECISION WERE FOUND WITHIN RANGE AS PER KIT INSERT DURING INSTALLATION.

- **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: 703ES0H11096

Parameters	WBC 10 <sup>9</sup> /mm <sup>3</sup>	RBC 10 <sup>9</sup> /mm <sup>3</sup>	HGB g/dL	HCT %	PLT 10 <sup>9</sup> /mm <sup>3</sup>
Carry Over (%)	0	0.36	0	0	-1.25
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

Conducted By:

Verified By:

### B. PERFORMANCE CERTIFICATE:

Instrument Name : MICROS ES60.  
Serial Number : 703ES0H11096.  
Customer Details with complete address : PATHKIND Diagnostic Centre ,  
Installation Date : 27/7/2017  
Warranty expires on : 26/07/2022

Prepared by: HORIBA Medical - HORIBA India Pvt. Ltd.



Name:			
Title:		Sign:	
Application Specialist		<i>[Signature]</i>	
Reviewed by:	PATHKIND Diagnostic Center, BULANSAHAR		
Name:			
Title:	Sign:	Date:	
	<i>[Signature]</i>		
Approved by:	PATHKIND Diagnostic Center, BULANSAHAR		
Name:			
Title:	Sign:	Date:	
	<i>[Signature]</i>		

**Conclusion:** Instrument has been qualified for Performance.

### ATTACHMENTS

Attachment No	Document Title	Page Nos.	Verified By Sign/Date

**HORIBA**

Medical

HORIBA India Private Limited


Date: 01/02/2022    User: tech    Lot number: CX467    Name: MINOCAL

Summary view



Alarms :

Stat	WBC 10 <sup>3</sup> /mm <sup>3</sup>	RBC 10 <sup>6</sup> /mm <sup>3</sup>	HGB g/dL	HCT %	PLT 10 <sup>3</sup> /mm <sup>3</sup>	MPV μm <sup>3</sup>
Average	9.2	4.33	12.9	37.4	203	8.1
Target	9.1	4.42	13.3	38.0	248	8.5
CV	1.7	1.07	0.4	1.0	2	1.7
%BAL	1.4	2.08	3.1	1.6	18	4.7
Coef						
Old	1.07	0.80	1.24	1.00	1.00	0.94
▶ Auto	1.06	0.82	1.28	1.02	1.22	0.99
Manu						