



Aspen Diagnostics Pvt. Ltd.
(Rapid Diagnostic Group Of Companies)



ISO 9001:2015
CERTIFIED COMPANY

HIN/MED/2021-2022/100514
04th Nov 2021

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **MINDRAY/LABLIFE34D** bearing serial number: **RM-31103679** installed at **DELHI CLINICAL LABORATORY JIND 126102** as calibrated on 04th Nov 2021.

Calibrator : ABX MINOCAL
Lot No. : CX440
Expiry Date : 08th Nov_2021.

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

Next calibration cycle is due on **03rd Nov 2022.**

Pragati
Area Manager
Aspen Diagnostics Pvt Ltd
Delhi - 110033

Shrish Dixit

(Head- Products & Marketing)For
Area Manager Sales & Service



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Installation Qualification, Performance, Qualification and Operational Qualification

MINDRAY/LABLIFE34D

(RM-31103679)

Fully Automated Hematology Analyzer

For
DELHI CLINICAL LABORATORY



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General Instructions:

- Area Manager Sales & Service. is responsible for installation of MINDRAY/LABLIFE34D, Fully 3 part Part Automated Hematology Analyzer, at DELHI CLINICAL LABORATORY . As per the attached protocol.
- An authorized Area Manager Sales & Service., 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.
- An authorized Area Manager Sales & Service. 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
- DELHI CLINICAL LABORATORY along with an authorized Area Manager Sales & Service., 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 Area Manager Sales & Service., 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:	Area Manager Sales & Service.		
Name:	RAHUL RAJPUT		
Title; Engineer at Customer support	Sign:		Date: 04/11/2016



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Approved by:		
Name:	Mr. AMIT	
Title: Lab Incharge	Sign:	Date: 04/11/2016

MINDRAY/LABLIFE34D

(RM-31103679)

Fully Automated Hematology Analyzer

Installation Qualification

For

DELHI CLINICAL LABORATORY



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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: 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
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)
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1.	Instrument is identified Instrument Serial No. : RM-31103679	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 :

Mindray/Lablif43D, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No
Equipment Type : Hematology Analyzer	Yes
Model : Mindray/Lablif43D	Yes
Manufacturer mMindray Medical, France	Yes
Marketed By : Medical - Area Manager Sales & Service.	Yes
Equipment # : One	Yes
Serial Number : RM-31103679	Yes
Dimensions : 36(W) x 36(D) x 53(H)	Yes



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Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 150 VA	Yes
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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 Area Manager Sales & Service., engineer at a specified time interval as recommended by the manufacturer.

6. **Spare Parts :**

Area Manager Sales & Service 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 H500.



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6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to mindray43d.
8. Now from back side of the instrument turn the power switch ON. Mindray43d goes through its power up and self-test sequence.
9. The mindray43d login menu is displayed after the Start up cycle is completed. Enter the credentials.

C. INSTALLATION CERTIFICATE:

Instrument Name : MINDRAY 43D

Serial Number : RM31103679



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Customer Details : DELHI CLINICAL LABORATORY
Laboratory with complete address SHOP NO 25 BAL BHANWAN JIND

Installation Date : 04/11/2016

Warranty expires on : 03/11/2017

Prepared by:	Area Manager Sales & Service.		
Name:	Rahul Rajput		
Title: Engineer at Customer support	Sign:	Date:04/11/2016	
Approved by:	DELHI CLINICAL LABORATORY		
Name:	Mr. AMIT		
Title: Lab Incharge	Sign:	Date:04/11/2016	

Deviation:

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



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Fully Automated Hematology Analyzer

Operational Qualification

For

**DELHI CLINICAL LABORATORY ,
JIND**



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A. Operational Qualification

1. Instrument Identification:

Instrument Name : MINDRAY/LABLIFE43D

Serial Number : RM-31103679

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. Start up 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



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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 below:

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



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OPERATIONAL CERTIFICATE:

Instrument Name : MINDRAYLABLIFE43D.

Serial Number : RM31103679

Customer Details : DELHI CLINICAL LABORATORY

Laboratory with complete address SHOP NO 25 BAL BHANWAN JIND

Installation Date : 04/11/2016

Warranty expires on : 03/11/2017

Prepared by:	- Area Manager Sales & Service.
Name:	Rahul Rajput



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Title: Engineer at Customer support	Sign:	Date:04/11/2019
Approved by:	DELHI CLINICAL LABORATORY SHOP NO 25 BAL BHANWAN JIND	
Name:	Mr. AMIT	
Title: Lab incharge	Sign:	Date:04/11/2016

Deviation:

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



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MINDRAYLABLIFE43D

(Serial no:RM311003679)

Fully Automated Hematology Analyzer

Performance Qualification

For

DELHI CLINICAL LABORATORY ,
JIND

#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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A. Performance Qualification

A. Instrument Identification:

Instrument Name : MINDRATLABLIFE43D
Serial Number : RM 31103679

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: RM31103679

Parameters	Acceptable Range	Observed Value
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.0
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:

Verified By:



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- **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; **PX421; Exp:** 10/12/2016.

Serial No: RM-31103679

LEVEL	STATUS
LOW (PX 424L)	OK
NORMAL (PX 424N)	OK
HIGH (PX 424H)	OK

Conducted By:

Verified By:



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

Serial No: RM-31103679

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.6	
HGB g/dL	< 1.5	0.5	
HCT %	< 2.0	0.7	
PLT $10^3/\text{mm}^3$	< 5.0	3.9	
WBC $10^3/\text{mm}^3$	< 2.5	1.2	
GRA %	<4	2.0	
LYM%	<10	1.3	
MON%	<20	6.4	

Conducted By:

Verified By:



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- **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: RM-31103679

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 (%)	0.5	0.9	0	0.6	0.2
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

Conducted By:

Verified By:

B. PERFORMANCE CERTIFICATE:

Instrument Name : MINDRAYLABLIFE43D

Serial Number : RM-31103679

Customer Details : DELHI CLINICAL LABORATORY

Laboratory with complete address , SHOP NO 25 BAL BHANWAN JIND



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Installation Date : 04/11/2016

Warranty expires on : 03/11/2016.

Prepared by:	- Area Manager Sales & Service.		
Name:	Rahul Rajput		
Title:Engineer at Customer support	Sign:	04/11/2016	
Approved by:	DELHI CLINICAL LABORATORY Laboratory		
Name:	Mr.AMIT		
Title: Lab Incharge	Sign:	Date:04/11/2016	

Deviation:

Conclusion: Instrument has been qualified for Performance.

ATTACHMENTS

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

