



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



ISO 9001:2015  
CEROFED COMPANY

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

**MINDRAY/LABLIFE34D**  
**(RM-31103679)**

Fully Automated Hematology Analyzer

For

RSD Hospital & Research Center

Moradabad, Uttar Pradesh

---

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

---





## **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.

### **Section 5 Attachments**



# Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



## General Instructions:

- Area Manager Sales & Service. is responsible for installation of MINDRAY/LABLIFE34D, Fully 3 part Part Automated Hematology Analyzer, at RSD HOSPITAL & RESEARCH CENTER . 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
- RSD HOSPITAL & RESEARCH CENTER 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.

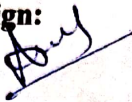
## Report Sign Off

Prepared by:	Area Manager Sales & Service.	
Name:	RAHUL RAJPUT	
Title; Engineer at Customer support	Sign:	Date: 04/11/2016



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



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

# **MINDRAY/LABLIFE34D**

**(RM-31103679)**

Fully Automated Hematology Analyzer

## **Installation Qualification**

For

**RSD HOSPITAL & RESEARCH CENTER**



**A. Installation Qualification**

**1. Installation Requirement :**

Sr. No.	Description	Compliance (Yes/No)
1.	<b>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%.</b>	yes
2.	<b>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.</b>	yes
3.	<b>Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.</b>	yes
4.	<b>UPS connection available.</b>	yes

**2. The instrument has been checked for the following:**

Sr. No.	Verification	Provided (Yes/No)
---------	--------------	-------------------



# Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



1.	Instrument is identified Instrument Serial No. : <b>RM-31103679</b>	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 : <b>RM-31103679</b>	Yes
Dimensions : 36(W) x 36(D) x 53(H)	Yes



1.	<b>Instrument is identified</b> <b>Instrument Serial No. : RM-31103679</b>	Yes
2.	<b>Manufacturer's specifications: Technical and Physical Requirement</b>	Yes
3.	<b>Accessories / consumables are listed as per checklist ( Provided along)</b>	Yes
4.	<b>System checked for any External / physical damage.</b>	Yes
5.	<b>Instrument User Manual (Soft Copy)</b>	Yes

**3. Equipment Description :**

Mindray/Lablif43D, Fully Automated Hematology Analyzer

<b>Instrument Identification</b>	<b>Verified Yes/No</b>
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 : <b>RM-31103679</b>	Yes
Dimensions : 36(W) x 36(D) x 53(H)	Yes



# Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 150 VA	Yes
--	-----

#### 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 on site 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.





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.

Prepared by:	Area Manager Sahar A. Nour
Name:	Rajal Kumar
File No. / Date:	103/11/2017
Report:	
APPROVED BY:	HEALTH CARE RESEARCH CENTER
Date:	10/11/2017

**C. INSTALLATION CERTIFICATE:**

**Instrument Name** : MINDRAY 43D

**Serial Number** : RM31103679





# Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)




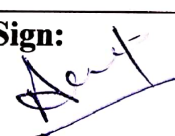
**Customer Details** : **RSD HOSPITAL & RESEARCH CENTER**

**Laboratory with complete address** **RAM GANGA VIHAR PHASE 2,  
MORADABAD, UTTAR PRADESH 244001**

**Installation Date** : **04/11/2016**

**Warranty expires on** : **03/11/2017**

## Operational Qualification

<b>Prepared by:</b>	<b>Area Manager Sales &amp; Service.</b>		
<b>Name:</b>	<b>Rahul Rajput</b>		
<b>Title: Engineer at Customer support</b>	<b>Sign:</b> 	<b>Date:04/11/2016</b>	
<b>Approved by:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER</b>		
<b>Name:</b>	<b>Mr. AMIT</b>		
<b>Title: Lab Incharge</b>	<b>Sign:</b> 	<b>Date:04/11/2016</b>	

### Deviation:

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





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



ISO 9001:2015  
CEROFED COMPANY

## Fully Automated Hematology Analyzer

# Operational Qualification

For

# RSD HOSPITAL & RESEARCH CENTER ,





**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



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



**OPERATIONAL CERTIFICATE:**

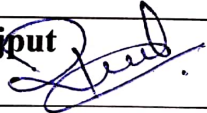
**Instrument Name** : MINDRAYLABLIFE43D.

**Serial Number** : RM31103679

**Customer Details** : RSD HOSPITAL & RESEARCH CENTER  
**Laboratory with complete address** RAM GANGA VIHAR PHASE 2,  
MORADABAD, UTTAR PRADESH 244001

**Installation Date** : 04/11/2016

**Warranty expires on** : 03/11/2017

<b>Prepared by:</b>	- Area Manager Sales & Service.
<b>Name:</b>	Rahul Rajput 



# Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



ISO 9001:2015  
CEROFED COMPANY

<b>Title: Engineer at Customer support</b>	<b>Sign:</b> 	<b>Date:04/11/2019</b>
<b>Approved by:</b>	<b>RSD HOSPITAL &amp; RESEARCH CENTER RAM GANGA VIHAR PHASE 2, MORADABAD, UTTAR PRADESH 244001</b>	
<b>Name:</b>	<b>Mr. AMIT</b>	
<b>Title: Lab incharge</b>	<b>Sign:</b> 	<b>Date:04/11/2016</b>

**Deviation:**

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



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



ISO 9001:2015  
CERTIFIED COMPANY

**MINDRAYLABLIFE43D**

(Serial no:RM311003679)

**Fully Automated Hematology Analyzer**

## **Performance Qualification**

For

**RSD HOSPITAL & RESEARCH CENTER ,**

---

**#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 : 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:**



# Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



ISO 9001:2015  
CEROFED COMPANY

- **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:





- **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:

# Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



ISO 9001:2015  
CEROFED COMPANY

- **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: RM-31103679

Parameters	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>
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:





# Aspen Diagnostics Pvt. Ltd.


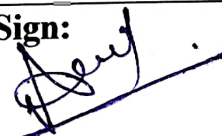
(Rapid Diagnostic Group Of Companies)



ISO 9001:2015  
CERTIFIED COMPANY

## B. PERFORMANCE CERTIFICATE:

**Instrument Name** : MINDRAYLABLIFE43D  
**Serial Number** : RM-31103679  
**Customer Details** : RSD HOSPITAL & RESEARCH CENTER  
**Laboratory with complete address** , RAM GANGA VIHAR PHASE 2,  
**MORADABAD, UTTAR PRADESH 244001**  
**Installation Date** : 04/11/2016  
**Warranty expires on** : 03/11/2016.

<b>Prepared by:</b>	- Area Manager Sales & Service.		
<b>Name:</b>	Rahul Rajput		
<b>Title: Engineer at Customer support</b>	<b>Sign:</b> 	<b>04/11/2016</b>	
<b>Approved by:</b>	RSD HOSPITAL & RESEARCH CENTER Laboratory		
<b>Name:</b>	Mr. AMIT		
<b>Title: Lab Incharge</b>	<b>Sign:</b> 	<b>Date: 04/11/2016</b>	

Deviation:

Conclusion: Instrument has been qualified for Performance.

ATTACHMENTS





HIN/MED/2019-2020/100514  
04<sup>th</sup> Nov 2022

## **CALIBRATION CERTIFICATE**

This is to certify that the Hematology Analyzer MINDRAYLABLIFE43D bearing serial number:RM-31103679 installed at RSD HOSPITAL & RESEARCH CENTER MORADABAD, UTTAR PRADESH as calibrated on 04<sup>th</sup> Nov 2022.

Calibrator : ABXMINOCALLot No. : CX440  
Expiry Date : 08<sup>th</sup> Nov 2022. -

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

Next calibration cycle is due on **03<sup>rd</sup> Nov 2023.**

Shrish Dixit

(Head- Products & Marketing)For

L-J QC Table

File No.: 4  
 Lot No.: DH2303  
 Mode: Whole Blood  
 Exp.Date: 05/05/2023  
 Level: Low  
 QC Type: CBC 5D  
 QC Sample ID:

Target	Date	Time	WBC	Neu#	Lym#	Mon#	Eos#	Bas#	Neu%	Lym%	Mon%	Eos%
Limit(#)			3.47	1.70	1.36	0.24	0.16	0.13	49.3	39.4	6.8	4.5
	09/05/2023	13:16	0.50	0.45	0.35	0.24	0.16	0.13	12.0	9.0	6.8	4.5
			3.30	1.68	1.27	0.21	0.14	0.09	50.8	38.5	6.5	4.2

Bas%	NLR	PLR	RBC	HGB	HCT	MCV	MCH	MCHC	RDW-CV	RDW-SD	PLT	MPV	PDW-CV	PDW-SD	PCT	P-LCC	P-LCR
3.7			1.96	5.1	15.4	78.5	26.1	33.3	16.8	54.5	51	9.2	0.151	16.2	0.470	13	26.1
3.7			0.24	0.6	2.0	5.0	2.5	3.0	3.0	8.0	20	3.0	0.050	5.0	0.470	13	10.1
2.8	1.32	37.01	2.08	5.3	16.8	80.7	25.5	31.6	16.8	48.7	47	8.3	0.138	12.2	0.039	9	20.1

CR L-J QC Table

File No.: 5  
 Lot No.: DH2303N  
 Mode: Whole Blood  
 Exp.Date: 05/05/2023  
 Level: Normal  
 QC Type: CBC -5D  
 QC Sample ID:

Target	Date	Time	WBC	Neu#	Lym#	Mon#	Eos#	Bas#	Neu%	Lym%	Mon%	Eos%
Limit(#)			7.85	4.48	2.34	0.52	0.51	0.31	57.1	29.8	6.6	6.5
	09/05/2023	13:18	1.00	0.95	0.65	0.52	0.51	0.31	12.0	8.0	6.6	6.5
			7.47	4.36	2.17	0.51	0.43	0.18	58.4	29.1	6.8	5.7

Bas%	NLR	PLR	RBC	HGB	HCT	MCV	MCH	MCHC	RDW-CV	RDW-SD	PLT	MPV	PDW-CV	PDW-SD	PCT	P-LCC	P-LCR
4.0			4.04	12.1	36.8	91.1	29.9	32.8	15.9	58.1	282	9.4	0.149	16.0		79	27.1
4.0			0.30	0.8	2.4	5.0	2.5	3.0	3.0	8.0	40	3.0	0.050	5.0		25	10.1
2.4	2.01	106.45	4.13	12.3	39.0	94.4	29.8	31.6	14.2	48.8	231	9.6	0.145	14.7	0.222	63	27.1

CR L-J QC Table

File No.: 6  
 Lot No.: DH2303H  
 Mode: Whole Blood  
 Exp.Date: 05/05/2023  
 Level: High  
 QC Type: CBC-5D  
 QC Sample ID:

Target	Date	Time	WBC	Neu#	Lym#	Mon#	Eos#	Bas#	Neu%	Lym%	Mon%	Eos%	Bas%
Limit(#)			17.84	11.58	3.54	1.17	1.55	0.37	64.9	19.9	6.6	8.7	2.1
	09/05/2023	13:19	2.50	2.15	1.25	1.17	1.55	0.37	12.0	7.0	6.6	8.7	2.1
			17.29	11.48	3.42	1.18	1.21	0.26	66.4	19.8	6.8	7.0	1.5

NLR	PLR	RBC	HGB	HCT	MCV	MCH	MCHC	RDW-CV	RDW-SD	PLT	MPV	PDW-CV	PDW-SD	PCT	P-LCC	P-LCR
		4.85	15.4	47.8	98.5	31.7	32.2	15.6	60.8	549	9.3	0.150	16.2		151	27.9
		0.40	1.0	2.7	5.0	2.5	3.0	3.0	8.0	60	3.0	0.050	5.0		35	1.0
3.36	143.57	4.67	15.9	47.3	101.3	34.0	33.6	14.0	51.6	491	9.6	0.135	13.5	0.470	127	25.8