H 560 – 3 Part Haematology Analyzer

INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION
(IQ/OQ/PQ)

HEALTHHEART DIAGNOSTICS
BUILDING-07,HARDEV PURI,
NATHU CHOWK,SHAHDARA,
DELHI-110093

By:- Avantor Performance Materials India Limited

CERTIFICATE OF INSTALLATION

INSTRUMENT NAME : H 560

SERIAL NUMBER : K1104B2146041

CUSTOMER NAME : HEALTHHEART DIAGNOSTICS

Address : BUILDING-07,HARDEV PURI,
NATHU CHOWK,SHAHDARA,
DELHI-110093

The undersigned performers certify that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Engineer

Signature :

Name : SANJEEV
Designation : Regional Service Manager

Company : Avantor Performance Materials India Limited

Quality Manager

Signature :

Name : DR.POOJA

Designation : DIECTOR

Organization : HEALTHHEART DIAGNOSTICS

INSTALLATION REPORT

Customer Name : HEALTHHEART DIAGNOSTICS
Place : DELHI

Department : Pathology / Laboratory

Contact Person : DR.POOJA

Instrument Name : H 560 (3 Part Hematology Analyzer)

Serial Number : K1104B2146041

Date of Installation : 23.06.2022

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

For Avantor Performance Materials India Limited

Nasim Ahmad
Regional Manager
Lucknow

INSTALLATION QUALIFICATION

IQ PROTOCOL

1. *System Unpacking*
2. *System Checking For any Damages*
3. *All accessories as per check List verification*
4. *Space Requirement*
5. *Power Requirement*
6. *Reagents, Control, Calibrators verification.*

1. SYSTEM UNPACKING & SYSTEM CHECKING

H 560 is unpacked and checked for physical Damages and found to be in good condition.

2. ACCESSORIES CHECK-

Check all accessories as per check List

3. SPACE REQUIREMENT –

- **Checked site for proper space allocation. At least 100 CM on each side and enough room on below the countertop to accommodate the instrument unit and waste & Reagents.**

DIMENTIONS	
PARAMETER	**Analyzer OV**
Width mm	320
Depth mm	400
Height mm	410
Weight Kg	<=24

4. POWER REQUIREMENT –

Requirement	*Acceptable Range*	*Observed Ranged*
Input Voltage	**100-240V~**	**225 V**
Line Frequency	**50 HZ**	**50 HZ**
Ambient Temperature	**15 C – 30 C**	**23**
Grounding Voltage	**0 to 5 V**	**3 v**

5. *Control, Calibrators/Standards Check-*

NAME	Status	Remark
Controls	YES	OK
Calibrator/Standards	YES	OK

OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OQ PROTOCOL

1. **System Connections**
2. **Waste Connections**
3. **Reagent connections**
4. **Customizing the Analyzer Software**
5. **System Booting , Initialization & Check**
6. **Maintenance procedures.**
7. **Customer Training – Operation & Maintenance.**

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	**NAME**	**Check**	**Remark**
1	Input Power supply	Connect, Operator manual 4.2.2	OK
2	System setting	operating manual 9.2	OK
3	Reagent Setup	operating manual 9.2.6	OK
4	Parameter Setting	operating manual 9.2.4	OK

2. REAGENT & WASTE CONNECTIONS -

REAGENT AND WASTE CONNECTION CHECK		
NAME	**CHECK**	**Remark**
Reagent Connection	Operation Manual 4.3, and 9.2.6	OK
Waste Connection	Operating Manual 4.3	OK

3. CUSTOMIZING ANALYZER SOFTWARE –

CUSTOMIZING ANALYZER SOFTWARE			
S/N	**Parameters**	**Check**	**Remark**
1	Analyzing Unit	Operating Manual 2.1	OK
2	Startup and Logon	Operating Manual 5.3	OK
3	QC and Control	Operating Manual 7.1	OK
4	Sample Analysis	Operating Manual 5.5.2	OK
5	Shutdown	Operating Manual 5.7	OK

4. SYSTEM BOOTING, INITIALIZATION & Check -

Power ON System and check instrument Initialization successfully.
Check following Parameters.

STARTUP		
S/N	**Parameters**	Remark
1	Reaction chamber	Ok
2	Ambience	Ok
3	Waste	Ok
4	Diluent	Ok
5	LH Lyse	Ok
6	Diff Lyse	Ok
7	Probe Cleaner	Ok
8	Control	Ok

MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	**Parameters**	**Check**	**Remark**
1	Maintenance	Operation Manual 10.2.1	OK
2	Troubleshooting	Operation Manual 11.1	OK

PERFORMANCE QUALIFICATION

The Performance of system is to be verified by below mentioned tests The results should be with in range as per the instruments and control sheet.

PQ Protocol:-

1. Background check
2. Carry over check
3. Reproducibility Check
4. Sample Precision, Accuracy and Performance test
5. Control Check (Three Levels)

1. Background check

BACKGROUND CHECK TEST						
	Date/Time	WBC	RBC	HGB	PLT	WBC-D
10	28/07/2022	0	0	0	0	0
9	28/07/2022	0	0	0	0	0
8	28/07/2022	0	0	0	0	0
7	28/07/2022	0	0	0	0	0
6	28/07/2022	0	0	0	0	0
5	28/07/2022	0	0	0	0	0
4	28/07/2022	0	0	0	0	0
3	28/07/2022	0	0	0	0	0
2	28/07/2022	0	0	0	0	0
1	28/07/2022	0.04	0	0	0	0
Limit		0.1	0.02	0.1	5	0.2
Result		Pass	Pass	Pass	Pass	Pass

2. Carry Over Check.

CARRYOVER CHECK TEST							
Substance	Control						
	Date/Time	WBC	RBC	HGB	HCT	PLT	WBC-D
High-Level 1	28/07/2022	21.06	5.87	17.7	63.6	467	21.78
High-Level 2	28/07/2022	20.99	5.8	17.4	63	463	21.28
High-Level 3	28/07/2022	20.69	5.81	17.5	62.8	458	21.96
Low-Level 1	28/07/2022	3.83	2.24	5.8	22.5	57	3.82
Low-Level 2	28/07/2022	3.7	2.23	5.7	22.3	61	3.8
Low-Level 3	28/07/2022	3.67	2.23	5.7	22.3	65	3.8
Carryover%		0.90%	0.30%	0.80%	0.50%	-2.00%	0.10%
Limit%		≤1.0%	≤1.0%	≤1.0%	≤1.0%	≤1.0%	≤1.0%
Result		Pass	Pass	Pass	Pass	Pass	Pass

3. Reproducibility Check

Reproducibility Check						
Date/Time	Run time	WBC	RBC	HGB	MCV	PLT
28/07/2022	1	7.29	4.69	13.1	101	223
28/07/2022	2	7.16	4.7	13.1	100.9	227
28/07/2022	3	7.11	4.66	13.1	101.3	226
28/07/2022	4	7.24	4.6	12.9	101.2	226
28/07/2022	5	6.94	4.69	13.1	100.9	223
28/07/2022	6	7.36	4.7	13.1	101	219
28/07/2022	7	7.34	4.68	13	101.1	228
28/07/2022	8	7.4	4.74	13.2	100.9	231
28/07/2022	9	7.48	4.74	13.2	101.1	222
28/07/2022	10	7.16	4.77	13.2	101.3	220
28/07/2022	11	7.23	4.73	13.3	101.7	237
28/07/2022	**Mean**	7.25	4.71	13.1	101.1	226

28/07/2022	**SD**	0.16	0.034	0.08	0.25	5.5
28/07/2022	**Min**	6.94	4.66	13.1	100.9	219
28/07/2022	**Max**	7.48	4.77	13.3	101.7	237
28/07/2022	**R**	0.54	0.11	0.3	0.8	18
28/07/2022	**d(Min)**	0.02	0.01	0	0	0
28/07/2022	**d(Max)**	0.31	0.06	0.2	0.6	11
	CV%	2.2	0.7	0.6	0.3	2.4
	Limit(%)	2.5	1.5	1	1	4
	Result	Pass	Pass	Pass	Pass	Pass

Reproducibility Check

Date/Time	Run time	Neu#	Lym#	Mon#	Eos#	Bas#	IMG#
28/07/2022	1	4.14	1.48	0.24	1.42	0.01	0.02
28/07/2022	2	4.14	1.41	0.23	1.37	0.01	0.01
28/07/2022	3	4.1	1.4	0.24	1.36	0.01	0.02
28/07/2022	4	4.25	1.41	0.24	1.33	0.01	0.03
28/07/2022	5	3.99	1.38	0.23	1.33	0.01	0.02
28/07/2022	6	4.34	1.41	0.25	1.35	0.01	0.02
28/07/2022	7	4.28	1.48	0.23	1.34	0.01	0.03
28/07/2022	8	4.29	1.52	0.21	1.37	0.01	0.03
28/07/2022	9	4.18	1.58	0.26	1.45	0.01	0.02
28/07/2022	10	4.18	1.39	0.24	1.34	0.01	0.02
28/07/2022	11	4.08	1.47	0.29	1.38	0.01	0.03
28/07/2022	**Mean**	4.17	1.45	0.24	1.37	0.01	0.02
28/07/2022	**SD**	0.107	0.065	0.021	0.038	0	0.006
28/07/2022	**Min**	3.99	1.38	0.21	1.33	0.01	0.01
28/07/2022	**Max**	4.34	1.58	0.29	1.45	0.01	0.03
28/07/2022	**R**	0.35	0.2	0.08	0.12	0	0.02
28/07/2022	**d(Min)**	0.01	0.02	0	0	0	0
28/07/2022	**d(Max)**	0.18	0.13	0.05	0.08	0	0.01
	CV%	2.6	4.5	8.9	2.8	0	28.7
	Limit(%)	6	6	16	20	30	25

	Result	Pass	Pass	Pass	Pass	Pass	Pass

Reproducibility Check							
Date/Time	Run time	Neu%	Lym%	Mon%	Eos%	Bas%	IMG%
28/07/2022	1	56.9	20.2	3.3	19.4	0.2	0.3
28/07/2022	2	57.7	19.7	3.3	19.1	0.2	0.2
28/07/2022	3	57.8	19.6	3.4	19.1	0.1	0.3
28/07/2022	4	58.7	19.5	3.4	18.3	0.1	0.4
28/07/2022	5	57.6	19.8	3.3	19.1	0.2	0.3
28/07/2022	6	59.1	19.1	3.4	18.3	0.1	0.3
28/07/2022	7	58.3	20.2	3.1	18.2	0.2	0.4
28/07/2022	8	58.1	20.5	2.8	18.5	0.1	0.4
28/07/2022	9	55.9	21.1	3.5	19.4	0.1	0.3
28/07/2022	10	58.3	19.4	3.4	18.8	0.1	0.2
28/07/2022	11	56.5	20.3	4	19.1	0.1	0.5
28/07/2022	**Mean**	57.6	20	3.3	18.9	0.1	0.3
28/07/2022	**SD**	0.95	0.59	0.3	0.43	0.05	0.09

28/07/2022	**Min**	55.9	19.1	2.8	18.2	0.1	0.2
28/07/2022	**Max**	59.1	21.1	4	19.4	0.2	0.5
28/07/2022	**R**	3.2	2	1.2	1.2	0.1	0.3
28/07/2022	**d(Min)**	0	0.2	0	0.1	0	0
28/07/2022	**d(Max)**	1.7	1.1	0.7	0.7	0.1	0.2
	CV%	1.6	2.9	9	2.3	36.9	28.7
	Limit(%)	6	6	16	20	30	25
	Result	Pass	Pass	Pass	Pass	Pass	Pass

Reproducibility Check							
Date/Time	Run time	HCT	MCH	MCHC	RDW-CV	RDW-SD	MPV
28/07/2022	1	47.3	28	27.7	16.5	56.4	10.1
28/07/2022	2	47.4	27.9	27.7	16.3	55.7	9.8
28/07/2022	3	47.2	28	27.7	16.3	55.6	9.9
28/07/2022	4	46.6	27.9	27.6	16.3	55.9	10.1
28/07/2022	5	47.3	27.9	27.6	16.7	56.8	9.8
28/07/2022	6	47.5	27.9	27.6	16.3	55.5	9.9

28/07/2022	7	47.3	27.9	27.6	16.3	55.7	9.9
28/07/2022	8	47.8	27.8	27.6	16.2	55.3	10.1
28/07/2022	9	48	27.8	27.5	16	54.6	10.1
28/07/2022	10	48.4	27.7	27.3	16.1	55	9.8
28/07/2022	11	48.1	28.1	27.7	16.3	55.8	10
28/07/2022	**Mean**	47.6	27.9	27.6	16.3	55.6	9.9
28/07/2022	**SD**	0.42	0.12	0.12	0.19	0.63	0.13
28/07/2022	**Min**	47.2	27.7	27.3	16	54.6	9.8
28/07/2022	**Max**	48.4	28.1	27.7	16.7	56.8	10.1
28/07/2022	**R**	1.2	0.4	0.4	0.7	2.2	0.3
28/07/2022	**d(Min)**	0.1	0	0	0	0	0
28/07/2022	**d(Max)**	0.8	0.2	0.3	0.4	1.2	0.2
	CV%	0.9	0.4	0.4	1.2	1.1	1.3
	Limit(%)	1.5	1.5	1.5	2	2	3
	Result	Pass	Pass	Pass	Pass	Pass	Pass

Reproducibility Check

Date/Time	Run time	PDW	PCT	P-LCC	P-LCR	NRBC#	NRBC%
28/07/2022	1	16.4	0.225	60	26.6	0	0
28/07/2022	2	16.4	0.222	60	26.3	0	0
28/07/2022	3	16.4	0.224	59	25.9	0.002	0.02
28/07/2022	4	16.7	0.228	61	27.3	0.005	0.06
28/07/2022	5	16.4	0.219	59	26.4	0.005	0.06
28/07/2022	6	16.6	0.217	57	26.1	0.002	0.02
28/07/2022	7	16.5	0.226	60	26.1	0.002	0.02
28/07/2022	8	16.9	0.234	66	28.3	0.003	0.04
28/07/2022	9	16.6	0.223	62	27.8	0.003	0.04
28/07/2022	10	16.4	0.217	57	25.9	0.002	0.02
28/07/2022	11	16.5	0.238	65	27.5	0.002	0.02
28/07/2022	**Mean**	16.5	0.224	61	26.7	0.002	0.02
28/07/2022	**SD**	0.16	0.0069	3	0.86	0.0014	0.018
28/07/2022	**Min**	16.4	0.217	57	25.9	0	0
28/07/2022	**Max**	16.9	0.238	66	28.3	0.005	0.06
28/07/2022	**R**	0.5	0.021	9	2.4	0.005	0.06
28/07/2022	**d(Min)**	0	0	1	0.1	0	0
28/07/2022	**d(Max)**	0.4	0.014	6	1.6	0.003	0.04
	CV%	1	3.1	5	3.2	69	76.6
	Limit(%)	10	5	15	15	20	20
	Result	Pass	Pass	Pass	Pass	Pass	Pass

4. Sample Precision, Accuracy and Performance test

Nine tests of a sample in different time interval in two days have been run for the parameters and a statistical analysis of the data. The results are within defined range & with following precision & accuracy limits based on the reference range given by the manufacturer.

DAY - 1	DATE : 21/07/2022	PERFORMANCE QUALIFICATION PERFORMED FOR MINDRAY H 560HEMOTOLOGY WITH PATIENT SAMPLE							
		RUN	TIME	HB	WBC	RBC	HCT	PLT	MCV
		RUN 1	9:44 AM	12.4	7.68	4.23	34.4	277	81.4
		RUN 2	9:44 AM	12.4	7.9	4.21	34.3	273	81.6
		RUN 3	09.51am	12.4	7.67	4.21	34.4	276	81.8
		RUN 4	09.51am	12.4	7.76	4.24	34.9	268	82.4
		RUN 5	12.47pm	12.4	7.76	4.26	35.5	272	82.5
		RUN 6	12.51pm	12.4	7.74	4.21	34.7	268	82.4
		RUN 7	03.40pm	12.4	7.77	4.15	33.6	271	81.1
		RUN 8	03.43pm	12.5	7.79	4.21	34.5	274	81.9
		RUN 9	3.46pm	12.5	7.86	4.27	35	286	81.1
		MEAN		12.42	7.77	4.22	34.59	273.89	81.80
		SD		0.04	0.07	0.04	0.53	5.51	0.55
		CV%		0.35	0.96	0.83	1.53	2.01	0.67
Result				Pass	Pass	Pass	Pass	Pass	Pass

DAY - 2	DATE : 22/07/2022	PERFORMANCE QUALIFICATION PERFORMED FOR MINDRAY H 560HEMOTOLOGY WITH PATIENT SAMPLE							
		RUN	**TIME**	**HB**	**WBC**	**RBC**	**HCT**	**PLT**	**MCV**
		RUN 1	9:50 AM	**12.4**	**7.75**	**4.22**	**34.7**	**278**	**82.2**
		RUN 2	09.53am	**12.4**	**7.64**	**4.18**	**34.6**	**261**	**82.7**
		RUN 3	09.56am	**12.3**	**8.05**	**4.09**	**33.7**	**271**	**82.5**
		RUN 4	12.56pm	**12.4**	**7.67**	**4.2**	**34.5**	**272**	**82**
		RUN 5	12.59pm	**12.4**	**7.74**	**4.19**	**34.4**	**277**	**82.1**
		RUN 6	13.02pm	**12.4**	**7.79**	**4.19**	**34.4**	**267**	**82.2**
		RUN 7	03.20pm	**12.4**	**7.79**	**4.24**	**34.8**	**268**	**82**
		RUN 8	03.23pm	**12.4**	**7.62**	**4.21**	**34.7**	**264**	**82.4**
		RUN 9	3.26pm	**12.3**	**7.68**	**4.14**	**34.1**	**267**	**82.4**
		MEAN		**12.38**	**7.75**	**4.18**	**34.43**	**269.44**	**82.28**
		SD		**0.04**	**0.13**	**0.05**	**0.35**	**5.64**	**0.24**
		CV%		**0.36**	**1.67**	**1.08**	**1.01**	**2.09**	**0.29**
Result				**Pass**	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

5. Control Check

Name	Lot no	Expiry		Result
BC 5D Level-L	BC1901BL	10.09.2022		Pass
BC 5D level-N	BC1901BN	10.09.2022		Pass
BC 5D level-H	BC1901BH	10.09.2022		Pass

CALIBRATION CERTIFICATE

NAME OF THE INSTRUMENT : H560

INSTRUMENT SL. NO. :K1104B2146041

USER NAME : HEALTHHEART DIAGNOSTICS

ADDRESS : BUILDING NO-07,HARDEV PURI,NATHU CHOWK,
SHAHDARA DELHI-110093

DATE OF CALIBRATION : 01st August 2022

CALIBRATOR LOT NO. : SC350

CALIBRATION:

- Calibration must be performed initially at installation and then every 6 months thereafter.
- Interim recalibration must be performed when
  - The instrument is moved to a different location
  - After replacing any component related to the process of dilution or measurement
  - When QC results indicate recalibration may be needed
  - When instructed by technical support to recalibrate as part of troubleshooting

The package insert which comes with the calibrator contains the target values to be used in calibrating. This insert must be saved per local regulations.

REPORTABLE RANGES (ANALYTICAL MEASUREMENT RANGES)

The manufacturer's claims for Reportable Range are as follows:

Parameter	Reportable Range (AMR) Low	Reportable Range (AMR) High
WBC (10^3/µl)	0.95	83.45
HGB (g/dl)	1.4	23.7
RBC (10^6/µl)	0.44	7.74
PLT (10^3/µl)	11	975

CALIBRATION DATA

	Select	WBC	RBC	HGB	MCV	PLT
Target		9.60	4.50	13.7	88.9	259
1	Yes	9.9	4.49	13.9	88.9	255
2	Yes	9.8	4.47	13.6	88.9	251
3	Yes	9.7	4.46	13.8	89.6	241
4	Yes	9.8	4.47	13.8	89.7	247
5	Yes	9.9	4.42	13.6	89.6	236
6	Yes	9.6	4.48	13.7	89.5	245
7	Yes	9.7	4.47	13.5	89.7	246
8	Yes	9.9	4.48	13.8	89.7	242
9	Yes	9.8	4.45	13.8	89.6	243
10	Yes	9.7	4.46	13.9	89.6	243
Mean		9.8	4.47	13.7	89.7	245
CV%		1.1	0.4	0.9	0.2	2.2
New Factor %		97.98	100.99	99.77	99.13	105.77
Old Factor %		97	100	94	100	100

CALIBRATION FACTOR

Parameter	Calibration Factor (%)	Date
WBC	97.98	1/08/2022
RBC	100.99	1/08/2022
HGB	99.77	1/08/2022
MCV	99.13	1/08/2022
PLT	105.77	1/08/2022

This Certificate is valid up to July 2023

(Sanjeev Gupta)

Manager –Technical Services