

Installation Qualification for Avantor H33s Sr.No :Bc23012078

Customer Name : SHRI GULAB SINGH HOSPITAL
Customer Address : Phaphund Rd Auraiya Uttar Pradesh 206122
Contact Person : Dr. RAMKUMAR
Instrument Model : AVANTOR H33S
Serial No. : BC-23012078
Date Of installation : **01-03-2021**

The instrument was installed And was found to be working satisfactory. Preliminary Customer Training was provided And standardization of the parameters Were done. The results were found to be within the expected range and system found to be working satisfactorily.

Customer: Shri Gulab Singh Hospital Phaphund Rd Auraiya Uttar Pradesh 206122

MRIN, Technical Services Department

Name	: Kali	Contact Person	: Varun K Sharma
Designation	: Sr. Service Engineer	Designation	: Asst. Application Manager
Signature	: 		: 

Installation Certificate For H33s Sr.No :TH23012078

This is to certify that the instrument H33s Sr.No :BC23012078 is successfully installed and commissioned at : Shri Gulab Singh Hospital Phaphund Rd Auraiya Uttar Pradesh 206122, : and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : 01/03/2021

MRIN, Technical Services Department

Name : Kali 

Designation : Sr. Service Engineer

Installation Qualification for Avantor H33s Sr.No :Bc23012078

Customer Name : Shri Gulab Singh Hospital Phaphund Rd Auraiya Uttar Pradesh 206122

Instrument Name : H33

Serial No : BC23012078

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Found the system to have been delivered in satisfactory condition and no external physical damaged observed on the same,Package was kept in good Condition as per the directional indicators like not tilt, indicating the system has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

Intallation Procedure And Checklist Attached for the records.

External Requirement for Installation:

- 1. Input voltage of 220V-240V/50Hz or 60 Hz.**
- 2. Recommended operating Temperature is 15-30 degree Celsius, with in Relative Humidity 30-85% and Atmospheric pressure 70-106kPa.**

Installation Qualification for Avantor H33s Sr.No :BC23012078

Carried out all the installation procedures as per the installation procedure and checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Handover the Instrument for operatos Training And Qualifications

For MRIN, Technical Services Department

Name : Kali 

Designation : Sr. Service Engineer

Performance Qualification for H33s Sr.No :BC23012078

Calibration Parameters

Checked and found all the control [parameters to be with in the acceptable CV limits and in range.

Checked and found all controls to be within The acceptable SD.

System Certification:

Study data has determined that the system described in this document either meets thenecessary criteria outlined inthis Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The system is ready for Specific Usage.

Protocol Performed By:

Name : Varun Kumar Sharma

A handwritten signature in black ink, appearing to be 'V. Sharma', followed by a horizontal line.

Designation :Asst. Application Manager

PERFORMANCE QUALIFICATION DONE BY

Name : Varun Kumar Shrama

A handwritten signature in black ink, appearing to be 'V. Sharma', followed by a horizontal line.

Designation : Asst. Appplication Manager

Operation Qualification for H33s Sr.No :BC23012078

System Certification:

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

The System is ready for specific usage.

Protocol Performed by : MRIN, Ahmedabad

Name: Kali 

Designation: Sr. Service Engineer

Customer Authorization : Shri Gulab Singh Hospital Phaphund Rd Auraiya Uttar Pradesh 206122

Name: Dr. RAMKUMAR

Designation : **Lab Owner**

Company Representative Name And Sign

Customer Name And Sign

Mr. Kali 

Dr. RAMKUMAR

Date: 01/03/2021

Date: 01/03/2021

Operation Qualification for H33s Sr.No :BC23012078

1. Verified all the Mechanical Movements : Done
2. Verifeied Hydraulics : Done
3. Verified Electrical Systems : Done
4. Verified the all reagents Systems : Done

MRIN, Technical Services Department

Name : Kali 

Designation : Sr. Service Engineer

Date : 01/03/2021

Instrument Setup

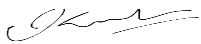
1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Connected the LYSE REAGENT .
4. Connected the DILUENT REAGENT.
5. Connected the Waste Tubing
6. Connected the Power cord and connection cord.
7. Initialise the machine and follow the installation procedure.

Operational Inspection

1. Checked and found Mechanical Movements OK.
2. Checked and found Hydraulics OK.
3. Checked and found Electricals OK.
4. Checked with Controls And Samples, Results Are found OK.

MRIN, Technical Services Department

Name : Kali

A handwritten signature in black ink, appearing to be 'Kali', written over a horizontal line.

Designation : Sr. Service Engineer

BC30

HEMATOLOGY ANALYSER

CALIBRATION CERTIFICATE

FOR

: SHRI GULAB SINGH HOSPITAL

BY


AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

CERTIFICATE OF QUALITY
CONTROLS


INSTRUMENT NAME : BC30
SERIAL NUMBER : BC23012078
CUSTOMER NAME : SHRI GULAB SINGH HOSPITAL
ADDRESS : Phaphund Rd Auraiya Uttar Pradesh 206122

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE INSTALLATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

ENGINEER

Signature : 
Name : Jinesh Vadera
Designation : Regional Service Manager
Company : AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

LABORATORY

Signature : 
Name : Varun K Sharma

PQ BEFOR CALIBRATION

PQ Protocol: -

1. Background check
2. Reproducibility Check
3. Carry over check

BACKGROUND CHECK:

Serial No. BC23012078
Mode WB
Substance Blood sample
Number of Summaries 5

Mode	WB							
	Select	Date/Time	Operator	WBC	RBC	HGB	HCT	PLT
5	Yes	18-12-2023 12:17	service	0	0	0	0	0
4	Yes	18-12-2023 12:16	service	0	0	0	0	0
3	Yes	18-12-2023 12:15	service	0	0	0	0	0
2	Yes	18-12-2023 12:14	service	0	0	0	0	0
1	Yes	18-12-2023 12:12	service	0	0	0	0	0
Limit				0.2	0.02	0.1	0.5	5
Result				Pass	Pass	Pass	Pass	Pass
Number of Summaries	5							



Jinesh Vadera
Regional Service Manager

REPRODUCIBILITY CHECK:

Serial No. BC23012078
 Mode WB
 Substance Blood
 sample Number of Summaries 5
 Lot No. patient sample

	Select	Date/Time	Operator	WBC	RBC	HGB	MCV	PLT	Lymph%	Mid%	Gran%	RDW-CV	RDW-SD	MPV
20	Yes	18-12-2023 15:42	service	11.7	5.57	14.3	88.6	367	32	16.1	51.9	15.7	49.5	10.2
19	Yes	18-12-2023 15:41	service	11.1	5.44	14.4	88.9	360	34.3	15.5	50.2	15.9	50.6	10.5
18	Yes	18-12-2023 15:40	service	11.1	5.6	14.3	88.8	388	32.6	15.1	52.3	15.6	49.6	10.4
17	Yes	18-12-2023 15:39	service	10.9	5.74	14.4	88.9	390	32.8	16.3	50.9	15.9	50.5	10.4
16	Yes	18-12-2023 15:38	service	11.3	5.69	14.3	88.7	392	34.3	15.8	49.9	15.9	50.3	10.4
15	Yes	18-12-2023 15:37	service	11.3	5.72	14.4	88.9	398	35.3	15.3	49.4	15.8	50.1	10.4
14	Yes	18-12-2023 15:36	service	11.2	5.71	14.3	89	392	32.6	16.1	51.3	15.9	50.4	10.2
13	Yes	18-12-2023 15:05	service	11.2	5.61	14.4	88.9	383	33.1	15.6	51.3	15.8	50	10.3
12	Yes	18-12-2023 14:59	service	11.1	5.21	14.3	89.2	370	32.5	15.4	52.1	15.6	49.7	10.4
11	Yes	18-12-2023 14:57	service	11	5.5	14.3	88.9	388	33.2	15.5	51.3	15.9	50.3	10.3
10	Yes	18-12-2023 14:55	service	11	5.58	14.2	88.9	392	31.9	16.5	51.6	15.7	49.9	10.4
9	Yes	18-12-2023 14:54	service	11	5.57	14.2	89	382	35.1	15.2	49.7	15.9	50.5	10.3
8	Yes	18-12-2023 14:51	service	11.1	5.52	14.2	88.9	388	34	15.7	50.3	15.7	49.7	10.3
7	Yes	18-12-2023 14:48	service	10.9	5.49	14.2	88.8	393	35.6	14.9	49.5	15.8	50.1	10.5
6	Yes	18-12-2023 14:45	service	11.1	5.57	14.2	89	388	34.5	15.8	49.7	16	50.6	10.4
5	Yes	18-12-2023 14:42	service	11.1	5.57	14.2	89	388	34.5	15.8	49.7	16	50.6	10.4
4	Yes	18-12-2023 14:39	service	11.3	5.73	14.1	88.9	416	33	16.4	50.6	15.8	50	10.4
3	Yes	18-12-2023 14:35	service	11.1	5.68	14.2	89.1	404	36.1	15.7	48.2	15.9	50.6	10.4
2	Yes	18-12-2023 14:31	service	11.5	5.51	14.4	89.1	397	33.9	16.1	50	15.7	50.1	10.3
1	Yes	18-12-2023 14:26	service	11.2	5.54	14.2	88.9	373	34.7	15.7	49.6	15.7	49.9	10.4
Mean				11	5.58	14.2	88.9	392	34.3	15.78	49.89	15.82	50.20	10.38
SD				0.170	0.075	0.074	0.097	11	1.225	0.487	0.51	0.123	0.343	0.06
Min				11.7	5.65	14.2	88	373	32	16.1	50.1	15.7	49.5	10.2
Max				10.9	5.76	14.4	89	390	36	16.5	51.2	16	50.6	10.3
R				0.3	0.11	0.4	0.1	14	1.2	1.6	1.1	0.3	1	0.2
d(Min)				0	0.01	0	0	1	0.1	0.2	0.2	0.1	0.2	0
d(Max)				0.2	0.07	0.3	0.1	10	0.6	1	0.6	0.2	0.6	0.1
CV %				1.530	1.348	0.519	0.109	3.1	3.2	3.087	1	0.77	0.684	0.609
Limit(%)				2.5	1.5	1.5	0.5	4	12	25	12	3.5	3.5	4
Result				Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass



Jinesh Vadera
 Regional Service Manager

CARRYOVER

3 consecutive analyses of a patient sample with high analyte concentration (H1, H2, and H3) were followed by 3 consecutive analyses of a patient sample with low analyte concentration (L1, L2, and L3). Carryover (%) was calculated from the formula: $100 * (L1-L3)/(H3-L3)$.

Serial No. BC23012078
 Mode WB
 Substance QC-Mindray

Mode	WB					
	Date/Time	Operator	WBC	RBC	HGB	PLT
High-Level 1	18-12-2023 12:25	Service	21.3	5.69	17.4	632
High-Level 2	18-12-2023 12:26	Service	21.5	5.66	17.7	637
High-Level 3	18-12-2023 12:27	Service	21.5	5.66	17.5	644
Low-Level 1	18-12-2023 12:28	Service	2.0	2.27	6.3	66
Low-Level 2	18-12-2023 12:29	Service	2.1	2.24	6.2	65
Low-Level 3	18-12-2023 12:31	Service	2.1	2.22	6.2	66
Carryover%			0.00%	1.80%	1.10%	0.40%
Limit%			0.50%	0.50%	0.50%	1.00%



Jinesh Vadera
 Regional Service Manager

QC Before Calibration

LOW CONTROL

File No.	Lot No.	Expiration Date	QC Test Panel	Level
1	B1123	05-02-2024	WB	Low

No.	Target	Limit(#)	8
Date	/	/	18-12-2023
Time	/	/	12:31
WBC($10^9/L$)	3.5	1.5 – 2.5	2
Lymph#($10^9/L$)	1.3	1.0 – 1.6	1.3
Mid#($10^9/L$)	0.1	0.0 – 0.2	0.1
Gran#($10^9/L$)	0.2	0.4 – 0.8	0.6
Lymph%(%)	62	52.9 – 76.9	64.7
Mid%(%)	7.2	4.2-10.2	4.9
Gran%(%)	26.1	19.9 - 39.9	30.4
RBC($10^{12}/L$)	2.52	4.25 – 4.73	2.28
HGB(g/dL)	6.2	5.5 – 6.3	6.3
HCT(%)	20.6	15.7 – 18.7	17.4
MCV(fL)	80.2	72.2 – 82.2	76.3
MCH(pg)	24.6	28 – 33	27.5
MCHC(g/dL)	30.7	32.1 – 38.1	36
RDW-CV(%)	15.6	13.2 – 19.2	17
RDW-SD(fL)	50.4	42.5 – 54.5	46
PLT($10^9/L$)	54	40 – 80	66
MPV(fL)	8	6.4 – 12.4	10.1
PDW()			18.3
PCT(mL/L)			0.066
P-LCC($10^9/L$)			20
P-LCR(%)			30.4



Jinesh Vadera
Regional Service Manager

MEDIUM CONTROL

File No.	Lot No.	Expiration Date	QC Test Panel	Level
2	B1123N	05-02-2024	WB	Normal

No.	Target	Limit(#)	10
Date	/	/	18-12-2023
Time	/	/	12:23
WBC($10^9/L$)	9.8	10.8 – 7.5	8.1
Lymph#($10^9/L$)	5	4.7 – 2.3	2.7
Mid#($10^9/L$)	1	1.7 – 0.3	0.7
Gran#($10^9/L$)	3.8	5.4 – 3.4	4.7
Lymph%(%)	51.4	39.4 – 23.4	32.8
Mid%(%)	10.5	18.5 – 2.5	8.4
Gran%(%)	38.1	46.1 – 30.1	56.8
RBC($10^{12}/L$)	4.65	4.9 – 4.4	4.62
HGB(g/dL)	12.5	13.0 – 12.0	13.8
HCT(%)	42.3	46.9 – 37.7	39.6
MCV(fL)	91	96 – 86	85.7
MCH(pg)	28	30.8 – 25.2	30
MCHC(g/dL)	30.7	35.5 – 25.9	35
RDW-CV(%)	14.2	17.2 – 11.2	15.5
RDW-SD(fL)	52.4	60.4 – 44.4	47.3
PLT($10^9/L$)	244	284 - 204	284
MPV(fL)	8.1	11.1 – 5.1	9.3
PDW()			16.5
PCT(mL/L)			0.263
P-LCC($10^9/L$)			67
P-LCR(%)			23.5



Jinesh Vadera
Regional Service Manager

HIGH CONTROL

File No.	Lot No.	Expiration Date	QC Test Panel	Level
3	B1123H	05-02-2024	WB	High

No.	Target	Limit(#)	1
Date	/	/	18-12-2023
Time	/	/	12:22
WBC($10^9/L$)	21.2	23.7 – 18.7	22.4
Lymph#($10^9/L$)	8.9	10.6 – 7.2	9.3
Mid#($10^9/L$)	1.6	2.0 – 1.2	1.7
Gran#($10^9/L$)	10.7	12.4 – 9.0	11.4
Lymph%(%)	41.8	45.8 – 37.8	41.6
Mid%(%)	7.6	11.6 – 3.6	7.5
Gran%(%)	50.6	58.6 – 42.6	50.9
RBC($10^{12}/L$)	5.57	5.87 – 5.27	5.35
HGB(g/dL)	17	17.8 – 16.2	L 15.8
HCT(%)	54.7	60.2 – 49.0	50.5
MCV(fL)	98.2	103.2 – 93.8	94.5
MCH(pg)	30.5	33.6 – 27.4	29.6
MCHC(g/dL)	31.1	35.9 – 27.0	31.3
RDW-CV(%)	14.3	17.3 – 11.3	15.2
RDW-SD(fL)	57	65 - 49	52.3
PLT($10^9/L$)	495	555 - 435	H 585
MPV(fL)	8.1	11.1 – 5.1	8.4
PDW()			14.9
PCT(mL/L)			4.92
P-LCC($10^9/L$)			80
P-LCR(%)			13.7



Jinesh Vadera
Regional Service Manager

CALIBRATION FACTOR DATA

The calibrator of below mentioned lot no. has been run Ten times and its MEAN and CV% is calculated automatically and the factors are automatically obtained by the instrument.

Calibrator Lot No. BC10923C-1
Calibrator Exp. 27/01/2024
Instrument BC30
Sr. No. BC23012078
Calibration Date 18-12-2023

	Select	WBC	RBC	HGB	MCV	PLT
		10 ⁹ /L	10 ¹² /L	g/dL	fL	10 ⁹ /L
Target		8.3	4.11	13.5	96.4	244
1	Yes	8.5	4.16	13.9	96.3	244
2	Yes	8.5	4.11	13.8	96.1	245
3	Yes	8.6	4.12	13.8	96.1	243
4	Yes	8.6	4.11	13.7	96.2	240
5	Yes	8.5	4.17	13.8	96.1	240
6	Yes	8.5	4.16	13.7	96.1	244
7	Yes	8.6	4.15	13.9	96.1	246
8	Yes	8.5	4.13	13.7	98.8	243
9	Yes	8.5	4.14	13.7	97.9	243
10	Yes	8.6	4.14	13.6	96.1	240
Mean		8.5	4.14	13.8	90.1	244
CV (%)		0.6	1	0.7	0.2	3.2
New Factor (%)		100.62	99.26	99.63	98.7	94.42
Old Factor (%)		97	100	94	100	100

CALIBRATION FACTOR: -

Parameter	Calibration Factor (%)	Date
WBC	100.62	18-12-2023
RBC	99.26	18-12-2023
HCG	99.63	18-12-2023
MCV	98.7	18-12-2023
PLT	94.42	18-12-2023

Next Calibration Due Date 18-12-2024

For Avantor Performance Materials India Limited



Jinesh Vadera
 Regional Service Manager
 +91 9820442240

QC After Calibration

LOW CONTROL

File No.	Lot No.	Expiration Date	QC Test Panel	Level
1	B1123L	05-02-2024	WB	Low

No.	Target	Limit(#)	1
Date	/	/	18-12-2023
Time	/	/	20:21
WBC($10^9/L$)	3.5	4.0 – 3.0	4
Lymph#($10^9/L$)	2.1	2.4 – 1.8	2.3
Mid#($10^9/L$)	0.6	0.9 – 0.6	0.6
Gran#($10^9/L$)	0.9	1.2 – 0.6	1.1
Lymph%(%)	57.6	48.6 – 66.6	58.4
Mid%(%)	16.3	25.3 – 7.3	15.8
Gran%(%)	26.1	35.1 – 17.1	25.8
RBC($10^{12}/L$)	2.52	2.77 – 2.27	2.43
HGB(g/dL)	6.2	6.8 – 5.6	6.6
HCT(%)	20.6	23.9 – 17.3	19.2
MCV(fL)	80.2	85.2 – 75.2	79
MCH(pg)	24.6	29.5 – 19.7	27.3
MCHC(g/dL)	30.7	38.8 – 22.6	34.5
RDW-CV(%)	15.6	18.6 – 12.6	18.3
RDW-SD(fL)	50.4	58.4 – 42.4	53.3
PLT($10^9/L$)	54	34 - 74	61
MPV(fL)	8	11 - 5	8.5
PDW()			15.3
PCT(mL/L)			0.52
P-LCC($10^9/L$)			10
P-LCR(%)			15.5



Jinesh Vadera
Regional Service Manager

MEDIUM CONTROL

File No.	Lot No.	Expiration Date	QC Test Panel	Level
2	B1123N	05-02-2024	B30	Normal

No.	Target	Limit(#)	1
Date	/	/	18-12-2023
Time	/	/	20:22
WBC($10^9/L$)	9.8	10.8 – 8.8	10.6
Lymph#($10^9/L$)	5	5.7 – 4.3	5.4
Mid#($10^9/L$)	1	1.7 – 0.3	1.1
Gran#($10^9/L$)	3.8	4.5 – 3.1	4.1
Lymph%(%)	51.4	59.4 – 43.4	50.9
Mid%(%)	10.5	18.5 – 2.5	10.3
Gran%(%)	38.1	46.1 – 30.1	38.8
RBC($10^{12}/L$)	4.65	4.9 – 4.4	4.4
HGB(g/dL)	12.5	13.0 – 12.0	12.9
HCT(%)	42.3	46.9 – 37.7	38.3
MCV(fL)	91	96 – 86	87.1
MCH(pg)	28	30.8 – 25.2	29.4
MCHC(g/dL)	30.7	35.5 – 25.9	33.8
RDW-CV(%)	14.2	17.2 – 11.2	15.7
RDW-SD(fL)	52.4	60.4 – 44.4	50.4
PLT($10^9/L$)	244	284 – 204	245
MPV(fL)	8.1	11.1 – 5.1	8.5
PDW()			15
PCT(mL/L)			2.07
P-LCC($10^9/L$)			36
P-LCR(%)			14.7



Jinesh Vadera
Regional Service Manager

HIGH CONTROL

File No.	Lot No.	Expiration Date	QC Test Panel	Level
3	B1123H	05-02-2024	B30	High

No.	Target	Limit(#)	2
Date	/	/	18-12-2023
Time	/	/	20:26
WBC($10^9/L$)	21.2	23.7 – 18.7	22.9
Lymph#($10^9/L$)	8.9	10.6 – 7.2	9.5
Mid#($10^9/L$)	1.6	2.0 – 1.2	1.8
Gran#($10^9/L$)	10.7	12.4 – 9.0	11.6
Lymph%(%)	41.8	45.8 – 37.8	41.5
Mid%(%)	7.6	11.6 – 3.6	7.9
Gran%(%)	50.6	58.6 – 42.6	50.6
RBC($10^{12}/L$)	5.57	5.87 – 5.27	5.37
HGB(g/dL)	17	17.8 – 16.2	16.6
HCT(%)	54.7	60.2 – 49.0	51.7
MCV(fL)	98.2	103.2 – 93.8	96.2
MCH(pg)	30.5	33.6 – 27.4	31
MCHC(g/dL)	31.1	35.9 – 27.0	32.2
RDW-CV(%)	14.3	17.3 – 11.3	15
RDW-SD(fL)	57	65 - 49	51.4
PLT($10^9/L$)	495	555 - 435	530
MPV(fL)	8.1	11.1 – 5.1	8.6
PDW()			15
PCT(mL/L)			4.54
P-LCC($10^9/L$)			79
P-LCR(%)			14.9



Jinesh Vadera
Regional Service Manager