



# Installation Qualification

## For Mindray BC-20s Sr No- TK-36015006

Customer Name : **PRO BIOTIC DIAGNOSTICS PVT.LTD.**  
Customer Address : 3<sup>rd</sup> Floor, C-4/206, Sector 6 Rd,Pocket-4, Sector 6, New Delhi -110085  
Contact Person : MS - JIYA MAKKAR  
Instrument Model : **BC-20S – Auto Hematology Analyser**  
Serial No. : SR.No.-TK- 36015006  
Date of Installation : 15<sup>TH</sup> DEC-2023

Site survey done and pre-installation checklist was made and found that the site is complying to all the requirements. The instrument packaging was checked and opened for installation.

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

#### System Condition Report:

System delivered in satisfactory condition and no external physical damage 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 are present.

Attached are the Check-Lists for the same.

**AVIENCE BIOMEDICALS PVT.LTD**

**Technical Services Department**

**Engineer Name : RAHUL PAL**  
**Designation: Sr. Service Engineer-IVD**

**Signature :**

**PRO BIOTIC DIAGNOSTICS PVT.LTD.**

**Lab Services**

**Contact Person : MS-JIYA MAKKAR**

**Signature:**

## 1. Installation Site Checklist

S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks	
1	Working Environment	Ambient Temperature	Within normal operation temperature	10°C to 30°C	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Humidity	Within operating humidity range	20% to 85%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Atmospheric Pressure	Within operating atmospheric pressure	70KPa to 106 Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Electromagnetic Interferences	Keep Away from electromagnetic interference sources	-	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
2	Space Requirements	Space	Meet the Space Requirements	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
3	Heat Dissipation	Space requirement for Radiator Fan	At least 100mm to each side of the analyzer	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
4	Power Requirements of the main unit and pneumatic unit	Power Supply Voltage and Frequency	Meet the requirements	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		

## 2. Instrument Installation Checklist

S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
1	The package box and appearance of the main unit	Package and Appearance	Package and Appearance	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
2	The package box and appearance of the pneumatic unit	Package and Appearance	Package and Appearance	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
3	The package box and appearance of the autoloader unit	Package and Appearance	Package and Appearance	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
4	Item Packing List	Package and Appearance	All Items are included	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
5	Removing the fixing components of the pneumatic unit	Remove the fixing screws	The fixing screws are removed	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
6	Removing the fixing components of the Analyzer	Stop bar of the Front Cover	Cut the cable ties	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Manual Sampling Assembly	Cut the cable ties	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Cylinder of the mixing assembly	Cut the cable ties	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Piercing probe residual liquid tray	Cut the cable ties	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	

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S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
7	Removing the plastic ties fixing the autoloader	Removing the plastic ties on autoloader	Ties are cut off	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
8	Remove the separator plate of the SRV	Separator plate of the SRV	Separator Plate of the SRV removed	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
11	Connection of Waste	Waste tube and sensor	Tube connected properly and not bent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
12	Connection of Diluent	Connection of diluent container cap	Tube connected properly and not bent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
13	Connections of the Optional Equipments	Connection of Printer	Connected Properly and working	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	



# Operational Qualification

**For Mindray BC-20s Sr No- TK-36015006**

Customer Name : **PRO BIOTIC DIAGNOSTICS PVT.LTD.**  
Customer Address : **3<sup>rd</sup> Floor, C-4/206, Sector 6 Rd, Pocket-4, Sector 6, New Delhi -110085**  
Contact Person : **MS –JIYA MAKKAR**  
Instrument Model : **BC 20S – Auto Hematology Analyser**  
Serial No. : **SR.NO-TK-36015006**  
Date of Installation : **15<sup>TH</sup> DEC 2023**

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

**Initial Inspection of the unit carried out after installation:**

All the checks of the instrument were performed as per the Operational Checklist. Analyzer configuration and status for Temperature, Pressure and other test points was checked.

Attached are the Check-Lists for the same.

**AVIENCE BIOMEDICALS PVT.LTD**

**Technical Services Department**

**Engineer Name : RAHUL PAL**

**Designation: Sr. Service Engineer –IVD**

**Signature :**

**PRO BIOTIC DIAGNOSTICS PVT.LTD**  
**Lab Services**

**Contact Person : JIYA MAKKAR**  
**Signature**



### 1. Instrument Operational Setup Checklist

S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
1	Analyzer Version Information	Version Information	Correct Version	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
2	Analyzer Pressure Status	250KPa	250Kpa $\pm$ 5Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		-70Kpa	No Alarms or Warnings	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		106Kpa	106Kpa $\pm$ 2Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		70Kpa	70Kpa $\pm$ 1Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		40Kpa	40Kpa $\pm$ 1Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		-38Kpa	-38Kpa $\pm$ 0.5Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
3	Analyzer Temperature Status	Temperature Values	Meet Requirements	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
4	Voltage and Current	Voltage and Currents	Meet Requirements	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
5	Software function configuration	Configurations	Correct	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	



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S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
6	Confirm the Pierce Probe Piercing Depth	Pierce Probe Piercing Depth	Analyzer can well aspirate from a 1ml Sample	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
7	SRV Hole Alignment Verification	The pin is properly aligned with the positioning hole	Meet Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
8	Sample Aspiration	Aspiration Position	Meet Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
9	Piercing	Piercing Position	Meet Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
11	Date Format	Date Setup	Meet Client's Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
12	Auxiliary Setup	Auxiliary Setup Items	Meet Client's Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
13	Reagent Setup	Reagent Barcode and Lot number Information	Reagent Barcode and Lot number Information entered correctly	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
14	Maintenance Setup	Settings of the maintenance setup	Settings are suitable for the laboratory	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	

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S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
15	HgB Blank Voltage Check	Hgb Blank Voltage Value	4.5V $\pm$ 0.1V	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
16	Advanced Setup	Settings of the advanced setup	Correctly Setup	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
17	Sensor Level Setup	Blood Sample Sensor	2.30V to 2.4V	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Fluorescent Reagent Sensor	2.30V to 2.4V	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	





## 2. Instrument Installation Operational Performance Checklist

### a. Background Test

S.No.	Inspection Item	Description	Acceptance Criteria	Obtained Value	Result	Remarks	
1	Background	WBC	$\leq 0.2 \times 10^9 / L$	$0.0 \times 10^9 / L$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
		RBC	$\leq 0.02 \times 10^{12} / L$	$0.0 \times 10^{12} / L$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
		Hgb	$\leq 0.1 \text{ gm} / L$	$0.0 \text{ gm} / L$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
		PLT	$\leq 10 \times 10^9 / L$	$0 \times 10^9 / L$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		



**b. Carry-Over Test**

S.No.	Inspection Item	Description	Acceptance Criteria	Obtained Value	Result	Remarks
2	Carryover	WBC	$\leq 0.50\%$	0.10%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		RBC	$\leq 0.50\%$	0.00%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Hgb	$\leq 0.60\%$	0.00%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
					<input type="checkbox"/> Fail	
		PLT	$\leq 1.00\%$	0.00%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	



**c. Repeatability Test**

S.No.	Inspection Item	Description	Acceptance Criteria	Obtained Value	Result	Remarks
3	Repeatability	WBC	$\leq 2.5\%$	0.8%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		RBC	$\leq 1.5\%$	0.9%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		Hgb	$\leq 1.5\%$	0.5%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		PLT	$\leq 4.0\%$	2.1%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	

### CARRYOVER

Abnormal high peripheral blood was analysed 3x consecutively to obtain high concentrations (H1-H3). Then CELLPACK DCL was analysed 3x consecutively to obtain low concentrations (L1-L3). The % Carryover was calculated as follows:

$$\% \text{ Carryover} = \frac{L1 - L3}{H3 - L3} \times 100$$

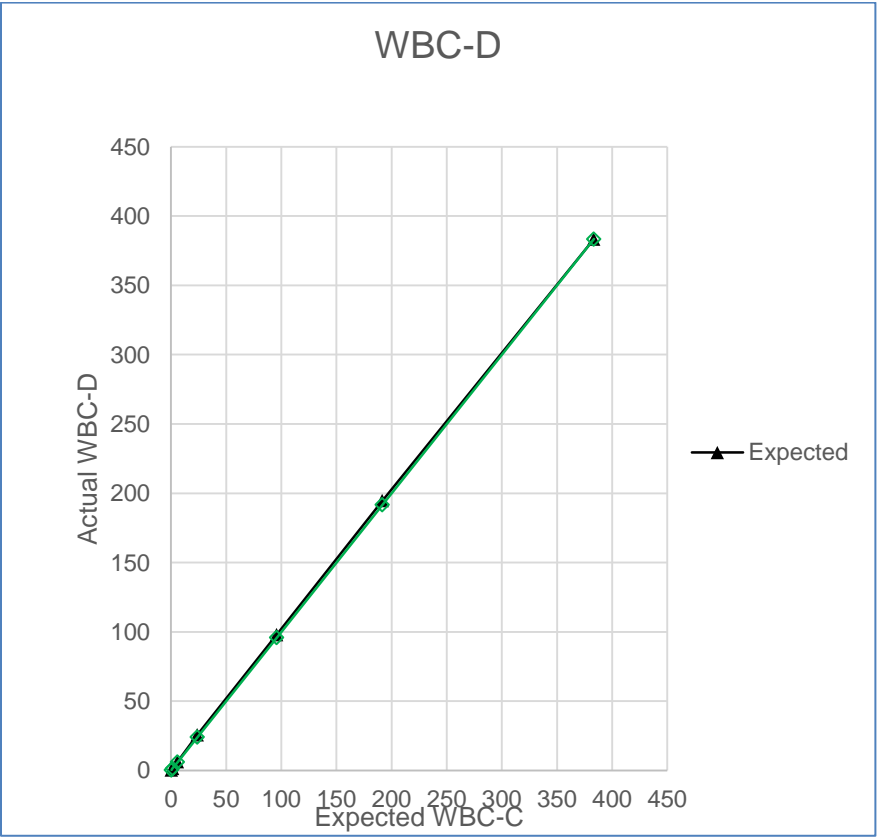
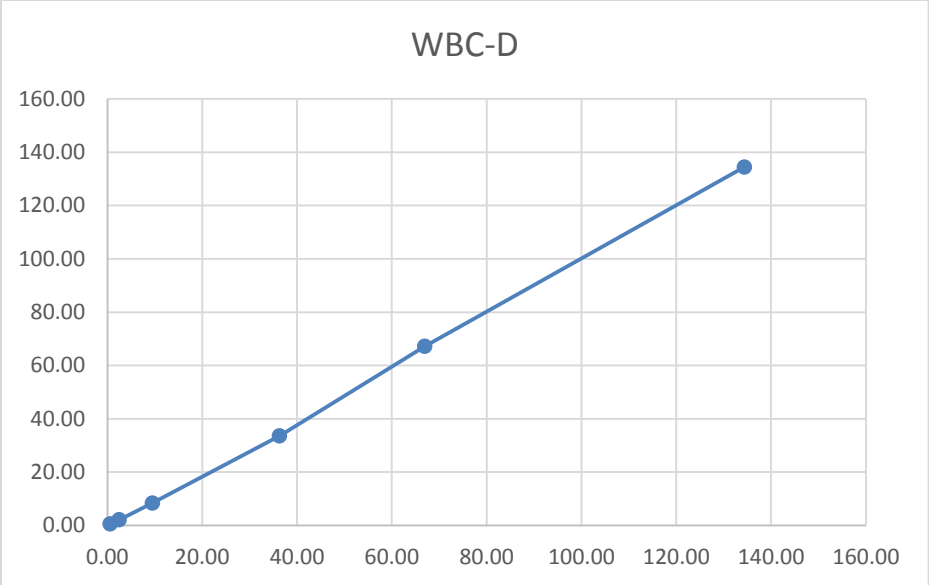
### BC-20s SR.NO-TK-36015006

Sample 1	WBC (x10 <sup>3</sup> /μL)	RBC (x10 <sup>6</sup> /μL)	HGB (g/dL)	HCT (%)	PLT (x10 <sup>3</sup> /μL)
H1	20.31	5.05	15.8	49.5	409
H2	20.25	4.96	15.8	48.5	417
H3	20.59	5	15.8	49.1	420
L1	0	0	0	0	0
L2	0	0	0	0	0
L3	0	0	0	0	0
% Carryover	0.00	0.0	0.0	0.0	0.0
Criteria	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %
Judgement	Pass	Pass	Pass	Pass	Pass

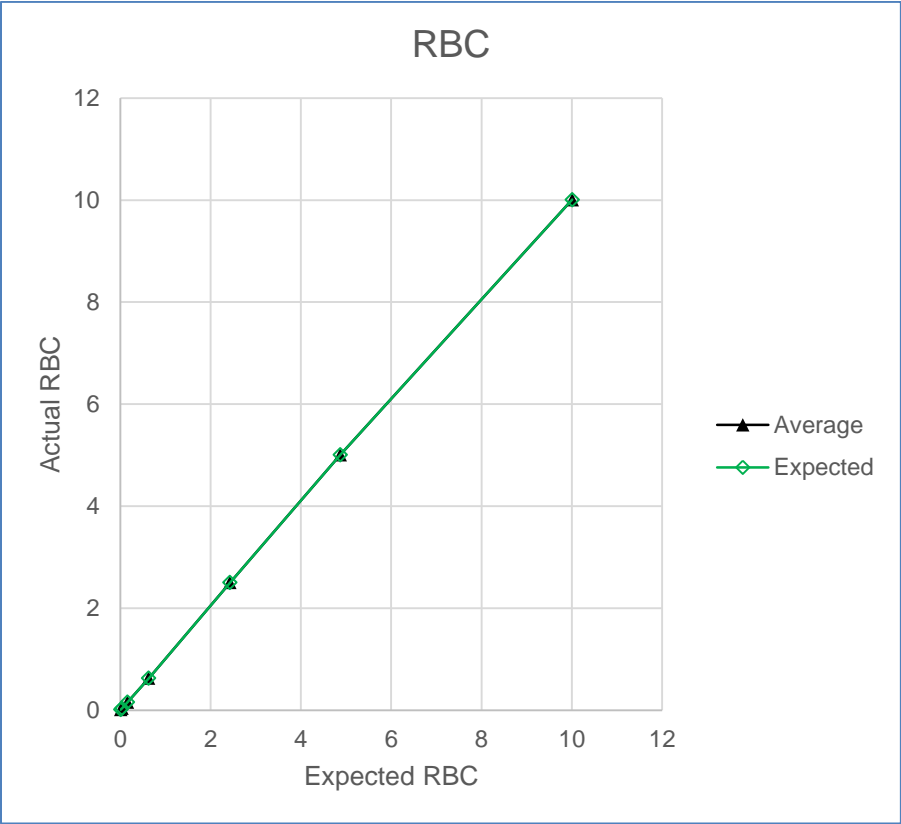
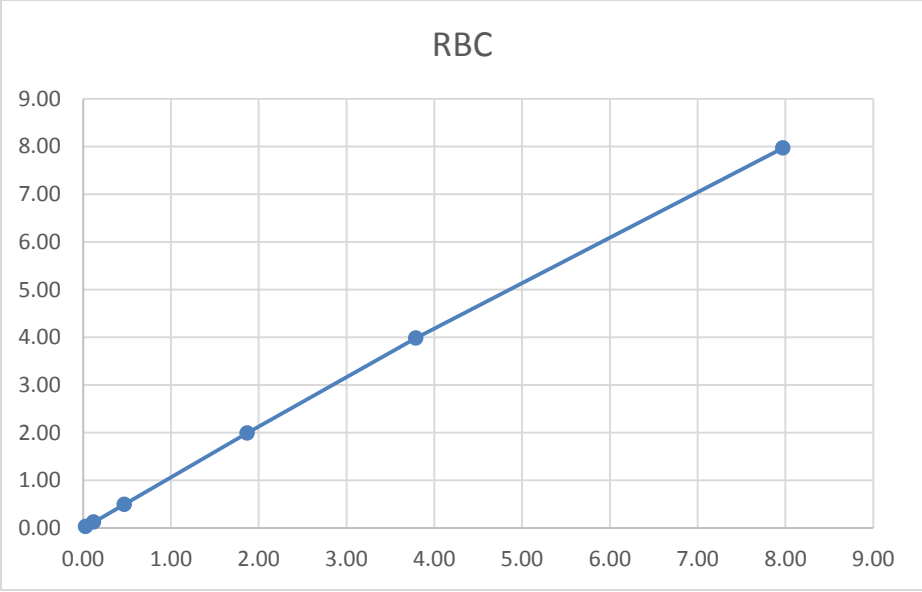
### 3. Linearity (Whole Blood Mode)

Patient sample with High counts was analysed was analysed. Actual vaues was plotted against Expected values.

BC-20s SR.NO- TK-36015006					
WBC (x10 <sup>3</sup> /μL)	Patient Sample			Range	
	Achieved run 1	Average	Achieved	Lower	Upper
1/1	134.40	134.40	134.40	120.96	147.84
1/2	66.99	66.99	67.20	60.48	73.92
1/4	36.34	36.34	33.60	30.24	36.96
1/16	9.49	9.49	8.40	7.56	9.24
1/64	2.47	2.47	2.10	1.89	2.31
1/256	0.6	0.60	0.52	0.47	0.57
1/512	0.25	0.25	0.26	0.20	0.29
<b>r<sup>2</sup></b>				0.9996	
<b>Slope</b>				1.00	
<b>Intercept</b>				0.71	
<b>Judgement</b>				Pass	

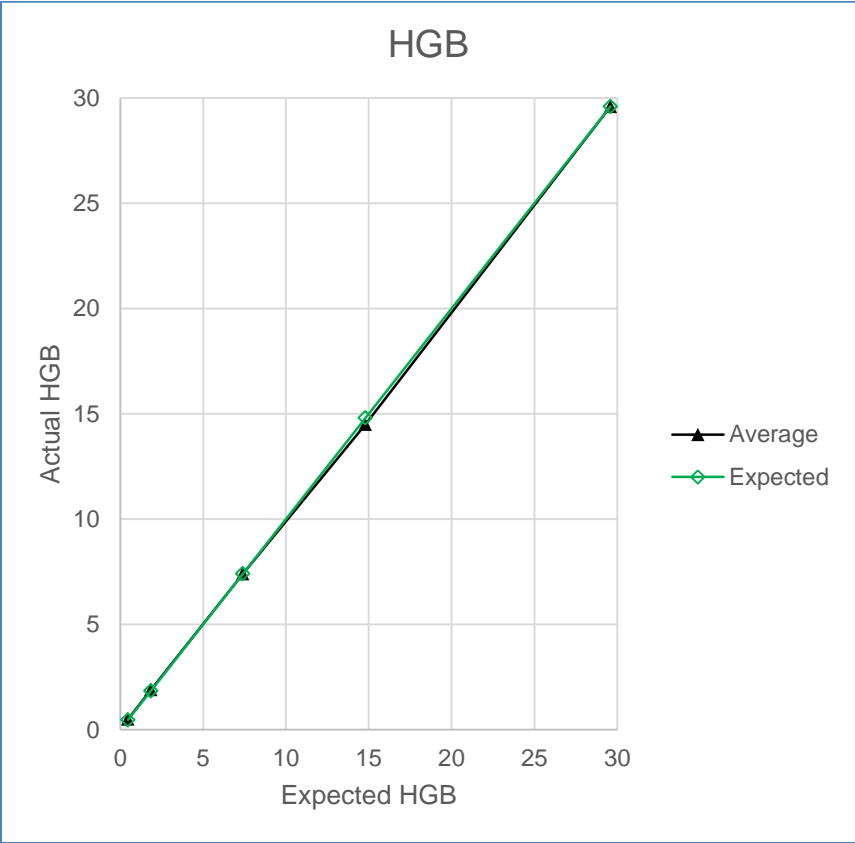
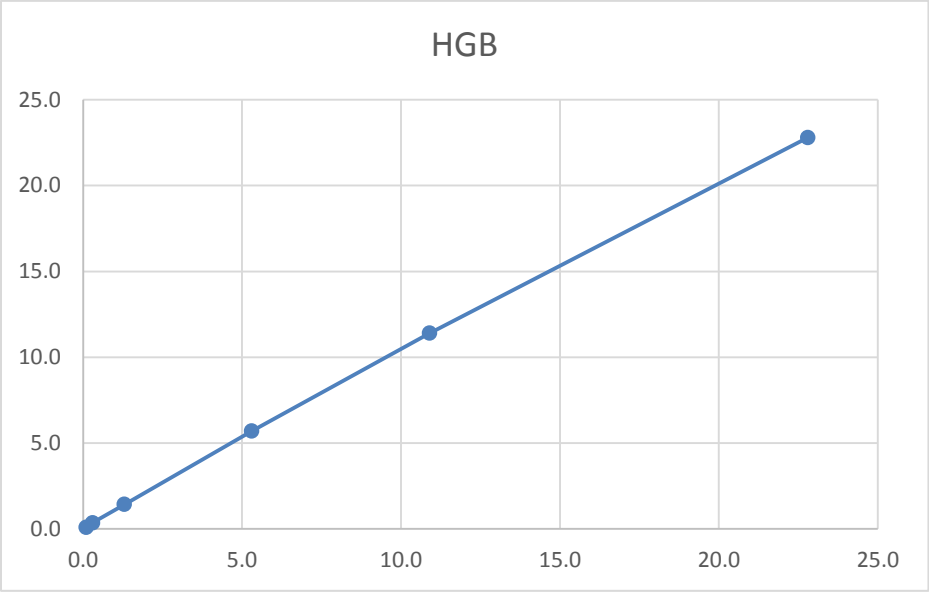


BC-20s SR.NO- TK-36015006					
	Patient Sample				
RBC (x10 <sup>6</sup> /μL)	Achieved run 1	Average	Expected	Range	
				Lower	Upper
1/1	7.97	7.97	7.97	7.17	8.77
1/2	3.79	3.79	3.99	3.59	4.38
1/4	1.87	1.87	1.99	1.79	2.19
1/16	0.47	0.47	0.50	0.45	0.55
1/64	0.12	0.12	0.12	0.08	0.17
1/256	0.03	0.03	0.03	0.02	0.04
			<b>r<sup>2</sup></b>	1.0000	
			<b>Slope</b>	0.94	
			<b>Intercept</b>	0.00	
			<b>Judgement</b>	Pass	

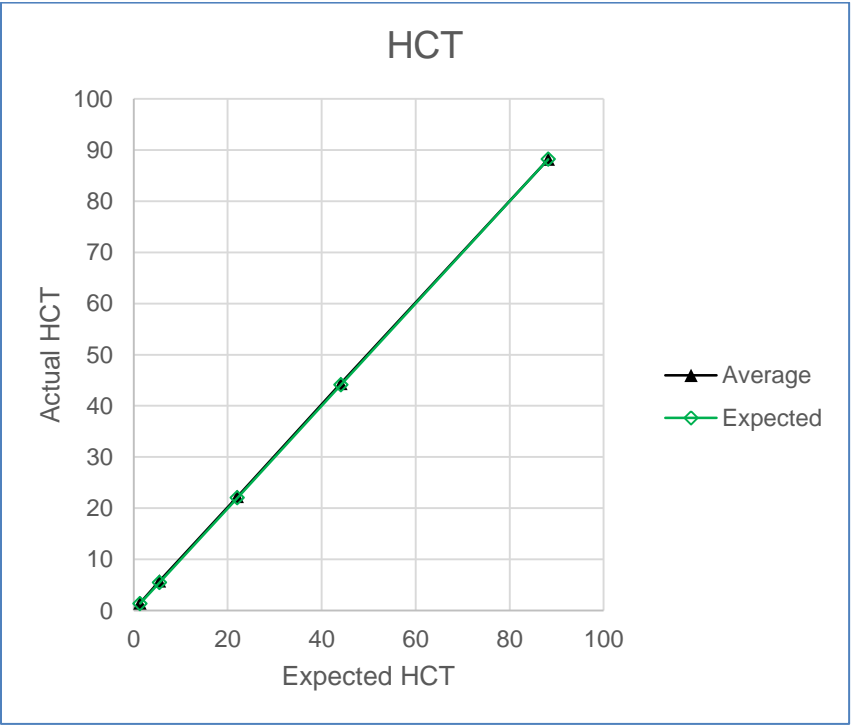
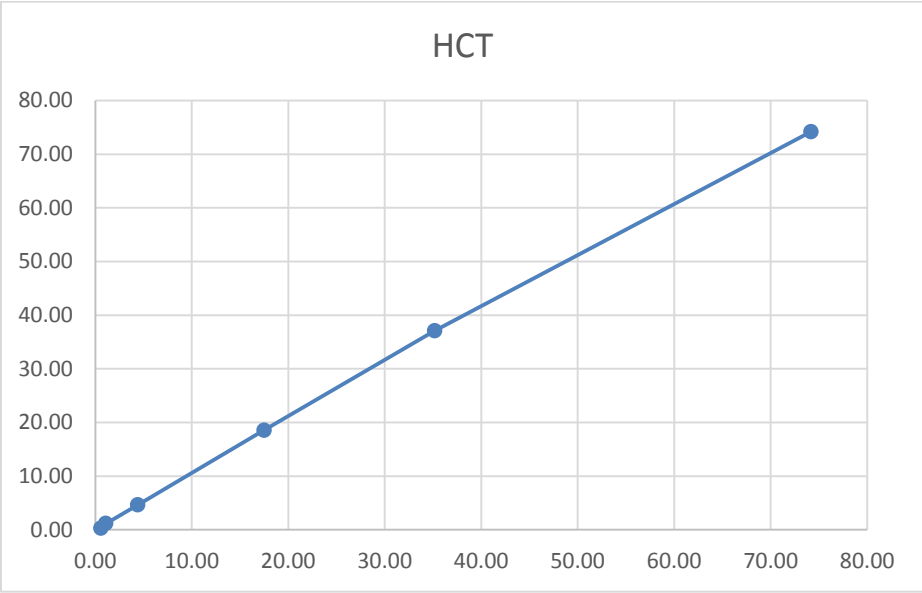




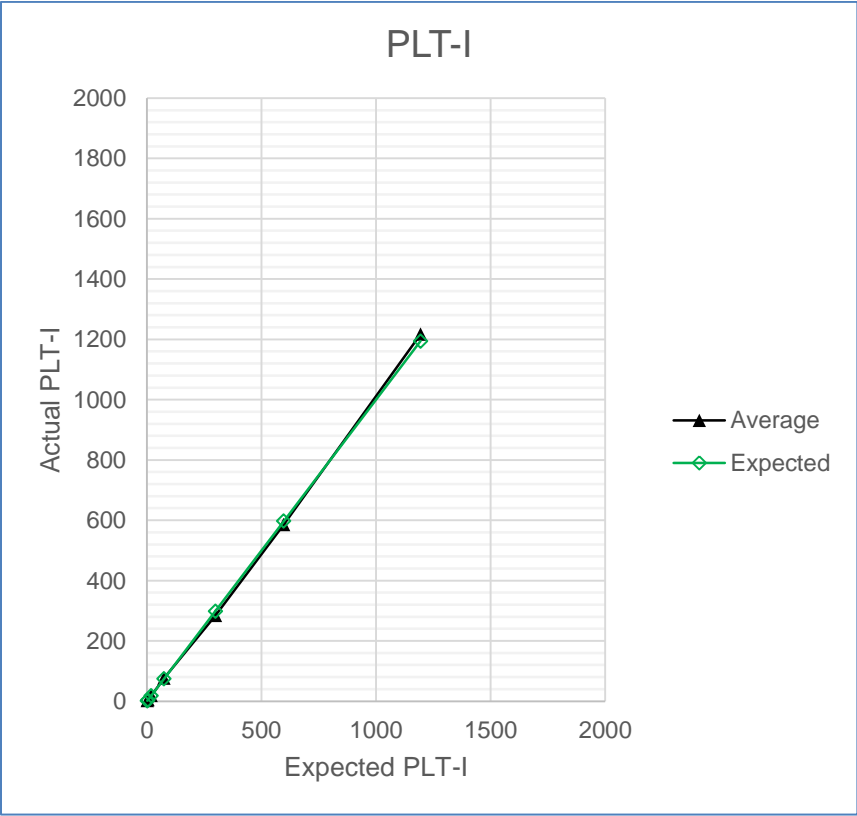
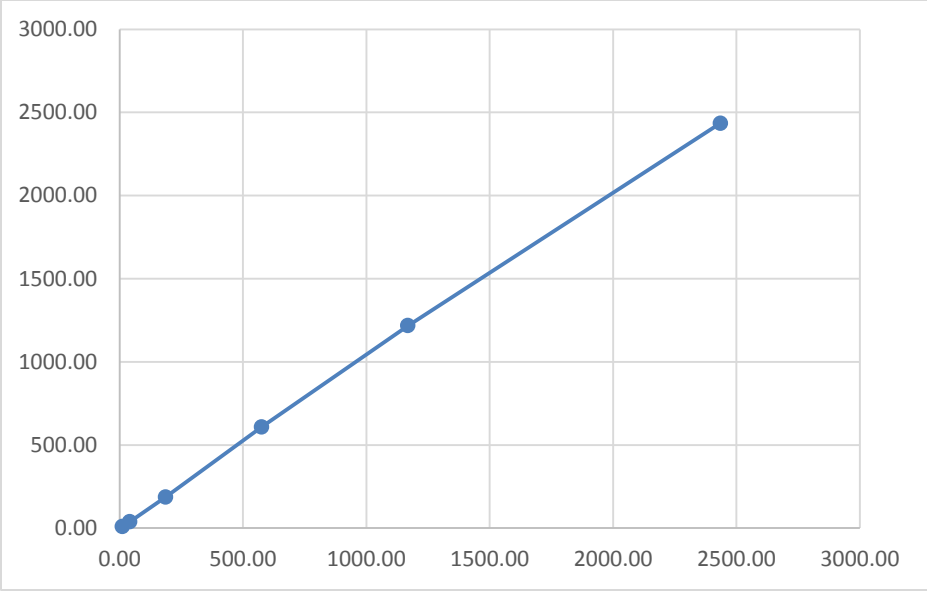
BC-20s SR.NO- TK-36015006					
	Patient Sample				
HGB (g/dL)	Achieved	Average	Expected	Range	
	run 1			Lower	Upper
1/1	22.8	22.8	22.8	20.52	25.08
1/2	10.9	10.9	11.4	10.26	12.54
1/4	5.3	5.3	5.7	5.13	6.27
1/16	1.3	1.3	1.4	1.28	1.57
1/64	0.3	0.3	0.4	0.23	0.48
1/128	0.1	0.1	0.1	0.08	0.10
			<b>r<sup>2</sup></b>	0.9994	
			<b>Slope</b>	1.00	
			<b>Intercept</b>	-0.17	
			<b>Judgement</b>	Pass	



BC-20s SR.NO- TK-36015006					
	Patient Sample				
HCT (%)	Achieved	Average	Expected	Range	
	run 1			Lower	Upper
1/1	74.2	74.20	74.20	66.78	81.62
1/2	35.2	35.20	37.10	33.39	40.81
1/4	17.5	17.50	18.55	16.70	20.41
1/16	4.4	4.40	4.64	4.17	5.10
1/64	1.1	1.10	1.16	0.75	1.57
1/128	0.6	0.60	0.29	0.19	0.39
			<b>r<sup>2</sup></b>	0.9992	
			<b>Slope</b>	0.99	
			<b>Intercept</b>	-0.36	
			<b>Judgement</b>	Pass	



BC-20s SR.NO- TK-36015006					
PLT-I (x10 <sup>3</sup> /μL)	Patient Sample			Range	
	Achieved	Average	Expected	Lower	Upper
	run 1				
1/1	2435.00	2435.00	2435.00	2191.50	2678.50
1/2	1169	1169.00	1217.50	1095.75	1339.25
1/4	576	576.00	608.75	547.88	669.63
1/16	187	187.00	187.00	168.30	190.00
1/64	41	41.00	38.05	34.24	41.85
1/256	12	12.00	9.51	8.56	14.00
<b>r<sup>2</sup></b>				0.9995	
<b>Slope</b>				1.00	
<b>Intercept</b>				-8.92	
<b>Judgement</b>				Pass	



### 1. Precision (Whole Blood Mode)

Peripheral blood was analysed 11x. The first run was excluded and the Average, SD, and CV% were calculated. Judgement is applicable only if the condition is satisfied.

BC-20s Sr.NO.- TK-36015006				
Run	WBC-D (x10 <sup>3</sup> /μL)	RBC (x10 <sup>6</sup> /μL)	HGB (g/dL)	
	Sample 1	Sample 1	Sample 1	
1	<del>9.79</del>	<del>4.5</del>	<del>12.3</del>	-
2	9.79	4.5	12.3	
3	9.81	4.46	12.2	
4	9.89	4.42	12.2	
5	9.68	4.46	12.1	
6	9.88	4.45	12.3	
7	9.83	4.39	12.1	
8	9.69	4.48	12.3	
9	9.89	4.4	12.1	
10	9.66	4.38	12.2	
11	9.92	4.41	12.3	
Average	9.80	4.44	12.2	
SD	0.14	0.03	0.1	
CV%	1.5	0.8	0.6	
Criteria	≤ 2.5 %	≤ 1.5 %	≤ 1.0 %	
Condition	WBC ≥ 4.00x10 <sup>3</sup> /μL	RBC ≥ 4.00x10 <sup>6</sup> /μL	NA	
Judgement	Pass	Pass	Pass	

**BC-20s Sr.NO.- TK-36015006**

Run	MCV (fL)	MCHC(g/dL)	RDW-SD (fL)	RDW-CV (%)
	Sample 1	Sample 1	Sample 1	Sample 1
1	87.6	31.3	49.6	15
2	87.6	31.3	49.6	15
3	87.9	31	49.4	14.9
4	87.7	31.1	49.3	14.9
5	87.7	31	50.2	15.2
6	87.7	31.3	49.6	15
7	87.5	31.3	48.8	14.7
8	87.9	31.3	49.6	15
9	87.7	31.1	49.7	14.9
10	87.8	31.4	49.2	14.8
11	87.2	31.2	49.4	14.9
Average	87.7	31.2	49.5	14.9
SD	0.6	0.3	0.5	0.1
CV%	0.7	0.9	1.1	0.9
Criteria	≤ 1 %	≤ 1.5 %	≤ 2.0 %	≤ 2.0 %
Condition	NA	NA	NA	NA
Judgement	Pass	Pass	Pass	Pass



BC-20s SR.NO.- TK-36015006					
Run	PLT-I ( $\times 10^3/\mu\text{L}$ )	PDW (fL)	MPV (fL)	P-LCR (%)	PCT (%)
	Sample 1	Sample 1	Sample 1	Sample 1	Sample 1
1	345	15.9	13.4	49.7	0.461
2	345	15.9	13.4	49.7	0.461
3	344	15.8	13.1	48	0.45
4	343	15.8	13.5	51.2	0.463
5	337	15.7	13.2	50.7	0.447
6	337	16	13.4	50.2	0.451
7	340	15.8	13.5	51.7	0.458
8	344	15.8	13	47.7	0.447
9	341	15.9	13.5	50.5	0.459
10	323	15.9	13.4	50.3	0.434
11	334	15.7	13.4	50.5	0.447
Average	338.80	15.8	13.3	50.1	0.45
SD	9.16	0.3	0.1	0.8	0.01
CV%	2.7	1.9	1.3	2.6	1.9
Criteria	$\leq 4.0 \%$	$\leq 10.0 \%$	$\leq 3.0 \%$	$\leq 15 \%$	$\leq 5.0 \%$
Condition	PLT $\geq 100 \times 10^3/\mu\text{L}$	NA	NA	NA	NA
Judgement	Pass	Pass	Pass	Pass	Pass

BC-20s SR.NO- TK-36015006				
Run	MONO# (x10 <sup>3</sup> /μL)	MONO% (%)	EO# (x10 <sup>3</sup> /μL)	EO% (%)
	Sample	Sample	Sample	Sample
1	0.49	5.4	0.34	3.7
2	0.49	5.4	0.35	3.8
3	0.54	5.7	0.33	3.5
4	0.55	5.8	0.35	3.7
5	0.56	5.9	0.35	3.8
6	0.49	5.4	0.37	4.1
7	0.52	5.7	0.32	3.4
8	0.56	6	0.38	4.2
9	0.51	5.5	0.33	3.5
10	0.52	5.4	0.35	3.8
11	0.53	5.6	0.37	4
Average	0.53	5.6	0.35	3.8
SD	0.03	0.2	0.02	0.3
CV%	4.9	3.8	5.6	7.0
Criteria	≤ 16.0 %	≤ 16.0 %	≤ 25.0 % or ± 0.12 x 10 <sup>3</sup> /μL	≤ 25.0 % or ± 1.5 EO%
Condition	MONO# ≥ 0.20x10 <sup>3</sup> /μL	MONO% ≥ 5.0%	NA	WBC ≥ 4.00x10 <sup>3</sup> /μL
Judgement	Pass	Pass	Pass	Pass

