



**UNIQUE**  
DIAGNOSTICS & SCIENTIFIC  
**CALIBRATION CERTIFICATE**  
Partners for Excellence

**Date: 07/02/2022**

**Equipment Name** : DXH 560AL

**Sr.No.** : BE060208

**Location** : Welfare Medical Foundation's Viloo Poonawalla Memorial Hospital  
Sr. No. 156, Plot No. 1/3A+3B/1+2/3,  
Pune Solapur Road, Hadapsar, Pune - 411 028.

**Material user for calibration** : DXH 560  
Lot No. 492114700  
Exp Date: 02/05/2022  
Been Run on: - 04/02/2022  
Next Calibration due on 03/02/2023.

**Calibration details of the Instrument:**

Instrument was calibrated using DXH calibrator. Following values were observed

PARAMETER	TARGET VALUE	OBSERVED VALUE
WBC	9.25	8.73
RBC	4.35	4.28
HGB	13.80	14.05
MCV	90.5	91.6
PLT	266.0	271.5
MPV	9.90	10.00

**Calibration Factor Limits**

PARAMETER	OLD CAL FACTORS	NEW CAL FACTORS
WBC	1.074	1.138
RBC	1.005	1.021
HGB	1.079	1.060
MCV	1.123	1.110
PLT	1.163	1.139
MPV	1.040	1.030

**REMARKS:** INSTRUMENT GOT AUTOCALIBRATED AS PER THE TARGET

**Authorised Signatory**



**For Unique Diagnostics & Scientific**

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7th Floor, Madhu Industrial Park, Avadh Narayan Tiwari Marg, Off Old Nagardas Road, Andheri (E), Mumbai - 4000 69

Run Date/Time: 02/04/2022 12:12

Sequence #: 2

Operator SERVICE

Last Shutdown: 07/20/2021 14:28

	Result	Limit	Units	Status
WBC	0.01	0.20	$\times 10^3/\mu\text{L}$	Pass
RBC	0.00	0.03	$\times 10^6/\mu\text{L}$	Pass
HGB	0.00	0.10	g/dL	Pass
PLT	0.5	7.0	$\times 10^3/\mu\text{L}$	Pass

	Status
Vacuum	Pass
Temperature	Pass
Syringe	Pass
Probe	Pass
Probe Mech.	Pass

	Status	Cycles
Diluent	Pass	717
Lyse	Pass	752
Cleaner	Pass	1120
Waste	Pass	18%

Daily check - Pass  
Mubensip  
04/02/2022

Diluent	51170	04/05/2022
Lyse	8300044	04/05/2022
Cleaner	8310147	05/05/2022

**Lot Number:** 302113212

**Level:** Normal

**Excluded:** No

**Test:** CD

**Expiration date:** 03/05/2022

**Source:** BEC

**Run Date/Time:** 02/04/2022 12:55

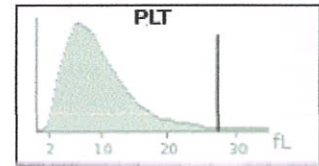
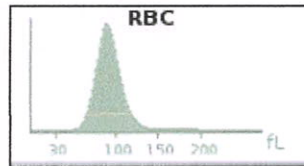
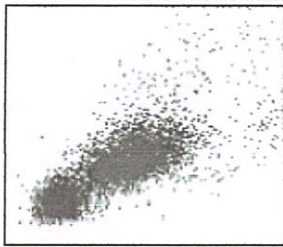
**Sequence #:** 20

**Comments:**

Test	Result	Flags	Units	Low	High
WBC	6.84		x10 <sup>3</sup> /μL	6.10	8.30
LY	32.99		%	22.00	40.00
MO	1.19		%	0.00	3.00
NE	63.44		%	56.50	70.50
EO	2.35		%	0.00	7.00
BA	0.03		%	0.00	1.00
LY#	2.26		x10 <sup>3</sup> /μL	1.58	2.88
MO#	0.08		x10 <sup>3</sup> /μL	0.00	0.22
NE#	4.34		x10 <sup>3</sup> /μL	4.06	5.08
EO#	0.16		x10 <sup>3</sup> /μL	0.00	0.50
BA#	0.00		x10 <sup>3</sup> /μL	0.00	0.08

Test	Result	Flags	Units	Low	High
RBC	4.73		x10 <sup>6</sup> /μL	4.52	4.92
HGB	15.20		g/dL	14.40	15.60
HCT	42.7		%	40.2	45.2
MCV	90.3		fL	85.5	95.5
MCH	32.1		pg	29.3	34.3
MCHC	35.6		g/dL	32.1	38.1
RDW	12.0		%	10.0	16.0
RDW-SD	44.7		fL	39.5	54.5
PLT	274.2		x10 <sup>3</sup> /μL	205.0	285.0
MPV	10.22		fL	8.70	11.10

Flags & Messages
System: Service Access



*Control Run  
Before Calibration  
Mukulisp  
04/02/2022*

Diluent	0051170	04/05/2022	
Lyse	8300044	04/05/2022	
Cleaner	8310147	05/05/2022	
Control	372113213	02/04/2022	12:51
Calibration	492114100	07/20/2021	12:06



Lot Number: 352113211

Test: CD

Source: BEC

Level: Ab. Low

Expiration date: 03/05/2022

Excluded: No

Run Date/Time: 02/04/2022 12:56

Sequence #: 21

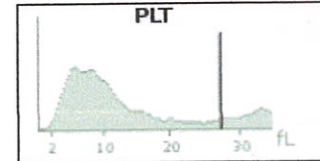
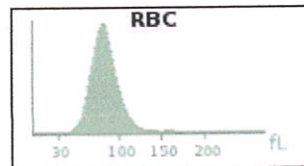
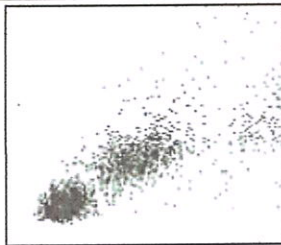
Comments:

Test	Result	Flags	Units	Low	High
WBC	2.05		x10 <sup>3</sup> /μL	1.80	2.60
LY	49.88		%	35.50	59.50
MO	0.91		%	0.00	3.00
NE	39.41		%	30.00	50.00
EO	9.75		%	0.50	20.50
BA	0.05		%	0.00	1.00
LY#	1.02		x10 <sup>3</sup> /μL	0.78	1.32
MO#	0.02		x10 <sup>3</sup> /μL	0.00	0.06
NE#	0.81		x10 <sup>3</sup> /μL	0.66	1.10
EO#	0.20		x10 <sup>3</sup> /μL	0.01	0.45
BA#	0.00		x10 <sup>3</sup> /μL	0.00	0.02

Test	Result	Flags	Units	Low	High
RBC	2.38		x10 <sup>6</sup> /μL	2.28	2.58
HGB	6.67		g/dL	6.25	7.05
HCT	19.5		%	17.4	21.4
MCV	82.1		fL	75.0	85.0
MCH	28.0		pg	24.9	29.9
MCHC	34.2		g/dL	31.2	37.2
RDW	14.2		%	12.5	18.5
RDW-SD	46.2		fL	38.5	53.5
PLT	75.1		x10 <sup>3</sup> /μL	45.0	85.0
MPV	10.76		fL	9.30	11.70

Flags & Messages

System:  
Service Access



*Before Calibration  
Mulewisp  
04/02/2022*

Diluent	0051170	04/05/2022	
Lyse	8300044	04/05/2022	
Cleaner	8310147	05/05/2022	
Control	362113212	02/04/2022	12:55
Calibration	492114100	07/20/2021	12:06

Lot Number: 372113213

Level: Ab. High

Excluded: No

Test: CD

Source: BEC

Expiration date: 03/05/2022

Run Date/Time: 02/04/2022 12:58

Sequence #: 22

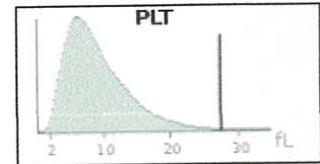
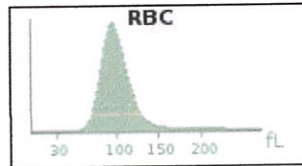
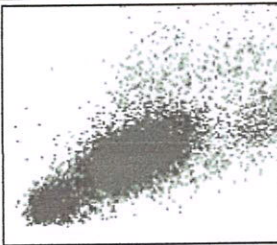
Comments:

Test	Result	Flags	Units	Low	High
WBC	17.24		x10 <sup>3</sup> /μL	15.10	20.10
LY	15.32		%	7.00	23.00
MO	1.64		%	0.00	3.00
NE	76.03		%	64.50	86.50
EO	6.98		%	0.00	15.00
BA	0.03		%	0.00	1.00
LY#	2.64		x10 <sup>3</sup> /μL	1.23	4.05
MO#	0.28		x10 <sup>3</sup> /μL	0.00	0.52
NE#	13.11		x10 <sup>3</sup> /μL	11.35	15.23
EO#	1.20		x10 <sup>3</sup> /μL	0.00	2.64
BA#	0.01		x10 <sup>3</sup> /μL	0.00	0.18

Test	Result	Flags	Units	Low	High
RBC	5.15		x10 <sup>6</sup> /μL	4.97	5.47
HGB	17.90		g/dL	16.80	18.40
HCT	50.2		%	47.1	53.1
MCV	97.5		fL	91.0	101.0
MCH	34.8		pg	31.2	36.2
MCHC	35.7		g/dL	32.1	38.1
RDW	12.0		%	9.5	15.5
RDW-SD	49.9		fL	41.5	56.5
PLT	509.5		x10 <sup>3</sup> /μL	395.0	515.0
MPV	9.90		fL	8.00	10.40

Flags & Messages

System:  
Service Access



*Before calibration*  
*Mulanis P*  
*04/02/2022*

Diluent	0051170	04/05/2022	
Lyse	8300044	04/05/2022	
Cleaner	8310147	05/05/2022	
Control	352113211	02/04/2022	12:56
Calibration	492114100	07/20/2021	12:06



Analysis Type: WB Start Date/Time: 02/04/2022 12:24 Operator: SERVICE

Run Date/Time	OPR.	Exd Run	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV	LY	MO	ME	EO	BA
02/04/2022 12:24	SERVICE	N 1	13.40	324	8.25	25.7	79.3	25.5	32.1	25.9	60.1	173.8 R	8.89 R	6.92	7.41	84.24	1.05	0.38
02/04/2022 12:25	SERVICE	N 2	13.43	318	8.27	25.2	79.1	26.0	32.8	26.4	60.6	171.9 R	8.68 R	7.06	7.54	83.98	1.05	0.36
02/04/2022 12:26	SERVICE	N 3	13.18	320	8.28	25.4	79.5	25.9	32.6	26.3	60.6	172.4 R	9.05 R	6.93	7.20	84.42	1.12	0.33
02/04/2022 12:27	SERVICE	N 4	13.25	318	8.22	25.3	79.5	25.8	32.5	26.4	60.1	169.9 R	9.05 R	0.91	0.95	11.13	0.15	0.04
02/04/2022 12:29	SERVICE	N 5	13.20	315	8.24	24.9	79.0	26.2	33.1	25.8	60.7	164.4 R	8.84 R	7.18	7.35	84.00	1.06	0.42
02/04/2022 12:30	SERVICE	N 6	13.32	319	8.28	25.3	79.3	26.0	32.7	26.0	60.7	187.9 R	9.79 R	7.32	7.62	83.92	0.86	0.29
02/04/2022 12:31	SERVICE	N 7	13.50	321	8.35	25.2	78.6	26.0	33.1	25.8	60.5	175.0 R	9.14 R	7.10	7.75	83.58	1.16	0.41
02/04/2022 12:32	SERVICE	N 8	13.77	316	8.24	24.9	78.8	26.1	33.1	25.7	60.3	171.8 R	8.95 R	7.44	7.43	83.57	1.13	0.42
02/04/2022 12:34	SERVICE	N 9	13.21	322	8.30	25.2	78.4	25.8	32.9	26.6	60.4	178.2 R	8.93 R	7.36	7.67	83.55	1.10	0.32
02/04/2022 12:35	SERVICE	N 10	13.42	326	8.31	25.8	79.1	25.5	32.2	26.8	60.3	174.1 R	9.32 R	7.26	7.88	83.37	1.09	0.42

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV	LY	MO	ME	EO	BA
Mean	13.37	320	8.21	25.3	79.1	25.9	32.7	26.2	60.4	173.9	9.06	7.22	7.51	83.84	1.06	0.37
2SD	0.36	0.06	0.08	0.6	0.8	0.4	0.8	0.8	2.2	12.2	0.62	0.44	0.44	0.66	0.18	0.10
%CV	1.35	0.94	0.48	1.19	0.51	0.77	1.22	1.53	1.51	3.51	3.42	3.05	2.93	0.39	0.49	13.51
Min	13.18	315	8.22	24.9	78.4	25.5	32.1	25.7	60.3	164.4	8.68	6.92	7.20	83.37	0.86	0.29
Max	13.77	326	8.35	25.8	79.5	26.2	33.1	26.8	60.7	187.9	9.79	7.60	7.88	84.42	1.16	0.42
Range	0.59	0.11	0.13	0.9	1.1	0.7	1.0	1.1	3.4	23.5	1.11	0.68	0.68	1.05	0.30	0.13

	LY#	MO#	ME#	EO#	BA#
Mean	0.96	1.00	11.21	0.14	0.05
2SD	0.06	0.08	0.28	0.02	0.02
%CV	3.13	4.00	1.25	7.14	20.00
Min	0.91	0.95	11.04	0.11	0.04
Max	1.02	1.06	11.51	0.16	0.06
Range	0.11	0.11	0.47	0.04	0.02

Repeatability - OK  
 Analyze  
 04/10/2022

Repeatability Report

Accept Date/Time: 02/04/2022 13:21  
Status: PASS

Test: WB

Operator: SERVICE

Run Date/Time	OPR	Run	WBC	RBC	HGB	PLT
02/04/2022 13:16	SERVICE	Blood 1	5.80	4.37	11.98	1735
02/04/2022 13:17	SERVICE	Blood 2	5.72	4.20	11.78	180.4
02/04/2022 13:18	SERVICE	Blood 3	5.79	4.24	11.69	1739
02/04/2022 13:19	SERVICE	Diluent 1	0.01 -	0.00 -	0.00 -	0.7 -R
02/04/2022 13:20	SERVICE	Diluent 2	0.01 -	0.00 -	0.00 -	0.2 -R
02/04/2022 13:21	SERVICE	Diluent 3	0.01 -	0.00 -	0.00 -	0.5 -R

	WBC	RBC	HGB	PLI
Result	0.00%	0.00%	0.00%	0.12%
Limit	1.00%	1.00%	1.00%	1.00%
Background Limit	0.20	0.03	0.10	7.0
Status	PASS	PASS	PASS	PASS

Carryover - Pass  
MulanisP  
04/02/2022

Diluent	0051170	04/05/2022	
Lyse	8300044	04/05/2022	
Cleaner	8310147	05/05/2022	
Control	372113213	02/04/2022	12:58
Calibration	492114100	07/20/2021	12:06



Lot Number: 492114700

Source: BEC

Accept Date/Time: 02/04/2022 13:37

Expiration Date: 02/05/2022

Run Date/Time	OPR.	Excl	Run	WBC	RBC	HGB	MCV	PLT	MPV
02/04/2022 13:26	SERVICE	N	1	8.77	4.36	14.25	90.8	293.7	9.81
02/04/2022 13:27	SERVICE	N	2	8.74	4.24	13.85	91.4	276.6	10.01
02/04/2022 13:28	SERVICE	N	3	8.62	4.25	14.03	91.8	269.9	9.95
02/04/2022 13:29	SERVICE	N	4	8.58	4.28	14.03	91.7	256.6	9.86
02/04/2022 13:30	SERVICE	N	5	8.88	4.26	14.02	91.7	267.3	9.92
02/04/2022 13:31	SERVICE	N	6	8.85	4.33	14.11	91.6	270.5	10.35
02/04/2022 13:32	SERVICE	N	7	8.59	4.25	14.04	91.6	284.4	9.92
02/04/2022 13:33	SERVICE	N	8	8.72	4.28	14.04	91.5	251.6	10.04
02/04/2022 13:34	SERVICE	N	9	8.65	4.31	14.03	91.7	267.9	9.99
02/04/2022 13:35	SERVICE	N	10	8.81	4.26	14.05	91.9	272.2	9.97
02/04/2022 13:36	SERVICE	N	11	8.87	4.30	14.14	91.7	276.0	10.18

	WBC	RBC	HGB	MCV	PLT	MPV
Mean	8.73	4.28	14.05	91.6	271.5	10.00
%CV	1.26	0.93	0.71	0.33	4.31	1.50
Target	9.25	4.35	13.80	90.5	266.0	9.90
Factor % Diff	5.96	1.59	-1.76	-1.16	-2.06	-0.96
Delta Diff	0.52	0.07	0.25	1.1	5.5	0.10
In-Use Factors	1.074	1.005	1.079	1.123	1.163	1.040
New Factor	1.138	1.021	1.060	1.110	1.139	1.030
Status	PASS	PASS	PASS	PASS	PASS	PASS

*Calibration Done*  
*Mulen'sp*  
*04/02/2022*

Diluent	0051170	04/05/2022	
Lyse	8300044	04/05/2022	
Cleaner	8310147	05/05/2022	
Control	372113213	02/04/2022	12:58
Calibration	492114100	07/20/2021	12:06



Lot Number: 362113212

Test: CD

Source: BEC

Level: Normal

Expiration date: 03/05/2022

Excluded: No

Run Date/Time: 02/04/2022 13:50

Sequence #: 54

Cass / Pos: 01 01 1

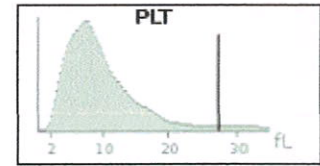
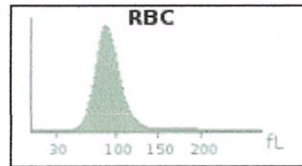
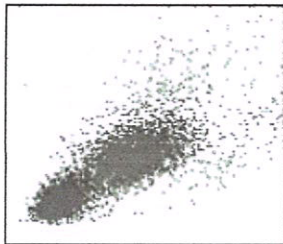
Comments:

Test	Result	Flags	Units	Low	High
WBC	7.48		x10 <sup>3</sup> /μL	6.10	8.30
LY	33.37		%	22.00	40.00
MO	1.44		%	0.00	3.00
NE	62.39		%	56.50	70.50
EO	2.72		%	0.00	7.00
BA	0.08		%	0.00	1.00
LY#	2.50		x10 <sup>3</sup> /μL	1.58	2.88
MO#	0.11		x10 <sup>3</sup> /μL	0.00	0.22
NE#	4.67		x10 <sup>3</sup> /μL	4.06	5.08
EO#	0.20		x10 <sup>3</sup> /μL	0.00	0.50
BA#	0.01		x10 <sup>3</sup> /μL	0.00	0.08

Test	Result	Flags	Units	Low	High
RBC	4.82		x10 <sup>6</sup> /μL	4.52	4.92
HGB	15.25		g/dL	14.40	15.60
HCT	43.1		%	40.2	45.2
MCV	89.4		fL	85.5	95.5
MCH	31.6		pg	29.3	34.3
MCHC	35.4		g/dL	32.1	38.1
RDW	12.2		%	10.0	16.0
RDW-SD	44.6		fL	39.5	54.5
PLT	278.6		x10 <sup>3</sup> /μL	205.0	285.0
MPV	10.23		fL	8.70	11.10

Flags & Messages
System: Service Access

*After calibration  
Mulevisp  
04/02/2022*



Diluent	0051170	04/05/2022	
Lyse	8300044	04/05/2022	
Cleaner	8310147	05/05/2022	
Control	372113213	02/04/2022	12:58
Calibration	492114700	02/04/2022	13:37

Lot Number: 352113211

Test: CD

Source: BEC

Level: Ab. Low

Expiration date: 03/05/2022

Excluded: No

Run Date/Time: 02/04/2022 13:51

Sequence #: 55

Cass / Pos: 01 01 2

Comments:

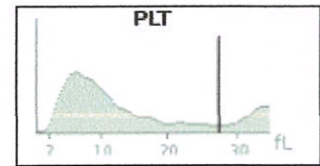
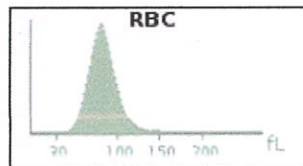
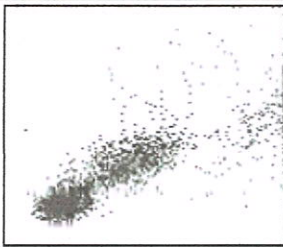
Test	Result	Flags	Units	Low	High
WBC	2.28		x10 <sup>3</sup> /μL	1.80	2.60
LY	50.07		%	35.50	59.50
MO	0.96		%	0.00	3.00
NE	38.23		%	30.00	50.00
EO	10.74		%	0.50	20.50
BA	0.00		%	0.00	1.00
LY#	1.14		x10 <sup>3</sup> /μL	0.78	1.32
MO#	0.02		x10 <sup>3</sup> /μL	0.00	0.06
NE#	0.87		x10 <sup>3</sup> /μL	0.66	1.10
EO#	0.24		x10 <sup>3</sup> /μL	0.01	0.45
BA#	0.00		x10 <sup>3</sup> /μL	0.00	0.02

Test	Result	Flags	Units	Low	High
RBC	2.40		x10 <sup>6</sup> /μL	2.28	2.58
HGB	6.57		g/dL	6.25	7.05
HCT	19.6		%	17.4	21.4
MCV	81.6		fL	75.0	85.0
MCH	27.4		pg	24.9	29.9
MCHC	33.5		g/dL	31.2	37.2
RDW	14.4		%	12.5	18.5
RDW-SD	46.9		fL	38.5	53.5
PLT	66.1		x10 <sup>3</sup> /μL	45.0	85.0
MPV	11.05		fL	9.30	11.70

Flags & Messages

System:  
Service Access

*After Calibration  
Mulevisp  
04/02/2022*



Diluent	0051170	04/05/2022	
Lyse	8300044	04/05/2022	
Cleaner	8310147	05/05/2022	
Control	362113212	02/04/2022	13:50
Calibration	492114700	02/04/2022	13:37



Lot Number: 372113213

Test: CD

Source: BEC

Level: Ab. High

Expiration date: 03/05/2022

Excluded: No

Run Date/Time: 02/04/2022 13:52

Sequence #: 56

Cass / Pos: 01 01 3

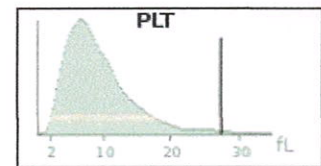
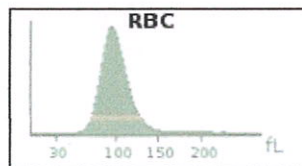
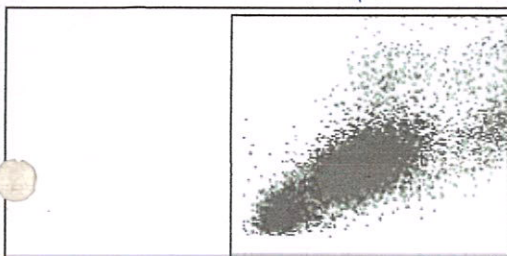
Comments:

Test	Result	Flags	Units	Low	High
WBC	18.19		x10 <sup>3</sup> /μL	15.10	20.10
LY	16.13		%	7.00	23.00
MO	1.85		%	0.00	3.00
NE	75.32		%	64.50	86.50
EO	6.67		%	0.00	15.00
BA	0.03		%	0.00	1.00
LY#	2.93		x10 <sup>3</sup> /μL	1.23	4.05
MO#	0.34		x10 <sup>3</sup> /μL	0.00	0.52
NE#	13.70		x10 <sup>3</sup> /μL	11.35	15.23
EO#	1.21		x10 <sup>3</sup> /μL	0.00	2.64
BA#	0.01		x10 <sup>3</sup> /μL	0.00	0.18


Test	Result	Flags	Units	Low	High
RBC	5.03		x10 <sup>6</sup> /μL	4.97	5.47
HGB	17.45		g/dL	16.80	18.40
HCT	49.1		%	47.1	53.1
MCV	97.7		fL	91.0	101.0
MCH	34.7		pg	31.2	36.2
MCHC	35.5		g/dL	32.1	38.1
RDW	12.0		%	9.5	15.5
RDW-SD	48.5		fL	41.5	56.5
PLT	497.6		x10 <sup>3</sup> /μL	395.0	515.0
MPV	9.79		fL	8.00	10.40

Flags & Messages
System: Service Access

*After calibration  
Mulaenisp  
04/02/2022*



Diluent	0051170	04/05/2022	
Lyse	8300044	04/05/2022	
Cleaner	8310147	05/05/2022	
Control	352113211	02/04/2022	13:51
Calibration	492114700	02/04/2022	13:37



# Installation, Operation, and Performance Qualification

DxH 500 Series

Published Version: v2



PN B75977AD  
July 2020

Manufactured for  
Beckman Coulter Ireland Inc.  
Lismeehan  
O'Callaghan's Mills  
Co. Clare, Ireland 353-65-683-1100





**LXH 500 Series**

Installation, Operation, and Performance Qualification  
PN B75977AD (July 2020)

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Symbols Glossary is available at  
[www.beckmancoulter.com/techdocs](http://www.beckmancoulter.com/techdocs). See **Related Documents** for the part number.

Rx Only in the U.S.A.

Original Instructions

# Revision History

*This document applies to the latest software listed and higher versions. When a subsequent software version affects the information in this document, a new issue will be released to the Beckman Coulter Web site. For labeling updates, go to [www.beckmancoulter.com/techdocs](http://www.beckmancoulter.com/techdocs) and download the latest version of the manual or system help for your instrument.*

Initial Issue AA, 09/2015

Issue AB, 10/2016

The following sections were modified:

- Trademark statement on the [DxH 500 Series Installation, Operation, and Performance Qualification](#) copyright page
- IQ Checklist in [CHAPTER 1, Installation Qualification \(IQ\)](#)
- OQ Checklist in [CHAPTER 2, Operation Qualification \(OQ\)](#)
- PQ Checklist in [CHAPTER 3, Performance Qualification \(PQ\)](#)
- Chapter 4, Additional Qualifications has been deleted.

Issue AC, 06/2020

The following sections were modified:

- Added links to patent information and the symbols glossary on the [DxH 500 Series Installation, Operation, and Performance Qualification](#) copyright page
- Removed performing an RBC check (RBC latex is required) from the [OQ Checklist in CHAPTER 2, Operation Qualification \(OQ\)](#)
- Updated part numbers in [Related Documents](#)

Issue AD, 07/2020

The following sections were modified:

- Added the DxH 560 to the cover graphic
- Added the DxH 560 to the [IQ Checklist in CHAPTER 1, Installation Qualification \(IQ\)](#)
- Added the DxH 560 to [Related Documents](#)

**Note:** Changes that are part of the most recent revision are indicated by a change bar in the left margin of the page.



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IQ Checklist, 1-1

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**CHAPTER 2: Operation Qualification (OQ), 2-1**

OQ Checklist, 2-1

**CHAPTER 3: Performance Qualification (PQ), 3-1**

PQ Checklist, 3-1

**References**

Related Documents

# Introduction

## Overview

---

This document provides a checklist guideline for the management of installation processes for a new hematology instrument.

The following definitions are excerpted from the Clinical and Laboratory Standards Institute's *QMS18, Process Management* guideline<sup>1</sup>:

*Installation qualification (IQ) - a set of formal checks and records that confirms the equipment or process and its components, including any integral hardware or software, were supplied as ordered and properly installed in the laboratory or other environment; NOTE: IQ can be performed by the manufacturer's technical service engineer.*

*Operational qualification (OQ) - process and records to confirm that the equipment or process is operational for its intended use and operation; NOTE: OQ can be performed by the manufacturer's technical service engineer.*

*Performance qualification (PQ) - process and records to confirm that the equipment or process will perform to specified needs, producing acceptable results under normal operating conditions; NOTE: PQ must be performed by laboratory staff.*

IQ, OQ, and PQ are validation activities.<sup>2</sup>

Facility:	Welfare Medical Foundation's Viloo Poonawalla Memorial Hospital
Address/Location:	Sr. No. 156, Plot No. 1/3A+3B/1+2/3, Pune Solapur Road, Hadapsar, Pune - 411 028.
Instance Number:	9423240169
Instrument Serial Number:	BE060208
Laboratory Representative:	Dr. Vijay Patil



# Installation Qualification (IQ)

## IQ Checklist

Instrument/SN: BE060208

See next page for approval signatures.

Table 1.1 IQ Checklist


Action	Select One	
	N/A*	✓
All the cartons on the shipping list have arrived.		✓
All of the cartons are intact and undamaged. If any cartons are damaged, a claim was filed with the carrier.		✓
The instrument area is easily accessible for maintaining and servicing the instrument, and has at least 30.5 cm (12 in.) of space on each side and 10 cm (4 in.) behind the instrument for tubing, cabling, and ventilation.		✓
The electrical outlet is within 1.83 m (6 ft) of the area designated for the instrument.		✓
The main ac outlet is a three-wire outlet supplying 100 to 240 Vac; 50 to 60 Hz; single-phase with ground.		✓
The ground is a confirmed third-wire earth ground that can carry the full current of the circuit.		✓
The circuit is independent and protected.		✓
The power receptacle meets the local required configuration.		✓
If the waste from the instrument will drain into an open drain instead of a waste container, the drain is chemically resistant and is appropriate for biohazardous waste.		✓
The drain or waste container is located so that the waste drain tubing is always below the waste fitting on the back of the instrument.		✓
The typical ambient room temperature range is 18 to 32°C (64.4 to 89.6°F) and is in agreement with the ambient temperature in the Instructions for Use (IFU).		✓
The relative humidity (non-condensing) and ambient temperature does not exceed a maximum of 80% relative humidity (non-condensing) at 32°C (89.6°F).		✓
The instrument reagents, calibrators, and controls are available and within expiration dating.		✓
The paper supplies and blood collection tubes are available.		✓
<b>DOCUMENTATION</b>		✓
All appropriate installation instructions, instrument and consumable instructions for use, and safety data sheets (SDS) are available on the Beckman Coulter website.		✓
Replacements for missing components have been ordered.		✓
<b>INTERFACE</b>		✓
Ensure that the DB-9 connector for the Null Modem cable is securely connected.		✓

Table 1.1 IQ Checklist (Continued)

Action	Select One	
	N/A*	✓
If you are using the Ethernet TCP/IP protocol for LIS, ensure that the Ethernet cable is connected.		✓
Power ON the instrument.		✓
From the DxH 500/DxH 520/DxH 560 LIS Setup screen, ensure that either the Serial Communication parameters (baud rate, parity, data bits, and stop bits) or the Ethernet Communication parameters for the Host and Analyzer Settings match the host system.		✓

\* Some items do not apply depending on instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for IQ Checklist

Date:	04/02/2022
Beckman Coulter Representative and Title (sign):	Miss. Sana Mulani
Beckman Coulter Representative and Title (print):	<u>Mulani, SP</u>
Date:	04/02/2022
Laboratory Representative and Title (sign):	Dr. Vijay Patil 
Laboratory Representative and Title (print):	
Comments:	

## System Components

---

Instrument/SN: BE060208

See next page for approval signatures.

Table 1.2 System Components

---

Instrument

Model: DXH 560 AL

Serial Number: BE060208

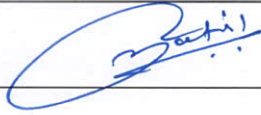
Report Printer: HP Office Jet Pro 8210

Table 1.2 System Components (*Continued*)

Model:	
Serial Number:	
Verify default printer:	
Print test page from printer:	
IP Address	
UPS (optional)	
Model:	
Serial Number:	
Handheld Bar-Code Scanner	
Model:	
Serial Number:	
Software	
Version:	



Approvals for System Components

Date:	04/02/2022
Beckman Coulter Representative and Title (sign):	Miss. Sana Mulani
Beckman Coulter Representative and Title (print):	<i>Mulani SP</i>
Date:	04/02/2022
Laboratory Representative and Title (sign):	Dr. Vijay Patil 
Laboratory Representative and Title (print):	
Comments:	

# Operation Qualification (OQ)

## OQ Checklist

Instrument/SN: BE060208


See next page for approval signatures.

Table 2.1 OQ Checklist

Action	Select One	
	N/A*	✓
Ensure that all panels and covers are installed.		✓
Perform a daily checks cycle and verify that the results are acceptable.		✓
Ensure that the correct altitude configuration is selected.		✓
Perform Hgb and optic adjustments.		✓
Perform a WBC check (G-Cal is required).		✓
Perform a calibration of the instrument using DxH 500 Series Calibrator.		✓
Run the DxH 500 Series Control and verify that all the parameters are within acceptable limits.		✓
Retain printouts of the control results.		✓
NOTE If this is a new installation, retain printouts of the: <ul style="list-style-type: none"> <li>• Carryover</li> <li>• Repeatability</li> <li>• Current calibration and calibration factors</li> </ul>		
If this is a system upgrade, verify the instrument's whole-blood performance.		✓
Ensure that enrollment in IQAP is complete.		✓
Ensure access to all manuals and other support documents.		✓

\* Some items do not apply depending on instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for OQ Checklist

Date:	04/02/2022
Beckman Coulter Representative and Title ( <i>sign</i> ):	Miss. Sana Mulani
Beckman Coulter Representative and Title ( <i>print</i> ):	<u>Mulani SP</u>
Date:	04/02/2022
Laboratory Representative and Title ( <i>sign</i> ):	Dr. Vijay Patil 
Laboratory Representative and Title ( <i>print</i> ):	
Comments:	



# Performance Qualification (PQ)

## PQ Checklist

Instrument/SN: BE060208


See next page for approval signatures.

Table 3.1 PQ Checklist

Action	Select One	
	N/A*	✓
Familiarization with software and software icons		✓
Daily Checks		✓
Carryover		✓
Repeatability		✓
Calibration		✓
System and reporting options set up		✓
QC files set up		✓
QC lab limits (per lab protocol)		✓
Quality Assurance set up and IQAP/eIQAP enrollment		✓
Set up and verify LIS interface		✓
Flagging limits set up		✓
Method comparison data collated		✓
Linearity		✓
Reference interval (normal ranges)		✓
Data analysis reports reviewed with appropriate lab staff		✓
Proficiency testing plan established		✓

Some items do not apply depending on instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for PQ Checklist

Date:	04/02/2022
Beckman Coulter Representative and Title (sign):	Miss. Sana Mulani
Beckman Coulter Representative and Title (print):	<u>Mulani SP</u>
Date:	04/02/2022
Laboratory Representative and Title (sign):	Dr. Vijay Patil 
Laboratory Representative and Title (print):	
Comments:	

## References

1. QMS18 Process management; 2015. Clinical and Laboratory Standards Institute (CLSI), Wayne, PA.
2. QMS01-A4 Process management; 2011. Clinical and Laboratory Standards Institute (CLSI), Wayne, PA.



## Related Documents

Your documentation can be found on our website at [www.beckmancoulter.com/techdocs](http://www.beckmancoulter.com/techdocs).

### Instructions for Use

- System Overview
- Operation Principles
- Daily Checks
- Quality Control
- Sample Analysis
- Data Review
- Worklist
- Shutdown
- Setup
- Troubleshooting
- Quality Assurance
- Cleaning Procedures
- Replacement/Adjustment Procedures
- Appendices
- Abbreviations and Acronyms
- Glossary
- References
- Index
- Warranty

### Host Transmission

PN B38989

Hematology Tube List (DxH 520 and DxH 560)

PN C12794

Symbols Glossary

PN C29230

[www.beckmancoulter.com](http://www.beckmancoulter.com)

