



UNMATCHED SERVICE

SINCE 1979...

Date: 09-03-2022
Effective Date: 09-03-2022

Certificate of Calibration

Customer Name: BIOLINE LABORATORY

Model : Automated Hematology Analyzer Sysmex XP-100

Serial No. : A4109

Calibration Done Date: 9.3.22

Next Calibration Due Date On or Before: 08-03-2023

Lab In-charge: . Mr.Dinesh

This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, HCT and PLT) according to the standard procedures provided by Sysmex Corporation, Japan.

The reference instruments used for value-assignment are managed by the traceability system in Sysmex Corporation and these are traceable to the International Standards, such as ICSH.

Calibration at site performed by
Engineer Name: Ayyappan
Designation: Sr.Application Specialist
Transasia Bio-Medicals Ltd
Location: Coimbatore

Encl:

1. Certificate of Inspection
2. Assay Sheet of Calibrator SCS-1000
3. Printouts
4. Traceability & Uncertainty document





Date: 09-03-2022
Effective Date: 09-03-2022

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100
2. Serial No.: A4109
3. Calibration Date: 09-03-2022
4. Material used: SCS-1000 (Lot No. 20530525, Expiry date: 27-Mar-2022)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 5 parameters using the measurement standard material (SCS-1000) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department
Transasia Bio-Medicals Ltd





6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	HCT	PLT
1	4.9	4.56	13.9	38.5	238
2	4.7	4.53	13.7	38.3	240
3	4.8	4.60	13.7	39.1	245
4	5	4.53	13.6	38.4	249
5	5.00	4.65	13.6	39.1	246
6	4.9	4.60	13.6	39.1	241
7	4.9	4.63	13.5	39.2	245
8	5	4.63	13.6	39.0	243
9	4.9	4.60	13.6	38.8	245
10	5.10	4.63	13.6	39.1	242
Mean	4.92	4.60	13.64	38.86	243.40
SD	0.114	0.043	0.107	0.337	3.239
CV%	2.308	0.930	0.788	0.868	1.331
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS

Technical Service Department
Transasia Bio-Medicals Ltd





UNMATCHED SERVICE

SINCE 1979...

Date:
Effective Date:

09-03-2022
09-03-2022

Certificate of Calibration

Customer Name: BIOLINE LABORATORY

Model : Automated Hematology Analyzer Sysmex XP-100

Serial No. : A4109

Calibration Done Date: 9.3.22

Next Calibration Due Date On or Before: 08-03-2023

Lab In-charge: . Mr.Dinesh

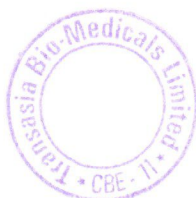
This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, HCT and PLT) according to the standard procedures provided by Sysmex Corporation, Japan.

The reference instruments used for value-assignment are managed by the traceability system in Sysmex Corporation and these are traceable to the International Standards, such as ICSH.

Calibration at site performed by
Engineer Name: Ayyappan
Designation: Sr.Application Specialist
Transasia Bio-Medicals Ltd
Location: Coimbatore

Encl:

1. Certificate of Inspection
2. Assay Sheet of Calibrator SCS-1000
3. Printouts
4. Traceability & Uncertainty document





Date: 09-03-2022
Effective Date: 09-03-2022

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100
2. Serial No.: A4109
3. Calibration Date: 09-03-2022
4. Material used: SCS-1000 (Lot No. 20530525, Expiry date: 27-Mar-2022)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 5 parameters using the measurement standard material (SCS-1000) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department
Transasia Bio-Medicals Ltd





6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	HCT	PLT
1	4.9	4.56	13.9	38.5	238
2	4.7	4.53	13.7	38.3	240
3	4.8	4.60	13.7	39.1	245
4	5	4.53	13.6	38.4	249
5	5.00	4.65	13.6	39.1	246
6	4.9	4.60	13.6	39.1	241
7	4.9	4.63	13.5	39.2	245
8	5	4.63	13.6	39.0	243
9	4.9	4.60	13.6	38.8	245
10	5.10	4.63	13.6	39.1	242
Mean	4.92	4.60	13.64	38.86	243.40
SD	0.114	0.043	0.107	0.337	3.239
CV%	2.308	0.930	0.788	0.868	1.331
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS

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5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3×10^3 /U1 or Less
RBC	0.00	0.02×10^6 /uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10×10^3 /uL or Less

Technical Service Department
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7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
1/16:01	7.00	4.28	11.8	33.40	261
2/16:02	7.00	4.22	11.8	32.90	273
3/16:04	6.80	4.34	11.8	33.90	266
4/16:05	7.00	4.40	11.8	34.30	253
5/16:08	6.90	4.36	11.8	33.40	268
MEAN	6.94	4.320	11.80	33.58	264.2
Acceptable Limits	6.74 - 7.35	4.277 - 4.452	11.76 - 11.99	32.43 - 33.90	247.6 - 273.7
Result	PASS	PASS	PASS	PASS	PASS

8. (Traceability System) :

The traceability system of Sysmex Hematology analyzers are shown in attached sheet.

Technical Service Department
Transasia Bio-Medicals Ltd





Traceability and Uncertainty

SCS-1000 Sysmex Calibrator System

XP-Series, Automated Hematology Analyzer

LOT NO: 20530525
EXP. DATE: 27-Mar-2022

Paramter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC	*1	-	7.044	0.15	10 ⁹ /L
RBC	*1	-	4.364	0.073	10 ¹² /L
PLT	*2	-	260.6	14	10 ⁹ /L
HGB	*3, *4	-	11.88	0.13	g / dL
HCT	*5, *6	-	33.16	0.81	%

*: This uncertainty (expanded uncertainty: k=2 was calculated in accordance with the "Guide to the expression of Uncertainty in Measurement" (GUM: 1995).

*1: ICSH Expert Panel on Cytometry, Clinical Laboratory Haematology, 16, 131-138, 1994
"Reference method for the enumeration of erythrocytes and leucocytes"

*2: ICSH Expert Panel on Cytometry and International Society of Laboratory Hematology Task Force on Platelet Counting, American Journal of Clinical Pathology, 115, 460-464, 2001
"Platelet Counting by the RBC/Platelet Ratio method – A reference Method"

*3: CLSI, H15-A3
"Reference and selected procedures for the quantitative determination of hemoglobin in blood – 3rd edition; Approved"

*4: Journal of Clinical Pathology, 49, 271-274, 1996
"Recommendation for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specification for international haemoglobinocyanide reference preparation (4th ed.)"

*5: CLSI H7-A3
"Procedure for Determining Packed Cell Volume by the Microhematocrit Method – 3rd edition; Approved Standard"

*6: Laboratory Hematology, 7, 148-170, 2001
"Recommendations for reference method for the packed cell volume (ICSH Standard 2001)"

CALICUT

ID.

---BLANK CHECK---

Date 04/03/2022

Time 10:50

Mode

WBC 0.0 $\times 10^9/\mu\text{L}$
 RBC 0.00 $\times 10^6/\mu\text{L}$
 HGB 0.0 g/dL
 HCT 0.0 %
 MCV ---.--- fL
 MCH ---.--- pg
 MCHC ---.--- g/dL
 PLT 0 $\times 10^3/\mu\text{L}$

ResearchW 0.029 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 1

Date 09/03/2022

Time 15:40

Mode WB

WBC 4.9 $\times 10^9/\mu\text{L}$
 RBC 4.56 $\times 10^6/\mu\text{L}$
 HGB 13.9 g/dL
 HCT 38.5 %
 MCV - 84.4 fL
 MCH 30.5 pg
 MCHC 36.1 g/dL
 PLT 238 $\times 10^3/\mu\text{L}$

ResearchW 4.314 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 2

Date 09/03/2022

Time 15:42

Mode WB

WBC 4.7 $\times 10^9/\mu\text{L}$
 RBC 4.53 $\times 10^6/\mu\text{L}$
 HGB 13.7 g/dL
 HCT 38.3 %
 MCV - 84.5 fL
 MCH 30.2 pg
 MCHC 35.8 g/dL
 PLT 240 $\times 10^3/\mu\text{L}$

ResearchW 4.655 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 3

Date 09/03/2022

Time 15:43

Mode WB

WBC 4.8 $\times 10^9/\mu\text{L}$
 RBC 4.60 $\times 10^6/\mu\text{L}$
 HGB 13.7 g/dL
 HCT 39.1 %
 MCV - 85.0 fL
 MCH 29.8 pg
 MCHC 35.0 g/dL
 PLT 245 $\times 10^3/\mu\text{L}$

ResearchW 4.848 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 4

Date 09/03/2022

Time 15:45

Mode WB

WBC 5.0 $\times 10^9/\mu\text{L}$
 RBC 4.53 $\times 10^6/\mu\text{L}$
 HGB 13.6 g/dL
 HCT 38.4 %
 MCV - 84.8 fL
 MCH 30.0 pg
 MCHC 35.4 g/dL
 PLT 249 $\times 10^3/\mu\text{L}$

ResearchW 4.970 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 5

Date 09/03/2022

Time 15:46

Mode WB

WBC 5.0 $\times 10^9/\mu\text{L}$
 RBC 4.65 $\times 10^6/\mu\text{L}$
 HGB 13.6 g/dL
 HCT 39.1 %
 MCV - 84.1 fL
 MCH 29.2 pg
 MCHC 34.8 g/dL
 PLT 246 $\times 10^3/\mu\text{L}$

ResearchW 4.968 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 6

Date 09/03/2022

Time 15:47

Mode WB

WBC 4.9 $\times 10^9/\mu\text{L}$
 RBC 4.60 $\times 10^6/\mu\text{L}$
 HGB 13.6 g/dL
 HCT 39.1 %
 MCV - 85.0 fL
 MCH 29.6 pg
 MCHC 34.8 g/dL
 PLT 241 $\times 10^3/\mu\text{L}$

ResearchW 4.942 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 7

Date 09/03/2022

Time 15:48

Mode WB

WBC 4.9 $\times 10^9/\mu\text{L}$
 RBC 4.63 $\times 10^6/\mu\text{L}$
 HGB 13.5 g/dL
 HCT 39.2 %
 MCV - 84.7 fL
 MCH 29.2 pg
 MCHC 34.4 g/dL
 PLT 245 $\times 10^3/\mu\text{L}$

ResearchW 4.255 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 8

Date 09/03/2022

Time 15:49

Mode WB

WBC 5.0 $\times 10^9/\mu\text{L}$
 RBC 4.63 $\times 10^6/\mu\text{L}$
 HGB 13.6 g/dL
 HCT 39.0 %
 MCV - 84.2 fL
 MCH 29.4 pg
 MCHC 34.9 g/dL
 PLT 243 $\times 10^3/\mu\text{L}$

ResearchW 5.029 $\times 10^9/\mu\text{L}$

CALICUT

Operator

ID. 9
Date 09/03/2022
Time 15:50
Mode WB

WBC 4.9 ×10⁹/μL
RBC 4.60 ×10⁶/μL
HGB 13.6 g/dL
HCT 38.8 %
MCV 84.3 fL
MCH 29.6 pg
MCHC 35.1 g/dL
PLT 245 ×10³/μL

ResearchW 4.918 ×10⁹/μL

CALICUT

Operator

ID. 10
Date 09/03/2022
Time 15:52
Mode WB

WBC 5.1 ×10⁹/μL
RBC 4.63 ×10⁶/μL
HGB 13.6 g/dL
HCT 39.1 %
MCV 84.4 fL
MCH 29.4 pg
MCHC 34.8 g/dL
PLT 242 ×10³/μL

ResearchW 5.131 ×10⁹/μL

CALICUT

ID. 1
Date 09/03/2022
Time 16:01
Mode CL

WBC 7.0 ×10⁹/μL
RBC 4.28 ×10⁶/μL
HGB 11.8 g/dL
HCT 33.4 %
MCV ----.- fL
MCH ----.- pg
MCHC ----.- g/dL
PLT 261 ×10³/μL

ResearchW 6.988 ×10⁹/μL

CALICUT

ID. 2
Date 09/03/2022
Time 16:02
Mode CL

WBC 7.0 ×10⁹/μL
RBC 4.22 ×10⁶/μL
HGB 11.8 g/dL
HCT 32.9 %
MCV ----.- fL
MCH ----.- pg
MCHC ----.- g/dL
PLT 273 ×10³/μL

ResearchW 6.988 ×10⁹/μL

CALICUT

ID. 3
Date 09/03/2022
Time 16:04
Mode CL

WBC 6.8 ×10⁹/μL
RBC 4.34 ×10⁶/μL
HGB 11.8 g/dL
HCT 33.9 %
MCV ----.- fL
MCH ----.- pg
MCHC ----.- g/dL
PLT 266 ×10³/μL

ResearchW 6.811 ×10⁹/μL

CALICUT

ID. 4
Date 09/03/2022
Time 16:05
Mode CL

WBC 7.0 ×10⁹/μL
RBC 4.40 ×10⁶/μL
HGB 11.8 g/dL
HCT 34.3 %
MCV ----.- fL
MCH ----.- pg
MCHC ----.- g/dL
PLT 253 ×10³/μL

ResearchW 7.022 ×10⁹/μL

CALICUT

ID. 5
Date 09/03/2022
Time 16:08
Mode CL

WBC 6.9 ×10⁹/μL
RBC 4.38 ×10⁶/μL
HGB 11.8 g/dL
HCT 33.4 %
MCV ----.- fL
MCH ----.- pg
MCHC ----.- g/dL
PLT 268 ×10³/μL

ResearchW 6.926 ×10⁹/μL

CALICUT

ID.

___BLANK CHECK___

Date 04/03/2022

Time 10:50

Mode

WBC 0.0 $\times 10^3/\mu\text{L}$
 RBC 0.00 $\times 10^6/\mu\text{L}$
 HGB 0.0 g/dL
 HCT 0.0 %
 MCV --- fL
 MCH --- pg
 MCHC --- g/dL
 PLT 0 $\times 10^3/\mu\text{L}$

ResearchW 0.029 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 1

Date 09/03/2022

Time 15:40

Mode WB

WBC 4.9 $\times 10^3/\mu\text{L}$
 RBC 4.56 $\times 10^6/\mu\text{L}$
 HGB 13.9 g/dL
 HCT 38.5 %
 MCV 84.4 fL
 MCH 30.5 pg
 MCHC 36.1 g/dL
 PLT 238 $\times 10^3/\mu\text{L}$

ResearchW 4.314 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 2

Date 09/03/2022

Time 15:42

Mode WB

WBC 4.7 $\times 10^3/\mu\text{L}$
 RBC 4.53 $\times 10^6/\mu\text{L}$
 HGB 13.7 g/dL
 HCT 38.3 %
 MCV 84.5 fL
 MCH 30.2 pg
 MCHC 35.8 g/dL
 PLT 240 $\times 10^3/\mu\text{L}$

ResearchW 4.655 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 3

Date 09/03/2022

Time 15:43

Mode WB

WBC 4.8 $\times 10^3/\mu\text{L}$
 RBC 4.60 $\times 10^6/\mu\text{L}$
 HGB 13.7 g/dL
 HCT 39.1 %
 MCV 85.0 fL
 MCH 29.8 pg
 MCHC 35.0 g/dL
 PLT 245 $\times 10^3/\mu\text{L}$

ResearchW 4.848 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 4

Date 03/03/2022

Time 15:45

Mode WB

WBC 5.0 $\times 10^3/\mu\text{L}$
 RBC 4.53 $\times 10^6/\mu\text{L}$
 HGB 13.6 g/dL
 HCT 38.4 %
 MCV 84.8 fL
 MCH 30.0 pg
 MCHC 35.4 g/dL
 PLT 249 $\times 10^3/\mu\text{L}$

ResearchW 4.970 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 5

Date 09/03/2022

Time 15:46

Mode WB

WBC 5.0 $\times 10^3/\mu\text{L}$
 RBC 4.65 $\times 10^6/\mu\text{L}$
 HGB 13.6 g/dL
 HCT 39.1 %
 MCV 84.1 fL
 MCH 29.2 pg
 MCHC 34.8 g/dL
 PLT 246 $\times 10^3/\mu\text{L}$

ResearchW 4.968 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 6

Date 09/03/2022

Time 15:47

Mode WB

WBC 4.9 $\times 10^3/\mu\text{L}$
 RBC 4.60 $\times 10^6/\mu\text{L}$
 HGB 13.6 g/dL
 HCT 39.1 %
 MCV 85.0 fL
 MCH 29.6 pg
 MCHC 34.8 g/dL
 PLT 241 $\times 10^3/\mu\text{L}$

ResearchW 4.942 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 7

Date 09/03/2022

Time 15:48

Mode WB

WBC 4.9 $\times 10^3/\mu\text{L}$
 RBC 4.63 $\times 10^6/\mu\text{L}$
 HGB 13.5 g/dL
 HCT 39.2 %
 MCV 84.7 fL
 MCH 29.2 pg
 MCHC 34.4 g/dL
 PLT 245 $\times 10^3/\mu\text{L}$

ResearchW 4.855 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 8

Date 09/03/2022

Time 15:49

Mode WB

WBC 5.0 $\times 10^3/\mu\text{L}$
 RBC 4.63 $\times 10^6/\mu\text{L}$
 HGB 13.6 g/dL
 HCT 39.0 %
 MCV 84.2 fL
 MCH 29.4 pg
 MCHC 34.9 g/dL
 PLT 243 $\times 10^3/\mu\text{L}$

ResearchW 5.029 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 9
Date 09/03/2022
Time 15:50
Mode WB

WBC 4.9 $\times 10^3/\mu\text{L}$
RBC 4.60 $\times 10^6/\mu\text{L}$
HGB 13.6 g/dL
HCT 38.8 %
MCV 84.3 fL
MCH 29.6 pg
MCHC 35.1 g/dL
PLT 245 $\times 10^3/\mu\text{L}$

ResearchW 4.918 $\times 10^3/\mu\text{L}$

CALICUT

Operator

ID. 10
Date 09/03/2022
Time 15:52
Mode WB

WBC 5.1 $\times 10^3/\mu\text{L}$
RBC 4.63 $\times 10^6/\mu\text{L}$
HGB 13.6 g/dL
HCT 39.1 %
MCV 84.4 fL
MCH 29.4 pg
MCHC 34.8 g/dL
PLT 242 $\times 10^3/\mu\text{L}$

ResearchW 5.131 $\times 10^3/\mu\text{L}$

CALICUT

ID. 1
Date 09/03/2022
Time 16:01
Mode CL

WBC 7.0 $\times 10^3/\mu\text{L}$
RBC 4.28 $\times 10^6/\mu\text{L}$
HGB 11.8 g/dL
HCT 33.4 %
MCV --- fL
MCH --- pg
MCHC --- g/dL
PLT 261 $\times 10^3/\mu\text{L}$

ResearchW 6.988 $\times 10^3/\mu\text{L}$

CALICUT

ID. 2
Date 09/03/2022
Time 16:02
Mode CL

WBC 7.0 $\times 10^3/\mu\text{L}$
RBC 4.22 $\times 10^6/\mu\text{L}$
HGB 11.8 g/dL
HCT 32.9 %
MCV --- fL
MCH --- pg
MCHC --- g/dL
PLT 273 $\times 10^3/\mu\text{L}$

ResearchW 6.988 $\times 10^3/\mu\text{L}$

CALICUT

ID. 3
Date 09/03/2022
Time 16:04
Mode CL

WBC 6.8 $\times 10^3/\mu\text{L}$
RBC 4.34 $\times 10^6/\mu\text{L}$
HGB 11.8 g/dL
HCT 33.9 %
MCV --- fL
MCH --- pg
MCHC --- g/dL
PLT 266 $\times 10^3/\mu\text{L}$

ResearchW 6.811 $\times 10^3/\mu\text{L}$

CALICUT

ID. 4
Date 09/03/2022
Time 16:05
Mode CL

WBC 7.0 $\times 10^3/\mu\text{L}$
RBC 4.40 $\times 10^6/\mu\text{L}$
HGB 11.8 g/dL
HCT 34.3 %
MCV --- fL
MCH --- pg
MCHC --- g/dL
PLT 253 $\times 10^3/\mu\text{L}$

ResearchW 7.022 $\times 10^3/\mu\text{L}$

CALICUT

ID. 5
Date 09/03/2022
Time 16:08
Mode CL

WBC 6.9 $\times 10^3/\mu\text{L}$
RBC 4.36 $\times 10^6/\mu\text{L}$
HGB 11.8 g/dL
HCT 33.4 %
MCV --- fL
MCH --- pg
MCHC --- g/dL
PLT 268 $\times 10^3/\mu\text{L}$

ResearchW 6.926 $\times 10^3/\mu\text{L}$