

Date: 23.12.20

Effective Date: 23.12.20

Certificate of Calibration

Customer Name: POLO LABS PVT. LTD.

Model : Automated Hematology Analyzer Sysmex XS-800i

Serial No. : 67677

Calibration Done Date: 23.12.20

Next Calibration Due Date On or Before: 22.12.21

Lab In-charge: . Dr. SUKSHAM SAMIR

This is to certify that the above-mentioned product has been verified of calibration for CBC 6 parameters (WBC, RBC, HGB, HCT, MCV 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
GIAN CHAND

Designation : SR.SERVICE ENGG.

Transasia Bio-Medicals Ltd

Location : JALANDHAR

Encl:


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

Date: 23.12.2020
Effective Date: 23.12.20

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XS-800i
2. Serial No.: 67677
3. Calibration Date: 23.12.20
4. Material used: SCS-1000 (Lot No. 0336 0525, Expiry date: 03-Jan-2021)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 6 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

5. BACKGROUND CHECK

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

ELP
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	MCV	PLT
102	7.92	4.60	12.10	36.6	79.6	248
103	7.66	4.64	12.10	36.80	79.3	245
104	7.72	4.64	12.20	36.8	79.3	251
105	7.75	4.61	12.20	36.4	79.0	248
106	8.00	4.61	12.10	36.3	78.7	254
107	7.77	4.65	12.30	36.5	78.5	257
108	7.6	4.65	12.20	36.4	78.3	243
109	7.67	4.57	12.20	35.7	78.1	243
110	7.48	4.68	12.10	36.5	78.0	249
111	7.61	4.66	12.20	36.2	77.7	253
Mean	7.72	4.63	12.17	36.42	78.65	249.10
SD	0.153	0.033	0.067	0.319	0.636	4.701
CV%	1.988	0.709	0.555	0.876	0.809	1.887
Acceptable CV%	Within 3.0%	Within 1.5%	Within 1.5%	Within 1.5%	Within 1.5%	Within 4.0%
Result	PASS	PASS	PASS	PASS	PASS	PASS

ed
Technical Service Department
Transasia Bio-Medicals Ltd

7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	MCV	PLT
203	6.59	4.39	12.5	36.1	82.2	244
204	6.66	4.40	12.5	36.1	82.0	254
205	6.58	4.36	12.3	35.8	82.1	237
2.06	6.76	4.42	12.2	36.3	82.1	254
207	6.58	4.38	12.4	36.0	82.2	256
MEAN	6.63	4.390	12.38	36.06	82.12	249.0
Acceptable Limits	6.472 - 7.005	4.328 - 4.464	12.30 - 12.49	35.42 - 37.02	81.35 - 83.45	239.3 - 256.8
Result	PASS	PASS	PASS	PASS	PASS	PASS

8. (Traceability System) :

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

Chitra
Technical Service Department
Transasia Bio-Medicals Ltd

BACKGROUND DATA

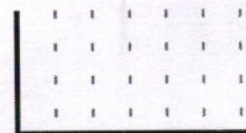
Sample No.: BACKGROUNDCHECK
 Patient ID:
 Name:
 Comments:

Rack:
 Ward:

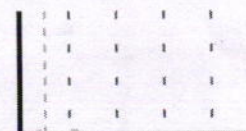
Tube: 23/12/2020 14:09:19
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

WBC	0.00	[10 ³ /uL]		
RBC	0.00	[10 ⁶ /uL]		
HGB	0.0	[g/dL]		
HCT	0.0	[%]		
MCV	----	[fL]		
MCH	----	[pg]		
MCHC	----	[g/dL]		
PLT	3	[10 ³ /uL]		
RDW-SD	----	[fL]		
RDW-CV	----	[%]		
PDW	----	[fL]		
MPV	----	[fL]		
P-LCR	----	[%]		
PCT	----	[%]		
NEUT	----	[10 ³ /uL]	----	[%]
LYMPH	----	[10 ³ /uL]	----	[%]
MONO	----	[10 ³ /uL]	----	[%]
EO	----	[10 ³ /uL]	----	[%]
BASO	----	[10 ³ /uL]	----	[%]

WBC



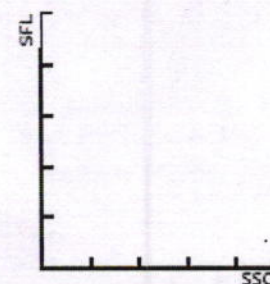
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

SAMPLE PRECISION DATA

Sample No.: 102
 Patient ID:
 Name:
 Comments:

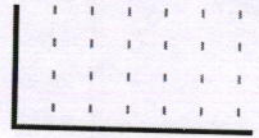
Rack:
 Ward:

Tube: 23/12/2020 14:23:04
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

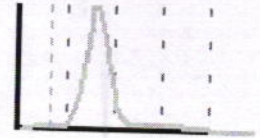
Positive
 Morph.

WBC	7.92	[10 ³ /uL]		
RBC	4.60	[10 ⁶ /uL]		
HGB	12.1	[g/dL]		
HCT	36.6	[%]		
MCV	79.6	[fL]		
MCH	26.3	[pg]		
MCHC	33.1	[g/dL]		
PLT	248	[10 ³ /uL]		
RDW-SD	38.7	[fL]		
RDW-CV	13.9	[%]		
PDW	12.7	[fL]		
MPV	10.5	[fL]		
P-LCR	28.3	[%]		
PCT	0.26	[%]		
NEUT	5.99 *	[10 ³ /uL]	75.6 *	[%]
LYMPH	1.42 *	[10 ³ /uL]	17.9 *	[%]
MONO	0.49 *	[10 ³ /uL]	6.2 *	[%]
EO	0.02	[10 ³ /uL]	0.3	[%]
BASO	0.00	[10 ³ /uL]	0.0	[%]

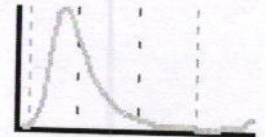
WBC



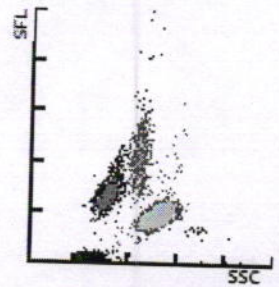
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

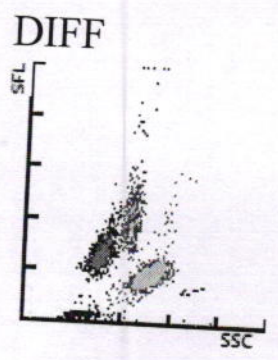
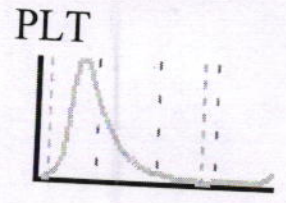
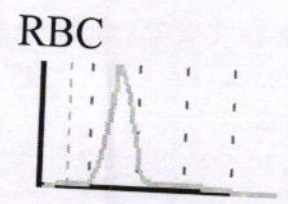
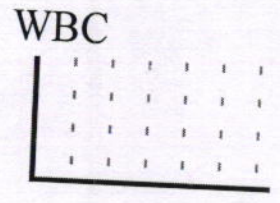
Atypical Lympho?

Sample No.: 103
 Patient ID:
 Name:
 Comments:
 Positive Morph.

Rack:
 Ward:

Tube: 23/12/2020 14:32:48
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

WBC	7.66	[10 ³ /uL]		
RBC	4.64	[10 ⁶ /uL]		
HGB	12.1	[g/dL]		
HCT	36.8	[%]		
MCV	79.3	[fL]		
MCH	26.1	[pg]		
MCHC	32.9	[g/dL]		
PLT	245	[10 ³ /uL]		
RDW-SD	38.7	[fL]		
RDW-CV	13.9	[%]		
PDW	11.8	[fL]		
MPV	10.1	[fL]		
P-LCR	26.4	[%]		
PCT	0.25	[%]		
NEUT	5.76 *	[10 ³ /uL]	75.2 *	[%]
LYMPH	1.40 *	[10 ³ /uL]	18.3 *	[%]
MONO	0.47 *	[10 ³ /uL]	6.1 *	[%]
EO	0.02	[10 ³ /uL]	0.3	[%]
BASO	0.01	[10 ³ /uL]	0.1	[%]



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Atypical Lympho?

Sample No.: 104

Patient ID:

Name:

Comments:

Positive

Morph.

Ward: Rack:

Tube: 23/12/2020 14:34:02

Dr.:

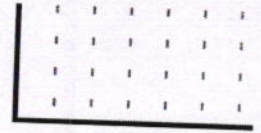
Birth:

Sex:

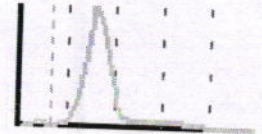
Inst.ID:XS-800i^67677

WBC	7.72	[10 ³ /uL]		
RBC	4.64	[10 ⁶ /uL]		
HGB	12.2	[g/dL]		
HCT	36.8	[%]		
MCV	79.3	[fL]		
MCH	26.3	[pg]		
MCHC	33.2	[g/dL]		
PLT	251	[10 ³ /uL]		
RDW-SD	38.7	[fL]		
RDW-CV	13.9	[%]		
PDW	12.1	[fL]		
MPV	10.2	[fL]		
P-LCR	26.2	[%]		
PCT	0.26	[%]		
NEUT	5.88 *	[10 ³ /uL]	76.1 *	[%]
LYMPH	1.34 *	[10 ³ /uL]	17.4 *	[%]
MONO	0.47 *	[10 ³ /uL]	6.1 *	[%]
EO	0.02	[10 ³ /uL]	0.3	[%]
BASO	0.01	[10 ³ /uL]	0.1	[%]

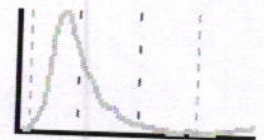
WBC



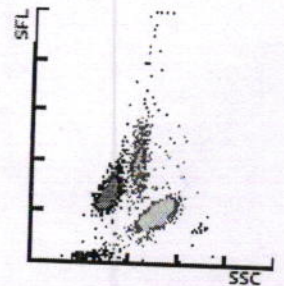
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Atypical Lympho?

Sample No.: 105

Patient ID:

Name:

Comments:

Negative

Ward: Rack:

Tube: 23/12/2020 14:36:33

Dr.:

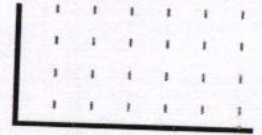
Birth:

Sex:

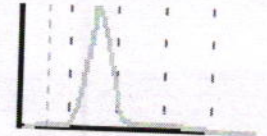
Inst.ID:XS-800i^67677

WBC	7.75	[10 ³ /uL]		
RBC	4.61	[10 ⁶ /uL]		
HGB	12.2	[g/dL]		
HCT	36.4	[%]		
MCV	79.0	[fL]		
MCH	26.5	[pg]		
MCHC	33.5	[g/dL]		
PLT	248	[10 ³ /uL]		
RDW-SD	38.6	[fL]		
RDW-CV	14.0	[%]		
PDW	11.6	[fL]		
MPV	10.2	[fL]		
P-LCR	25.9	[%]		
PCT	0.25	[%]		
NEUT	5.89	[10 ³ /uL]	76.1 +	[%]
LYMPH	1.36	[10 ³ /uL]	17.5 -	[%]
MONO	0.49	[10 ³ /uL]	6.3	[%]
EO	0.01	[10 ³ /uL]	0.1	[%]
BASO	0.00	[10 ³ /uL]	0.0	[%]

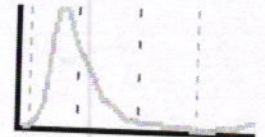
WBC



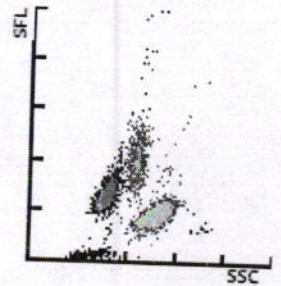
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Sample No.: 106

Patient ID:

Name:

Comments:

Negative

Ward: Rack:

Tube: 23/12/2020 14:38:01

Dr.:

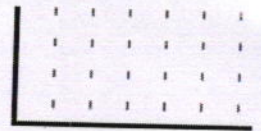
Birth:

Sex:

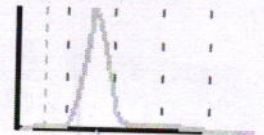
Inst.ID:XS-800i^67677

WBC	8.00	[10 ³ /uL]		
RBC	4.61	[10 ⁶ /uL]		
HGB	12.1	[g/dL]		
HCT	36.3	[%]		
MCV	78.7	[fL]		
MCH	26.2	[pg]		
MCHC	33.3	[g/dL]		
PLT	254	[10 ³ /uL]		
RDW-SD	38.6	[fL]		
RDW-CV	14.0	[%]		
PDW	12.1	[fL]		
MPV	10.1	[fL]		
P-LCR	25.6	[%]		
PCT	0.26	[%]		
NEUT	6.05	[10 ³ /uL]	75.6 +	[%]
LYMPH	1.42	[10 ³ /uL]	17.8 -	[%]
MONO	0.49	[10 ³ /uL]	6.1	[%]
EO	0.03	[10 ³ /uL]	0.4	[%]
BASO	0.01	[10 ³ /uL]	0.1	[%]

WBC



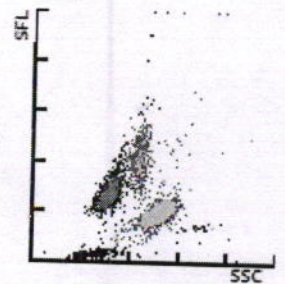
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Sample No.: 107

Patient ID:

Name:

Comments:

Negative

Ward: Rack:

Tube: 23/12/2020 14:39:32

Dr.:

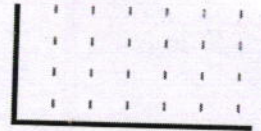
Birth:

Sex:

Inst.ID:XS-800i^67677

WBC	7.77	[10 ³ /uL]		
RBC	4.65	[10 ⁶ /uL]		
HGB	12.3	[g/dL]		
HCT	36.5	[%]		
MCV	78.5	- [fL]		
MCH	26.5	[pg]		
MCHC	33.7	[g/dL]		
PLT	257	[10 ³ /uL]		
RDW-SD	38.1	[fL]		
RDW-CV	13.8	[%]		
PDW	12.3	[fL]		
MPV	10.1	[fL]		
P-LCR	25.6	[%]		
PCT	0.26	[%]		
NEUT	5.85	[10 ³ /uL]	75.3	+ [%]
LYMPH	1.42	[10 ³ /uL]	18.3	- [%]
MONO	0.47	[10 ³ /uL]	6.0	[%]
EO	0.02	[10 ³ /uL]	0.3	[%]
BASO	0.01	[10 ³ /uL]	0.1	[%]

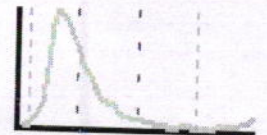
WBC



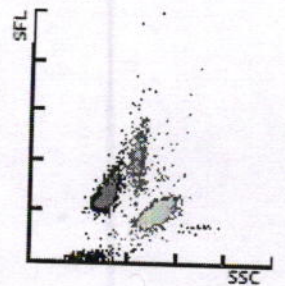
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

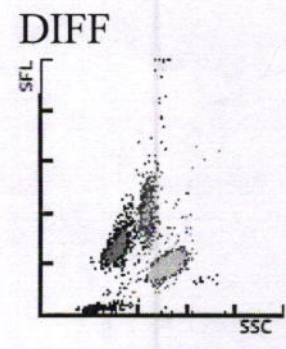
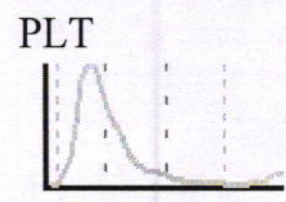
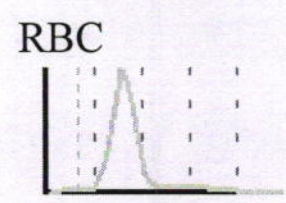
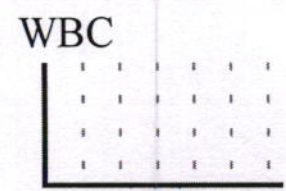
Sample No.: 108
 Patient ID:
 Name:
 Comments:

Rack:
 Ward:

Tube: 23/12/2020 14:41:01
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

Positive
 Morph.

WBC	7.62	[10 ³ /uL]		
RBC	4.65	[10 ⁶ /uL]		
HGB	12.2	[g/dL]		
HCT	36.4	[%]		
MCV	78.3	[fL]		
MCH	26.2	[pg]		
MCHC	33.5	[g/dL]		
PLT	243	[10 ³ /uL]		
RDW-SD	37.8	[fL]		
RDW-CV	13.8	[%]		
PDW	11.5	[fL]		
MPV	10.1	[fL]		
P-LCR	25.4	[%]		
PCT	0.25	[%]		
NEUT	5.75 *	[10 ³ /uL]	75.5 *	[%]
LYMPH	1.40 *	[10 ³ /uL]	18.4 *	[%]
MONO	0.46 *	[10 ³ /uL]	6.0 *	[%]
EO	0.01	[10 ³ /uL]	0.1	[%]
BASO	0.00	[10 ³ /uL]	0.0	[%]



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Atypical Lympho?

Sample No.: 109
 Patient ID:
 Name:
 Comments:

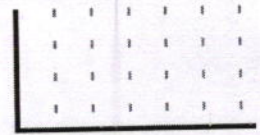
Rack:
 Ward:

Tube: 23/12/2020 14:42:22
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

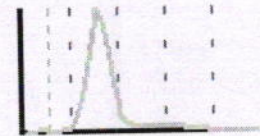
Positive
 Morph.

WBC	7.67	[10 ³ /uL]		
RBC	4.57	[10 ⁶ /uL]		
HGB	12.2	[g/dL]		
HCT	35.7	[%]		
MCV	78.1	[fL]		
MCH	26.7	[pg]		
MCHC	34.2	[g/dL]		
PLT	243	[10 ³ /uL]		
RDW-SD	37.9	[fL]		
RDW-CV	13.8	[%]		
PDW	11.9	[fL]		
MPV	9.9	[fL]		
P-LCR	25.0	[%]		
PCT	0.24	[%]		
NEUT	5.78 *	[10 ³ /uL]	75.4 *	[%]
LYMPH	1.41 *	[10 ³ /uL]	18.4 *	[%]
MONO	0.47 *	[10 ³ /uL]	6.1 *	[%]
EO	0.01	[10 ³ /uL]	0.1	[%]
BASO	0.00	[10 ³ /uL]	0.0	[%]

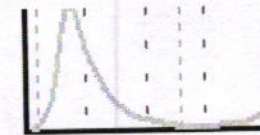
WBC



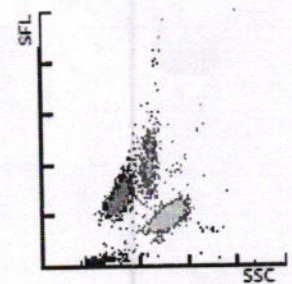
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Atypical Lympho?

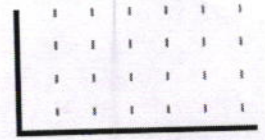
Sample No.: 110
 Patient ID:
 Name:
 Comments:
 Negative

Rack:
 Ward:

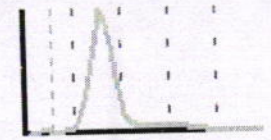
Tube: 23/12/2020 14:44:49
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

WBC	7.48	[10 ³ /uL]	
RBC	4.68	[10 ⁶ /uL]	
HGB	12.1	[g/dL]	
HCT	36.5	[%]	
MCV	78.0	- [fL]	
MCH	25.9	- [pg]	
MCHC	33.2	[g/dL]	
PLT	249	[10 ³ /uL]	
RDW-SD	37.7	[fL]	
RDW-CV	13.7	[%]	
PDW	12.3	[fL]	
MPV	9.9	[fL]	
P-LCR	24.7	[%]	
PCT	0.25	[%]	
NEUT	5.60	[10 ³ /uL]	74.9 + [%]
LYMPH	1.40	[10 ³ /uL]	18.7 - [%]
MONO	0.46	[10 ³ /uL]	6.1 [%]
EO	0.02	[10 ³ /uL]	0.3 [%]
BASO	0.00	[10 ³ /uL]	0.0 [%]

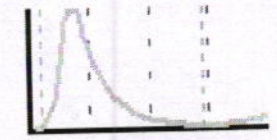
WBC



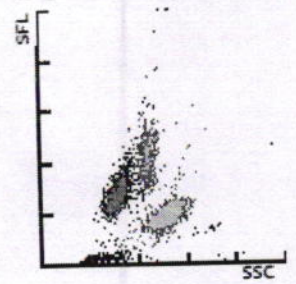
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

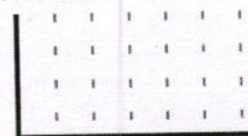
Sample No.: 111
 Patient ID:
 Name:
 Comments:
 Negative

Rack:
 Ward:

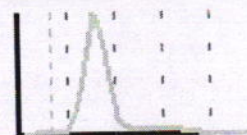
Tube: 23/12/2020 14:46:22
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

WBC	7.61	[10 ³ /uL]		
RBC	4.66	[10 ⁶ /uL]		
HGB	12.2	[g/dL]		
HCT	36.2	[%]		
MCV	77.7	[fL]		
MCH	26.2	[pg]		
MCHC	33.7	[g/dL]		
PLT	253	[10 ³ /uL]		
RDW-SD	37.6	[fL]		
RDW-CV	13.8	[%]		
PDW	11.2	[fL]		
MPV	10.0	[fL]		
P-LCR	24.9	[%]		
PCT	0.25	[%]		
NEUT	5.70	[10 ³ /uL]	74.9 +	[%]
LYMPH	1.36	[10 ³ /uL]	17.9 -	[%]
MONO	0.52	[10 ³ /uL]	6.8	[%]
EO	0.02	[10 ³ /uL]	0.3	[%]
BASO	0.01	[10 ³ /uL]	0.1	[%]

WBC



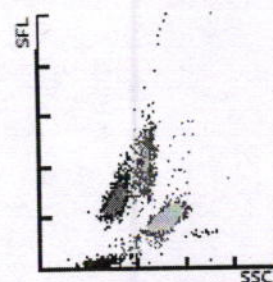
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

CALIBRATOR RUN DATA

Sample No.:
 Patient ID:
 Name:
 Comments:

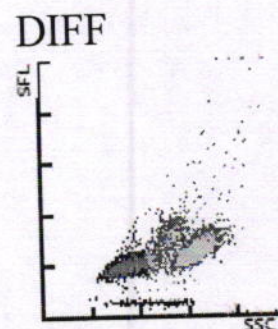
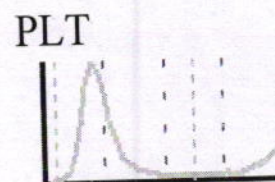
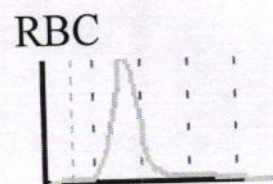
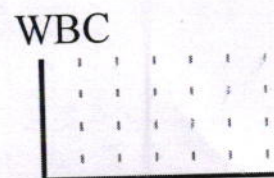
203

Rack:
 Ward:

Tube: 23/12/2020 15:16:12
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

Positive
 Morph.

WBC	6.59	[10 ³ /uL]		
RBC	4.39	[10 ⁶ /uL]		
HGB	12.5	[g/dL]		
HCT	36.1	[%]		
MCV	82.2	- [fL]		
MCH	28.5	[pg]		
MCHC	34.6	[g/dL]		
PLT	244	[10 ³ /uL]		
RDW-SD	42.4	[fL]		
RDW-CV	14.9	[%]		
PDW	8.1	- [fL]		
MPV	9.6	[fL]		
P-LCR	17.5	[%]		
PCT	0.23	[%]		
NEUT	4.48 *	[10 ³ /uL]	67.9 *	[%]
LYMPH	1.77	[10 ³ /uL]	26.9	[%]
MONO	0.33	[10 ³ /uL]	5.0	[%]
EO	0.01 *	[10 ³ /uL]	0.2 *	[%]
BASO	0.00 *	[10 ³ /uL]	0.0 *	[%]



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Immature Gran?
 Left Shift?

Sample No.: 204
 Patient ID:
 Name:
 Comments:

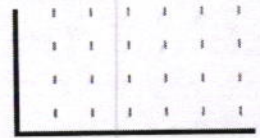
Rack:
 Ward:

Tube: 23/12/2020 15:19:52
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

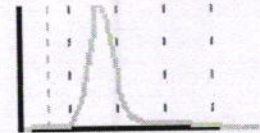
Positive
 Morph.

WBC	6.66	[10 ³ /uL]		
RBC	4.40	[10 ⁶ /uL]		
HGB	12.5	[g/dL]		
HCT	36.1	[%]		
MCV	82.0	- [fL]		
MCH	28.4	[pg]		
MCHC	34.6	[g/dL]		
PLT	254	[10 ³ /uL]		
RDW-SD	42.6	[fL]		
RDW-CV	14.9	[%]		
PDW	8.5	- [fL]		
MPV	9.6	[fL]		
P-LCR	17.9	[%]		
PCT	0.24	[%]		
NEUT	4.58 *	[10 ³ /uL]	68.8 *	[%]
LYMPH	1.68	[10 ³ /uL]	25.2	[%]
MONO	0.40	[10 ³ /uL]	6.0	[%]
EO	0.00 *	[10 ³ /uL]	0.0 *	[%]
BASO	0.00 *	[10 ³ /uL]	0.0 *	[%]

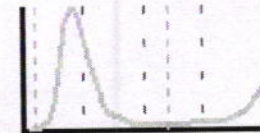
WBC



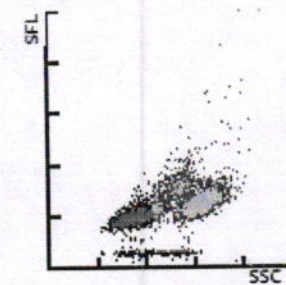
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Immature Gran?
 Left Shift?

Sample No.: 205
 Patient ID:
 Name:
 Comments:

Rack:
 Ward:

Tube: 23/12/2020 15:25:18
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

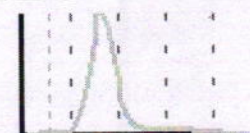
Positive
 Morph.

WBC	6.58	[10 ³ /uL]		
RBC	4.36	[10 ⁶ /uL]		
HGB	12.3	[g/dL]		
HCT	35.8	[%]		
MCV	82.1	- [fL]		
MCH	28.2	[pg]		
MCHC	34.4	[g/dL]		
PLT	237	[10 ³ /uL]		
RDW-SD	42.7	[fL]		
RDW-CV	14.9	[%]		
PDW	8.7	- [fL]		
MPV	9.5	[fL]		
P-LCR	17.4	[%]		
PCT	0.22	[%]		
NEUT	4.57 *	[10 ³ /uL]	69.4 *	[%]
LYMPH	1.66	[10 ³ /uL]	25.2	[%]
MONO	0.34	[10 ³ /uL]	5.2	[%]
EO	0.01 *	[10 ³ /uL]	0.2 *	[%]
BASO	0.00 *	[10 ³ /uL]	0.0 *	[%]

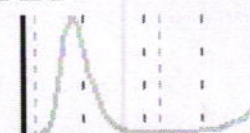
WBC



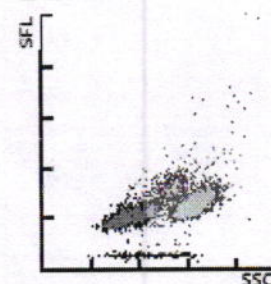
RBC



PLT



DIFF



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Immature Gran?
 Left Shift?

Sample No.: 206
 Patient ID:
 Name:
 Comments:

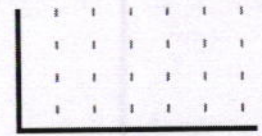
Rack:
 Ward:

Tube: 23/12/2020 15:28:33
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

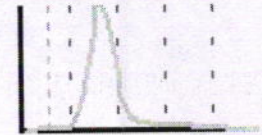
Positive
 Morph.

WBC	6.76	[10 ³ /uL]		
RBC	4.42	[10 ⁶ /uL]		
HGB	12.2	[g/dL]		
HCT	36.3	[%]		
MCV	82.1	- [fL]		
MCH	27.6	[pg]		
MCHC	33.6	[g/dL]		
PLT	254	[10 ³ /uL]		
RDW-SD	43.0	[fL]		
RDW-CV	14.9	[%]		
PDW	8.7	- [fL]		
MPV	9.9	[fL]		
P-LCR	19.3	[%]		
PCT	0.25	[%]		
NEUT	----	[10 ³ /uL]	----	[%]
LYMPH	----	[10 ³ /uL]	----	[%]
MONO	0.01	[10 ³ /uL]	0.1	[%]
EO	0.00 *	[10 ³ /uL]	0.0 *	[%]
BASO	0.00 *	[10 ³ /uL]	0.0 *	[%]

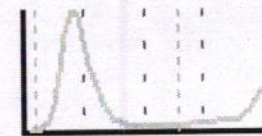
WBC



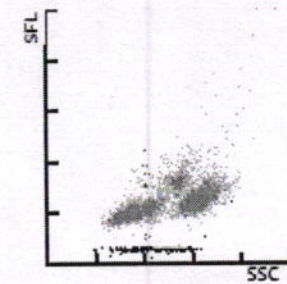
RBC



PLT



DIFF



WBC IP Message(s)
 WBC Abn Scattergram

RBC IP Message(s)

PLT IP Message(s)

Immature Gran?
 Left Shift?

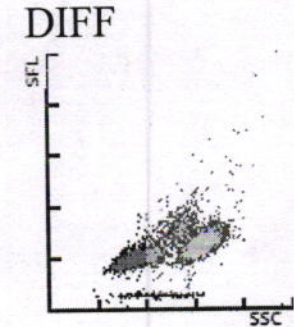
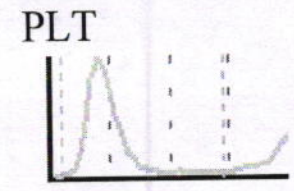
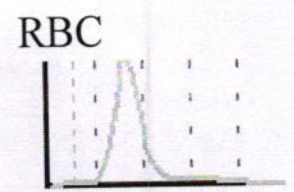
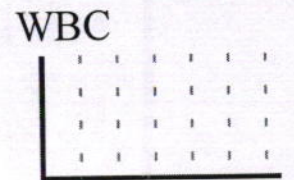
Sample No.: 207
 Patient ID:
 Name:
 Comments:

Rack:
 Ward:

Tube: 23/12/2020 15:31:49
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

Positive
 Morph.

WBC	6.58	[10 ³ /uL]		
RBC	4.38	[10 ⁶ /uL]		
HGB	12.4	[g/dL]		
HCT	36.0	[%]		
MCV	82.2	- [fL]		
MCH	28.3	[pg]		
MCHC	34.4	[g/dL]		
PLT	256	[10 ³ /uL]		
RDW-SD	42.8	[fL]		
RDW-CV	14.9	[%]		
PDW	8.4	- [fL]		
MPV	10.2	[fL]		
P-LCR	20.6	[%]		
PCT	0.26	[%]		
NEUT	4.65 *	[10 ³ /uL]	70.6 *	[%]
LYMPH	1.41	[10 ³ /uL]	21.4	[%]
MONO	0.51	[10 ³ /uL]	7.8	[%]
EO	0.01 *	[10 ³ /uL]	0.2 *	[%]
BASO	0.00 *	[10 ³ /uL]	0.0 *	[%]



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)

Immature Gran?
 Left Shift?

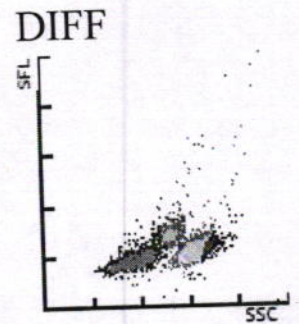
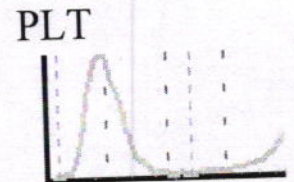
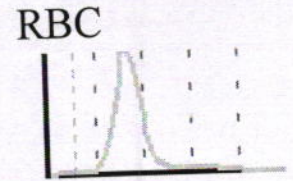
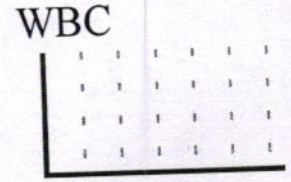
CONTROL RUN DATA

Sample No.: QC-02930805
 Patient ID:
 Name:
 Comments:

Rack:
 Ward:

Tube: 23/12/2020 16:27:03
 Dr.:
 Birth: Sex:
 Inst.ID:XS-800i^67677

WBC	6.65	[10 ³ /uL]		
RBC	4.43	[10 ⁶ /uL]		
HGB	12.7	[g/dL]		
HCT	37.1	[%]		
MCV	83.7	[fL]		
MCH	28.7	[pg]		
MCHC	34.2	[g/dL]		
PLT	215	[10 ³ /uL]		
RDW-SD	45.4	[fL]		
RDW-CV	15.4	[%]		
PDW	9.3	[fL]		
MPV	9.8	[fL]		
P-LCR	16.2	[%]		
PCT	0.21	[%]		
NEUT	2.89	[10 ³ /uL]	43.5	[%]
LYMPH	2.44	[10 ³ /uL]	36.7	[%]
MONO	0.32	[10 ³ /uL]	4.8	[%]
EO	0.64	[10 ³ /uL]	9.6	[%]
BASO	0.36	[10 ³ /uL]	5.4	[%]



WBC IP Message(s)

RBC IP Message(s)

PLT IP Message(s)



Traceability and Uncertainty

SCS-1000 Sysmex Calibrator System

XS-1000i, XS-800i, XS-500i Automated Hematology Analyzer

LOT NO: 03360525
 EXP. DATE: 3-Jan-2021

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC	*1	-	6.739	0.20	10 ⁹ /L
RBC	*1	-	4.396	0.072	10 ¹² /L
PLT	*2	-	248.1	11	10 ⁹ /L
HGB	*3, *4	-	12.40	0.15	g / dL
HCT	*5, *6	-	36.22	0.88	%

* : 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)"



SCS-1000



LOT 03360525
3-Jan-2021

Sysmex Calibrator System Assay Sheet

For Asian Pacific

Parameter	XE-Series		XT-Series		XS-Series*	
	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.139	6.857 - 7.421	7.145	6.862 - 7.427	6.739	6.472 - 7.005
RBC M/uL	4.445	4.377 - 4.514	4.345	4.278 - 4.412	4.396	4.328 - 4.464
HGB g/dL	12.54	12.44 - 12.63	12.30	12.21 - 12.39	12.40	12.30 - 12.49
HCT %	35.86	35.07 - 36.66	34.59	33.82 - 35.35	36.22	35.42 - 37.02
MCV fL	80.67	79.65 - 81.70	79.59	78.58 - 80.61	82.40	81.35 - 83.45
PLT K/uL	251.4	242.5 - 260.3	249.3	240.5 - 258.1	248.1	239.3 - 256.8

Parameter	K-4500 / K-1000 / K-800		pochH-100i**		KX-21		XP-Series	
	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.06	6.75 - 7.36	6.88	6.58 - 7.18	7.08	6.78 - 7.38	6.54	6.26 - 6.82
RBC M/uL	4.358	4.271 - 4.446	4.387	4.299 - 4.475	4.306	4.220 - 4.393	4.325	4.238 - 4.411
HGB g/dL	12.45	12.33 - 12.58	12.02	11.90 - 12.14	12.43	12.31 - 12.56	12.08	11.96 - 12.20
HCT %	33.05	32.32 - 33.78	34.97	34.20 - 35.74	32.96	32.23 - 33.69	33.09	32.36 - 33.82
MCV fL	75.84	75.00 - 76.67	79.71	78.84 - 80.59	76.54	75.70 - 77.38	76.51	75.67 - 77.35
PLT K/uL	253.7	241.0 - 266.3	246.8	234.5 - 259.2	273.3	259.6 - 286.9	263.4	250.2 - 276.5

SCS-1000 ASSAY TERM DEFINED

Assay Target – This is the assigned value for calibration.

Acceptable Limits – These limits represent the interval around the Assay Target that can be attributed to the expanded uncertainty of the total traceability chain.
A calibrator mean (n=5) that falls within these limits indicates an accurately calibrated instrument.

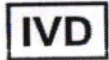
* XS-1000i/XS-800i – Assay target for WBC only for operation in CBC+Diff mode

**pochH-100i – Assay Target for WBC only for systems operating under software version 00-18 and following

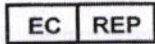
SYMBOL EXPLANATIONS



Biological risks



In Vitro Diagnostic Medical Device



Authorized Representative in the
European Community



Consult Instructions for Use



Batch code



Use by ...



Temperature limitation



Manufacturer