



PROFICIENCY TESTING REPORT
ISHTM-AIIMS EXTERNAL QUALITY ASSURANCE PROGRAMME
 NABL accredited program as per ISO/IEC 17043:2010 standard
 Organized By Department of Hematology, AIIMS, New Delhi-110029



Duration of stability testing - minimum upto 8 days at ambient temp. after dispatch of specimens

EQAP CODE No. : 5929

Distribution No.: 160-O

Month/Year: July/2023

Instrument ID: ERMA PCE-210

Name & Contact No. of PT Co-ordinator: Dr. Manoranjan Mahapatra (Prof. & Head), Hematology, AIIMS, Delhi,
 Tel: 9013085730 , E-Mail : accuracy2000@gmail.com

Date of issue & status of the report: 19-09-2023[Final].

CBC and Retic Assessment

Test Parameters	S.No.	Among Lab (Accuracy Testing)						Within Lab (Precision Testing)			
		Your Result 1	Your Result 2	Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score	Yours Results Diff. of 2 Values	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score
WBC x10³/μl	1	4.2	4.2	8.4	6.85	0.043	1.77	0	0.08	0.006	-1.08
RBC x10⁶/μl	1	4.98	4.96	9.94	9.51	0.016	1.38	0.02	0.05	0.004	-0.58
Hb g/dl	1	12.8	12.7	25.5	25.3	0.036	0.25	0.1	0.1	0.011	0.00
HCT%	1	40.7	40.6	81.3	80.7	0.256	0.11	0.1	0.4	0.045	-0.51
MCV-fL	1	82	81.3	163.3	169.2	0.451	-0.60	0.7	0.3	0.030	0.90
MCH-Pg	1	25.6	25.6	51.2	53	0.104	-0.92	0	0.2	0.018	-0.90
MCHC-g/dl	1	31.5	31.2	62.7	63.1	0.231	-0.09	0.3	0.3	0.027	0.00
Plt. x10³/μl	1	247	232	479	318	2.317	3.12	15	7	0.578	1.20
Retic %	2	0.2	0.1	0.3	1.59	0.054	-0.93	0.1	0.2	0.014	-0.45

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT
DLC%	3	Nrbcs=0 , Poly=25 L=05, E=01, Mono/Promono=00 , B1=01 P.M.=00, Mye=29, Meta=27, Other=NIL	Poly: 37 - 52, Myelo: 15 - 27, Meta: 9- 17, Promyelo: 2-8, Lympho: 2- 5, Blast: 1-4, Eosino: 1-3, Mono: 1-2, nRBC/ Baso: 0-5
RBC Morphology	3	NORMOCHROMIC ,NORMOCYTIC, ANISOCYTOSIS(+)	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromic, Mild: Poikilocytosis
Diagnosis	3	CHRONIC MYELO PROLIFERATIVE DISEASE, CHRONIC MYELOID LEUKEMIA CHRONIC PHAGE	Chronic Myeloid Leukemia (Chronic Phase)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 160--O	Total No. responded	% of Labs with Z Score 0-2		% of Labs with Z Score 2-3		% of Labs with Z Score >3	
				Among labs	Within lab	Among labs	Within lab	Among labs	Within lab
WBC x10³/µl	1	200	199	86.43	92.96	3.52	1.01	10.05	6.03
RBC x10⁶/µl	1	200	200	86.5	86.5	6	5.5	7.5	8
Hb g/dl	1	200	200	86.5	87.5	7	4.5	6.5	8
HCT%	1	200	199	92.96	89.95	2.51	3.02	4.53	7.03
MCV-fL	1	200	199	91.96	87.94	7.04	4.02	1	8.04
MCH-Pg	1	200	199	83.42	92.46	9.05	1.01	7.53	6.53
MCHC-g/dL	1	200	199	90.95	85.43	5.03	5.03	4.02	9.54
Plt. x10³/µl	1	200	199	88.94	92.96	6.53	3.52	4.53	3.52
ReticCount%	2	200	152	84.87	92.76	7.24	9.87	7.89	-2.63
PS Assessment	3	200	163	Satisfactory :98.5%, Borderline Sat. :0%, Unsatisfactory :1.50%					

*Comments:

1). **Among Lab (EQA) :** CBC result for PLT unacceptable, may be due to random/human error

2). **Within Lab (IQA) :** Precision acceptable.

Note-1: EQA (External Quality Assurance) : Your Performance among various of participating labs in PT, to determine the accuracy of your results.

IQA (Internal Quality Assurance) : Your Performance of comparison of two consecutive measurement values within your lab to test the precision of your autoanalyzer.

Note-2: Z score among & within lab were calculated, as per to ISO/IEC 13528:2015 standard. Z score among lab (EQA)= (Your Result Sum of two values - Consensus Result sum of two values)/(Normalised IQR)

Z score within lab (IQA)= (Your Result Difference of two values - Consensus Result difference of two values)/(Normalised IQR)

IQR = Quartile 3 - Quartile 1 of participant data, Normalised IQR = 0.7413 x IQR

Note-3: Z score 0 to ±2: Acceptable, Z score ±2 to ±3 :Warning Signal, Z score > ±3 : Unacceptable [As per ISO/IEC 13528:2015 standard]

Note-4: Z score value between "0 to ±2" are texted in green colour. Z score value between "±2 to ±3" are texted in orange colour. Z score value > ±3 are texted in red colour.

Note-5: Homogeneity and stability testing of PT sample were done as per ISO 13528:2015 standard. To pass homogeneity test, between sample SD (Ss) should be smaller than the check value (0.3*SDPA). To pass the stability test, average difference in measurement values of first and last day sample (\bar{x} - \bar{y}) should be smaller than the check value (0.3*SDPA).

Note-6: ISHTM-AIIMS-EQAP does not subcontract any task of its scheme

Note-7: Participants are free to use methods/analyzer of their own choice.

Note-8: Proficiency testing (PT) samples are sent quarterly to each participant.

Note-9: All the necessary details regarding design and implementation of PT, are provided in the instruction sheet as well as on programme's website www.ishtmaiimseqap.com.

Note 10: Reports are kept confidential.

Report authorized by,

Dr. Manoranjan Mahapatra (Prof. & Head)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

-----End Of Report-----



PROFICIENCY TESTING REPORT
ISHTM-AIIMS EXTERNAL QUALITY ASSURANCE PROGRAMME
 NABL accredited program as per ISO/IEC 17043:2010 standard
 Organized By Department of Hematology, AIIMS, New Delhi-110029

Duration of stability testing - minimum upto 8 days at ambient temp. after dispatch of specimens

EQAP CODE No. : 5929

Distribution No.: 161-O

Month/Year: October/2023

Instrument ID: AGD BIOMEDICALS

Name & Contact No. of PT Co-ordinator: Dr. Manoranjan Mahapatra (Prof. & Head), Hematology, AIIMS, Delhi,
 Tel: 9013085730 , E-Mail : accuracy2000@gmail.com

Date of issue & status of the report: 15-01-2024[Final].

CBC and Retic Assessment

Test Parameters	S.No.	Among Lab (Accuracy Testing)						Within Lab (Precision Testing)			
		Your Result 1	Your Result 2	Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score	Yours Results Diff. of 2 Values	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score
WBC x10³/µl	1	4	3.9	7.9	7.3	0.032	0.67	0.1	0.1	0.007	0.00
RBC x10⁶/µl	1	3.8	3.76	7.56	7.02	0.009	2.35	0.04	0.04	0.002	0.00
Hb g/dl	1	10.3	10.2	20.5	21.8	0.027	-1.95	0.1	0.1	0.008	0.00
HCT%	1	35.3	35	70.3	68.2	0.165	0.48	0.3	0.4	0.024	-0.22
MCV-fL	1	93	92.8	185.8	194.8	0.360	-0.88	0.2	0.3	0.020	-0.27
MCH-Pg	1	27.1	27.1	54.2	61.8	0.091	-3.25	0	0.3	0.018	-1.35
MCHC-g/dl	1	29.1	29.1	58.2	63.9	0.164	-1.29	0	0.3	0.022	-1.01
Plt. x10³/µl	1	197	189	386	349	1.479	0.85	8	5	0.314	0.58
Retic %	2	13	12.5	25.5	13	0.313	1.09	0.5	0.5	0.036	0.00

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT
DLC%	3	Nrbcs=00 , Poly=07 L=89, E=00, Mono/Promono=04 , B1=00 P.M.=00, Mye=00, Meta=00, Other=NIL	Lymp: 77-88, Poly: 7-12, Eosino: 1-2, mono: 1-3, nRBC/blast/Myelo/Meta: 0-5
RBC Morphology	3	Normochromia Anisocytosis(+)	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Mild: Poikilocytosis.
Diagnosis	3	Chronic Lymphoproliferative Disease - Chronic Lymphocytic Leukemia	Chronic Lymphoproliferative Disorder

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 161--O	Total No. responded	% of Labs with Z Score 0-2		% of Labs with Z Score 2-3		% of Labs with Z Score >3	
				Among labs	Within lab	Among labs	Within lab	Among labs	Within lab
WBC x10³/µl	1	332	332	87.65	92.77	4.22	2.11	8.13	5.12
RBC x10⁶/µl	1	332	332	87.65	93.67	5.42	1.51	6.93	4.82
Hb g/dl	1	332	332	87.95	87.35	4.22	4.82	7.83	7.83
HCT%	1	332	332	88.55	88.25	6.63	4.82	4.82	6.93
MCV-fL	1	332	332	91.87	85.24	6.33	4.52	1.8	10.24
MCH-Pg	1	332	332	87.95	89.16	6.93	4.82	5.12	6.02
MCHC-g/dL	1	332	332	90.66	89.46	5.42	5.72	3.92	4.82
Plt. x10³/µl	1	332	332	93.07	90.06	3.31	3.92	3.62	6.02
ReticCount%	2	332	255	96.47	83.92	1.96	9.41	1.57	6.67
PS Assessment	3	332	260	Satisfactory :91.57%, Borderline Sat. :3.31%, Unsatisfactory :5.12%					

*Comments:

1). Among Lab (EQA) : CBC result for MCH unacceptable, may be due to random/human error

2). Within Lab (IQA) : Precision acceptable.

Note-1: EQA (External Quality Assurance) : Your Performance among various of participating labs in PT, to determine the accuracy of your results.

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Report authorized by,

Dr. Manoranjan Mahapatra (Prof. & Head)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

-----End Of Report-----

ASSAY VALUES AND EXPECTED RANGES

LOT

B0823

QCP Data Months :

August, September, October



2023-11-05

Instruments : ERMA (1)

Instrument	Parameter / Paramètre	CONTROL L		CONTROL N		CONTROL H	
		LOT	B0823L	LOT	B0823N	LOT	B0823H
		Mean Cibles	Limit Limites	Mean Cibles	Limit Limites	Mean Cibles	Limit Limites
ERMA Instruments	WBC/GB	10 ³ /µL & 10 ⁹ /L	2,2 ± 0,4	7,3 ± 1,0	20,9 ± 2,5		
	RBC/GR	10 ⁶ /µL & 10 ¹² /L	2,15 ± 0,20	4,60 ± 0,30	5,40 ± 0,40		
	Hgb	g/dL	5,4 ± 0,4	12,6 ± 0,7	16,4 ± 0,9		
		g/L	54 ± 4	126 ± 7	164 ± 9		
	PCE 210						
	PCE 170						
	PCE 140						
	Hct	%	16,7 ± 1,8	39,8 ± 3,6	53,3 ± 4,8		
		L/L	0,167 ± 0,018	0,398 ± 0,036	0,533 ± 0,048		
	MCV/VGM	fL	77,7 ± 5,0	86,5 ± 5,0	98,7 ± 5,0		
	MCH/TCMH	pg	25,1 ± 2,5	27,4 ± 3,0	30,4 ± 3,2		
		fmol	1,58 ± 0,16	1,70 ± 0,19	1,89 ± 0,20		
	MCHC/CCMH	g/dL	32,3 ± 4,0	31,7 ± 4,0	30,8 ± 4,0		
		g/L	323 ± 40	317 ± 40	308 ± 40		
		mmol/L	20,4 ± 2,5	19,6 ± 2,5	19,1 ± 2,5		
	RDW/IDR	%	20,0 ± 5,0	17,0 ± 4,5	16,5 ± 4,5		
	Plt	10 ³ /µL & 10 ⁹ /L	80 ± 25	265 ± 75	545 ± 90		
	MPV/VPM	fL	8,1 ± 3,0	7,4 ± 3,0	8,4 ± 3,0		
	PDW/IDP	%	16,5 ± 3,0	15,0 ± 3,0	14,5 ± 3,0		
	LYM%	%	49,0 ± 14,0	31,5 ± 10,0	28,5 ± 8,0		
	MONO%	%	5,0 ± 5,0	6,0 ± 6,0	2,5 ± 2,5		
	GRA%	%	46,0 ± 14,0	62,5 ± 12,0	69,0 ± 12,0		
	LYM#	10 ³ /µL & 10 ⁹ /L	1,1 ± 0,3	2,3 ± 0,7	6,0 ± 1,7		
	MONO#	10 ³ /µL & 10 ⁹ /L	0,1 ± 0,1	0,4 ± 0,4	0,5 ± 0,5		
	GRA#	10 ³ /µL & 10 ⁹ /L	1,0 ± 0,3	4,6 ± 0,9	14,4 ± 2,5		

(1)Assay values provided by Bio-technie®, France.

EC REP



Bio-technie® - 19 Rue Louis Delourmel
35230 - NOYAL CHATILLON / SEICHE - FRANCE

R&D Systems, Inc. - 614 Mc Kinley Place N.E. - Minneapolis, MN USA 55413



IVD

CE

AV03D01-V26 07/2023

No. 00001

2023/12/27 9:33

WBC - 0.0 × 10⁹/ul

LYM - 0.0 × 10⁹/ul

MID - 0.0 × 10⁹/ul

GRA - 0.0 × 10⁹/ul

LYM% - 0.0 %

MID% - 0.0 %

GRA% - 0.0 %

RBC - 0.00 × 10⁶/ul

Hgb - 0.0 g/dl

HCT - 0.0 %

MCV - 0.0 fl

MCH - 0.0 pg

MCHC - 0.0 g/dl

RDW - 0.0 %

PLT - 0 × 10⁹/ul

PCT - 0.000 %

MPV - 0.0 fl

PDW - 0.0 fl



AGD Biomedicals (P) Ltd.
Address- Mehta Trade Center, Sir M.V.Road ,
Andheri East, Mumbai-400099
Tel – +91-22-28231061/66
Email : sales@agdbio.com

DOC.NO.- CC/PCE 210/RARI/008/00
DATE: 27 December 2023

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer ERMA PCE-210 bearing serial number 29168 installed at Regional Ayurved Research Institute Ahmedabad,GJ

Verified with Quality control material CBC-3D R & D systems (Normal) .The reports of Blank Cycle, Control values were all found in acceptable range.
Data given to laboratory.
Instrument is ready for routine work.

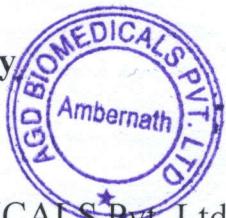
Please refer our Service Report No. 92012 on dated 27th Dec,2023 for your reference.

Calibration Date: 27th Dec, 2023
Next Calibration Due on: 26th Dec, 2024.

Enclosed :

- 1) IQC Run Data
- 2) Assay Sheet of Control
- 3) Printouts

Authorized Signatory



For AGD BIOMEDICALS Pvt. Ltd.

CONTROL DATA

	WBC [*10^3/uL]	RBC [*10^6/uL]	HgB [g/dL]	MCV	PLT [*10^3/uL]
LOW					
TARGET					
Range					
Normal					
	WBC 7.9	RBC 4.61	HgB 13.0	MCV 86.1	PLT 308
TARGET	7.3	4.6	12.6	86.5	265
Range	6.3-8.3	4.3-4.9	11.9-13.3	81.5-91.5	190-340
High					
TARGET					
Range					

This is to certify that the Hematology Analyzer ERMA PCE-210 bearing serial number: 29168 installed at Regional Ayurved Research Institute Ahmedabad,GJ. has been Calibrated using the standardreference material CBC-3D control.

Calibration At site Performed by:

Engineer Name :Prahlabhai Dodiya

Designation /Sign : Service Engineer

AGD Biomedicals Pvt Ltd



AGD Biomedicals (P) Ltd.
Mehta Trade Center,
Sir M. V. Road, Andheri East
Mumbai – 400 099 INDIA

P : +91-22-28231061/ 66
+91-22-28257999
E : sales@agdbio.com
W : www.agdbio.com

ISO : 9001 : 2015
ISO : 13485 : 2016
Page 2 of 2

Calibration done

No. 00004
2023/12/7 14:12

WBC	7.9	$\times 10^3/\mu\text{l}$
LY	2.5	$\times 10^3/\mu\text{l}$
MO	0.5	$\times 10^3/\mu\text{l}$
GR	4.9	$\times 10^3/\mu\text{l}$
LY%	32.2	%
MO%	6.2	%
GR%	61.6	%
RBC	4.61	$\times 10^6/\mu\text{l}$
Hgb	13.0	g/dl
HCT	39.7	%
MCV	86.1	fL
MCH	28.1	pg
MCHC	32.7	g/dl
RDW	+ 14.7	%
PLT	308	$\times 10^3/\mu\text{l}$
PCT	+0.295	%
MPV	9.6	fL
PDW	- 10.3	fL

AGD Biomedicals Pvt. Ltd.

Mehta Trade Centre, No.1 Shivaji Colony, Sir M. V. Road, Andheri East, Mumbai 400099. India
 TEL: 91 22 2823 1061 / 2823 1066 FAX : 91 22 28224297 email :ho-service@agdbio.com
 visit us at : www.agdbio.com



Sr. No

92012

SERVICE REPORT

Customer Name:		RARI Hospital										
Address/Area:		Ascomal - Ahmedabad										
Name Contact Person:		Mr. Diptesh bhai										
Phone/ Mob:		9016167776.										
Instrument status	Warranty	<input type="checkbox"/>	Free AMC	<input type="checkbox"/>	AMC	<input checked="" type="checkbox"/>	Not in AMC	<input type="checkbox"/>	Courtesy	<input type="checkbox"/>	Paid Visit	<input type="checkbox"/>
Type Of Call	Installation	<input type="checkbox"/>	Preventative Maintenance	<input checked="" type="checkbox"/>	Break Down	<input type="checkbox"/>	APPLICATION	<input type="checkbox"/>				

CALL DETAILS

CALL RECEIVED		RESPONSE			CALL COMPLETED						
DATE:	06/12/23	TIME:	18:00	DATE:	07/12/23	TIME:	12:00	DATE:	07/12/23	TIME:	14:30.
Problem Reported : pm service & am kit change.											
Observation : → change pm KIT. of PCE-210											
Engineer Remark → Run Start up & Check Background - OK → Run P&D Hematology Control - LEVEL-0 & it's All value found in the range → Instrument working Satisfactorily											
Hemat Reagent	CCR		Voltage Details	L-N	830	E-N	00				
Lot No:				L-E	230	CVT / UPS Y [] N []					

<input type="checkbox"/> FOLLOWING PARTS HAVE BEEN REPLACED	Spare Billing Details (If Any)		
<input type="checkbox"/> FOLLOWING PARTS NEED TO BE REPLACED PLEASE APPROVE	Customer Remarks		
SPARES/AMC / CMC / VISIT CHARGE			
Description	QTY	COST	Service : Poor <input type="checkbox"/> Average <input type="checkbox"/> Good <input type="checkbox"/> Excellent <input type="checkbox"/>
			Comments:
			WE HEREBY AGREED TO PAY SUM OF Rs: -----

FOLLOW UP ACTION (If Require)			Payment Collected: Cheque / DD / Others		
Machine is working satisfactorily. ✓					
Engineer Name:	Brijesh Dodiyal		Customer Signature:		
Engineer Signature:			Date:		
Date :	07/12/23		Stamp		
FOR OFFICE USE ONLY					

Internal. Q.C

Date - 06/02/2021

No. 00001

2024/ 2/ 6 10:24
WBC - 0.0 $\times 10^9/\mu\text{l}$
LYM - 0.0 $\times 10^9/\mu\text{l}$
MID - 0.0 $\times 10^9/\mu\text{l}$
GRA - 0.0 $\times 10^9/\mu\text{l}$
LYM% - 0.0 %
MID% - 0.0 %
GRA% - 0.0 %
RBC - 0.00 $\times 10^6/\mu\text{l}$
Hgb - 0.0 g/dl
HCT - 0.0 %
MCV - 0.0 fl
MCH - 0.0 pg
MCHC - 0.0 g/dl
RDW - 0.0 %
PLT - 0 $\times 10^3/\mu\text{l}$
PCT - 0.000 %
MPV - 0.0 fl
PDW - 0.0 fl

No. 00002 QC

2024/ 2/ 6 10:26
WBC - 7.6 $\times 10^9/\mu\text{l}$
LYM - 2.5 $\times 10^9/\mu\text{l}$
MID - 0.5 $\times 10^9/\mu\text{l}$
GRA - 4.6 $\times 10^9/\mu\text{l}$
LYM% - 32.9 %
MID% - 5.9 %
GRA% - 61.2 %
RBC - 4.73 $\times 10^6/\mu\text{l}$
Hgb - 12.3 g/dl
HCT - 40.5 %
MCV - 85.6 fl
MCH - 26.0 pg
MCHC - 30.3 g/dl
RDW - 14.0 %
PLT - 273 $\times 10^3/\mu\text{l}$
PCT - 0.245 %
MPV - 9.0 fl
PDW - 8.8 fl

Signature

ASSAY VALUES AND EXPECTED RANGES

LOT

B0823

QCP Data Months :

August, September, October



2023-11-05

Instruments : ERMA (1)

Instrument	Parameter / Paramètre	CONTROL L		CONTROL N		CONTROL H	
		LOT	B0823L	LOT	B0823N	LOT	B0823H
		Mean Cibles	Limit Limites	Mean Cibles	Limit Limites	Mean Cibles	Limit Limites
ERMA Instruments	WBC/GB	10 ³ /µL & 10 ⁹ /L	2,2 ± 0,4	7,3 ± 1,0	20,9 ± 2,5		
	RBC/GR	10 ⁶ /µL & 10 ¹² /L	2,15 ± 0,20	4,60 ± 0,30	5,40 ± 0,40		
	Hgb	g/dL	5,4 ± 0,4	12,6 ± 0,7	16,4 ± 0,9		
		g/L	54 ± 4	126 ± 7	164 ± 9		
	PCE 210						
	PCE 170						
	PCE 140						
	Hct	%	16,7 ± 1,8	39,8 ± 3,6	53,3 ± 4,8		
		L/L	0,167 ± 0,018	0,398 ± 0,036	0,533 ± 0,048		
	MCV/VGM	fL	77,7 ± 5,0	86,5 ± 5,0	98,7 ± 5,0		
	MCH/TCMH	pg	25,1 ± 2,5	27,4 ± 3,0	30,4 ± 3,2		
		fmol	1,58 ± 0,16	1,70 ± 0,19	1,89 ± 0,20		
	MCHC/CCMH	g/dL	32,3 ± 4,0	31,7 ± 4,0	30,8 ± 4,0		
		g/L	323 ± 40	317 ± 40	308 ± 40		
		mmol/L	20,4 ± 2,5	19,6 ± 2,5	19,1 ± 2,5		
	RDW/IDR	%	20,0 ± 5,0	17,0 ± 4,5	16,5 ± 4,5		
	Plt	10 ³ /µL & 10 ⁹ /L	80 ± 25	265 ± 75	545 ± 90		
	MPV/VPM	fL	8,1 ± 3,0	7,4 ± 3,0	8,4 ± 3,0		
	PDW/IDP	%	16,5 ± 3,0	15,0 ± 3,0	14,5 ± 3,0		
	LYM%	%	49,0 ± 14,0	31,5 ± 10,0	28,5 ± 8,0		
	MONO%	%	5,0 ± 5,0	6,0 ± 6,0	2,5 ± 2,5		
	GRA%	%	46,0 ± 14,0	62,5 ± 12,0	69,0 ± 12,0		
	LYM#	10 ³ /µL & 10 ⁹ /L	1,1 ± 0,3	2,3 ± 0,7	6,0 ± 1,7		
	MONO#	10 ³ /µL & 10 ⁹ /L	0,1 ± 0,1	0,4 ± 0,4	0,5 ± 0,5		
	GRA#	10 ³ /µL & 10 ⁹ /L	1,0 ± 0,3	4,6 ± 0,9	14,4 ± 2,5		

(1)Assay values provided by Bio-technie®, France.

EC REP



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IVD

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AV03D01-V26 07/2023

1. At SCOPE applied in hematology : the test mentioned in application as Heamogram,TC, DC, Platelets Count, MCV,MCH, MCHC etc are performed **by Non-cyanide Hemoglobin detection Method.**
2. The Calibration Raw data of dated 27.12.2023 are being submitted as Annexure-1.
3. The comments received from NABL about results of MCH has been forwarded to Service Engineer. The results getting on 06.02.2023 was monitored by Engineer. As per their suggestion, the action is not required. If the result may vary in future, the respective action will be taken. The data of instrument are herewith submitting as Blank, Internal Q.C by Annexure-2