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EXCELLAS CLINIC

ILC (Inter-laboratory Comparisons)

Discipline : Haematology

Month : DEC 2022

Date	Test Parameters	Sample Details	Sent to	Sending Date	Report Received on	Method	Findings			QM/ID Remarks
							Our Results	Referral lab results	Difference in Reading	
29/11/2022	CBC	EDTA whole blood	Genetic Diagnostics	29/11/2022	29/11/2022	As Mentioned in report				
						HB	14.7	14.6	0.1	RESULT SATISFACTORY (Ref. Delta check establishment)
						RBC	4.8	4.9	-0.1	
						WBC	6200	7300	-1100	
						PLT	316	343	-27	
FORM NAME : ILC EVALUATION FORM-HAEMATOTOLOGY							FM/ILC-HAEMAT/TP/08			
ISSUE NO: 01							ISSUE BY : QM			
AMMEN NO: 00							APPROVED BY: LD			

[Signature]
DR. ABIR KUMAR





' 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. : 5115

Distribution No.: 157-M

Month/Year: October/2022

Instrument ID: KX-21 (SN-B8406)

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

Date of issue & status of the report: 24-11-2022[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 x10 ³ /µl	1	5.5	5.1	10.6	11.2	0.0290	-0.74	0.4	0.1	0.0060	2.89
RBC x10 ⁶ /µl	1	3.64	3.6	7.24	7.56	0.0080	-1.47	0.04	0.04	0.0030	0.00
Hb g/dl	1	11.9	11.8	23.7	23.7	0.0270	0.00	0.1	0.1	0.0080	0.00
HCT%	1	34.7	34.5	69.2	73.3	0.1660	-0.86	0.2	0.4	0.0250	-0.39
MCV-fl	1	95.8	95.3	191.1	194.55	0.3960	-0.30	0.5	0.3	0.0210	0.63
MCH-Pg	1	33.1	32.4	65.5	62.6	0.0840	1.25	0.7	0.3	0.0200	1.08
MCHC-g/dl	1	34.5	34	68.5	64.5	0.1500	0.93	0.5	0.3	0.0220	0.54
Plt. x10 ³ /µl	1	132	125	257	281.5	1.19	-0.76	7	4	0.28	0.67
Retic %	2	8	7.5	15.5	10.5	0.23	0.75	0.5	0.5	0.03	0.00

P.S . Assesment

YOUR REPORT		CONSENSUS REPORT
DLC%	3	Nrbcs=3 , Poly=45 L=7, E=2, Mono/Promono=3 , B1=1 P.M.=2, Mye=20, Meta=07, Other=Band Form-12, Wbc morphology -Marked Leucocytosis with shift to left present with occasional blast cell ,platelet reduced on smear
RBC Morphology	3	Mild Anisopoikilocytosis.Predominantly Normocytic Normchromic with occasional nRBC
Diagnosis	3	Suggestive of chronic myeloproliferative disorder



QUALITY MANA

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 157-- M	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 x10 ³ /μl	1	333	332	83.13	88.55	6.63	5.12	10.24	6.33
RBC x10 ⁶ /μl	1	333	333	88.89	88.89	5.11	5.71	6	5.4
Hb g/dl	1	333	333	86.49	85.89	6.01	6.91	7.5	7.2
HCT%	1	333	331	93.96	91.54	4.23	3.32	1.81	5.14
MCV-fl	1	333	332	95.48	91.27	3.01	2.41	1.51	6.32
MCH-Pg	1	333	332	90.36	85.54	5.72	7.83	3.92	6.63
MCHC-g/dl	1	333	332	93.67	91.87	3.92	2.11	2.41	6.02
Plt. x10 ³ /μl	1	333	332	91.57	92.17	5.72	4.22	2.71	3.61
ReticCount%	2	333	296	88.18	88.18	7.43	7.09	4.39	4.73
PS Assessment	3	333	269	Satisfactory :87.66%, Borderline Sat. :11.14%, Unsatisfactory :1.20%					

Comments:

1). Among Lab (EQA) : Results acceptable.

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. Seema Tyagi (Prof.)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

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

QUALITY MANAGER



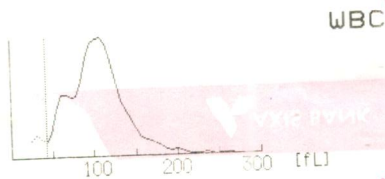
Date:- 18/10/2022

AIIMS 157

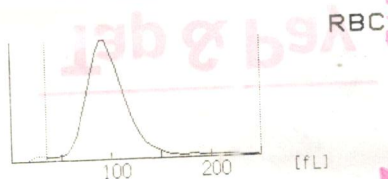
AIIMS QC I

No. 10
Date 18/10/22 10:37
Mode WB

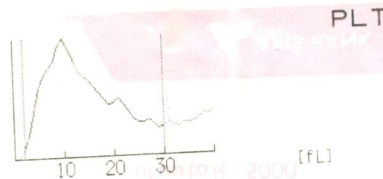
WBC	5.1 × 10 ³ / μL
RBC	3.60 × 10 ⁶ / μL
HGB	11.9 g/dL
HCT	34.5%
MCV	95.8 fL
MCH	33.1 Pg
MCHC	34.5 g/dL
PLT	132 × 10 ³ / μL



LYM%	T1	---	-%
MYD%	T1	---	-%
NEUT%	T1	---	-%
LYM#	T1	---	-x10 ³ / μL
MYD#	T1	---	-x10 ³ / μL
NEUT#	T1	---	-x10 ³ / μL



RDW 14.2%



PDW	DW	---	-fL
MPV	DW	---	-fL
P-LCR	DW	---	-%

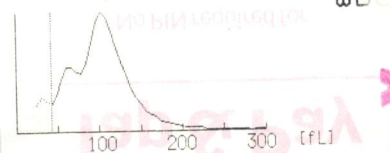
✓

QUALITY MANAGER

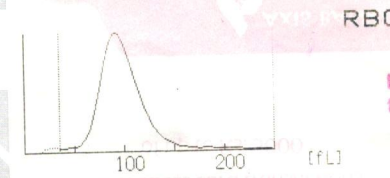
AIIMS QC II

No. 11
Date 18/10/22 10:38
Mode WB

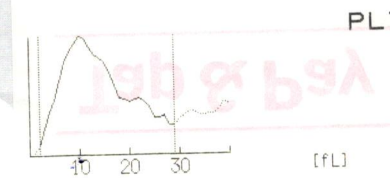
WBC	WL*	5.5 × 10 ³ / μL
RBC		3.64 × 10 ⁶ / μL
HGB		11.8 g/dL
HCT		34.7%
MCV		95.3 fL
MCH		32.4 Pg
MCHC		34.0 g/dL
PLT	AG	125 × 10 ³ / μL



LYM%	WL	---	-%
MYD%	WL	---	-%
NEUT%	WL	---	-%
LYM#	WL	---	-x10 ³ / μL
MYD#	WL	---	-x10 ³ / μL
NEUT#	WL	---	-x10 ³ / μL



RDW 14.3%



PDW	DW	---	-fL
MPV	DW	---	-fL
P-LCR	DW	---	-%

✓

LAB DIRECTOR



Clinical Summary - P.S-3/157 M

A 35 year old male with dragging pain in left upper quadrant of abdomen.
Hemogram revealed WBC: $97.28 \times 10^3/uL$, Hb: 9.5 g/dL & Plt: $95 \times 10^3/UL$

3/157 m

PS -

RBC - mild Anisopoikilocytosis. Predominantly normocytic normochromic, with occasional nRBC

WBC - marked leucocytosis with shift to left present with occasional blast cell.

PL - Reduced on smear.

Imp - suggestive of chronic myeloid life-
-active
disorder.

Blast - 01

~~Pr~~ Proryelocytes - 02

myelocytes - 20% metamyelocytes = 07%

N - 45

BF = 12%

L - 07

E - 02

m - 03

LD

B - 01

nRBC - 03%

O

2/157 m

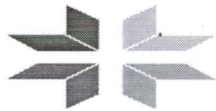
- Retic count

High count - 8.0 %

Low count - 7.5 %



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Excellas Clinics
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CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

DATE: 29/11/2022	CAPA NO: 02	NC NO:
DISCIPLINE: Haematology	INITIAL BY:	ISSUED BY: QUALITY MANAGER
PARTICULAR: EQAS	SIGN :	SIGN

DESCRIPTION OF NON-CONFORMITY:

SN - 157-M founds outlier WBC (2.89 z-score)

Root Cause Analysis :

1. Specimen Handling - (For PT / EQAS Programme)

- Check Condition of Material when received ---Expiry and Temperature? Yes No
- Check Reconstitution Water quality? Yes No
- Check Personnel Handling and Analyzing - Satisfactory? Yes No
- Were your results graded in the appropriate peer group based on the method? Yes No
- Were PT specimen reconstituted as the kit instruction? NA Yes No
- Were PT specimen stored as indicated.? Yes No

2. Clerical Errors or Transcription Error: -

- ❖ Were the results transcribed onto the worksheets correctly? Yes No
- ❖ Were the results recorded on the correct worksheet? Yes No
- ❖ Was the correct instrument/reagent/kit selected? Yes No
- ❖ Were the results recorded in the correct units? Yes No
- ❖ Were the results on your evaluation the same as the results you reported? Yes No

3. Internal Quality Control -

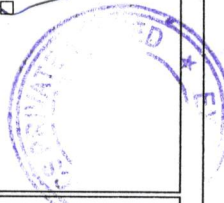
- ❖ Were controls in range on the date the proficiency samples were tested? Yes No
- ❖ Is there any indication of trending or shifting of the control results? Yes No

4. Calibration

- ❖ Were there any problems with the most recent calibration? Yes No
- ❖ When was the last calibration performed? NA
- ❖ How often is a calibration performed? NA

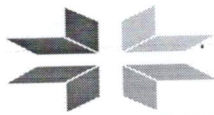
5. Instrument

- ❖ Were instrument problems noted the day the samples were tested? Yes No
- ❖ Has there been any recent maintenance on the analyser? Yes No
- ❖ Have you contacted your analyser manufacturer for assistance? Yes No



FORM NO: 04	FORM NAME: CAPA	FORM NO: FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY : QM <i>[Signature]</i>
AMEND NO: 00	AMEND DATE : 00	APPROVED BY: LD <i>[Signature]</i> Dr. Santosh Khairnar M.D. Pathologist

QUALITY MANAGER



CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

6. Reagents

- ❖ Were the reagents stored properly? Yes No
- ❖ Were the reagents expired or was the open vial stability exceeded? Yes No
- ❖ Have there been any changes in reagent manufacturer or formulation? Yes No

7. Specimen /Sample Handling: - (For Patient Sample)

- ❖ Were specimens received in an acceptable condition? **NA** Yes No
- ❖ Were specimens stored according to the instructions on the result forms? **NA** Yes No
- ❖ Were the samples haemolyzed (Palin tube) ? Yes No
- ❖ Were samples tested within the time allowed for sample stability? Yes No

8. Regarding Patient

- ❖ Any major complaint received from Patient? Yes No **NA**
- ❖ Complaint related to reception behavior, technician, or results? Yes No
- ❖ Get back to the patient within 24 hrs. for the answer? Yes No

9. Culture

- ❖ Was the media stored according to manufacturer's instructions? **NA** Yes No
- ❖ Was the media expired? **NA** Yes No
- ❖ Was the appropriate QC performed on the media? Yes No
- ❖ Was the incubator temperature/gas/humidity within acceptable limits? Yes No
- ❖ If applicable, have you contacted your kit manufacturer for assistance? Yes No
- ❖ Notes: _____

10. Could patient results have been affected? If so, explain course of action:

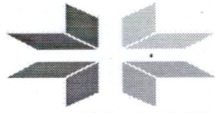
_____ **NA** _____



Corrective Action Taken:

FORM NO: 04	FORM NAME: CAPA	FORM NO: FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY : QM
AMEND NO: 00	AMEND DATE : 00	APPROVED BY: LD <small>Dr. Santosh Kumar M.D. Pathologist</small>

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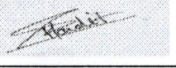

CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

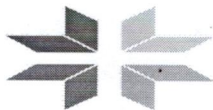
Corrective action :-
sending ILC to NABL accredited lab for
WBC parameter.
Result satisfactory.

Preventive Action Taken:

NA



FORM NO: 04	FORM NAME:CAPA	FORM NO:FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY :QM 
AMEND NO:00	AMEND DATE :00	APPROVED BY: LD  <small>Dr. Santosh Khatri M.D. Pathologist</small>



CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

❖ **Corrective Action for PT Failure?**

CA 1 - Re-run Recalled EQAS sample of previous ---Results Satisfactory? Yes No Yes No

CA 2 - EQAS -Z SCORE Results Satisfactory? Yes No Yes No

- Report attached? NA Yes No

-Z SCORE for Corrected Parameter:

CA 3 – Calibration done for outlier parameter? Yes No

- Re-run Recalled EQAS sample of previous ---Results Satisfactory? Yes No

- Z SCORE Results Satisfactory? NA Yes No

CA 4 -Random Patient sample for the analyte outlier for ILC ?

Yes No

- ILC Results Satisfactory?

Yes No

- Report Attached?

Yes No

CA 5- comparable results if any?

Yes No

-Report Attached?

Yes No

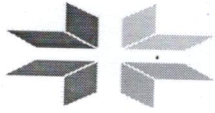
CA 6 – If Any other --

NA



FORM NO: 04	FORM NAME:CAPA	FORM NO:FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY :QM <i>Hobait</i>
AMEND NO:00	AMEND DATE :00	APPROVED BY: LD <i>Dr. Santosh Khairnar</i> M.D. Pathologist

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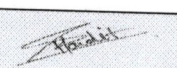
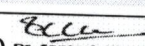
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EXCELLENCE IN HEALTHCARE

CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

Preventive Action Report:

NA



FORM NO: 04	FORM NAME:CAPA	FORM NO:FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY :QM 
AMEND NO:00	AMEND DATE :00	APPROVED BY: LD  <small>Dr. Sanjosh Khairnar M.D. Pathologist</small>

LABORATORY TEST REPORT

ID : 2193337 Collection : 29/11/22, 05:05 PM Client Name : Excellas Clinics pvt
 Name : ASHUTOSH KANOJIYA Received : 29/11/22, 05:05 PM ltd - TTFRCPL10
 DOB/Age : 25 years Reported : 29/11/22, 06:13 PM Client Address :
 Gender : Male Ref. Doctor : SELF
 Nationality : 0 Passport No. :-



Test Description	Value(s)	Unit(s)	Reference Range
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HAEMATOLOGY

Complete Blood Count; CBC (EDTA whole blood)

Erythrocytes (Whole Blood)

Hemoglobin (Hb)* (NonCyanmethemoglobin Photometric Measurement)	14.6	gm/dL	13.5 - 18.0
Erythrocyte (RBC) Count* (Electrical Impedance)	4.90	mil/cu.mm	4.7 - 6.0
Packed Cell Volume (PCV)* (Calculated)	44.7	%	42 - 52
Mean Cell Volume (MCV)* (Electrical Impedance)	91.2	fL	78 - 100
Mean Cell Haemoglobin (MCH)* (Calculated)	29.9	pg	27 - 31
Mean Corpuscular Hb Conc. (MCHC)* (Calculated)	32.8	gm/dL	32 - 36
Red Cell Distribution Width (RDW)* (Electrical Impedance)	13.7	%	11.5 - 14.0

RBC Morphology

Remarks: Normocytic normochromic

Leucocytes (Whole, Blood)

Total Leucocytes (WBC) Count* (Electrical Impedance)	<u>7300</u>	cell/cu.mm	4000-10000
Neutrophils* (VCSn Technology)	40	%	40 - 80
Lymphocytes* (VCSn Technology)	43	%	20 - 40
Monocytes* (VCSn Technology)	9	%	2 - 10
Eosinophils* (VCSn Technology)	7	%	1 - 6
Basophils* (VCSn Technology)	1	%	1-2

Absolute Count

Absolute Neutrophil Count* (Calculated)	2.92	* 10 ⁹ /L	2.0 - 7.0
--	------	----------------------	-----------

Absolute Lymphocyte Count* (Calculated)	3.14	* 10 ⁹ /L	1-3
--	------	----------------------	-----

Ground Floor, Plot No. 6/19, Compound No. 82 Transmission House, Marol Co-Operative Industrial Estate, Near Marol Bhavan, Sir Mathuradas VasANJI Rd, Ganesh Nagar, Marol, Andheri East, Mumbai, Maharashtra – 400059

LABORATORY TEST REPORT

ID : 2193337
 Name : ASHUTOSH KANOJIYA
 DOB/Age : 25 years
 Gender : Male
 Nationality : 0
 Collection : 29/11/22, 05:05 PM
 Received : 29/11/22, 05:05 PM
 Reported : 29/11/22, 06:13 PM
 Ref. Doctor : SELF
 Passport No. :-

Client Name : Excellas Clinics pvt
 Ltd - TTFRCPL10
 Client Address :



Test Description	Value(s)	Unit(s)	Reference Range
Absolute Monocyte Count* (Calculated)	0.66	* 10 ⁹ /L	0.2-1.0
Absolute Eosinophil Count* (Calculated)	0.51	* 10 ⁹ /L	0.0-0.5
Absolute Basophils Count* (Calculated)	0.07	* 10 ⁹ /L	1-2
WBC	Lymphocytosis		
Platelets (Whole, Blood)			
Platelet Count* (Electrical Impedence)	343	10 ³ /ul	150 - 450
Mean Platelet Volume (MPV)* (Electrical Impedence)	7.9	fL	7.2 - 11.7
Platelet Morphology	Adequate on smear		
PCT* (Calculated)	0.270	%	0.2 - 0.5
PDW* (Calculated)	17.1	%	9.0 - 17.0

Tests done on Automated Five Part Cell Counter. (WBC, RBC, Platelet count by impedance method, colorimetric method for Hemoglobin, WBC differential by flow cytometry using laser technology other parameters are calculated). All Abnormal Haemograms are reviewed confirmed microscopically.



****END OF REPORT****

P. K. Shetty

Dr. Prashant Shetty
(M.D. Pathology)

Patient Name : **MR. ASHUTOSH ASHOK KANOJIYA**
Age/Gender : 25 YEARS/MALE
Sample Collected At : KOTAK LIFE INSURANCE
Referred by Dr. : KOTAK LIFE INSURANCE / N

Reg.No. : 37050
Reg.Date : 29/11/2022 / 09:11 AM
Patient ID : 65079
Print Date : 09/12/2022 / 12:42PM

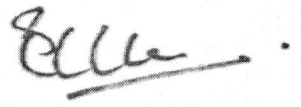
COMPLETE BLOOD COUNT WITH E.S.R

<u>TEST DONE</u>	<u>RESULT</u>	<u>UNIT</u>	<u>REFERENCE RANGE</u>
Haemoglobin	: 14.7	gm %	13.0 - 18.0
R.B.C. Count	: 4.80	/ c.mm	3 - 6
Packed Cell Volume	: 42.3	%	36.0 - 54.0
MCV	: 88.12	fl	78 - 101
MCH	: 30.62	pg	27 - 32
MCHC	: 34.75 H	g / dl	31.5 - 34.5
RDW	: 12.5	%	11.6 - 14.0
Leucocytes Count	: <u>6200</u>	/ c.mm	4000 - 11000
<u>DIFFERENTIAL COUNT</u>			
Neutrophils	: 45	%	40 - 75
Eosinophils	: 02	%	01 - 06
Basophils	: 00	%	00 - 01
Lymphocytes	: 45	%	20 - 45
Monocytes	: 08	%	1 - 10
Abnormalities of RBC	: Normocytic Normochromic		
Abnormalities of W B C	: Normal Morphology		
Platelet Count	: 316	10 ³ / c.mm	150 - 450
Platelet On Smear	: Adequate on smear		
<u>ERYTHROCYTE SEDIMENTATION RATE</u>			
E.S.R.	: 07	mm/hr	0 - 20

Method

EDTA Whole Blood - Tests done on Automated three Part Cell Counter. (WBC, RBC Platelet count by DC impedance method, other parameters calculated) All Abnormal Haemograms are reviewed confirmed microscopically.

CHECKED BY


Dr. Santosh Khairnar
M.D. Pathologist

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EXCELLAS CLINICS

EXTERNAL QUALITY ASSURANCE PROGRAM FORM

DISCIPLINE : HAEMATOTOLOGY

EQAS : AIIMS-EQAP		CYCLE NO : 5115		SAMPLE NO: 158-M		MONTH: JANUARY-2023	
Date	Test / Parameters	Sample Details	Date of run	Report Received on	Zscore	Corrective Action	QM/LD Remarks
20/04/2023	HB	EDTA whole Blood	26/01/2023	15/04/2023	4.05	REFER CAPA NO 04	RESULT STATISFACOTRY
	HCT				-0.26		
	MCH				4.5		
	MCHC				4.05		
	MCV				-0.32		
	PLT				0.49		
	RBC				0		
	WBC				0		
	SMEAR STUDY						
	DLC%						
	RBC MORPHOLOGY				WITHIN CONSENSUS		
	DIAGNOSIS				ACUTE LEUKEMIA		
FORM NO: 02	FORM NAME : EQAS EVALUATION FORM-HEAMTOLOGY						FM/EQAS-EVAL-HEAMT/QM/TP/02
ISSUE NO: 01	ISSUE DATE: 01/06/2022						ISSUE BY : QM
AMMEN NO: 00	AMMEND DATE : 00						APPROVED BY: L



[Signature]

LAB DIRECTOR



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. : 5115

Distribution No.: 158-M

Month/Year: January/2023

Instrument ID: B8406

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

Date of issue & status of the report: 28-02-2023[Final].

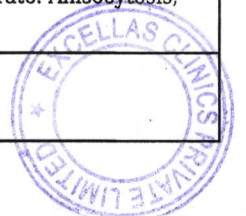
CBC and Retic Assessment

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 x10 ³ /µl	1	5.7	5.6	11.3	13.31	0.0350	-2.30	0.1	0.1	0.0070	0.00
RBC x10 ⁶ /µl	1	4.8	4.75	9.55	10.25	0.0120	-1.95	0.05	0.05	0.0030	0.00
Hb g/dl	1	13.5	12.8	26.3	26.5	0.0270	-0.27	0.7	0.1	0.0080	4.05
HCT%	1	39.7	39.4	79.1	85.7	0.2190	-0.89	0.3	0.4	0.0250	-0.26
MCV-fl	1	82.9	82.7	165.6	169.35	0.3530	-0.33	0.2	0.3	0.0190	-0.32
MCH-Pg	1	28.1	26.9	55	51.5	0.0590	2.15	1.2	0.2	0.0140	4.50
MCHC-g/dl	1	34	32.5	66.5	61	0.1400	1.01	1.5	0.3	0.0210	4.05
Plt. x10 ³ /µl	1	405	392	797	781	2.99	0.18	13	9	0.52	0.49
Retic %	2	14.5	13.5	28	15.35	0.22	2.12	1	0.5	0.03	0.84

P.S . Assesment

YOUR REPORT		CONSENSUS REPORT
DLC%	3	Nrbcs=3 , Poly=06 L=12, E=02, Mono/Promono=02 , B1=0 P.M.=0, Mye=0, Meta=0, Other=Atypical cells - 80%
RBC Morphology	3	Predominantly Normocytic Normochromic with nRBC's
Diagnosis	3	Suggestive of Acute Leukemia

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COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist.- 158--M	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 x10 ³ /µl	1	338	335	83.88	84.18	6.27	6.27	9.85	9.55
RBC x10 ⁶ /µl	1	338	338	89.64	89.35	5.92	5.03	4.44	5.62
Hb g/dl	1	338	338	88.76	85.21	5.03	4.44	6.21	10.35
HCT%	1	338	336	97.92	89.88	0.89	5.36	1.19	4.76
MCV-fl	1	338	336	97.62	87.2	1.79	6.55	0.59	6.25
MCH-Pg	1	338	336	88.39	89.58	7.44	4.76	4.17	5.66
MCHC-g/dl	1	338	336	98.21	86.9	0.89	7.74	0.9	5.36
Plt. x10 ³ /µl	1	338	336	94.64	92.26	3.27	2.98	2.09	4.76
ReticCount%	2	338	296	91.22	85.14	6.08	9.8	2.7	5.06
PS Assessment	3	338	283	Satisfactory :97.93%, Borderline Sat. :1.18%, Unsatisfactory :0.890%					

***Comments:**

1). Among Lab (EQA) : Results acceptable.

2). Within Lab (IQA) : Difference in the CBC measurement values for HB, MCH & MCHC unacceptable, please check precision/human error.Remaining 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. Seema Tyagi (Prof.)

PT Co-ordinator: ISHTM-AIIMS-EQAP

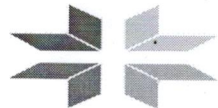
Department of Hematology, AIIMS, New Delhi

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

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CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

DATE: 20/04/2023	CAPA NO: 04	NC NO:
DISCIPLINE: Haematology	INITIAL BY:	ISSUED BY: QUALITY MANAGER
PARTICULAR: EQAS	SIGN:	SIGN

DESCRIPTION OF NON-CONFORMITY:
SN - 158-M founds outlier HB, MCH & MCHC
↓
Z score (4.05) (4.50) (4.05)

Root Cause Analysis :

1. Specimen Handling: - (For PT / EQAS Programme)

- Check Condition of Material when received ---Expiry and Temperature? Yes No
- Check Reconstitution Water quality? Yes No
- Check Personnel Handling and Analyzing - Satisfactory? Yes No
- Were your results graded in the appropriate peer group based on the method? Yes No
- Were PT specimen reconstituted as the kit instruction? NA Yes No
- Were PT specimen stored as indicated.? Yes No

2. Clerical Errors or Transcription Error: -

- ❖ Were the results transcribed onto the worksheets correctly? Yes No
- ❖ Were the results recorded on the correct worksheet? Yes No
- ❖ Was the correct instrument/reagent/kit selected? Yes No
- ❖ Were the results recorded in the correct units? Yes No
- ❖ Were the results on your evaluation the same as the results you reported? Yes No

3. Internal Quality Control -

- ❖ Were controls in range on the date the proficiency samples were tested? Yes No
- ❖ Is there any indication of trending or shifting of the control results? Yes No

4. Calibration

- ❖ Were there any problems with the most recent calibration? Yes No
- ❖ When was the last calibration performed? NA
- ❖ How often is a calibration performed? NA

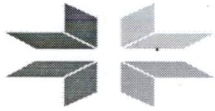
5. Instrument

- ❖ Were instrument problems noted the day the samples were tested? Yes No
- ❖ Has there been any recent maintenance on the analyser? Yes No
- ❖ Have you contacted your analyser manufacturer for assistance? Yes No

FORM NO: 04	FORM NAME: CAPA	FORM NO: FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY : QM <i>[Signature]</i>
AMEND NO: 00	AMEND DATE : 00	APPROVED BY: LD <i>[Signature]</i> Dr. Smitesh Kharnar M.D. Pathologist



QUALITY MANAGER



CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

6.Reagents

- ❖ Were the reagents stored properly? Yes No
- ❖ Were the reagents expired or was the open vial stability exceeded? Yes No
- ❖ Have there been any changes in reagent manufacturer or formulation? Yes No

7.Specimen /Sample Handling: - (For Patient Sample)

- ❖ Were specimens received in an acceptable condition? Yes No
- ❖ Were specimens stored according to the instructions on the result forms? NA Yes No
- ❖ Were the samples haemolyzed (Palin tube) ?Yes No
- ❖ Were samples tested within the time allowed for sample stability? Yes No

8. Regarding Patient

- ❖ Any major complaint received from Patient?Yes No
- ❖ Complaint related to reception behavior, technician, or results? NA Yes No
- ❖ Get back to the patient within 24 hrs. for the answer? Yes No

9.Culture

- ❖ Was the media stored according to manufacturer's instructions? NA Yes No
- ❖ Was the media expired? Yes No
- ❖ Was the appropriate QC performed on the media? Yes No
- ❖ Was the incubator temperature/gas/humidity within acceptable limits? Yes No
- ❖ If applicable, have you contacted your kit manufacturer for assistance? Yes No
- ❖ Notes: _____

10.Could patient results have been affected? If so, explain course of action:

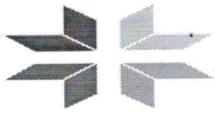
NA

Corrective Action Taken:

FORM NO: 04	FORM NAME:CAPA	FORM NO:FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY :QM
AMEND NO:00	AMEND DATE :00	APPROVED BY: LD Dr. Anvish Khanna M.D. Pathologist



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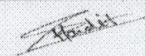
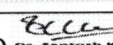
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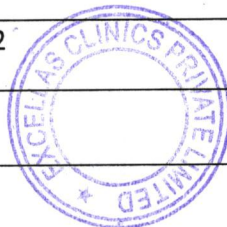
CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

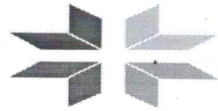
Corrective action:-
No correction action taken because
IQC on ~~st~~ date 26/01/23 within $\pm 1SD$
we will wait for next sample.

Preventive Action Taken:

NA

FORM NO: 04	FORM NAME:CAPA	FORM NO:FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY :QM 
AMEND NO:00	AMEND DATE :00	APPROVED BY: LD  <small>Dr. Santosh Khairnar M.D. Pathologist</small>





CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

❖ **Corrective Action for PT Failure?**

CA 1 - Re-run Recalled EQAS sample of previous ---Results Satisfactory? Yes No Yes No

CA 2 - EQAS -Z SCORE Results Satisfactory? **NA** Yes No

- Report attached? Yes No

-Z SCORE for Corrected Parameter:

CA 3 – Calibration done for outlier parameter? Yes No

- Re-run Recalled EQAS sample of previous ---Results Satisfactory? Yes No

- Z SCORE Results Satisfactory? **NA** Yes No

CA 4 -Random Patient sample for the analyte outlier for ILC ? Yes No

- ILC Results Satisfactory? Yes No

- Report Attached? Yes No

CA 5- comparable results if any? Yes No

-Report Attached? Yes No

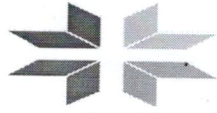
CA 6 – If Any other --

NA



FORM NO: 04	FORM NAME:CAPA	FORM NO:FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY :QM
AMEND NO:00	AMEND DATE :00	APPROVED BY: LD Dr. Santosh Khairnar M.D. Pathologist

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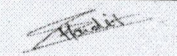
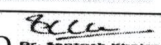
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CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

Preventive Action Report:

NA



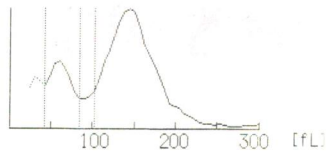
FORM NO: 04	FORM NAME:CAPA	FORM NO:FM/CAPA/04
ISSUE NO: 01	ISSUE DATE: 01/06/2022	ISSUE BY :QM 
AMEND NO:00	AMEND DATE :00	APPROVED BY: LD  <small>Dr. Santosh Kumar M.D. Pathologist</small>

EQAS - Sample No. 158 M

Date - 26/01/23

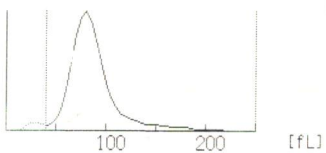
No. 7
Date 26/01/23 10:43
Mode WB

JBC WL* $5.6 \times 10^9 / \mu\text{L}$
RBC $4.75 \times 10^6 / \mu\text{L}$
HGB 12.8 g/dL
HCT 39.4%
MCV - 82.9 fL
MCH 26.9 pg
MCHC 32.5 g/dL
PLT AG $392 \times 10^3 / \mu\text{L}$



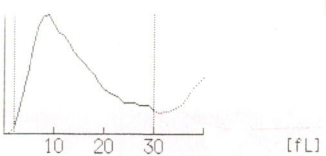
WBC

LYM% WL* 20.1%
MYD% WL* 5.2%
NEUT% WL* 74.7%
LYM# WL* $1.1 \times 10^9 / \mu\text{L}$
MYD# WL* $0.3 \times 10^9 / \mu\text{L}$
NEUT# WL* $4.2 \times 10^9 / \mu\text{L}$



RBC

RDW 15.2%

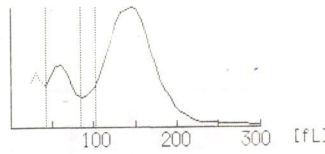


PLT

PDW + 27.5 fL
MPV + 13.6 fL
P-LCR + 51.7%

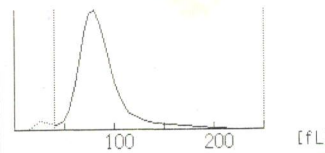
No. 9
Date 26/01/23 10:45
Mode WB

JBC WL* $5.7 \times 10^9 / \mu\text{L}$
RBC $4.80 \times 10^6 / \mu\text{L}$
HGB 13.5 g/dL
HCT 39.7%
MCV - 82.7 fL
MCH 28.1 pg
MCHC 34.0 g/dL
PLT AG+ $405 \times 10^3 / \mu\text{L}$



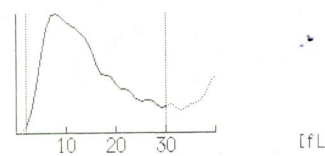
WBC

LYM% WL* 18.8%
MYD% WL* 5.6%
NEUT% WL* 75.6%
LYM# WL* $1.1 \times 10^9 / \mu\text{L}$
MYD# WL* $0.3 \times 10^9 / \mu\text{L}$
NEUT# WL* $4.3 \times 10^9 / \mu\text{L}$



RBC

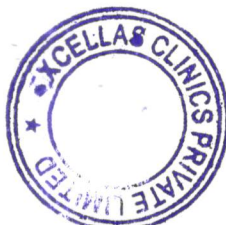
RDW 15.1%



PLT

PDW DW ---. -fL
MPV DW ---. -fL
P-LCR DW ---. -%

Griff
DONE BY



Pradi
QUALITY MANAGER



mild Anisopoikilocytosis

RBC - Predominantly Normocytic Normochromic
with nRBC's.

WBC - marked leucocytosis with atypical
(abnormal cells)

PL - Reduced on smear.

imp - suggestive of Acute leukemia.

PL -

Abnormal (Atypical cells) - 80%.

N - 06

L - 12

E - 02

m - 02

3% nRBC's.

Retic count.

Reading ① 13.5

Reading ② 14.5



Ecce

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