HYTECH INSTRUMENT

2SF, C-2 Shriram Complex, Nyay Khand-I, Indirapuram, Ghaziabad-201014 (U.P) INDIA
Ph. No. +91-9899380410, +91-9716668085, +91-7669021291-95

AN ISO 9001-2015 Certified Company

Calibration Certificate

Format No. : HY/FM/33

Certificate No.	**HY/21/1371-174**
Date of Calibration :	26.11.2021
Next Date for Calibration (As per agreed with the Customer)	26.11.2022
Certificate Issue Date	27.11.2021

CALIBRATION CERTIFICATE OF

Cell Counter

CUSTOMER ADDRESS

M/s Care Hospital
(A Unit of Goel Superspeciality Medical Centre Pvt.Ltd.)
Near Delapeer Petrol Pump, Stadium Road, Bareilly - 243001 INDIA

SERVICE REQUEST FORM DETAILS

Service Request / Job No.	1371/1371-174
Service Request Dated	24.11.2021

DESCRIPTION OF DEVICE UNDER CALIBRATION

Make / Model	ERME/PCE 210
Instrument Sr. No.	29210
Resolution / Least Count	As Per Range
Range / Size	As Per Insrument
Asset Code / I.D No.	----
Location	LAB
Instrument Condition	In working

Calibration Procedure	HY/WI/2MD08		**Calibration Performed At**		At Site
Reference Standard	NABL-126		**Discipline**		Medical
ENVIRONMENTAL CONDITIONS	**Temperature**	(25 ± 15) °C	**Relative Humidity**		(60 ± 15) %RH

DETAILS OF REFERENCE STANDARDS AND MAJOR EQUIPMENTS USED FOR CALIBRATION

Sr. No	Instrument Details	Certificate No.	Calibrated By	Calibration Due Date
1	Process Calibrator with Analyzer	CC205521000004619F	TNC	17.03.2022
2	RTD Sensor with Indicator	GC/AV/P1398A/08/21	GC	12.08.2022
3	Std. Weights	CC205521000004622F	TNC	17.03.2022
4	Digital Weighing Machine	CC205520000004620F	TNC	17.03.2022
5	Electrical Safety Analyzer	CCTPL/DAM/0009/02	CCTPL	19.01.2023

The Standards used for calibration are traceable to National Standards.

CALIBRATION RESULT

PARAMETER	DUC VALUE(µl)	STANDARD VALUE(µl)	ERROR(µl)	Uncertainty± (µl)
Volume	200	200.45	-0.45	4.0
	500	500.27	-0.27	4.0
PARAMETER	**DUC VALUE(µm)**	**STANDARD VALUE(µm)**	**ERROR(µm)**	**Uncertainty± (µm)**
Cell Diameter	10	10.02	-0.02	0.4
	30	30.04	-0.04	0.4
	50	50.07	-0.07	0.4
PARAMETER	**DUC VALUE(count)**	**STANDARD VALUE(count)**	**ERROR(count)**	**Uncertainty± (count)**
Count Data Storage	200	201	-1	0.4
	500	502	-2	0.4
	1000	1002	-2	0.4
PARAMETER	**DUC VALUE(count)**	**STANDARD VALUE(count)**	**ERROR(count)**	**Uncertainty± (count)**
Protocol Storage	100	101	-1	0.4
	200	201	-1	0.4
	300	302	-2	0.4
Maxima Found at	**Standard Wavelength**		**Tolerance Limit**	
365nm	365.60nm		(upto 400 nm)±1nm	
537nm	536.40nm		(400 upto 600 nm)±3nm	
600nm	631.30nm		(600 upto 800 nm)±4nm	
PARAMETER	**DUC VALUE (°C)**	**STANDARD VALUE(°C)**	**ERROR(°C)**	**Uncertainty± (%)**
Temperature	25.0	25.003	-0.003	0.95
	30.0	30.008	-0.008	0.95
	35.0	35.043	-0.043	0.95

Expanded Uncertainty of measurment at approximately 95% Confidence Level with coverage factor $k = 2$

Note :-
1. DUC = Device Under Calibration
2. The Certificate refers only to the particular items submitted for Calibration.
3. This Certificate shall not be reproduced, except in full, without permission of CEO Hytech Instrument, Ghaziabad.
4. Result Reported are Valid at the time of and under the stated conditions of measurement.
5. Calibration Certificate issue for weight & Measure parameters i.e. Mass, Balance, Volumetric equipment, Measuring Scale/Tapes etc. for scientific purpose only and should not be used for Trade / Commerical use.

CALIBRATED BY
(Calib. Engineer)

APPROVED BY
(QM / TM)

HYTECH INSTRUMENT HYTECH GHAZIABAD (U.P)

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

NABL Certificate No PC - 1002

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

EQAP CODE No. : 2834 **Distribution No.:** 155-G **Month/Year:** March/2022

Instrument ID: ErmaPCE 210,S.N-29210

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: 11-05-2022[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	6.4	6.3	12.7	12.4	0.0660	0.23	0.1	0.11	0.0120	-0.06
RBC x10^6/µl	1	4.42	4.37	8.79	8.19	0.0100	2.42	0.05	0.03	0.0030	0.54
Hb g/dl	1	11.3	11.2	22.5	24.4	0.0300	-2.85	0.1	0.1	0.0080	0.00
HCT%	1	35.6	35.4	71	71.8	0.1490	-0.22	0.2	0.4	0.0280	-0.54
MCV-fl	1	81	80.5	161.5	176.3	0.3030	-2.01	0.5	0.4	0.0290	0.20
MCH-Pg	1	25.8	25.3	51.1	59.7	0.0880	-4.00	0.5	0.2	0.0180	1.35
MCHC-g/dl	1	31.9	31.4	63.3	67.4	0.1350	-1.09	0.5	0.3	0.0240	0.57
Plt. x10^3/µl	1	207	207	414	388	1.73	0.65	0	7	0.42	-1.18
Retic %	2	6	5	11	12.4	0.26	-0.21	1	0.4	0.03	1.35

P.S . Assesment

	YOUR REPORT		CONSENSUS REPORT
DLC%	3	Nrbcs= , Poly=55 L=05, E=02, Mono/Promono= , B1=05 P.M.=10, Mye=08, Meta=13, Other=2% band cells	Poly: 40 – 55, Myelo: 14 - 25, Meta: 7 – 16, Blast: 2-8, Lympho: 2-6 , Promyelo: 1-5 nRBC/Eos/Baso/Mono: 0 – 5
RBC Morphology	3	Normocytic normochromic, mild poikilocytosis with schistiocytes & target cells	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, hypochromia, Microcytosis; Mild: Macrocytosis, Poikilocytosis
Diagnosis	3	Chronic myeloid leukemia	Chronic Myeloid Leukemia (Chronic Phase)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 155--G	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 $x10^3/\mu l$	1	264	262	82.06	84.35	3.44	3.44	14.5	12.21
RBC $x10^6/\mu l$	1	264	264	90.15	88.26	4.92	5.3	4.93	6.44
Hb g/dl	1	264	264	85.98	89.39	7.95	4.17	6.07	6.44
HCT%	1	264	262	89.31	90.08	7.25	4.58	3.44	5.34
MCV-fl	1	264	262	89.69	91.98	8.02	2.29	2.29	5.73
MCH-Pg	1	264	262	89.69	90.46	6.11	4.58	4.2	4.96
MCHC-g/dl	1	264	262	94.27	89.69	4.2	4.58	1.53	5.73
Plt. $x10^3/\mu l$	1	264	261	87.74	88.51	7.66	4.21	4.6	7.28
ReticCount%	2	264	264	90.53	86.74	1.89	5.68	7.58	7.58
PS Assessment	3	264	250	Satisfactory :85.62%, Borderline Sat. :10.22%, Unsatisfactory :4.16%					

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).

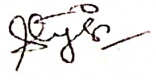
Note-6: ISHTM-AIIMS-EQAP does not subcontract any task of its scheme

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.

Report authorized by,



Dr. Seema Tyagi (Prof.)
PT Co-ordinator: ISHTM-AIIMS-EQAP
Department of Hematology, AIIMS, New Delhi

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

Page 1 of 2

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

NABL Certificate No. PC - 1002

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

EQAP CODE No. : 2834 **Distribution No.:** 154-G **Month/Year:** December/2021

Instrument ID: Erma PCE 210,S.No. 29210

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: 06-03-2022[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	5.3	5.2	10.5	11.49	0.0430	-1.15	0.1	0.1	0.0090	0.00
RBC x10^6/µl	1	4.88	4.57	9.45	8.66	0.0110	3.23	0.31	0.04	0.0030	6.07
Hb g/dl	1	12.8	12.7	25.5	25.5	0.0270	0.00	0.1	0.1	0.0090	0.00
HCT%	1	35.9	34.3	70.2	81.6	0.1940	-2.52	1.6	0.4	0.0290	3.24
MCV-fl	1	78.5	70.2	148.7	188.1	0.3850	-4.15	8.3	0.3	0.0290	17.99
MCH-Pg	1	27.7	26.2	53.9	59	0.0980	-2.55	1.5	0.3	0.0200	4.05
MCHC-g/dl	1	37.3	35.3	72.6	62.6	0.1560	2.75	2	0.2	0.0210	6.07
Plt. x10^3/µl	1	181	167	348	311	1.63	1.00	14	5	0.46	1.73
Retic %	2	7.5	6.5	14	13	0.27	0.17	1	0.5	0.03	0.84

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Nrbcs=1.00 , Poly=57.00 L=1.00, E=5.00, Mono/Promono= , B1=3.00 P.M.=15.00, Mye=6.00, Meta=4.00, Other=0.00	Poly: 40 – 60, Myelo: 11 – 22, Meta: 6 – 14, Blast/nRBC: 1 – 15, Promyelo/Eos/Baso/Lympho/Mono: 0 – 5
RBC Morphology	3	Normocytic normochromic with normoblast seen in smear	Predominantly: Microcytosis, Anisocytosis; Moderate: Hypochromia, Poikilocytosis; Mild: Normocytic/Normochromic, Macrocytosis, Tear drop cells
Diagnosis	3	Chronic myeloid leukemia	Chronic Myeloid Leukemia (CML)

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 154--G	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 $x10^3/\mu l$	1	218	217	82.95	96.31	7.83	1.38	9.22	2.31
RBC $x10^6/\mu l$	1	218	218	89.45	92.66	6.42	3.21	4.13	4.13
Hb g/dl	1	218	218	93.12	93.12	5.05	4.13	1.83	2.75
HCT%	1	218	217	94.93	90.78	3.23	5.53	1.84	3.69
MCV-fl	1	218	217	97.24	93.09	1.84	2.76	0.92	4.15
MCH-Pg	1	218	217	91.71	94.93	6.45	2.76	1.84	2.31
MCHC-g/dl	1	218	217	94.47	88.94	4.15	6.91	1.38	4.15
Plt. $x10^3/\mu l$	1	218	217	92.63	92.17	4.61	4.61	2.76	3.22
ReticCount%	2	218	218	90.37	91.74	9.17	5.96	0.46	2.3
PS Assessment	3	218	206	Satisfactory :90.37%, Borderline Sat. :8.71%, Unsatisfactory :0.91%					

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.

Report authorized by,

Dr. Seema Tyagi (Prof.)
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

NABL Certificate No. MC - 1002

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

EQAP CODE No. : 2834 **Distribution No.:** 153-G **Month/Year:** September/2021

Instrument ID: ERMA PCE 210, 3 PART ANALYSER, S.N. 29210

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: 26-10-2021[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	7.8	7.6	15.4	16.18	0.0590	-0.72	0.2	0.13	0.0130	0.63
RBC x10^6/µl	1	4.42	4.38	8.8	9.08	0.0110	-1.40	0.04	0.04	0.0030	0.00
Hb g/dl	1	10.6	10.5	21.1	23	0.0260	-3.94	0.1	0.1	0.0090	0.00
HCT%	1	36.1	35.6	71.7	74.2	0.2090	-0.53	0.5	0.3	0.0310	0.67
MCV-fl	1	81.6	81.2	162.8	162.5	0.3910	0.03	0.4	0.3	0.0270	0.27
MCH-Pg	1	24.2	23.7	47.9	50.6	0.0670	-2.02	0.5	0.2	0.0180	1.35
MCHC-g/dl	1	29.7	29	58.7	61.8	0.1770	-0.76	0.7	0.3	0.0240	1.35
Plt. x10^3/µl	1	307	281	588	630	2.69	-0.70	26	6	0.53	3.00
Retic %	2	5	4.5	9.5	5.5	0.15	1.10	0.5	0.2	0.02	1.01

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT
DLC%	3	Nrbcs=2% , Poly=10% poly L=81% lympho, 5% prolympho, E=, Mono/Promono= , B1=2% P.M.=, Mye=, Meta=, Other=	Lymp: 80-94, Poly: 4-12, blast: 1-8, nRBC/mono/Eosino/Myelo/Meta: 0-1
RBC Morphology	3	normocytic, normochromic, target cells seen	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Microcytosis, Hypochromia; Mild: Macrocytosis, Poikilocytosis
Diagnosis	3	chronic lymphocytic leukemia	Chronic Lymphocytic Leukemia (CLL)

EQAP Code No.: 2834 *Distribution No.: 153-G* *Month/Year: September/2021* *Instrument ID: ERMA PCE 210, 3 PART ANALYSER, S.N. 29210*

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist.	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 $x10^3/\mu l$	1	187	187	79.14	89.3	8.02	3.74	12.83	6.95
RBC $x10^6/\mu l$	1	187	187	86.63	90.91	7.49	5.88	5.88	3.21
Hb g/dl	1	187	187	88.24	48.66	4.81	0.53	6.95	51.34
HCT%	1	187	187	95.72	89.3	2,67	6.95	1.6	3.74
MCV-fl	1	187	187	96.26	85.56	2.67	8.02	1.07	6.42
MCH-Pg	1	187	187	88.24	91.44	8.56	5.88	3.21	2.67
MCHC-g/dl	1	187	187	94.12	93.05	4.81	4.81	1.07	2.14
Plt. $x10^3/\mu l$	1	187	187	95.19	89.84	3.74	5.88	1.07	4.28
ReticCount%	2	187	173	95.38	86.71	2.89	10.98	0.58	2.89
PS Assessment	3	187	177	Acceptable:83.63%,Warning Signal:8.47%,Unacceptable :7.90%					

Comments:

1). Among Lab (EQA) : CBC result for *HB* 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.

Report authorized by,

Dr. Seema Tyagi (Prof.)
PT Co-ordinator: ISHTM-AIIMS-EQAP
Department of Hematology, AIIMS, New Delhi

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