

RCA FORM OF ILC / PT / EQAS OUTLIERS

Department:	Date: 18/9/21
1. Proficiency test exception for: WBC COUNT	Poport Date:
2. Proficiency test provider: ISHTM AIMS AUGUST 2021 3. Proficiency test analyte group: PEGR METHOD	13/9/21
3. Proficiency test analyte group: PEER METHOD	
4. Cause for PT exception: - WBC Count investigation carried out by Hon [Letter Athached), Butther due to limited f for HORIBA YUMIZEN. However HORIBA YUMIZEN 5. How did the section investigate the cause: Succenfully validated Examples of the Horiba	CEER group data Lon been on BIORAD and JOOX EPAS
6. What was the status of the internal QC on the day PT initially analysed:	
7. Category into which the cause will fit into:	
Method	Technique
Clerical No explanation after investigation	
Problem with PT material Other RANDOM	
8. Evidence that the problem was corrected successfully: - Horiba Team is Wolking on this soncern. - We have enrolled for an additional EPAS 9. Specific corrections taken to prevent the recurrence if possible: O IQC and LJ Chart for WBC is in range. O Enrollment for additional EPAS Programme by N 10. Signatures:: Quality manager:	Programme by NEUPAP: EUPAP [baulti awaited]
Pathologist:	
	₹.



HORIBA India Private Limited

246, Okhla Industrial Estate Phase-III, New Delhi 110020, India Tel :+91 (11) 4646 5000 / 4669 5001 Fax :+91 (11) 4646 5020 https://www.horiba.com CIN :U73100DL2006PTC153232

14th, April 2021

To Whom so ever it may concern

Subject: Proficiency Testing

Dear Sir / Madam,

We would like to inform that performance of HORIBA Yumizen 500/550 has been successfully validated on different Proficiency testing programs, including Bio-Rad (EQAS) & Randox (RIQAS) programs. There are large number of users across the globe including India using Bio-Rad (EQAS) & Randox (RIQAS) successfully.

However, we had received few concerns specially with non-correlation of WBC counts from customers enrolled with AIIMS proficiency testing. In Initial investigation we had observed that there are limited Peer group data for HORIBA Yumizen 500/550 which might be reasons for difference in correlation. However, our technical team is working on the same and any development would be shared shortly.

Thank you for your continued trust in HORIBA Medical products & let us know should you need any additional information.





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

Instrument ID: 710YOXH01128

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:** 13-09-2021[Final].

CBC and Retic Assessment

				Among Lab (Accuracy Testing)			Within Lab (Precision Testing)				
Test Parameters	S.No.	Your Result 1		Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty		Results		Uncertainty of Assigned Values	Z Score
WBC x10³/μl	1	6.85	4.96	11.81	5.5	0.0230	10.84	1.89	0.08	0.0050	27.13
RBC x10 ⁶ /μl	1	3.85	3.82	7.67	7.54	0.0070	0.70	0.03	0.03	0.0020	0.00
Hb g/dl	1	12.1	12	24.1	23.8	0.0200	0.58	0.1	0.1	0.0070	0.00
НСТ%	1	37.8	37. <mark>5</mark>	75.3	74.3	0.1290	0.27	0.3	0.3	0.0230	0.00
MCV-fl	1	98.1	97.9	196	196.6	0.2900	-0.07	0.2	0.3	0.0250	-0.22
MCH-Pg	1	31.5	31.4	62.9	63.1	0.0300	-0.13	0.1	0.2	0.0160	-0.45
MCHC-g/dl	1	32.1	32.1	64.2	64.2	0.1170	0.00	0	0.2	0.0170	-0.90
Plt. x10³/μl	1	141	126	267	222	1.09	1.41	15	4	0.28	2.12
Retic %	2	0.7	0.5	1.2	1.2	0.03	0.00	0.2	0.1	0.01	1.35

P.S. Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3		Poly: 40 - 60, Myelo: 10 - 25, Meta: 5 - 20, Promyelo: 1-10, nRBC/Lympho/Blast/Eos/Baso/Mono: 0 - 5
RBC Morphology	3		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	C No	Total participants Total No.			% of Labs with Z Score 0-2		s with Z e 2-3	% of Labs with Z Score >3	
parameters	S.No.	covered in the current dist.	responded	Among labs	Within lab	Among labs	Within lab	Among labs	Within lab
WBC x10³/μl	1	317	315	84.76	87.94	3.49	1.59	11.75	9.84
RBC x10 ⁶ /μl	1	317	315	92.7	91.11	4.13	3.81	3.17	4.76
Hb g/dl	1	317	315	88.25	91.75	6.67	0.32	5.08	4.44
НСТ%	1	317	315	95.24	90.16	2.22	3.49	2.54	6.03
MCV-fl	1	317	315	96.51	<mark>9</mark> 2.7	2.22	3.17	1.27	4.13
MCH-Pg	1	317	315	88.57	91.75	8.25	3.49	3.17	4.76
MCHC-g/dl	1	317	315	94.6	88.25	3.49	3.17	1.9	8.57
Plt. x10³/μl	1	317	315	93.33	90.48	4.44	4.13	2.22	5.4
ReticCount%	2	317	283	90.46	87.63	4.95	6.71	3.89	5.65
PS Assessment	3	317	296	Acceptable	e:98.65%,W	arning Sig	nal:1.35%	,Unaccepta	ble :0%

*Comments:

- 1). Among Lab (EQA): CBC result for WBC unacceptable, may be due to random/human error
- 2). Within Lab (IQA): Difference in the CBC measurement values for WBC unacceptable, may be due to random/human error.

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 $> \pm 3$: 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 $> \pm 3$ 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-----



RCA FORM OF ILC / PT / EQAS OUTLIERS

	partment: HAEMATOLOGY	Date:	9/9/21
1.	Proficiency test exception for: WBC Febr Proficiency test provider: 15HTM AIIM.	nary 2021 Cycle	Report on 7 2/3/21
2.	Proficiency test provider: 15HTM AIM.	5	
3.	Proficiency test analyte group: PEER / METH	to D	
4.	Cause for PT exception: In Initial investigation carried limited feer group data for Horist be the cause of WBC outlier (Horist How did the section investigate the cause: We had escalated the outlier	out by HORIBA, A YUMIZEN 500/550 21BA'S PT Testing &	they observed, this could tatement
5.	How did the section proestigate the cause: We had excalated the outlier	r issue to Hory	Hached) BA.
	However their HORIBA YUMIZEN K What was the status of the internal QC on the day PT	Team is still wo an been successfully of initially analysed: B1	validated in ORAD a
	IPC had passed.	<i>1 K i</i>	ANDOX EQAS
7.	Category into which the cause will fit into:		
	, Method	Technique	
	Clerical No explanation after investi	gation	
4	Problem with PT material Other		
① 9.	Evidence that the problem was corrected successfully Awaiting results of August 2021 / Horisa Team is working on this Specific corrections taken to prevent the recurrence in Wall Williams Will	SHTM EQAS	will be in rest cycle.
(2	Signatures:	n range.	que.
	Quality manager: M-C		
	Pathologist: M. M. C.	•	*



Troubleshooting Guidelines

Method	Technical	Clerical	Problem with PT	No explanation
	95. 9. 26		material	after investigation
Equipment function checks	Misinterpretation / Wrong identification / Wrong labeling	Transcription error	Leaked / broken vial / not fit for analysis	Use this choice only when the investigation has yielded no satisfactory explanation
Scheduled maintenance not carried out or out of acceptable range	Dilution error / incorrect pipetting	Registration of wrong method or method change is not updated	Bacterial contamination	
Problem with data processing functions	Time delay between reconstitution and analysis		Perceived survey bias / inappropriate target value	
Faulty standard or other reagent	0	d	·	
Incorrect calibration	Analysis accepted in nonlinear range		Unstable material	
Carry over from previous specimen	Analysis done even though controls were out of range or controls not assayed		Matrix effect incompatible with method	
Result close to the detection limit of method	QC data within acceptable limits but showed trend suggestive of problem with the assay		No comparable peer group	•
	The second section of the section	7.	Acceptable range too low	
	Sample mix up		Late shipment	, ,
Other method related problem	Other technical problem		Improper package and temperature control	

Note: When all identifiable sources of error have been excluded, a single unacceptable result may be attributed to random error, particularly when the result of repeat analysis is acceptable. In such cases, no corrective action should be taken; as such an action may actually increase the probability of a future unacceptable result.



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14th, April 2021

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However, we had received few concerns specially with non-correlation of WBC counts from customers enrolled with AIIMS proficiency testing. In Initial investigation we had observed that there are limited Peer group data for HORIBA Yumizen 500/550 which might be reasons for difference in correlation. However, our technical team is working on the same and any development would be shared shortly.

Thank you for your continued trust in HORIBA Medical products & let us know should you need any additional information.





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.: 1302 **Distribution No.**: 152-D **Month/Year:** February/2021

Instrument ID: 710YOXH01128

Name & Contact No. of PT Co-ordinator: Dr. Seema Tyagi (Prof.), Hematology, AIIMS, Delhi,

 $\label{eq:compare} Tel: 9013085730 \ , \ E-Mail: accuracy 2000@gmail.com \\ \textbf{Date of issue \& status of the report: } 02-03-2021[Final].$

CBC and Retic Assessment

				Among Lab (Accuracy Testing)				Within Lab (Precision Testing)			
Test Parameters	S.No.	Your Result 1		Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score	Doculte	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score
WBC x10³/μl	1	1.06	0.92	1.98	5.5	0.0200	-6.17	0.14	0.1	0.0050	0.62
RBC x10 ⁶ /μl	1	4.57	4.47	9.04	9.32	0.0080	-1.35	0.1	0.03	0.0020	2.36
Hb g/dl	1	13.7	13.7	27.4	27	0.0200	0.67	0	0.1	0.0070	-1.35
НСТ%	1	39.1	38.3	77.4	83.9	0.1780	-1.11	0.8	0.3	0.0200	1.35
MCV-fl	1	85.8	85.7	171.5	179.9	0.3170	-0.80	0.1	0.2	0.0170	-0.45
МСН-Рд	1	30.6	29.9	60.5	57.7	0.0540	1.84	0.7	0.2	0.0140	2.25
MCHC-g/dl	1	35.7	34.9	70.6	64.15	0.1300	1.44	0.8	0.3	0.0120	1.69
Plt. x10³/μl	1	127	121	248	196	0.75	2.44	6	4	0.26	0.45
Retic %	2	2	1.7	3.7	5	0.08	-0.57	0.3	0.2	0.01	0.34

P.S . Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3	Mono/Promono=3 , B1=- P.M.=-, Mye=-, Meta=-, Other=	nRBC: 30 - 65, Poly: 60 - 75, Lympho: 15-30, Eos/Mono: 1-5, Blast/Myelo/Meta: 0-1
RBC Morphology	3	macrocytes, microcytic hypochromic cells, target cells, tear drop cells, polychromatophils and nucleated erythrocytes	Predominantly: Macrocytosis, Microcytosis, Spherocytosis, Polychromasia, Anisocytosis; Moderate: Normocytic/Normochromic, Hypo.
Diagnosis	3	Haemolytic Anaemia	Hemolytic Anemia

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COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test	C No	C N-	Total participants covered in	Total No.	% of Lab		% of Labs with Z Score 2-3		% of Labs with Z Score >3	
parameters	S.No.	the current dist.	responded	Among labs	Within lab	Among labs	Within lab	Among labs	Within lab	
WBC x10³/μl	1	312	346	89.31	92.2	2.31	1.45	8.38	6.36	
RBC x10 ⁶ /μl	1	312	346	89.88	91.04	6.94	3.47	3.18	5.2	
Hb g/dl	1	312	347	91.07	99.42	6.92	3.17	2.02	0.58	
HCT%	1	312	346	97.69	92.2	1.73	3.47	0.58	4.34	
MCV-fl	1	312	345	97.68	86.09	1.45	8.99	0.87	4.93	
MCH-Pg	1	312	346	91.62	91.04	6.07	3.47	2.31	5.49	
MCHC-g/dl	1	312	346	98.55	92.2	0.29	3.76	1.16	3.76	
Plt. x10³/μl	1	312	346	93.35	91.91	3.47	5.49	3.18	2.6	
ReticCount%	2	312	318	93.71	86.48	4.09	2.2	2.2	11.64	
PS Assessment	3	312	312	Acceptable	:91.4,Warı	Acceptable:91.4,Warning Signal:7.7,Unacceptable:0.9				

*Comments:

- 1). Among Lab (EQA): CBC result for WBC 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 $> \pm 3$ 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.ishtmaiimsegap.com.

Report authorized by,

Dr. Seema Tyagi (Prof.)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

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



RCA FORM OF ILC / PT / EQAS OUTLIERS

Dep	epartment: HAE MATOLOGY Date: 1/	12/20
1.	Proficiency test exception for: WBC COUNT (AUGUST 2020 (yde) Re	PORTED ON
2.	<u></u>	
3.	Proficiency test analyte group: PEER / METHOD	
	/	Wise) cy Wise
5.	How did the section investigate the cause: Investigated for Random Error.	
6.	What was the status of the internal QC on the day PT initially analysed: faxed	
7.	Category into which the cause will fit into:	
ža,	Method Tecl	nnique
	Clerical No explanation after investigation	
	Problem with PT material Other	1 1
8. ₇	passed and LI graphs were passed.	
9.	Intrument Clean. Up is given daily and will be	prior to
10.	0. Signatures ::	•
	Quality manager:	
.3	Pathologist:	
		*



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

Instrument ID: 710YOXH01128

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:** 27-11-2020[Final].

CBC and Retic Assessment

				Among Lab (Accuracy Testing)				Within Lab (Precision Testing)			
Test Parameters	S.No.	Your Result 1		Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty		Results		Uncertainty of Assigned Values	Z Score
WBC x10³/μl	1	3.18	2.7	5.88	9.8	0.0460	-2.76	0.48	0.1	0.0060	3.66
RBC x10 ⁶ /μl	1	3.2	3.18	6.38	6.4	0.0060	-0.11	0.02	0.03	0.0010	-0.27
Hb g/dl	1	11.5	11.4	22.9	23.4	0.0210	-0.84	0.1	0.1	0.0070	0.00
НСТ%	1	34.9	34.7	69.6	72.05	0.1860	-0.40	0.2	0.3	0.0200	-0.27
MCV-fl	1	109.1	109	218.1	223.5	0.4950	-0.31	0.1	0.3	0.0230	-0.45
MCH-Pg	1	36	35.8	71.8	73.2	0.0760	-0.67	0.2	0.3	0.0200	-0.34
MCHC-g/dl	1	33	32.8	65.8	65.3	0.1640	0.09	0.2	0.3	0.0200	-0.34
Plt. x10³/μl	1	276	275	551	512	1.38	1.02	1	6	0.32	-0.87
Retic %	2	3.5	3	6.5	7.2	0.13	-0.19	0.5	0.3	0.02	0.72

P.S. Assesment

		YOUR REPORT	CONSENSUS REPORT
DLC%	3		Poly: 25-50, Lymph; 2-7, nRBC/Mono/Eo/Blast/Pro: 0-5, Myelo: 20-35, Meta: 15-25, Baso: 0-3
RBC Morphology	3	1 "	Predominantly: Normocytic Normochromic. Moderate: Anisocytosis. Mild: Microcytic
Diagnosis	3	Acute Myeloid Leukemia	Chronic Myeloid Leukemia (Chronic Phase) : CML-CP

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 x10³/μl	1	450	362	88.67	86.46	4.7	5.8	6.63	7.73
RBC x10 ⁶ /μl	1	450	3 <mark>62</mark>	88.67	89.23	4.97	6.08	6.35	4.7
Hb g/dl	1	450	363	85.12	90.91	6.34	0.28	8.54	4.68
HCT%	1	450	362	95.03	92.54	3.04	2.76	1.93	4.7
MCV-fl	1	450	361	98.34	<mark>9</mark> 2.8	0.55	3.05	1.11	4.16
MCH-Pg	1	450	361	89.47	91.41	5.54	5.26	4.99	3.05
MCHC-g/dl	1	450	362	97.24	87.29	1.38	6.08	1.38	6.08
Plt. x10³/μl	1	450	362	90.06	91.16	5.25	5.52	4.7	3.31
ReticCount%	2	450	323	92.88	83.59	4.33	1.55	2.79	16.1
PS Assessment	3	450	332	Acceptable:75.4%, Warning Signal:24.6%, Unacceptable:0%					

*Comments:

- 1). Among Lab (EQA): PS partially correct, remaining results acceptable
- 2). Within Lab (IQA): Difference in the CBC measurement values for WBC unacceptable, may be due to random/human error.

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 $> \pm 3$: 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 $> \pm 3$ are texted in red colour.

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