RCA FORM OF ILC / PT / EQAS OUTLIERS

Department:

Date: 18/9/21

1. Proficiency test exception for: WBC COUNT
2. Proficiency test provider: ISHTM AIIMS AUGUST 2021 Report Date:- 13/9/21
3. Proficiency test analyte group: PEER / METHOD
4. Cause for PT exception:
   - WBC Count investigation carried out by HORIBA Team [Letter Attached), Outlier due to limited PEER group data for HORIBA YUMIZEN. However HORIBA YUMIZEN has been Succesfully validated on BIORAD and RANDOX EQAS
5. How did the section investigate the cause:

   Escalated Outlier issue to HORIBA
6. What was the status of the internal QC on the day PT initially analysed:

   IQC HAD PASSED
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 Working on this concern.
   - We have Enrolled for an additional EQAS Programme by NEQAP.
9. Specific corrections taken to prevent the recurrence if possible:
   1. IQC and LJ Chart for WBC is in range.
   2. Enrollment for additional EQAS Programme by NEQAP [Results awaited]
   3. WBC under observation
10. Signatures ::

    Quality manager:

    Pathologist:

HORIBA

HORIBA India Private Limited

246, Okhla Industrial Estate Phase-III,
New Delhi 110020, India
Tel : +91 (11) 4646 5000 / 4669 5001
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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.

HORIBA India Private Limited New Delhi

Thanking with Regards

F-PD-WF/QSP/12-RILC PRIMA DIAGNOSTICS

RCA FORM OF ILC / PT / EQAS OUTLIERS

Department: HAEMATOLOGY **Date:** 9/9/21

1. Proficiency test exception for: WBC [February 2021 Cycle. Report on 2/3/21]
2. Proficiency test provider: ISHTM AIIMS
3. Proficiency test analyte group: PEER / METHOD
4. Cause for PT exception:
In Initial investigation carried out by HORIBA, they observed limited Peer group data for HORIBA YUMIZEN 500/550, this could be the cause of WBC outlier. (HORIBA's PT Testing Statement Attached)
5. How did the section investigate the cause:
We had escalated the outlier issue to HORIBA. They state that their Technical Team is still working on it. However their HORIBA YUMIZEN has been successfully validated on BIORAD & RANDOX EQAS
6. What was the status of the internal QC on the day PT initially analysed:
IQC had passed.
7. Category into which the cause will fit into:

Method	☐	Technique	☐
Clerical	☐	No explanation after investigation	☐
Problem with PT material	☐	Other	☑

8. Evidence that the problem was corrected successfully:
① Awaiting results of August 2021 ISHTM EQAS
② HORIBA Team is working on this concern ③ Problem will be rectified in next cycle.
9. Specific corrections taken to prevent the recurrence if possible:
① WBC Parameter under observation
② IQC & LJ chart for WBC is in range.
10. Signatures ::

Quality manager: M.M.C

Pathologist: M.M.C

Troubleshooting Guidelines

Method	Technical	Clerical	Problem with PT material	No explanation 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	Calculation error			
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	
			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.

HORIBA India Private Limited New Delhi

Thanking with Regards

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, Tel: 9013085730 , E-Mail : accuracy2000@gmail.com

Date of issue & status of the report: 02-03-2021[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	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**
HCT%	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**
MCH-Pg	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. x10^3/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	Nrbcs=41 , Poly=30/3 L=22, E=1, 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

EQAP Code No.: 1302 Distribution No.: 152-D Month/Year: February/2021 Instrument ID: 710YOXH01128

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/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. x10^3/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,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 > ±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

Department: HAEMATOLOGY **Date:** 1/12/20

1. Proficiency test exception for: WBC COUNT (AUGUST 2020 Cycle) REPORTED ON 27/11/20
2. Proficiency test provider: ISHTM AIIMS EQAS
3. Proficiency test analyte group: PEER / METHOD
4. Cause for PT exception:
   Accuracy for WBC is within range (Correct Method Wise)
   Precision Testing Value is 3.66, hence acceptable Accuracy 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: Passed
7. Category into which the cause will fit into:
   - ☐ Method
   - ☐ Technique
   - Clerical ☐
   - ☐ No explanation after investigation
   - Problem with PT material ☐
   - Other ☑
8. Evidence that the problem was corrected successfully: The same day's QC had passed and LJ graphs were passed.
9. Specific corrections taken to prevent the recurrence if possible:
   Instrument clean up is given daily and will be done prior to running EQAS sample along with QC pass check.
10. Signatures ::

    M.M.C
    Quality manager:

    M.M.C
    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

NABL Certificate No. PC - 1002

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

EQAP CODE No. : 1302 **Distribution No.:** 151-D **Month/Year:** August/2020

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

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	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**
HCT%	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. x10^3/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	Nrbcs=2 , Poly=15/9 L=2, E=4, Mono/Promono=1 , B1=22 P.M.=18, Mye=17, Meta=10, Other=-	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	Normocytic normochromic with few macrocytes.	Predominantly: Normocytic Normochromic. Moderate: Anisocytosis. Mild: Microcytic
Diagnosis	3	Acute Myeloid Leukemia	Chronic Myeloid Leukemia (Chronic Phase) : CML-CP

EQAP Code No.: 1302 Distribution No.: 151-D Month/Year: August/2020 Instrument ID: 710YOXH01128

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	
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WBC x10^3/µl	1	450	362	88.67	86.46	4.7	5.8	6.63	7.73
RBC x10^6/µl	1	450	362	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	92.8	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. x10^3/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.
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