

Lab Id / Name : 1013 / VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS HEALTHCARE PVT LTD)

Analyzer : Mindray BC 760													
Analyte	Unit	Round Nos.											
		01	02	03	04	05	06	07	08	09	10	11	12
Erythrocyte (RBC) Count	mill/cu.mm	-	-	-0.21	-	-	-	-	-	-	-	-	-
Haemoglobin	g/dL	-	-	0.19	-	-	-	-	-	-	-	-	-
Hematocrit	%	-	-	0.84	-	-	-	-	-	-	-	-	-
MCH (Mean Corpuscular Hb)	pg	-	-	0.8	-	-	-	-	-	-	-	-	-
MCHC (Mean Corpuscular Hb Concentration)	g/dL	-	-	-0.73	-	-	-	-	-	-	-	-	-

Legend :

- : Average SDI less than 3: with z score of one or more sample >2 but < 3
- : Average SDI >= 3: z score >=3 in one or more than one sample
- : Average SDI less than 3 : z score >= 3 in one sample
- : Average SDI less than 3: z score >=3 in more than one sample
- : Average SDI ≤ 2; with z score for all samples less than equal to 2
- : Delayed Result Entry

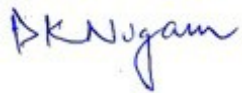
Lab Id / Name : 1013 / VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS HEALTHCARE PVT LTD)

Analyzer : Mindray BC 760													
Analyte	Unit	Round Nos.											
		01	02	03	04	05	06	07	08	09	10	11	12
MCV (Mean Corpuscular Volume)	fL	-	-	1.55	-	-	-	-	-	-	-	-	-
Platelet Count	1000/ μ L	-	-	-5.93 ■	-	-	-	-	-	-	-	-	-
RDW CV%	%	-	-	-1.82 ■	-	-	-	-	-	-	-	-	-
Total Leucocytes (WBC) count	/c.mm	-	-	0.22	-	-	-	-	-	-	-	-	-

- Legend :**
- : Average SDI less than 3: with z score of one or more sample >2 but <3
 - : Average SDI ≥ 3 : z score ≥ 3 in one or more than one sample
 - : Average SDI less than 3 : z score ≥ 3 in one sample
 - : Average SDI less than 3: z score ≥ 3 in more than one sample
 - : Average SDI ≤ 2 ; with z score for all samples less than equal to 2
 - : Delayed Result Entry

Lab Id / Name : 1013 / VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS HEALTHCARE PVT LTD)

EQAS SCORE	-	-	88.89%	-	-	-	-	-	-	-	-
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Lab Id / Name : 1013 / VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS HEALTHCARE PVT LTD)

Analyzer : Lifotronic-H8													
Analyte	Unit	Round Nos.											
		01	02	03	04	05	06	07	08	09	10	11	12
HbA1c	%	-	-	-0.58	-	-	-	-	-	-	-	-	-

- Legend :**
- : Average SDI less than 3: with z score of one or more sample >2 but < 3
 - : Average SDI >= 3: z score >=3 in one or more than one sample
 - : Average SDI less than 3 : z score >= 3 in one sample
 - : Average SDI less than 3: z score >=3 in more than one sample
 - : Average SDI ≤ 2; with z score for all samples less than equal to 2
 - : Delayed Result Entry

Lab Id / Name : 1013 / VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS HEALTHCARE PVT LTD)

EQAS SCORE	-	-	100.00%	-	-	-	-	-	-	-	-	-
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AK Nigam

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Metropolis Healthcare Ltd., EQAS
VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS
HEALTHCARE PVT LTD) (1013)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 230310 and Sample No 03

Report Date : 19/12/2023

Analyte	Instrument	Result Value	Standard Unit	Z-Score
* Platelet Count	Mindray BC 760	0.06	/ μ l	*
Legend @ : z score \leq 2.0 - Acceptable ! : 2.0 < z score < 3.0 - Warning X : z score \geq 3 - Unacceptable # : Not Evaluated ⌚ : Delayed Result Entry * : Not considered for evaluation.				

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____

Dated: _____

Instrument : Mindray BC 760

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
* Platelet Count	1000/ μ L	0.06	69.00	-5.30 *	0.00
@ Erythrocyte (RBC) Count	mill/cu.mm	1.00	0.98	-0.31	-0.21
@ Total Leucocytes (WBC) count	/c.mm	2490.00	2400.00	-0.03	0.22
@ Haemoglobin	g/dL	3.00	2.90	0.09	0.19
@ MCV (Mean Corpuscular Volume)	fL	151.00	148.40	1.78	1.55
@ MCH (Mean Corpuscular Hb)	pg	30.00	29.65	0.82	0.80
@ MCHC (Mean Corpuscular Hb Concentration)	g/dL	19.87	19.99	-0.59	-0.73
@ Hematocrit	%	15.10	14.55	0.83	0.84
@ RDW CV%	%	23.20	26.15	-1.59	-1.82

Legend @ : Acceptable

! : 2.0 < z score < 3.0 - Warning

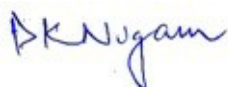
X : z score \geq 3 - Unacceptable

: Not Evaluated

⌚ : Delayed Result Entry

* : Not considered for evaluation.

Total Parameters	9
Not Evaluated Parameters	0
Evaluated Parameters	9
Outlier Parameters (X)	1
EQAS Score Haematology - CBC	88.89 %



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CORRECTIVE & PREVENTIVE ACTIONS

ROOT CAUSE ANALYSIS, CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Date : 22/12/23

Non Compliance Reference
No. <u>1</u> dated <u>19/12/23</u>
Dept: <u>Hematology (RDW-CV)</u>

Incident	'EQAS' Hematology sample no. 4 - Result of RDW-CV showed warning level.
Root cause analysis/Investigation	All Internal controls were under acceptable limits. Calibration is in a place. There was a difference of 6 points than actual mean result. It looks like random error. Done By: <u>Rishi</u> Date & Sign: <u>Rishi</u> <u>22/12/23</u>
Tool Used/ Risk Assessment	Arithmetic Mistake, Brainstorming.
Immediate Correction	Recalibrate the machine & check QC for that time period.
Corrective Action	No issue was identified as far as calibration, internal controls and machines are concern. We have kept the parameter under observation. as RDW-CV is calculating factor and it doesn't affect patients directly. Done By: _____ Date & Sign: _____
Preventive Action	Daily monitoring will done on daily basis and internal controls of both high & low levels will we checked until we received another 'EQAS' sample.
Verification of CAPA Done	Done By: <u>Dr Supriya</u> Date & Sign: <u>Dr</u> <u>23/12/23</u>

Rishi
Prepared By

Shree
Immediate Incharge

Dr
HOD



Metropolis Healthcare Ltd., EQAS
 VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS
 HEALTHCARE PVT LTD) (1013)

Result Details For Cycle No 230310 and Sample No 04

Report Date : 19/12/2023

Instrument : Mindray BC 760

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
@ Erythrocyte (RBC) Count	mill/cu.mm	1.46	1.43	-0.11	-0.21
@ Total Leucocytes (WBC) count	/c.mm	4730.00	4680.00	0.47	0.22
@ Haemoglobin	g/dL	4.50	4.40	0.29	0.19
@ MCV (Mean Corpuscular Volume)	fL	150.60	149.55	1.32	1.55
@ MCH (Mean Corpuscular Hb)	pg	30.82	30.86	0.78	0.80
@ MCHC (Mean Corpuscular Hb Concentration)	g/dL	20.45	20.63	-0.86	-0.73
* Platelet Count	1000/ μ L	0.12	124.00	-6.56 *	0.00
@ Hematocrit	%	22.00	21.30	0.84	0.84
RDW CV%	%	23.80	31.70	-2.04	-1.82

- Legend @ : Acceptable
 ! : 2.0 < z score < 3.0 - Warning
 X : z score \geq 3 - Unacceptable
 # : Not Evaluated
 O : Delayed Result Entry
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Total Parameters	9
Not Evaluated Parameters	0
Evaluated Parameters	9
Outlier Parameters (X)	1
EQAS Score Haematology - CBC	88.89 %

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Corp Office: Off Swami Vivekananda Road, Azad Nagar, Sandoz Baug, P.O. Thane (W), Maharashtra, 400607, India.
Website: www.viomalife.com CIN no: U74999MH2017PTC295120

Patient Name : EQAS 4 HEMAT DEC23

Age / Gender : 4 years / Male

Mobile No. : -

Patient ID : 3772

Source : DIRECT

Scan to Validate



Referral : SELF

Collection Time : Dec 01, 2023, 03:51 p.m.

Receiving Time : Dec 01, 2023, 03:51 p.m.

Reporting Time : Dec 12, 2023, 03:49 p.m.

Sample ID :



002733523

Test Description	Value(s)	Reference Range	Unit(s)
COMPLETE BLOOD COUNT			
Hemoglobin (Hb)* Method : Cynmeth Photometric Measurement	4.5	11.0 - 14.0	gm/dL
Erythrocyte (RBC) Count* Method : Electrical Impedence	1.46	4.0 - 6.2	mil/cu.mm
Packed Cell Volume (PCV)* Method : Calculated	22	34 - 40	%
Mean Cell Volume (MCV)* Method : Electrical Impedence	150.68	75 - 87	fL
Mean Cell Haemoglobin (MCH)* Method : Calculated	30.82	24 - 30	pg
Mean Corpuscular Hb Concn. (MCHC)* Method : Calculated	20.45	31 - 37	gm/dL
Red Cell Distribution Width (RDW)* Method : Electrical Impedence	23.8	11.5 - 14.0	%
Total Leucocytes (WBC) Count* Method : Electrical Impedence	4730	5000-15000	cell/cu.mm
Neutrophils* Method : VCSn Technology	41	23 - 56	%
Lymphocytes* Method : VCSn Technology	1.2	35 - 65	%
Monocytes* Method : VCSn Technology	57.3	3 - 6	%
Eosinophils* Method : VCSn Technology	0.5	0 - 3	%
Basophils* Method : VCSn Technology	0	0 - 1	%
Absolute Neutrophil Count* Method : Calculated	1.94	1.5 - 8	* 10 ⁹ /L
Absolute Lymphocyte Count* Method : Calculated	0.06	6-9	* 10 ⁹ /L
Absolute Monocyte Count* Method : Calculated	2.71	0.2-1.0	* 10 ⁹ /L
Absolute Eosinophil Count* Method : Calculated	0.02	0.1-1.0	* 10 ⁹ /L
Absolute Basophils Count* Method : Calculated	0	0-1	* 10 ⁹ /L
Platelet Count* Method : Electrical Impedence	123	200 - 490	10 ³ /ul
Mean Platelet Volume (MPV)* Method : Electrical Impedence	9.7	7.2 - 11.7	fL



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Outlier And Analyte Summary Report

Outlier Details For Cycle No 230310 and Sample No 04

Report Date : 19/12/2023

Analyte	Instrument	Result Value	Standard Unit
X Neutrophil.	-	<40%	%
# Lymphocyte.	-	>40%	%
Legend @ : Acceptable X : Unacceptable # : Not Evaluated ⌚ : Delayed Result Entry			

Problem Classification: _____

Corrective Action: _____

Reviewed by: _____

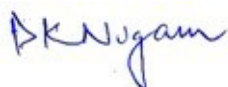
Dated: _____

Instrument : -

Analyte	Standard Unit	Result Value	Accepted Value
X Neutrophil.	-	<40%	40-70%
# Lymphocyte.	-	>40%	
@ Eosinophil.	-	<6%	<6%

Legend @ : Acceptable
 @ : Acceptable
 X : Unacceptable
 # : Not Evaluated
 Ⓞ : Delayed Result Entry

Total Parameters	3
Not Evaluated Parameters	1
Evaluated Parameters	2
Outlier Parameters (X)	1
EQAS Score Haematology-PS Slide Count Qualitative	50.00 %



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CORRECTIVE & PREVENTIVE ACTIONS

ROOT CAUSE ANALYSIS, CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Date : 23/12/23

Non Compliance Reference

No. 4 dated 19/12/23
Dept: Hemat (p. smear)

Incident	Slide was checked manually and found 43 Neutrophils, while filling the report we mistakenly close the option "less than 40" but it should have been "40 to 70".
Root cause analysis/Investigation	It is man made error, instead of selecting option B we went for option A as it was our first time handling 'EQAS'. Done By: ANIKET Date & Sign: <u><i>Aniket</i></u> <u>23/12/23</u>
Tool Used/ Risk Assessment	<u>Brainstorming</u>
Immediate Correction	<u>couldn't correct as it was already passed to the next step.</u>
Corrective Action	It was first time mistake, will be careful and choose the right selection to help get correct result. Done By: ANIKET Date & Sign: <u><i>Aniket</i></u> <u>23/12/23</u>
Preventive Action	Should read manual of the test properly and get good knowledge of tests before feeding the report.
Verification of CAPA Done	Done By: <u>Dr. Rupriya</u> Date & Sign: <u><i>R</i></u> <u>24/12/23</u>

Aniket

Prepared By

Aniket

Immediate Incharge

R

HOD



Metropolis Healthcare Ltd., EQAS
 VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS
 HEALTHCARE PVT LTD) (1013)

Result Details For Cycle No 230310 and Sample No 04

Report Date : 19/12/2023

Instrument : -

Analyte	Standard Unit	Result Value	Accepted Value
X Neutrophil.	-	<40%	40-70%
# Lymphocyte.	-	>40%	
@ Eosinophil.	-	<6%	<6%

Legend @ : Acceptable
 ⊙ : Acceptable
 X : Unacceptable
 # : Not Evaluated
 ⊖ : Delayed Result Entry

Total Parameters	3
Not Evaluated Parameters	1
Evaluated Parameters	2
Outlier Parameters (X)	1
EQAS Score Haematology-PS Slide Count Qualitative	50.00 %

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Date

Patient Name.

Neutro

Lympho

Mono

Eosin

10/12/23

EQAS P.S. 4

43

50

02

05



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VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS
HEALTHCARE PVT LTD) (1013)

Outlier And Analyte Summary Report

Outlier Details For Cycle No 230310 and Sample No 01

Report Date : 19/12/2023

Analyte	Instrument	Result Value	Standard Unit	Z-Score
No Outlier				
Legend @ : z score \leq 2.0 - Acceptable ! : 2.0 < z score < 3.0 - Warning X : z score \geq 3 - Unacceptable # : Not Evaluated ⌚ : Delayed Result Entry * : Not considered for evaluation.				

Problem Classification: _____

Corrective Action: _____

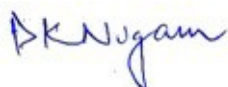
Reviewed by: _____

Dated: _____

Instrument : Lifotronic-H8

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
@ HbA1c	%	6.90	7.20	-0.95	-0.58

Legend @ : Acceptable	Total Parameters	1
! : 2.0 < z score < 3.0 - Warning	Not Evaluated Parameters	0
X : z score ≥3 - Unacceptable	Evaluated Parameters	1
# : Not Evaluated	Outlier Parameters (X)	0
⌚ : Delayed Result Entry	EQAS Score HbA1c	100.00 %
* : Not considered for evaluation.		



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VIOMA LIFESCIENCES PVT LTD(FORMERLY HWELL24 PLUS
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Outlier And Analyte Summary Report

Outlier Details For Cycle No 230310 and Sample No 02

Report Date : 19/12/2023

Analyte	Instrument	Result Value	Standard Unit	Z-Score
No Outlier				
Legend @ : z score \leq 2.0 - Acceptable ! : 2.0 < z score < 3.0 - Warning X : z score \geq 3 - Unacceptable # : Not Evaluated ⌚ : Delayed Result Entry * : Not considered for evaluation.				

Problem Classification: _____

Corrective Action: _____

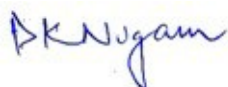
Reviewed by: _____

Dated: _____

Instrument : Lifotronic-H8

Analyte	Standard Unit	Result Value	Mean	Z-Score	RMZ
@ HbA1c	%	5.80	5.86	-0.20	-0.58

Legend @ : Acceptable	Total Parameters	1
! : 2.0 < z score < 3.0 - Warning	Not Evaluated Parameters	0
X : z score ≥3 - Unacceptable	Evaluated Parameters	1
# : Not Evaluated	Outlier Parameters (X)	0
⌚ : Delayed Result Entry	EQAS Score HbA1c	100.00 %
* : Not considered for evaluation.		



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