

Laboratory, Department of Pathology, Care Hospital, Bareilly
RCA/ CAPA FORMAT

Reference NC/ Issue Reference to: EQAS – Biochemistry, CMC Vellore

Details of the NC raised:

- In EQAS of Biochemistry from CMC Vellore on report dated 5/5/ 2022 the SDI for Total bilirubin >3 (-3.03)

Investigation to determine root-cause:

- All inputs including Equipment calibration, reagents, controls, technical manpower, environmental controls like temperature, humidity and storage conditions including fridge temperature etc. was examined for any deficiencies and deviations.
- The Root Case Identified was a Reagent O.D. Error

Implementation of corrective action:

- Fresh Reagent O.D. Taken and Resetting done in the Analyzer

Preventive Action:

- Routine checking of all reagents with respect to their procurement, transport conditions, storage in Laboratory conditions and duration of usage to be followed as per manufacturer guidelines.

Prepared by Technical Incharge:

(Mohd. Hasnain Saifi)

Closed out by: Quality Manager

(Girja Shanker)

Approved by Lab Director:

(DR. Monika Goel)

डॉ० मोनिका गोयल

M.B.B.S., DCP

(पैथोलॉजिस्ट)

REG NO- 08-6177



Laboratory, Department of Pathology, Care Hospital, Bareilly

RCA/ CAPA FORMAT

Reference NC/ Issue Reference to: EQAS – Biochemistry, CMC Vellore

Details of the NC raised:

- In EQAS of Biochemistry from CMC Vellore on report dated 6/4/ 2022 the SDI for Total protein >3 (6.7)

Investigation to determine root-cause:

- All inputs including Equipment calibration, reagents, controls, technical manpower, environmental controls like temperature, humidity and storage conditions including fridge temperature etc. was examined for any deficiencies and deviations.
- The Root Cause Identified was in the machine with a Machine Filter gain error

Implementation of corrective action:

- A service by the company service provider alongwith a preventive maintenance was done to rectify the error.

Preventive Action:

- The issue to be logged and cross checked again in the next routine preventive maintenance service to ensure the same problem does not arise again.

Prepared by Technical Incharge: *Sayee*

Mohd. Hasreen Saifi

Closed out by: Quality Manager

C. S. Shanker
Girja Shanker

Approved by Lab Director: *Dr. Monika Goel*

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REG NO- 08-6177



Laboratory, Department of Pathology, Care Hospital, Bareilly
RCA/ CAPA FORMAT

Reference NC/ Issue Reference to: EQAS – Biochemistry, CMC Vellore

Details of the NC raised:

- In EQAS of Biochemistry from CMC Vellore on report dated 03/01/2022 the SDI for Triglyceride >3 (6.31)

Investigation to determine root-cause:

- All inputs including Equipment calibration, reagents, controls, technical manpower, environmental controls like temperature, humidity and storage conditions including fridge temperature etc. was examined for any deficiencies and deviations.
- The Root Cause Identified was a contamination of reagent as the kit was nearing finishing mode

Implementation of corrective action:

- Fresh Reagent kit was calibrated with new factor and adsorbance and then used.

Preventive Action:

- Routine checking of all reagents with respect to their procurement, transport conditions, storage in Laboratory conditions and duration of usage to be followed as per manufacturer guidelines.

Prepared by Technical Incharge:

Mohel. Haseen Saifee

Closed out by: Quality Manager

Chirja Shanker

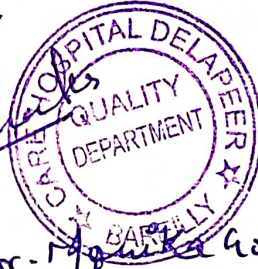
Approved by Lab Director:

डॉ० मोनिका गोयल

M.B.B.S., DCP

(पैथोलॉजिस्ट)

REG NO- 08-6177



VIEW LAB MONTHLY SUMMARY

Lab Name	CARE HOSPITAL	Details About Robust Analysis
Lab No	9041	Detail About Monthly Summary
Month	April	Detail about SDI
Year	2022	
Constituent Group	Chemistry II	

Click on the analyte to view Graphical Data

All Analyser Result

Print

Date of Result Entered : 05/04/2022

Date of Report Published : 05/05/2022

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants CV	Participants SD	Your Value	SDI	U
1	GLUCOSE II	GOD-POD II	Transasia / Erba	799	223.18	10.20	22.77	210 mg/dL	-0.58	1.61
2	UREA II	Others (Urease Berthelot / Ned Dye) II	Any Analyser (Automation / Semi Automation)	784	38.76	12.99	5.03	42.62 mg/dL	0.77	0.36
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Transasia / Erba	518	4.68	10.61	0.50	4.28 mg/dL	-0.80	0.04
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Transasia / Erba	703	2.90	11.57	0.34	1.87 mg/dL	-3.03	0.03
5	T-PROTEIN II	Biuret - Colorimetric II	Transasia / Erba	672	5.80	8.17	0.47	5.84 g/dL	0.08	0.04
6	ALBUMIN II	BCG - Colorimetric II	Transasia / Erba	649	3.38	8.14	0.28	2.97 g/dL	-1.49	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Transasia / Erba	730	7.12	12.13	0.86	7.06 mg/dL	-0.07	0.06
8	CHOLESTROL II	CHOD-PAP II	Transasia / Erba	754	111.29	11.48	12.78	97 mg/dL	-1.12	0.93
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Transasia / Erba	726	114.85	16.13	18.52	119.7 mg/dL	0.26	1.37

SDI Range	Interpretation
Within -1.00 to +1.00	Excellent.
Within ± 1.01 to ± 2.00	Good.
Within ± 2.01 to ± 2.99	Accept with caution. Warning Signal.
Beyond ± 3.0	Unacceptable performance. Action Signal.

VIEW LAB MONTHLY SUMMARY

Lab Name	CARE HOSPITAL	Details About Robust Analysis
Lab No	9041	Detail About Monthly Summary
Month	March	Detail about SDI
Year	2022	
Constituent Group	Chemistry II	

Click on the analyte to view Graphical Data

All Analyser Result

Print

Date of Result Entered : 04/03/2022

Date of Report Published : 06/04/2022

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants CV	Participants SD	Your Value	SDI	U
1	GLUCOSE II	GOD-POD II	Transasia / Erba	791	109.92	9.69	10.65	104 mg/dL	-0.56	0.76
2	UREA II	Others (Urease Berthelot / Ned Dye) II	Any Analyser (Automation / Semi Automation)	741	78.61	11.58	9.11	79.42 mg/dL	0.09	0.67
3	CREATININE II	Jaffes Kinetic- Alkaline Picrate II	Transasia / Erba	459	3.84	11.18	0.43	3.59 mg/dL	-0.58	0.04
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Transasia / Erba	668	1.57	19.28	0.30	1.46 mg/dL	-0.36	0.02
5	T-PROTEIN II	Biuret - Colorimetric II	Transasia / Erba	593	5.34	8.62	0.46	8.42 g/dL	6.7	0.04
6	ALBUMIN II	BCG - Colorimetric II	Transasia / Erba	633	3.15	9.30	0.29	3.62 g/dL	1.60	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Transasia / Erba	637	8.01	11.65	0.93	7.51 mg/dL	-0.54	0.07
8	CHOLESTROL II	CHOD-PAP II	Transasia / Erba	700	105.41	11.28	11.89	101 mg/dL	-0.37	0.90
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Transasia / Erba	679	188.91	11.47	21.66	186 mg/dL	-0.13	1.66

SDI Range	Interpretation
Within -1.00 to +1.00	Excellent.
Within ±1.01 to ±2.00	Good.
Within ±2.01 to ±2.99	Accept with caution. Warning Signal.
Beyond ±3.0	Unacceptable performance. Action Signal.

VIEW LAB MONTHLY SUMMARY

Lab Name	CARE HOSPITAL	Details About Robust Analysis
Lab No	9041	Detail About Monthly Summary
Month	February	Detail about SDI
Year	2022	
Constituent Group	Chemistry II	

Click on the analyte to view Graphical Data

[All Analyser Result](#)

[Print](#)

Date of Result Entered : 08/02/2022

Date of Report Published : 05/03/2022

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants CV	Participants SD	Your Value	SDI	U
1	GLUCOSE II	GOD-POD II	Transasia / Erba	728	278.22	10.88	30.27	253.8 mg/dL	-0.81	2.24
2	UREA II	Others (Urease Berthelot / Ned Dye) II	Any Analyser (Automation / Semi Automation)	774	31.02	13.91	4.32	36.2 mg/dL	1.20	0.31
3	CREATININE II	Jaffes Kinetic- Alkaline Picrate II	Transasia / Erba	480	1.14	12.72	0.14	1.38 mg/dL	1.66	0.01
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Transasia / Erba	614	5.06	11.12	0.56	3.6 mg/dL	-2.59	0.05
5	T-PROTEIN II	Biuret - Colorimetric II	Transasia / Erba	604	5.81	9.02	0.52	6.16 g/dL	0.67	0.04
6	ALBUMIN II	BCG - Colorimetric II	Transasia / Erba	597	3.40	8.90	0.30	3.5 g/dL	0.33	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Transasia / Erba	524	4.45	12.44	0.55	5.01 mg/dL	1.01	0.05
8	CHOLESTROL II	CHOD-PAP II	Transasia / Erba	678	112.37	11.73	13.18	108 mg/dL	-0.33	1.01
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Transasia / Erba	661	88.35	21.56	19.05	87.6 mg/dL	-0.04	1.48

SDI Range	Interpretation
Within -1.00 to +1.00	Excellent.
Within ±1.01 to ±2.00	Good.
Within ±2.01 to ±2.99	Accept with caution. Warning Signal.
Beyond ±3.0	Unacceptable performance. Action Signal.

VIEW LAB MONTHLY SUMMARY

Lab Name	CARE HOSPITAL	Details About Robust Analysis
Lab No	9041	Detail About Monthly Summary
Month	January	Detail about SDI
Year	2022	
Constituent Group	Chemistry II	

Click on the analyte to view Graphical Data

All Analyser Result

Print

Date of Result Entered : 20/01/2022

Date of Report Published : 07/02/2022

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
1	GLUCOSE II	GOD-POD II	Transasia / Erba	687	130.44	8.67	11.30	133.1 mg/dl	0.24	0.86
2	UREA II	Others (Urease Berthelot / Ned Dye) II	Any Analyser (Automation / Semi Automation)	740	47.34	12.33	5.84	54.2 mg/dl	1.18	0.43
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Transasia / Erba	434	1.70	10.33	0.18	1.72 mg/dl	0.11	0.02
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Transasia / Erba	615	2.30	15.28	0.35	2.01 mg/dl	-0.83	0.03
5	T-PROTEIN II	Biuret - Colorimetric II	Transasia / Erba	556	5.38	9.07	0.49	5.82 g/dl	0.90	0.04
6	ALBUMIN II	BCG - Colorimetric II	Transasia / Erba	577	3.15	8.76	0.28	2.87 g/dl	-1.01	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Transasia / Erba	592	7.17	12.44	0.89	7.1 mg/dl	-0.08	0.07
8	CHOLESTROL II	CHOD-PAP II	Transasia / Erba	636	101.83	11.62	11.83	100.3 mg/dl	-0.13	0.94
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Transasia / Erba	577	115.89	15.40	17.85	103.2 mg/dl	-0.71	1.49

SDI Range	Interpretation
Within -1.00 to +1.00	Excellent.
Within ± 1.01 to ± 2.00	Good.
Within ± 2.01 to ± 2.99	Accept with caution. Warning Signal.
Beyond ± 3.0	Unacceptable performance. Action Signal.

VIEW LAB MONTHLY SUMMARY

Lab Name	CARE HOSPITAL	Details About Robust Analysis
Lab No	9041	Detail About Monthly Summary
Month	December	Detail about SDI
Year	2021	
Constituent Group	Chemistry II	

Click on the analyte to view Graphical Data

All Analyser Result

Print

Date of Result Entered : 11/12/2021

Date of Report Published : 03/01/2022

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
1	GLUCOSE II	GOD-POD II	Transasia / Erba	735	220.59	10.06	22.19	175.8 mg/dl	-2.02	1.64
2	UREA II	Others (Urease Berthelot / Ned Dye) II	Any Analyser (Automation / Semi Automation)	762	105.93	13.00	13.77	109.1 mg/dl	0.23	1.00
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Transasia / Erba	488	2.27	9.44	0.21	2.22 mg/dl	-0.23	0.02
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Transasia / Erba	649	2.93	11.30	0.33	3.34 mg/dl	1.24	0.03
5	T-PROTEIN II	Biuret - Colorimetric II	Transasia / Erba	665	5.34	9.22	0.49	5.7 g/dl	0.73	0.04
6	ALBUMIN II	BCG - Colorimetric II	Transasia / Erba	650	3.21	9.20	0.30	3.13 g/dl	-0.27	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Transasia / Erba	637	4.08	14.87	0.61	4.65 mg/dl	0.94	0.05
8	CHOLESTROL II	CHOD-PAP II	Transasia / Erba	716	104.99	12.01	12.61	99.78 mg/dl	-0.41	0.94
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Transasia / Erba	605	85.49	17.53	14.98	180 mg/dl	6.31	1.22

SDI Range	Interpretation
Within -1.00 to +1.00	Excellent.
Within ± 1.01 to ± 2.00	Good.
Within ± 2.01 to ± 2.99	Accept with caution. Warning Signal.
Beyond ± 3.0	Unacceptable performance. Action Signal.

LAB MONTHLY SUMMARY



Lab Name CARE HOSPITAL
 Month November
 Constituent Group Chemistry II

Lab No 9041
 Year 2021



Date of Result Entered : 17/11/2021

Date of Report Published : 03/12/2021

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
1	GLUCOSE II	GOD-POD II	Transasia / Erba	775	144.88	10.50	15.21	141 mg/dl	-0.26	1.09
2	UREA II	Others (Urease Berthelot / Ned Dye) II	Any Analyser (Automation / Semi Automation)	844	43.73	12.85	5.62	44 mg/dl	0.05	-0.39
3	CREATININE II	Jaffes Kinetic-Alkaline Picrate II	Transasia / Erba	484	9.03	13.47	1.22	8.56 mg/dl	-0.39	0.11
4	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Transasia / Erba	699	2.27	16.68	0.38	2.1 mg/dl	-0.45	0.03
5	T-PROTEIN II	Biuret - Colorimetric II	Transasia / Erba	624	5.52	8.94	0.49	5.94 g/dl	0.85	0.04
6	ALBUMIN II	BCG - Colorimetric II	Transasia / Erba	634	3.25	9.15	0.30	3.22 g/dl	-0.10	0.02
7	URIC ACID II	Enzymatic / Uricase Colorimetric II	Transasia / Erba	665	8.17	14.31	1.17	8.28 mg/dl	0.09	0.09
8	CHOLESTROL II	CHOD-PAP II	Transasia / Erba	734	108.76	10.65	11.58	135.1 mg/dl	2.27	0.85
9	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Transasia / Erba	675	145.97	13.24	19.32	183 mg/dl	1.92	1.49

SDI Range	Interpretation
Within -1.00 to +1.00	Excellent.
Within ± 1.01 to ± 2.00	Good.
Within ± 2.01 to ± 2.99	Accept with caution. Warning Signal.
Beyond ± 3.0	Unacceptable performance. Action Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

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Contact Number: 0416-2283102

Pamela Christudoss

Dr. Pamela Christudoss
 CMC EQAS Co-Ordinator
 Christian Medical College, Vellore

***** End of Report *****