



CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY
CMC EXTERNAL QUALITY ASSURANCE SCHEME
MONTHLY SUMMARY REPORT - JUNE 2023



Lab Name Govt. UPHC, Arcot Lab No 9367
Constituent Group Chemistry III Date of Result Entered : 21/06/2023
PT item Lyophilized human serum based Date of Report Published : 04/07/2023

Sl. No.	Parameter	Method	Instrument	Result	Target	Delta	Delta	Delta	Delta	Delta
1	GLUCOSE III	GOD-POD III	Robonik (Semi automatic / Fully Automatic)	1823	286.63	5.17	14.82	159 mg/dL	-8.61	0.69
2	CREATININE III	Jaffes Kinetic - Alkaline Picrate III	Robonik (Semi automatic / Fully Automatic)	1848	2.57	6.64	0.17	1.8 mg/dL	-4.53	0.01
3	CHOLESTROL III	CHOD-PAP III	Robonik (Semi automatic / Fully Automatic)	1804	113.73	4.46	5.07	102 mg/dL	-2.31	0.24

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 ADDRESS :
Govt. UPHC, Arcot
THE MEDICAL OFFICER, ARNI ROAD, TOPUKANNA, ARCOT
Arcot
TAMILNADU632503

Coordinator Contact Details:
Email: clinqc@cmcvellore.ac.in
Contact Number: 0416-2283102

Pamela Christudoss
Dr. Pamela Christudoss
CMC EQAS Coordinator
Christian Medical College, Vellore

Homogeneity and Stability of the sample is passed.
Data in CMC EQAS reports is confidential
CMC EQAS does not sub contract any components
***** End of Report *****

R. Vijay
MEDICAL OFFICER
URBAN PRIMARY HEALTH CENTRE
ARCOT, RANIPET DISTRICT - 632 503.

CORRECTIVE AND PREVENTIVE ACTION (CAPA) REPORT

CAPA NO	: AUPHC_LAB_CAPA001
ISSUE DATE	: 05/07/2023
PRODUCT OF PROCESS	: Creatinine
CUSTOMER	: Government Urban Primary Health Centre, Arcot
BATCH/LOT NO & MANUFACTURER	: CMC Vellore, EQAS June 2023

SECTION 1: PROBLEM IDENTIFICATION

DESCRIPTION OF PROBLEM:

CMC EQAS Failed for Creatinine Parameter. The SDI Range for Creatinine is -4.53 (Acceptable Limit \pm 2.0)

Arcot Urban PHC Value for Creatinine is 1.8 whereas CMC derived value is 2.57

EVIDENCE: Photograph Email Verbal Other Not Applicable

SOURCE : Instrument Generated Result

CAPA INITIATOR : Poomani Lab Technician Gr-III

DATE : 05/07/2023

PROCESS : Biochemical Analysis

SECTION 2: INVESTIGATION

SOURCE CAUSE OF NON-CONFORMITY: PRODUCT PROCESS QUALITY SYSTEM

RESULT OF ROOT CAUSE ANALYSIS

Instrument maintenance and pump calibration not done for a prolonged time

INVESTIGATION TEAM

NAME	DEPARTMENT	SIGNATURE	DATE
Poomani R	Laboratory Technician	<i>R. Poomani</i>	10/07/2023
Dr. Jayaprakash	Medical Officer	<i>R. Jayaprakash</i>	10/07/2023

SECTION 3: CORRECTIVE & PREVENTIVE ACTION

TYPE OF ACTION REQUIRED:

TYPE OF ACTION	ACTION DESCRIPTION				
CORRECTIVE ACTION	Called Boi-Medical service Engineer, complete maintenance and calibration done for semi auto analyser.				
RESPONSIBLE PERSON	Poomani R	DUE DATE	05/08/2023	COMPLETION DATE	10/07/2023
PREVENTIVE ACTION	CMC EQAS (Lyophilized form of sample) should be kept room temperature for 20 minutes (after taken out from the refrigerator) before aliquot. Further proceed with aliquotion with sterile water and wait until complete dissolve of lyophilized form of sample. (Atleast 30 minutes).				
RESPONSIBLE PERSON	Poomani R	DUE DATE	05/08/2023	COMPLETION DATE	10/07/2023

PROCESS OWNER FOR IMPLEMENTATION: Poomani R Lab Technician Gr-III

SIGNATURE: *R. Poomani*

SECTION 4: REVIEW


TYPE OF ACTION REQUIRED:			
CHANGES MADE AS PER ACTION	EVIDENCES REVIEWED	DEPARTMENT	DATE
Sterile water to be used for aliquotion of CMC EQAS Sample (Lyophilized form)Process has been changed.	Reviewed	Laboratory	10/07/2023

COMMENTS OF CAPA COORDINATOR/REVIEWER:

Process has been changed for CMC EQAS sample preparation

CAPA COORDINATOR/REVIEWER NAME: Dr. Jayaprakash. (Medical Officer)

DATE: 10/07/2023


MEDICAL OFFICER
URBAN PRIMARY HEALTH CENTRE
ARCOT, RANIPET DISTRICT - 632 503


SECTION 5: CAPA CLOSURE

COMMENTS:

Instrument needs to be Standardised for once in a week.

CAPA COORDINATOR/REVIEWER NAME: Dr. Jayaprakash. (Medical Officer)

DATE: 10/07/2023


MEDICAL OFFICER
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CORRECTIVE AND PREVENTIVE ACTION (CAPA) REPORT

CAPA NO	: AUPHC_LAB_CAPA002
ISSUE DATE	: 05/07/2023
PRODUCT OF PROCESS	: Glucose
CUSTOMER	: Government Urban Primary Health Centre, Arcot
BATCH/LOT NO & MANUFACTURER	: CMC Vellore, EQAS June 2023

SECTION 1: PROBLEM IDENTIFICATION

DESCRIPTION OF PROBLEM:

CMC EQAS Failed for Glucose Parameter. The SDI Range for Glucose is -8.61 (Acceptable Limit ± 2.0)

Arcot Urban PHC Value for Glucose is 159 whereas CMC derived value is 286.63

EVIDENCE: Photograph Email Verbal Other Not Applicable

SOURCE : Instrument Generated Result

CAPA INITIATOR : Poomani Lab Technician Gr-III

DATE : 05/07/2023

PROCESS : Biochemical Analysis

SECTION 2: INVESTIGATION

SOURCE CAUSE OF NON-CONFORMITY: PRODUCT PROCESS QUALITY SYSTEM

RESULT OF ROOT CAUSE ANALYSIS

Instrument maintenance and pump calibration not done for a prolonged time

INVESTIGATION TEAM

NAME	DEPARTMENT	SIGNATURE	DATE
Poomani R	Laboratory Technician	<i>R. Poomani</i>	10/07/2023
Dr. Jayaprakash	Medical Officer	<i>P. Jayaprakash</i>	10/07/2023

SECTION 3: CORRECTIVE & PREVENTIVE ACTION

TYPE OF ACTION REQUIRED:

TYPE OF ACTION	ACTION DESCRIPTION				
CORRECTIVE ACTION	Called Boi-Medical service Engineer, complete maintenance and calibration done for semi auto analyser.				
RESPONSIBLE PERSON	Poomani R	DUE DATE	05/08/2023	COMPLETION DATE	10/07/2023
PREVENTIVE ACTION	CMC EQAS (Lyophilized form of sample) should be kept room temperature for 20 minutes (after taken out from the refrigerator) before aliquot. Further proceed with aliquotion with sterile water and wait until complete dissolve of lyophilized form of sample. (Atleast 30 minutes).				
RESPONSIBLE PERSON	Poomani R	DUE DATE	05/08/2023	COMPLETION DATE	10/07/2023

PROCESS OWNER FOR IMPLEMENTATION: Poomani R Lab Technician Gr-III

SIGNATURE: *R. Poomani*

SECTION 4: REVIEW

TYPE OF ACTION REQUIRED:

CHANGES MADE AS PER ACTION	EVIDENCES REVIEWED	DEPARTMENT	DATE
Sterile water to be used for aliquotion of CMC EQAS Sample (Lyophilized form)Process has been changed.	Reviewed	Laboratory	10/07/2023

COMMENTS OF CAPA COORDINATOR/REVIEWER:
Process has been changed for CMC EQAS sample preparation

CAPA COORDINATOR/REVIEWER NAME: Dr. Jayaprakash. (Medical Officer)
DATE: 10/07/2023

R. Jayaprakash
MEDICAL OFFICER
URBAN PRIMARY HEALTH CENTRE
ARCOT, RANIPET DISTRICT - 632 503.

SECTION 5: CAPA CLOSURE

COMMENTS:
Instrument needs to be Standardised for once in a week.

CAPA COORDINATOR/REVIEWER NAME: Dr. Jayaprakash. (Medical Officer)
DATE: 10/07/2023

R. Jayaprakash
MEDICAL OFFICER
URBAN PRIMARY HEALTH CENTRE
ARCOT, RANIPET DISTRICT - 632 503.

ORRECTIVE AND PREVENTIVE ACTION (CAPA) REPORT

CAPA NO	: AUPHC_LAB_CAPA003
ISSUE DATE	: 05/07/2023
PRODUCT OF PROCESS	: Cholesterol
CUSTOMER	: Government Urban Primary Health Centre, Arcot
BATCH/LOT NO & MANUFACTURER	: CMC Vellore, EQAS June 2023

SECTION 1: PROBLEM IDENTIFICATION

DESCRIPTION OF PROBLEM:

CMC EQAS Failed for Cholesterol Parameter. The SDI Range for Cholesterol is -2.31 (Acceptable Limit ± 2.0)

Arcot Urban PHC Value for Cholesterol is 102 whereas CMC derived value is 113.73

EVIDENCE: Photograph Email Verbal Other Not Applicable

SOURCE : Instrument Generated Result

CAPA INITIATOR : Poomani Lab Technician Gr-III

DATE : 05/07/2023

PROCESS : Biochemical Analysis

SECTION 2: INVESTIGATION

SOURCE CAUSE OF NON-CONFORMITY: PRODUCT PROCESS QUALITY SYSTEM

RESULT OF ROOT CAUSE ANALYSIS

Instrument maintenance and pump calibration not done for a prolonged time

INVESTIGATION TEAM

NAME	DEPARTMENT	SIGNATURE	DATE
Poomani R	Laboratory Technician	<i>R. Poomani</i>	10/07/2023
Dr. Jayaprakash	Medical Officer	<i>R. Jayaprakash</i>	10/07/2023

SECTION 3: CORRECTIVE & PREVENTIVE ACTION

TYPE OF ACTION REQUIRED:

TYPE OF ACTION	ACTION DESCRIPTION				
CORRECTIVE ACTION	Called Boi-Medical service Engineer, complete maintenance and calibration done for semi auto analyser.				
RESPONSIBLE PERSON	Poomani R	DUE DATE	05/08/2023	COMPLETION DATE	10/07/2023
PREVENTIVE ACTION	CMC EQAS (Lyophilized form of sample) should be kept room temperature for 20 minutes (after taken out from the refrigerator) before aliquot. Further proceed with aliquotion with sterile water and wait until complete dissolve of lyophilized form of sample. (Atleast 30 minutes).				
RESPONSIBLE PERSON	Poomani R	DUE DATE	05/08/2023	COMPLETION DATE	10/07/2023

PROCESS OWNER FOR IMPLEMENTATION: Poomani R Lab Technician Gr-III

SIGNATURE: *R. Poomani*

SECTION 4: REVIEW


TYPE OF ACTION REQUIRED:			
CHANGES MADE AS PER ACTION	EVIDENCES REVIEWED	DEPARTMENT	DATE
Sterile water to be used for aliquotion of CMC EQAS Sample (Lyophilized form)Process has been changed.	Reviewed	Laboratory	10/07/2023

COMMENTS OF CAPA COORDINATOR/REVIEWER:

Process has been changed for CMC EQAS sample preparation

CAPA COORDINATOR/REVIEWER NAME: Dr. Jayaprakash. (Medical Officer)

DATE: 10/07/2023


MEDICAL OFFICER
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SECTION 5: CAPA CLOSURE

COMMENTS:

Instrument needs to be Standardised for once in a week.

CAPA COORDINATOR/REVIEWER NAME: Dr. Jayaprakash. (Medical Officer)

DATE: 10/07/2023


MEDICAL OFFICER
URBAN PRIMARY HEALTH CENTRE
ARCOT, RANIPET DISTRICT - 632 503.