

- Sub: PH&PM – Laboratory Services – Implementation of Quality Assurance in PHC Labs - CMC Vellore Biochemistry EQAS Program 2021 Cycle – Guidelines Issued – Regarding
- Ref: 1) Letter from Dept.of Clinical Biochemistry,CMC, Vellore dated 08.01.2021
- 2) Email from Department of Clinical Biochemistry, CMC-Vellore dated 14.12.2020.

The Quality of Laboratory investigation being done in PHC Laboratory is covered under EQAS Program for ensuring delivery of reliable and reproducible lab results to the poor and needy community.

The Dept of Biochemistry, CMC Vellore is conducting an EQAS Program for the Clinical Laboratories. This EQAS Biochemistry Program covers both External Quality Assurance Scheme (EQAS) and Internal Quality Control (IQC). The Chemistry-III Program of EQAS consists of evaluation of the following Biochemical analytes which are essential at the level of PHC Laboratories.

- | | |
|-------------------|-------------------|
| 1.Glucose | 6.Albumin |
| 2.Urea | 7.Uric acid |
| 3.Creatinine | 8.Cholesterol and |
| 4.Total Bilirubin | 9.Triglyceride |
| 5.Total Protein | |

PHC Labs under DPH&PM have been participating in this Program since 2013. In the year 2020, a total of 1861 PHC laboratories (87%) have participated in the CMC-EQAS program and are eligible for Certification. Among the 1861 PHCs, 95-96% of the PHCs have secured Excellent/Good scores indicating the quality of lab services rendered by the PHC labs under DPH&PM vide reference 1st cited.

Human resources is a critical need for the PHC labs and in 2020, a total of 1506 Lab Technicians have been posted by DPH&PM from candidates selected by MRB. Currently all the 2126 PHC Labs are functional with qualified LTs. Hence all the 2126 PHCs under DPH&PM will be brought under the CMC-Vellore, Biochemistry EQAS Program for the year 2021 to ensure that quality of lab investigations carried out in PHC labs vide reference 2nd cited.

In this regard, the following guidelines are issued to all the DDHS for proper implementation of EQAS Program to ensure quality of lab investigations carried out in PHCs

1. All the DDHS are requested to conduct a Review Meeting cum Training for the Lab Technicians of their HUDs in the concerned O/o DDHS during the 1st week of every month.
2. EQAS/IQC Training to the PHC LTs should be immediately conducted by the DDHS.
3. Training on EQAS and IQC protocols should be handled by the concerned District Microbiologist.
4. The District Microbiologist should conduct the EQAS/IQC training based on the Training Module and PowerPoint Presentation prepared by QMS Training Lab, SPHL, O/o DPH&PM, Chennai-6.
5. CMC, Vellore has dispatched EQAS & IQC Samples for a period of 4 months (Jan-April 2021) to all the District Microbiologists at DPHL, IDSP, who are given the responsibility to implement QA Program in PHC Laboratories. All the Lab Technicians of PHCs should be given the EQAS Samples (4 months) and IQC Samples (4 months) by the District Microbiologist at the time of Review / Training.
6. Processing of EQAS and IQC with LJ Charts should be given priority in the training.
7. All the PHC Lab Technicians should be instructed to process the EQAS samples in their place of working using Semiautoanalyzer available in their PHC lab.
8. All the Lab Technicians working in the PHCs should be strictly instructed to maintain an EQAS file in the PHC Lab itself. Concerned District Microbiologist should guide them and ensure that the EQAS file is ready upon inspection.
9. Print out of the EQAS values generated from the Semiautoanalyzer should be maintained in the EQAS file and the same value should be uploaded in the CMC-EQAS portal every month.
10. If the print out could not be taken, EQAS value displayed in the Semiautoanalyzer should be taken a photo followed by print out and the same should be kept in the EQAS file for verification. All PHC Lab Technicians should submit the EQAS value to the concerned Medical Officer for verification and the same should be countersigned every month before uploading the results in CMC-EQAS portal.
- 11. It has been brought to the notice of this Directorate that many Lab Technicians are not testing the EQAS Samples in their PHC instead, they collectively discuss among the fellow Lab Technicians, decide a common value and upload the EQAS value in the CMC portal which is totally unwarranted, unscrupulous and against the ethics of ensuring the lab quality.**
12. The District Microbiologists who have been given the responsibility to monitor the implementation of QA Program also failed to implement it properly eventually leading to this serious lapse in QA Program.

13. Hence all the DDHS should insist that all Lab Technicians should process the EQAS Samples in their place of working using the available Semiautoanalyzer, generate and upload the report every month before the stipulated time line given by CMC, Vellore.
14. If the Semiautoanalyser values are not maintained in the EQAS file, CMC, Vellore will not issue the participation certificate for the QA Program and the concerned LT and the District Microbiologist will be held responsible for the lapses.
15. Any deviation in this activity will lead to initiation of disciplinary proceedings by this Directorate against the erring Lab Technicians and also the concerned District Microbiologist who have failed to monitor these lapses on their side.
16. IQC should be tested on Monday, Tuesday and Thursday as per the protocol enclosed and the values should be plotted on a LJ Chart. This will help us to assess the quality of Reagent used, Performance of the Semiautoanalyzer, Protocol followed & the Skill of Lab Technicians to perform the Lab investigations in PHCs. Medical Officer of PHCs should verify the IQC values with the CMC Reference Ranges and also countersign the IQC Note and LJ Chart.

The DDHS are hereby requested to communicate these guidelines to the concerned Block Medical Officers/Medical Officers and make sure that guidelines are strictly adhered to by the Lab Technicians and District Microbiologist.

Encl: EQAS and IQC Protocols.

T.S.Selvavinayagam
Director of Public Health and
Preventive Medicine, Chennai-6

To
All the Deputy Director of Health Services
PC to DPH&PM OSD (M&F)
PC to DPH&PM OSD (PHCs)
Joint Director of PH&PM (Epidemics)
Joint Director of PH&PM (PHC Inspection)
District Malaria Officer/District Entomologist
District NCD Co-ordinators
Asst. Programme Managers (APM), O/o the DDHS
All the District Microbiologists, DPHL, IDSP
Copy Submitted to
The Mission Director, State Health Society, Chennai – 6.

/ True Copy / Forwarded /


27/01/2021

for Director of Public Health and
Preventive Medicine, Chennai-6

Directorate of Public Health and Preventive Medicine

CMC - Vellore – Biochemistry EQAS Program - 2021

EQAS & IQC General Guidelines

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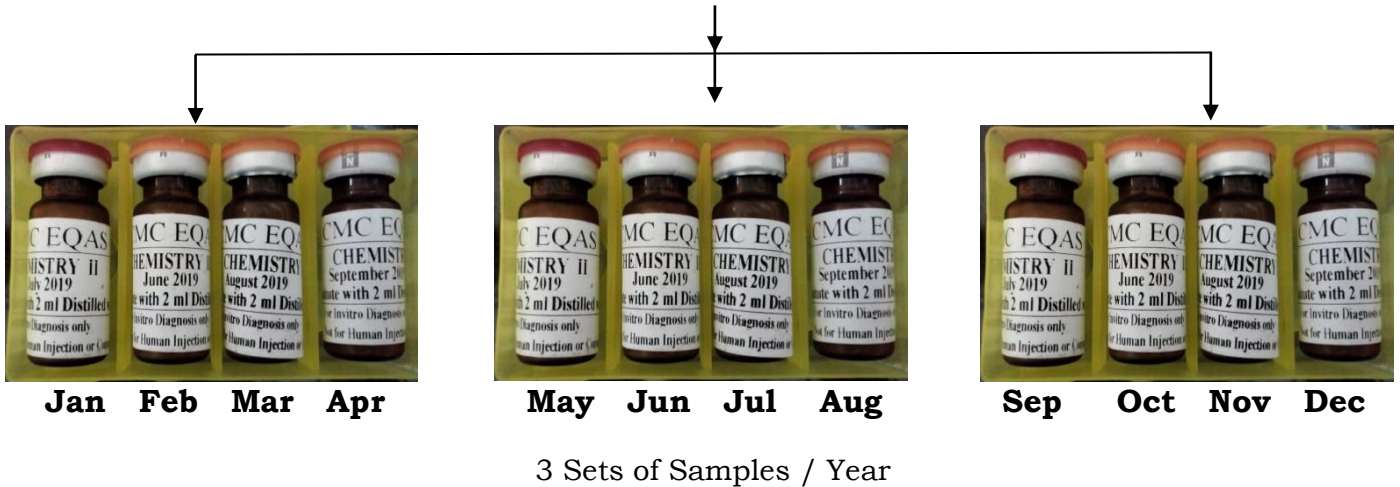
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for Director of Public Health and
Preventive Medicine, Chennai-6

Directorate of Public Health and Preventive Medicine

CMC - Vellore - Biochemistry External Quality Assurance Scheme (EQAS)

EQAS PROTOCOL



Reconstitution of Sample:

Add 2 ml of Deionized Water and Wait for 15 mins

1 Vial / Month

1. In each year, 3 sets of EQAS samples will be sent by CMC, Vellore to the District Microbiologist who in turn will personally hand over the EQAS samples to all LTs during the Review meeting at O/o DDHs Concerned.
2. Each set contains 4 vials of lyophilized/powdered analytes to cover 4 months.
3. Each vial should be reconstituted with 2 ml of deionized water and tested in the PHC laboratory and the values should be uploaded in the CMC, EQAS web site on or before 20th of every month.
4. Before testing the EQAS sample, the Lab. Technician should run the IQC to check the Internal Quality Control.
5. The EQAS sample is mandatory for Glucose, Cholesterol and Creatinine tests among the 9 analytes. Hence, all the LTs should strictly perform these tests using EQAS sample without fail on every month and file the SAA reports.
6. The values of the EQAS test results should be recorded in a separate note or file. Computer printout of the uploaded results should also be documented.
7. The results posted by CMC, Vellore in their web site should be taken a print out and maintained in the EQAS file.
8. The Dist. Microbiologist should follow-up, review and monitor EQAS performance at O/o DDHS concerned.

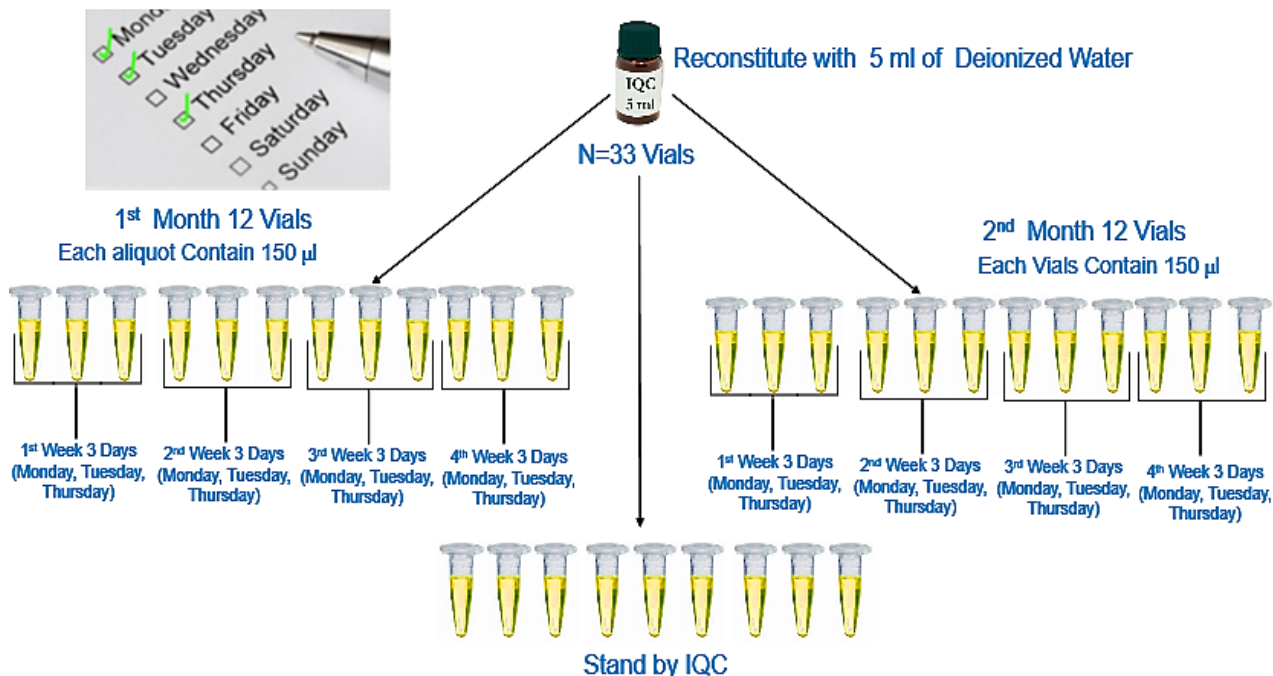

27/01/2021

for Director of Public Health and
Preventive Medicine, Chennai-6.

Directorate of Public Health and Preventive Medicine

CMC - Vellore – Biochemistry EQAS Program

IQC Aliquot Preparation & Protocol



1. In each year, 3 sets of IQC samples will be sent by CMC, Vellore
2. Each set contains 2 vials of lyophilized/powdered analytes. Each vial will be used for a period of 2 months.
3. Each vial should be reconstituted with 5 ml of deionized water as per the procedure given above, aliquots prepared and stored in the Deep Freezer (-20°C) compartment of the Refrigerator and strictly be used for 2 months only.
4. The Laboratory Technician working in Rural and Urban PHCs should strictly run IQC sample on **Monday, Tuesday and Thursday** before processing the clinical samples.
5. The IQC sample should be mandatory for Glucose, Cholesterol and Creatinine tests. Hence, all the Laboratory Technicians should strictly follow IQC run on the designated days.
6. The values of the IQC should be plotted on a LJ Chart in a Graph paper and displayed in the PHC.
7. A thermocoal based display board with black chart or file pouches to be readily available in the PHC laboratory to display the LJ Chart.
8. LJ chart should preferably be drawn using Graph paper and colour pens.

[Signature]
27/01/2021

for Director of Public Health and
Preventive Medicine, Chennai-6