

CURRENT

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Title: Biochemistry external and internal QCs

SOP No.: Biochemistry 09/02

Date first effective: 01st January 2025

Review date: 31st December 2025

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012

Category: Biochemistry

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure for estimation of external and internal QCs for biochemical parameters in the Biochemistry lab of Department of Clinical Pharmacology.

2. Scope

This SOP covers the procedures for analysis of external and internal QCs for biochemical parameters in the Biochemistry lab of Department of Clinical Pharmacology.

3. Responsibility

Lab technician, Lab attendant, or any other appropriately qualified staff in the team, designated by the Head of Department, will be responsible for analysis.

4. Reference

- Operational manual of minichem ARK Diagnostics.
- Biochemistry lab SOP no. 01/01 (Biochemistry analysis using semiautomated minichem ARK diagnostics).

5. Detailed Instructions

I. External QC

External QC samples for biochemistry are received from CMC QC Vellore in lyophilized form and are run once in a month before the 20th of each month.

Email: clinqc@cmcvellore.ac.in

Reconstitution Procedure

1. Remove the aluminium sealing and the rubber stopper slowly with care (since there is vacuum inside the bottle, the lyophilized powder material may pop up).
2. Keep the rubber stopper, upside down on the table.
3. Reconstitute the given vial for biochemistry with 2 ml of distilled water taken from Milli Q water purifier of Post PCR lab.

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4. Use appropriate graduated pipette to deliver the correct volume of 2 ml of distilled water.
5. Close the vial with the rubber stopper.
6. Do not shake the vial.
7. Leave it aside for 20 minutes.
8. After 20 minutes take the vial in hand slowly rotate, initially sideways and upside down carefully.
9. At any point do not shake the vial vigorously.
10. Write the date of reconstitution on the vial and analyze the sample for the following parameters: AST, ALT, ALP, urea, creatinine, Total Protein, and glucose.
11. Analyze the sample immediately as per biochemistry lab SOP no 10/01(SOP for semiautomated minichem ARK diagnostics) the remaining samples can be refrigerated for three days.
12. The results should be updated on CMC Vellore website before the 20th of each month.
13. Results are received online on <http://home.cmcvellore.ac.in/clinqc> after the 10th of next month.

II. Internal QC

1. Internal QCs (Randox) are done once in a week.
2. Internal QCs are done for all parameters whose standards are available in their respective kits kept in Biochemistry Refrigerator.
3. These standards are run as internal QCs and are processed as per biochemistry lab SOP no 01/01 (SOP for analysis using semi-automated minichem ARK Diagnostics).
4. The values of all these standards are checked as per the values on their respective vials or kit inserts.

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5. If the values deviate to a greater extent as mentioned on the kit insert, then an engineer of the company should be called for a visit to solve the problem.
6. The values are entered in a book of internal QC kept in biochemistry lab.