Clinical Chemistry Monthly Program (CCM 2026) [F01.P4.9]

YEAR : 2026
LOT: CCM 2026

INTENDED USE

This EQA-Darts program is a Clinical Chemistry Monthly Program that monitors accuracy of both manual techniques and assays on automated clinical chemistry analyzers. Any laboratory working in the field of routing clinical chemistry and dealing with human specimens can participate in this program. The program is designed to provide an independent and confidential external assessment of individual laboratory performance together with a simultaneous comparison of the methods currently in use in those laboratories. It is a 12-Month scheme consisting of 12 vials (rounds); one vial to be analyzed and its results submitted every month. The scheme can be sent semiannually or quarterly.

CHARACTERISTICS

The pack contains lyophilized 4 or 5 ml samples. Each vial is labeled with a unique, 4-digit sample number.

REACTIVE LYOPHILIZED COMPONENTS

Human-based lyophilized serum samples with chemical additives and tissue extracts of human and animal origin. Samples are prepared as closely as practicable to match the matrix, measurands and concentrations of items encountered in routine testing of patients' specimens.

PRECAUTIONS AND WARNINGS

For in vitro diagnostic use only. Exercise the normal precautions required for handling all laboratory reagents. This product has been prepared exclusively from the blood of donors tested individually and shown by FDA approved methods to be free from HBsAg and antibodies to HCV and HIV. However, as no method can rule out the potential risk of infection with absolute certainty, the material should be handled just as carefully as a patient sample. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

PREPARATION

The samples are sealed under vacuum. Open the vial very carefully, avoiding any loss of material and using a **calibrated pipette, reconstitute the contents with de-ionized/distilled water as mentioned on vail label *(4 or 5 ml)***. Replace the rubber stopper, close vial and leave to stand at **+20°C to +25°C** for **30 minutes out of bright light** before use. Ensure that the lyophilized contents are completely dissolved by occasional gentle swirling. Do not shake the vial.

STORAGE AND STABILITY

The samples are stable when stored **lyophilized and unopened at 2 to 8°C** until the expiration date. After reconstitution, and when closed tightly, components are stable for:

Storage temperature	All components	Bilirubin *(protected from light)*
20 to 25°C	12 hours	4 hours
2 to 8°C	1 day	8 hours
-15 to -25°C	1 month *(frozen once)*	2 weeks *(frozen once)*

Homogeneity and stability of vials were conducted according to Annex B in ISO 13528:2022 and were acceptable.

PROCEDURE

- Each month, one sample is analyzed according to the unique date printed on its label. The table below summarizes the schedule for result submission.
- **Any combination** of the **28 analytes** mentioned below can be measured in any sample.
- These samples should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit or reagent being used.
- The results should be submitted ***electronically*** to EQA-Darts before the "**Submit Before**" date printed on each vial. Results received after this dead-line **will not be accepted**.
- It is encouraged to report the result using the same number of significant figures/decimal places used while reporting actual patient results.
- It is recommended to analyze each sample within two-weeks of its dead-line.
- In the event that a sample result exceeds the linear range of the method used, handle high (out-of-range) samples in accordance with established laboratory procedures. Do not report results as more than (>) the linearity limit.

DESIGN, IMPLEMENTATION & DATA ANALYSIS OF THE PROGRAM

- Design, implementation and data Analysis of EQA-Darts strictly follow the guidelines of ISO/IEC 17043:2023 and ISO 13528:2022 standards.
- Assigned values and their uncertainties are based on consensus values from participant results. Analysis is conducted at three levels: all participants "All Methods group", participants using the same method "Method group" and participants using the same instrument/method combination "Peer group".
- Whenever possible, the participant is evaluated versus "Peer group" as it is the most homogeneous subset of participants, provided the number of this group is at least 5. The comparison group is bolded and underlined in the report and is mentioned for each analyte under "Comparator" column. If less than 5, performance is compared to the next larger group with at least 5 participants; the "Method group" or even to "All Methods group" in this order of preference.
- Robust analysis is used for calculation of target means and standard deviations, based on Algorithm A in Annex C of ISO 13528:2022.
- Standard deviation for proficiency assessment is based on robust estimate of the standard deviation of the results reported by all the participants.

CONFIDENTIALITY

EQA-Darts maintains a high respect for participant confidentiality. To protect the identity of a participant, each laboratory is identified by a unique code known only to EQA-Darts and the participant.

Sample	Month/Year	LOT	Submit before (Dead-line)
2607	Jul 2026	CCM 2026-07	25/07/2026
2608	Aug 2026	CCM 2026-08	25/08/2026
2609	Sep 2026	CCM 2026-09	26/09/2026
2610	Oct 2026	CCM 2026-10	25/10/2026
2611	Nov 2026	CCM 2026-11	25/11/2026
2612	Dec 2026	CCM 2026-12	26/12/2026

ATTENTION:

Each vial with Blue cap is to be reconstitute with 5 ml distilled water.

Each vial with Red cap is to be reconstitute with 4 ml distilled water.

LIST of ANALYTES			
1. Albumin	8. Calcium	15. HDL-C	22. Potassium
2. ALP	9. Chloride	16. Iron	23. Proteins, Total
3. ALT	10. Cholesterol, Total	17. LDH	24. Sodium
4. Amylase	11. CK, Total	18. LDL-C	25. TIBC
5. AST	12. Creatinine	19. Lipase	26. Triglyceride
6. Bilirubin, D	13. GGT	20. Magnesium	27. Urea
7. Bilirubin, T	14. Glucose	21. Phosphate	28. Uric acid

DECLARATION OF RESPONSIBILTY

Though purchasing, packaging, labelling, storage and transport of PT materials as well as homogeneity/stability studies are subcontracted to competent, ISO-certified/accredited bodies; EQA-Darts is responsible for maintaining the utmost quality of the whole program and its full compliance with ISO/IEC 17043:2023 requirements.

FOR COMMENTS, COMPLAINTS OR APPEAL AGAINST PERFORMANCE EVALUATION

Please log on: www.eqadarts.com or email our EQA-Darts support team (Consultants/Coordinators) at info@eqadarts.com. Please explain the reason for appealing and submit all supporting documents.

If the PT materials were not received in line with the schedule of dates provided, if any damaged or missing vials were received or if suitable transport conditions were not met (i.e., if not in ice box with ice bags still in the frozen state), please email your finding immediately to EQA-Darts. You can use the "Participants/customers complaint form" downloadable from www.eqadarts.com.

Response to the mail will be promptly initiated and the decision will be mailed back soon after a thorough analysis/evaluation/investigation is conducted.

More information on report explanation and calculations used can be found by logging onto: www.eqadarts.com and downloading "*Report Explanation*" and "*Calculations Used*" files.

Symbols in product labeling

LOT	Batch/Lot number
REF	Reference number
IVD	For in vitro diagnostic use
	Storage Temperature
	Use by/ Expiry date