

Clinical Chemistry Monthly Program (CCM 1026) [F01.P4.9]

YEAR : 2026
EXP : 02/2027
LOT: CCM 1026

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 routine 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 vial 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 (<i>protected from light</i>)
20 to 25°C	12 hours	4 hours
2 to 8°C	1 day	8 hours
-15 to -25°C	1 month (<i>frozen once</i>)	2 weeks (<i>frozen once</i>)

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)
2601	Jan 2026	CCM 1026-01	25/01/2026
2602	Feb 2026	CCM 1026-02	25/02/2026
2603	Mar 2026	CCM 1026-03	28/03/2026
2604	Apr 2026	CCM 1026-04	25/04/2026
2605	May 2026	CCM 1026-05	25/05/2026
2606	Jun 2026	CCM 1026-06	25/06/2026

ATTENTION:

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

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

DECLARATION OF RESPONSIBILITY

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

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.

DETERMINATION OF ASSIGNED VALUE

Consensus values from participants is the method used for the determination of the assigned values. With this approach, the assigned value X for the test material used in a round of a proficiency testing scheme is the robust average of the results reported by all the participants in the round, calculated using Algorithm A in Annex C of ISO 13528:2022.

This algorithm yields robust values of the average and standard deviation of the data to which it is applied.

Outliers are statistically treated with the use of robust statistical methods (determination of the consensus mean and standard deviation, without the need for outlier removal).

- Denote the p items of data, sorted into increasing order, by:
 $x_1, x_2, \dots, x_i, \dots, x_p$
- Denote the robust average and robust standard deviation of these data by x^* and s^* .
- Calculate initial values for x^* and s^* as:
 $x^* = \text{median of } x_i \ (i = 1, 2, \dots, p)$
 $s^* = 1.483 \text{ median of } x_i - x^* \ (i = 1, 2, \dots, p)$
- Update the values of x^* and s^* as follows. Calculate: $\delta = 1.5s^*$
- For each $x_i \ (i = 1, 2, \dots, p)$, calculate:

$$x_i^* = \begin{cases} x^* - \delta, & \text{if } x_i < x^* - \delta \\ x^* + \delta, & \text{if } x_i > x^* + \delta \\ x_i, & \text{otherwise} \end{cases}$$

- Calculate the new values of x^* and s^* from:

$$x^* = \sum x_i^* / p$$

$$s^* = 1,134 \sqrt{\sum (x_i^* - x^*)^2 / (p - 1)}$$

where the summation is over i .

The robust estimates x^* and s^* may be derived by an iterative calculation, i.e. by updating the values of x^* and s^* several times using the modified data, until the process converges.

Convergence may be assumed when there is no change from one iteration to the next in the third significant figure of the robust standard deviation and of the equivalent figure in the robust average.

The **standard uncertainty** of the assigned value u_X is estimated as:

$$u_X = 1.25 \times s^* / \sqrt{p}$$

where s^* is the robust standard deviation of the results and p the number of results.

PROCEDURE FOR HOMOGENEITY CHECK

- At least 6 key measurands are chosen which will be sensitive to heterogeneity between the samples. Behavior of these 6 measurands provide a good indication of stability/homogeneity of the remaining measurands, and hence assessment will be limited to that subset of 6 measurands only (ISO 13528:2022, clause 6.1.3).
- A suitable number of samples (10 for homogeneity and 3 for stability) from each of a high and low concentration batches in their final packaged form are selected at random.
- The 6 measurands are assayed in 2 test aliquots of each sample in a random order, completing the whole series of measurements under repeatability conditions.
- Eight more measurands are measured in the two aliquots of three vials only for basal stability studies.
- The general average $\bar{x}_{..}$, within-samples standard deviation s_w , and between-samples standard deviation s_s , are calculated as shown below:

The data from a homogeneity check are represented by $x_{t,k}$
where

t represents the proficiency test item ($t = 1, 2, \dots, g$)

k represents the test portion ($k = 1, 2, \dots, m$)

Define the sample averages as:

$$\bar{x}_t = (x_{t,1} + x_{t,2}) / 2$$

and the between-test-portion ranges as:

$$w_t = |x_{t,1} - x_{t,2}|$$

Calculate the general average:

$$\bar{\bar{x}} = \frac{1}{g} \sum_{t=1}^g \bar{x}_t$$

Estimate the standard deviation of sample averages:

$$s_{\bar{x}} = \sqrt{\sum_{t=1}^g (\bar{x}_t - \bar{\bar{x}})^2 / (g - 1)}$$

and the within-sample standard deviation:

$$s_w = \sqrt{\sum_{t=1}^g w_t^2 / (2g)}$$

Finally, estimate the between-sample standard deviation as:

$$s_s = \sqrt{\max(0, s_{\bar{x}}^2 - s_w^2 / 2)}$$

Assessment criterion for a homogeneity check

Duplicate values are inspected for a trend or for apparent differences

The between-samples standard deviation s_s is compared with the standard deviation for proficiency assessment σ_{pt} . The samples may be considered adequately homogeneous if: $s_s \leq 0.3 \sigma_{pt}$

A robust estimate of the standard deviation of the results reported by all the participants, calculated using a technique listed in Annex C of ISO 13528:2022, is used to calculate the **standard deviation for proficiency assessment (σ_{pt})** (ISO 13528:2022, clauses B.2.2 and 8.6).

PROCEDURE FOR A STABILITY CHECK

- Twelve months after the homogeneity check, stability study is conducted. This 12-month period is similar to the time delay that is experienced by the samples tested by the participants in the proficiency test.
- Each of the three stability-coded vial is reconstituted and divided into two similar aliquots.
- Taking the 2 test portions in a random order, obtain a measurement result $y_{t,k}$ on each, completing the whole series of measurements under repeatability conditions. The same – 14 analytes measured in base-line samples are measured in the 2g samples.
- The general average $\bar{y}_{..}$ of the measurements obtained in the stability test is calculated.

Assessment criterion for a stability check

The general average of the measurements obtained in the homogeneity check is compared with the general average of the results obtained in the stability check. The samples may be considered adequately stable if:

$$|\bar{x}_{..} - \bar{y}_{..}| \leq 0.3 \sigma_{pt}.$$

Summary tables for homogeneity and stability studies:

	High Sample Homogeneity							Low Sample Homogeneity					
	ALT	T Bil	Glucose	HDL-C	Mg	TIBC		ALT	T Bil	Glucose	HDL-C	Mg	TIBC
SD of PT, σ_{pt}	10.65	0.51	7.25	2.65	0.48	17.72		3.85	0.13	5.81	7.22	0.13	5.66
Number tested, g	10	10	10	10	10	10		10	10	10	10	10	10
SD of averages, S_x	3.3	0.13	4.2	0.9	0.12	10.5		1.7	0.06	2.6	4.0	0.06	1.3
Within vial SD, S_w	4.3	0.27	5.2	1.6	0.20	19.7		2.3	0.09	4.0	5.5	0.08	4.4
Between vial SD, S_s	1.3	0.000	2.0	0.0	0.00	0.0		0.6	0.000	0.0	0.8	0.02	0.0
Max allowed SD	3.20	0.153	2.18	0.80	0.14	5.32		1.16	0.039	1.74	2.17	0.04	1.70
Judgment	Accepted	Accepted	Accepted	Accepted	Accepted	Accepted		Accepted	Accepted	Accepted	Accepted	Accepted	Accepted

Analyte	Time	High Sample Stability			Low Sample Stability		
		Difference	SD of PT	Allowed SD	Difference	SD of PT	Allowed SD
ALT	Jan	1.90	10.65	3.20	-0.64	3.85	1.16
	Dec	Stability accepted			Stability accepted		
TBil	Jan	-0.04	0.51	0.15	-0.03	0.13	0.04
	Dec	Stability accepted			Stability accepted		
Glucose	Jan	-1.09	7.25	2.18	0.09	5.81	1.74
	Dec	Stability accepted			Stability accepted		
HDL-C	Jan	2.07	7.22	2.17	-0.50	2.65	0.80
	Dec	Stability accepted			Stability accepted		
Mg	Jan	0.04	0.48	0.14	0.00	0.13	0.04
	Dec	Stability accepted			Stability accepted		
TIBC	Jan	-3.02	17.72	5.32	1.18	5.66	1.70
	Dec	Stability accepted			Stability accepted		
Albumin	Jan	0.04	0.28	0.08	-0.02	0.23	0.07
	Dec	Stability accepted			Stability accepted		
ALP	Jan	3.06	24.65	7.40	0.11	5.25	1.57
	Dec	Stability accepted			Stability accepted		
Amy	Jan	-5.29	22.44	6.73	2.34	8.64	2.59
	Dec	Stability accepted			Stability accepted		
CK	Jan	-5.20	42.65	12.80	0.93	5.43	1.63
	Dec	Stability accepted			Stability accepted		
Creat	Jan	0.03	0.37	0.11	-0.04	0.13	0.04
	Dec	Stability accepted			Stability accepted		
GGT	Jan	1.48	32.02	9.60	-1.01	4.32	1.30
	Dec	Stability accepted			Stability accepted		
K	Jan	-0.05	0.36	0.11	-0.03	0.08	0.02
	Dec	Stability accepted			Stability not accepted		
Urea	Jan	-1.51	6.97	2.09	-0.11	2.63	0.79
	Dec	Stability accepted			Stability accepted		

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