GLUCOMETER EXTERNAL QUALITY CONTROL PROSPECTUS

PC	110	GC4 GC12	CONT	1 x 1 mL X x 1 mL	2C°		8C°	LOT	11026XX	IVD CE

PURPOSE OF USE

The Glucometer External Quality Control Program is designed to allow all participants to compare their analytical performance internally, both overall (all results) and according to method and method–device combinations.

SAFETY PRECUATIONS AND WARNINGS

The sample contains biologically derived material and should be treated as potentially infectious. Each human donor unit used in the production of this product is tested using FDA-approved methods and confirmed not to react for Hepatitis B Surface Antigen (HBsAg), antibodies against Hepatitis C (HCV), or antibodies against HIV-1/HIV-2. This product may also contain other human-derived materials for which no approved tests are yet available. In accordance with good laboratory practice, all human-derived materials should be considered potentially infectious and handled using the same precautions applied to patient samples.

SAMPLE PREPARATION

This product contains human blood prepared with added preservatives and should be treated in the same manner as patient samples and handled in accordance with the instructions provided with the instrument in use. The samples are supplied ready for use; tubes labeled for the relevant cycle month are removed from the refrigerator and allowed to reach room temperature (18–25 °C) for 15 minutes before mixing. For mixing, the tube is held horizontally between the palms of the hands and gently rolled back and forth for 20–30 seconds, occasionally inverted; do not shake and do not use a mechanical mixer. After use, the tubes should be returned to the refrigerator within 30 minutes. It is recommended that laboratory personnel process the samples as part of their routine daily procedure without prior notification. Any waste material should be disposed of in accordance with local waste management regulations, and in case of damage to the packaging, the sales office or technical service should be contacted. The samples are recommended to be analyzed in a single replicate.

STORAGE AND STABILITY

These samples are stable until the expiration date when stored unopened at 2–8 °C. After opening, all parameters remain stable for up to 48 hours, provided that the samples are handled appropriately, tightly capped, and stored at 2–8 °C. Protect the tubes from excessive heat and freezing. This product is shipped under refrigerated conditions. After use, the sample must not be returned to the original tube. Stored samples must be thoroughly mixed before reuse.

LIMITATONS

1. This product must not be used after the expiration date.
2. A syringe must not be used for reconstituting the sample.
3. If there is any indication of microbial contamination or excessive turbidity in the reconstituted product, the vial must be discarded.

TEST TIMES

The box contains **4-month (GC4)** and **12-month (GC12)** samples according to the program code. Each sample is labeled to indicate the **cycle month** for entering results into the **SEROCON Portal** via www.serocon.com. The samples should be analyzed on the dates specified below for the relevant cycle month according to the program schedule.

REPORTING OF RESULTS

Results must be entered into the SEROCON Portal via www.serocon.com using the assigned username and password no later than the last day of the relevant cycle month. When entering results, each institution uses the program opened for its own device and method. If a device change occurs during the program, SEROCON must be informed to make the necessary adjustments. Due to device changes, participants leave the previous device data as of the change date and enter results according to the newly defined program. Results are published starting from the second week of the month following the cycle. The system does not allow entry of results outside the specified limits for each parameter. Results that require “>” or “<” signs must be entered without the sign. Participants can view their reports through the SEROCON Portal. The program is based on the analysis of samples with unknown concentrations and periodic presentation of results obtained for each parameter. For each parameter, all participants’ results are calculated according to ISO 13528 requirements, and Z or Z’ scores (SDI) are generated. Values entered by other participants can be viewed in graphs without revealing participant names, in accordance with confidentiality principles. For monitoring purposes, results from previous cycles in which participation was made are provided in Levey-Jenings charts for each parameter and sample analysis period.

ABBREVIATIONS

PC	:	Program code
CONT	:	Contents
	:	Temperature Limitation
LOT	:	Lot Number
IVD	:	In Vitro Diagnostic Medical Device
CE	:	European Conformity

Note: You need to obtain the current documents by logging into SEROCON PORTAL via www.serocon.com website. Shared Documents;

- ✓ SEROCON DKD programs protocol
- ✓ EQC Programs Work Schedule
- ✓ Program Prospectuses

SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
January	1102601	23.01.2026	06.02.2026
February*	1102602	20.02.2026	06.03.2026
March	1102603	23.03.2026	04.04.2026
April	1102604	23.04.2026	05.05.2026
May*	1102605	22.05.2026	05.06.2026
June	1102606	23.06.2026	04.07.2026
July	1102607	24.07.2026	05.08.2026
August*	1102608	24.08.2026	04.09.2026
September	1102609	23.09.2026	05.10.2026
October	1102610	23.10.2026	05.11.2026
November*	1102611	23.11.2026	04.12.2026
December	1102612	24.12.2026	05.01.2027

*The months of operation for the GC4 program code.

**The sample vials display the Program Code and LOT number. The last two digits (XX) of the LOT number indicate the sample number for the relevant cycle month. The user performs the analysis by referring to the XX number for the corresponding cycle month.

CONTACT US

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