TORCH PANEL EXTERNAL QUALITY CONTROL PROSPECTUS

PC 680 TRC4 CONT 1 x 1 mL -15C°  -20C° LOT 68026XX IVD CE

PURPOSE OF USE
To enable all participants included in the Torch Panel External Quality Control Program to compare their analytical performance internally, in terms of overall results (all results), method, and method-device.

SAFETY PRECUATIONS AND WARNINGS
The sample contains biologically sourced 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 to ensure it does not react for Hepatitis B Surface Antigen (HBsAg), Hepatitis C antibody (HCV), and HIV-1/HIV-2 antibodies. This product may also include other human-derived materials for which no approved test currently exists. 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 is prepared using chemicals, stabilizers, and human-derived serum samples. It should be handled in the same manner as patient samples and used according to the instructions provided with the device, kit, or reagent in use. All products are ready to use. The sample indicated on the label for the cycle month should be allowed to reach room temperature (18–25°C) before analysis. After each use, the sample cap must be immediately replaced and stored at 2–8°C. It is recommended that it be used within daily procedures without the laboratory staff being notified. Any waste material should be disposed of according to the requirements of local waste management authorities. In case of package damage, contact the sales office or technical service. Samples are intended for single-use analysis only.

STORAGE AND STABILITY
This product should be stored unopened at -15 to -20°C. Once prepared and tightly sealed, it can be stored at -15 to -20°C for up to 30 days. After use, the sample must not be returned to the vial. Stored samples must be thoroughly mixed before reuse.

LIMITATIONS
1. This product must not be used after its expiration date.
2. If there is any indication of microbial contamination or excessive turbidity in the product, the vial should be discarded.

TEST TIMES
The box contains 4-month (TRC4) samples according to the program code. Each sample is labeled with the cycle month for entry of results into the SEROCON Portal via www.serocon.com. Samples should be analyzed on the dates specified below for the corresponding cycle month according to the program.

REPORTING OF RESULTS
Results must be entered into the SEROCON Portal at www.serocon.com using a 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 there is a device change during the program, SEROCON must be informed so that necessary adjustments can be made. In case of a device change, participants leave the old device data as of the change date and enter new data according to the newly defined program schedule. Results are published from the second week following the cycle month. The system does not allow entry of results outside the reference limits for any parameter. Results that require a ">" or "<" sign should be entered without the sign. Participants can view their reports via the SEROCON PORTAL. The program is based on the analysis of samples with unknown concentrations and the periodic presentation of results obtained for each parameter. All participants' results for each parameter are calculated according to ISO 13528 requirements, and Z or Z' scores (SDI) are generated. Values entered by other participants can be reviewed in graphs without revealing participant names, in accordance with confidentiality principles. To help participants track performance, values from previous cycles are provided in Levey-Jenings graphs for each parameter during the sample analysis periods.

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
February	6802602	21.02.2026	28.02.2026
May	6802605	23.05.2026	31.05.2026
August	6802608	22.08.2026	31.08.2026
November	6802611	24.11.2026	30.11.2026

** The sample vials display the Program Code and LOT number. The last two digits (XX) of the LOT number indicate the sample number corresponding to the relevant cycle month. The user should consider the XX number when performing the analysis for the respective cycle month.

CONTACT US

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