VIRAL MARKER EXTERNAL QUALITY CONTROL PROSPECTUS

PC 600 VM4 CONT X x 2 mL 2C°  8C°  LOT 60026XX IVD CE

PURPOSE OF USE
The Viral Marker External Quality Control Program aims to enable all participants to compare their analytical performance internally, both overall (all results) and by method or method-device combination.

SAFETY PRECUATIONS AND WARNINGS
The sample contains biologically derived material and should be treated as potentially infectious. In accordance with good laboratory practice, all human-derived materials must be considered potentially infectious and handled using the same precautions as those applied to patient samples.

SAMPLE PREPARATION
This product is prepared using chemicals, stabilizers, and human-derived serum. This lyophilized product should be treated the same as patient samples and used according to the instructions provided with the device, kit, or reagent in use. The vial labeled with the relevant cycle month should be reconstituted using 2.0 mL of distilled or deionized water with a volumetric pipette or equivalent. The cap should be replaced. The product should be gently mixed without shaking or creating foam and allowed to stand for approximately 30 minutes. Before sampling, the vial should reach room temperature (18–25°C). To ensure homogeneity, gently invert the vial several times. The reconstituted lyophilized product should be used within 1 hour after complete dissolution and reaching room temperature. After each use, the cap must be immediately replaced, and the vial stored at 2–8°C. It is recommended to work with the samples during routine laboratory procedures without alerting the laboratory personnel. Any waste material should be disposed of according to local waste management regulations. In case of damaged packaging, contact the sales office or technical service. Each sample is recommended to be tested in a single replicate.

STORAGE AND STABILITY
This product should be stored at 2–8°C before opening. Once reconstituted and tightly closed, 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 samples (VM4) according to the program code. Each sample is labeled with the cycle month to allow entry of results into the SEROCON Portal via www.serocon.com. The samples should be analyzed according to the program on the dates specified below for the corresponding cycle month.

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 corresponding 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 notified to make the necessary adjustments. In the case of a device change, participants leave the previous device's data as of the change date and enter new results according to the newly defined program schedule. Results are published starting from the second week of the month following the cycle. The system does not allow entry of results outside the defined limits for each parameter. Results that require a ">" or "<" symbol should be entered without the symbol. Participants can view their reports through the SEROCON Portal. The program is based on the analysis of samples with unknown concentrations and the periodic presentation of the 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 reviewed in charts without revealing participant names, in accordance with confidentiality principles. To allow participants to track their performance, values from previous cycles are provided for each parameter in Levey-Jenings charts corresponding to the sample analysis periods.

MATERIALS NOT PROVIDED IN THE BOX
Automatic pipette
Pipette tip
Distilled or deionized water

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	6002602	21.02.2026	28.02.2026
May	6002605	23.05.2026	31.05.2026
August	6002608	22.08.2026	31.08.2026
November	6002611	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 for the corresponding cycle month. The user performs the analysis for the cycle month by referring to the XX number.

CONTACT US

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