PRENATAL SCREENING EXTERNAL QUALITY CONTROL PROSPECTUS

PC 900 PS4 CONT 4 x 1 mL 2C°  8C° LOT 90026XX IVD CE

PURPOSE OF USE
The Prenatal Screening External Quality Control Program aims to enable all participants to compare their analytical performance internally, considering overall results (all results), method, and method-instrument.

SAFETY PRECUATIONS AND WARNINGS
The sample consists of 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), antibodies against Hepatitis C (HCV), or HIV-1/HIV-2 antibodies. This product may also contain other human-derived materials for which no approved test yet exists. In accordance with good laboratory practice, all human-derived materials should be considered potentially infectious and handled with the same precautions as patient samples.

SAMPLE PREPARATION
This product is prepared using chemicals, stabilizers, and a human serum sample. This lyophilized product should be treated in the same manner as patient samples and handled according to the instructions provided with the device, kit, or reagent being used. Reconstitute the vial indicated for the cycle month on the label with 1.0 mL of distilled or deionized water using a volumetric pipette or equivalent. Replace the cap. Allow the product to stand for approximately 15 minutes without shaking or foaming, stirring occasionally. Let the sample reach room temperature (18–25°C) before use. Gently mix the bottle several times to ensure homogeneity. The reconstituted lyophilized product should be used within 1 hour after complete dissolution and reaching room temperature. Replace the cap immediately after each use and store between 2–8°C. It is recommended to perform the procedure within the daily routine without informing laboratory personnel. Any waste material should be disposed of in accordance with local waste management regulations. In case of damage to the packaging, contact the sales office or technical service. **Samples should be analyzed in a single replicate.**

STORAGE AND STABILITY
This product should be stored between 2 and 8°C before opening. Once reconstituted and tightly closed, it can be stored for 3 days at 2–8°C or for 30 days at –20 to –70°C. Do not return any used material to the vial. Stored samples must be thoroughly mixed before reuse. Do not refreeze once the frozen product has been thawed; discard any remaining material.

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 (PS4) samples according to the program code. Each sample is labeled with the cycle month to allow entry of results into the SEROCON Portal at www.serocon.com. Samples should be analyzed on the dates specified 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. During data entry, each institution logs in through 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. Depending on the device change, participants leave the previous device's data as of the change date and enter results according to the newly defined program. Results are released from the second week of the month following the cycle. The system does not allow entries outside the reference limits for each parameter. Results that should be entered with ">" or "<" must be entered without the symbols. Participants can view their reports via the SEROCON Portal. The program is based on analyzing samples with unknown concentrations and presenting the obtained results for each parameter at specified intervals. 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 identifying participant names, maintaining confidentiality. To facilitate monitoring, values from previous cycles are provided for each parameter in Levey-Jennings charts during 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	9002602	21.02.2026	28.02.2026
May	9002605	23.05.2026	31.05.2026
August	9002608	22.08.2026	31.08.2026
November	9002611	24.11.2026	30.11.2026

**The sample tubes 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 by taking the XX number into account for the relevant cycle month.

CONTACT US

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