	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.01
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PC 100 **CC4** **CONT** 4 x 3 mL 8C° **LOT** 10026XX **IVD**
CC12 12 x 3 mL 2C°  **CE**

PURPOSE OF USE

To enable all participants included in the Clinical Chemistry External Quality Control Program to compare their analytical performance internally by overall results, by method, and by method-instrument.

SAFETY PRECAUTIONS AND WARNINGS

The sample content is of biological origin and should be treated as potentially infectious. Each human donor unit used in the production of this product is tested with FDA-approved methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C (HCV), and antibodies to HIV-1/HIV-2. This product may also contain 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 with the same precautions used for patient specimens.

SAMPLE PREPARATION

This product is prepared using chemicals, stabilizers, and human-derived serum samples. This lyophilized product should be handled in the same way as patient specimens and processed according to the instructions provided with the instrument, kit, or reagent in use. The vial, labeled with the cycle month, should be reconstituted with 3 mL of distilled or deionized water using a volumetric pipette or equivalent. The cap should then be replaced. Without shaking or creating foam, the product should be gently mixed occasionally and allowed to stand for about 15 minutes. Before sampling, it should be brought to room temperature (18–25°C). To ensure homogeneity, the vial should be gently mixed several times. The reconstituted lyophilized product should be used within 1 hour after dissolving and reaching room temperature. After each use, the cap should be immediately replaced, and the product should be stored between 2–8°C. It is recommended that laboratory staff use it as part of routine procedures without prior notice. Any waste material should be disposed of in accordance with the requirements of local waste management authorities. In case of damaged packaging, contact the sales office or technical service. **It is recommended to test the samples in a single replicate.**

STORAGE AND STABILITY

This product should be stored unopened at 2–8°C. Once reconstituted and tightly closed, it can be stored at 2–8°C for 3 days or at –20 to –70°C for 30 days. The sample should not be returned to the vial after use. Stored samples must be thoroughly mixed before reuse. Once a frozen product has been thawed, it should not be refrozen, and any remaining material must be discarded.

LIMITATIONS

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 samples for 4 (CC4) or 12 (CC12) months according to the program code. Each sample is labeled with the cycle month for entering results into the SEROCON Portal via www.serocon.com. Samples should be tested on the dates specified below for the relevant cycle month according to the program.


REPORTING OF RESULTS

Results must be entered into the SEROCON Portal via www.serocon.com using a username and password no later than the last day of the relevant cycle month. Each institution enters results through the program opened for its own instrument and method. If an instrument change occurs during the program, SEROCON must be informed so that necessary adjustments can be made. In the case of an instrument change, participants leave the previous instrument's data as of the change date and enter new 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 defined limits for each parameter. Results that should be entered with ">" or "<" signs must be entered without the signs. Participants can view their reports through the SEROCON Portal. The program is based on analyzing a sample with unknown concentrations and presenting the results obtained for each parameter at specific intervals. Results from all participants 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 viewed in graphs without revealing participant names, in accordance with confidentiality principles. To allow participants to monitor their performance, values from previous cycles are provided for each parameter using Levey-Jennings charts for 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

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SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
January	1002601	24.01.2026	31.01.2026
February*	1002602	21.02.2026	28.02.2026
March	1002603	24.03.2026	31.03.2026
April	1002604	23.04.2026	30.04.2026
May*	1002605	23.05.2026	31.05.2026
June	1002606	23.06.2026	30.06.2026
July	1002607	24.07.2026	31.07.2026
August*	1002608	22.08.2026	31.08.2026
September	1002609	23.09.2026	30.09.2026
October	1002610	24.10.2026	31.10.2026
November*	1002611	24.11.2026	30.11.2026
December	1002612	24.12.2026	31.12.2026

*CC4 is the working months for Program Code.

**Program code and LOT number are shown on the sample bottles. The last two digits (XX) in the LOT number represent the sample number of the related cycle month. The user performs the analysis by considering the XX number in the relevant cycle month.

CONTACT US

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