	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.14
		Effective Date	01.11.2022
		Rev. No / Date	02/22.12.2025
		Page	1/2
Procalcitonin External Quality Control Prospectus			

PC 470 **PCT4** **CONT** 4 x 1 mL **2C°**  **8C°** **LOT** 47026XX **IVD**


PURPOSE OF USE

The Procalcitonin External Quality Control Program aims to enable all participants to compare their analytical performance internally, in terms of overall results (all results), method, and method-instrument combination.

SAFETY PRECAUTIONS AND WARNING

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), antibodies against Hepatitis C (HCV), or HIV-1/HIV-2 antibodies. This product may also contain other human-derived materials for which no approved tests currently exist. 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. This lyophilized product must be handled in the same manner as patient samples and should be used according to the instructions provided with the device, kit, or reagent in use. The vial labeled for the cycle month should be reconstituted with 1.0 mL of distilled or deionized water using a volumetric pipette or its equivalent. The cap should be replaced. The product should be gently mixed occasionally without shaking or foaming and left to stand for approximately 30 minutes. Before sampling, allow the solution to reach room temperature (18–25°C). To ensure homogeneity, the vial should be gently inverted several times. The reconstituted lyophilized product should be used within 1 hour after complete dissolution and reaching room temperature. After each use, the cap should be immediately replaced, and the product stored at 2–8°C. It is recommended that laboratory personnel handle the product within routine procedures without being exposed unnecessarily. Any waste material should be disposed of according to local waste management regulations. In case of packaging damage, contact the sales office or technical service. Samples should 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 2–8°C for up to 3 days or at –20 to –70°C for up to 30 days. After use, the sample must not be returned to the vial. Stored samples should be thoroughly mixed before reuse. Once thawed, the product must not be refrozen, and any remaining material should 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 4-month (PCT4) 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. The 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 logs in through the program opened for its own device and method. If a device change occurs during the program, SEROCON must be informed so that necessary adjustments can be made. Due to a device change, participants leave the previous device data as of the date of the change and enter new data according to the newly defined program schedule. Results are released 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 ">" or "<" symbols should be entered without the symbols. Participants can view their reports via the SEROCON Portal. The program is based on the analysis of a sample with unknown concentrations, presenting results for each parameter at defined 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 reviewed in graphs without revealing participant identities, maintaining confidentiality. To allow participants to track performance, previous cycle results are provided in Levey-Jennings charts for each parameter over the 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

	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.14
		Effective Date	01.11.2022
		Rev. No / Date	02/22.12.2025
		Page	2/2
Procalcitonin External Quality Control Prospectus			

SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
Febraury	4702602	21.02.2026	28.02.2026
May	4702605	23.05.2026	31.05.2026
August	4702608	22.08.2026	31.08.2026
November	4702611	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 relevant cycle month. The user performs the analysis by referring to the XX number for the corresponding cycle month.

CONTACT US

SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC

Fevzi Çakmak District, 10739. Street No: 16-42050, Karatay, Konya, Türkiye

Tel: 0850 303 6644

Fax: 0332 353 8488

info@serocon.com

www.serocon.com

