


	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.30
		Effective Date	01.11.2022
		Rev. No / Date	02/22.12.2025
		Page	1/2
POCT-Cardiac Marker External Quality Control Prospectus			

PC 700 **POCT-CM4** **CONT** 4 x 1 mL 8C° **LOT** 70026XX **IVD**
POCT-CM12 12 x 1 mL 2C°  **CE**

PURPOSE OF USE

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

SAFETY PRECAUTIONS AND WARNINGS

The sample contains biological material and should be treated as potentially infectious. Each human donor unit used in the production of this product is tested by methods accepted by the FDA to ensure that it does not react for Hepatitis B Surface Antigen (HBsAg), antibodies against Hepatitis C (HCV), or antibodies against HIV-1/HIV-2. This product may also contain other human-derived materials for which no approved tests are currently available. In accordance with good laboratory practices, all human-derived materials should be considered potentially infectious and handled using the same precautions as 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. For reconstitution, use a volumetric pipette or equivalent to add 1.0 mL of distilled or deionized water to the vial labeled for the corresponding cycle month. Replace the cap. Allow the product to stand for approximately 15 minutes, mixing occasionally without shaking or foaming. Before taking a sample, let the vial reach room temperature (18–25°C). To ensure homogeneity, gently mix the vial several times. The reconstituted lyophilized product should be used within 1 hour after complete dissolution and reaching room temperature. After each use, immediately replace the cap and store the vial at 2–8°C. Work should be conducted within daily procedures without the laboratory staff being unaware. Dispose of any waste material according to local waste management regulations. In case of damaged packaging, contact the sales office or technical service. Each sample should be analyzed once only.

STORAGE AND STABILITY

This product should be stored at 2–8°C before opening. Once reconstituted and tightly closed, it can be stored for 1 day 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. Frozen product should **not** be refrozen after thawing; any remaining material must be discarded.

LIMITATIONS

1. This product must not be used after its expiration date.
2. A syringe must not be used for reconstitution of the sample.
3. If the reconstituted product shows any signs of microbial contamination or excessive turbidity, the vial must be discarded.

TEST TIMES

The box contains 4-month (POCT-CM4) and 12-month (POCT-CM12) 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 tested on the dates specified below for the corresponding cycle month according to the program.


SONUÇLARIN RAPORLANMASI

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. During result entry, each institution records data through the program opened for its own device and method. If a device change occurs during the program, SEROCON must be informed, and the necessary adjustments will be made. Due to device changes, participants leave the data from the old device as of the change date and enter subsequent results 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 "<" should be entered without these symbols. Participants can view their reports through the SEROCON Portal. The program is based on analyzing samples of unknown concentrations and presenting the obtained results for each parameter at defined intervals. 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 identifying participant names, in compliance with confidentiality. For participants' reference, values from previous cycles are provided as Levey-Jennings charts for each parameter 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

Not: Güncel Dokümanları www.serocon.com web sitesi üzerinden SEROCON PORTAL'a giriş yaparak edinmeniz gerekmektedir. Paylaşılan dokümanlar;

- ✓ SEROCON DKD programları protokolü
- ✓ DKD Programları Çalışma Takvimi
- ✓ Program Prospektüleri

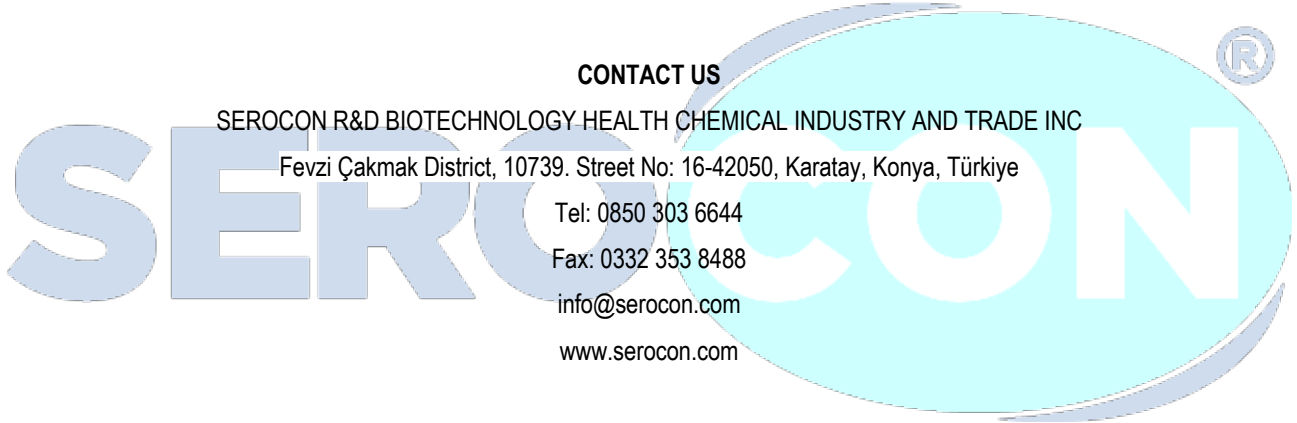
	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.30
		Effective Date	01.11.2022
		Rev. No / Date	02/22.12.2025
		Page	2/2
POCT-Cardiac Marker External Quality Control Prospectus			

SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
January	7002601	24.01.2026	31.01.2026
February*	7002602	21.02.2026	28.02.2026
March	7002603	24.03.2026	31.03.2026
April	7002604	23.04.2026	30.04.2026
May*	7002605	23.05.2026	31.05.2026
June	7002606	23.06.2026	30.06.2026
July	7002607	24.07.2026	31.07.2026
August*	7002608	22.08.2026	31.08.2026
September	7002609	23.09.2026	30.09.2026
October	7002610	24.10.2026	31.10.2026
November*	7002611	24.11.2026	30.11.2026
December	7002612	24.12.2026	31.12.2026

*CM4 indicates the cycle months for the program.

**The sample vials are labeled with 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 performs the analysis considering 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