	<b>SEROCON R&amp;D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC</b>	Document Code	PRP.18
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<b>Cardiac Marker-S External Quality Control Prospectus</b>			

PC

700

CM-S4

CONT

4 x 3 mL

-15C°



-20C°

LOT

70026XX

IVD

CE

#### PURPOSE OF USE

The purpose is to enable all participants included in the Cardiac Marker-S External Quality Control Program to compare their analytical performance internally, both overall (all results), by method, and by method-device combination.

#### SAFETY PRECAUTIONS AND WARNINGS

The sample contains biologically derived 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 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 using the same precautions as patient samples.

#### SAMPLE PREPARATION

This product is prepared using chemicals, stabilizers, and human-derived serum samples. This lyophilized product should be handled in the same manner as patient samples and must be processed according to the instructions provided with the device, kit, or reagent in use. The vial labeled for the corresponding cycle month should be reconstituted with 1.0 mL of distilled or deionized water using a volumetric pipette or equivalent. The cap should be replaced. The product should be gently mixed occasionally without shaking or foaming and left to stand for approximately 15 minutes. Before sampling, allow the product to reach room temperature (18–25°C). To ensure homogeneity, gently swirl the vial several times. The reconstituted lyophilized product should be used within 1 hour of 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 the product be used within routine daily procedures without laboratory staff being aware. 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 are recommended to be tested as single replicates.

#### STORAGE AND STABILITY

This product should be stored unopened at -15 to -20°C. Once reconstituted and tightly capped, it can be kept at 2–8°C for 12 hours or at -20 to -70°C for 30 days. After use, the sample must not be returned to the vial. Stored samples must be thoroughly mixed before reuse. Once thawed, the frozen product 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 4-month samples (CM-S4) according to the program code. Each sample is labeled with the cycle month for entering results into the SEROCON Portal via [www.serocon.com](http://www.serocon.com). 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 on [www.serocon.com](http://www.serocon.com) using a username and password no later than the last day of the relevant 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 informed so that necessary adjustments can be made. In case of a device change, participants leave the old device data on 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 reference limits for any parameter. Results that should be entered with a ">" or "<" sign must be entered without the sign. Participants can view their reports via the SEROCON Portal. The program is based on the analysis of a sample with unknown concentrations and the periodic presentation of results obtained for each parameter. The results of 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 reviewed in graphs without revealing participant names, maintaining confidentiality. For monitoring purposes, values from previous cycles in which participants took part are provided as Levey-Jennings charts for each parameter over 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](http://www.serocon.com) web sitesi üzerinden SEROCON PORTAL'a giriş yaparak edinmeniz gerekmektedir. Paylaşılan dokümanlar;

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

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#### SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
February	7002602	21.02.2026	28.02.2026
May	7002605	23.05.2026	31.05.2026
August	7002608	22.08.2026	31.08.2026
November	7002611	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

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