Cardiac Marker External Quality Control Prospectus

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

PURPOSE OF USE
Kardiyak Belirteç Dış Kalite Kontrol Programına dahil olan tüm katılımcıların analitik performanslarını kendi içlerinde genel (tüm sonuçlar), yöntem, yöntem-cihaz olacak şekilde kıyaslamasını sağlamaktır.

SAFETY PRECUATIONS 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-accepted methods to ensure that it does not react for Hepatitis B Surface Antigen (HBsAg), antibodies against Hepatitis C (HCV), and antibodies against HIV-1/HIV-2. This product may also contain other human-derived materials for which no approved test is currently available. In accordance with good laboratory practices, 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 human-derived serum samples. This lyophilized product should be handled in the same way as patient samples and must be processed according to the instructions provided with the device, kit, or reagent in use. The vial indicated for the 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 without shaking or foaming and left to stand for approximately 15 minutes. Before sampling, allow the vial to reach room temperature (18–25°C). To ensure homogeneity, gently invert the vial 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 vial stored at 2–8°C. It is recommended to work with the product as part of routine daily procedures without alerting laboratory personnel. Any waste material should be disposed of according to local waste management regulations. In case of package damage, contact the sales office or technical service. Samples are recommended to be tested in a single replicate.

STORAGE AND STABILITY
This product should be stored at 2–8°C without opening. Once reconstituted and tightly closed, it can be kept at 2–8°C for 1 day 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. Frozen product should not be refrozen after thawing, and any remaining material should be discarded.

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
According to the program code, the box contains 4-month (CM4) and 12-month (CM12) samples. Each sample is labeled with the cycle month to allow entry of results via the SEROCON Portal on www.serocon.com. Samples should be analyzed according to the dates specified for the relevant cycle month in 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 the necessary adjustments can be made. In the case of a device change, participants leave the old device data as of the change date and enter new results according to the newly defined program schedule. Results are published starting from the second week of the month following the cycle. The system does not allow entries outside the defined limits for any parameter. Results that require a “>” or “<” sign should be entered without the sign. Participants can view their reports via the SEROCON Portal. The program is based on analyzing samples with unknown concentrations and presenting the results for each parameter at defined intervals. All participants’ results for each parameter are calculated according to ISO 13528, and Z or Z’ scores (SDI) are generated. Values entered by other participants can be viewed in graphs without revealing participant identities, in accordance with confidentiality principles. To help participants track progress, values from previous cycles are provided for each parameter in Levey-Jenings charts for the respective 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
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

*These are the working months for the CM4 Program code.
**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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