

	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.12
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		Page	1/2
Therapeutic Drug Monitoring External Quality Control Prospectus			

PC 170 **TDM4** **CONT** 4 x 1 mL **2C°**  **8C°** **LOT** 17026XX **IVD** 

PURPOSE OF USE

The objective is to enable all participants enrolled in the Therapeutic Drug Monitoring External Quality Control Program to compare their analytical performance with one another at the overall level (all 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 using methods accepted by the FDA, and it is confirmed 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 yet available. In accordance with good laboratory practice, all human-derived materials should be considered potentially infectious and handled using the same precautions as those applied to patient samples.

SAMPLE PREPARATION

This product is prepared using chemicals, stabilizers, and human-derived serum samples. This lyophilized product must be treated in the same manner as patient samples and should be tested in accordance with the instructions provided with the instrument, kit, or reagent being used.

The vial corresponding to the cycle month indicated on the label is reconstituted with 1.0 mL of distilled or deionized water using a volumetric pipette or equivalent. Replace the cap. Allow the product to stand for approximately 30 minutes, mixing occasionally by gentle swirling without shaking or creating foam. Before sampling, allow the product to reach room temperature (18–25°C). Gently mix the vial several times to ensure homogeneity.

The reconstituted lyophilized product should be tested within 1 hour after complete dissolution and equilibration to room temperature. Replace the cap immediately after each use. It is recommended that the product be analyzed as part of the routine daily procedure without notifying laboratory personnel.

Dispose of any waste material in accordance with the requirements of local waste management authorities. In case of damage to the packaging, contact the sales office or technical service.

It is recommended that the samples be tested in a single replicate.

STORAGE AND STABILITY

This product should be stored at 2–8°C before opening.

Once prepared and tightly capped, the product may be stored at 2–8°C for up to 3 days or at –20 to –70°C for up to 30 days.

Following use, the sample must not be returned to the original vial. Stored samples must be thoroughly mixed before reuse. Once a frozen product has been thawed, it must 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

According to the program code, the box contains 4-month (TDM4) samples. Each sample is labeled with the cycle month for entry of results into the SEROCON Portal via www.serocon.com. Samples should be analyzed on the dates specified for the corresponding 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. 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 data from the old device as of the date of change and enter new results according to the defined new 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 limit values for each parameter. Results that should be entered with ">" or "<" must be entered without these symbols. Participants can view their reports via the SEROCON PORTAL. The program is based on the periodic presentation of results obtained for each parameter from the analysis of samples with unknown concentrations. 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 viewed on graphs without revealing participant names, in accordance with confidentiality principles. To help participants track their performance, values from previous cycles are provided as Levey-Jennings charts for each parameter at 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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TERAPÖTİK İLAÇ DÜZEYİ İZLEMİ DIŞ KALİTE KONTROL PROSPEKTÜSÜ			

SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
February	1702602	21.02.2026	28.02.2026
May	1702605	23.05.2026	31.05.2026
August	1702608	22.08.2026	31.08.2026
November	1702611	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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