	<b>SEROCON R&amp;D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC</b>	Document Code	PRP.29
		Effective Date	01.11.2022
		Rev. No / Date	02/22.12.2025
		Page	1/2
<b>Urine Toxicology External Quality Control Prospectus</b>			

**PC** 250      **UT4**      **CONT**      4 x 5 mL      8C°      **LOT**      25026XX      **IVD**  
**UT12**      12 x 5 mL      2C°            **CE**

#### PURPOSE OF USE

The purpose of the Urine Toxicology External Quality Control Program is to enable all participants to compare their analytical performance internally, both overall (all results) and according to method and method-device combinations.

#### 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 FDA-approved methods and is verified not to 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 patient samples.

#### SAMPLE PREPARATION

This product is prepared using chemicals, stabilizers, and human-derived urine samples. This lyophilized product must be treated the same as patient samples and used according to the instructions provided with the device, kit, or reagent in use. The bottle labeled for the cycle month should be reconstituted with 5.0 mL of distilled or deionized water using a volumetric pipette or equivalent. Replace the cap. The product should be mixed gently without shaking to avoid foaming and allowed to stand for approximately 30 minutes, occasionally swirling. Before taking a sample, allow it to reach room temperature (18–25°C). To ensure homogeneity, gently mix the bottle several times. The reconstituted lyophilized product should be used within 1 hour after complete dissolution and reaching room temperature. After each use, replace the cap immediately and store the product at 2–8°C. It is recommended that daily procedures be carried out without informing the laboratory staff. Dispose of any waste materials according to local waste management regulations. If the packaging is damaged, contact the sales office or technical service. Each sample should be tested only once.

#### STORAGE AND STABILITY

This product should be stored at 2–8°C before opening. Once reconstituted and tightly closed, it can be kept at 2–8°C for 3 days or at -20 to -70°C for 30 days. Do not return used samples to the bottle. Stored samples must be thoroughly mixed before reuse. Frozen products 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 reconstituting the sample under any circumstances.

3. If the reconstituted product shows any signs of microbial contamination or excessive turbidity, the bottle must be discarded.

#### TEST TIMES

The box contains samples for 4 (UT4) and 12 (UT12) months 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](http://www.serocon.com). The samples should be tested on the dates specified below according to the relevant cycle month in the program.


#### REPORTING OF RESULTS

Results must be entered into the SEROCON Portal at [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 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. In case of a device change, participants leave the old device data as of the change date 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 defined limits for each parameter. Results that require ">" or "<" symbols should be entered without these symbols. Participants can view their reports via the SEROCON Portal. The program is based on analyzing a sample with unknown concentrations and presenting the results obtained 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 viewed in graphs without identifying the participant, maintaining confidentiality. For monitoring purposes, participants are provided with the results of previous cycles, displayed in Levey-Jenings charts for each parameter at the defined analysis intervals.

#### 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](http://www.serocon.com) website. Shared Documents;

- ✓ SEROCON DKD programs protocol
- ✓ EQC Programs Work Schedule
- ✓ Program Prospectuses

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		Page	2/2
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#### SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
January	2502601	24.01.2026	31.01.2026
February*	2502602	21.02.2026	28.02.2026
March	2502603	24.03.2026	31.03.2026
April	2502604	23.04.2026	30.04.2026
May*	2502605	23.05.2026	31.05.2026
June	2502606	23.06.2026	30.06.2026
July	2502607	24.07.2026	31.07.2026
August*	2502608	22.08.2026	31.08.2026
September	2502609	23.09.2026	30.09.2026
October	2502610	24.10.2026	31.10.2026
November*	2502611	24.11.2026	30.11.2026
December	2502612	24.12.2026	31.12.2026

\*These are the working months for the UT4 program code.

\*\*The sample bottles 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 in the relevant cycle month by referring to the XX number.



**CONTACT US**

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