URINE CHEMISTRY EXTERNAL QUALITY CONTROL PROSPECTUS

PC	210	UC4 UC12	CONT	1 x 1 mL 1 x 1 mL	2C°		8C°	LOT	21026XX	IVD CE

PURPOSE OF USE

To enable all participants included in the Urine Chemistry External Quality Control Program to compare their analytical performance internally, in terms of overall results (all results), method, and method-device combination.

SAFETY PRECUATIONS 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-accepted methods to ensure 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 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 those applied to patient samples.

SAMPLE PREPARATION

This product is prepared using chemicals, stabilizers, and human-derived urine. This product must be handled in the same manner as patient samples and should be used according to the instructions provided with the device, kit, or reagent in use. 1. Tubes are removed from the refrigerator and left for 15 minutes to reach room temperature (18-25°C) before mixing. 2. To mix, hold the tube horizontally between the palms. a) Roll the tube back and forth for 20 to 30 seconds; occasionally invert the tube. Mix thoroughly but do not shake. b) Before processing each sample, invert the tube slowly 8 to 10 times. 3. After taking the sample: a. Automated Sample Preparation: Immediately remove the tube from the sample carrier after sampling. b. Manual Sample Preparation: Carefully wipe the tube rim and cap with gauze and replace the cap. 4. After each use, immediately replace the cap and store at 2-8°C. It is recommended that laboratory personnel work with this product during routine daily procedures without drawing special attention. 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. It is recommended to process samples as a single replicate.

STORAGE AND STABILITY

These samples are stable until the expiration date when stored unopened at 2 to 8°C. After opening, all parameters remain stable for up to 48 hours, provided they are used appropriately and tightly capped while stored at 2 to 8°C. Protect the tubes from EXCESSIVE HEAT and FREEZING. This product is shipped under refrigerated conditions.

LIMITATION

1. This product should not be used after the expiration date.
2. If there is any indication of microbial contamination or excessive turbidity in the product, the bottle must be discarded.

TEST TIMES

The box contains 4-month (UC4) and 12-month (U12) samples according to the program code. Each sample is labeled with the cycle month to enter the results into the SEROCON Portal via www.serocon.com. Samples should be processed on the dates specified below for the relevant 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 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. Due to a device change, participants leave the old device data as of the date of the change and enter new results according to the designated 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 “<” symbols must be entered without the symbol. Participants can view their reports through the SEROCON PORTAL.

The program is based on the analysis of a sample with unknown concentrations and the presentation of results obtained for each parameter at specific intervals. For each parameter, the results of all participants 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 indicating participant names, in accordance with confidentiality principles. For participant tracking, values from previous cycles in which participation was made are provided with Levey-Jennings charts for each parameter during the sample analysis periods.

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 Prospektüsleri

SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
January	2102601	24.01.2026	31.01.2026
February*	2102602	21.02.2026	28.02.2026
March	2102603	24.03.2026	31.03.2026
April	2102604	23.04.2026	30.04.2026
May*	2102605	23.05.2026	31.05.2026
June	2102606	23.06.2026	30.06.2026
July	2102607	24.07.2026	31.07.2026
August*	2102608	22.08.2026	31.08.2026
September	2102609	23.09.2026	30.09.2026
October	2102610	24.10.2026	31.10.2026
November*	2102611	24.11.2026	30.11.2026
December	2102612	24.12.2026	31.12.2026

*The study months for the UC4 Program code.

**The Program Code and LOT number are indicated on the sample bottles. The last two digits (XX) of the LOT number represent the sample number for the relevant cycle month. The user performs the analysis in the relevant cycle month by taking the XX number into account.

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