	<b>SEROCON R&amp;D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC</b>	Document Code	PRP.11
		Effective Date	01.11.2022
		Rev. No / Date	02/22.12.2025
		Page	1/2
<b>IMMUNOSUPPRESSIVE DRUG EXTERNAL QUALITY CONTROL PROSPECTUS</b>			

PC 530 ISD4 CONT 4 x 1 mL

2C°



8C°

LOT

53026XX

IVD

CE

#### PURPOSE OF USE

The Immunosuppressive Drug External Quality Control Program aims to enable all participants to compare their analytical performance internally, both overall (all results) and according to method and method-instrument.

#### SAFETY PRECAUTIONS AND WARNINGS

The sample contains biologically sourced 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), Hepatitis C antibodies (HCV), or HIV-1/HIV-2 antibodies. This product may also contain other human-derived materials for which no approved tests currently exist. In accordance with good laboratory practices, all human-derived materials should be considered potentially infectious and handled using the same precautions as patient samples.

#### SAMPLE PREPARATION

This lyophilized product is prepared using chemicals, stabilizers, and human whole blood/hemolysate. It should be handled in the same manner as patient samples and used according to the instructions provided with the device, kit, or reagent in use. The vial for the relevant cycle month, as indicated on its label, should be reconstituted with 1.0 mL of distilled or deionized water using a volumetric pipette or its equivalent. The cap should be securely replaced. The product should be gently mixed occasionally without shaking or causing foam and left to stand for approximately 20 minutes. Before sampling, allow the vial to reach room temperature (18–25°C). To ensure homogeneity, gently invert the vial a few times. The reconstituted lyophilized product should be used within 1 hour after dissolution and reaching room temperature. After each use, the cap must be tightly replaced, and the product stored at 2–8°C. It is recommended that the product be handled within the daily routine without the laboratory personnel being unaware. 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 should be tested in single replicates.

#### STORAGE AND STABILITY

This product should be stored at 2–8°C before opening. Once reconstituted and tightly closed, it can be stored for 7 days at 2–8°C or for 30 days at –20 to –70°C. After use, the sample must not be returned to the vial. Stored samples should always be mixed before reuse. Once the frozen product has been thawed, it must not be refrozen, and any remaining material should 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 according to the program code (ISD4). Each sample is labeled with the cycle month for entering results into the SEROCON Portal via [www.serocon.com](http://www.serocon.com). The samples should be tested according to the program on the dates specified for the corresponding cycle month.


#### REPORTING OF RESULTS

Results must be entered into the SEROCON Portal via [www.serocon.com](http://www.serocon.com) using a username and password no later than the last day of the corresponding 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 notified to make the necessary adjustments. In case of a device change, participants leave the old device data as of the date of change and enter results according to the newly defined program schedule. Results are published 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 the symbols. Participants can view their reports through the SEROCON Portal. The program is based on periodic presentation of results obtained for each parameter through the analysis of samples with unknown concentrations. All participants’ results 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 viewed in graphs without revealing participant names, in accordance with confidentiality principles. For participants to track their progress, values from previous cycles are provided in Levey-Jenings 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

**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

	<b>SEROCON R&amp;D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC</b>	Document Code	PRP.11
		Effective Date	02/22.12.2025
		Rev. No / Date	01/06.01.2025
		Page	2/2
<b>IMMUNOSUPPRESSIVE DRUG EXTERNAL QUALITY CONTROL PROSPECTUS</b>			

#### SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
February	5302602	21.02.2026	28.02.2026
May	5302605	23.05.2026	31.05.2026
August	5302608	22.08.2026	31.08.2026
November	5302611	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

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

