

	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.02
		Effective Date	14.02.2022
		Rev. No / Date	02/22.12.2025
		Page	1/2
Immunoassay / Immunoassay-S / Tumor Marker External Quality Control Prospectus			

PC	400	IMM4/IMM-S4	CONT	4 x 5 mL		8°C	LOT	40026XX	IVD
	450	IMM12		12 x 5 mL				45026XX	CE
		TM4/TM12							

PURPOSE OF USE

To enable all participants included in the Immunoassay / Immunoassay-S / Tumor Marker External Quality Control Program to compare their analytical performance internally by overall 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 FDA-approved methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C (HCV), and antibodies to 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 with the same precautions as patient specimens.

SAMPLE PREPARATION

This product is prepared using chemicals, stabilizers, and human-derived serum. This lyophilized product should be handled in the same way as patient specimens and processed according to the instructions provided with the instrument, kit, or reagent in use. Reconstitute the vial labeled for the cycle month with 5.0 mL of distilled or deionized water using a volumetric pipette or equivalent. Replace the cap. Without shaking or creating foam, gently mix occasionally and allow the product to stand for approximately 30 minutes. Bring the sample to room temperature (18–25°C) before use. To ensure homogeneity, gently mix the vial several times. The reconstituted lyophilized product should be used within 1 hour after dissolution and reaching room temperature. Immediately replace the cap after each use and store at 2–8°C. It is recommended to incorporate this into routine procedures without prior notification to laboratory personnel. Any waste material should be disposed of in accordance with local waste management regulations. In case of damaged packaging, contact the sales office or technical service. **It is recommended to test the samples in a single replicate.**

Note: For PTH and ACTH testing, do not use the available Immunoassay sample; testing should be performed with the Immunoassay-PTH and Immunoassay-ACTH samples provided separately by SEROCON.

For tests that exceed the device's upper detection limit, such as HCG (Beta) and folic acid, the analysis must be repeated after appropriate dilution.

STORAGE AND STABILITY

This product should be stored unopened at 2–8°C. Once reconstituted and tightly closed, it can be stored at 2–8°C for 3 days or at –20 to –70°C for 30 days. The sample should not be returned to the vial after use. Stored samples must be thoroughly mixed before reuse. Once a frozen product has been thawed, it should 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

The box contains samples for 4 months (IMM4 / IMM S4 / TM4) or 12 months (IMM12 / TM12) according to the program code. Each sample is labeled with the cycle month for entering results into the SEROCON Portal via www.serocon.com. Samples should be tested 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. Each institution enters results through the program opened for its own instrument and method. If an instrument change occurs during the program, SEROCON must be informed so that necessary adjustments can be made. In the case of an instrument change, participants leave the previous instrument's data as of the change date and enter new results according to the newly defined program. Results are published 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 should be entered with ">" or "<" signs must be entered without the signs. Participants can view their reports through the SEROCON Portal. The program is based on analyzing a sample with unknown concentrations and presenting the results obtained for each parameter at specific intervals. Results from all participants 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. To allow participants to monitor their performance, values from previous cycles are provided for each parameter using Levey-Jennings charts for 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

	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.02
		Effective Date	14.02.2022
		Rev. No / Date	02/22.12.2025
		Page	2/2
Immunoassay / Immunoassay-S / Tumor Marker External Quality Control Prospectus			

SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
January	4002601 4502601	24.01.2026	31.01.2026
February*	4002602 4502602	21.02.2026	28.02.2026
March	4002603 4502603	24.03.2026	31.03.2026
April	4002604 4502604	23.04.2026	30.04.2026
May*	4002605 4502605	23.05.2026	31.05.2026
June	4002606 4502606	23.06.2026	30.06.2026
July	4002607 4502607	24.07.2026	31.07.2026
August*	4002608 4502608	22.08.2026	31.08.2026
September	4002609 4502609	23.09.2026	30.09.2026
October	4002610 4502610	24.10.2026	31.10.2026
November*	4002611 4502611	24.11.2026	30.11.2026
December	4002612 4502612	24.12.2026	31.12.2026

*These are the testing months for the IMM4 / IMM S4 / TM4 program code.

**The program code and LOT number are indicated on the sample vials. The last two digits (XX) of the LOT number represent 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