IMMUNOASSAY-ACTH EXTERNAL QUALITY CONTROL PROSPECTUS

PC	400	IMM4 IMM12	CONT	4 x 1 mL 12 x 1 mL	-15C°		-20C°	LOT	40026XX	IVD CE

PURPOSE OF USE

The Immunoassay-ACTH External Quality Control Program is designed to allow all participants to compare their analytical performance internally, both overall (all results) and according to method and method-device combinations.

SAFETY PRECUATIONS AND WARNINGS

The sample contains biologically derived 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 and confirmed not to 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 tests are yet available. In accordance with good laboratory practice, all human-derived materials should be considered potentially infectious and handled using the same precautions applied to patient samples.

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 samples and used according to the instructions provided with the device, kit, or reagent in use. The vial labeled for the relevant cycle month should be reconstituted using a volumetric pipette or equivalent with 1.0 mL of distilled or deionized water. Replace the cap after reconstitution. The product should be gently mixed intermittently without shaking or foaming for approximately 30 minutes. Before sampling, allow the vial to reach room temperature (18–25°C). To ensure homogeneity, gently invert the vial several times. The reconstituted lyophilized product should be used within 1 hour after complete dissolution and reaching room temperature. After each use, the cap must be immediately replaced. It is recommended to perform testing as part of daily procedures without notifying laboratory personnel. All waste materials must be disposed of in accordance with local waste management regulations. If the packaging is damaged, contact the sales office or technical service. **Samples should be tested in a single replicate.**

STORAGE AND STABILITY

This product should be stored at -15 to -20°C before reconstitution. Once reconstituted and tightly closed, it can be stored at -20 to -70°C for 30 days. Do not return the sample to the original vial after use. Samples must be thoroughly mixed before any subsequent use. Frozen product should not be refrozen after thawing; any remaining material must be discarded.
Products must be transferred within 5 days at temperatures of 25°C or below. After transfer, the product must continue to be stored under the specified storage conditions.

LIMITATONS

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 (IMM4) or 12-month (IMM12) samples according to the program code. Each sample is labeled with the cycle month to enable entry of results into the SEROCON Portal via www.serocon.com. Samples must be tested according to the dates specified for the relevant cycle month in the program.

REPORTING OF RESULTS

Results must be entered into the SEROCON Portal via www.serocon.com using the assigned 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 to make the necessary adjustments. Due to device changes, participants leave the previous device data as of the change date and enter 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 specified limits for each parameter. Results that require “>” or “<” signs must be entered without the sign. Participants can view their reports through the SEROCON Portal. The program is based on the analysis of samples with unknown concentrations and periodic presentation of results obtained for each parameter. 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 revealing participant names, in accordance with confidentiality principles. For monitoring purposes, results from previous cycles in which participation was made are provided in Levey-Jenings charts for each parameter and sample analysis period.

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

SAMPLE WORK SCHEDULE

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

*The months of operation for the IMM4 program code.
**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