IMMUNOASSAY-PARATHORMONE 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 Coagulation-DDIM External Quality Control Program is designed to allow all participants to compare their analytical performance internally, considering overall results (all results), method, and method-instrument combinations.

SAFETY PRECUATIONS AND WARNINGS

The sample contains biological 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), 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 currently exist. 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 PREPARATIONS

This product is prepared using chemicals, stabilizers, and a human serum sample. This lyophilized material should be treated in the same manner as patient samples and handled according to the instructions provided with the device, kit, or reagent being used. Reconstitute the vial indicated on the label for the cycle month with 1.0 mL of distilled or deionized water using a volumetric pipette or equivalent. Replace the cap. Allow the product to stand for approximately 30 minutes without shaking or foaming, stirring occasionally. Before sampling, let the vial reach room temperature (18–25°C). Gently stir the vial several times to ensure homogenization. The reconstituted lyophilized product should be used within 1 hour of dissolution and reaching room temperature. Immediately replace the cap after each use and store at 2–8°C. It is recommended to perform the procedure within the daily routine without the knowledge of laboratory personnel. Dispose of any waste material according to local waste management regulations. In case of damaged packaging, contact the sales office or technical service. Samples should be run in a single replicate.

STORAGE AND STABILITY

This product should be stored unopened at -15 to -20°C. Once prepared and tightly closed, it can be stored at -20 to -70°C for up to 30 days. Do not return any used material to the original vial. Samples must be thoroughly mixed before reuse. Do not refreeze the product after it has been thawed; any remaining material should be discarded.

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 samples for 4 months (IMM4) or 12 months (IMM12) according to the program code. Each sample is labeled with the cycle month for entry of results into the SEROCON Portal via www.serocon.com. Samples should be analyzed on the dates specified for the corresponding cycle month according to the program.

REPORTING OF RESULTS

Results must be entered into the SEROCON Portal on www.serocon.com using a username and password no later than the last day of the relevant cycle month. Each institution enters data according to the program opened for its own device and method. In case of a device change during the program, SEROCON must be informed. When changing devices, participants leave the old device data as of the change date and enter results according to the new program/device setup. Results are released starting from the second week following the cycle month. The system does not allow entry of results outside the defined limit values for each parameter. Results that should be entered with “>” or “<” must be entered without the sign. Participants can view their reports via the SEROCON Portal. The program is based on analyzing samples with unknown concentrations and presenting results for each parameter at specific intervals. Results from 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 revealing participant names, in accordance with confidentiality principles. Participants can also track results from previous cycles for each parameter using Levey-Jenings 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

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 working months 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

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