D-Dimer External Quality Control Prospectus

PC	350	CGL4 CGL12	CONT	4 x 1 mL 12 x 1 mL	2C°		8C°	LOT	35026XX	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 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 plasma. This lyophilized product should be handled in the same manner 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 1.0 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. Samples should be tested in a single replicate.

STORAGE AND STABILITY

This product should be stored unopened at 2–8°C. Once reconstituted and tightly capped, it can be kept at 2–8°C for up to 4 hours. Do not return the used sample to the vial. Stored samples must be thoroughly mixed before reuse. Do not refreeze this product after thawing; 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 Coagulation-DDIM samples for 4 months (CGL4) or 12 months (CGL12) 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 tested on the dates specified below according to the program and the relevant cycle month.

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 created for its own instrument and method. If there is an instrument change during the program, SEROCON must be informed to make the necessary adjustments. In the case of an instrument change, participants leave the previous instrument data as of the change date and enter new results according to the updated program. Results are released 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 require a ">" or "<" sign should be entered without the sign. 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. 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 reviewed in graphs without revealing participant names, in accordance with confidentiality principles. For monitoring purposes, previous cycle values are provided for each parameter using Levey-Jennings charts at the designated sample analysis intervals.

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	3502601	24.01.2026	31.01.2026
February*	3502602	21.02.2026	28.02.2026
March	3502603	24.03.2026	31.03.2026
April	3502604	23.04.2026	30.04.2026
May*	3502605	23.05.2026	31.05.2026
June	3502606	23.06.2026	30.06.2026
July	3502607	24.07.2026	31.07.2026
August*	3502608	22.08.2026	31.08.2026
September	3502609	23.09.2026	30.09.2026
October	3502610	24.10.2026	31.10.2026
November*	3502611	24.11.2026	30.11.2026
December	3502612	24.12.2026	31.12.2026

*The working months for the CGL4 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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