Diabetes External Quality Control Prospectus

PC	500	GH4 GH12	CONT	4 x 1 mL 12 x 1 mL	2C°		8C°	LOT	50026XX	IVD CE

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 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 whole blood/hemolysate. 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 20 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.

SRORAGE 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.

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 (GH4) or 12 months (GH12) 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

ÖRNEK ÇALIŞMA TAKVİMİ

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
January	5002601	24.01.2026	31.01.2026
February*	5002602	21.02.2026	28.02.2026
March	5002603	24.03.2026	31.03.2026
April	5002604	23.04.2026	30.04.2026
May*	5002605	23.05.2026	31.05.2026
June	5002606	23.06.2026	30.06.2026
July	5002607	24.07.2026	31.07.2026
August*	5002608	22.08.2026	31.08.2026
September	5002609	23.09.2026	30.09.2026
October	5002610	24.10.2026	31.10.2026
November*	5002611	24.11.2026	30.11.2026
December	5002612	24.12.2026	31.12.2026

*These are the testing months for the GH4 program code.
**The sample vials are labeled with 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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