THALASSEMIA EXTERNAL QUALITY CONTROL PROSPECTUS

PC 540 TLS4 CON 4 x 1 mL 2C°  8C° LOT 54026XX IVD CE

PURPOSE OF USE
The Thalassemia External Quality Control Program aims to enable all participants to compare their analytical performance internally in terms of overall results (all results), method, and method-device.

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 and confirmed not to react with Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C (HCV), or antibodies to HIV-1/HIV-2. This product may also contain other human-derived materials for which no approved test exists. In accordance with good laboratory practices, all human-derived materials should be considered potentially infectious and handled with the same precautions as patient samples.

SAMPLE PREPARATION
This lyophilized product is prepared using chemicals, stabilizers, and human-derived whole blood/hemolysate. It 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 is reconstituted with 1.0 mL of distilled or deionized water using a volumetric pipette or equivalent. The cap is replaced. The product should be gently mixed occasionally without shaking or foaming and left to stand for approximately 20 minutes. Before sampling, allow the vial to reach room temperature (18–25°C). To ensure homogeneity, the vial should be gently inverted several times. The reconstituted lyophilized product should be used within 1 hour after it has fully dissolved and reached room temperature. After each use, the cap must be immediately replaced, and the product stored at 2–8°C. It is recommended that the product be handled during routine procedures without the knowledge of laboratory personnel. Any waste material should be disposed of according to local waste management regulations. In case of packaging damage, contact the sales office or technical service. Samples are recommended to be tested in a single replicate.

STORAGE AND STABILITY
This product should be stored at 2–8°C before opening. Once reconstituted and tightly closed, it can be stored at 2–8°C for 7 days or at –20 to –70°C for 30 days. After use, the sample must not be returned to the vial. Stored samples must be thoroughly mixed before reuse. Frozen product should not be refrozen after thawing, and 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 4-month (TLS4) samples according to the program code. Each sample is labeled to indicate the cycle month for entering the results into the SEROCON Portal at www.serocon.com. Samples should be tested according to the dates specified for the corresponding cycle month in the program.

REPORTING OF RESULTS
Results must be entered into the SEROCON Portal at www.serocon.com using a username and password no later than the last day of the relevant cycle month. When entering results, each institution logs in through the program opened for its own device and method. In case of a device change during the program, SEROCON must be informed so that the necessary adjustments can be made. Following a device change, participants leave the data from the old device as of the change date and enter new results according to the updated program setup. Results are released 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 “<” symbols should be entered without these symbols. Participants can view their reports through the SEROCON Portal. The program is based on the analysis of a sample with unknown concentration and periodic presentation of the 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 reviewed in graphs without revealing participant names, maintaining confidentiality. For monitoring purposes, values from previous cycles in which the participant took part are provided as Levey-Jenings charts for each parameter across 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
February	5402602	21.02.2026	28.02.2026
May	5402605	23.05.2026	31.05.2026
August	5402608	22.08.2026	31.08.2026
November	5402611	24.11.2026	30.11.2026

**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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