IMMUNOHEMATOLOGY EXTERNAL QUALITY CONTROL PROSPECTUS

PC 550 IH4 CONT

Manuel system;
1x2 ml Donor Erythrocyte Suspension
1x2 ml Patient Erythrocyte Suspension
1x1 ml Donor Plasma
1x1 ml Patient Plasma

Automatic device;
1x2 ml Donor Whole Blood
1x2 ml Patient Whole Blood

2C°  8C° LOT 55026XX IVD CE

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

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 methods accepted by the FDA, and it is confirmed that it does not react for Hepatitis B Surface Antigen (HBsAg), antibodies against Hepatitis C (HCV), and antibodies against HIV-1/HIV-2. This product may also contain other human-derived materials for which no approved test is yet available. In accordance with good laboratory practice, all human-derived materials should be considered potentially infectious and handled using the same precautions as those applied to patient samples.

SAMPLE PREPARATION
This product contains human erythrocyte suspensions and plasma samples for manual systems, or human whole blood samples for automatic devices, preserved in stabilizers. Therefore, it must be ensured that the sample is suitable for your method. This product must be handled in the same manner as patient samples and used according to the instructions provided with the device, kit, or reagent in use.
1. Tubes labeled with the cycle month are removed from the refrigerator and left for 15 minutes to reach room temperature (18-25°C) before mixing.
2. To mix whole blood and erythrocyte suspensions, hold the tube horizontally between the palms. It should not be pre-mixed with a mechanical mixer. a. Roll the tube back and forth for 20 to 30 seconds; occasionally invert the tube. Mix, but do not shake. b. Continue mixing in this manner until the cells are completely suspended. Tubes stored for a long period may require additional mixing. c. Before processing each sample, invert the tube slowly 8 to 10 times.
3. The following procedures are applied for manual or automated testing.

Manual system:
Erythrocyte suspensions are prepared at 2% and should be used without dilution. After taking the sample:

- ABO and D typing are performed using erythrocyte suspension (forward) and plasma samples (reverse).
- Crossmatch testing is performed using donor erythrocyte suspension and patient plasma.
- Direct Coombs Test (DAT) is performed using patient erythrocyte suspension, and Indirect Coombs Test (IAT) is performed using patient plasma.
- Depending on the test results, optional antibody screening and identification may be performed. In this case, contact with the company is required.
- During procedures, avoid contamination between erythrocytes and plasma. Hemolyzed samples may cause confusion in the evaluation of results.

Automatic device:
Donor and patient samples prepared as whole blood are placed in the device after centrifugation.

- Using patient blood, ABO and D typing, Direct Coombs Test (DAT), Indirect Coombs Test (IAT) (antibody screening and identification) (forward and reverse), and Rh subgroup determination (C, c, E, e, and K antigens) are performed.
- Crossmatch tests are performed using both patient and donor blood.

4. After use, place the tubes in the refrigerator within 30 minutes. It is recommended that laboratory personnel work with this product during routine daily procedures without drawing special attention. 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. **It is recommended to process samples as a single replicate.**

STORAGE AND STABILITY
These samples are stable until the expiration date when stored unopened at 2 to 8°C. After opening, all parameters remain stable for up to 48 hours, provided they are used appropriately, tightly capped, and stored at 2 to 8°C. Protect the tubes from EXCESSIVE HEAT and FREEZING. This product is shipped under refrigerated conditions. Do not return used samples to the bottle. Stored samples must be thoroughly mixed before reuse.

LIMITATIONS
1. This product should not be used after the expiration date.
2. his product is not intended to be used as a standard.
3. After mixing, the sample should appear similar to freshly drawn whole blood. In unmixed tubes, the sediment surface may appear cloudy and reddish. This is normal and does not indicate that the control is compromised. Any other color change, very dark red sediment surface, or unacceptable results may indicate that the control is spoiled. Do not use the sample if spoilage is suspected.
4. The performance of this product is ensured only when it is stored and used as described in the prospectus.
5. Insufficient mixing of a tube before use invalidates both the collected sample and any remaining material in the tube.

TEST TIMES
The box contains 4-month (IH4) samples according to the program code. Each sample is labeled with the cycle month to enter the results into the SEROCON Portal via www.serocon.com. Samples should be processed 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. When entering results, each institution logs in through the program opened for its own device and method. If a device change occurs during the program, SEROCON must be informed so that the necessary adjustments can be made. Due to a device change, participants leave the old device data as of the date of the change and enter new results according to the designated new program schedule. Results are released starting from the second week of the month following the cycle. The system does not allow entry of results outside the limit values for each parameter. Results that should be entered with ">" or "<" symbols must be entered without the symbol. Participants can view their reports through the SEROCON PORTAL. The program is based on the analysis of a sample with unknown concentrations and the presentation of results obtained for each parameter at specific intervals. For each parameter, the results of 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 indicating participant names, in accordance with confidentiality principles. For participant tracking, values from previous cycles in which participation was made are provided with Levey-Jennings charts for each parameter during the sample analysis periods.

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	5502602	21.02.2026	28.02.2026
May	5502605	23.05.2026	31.05.2026
August	5502608	22.08.2026	31.08.2026
November	5502611	24.11.2026	30.11.2026

**The sample bottles indicate the Program Code and LOT number. The last two digits (XX) of the LOT number represent the sample number for the relevant cycle month. The user performs the analysis in the relevant cycle month by taking the XX number into account.

CONTACT US

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