Hematology External Quality Control Prospectus

PC	580	HM4 HM12	CONT	X x 2 mL X x 2 mL	2C°		8C°	LOT	58025XX	IVD CE

PURPOSE OF USE

The Hematology External Quality Control Program aims to allow all participants to compare their analytical performance internally, both overall (all results), by method, and by method-instrument.

SAFETY PRECUATATIONS 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 to ensure 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 practices, all human-derived materials should be considered potentially infectious and handled with the same precautions applied to patient samples.

SAMPLE PREPARATION

This product contains human erythrocytes, leukocytes, and platelets suspended in a plasma-like liquid with protective agents. This product 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. 1. Tubes labeled for the respective cycle month are removed from the refrigerator and left for 15 minutes to reach room temperature (18–25°C) before mixing. 2. To mix, hold the tube horizontally between the palms. Do not pre-mix using a mechanical mixer. a. Roll the tube forward and backward for 20 to 30 seconds; occasionally invert the tube. Mix, but do not shake. b. Continue mixing in this way until the red cells are fully suspended. Tubes stored for a long time may require additional mixing. c. Before each test, slowly invert the tube 8 to 10 times. 3. After sample collection: a. Automatic Sample Preparation: After analysis, the tube is immediately removed from the sample carrier. b. Manual Sample Preparation: Carefully wipe the tube edge and cap with gauze, and replace the cap. 4. After use, tubes should be placed back in the refrigerator within 30 minutes. It is recommended that this be done as part of the daily procedure without laboratory personnel being unaware. Any waste material should be disposed of according to local waste management requirements. In case of packaging damage, contact the sales office or technical service. **Samples are recommended to be run in 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 closed, and stored at 2 to 8°C. Protect the tubes from EXCESSIVE HEAT and FREEZING. This product is shipped under refrigerated conditions. After use, it should not be poured back into the sample bottle. Stored samples must be thoroughly mixed before reuse.

LIMITATIONS

1. The expiration date of this product is the last day of the cycle month in which the respective sample is used.
2. This product is not intended to be used as a standard.
3. After mixing, the sample should resemble freshly drawn whole blood in appearance. In unmixed tubes, the sediment surface may appear cloudy and reddish. This is normal and does not indicate that the control is spoiled. Any other color change, a very dark red sediment surface, or unacceptable results may indicate that the control is compromised. 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 (HM4) or 12-month (HM12) samples according to the program code. Each sample is labeled with the cycle month to allow entry of the results into the SEROCON Portal via www.serocon.com. Samples should be analyzed on the dates specified below for the respective 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 respective cycle month. When entering results, each institution logs in through the program opened for its own device and method. If a device is changed during the program, SEROCON must be informed so that the necessary adjustments can be made. Due to device changes, participants leave the old device data as of the date of the change and enter new data according to the defined new program schedule. Results are published 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 “<” signs must be entered without the sign. Participants can view their reports via the SEROCON PORTAL. The program is based on the analysis of a sample with unknown concentrations and the periodic presentation of the results obtained for each parameter. All participants’ results for each parameter are calculated according to ISO 13528 requirements, and Z or Z’ scores (SDI) are generated. The values entered by other participants can be viewed in graphs without revealing participant names, in accordance with confidentiality principles. For participants to track their performance, values from previous cycles in which they participated are provided in 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
January	5802501	24.01.2025	31.01.2025
February*	5802502	21.02.2025	28.02.2025
March	5802503	24.03.2025	31.03.2025
April	5802504	23.04.2025	30.04.2025
May*	5802505	23.05.2025	31.05.2025
June	5802506	23.06.2025	30.06.2025
July	5802507	24.07.2025	31.07.2025
August*	5802508	22.08.2025	31.08.2025
September	5802509	23.09.2025	30.09.2025
October	5802510	24.10.2025	31.10.2025
November*	5802511	24.11.2025	30.11.2025
December	5802512	24.12.2025	31.12.2025

*The study months for the HM4 Program code.
**The sample bottles display the Program Code and LOT number. The last two digits (XX) of the LOT number indicate the sample number for the respective cycle month. The user performs the analysis by referring to the XX number for the relevant cycle month.

CONTACT US

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