

	SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICAL INDUSTRY AND TRADE INC	Document Code	PRP.19
		Effective Date	01.11.2022
		Rev. No / Date	02/22.12.2025
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ETHANOL-AMMONIA EXTERNAL QUALITY CONTROL PROSPECTUS			

PC 160 **EA4** **EA12** **CONT** X x 1 mL X x 1 mL 2C°  8C°  **LOT** 16025XX **IVD** **CE**

PURPOSE OF USE

The purpose is to enable all participants included in the Ethanol-Ammonia External Quality Control Program to compare their analytical performances within themselves in general (all results), by method, and by method-instrument.

SAFETY PRECUTATIONS AND WARNINGS

The sample content is of biological origin and is treated as potentially toxic and infectious. 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 is provided as a ready-to-use solution. It should be treated in the same manner as patient samples and analyzed in accordance with the instructions provided with the instrument, kit, or reagent in use. Before opening, the tube should be brought to 18–25°C, after which the solution should be promptly introduced into the instrument. It is recommended that the product be analyzed within the routine daily procedure without the laboratory staff being specifically informed. Any waste material should be disposed of in compliance with the requirements of local waste management authorities. In case of packaging damage, the sales office or technical service should be contacted. It is recommended that samples be analyzed in single replicate.

STORAGE AND STABILITY

These samples are stable until the expiration date when stored unopened at 2–8°C. Once opened, all parameters remain stable for up to 48 hours, provided they are used appropriately and stored tightly closed at 2–8°C. Protect the tubes from EXCESSIVE HEAT and FREEZING. This product is shipped under refrigerated conditions.

LIMITATIONS

1. This product must not be used after the expiration date.
2. If there is any indication of microbial contamination or excessive turbidity, the vial must be discarded.

TEST TIMES

The box contains 4-month (EA4) and 12-month (EA12) samples according to the program code. Each sample is labeled to indicate the corresponding cycle month for result entry into the SEROCON Portal via www.serocon.com. The samples must be analyzed during the cycle month specified in the program according to the dates listed below.

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 must use the program designated for its own instrument and method. In the event of an instrument change during the program, SEROCON must be informed so that the necessary adjustments can be made. Due to instrument changes, participants should stop entering data from the old instrument as of the change date and continue entering according to the new program setup. Results will be published starting from the second week of the month following the cycle. The system does not allow results outside the acceptable limits for each parameter to be entered. Results that require ">" or "<" signs must 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 concentrations, with the results for each parameter being presented periodically. For each parameter, the results of all participants are calculated according to ISO 13528 requirements, and Z or Z' scores (SDI) are generated. The values submitted by other participants can be reviewed in graphs without revealing participant identities, in line with confidentiality principles. To allow participants to track performance, the values from previous cycles are also presented in Levey-Jennings charts for each parameter across 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

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SAMPLE WORK SCHEDULE

Working Months**	Sample Lots	Proposed Study Date	Results Entry Deadline
January	1602501	24.01.2025	31.01.2025
February*	1602502	21.02.2025	28.02.2025
March	1602503	24.03.2025	31.03.2025
April	1602504	23.04.2025	30.04.2025
May*	1602505	23.05.2025	31.05.2025
June	1602506	23.06.2025	30.06.2025
July	1602507	24.07.2025	31.07.2025
August*	1602508	22.08.2025	31.08.2025
September	1602509	23.09.2025	30.09.2025
October	1602510	24.10.2025	31.10.2025
November*	1602511	24.11.2025	30.11.2025
December	1602512	24.12.2025	31.12.2025

*Working months for the EA4 Program code.

**Sample vials are labeled with the Program Code and LOT number. The last two digits (XX) of the LOT number indicate the sample number corresponding to the relevant cycle month. The user should perform the analysis by taking into account the XX number for the respective cycle month.



CONTACT US

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