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PROFICIENCY TESTING PT.UA.9.5.2024
MICROBIOLOGY OF BIOLOGICAL MATERIAL
(STERILE BIOLOGICAL LIQUID)
PROFICIENCY TESTING PROGRAMME
– ROUND 1

Kyiv-2024

1. INTRODUCTION

Given the key role of reliable test results that are needed during determining safety indicators in sanitary and bacteriological quality control of disinfection of industrial premises (food production, growing areas, hatcheries, etc.), requirements for the competence of laboratories that perform such tests should be confirmed.

The purpose of proficiency testing in microbiology testing is to demonstrate the laboratory's competence (as described in ISO/IEC 17043:2023[1]) and improve the reliability of test results.

This proficiency testing involves the use of inter-laboratory comparisons to confirm the performance of individual laboratories' abilities and/or identify areas of improvement.

This proficiency testing scheme is registered in the EPTIS database.

The functioning management system Metrology Service Ltd. (further – Provider) complies with ISO/IEC 17043[1] requirements and covers all aspects of proficiency testing (further – PT) for all proficiency tests.

2. DESCRIPTION

2.1. PARTICIPATION

2.1.1. Minimum methods for participation. Any organization, providing testing by at least one of Parameter /methods in clause 2.2 may participate in this voluntary Program.

2.1.2. Participant may provide results for all the methods according to clause 2.2

2.1.3. Metrology service Ltd. Assigns a unique identification number to each participant that is confidential and reported only to this participant.

2.1.4. Participation fee for participants from Ukraine is 5400.00 UAH with VAT. Participation fee for participants from outside of Ukraine is 150.00 USD.

2.1.5. We are expecting from 5 to 15 Participants.

2.1.6. Each participant has a unique identification number what are assigned according to Application form for every round every Programme. This identification number is confidential and can be published only by the permission of the Participant. The Participant should write this unique identification number at Task sheet form for testing and reporting results for identification. If Provider is suspecting collusion or falsification, it applies own procedure for the work with unsatisfied results.

2.2. METHODS

Participants can provide test results for the following Parameter /methods:

	Objective	Test method (ND)
1.	Bacteriological blood test for sterility (anaerobes and aerobes)	Chosen by laboratory

The Information for methods of preparation of samples and way of testing Participant should use from methods according to clause 2.2.

2.3. SAMPLES

2.3.1. Metrology service Ltd. is using contractors for the selection, production, homogenization and division designs that is satisfactory for the purposes of this program. The names and addresses of contractors can be given by request after publishing the final report.

Provider uses methods according to clause 2.2. for validation of homogeneity and stability. The quantity of methods can be decreased according to the decision of Provider's technical experts.

Tests, that are required to prove homogeneity and stability of samples are performed by competent contractors according to [1-6]. Provider uses a validated procedure of management system Metrology service Ltd for the samples' selection, production, division, checking of the quality and storage.

Sample will be packed in special package and hermetically sealed. Participant must check the packaging, the labeling and sample documents when accepting sample. In case of any damage to the packaging or identification questioning Participant must immediately inform the Provider.

A **Sterile biological liquids (blood in a sterile tube)** from each participant is used as a sample in Round 1.

2.3.2. Sample delivery. Metrology Service Ltd. will send appropriately identified and packaged sample together with task sheet form for testing and reporting. Shipping expenses for participants from Ukraine are not included in the price of participation. The Participant is responsible for the delivery of the samples on its own. Shipping expenses outside of Ukraine are not included in the price of participation.

2.4. SCHEME AND SCHEDULE

2.4.1. This proficiency testing program is a simultaneous participation schemes according to A.2 of appendix A ISO/IEC 17043[1]. Selected samples, prepared according to clause 2.3, from a source of material being distributed simultaneously to participants for concurrent testing. After completion of the testing, the results are returned to Metrology Service Ltd.

Task sheet form for testing and reporting results is distributed with the sample according to clause 2.3. Participant should use only this form for reporting.

Metrology Service Ltd use statistical methods to analyze results and provide report according to clause. 2.5.

2.4.2. Round 1 schedule.

Participants registration	till 13-00 EET 10.10.2025
Sample shipment	14.10.2025
Reporting results for participants	till 13-00 EET 30.10.2025
Report publication	till 20.11.2025

2.5. REPORT AND PROCESSING RESULTS

2.5.1. Metrology service Ltd. processes and analyses results according to [1-6].

2.5.2. Metrology service Ltd. publishes the Proficiency testing report according to [1].

2.5.3. Provider 'll express Participant's results for quantitative methods as traditional z-scores.

2.5.4. The assigned value for each analyte was calculated as the robust mean of the trial data using Huber H15 method or Algorithm A variation, Annex C.3.

2.5.5. Proficiency testing report will be published in two languages – English and Ukrainian. Basic (reference) language is English. Both version of the report 'll be published at internet <http://www.metrologyservice.com.ua>

3. PARTICIPANT INFORMATION

Participants must provide e-mail request for participation (Annex 1 to the Program) in accordance with the schedule Round (p.2.4.2.). Application form should be sent to the e-mail address pt.smetrology@gmail.com

4. PROVIDER CONTACTS AND PROGRAM MANAGER

Metrology service Ltd., Ukraine, 03022, Kyiv, 18 Yulii Zdanovskoi st. office 704.

e-mail: pt.smetrology@gmail.com

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tel: +38(099)305-79-78

5. NORMATIVE REFERENCE

1. ISO/IEC 17043:2023 Conformity assessment – General requirements for the competence of proficiency testing providers.
2. ISO 13528:2022 Statistical methods for use in proficiency testing by interlaboratory comparison.
3. FOOD ANALYSIS PERFORMANCE ASSESSMENT SCHEME (FAPAS). Protocol for proficiency testing schemes. version 4. September 2016. Part 3. FAPAS Food microbiology scheme (FEPAS)
4. Fearn, T. and Thompson, M, A new test for ‘sufficient homogeneity’, Analyst, 2001, 126, 1414-1417.
5. ISO 33405:2024 Reference materials — Approaches for characterization and assessment of homogeneity and stability.
6. ILAC Discussion Paper on Homogeneity and Stability Testing, April 2008.

Addition 1. Application form:

Назва програми ПК, номер раунду: <i>PT Program Name, number of raund:</i>	PT.UA.9.5.2024 MICROBIOLOGY OF BIOLOGICAL MATERIAL (STERILE BIOLOGICAL LIQUID) – ROUND 1
Дата подачі заявки: <i>Date of applying:</i>	
Повна назва лабораторії (українською або англійською мовою): <i>The full name of the laboratory (original language or in english):</i>	
Адреса доставки зразка або номер відділення ТОВ «Нова пошта»: <i>Address of samples delivery:</i> <i>(вказати, отримувач юридична чи фізична особа, місто, номер відділення чи адресу доставки, контактні дані отримувача (ППП, телефон, ЄДРПОУ):</i>	
ПІБ відповідальної особи від Учасника і телефон (при можливості мобільний): <i>Name of the responsible person from the Participant and telephone number (if possible, mobile):</i>	
Електронна адреса відповідальної особи від Учасника: <i>Contact email address of the responsible person from the Participant:</i>	
* Адреса доставки сертифіката: <i>Certificate delivery address:</i> номер відділення ТОВ «Нова пошта»: <i>(вказати, отримувач юридична чи фізична особа, місто, номер відділення чи адресу доставки, контактні дані отримувача (ППП, телефон, ЄДРПОУ)),</i> для доставки Укрпоштою вказати індекс і адресу:	
Для договору вказати: Повна назва юридичної особи: <i>Information for a contract: Full legal entity name:</i>	
Юридична адреса: <i>Full legal address:</i>	
Банківські реквізити, <u>ЄДРПОУ</u>, <u>ПІН</u>: <i>Company bank's detail(account, tax code, etc):</i>	
ППП, посада особи, що підписує Договір і на підставі чого: <i>Name of the person signing the Contract:</i>	

* All fields are required