LUXEMBOURG INSTITUTE OF HEALTH | INTEGRATED BIOBANK OF LUXEMBOURG IBBL

IBBL Biospecimen Proficiency Testing 2026 Programme

Participant's Manual

Table of Contents

Abbreviations

cfDNA	Cell-Free DNA
cfRNA	Cell-Free RNA
CSF	Cerebrospinal Fluid
DI	Dry ice
IBBL	Integrated BioBank of Luxembourg
LIH	Luxembourg Institute of Health
PIIS	Processing Item Information Sheet
PT	Proficiency testing
QC	Quality control
RT	Room temperature
TIIS	Test Item Information Sheet

Introduction

1. Who We Are

The provider of this Proficiency Testing (PT) Programme is IBBL, the Integrated BioBank of Luxembourg, based in 1 rue Louis Rech, L-3555 Dudelange, Luxembourg. Within the Luxembourg Institute of Health (LIH), IBBL is a biorepository, biorefinery, and technology centre that serves Luxembourg and its partners to collect, store and redistribute biospecimens and their related clinical data, and produces analytes suitable for analyses by state-of-the-art genomics and proteomics platforms. The major focus for IBBL's in-house research is Biospecimen Research. IBBL is ISO 9001 certified, ISO 17025 accredited. The scope of ISO 17025 accreditation covers the DNA quantification and purity by spectrophotometry, the DNA quantification by spectrofluorometry, the RNA quantification and purity by spectrophotometry and the RNA integrity assessment.

The PT Programme was endorsed by ISBER, the International Society for Biological and Environmental Repositories,.

2. Scope

Biospecimen Proficiency Testing (PT), as defined in ISO/IEC 17043:2010 (the International Standard on "Conformity assessment – General requirements for proficiency testing"), is seen as a powerful tool to help laboratories/repositories demonstrate their competence in biospecimen processing and characterisation to researchers, industry, and accreditation bodies. PT enables laboratories/repositories to monitor their Quality Control (QC) tests over time, identify longer term trends, and consider any necessary corrective actions.

The scope of this Programme is to develop, coordinate and implement PT Programmes for biospecimen processing, QC assays and biomolecular characterisation. The PT Programmes include assays performed by repositories and/or end-users for the validation/characterisation of biospecimens and their cellular and molecular derivatives. The PT Programmes also include processing methods for the extraction of such derivatives.

3. Vision

This Programme is expected to improve the quality management system of repositories through PT of their processing methods and Quality Control (QC) assays. PT Programmes are designed to promote the quality and the economic health of the particular industry of biorepositories by diminishing the actual "asymmetric information" gap between biospecimen providers and biospecimen end-users. Thus, the PT Programme here proposed represents an essential infrastructural development in the field of biomarker identification and validation.

4. Inter-laboratory Proficiency Testing

The PT Programme belongs to the category of inter-laboratory comparison Schemes involving simultaneous participation of Laboratories in different countries in the world. Randomly selected aliquots from a source material prepared at IBBL (the Processing Items and the Test Items) are distributed simultaneously to Participants for concurrent processing or testing.

In **Processing Schemes** (e.g. nucleic acid extraction), the Participants' processed "output materials" (e.g. DNA, RNA) are sent back to IBBL for isochronous testing. The results are used to assess Participants' processing efficiency.

In **Testing Schemes**, the Participants' results are returned to the PT provider (IBBL) and compared with the assigned value(s) derived from the reference laboratories or the participants' consensus mean to give an indication of the performance of the individual Participants and of the group as a whole.

A "split-level" design is implemented in some quantitative Schemes, which means that similar (but not identical) analyte concentration levels are included in two or three separate aliquots of Test Items. This is used to assess Participant's analytical accuracy. Multiple measurements are used to assess Participant's analytical precision.

5. Organization

IBBL acts as the PT Provider and has the responsibility for coordinating all of the activities involved in the operation of the PT Programmes and Schemes, in compliance with standard ISO/IEC 17043:2010. IBBL has the responsibility of the production and shipment of Processing Items and Test Items.

Design of the PT Schemes

The PT Programme for 2026 includes the following **Testing Schemes**:

- DNA Quantification and Purity
- DNA Integrity
- RNA Quantification and Purity
- RNA Integrity
- Cell Viability
- Tissue Histology

The PT Program for 2026 includes the following **Processing Schemes**:

- DNA Extraction from Whole Blood
- RNA Extraction from Whole Blood
- DNA Extraction from Buffy Coat
- RNA Extraction from Buffy Coat
- DNA Extraction from FFPE Material
- RNA Extraction from FFPE Material
- DNA Extraction from Frozen Tissue
- Total RNA Extraction from Frozen Tissue
- Dual DNA/RNA Extraction from Frozen Tissue
- Microbial DNA Extraction from Stool
- Microbial DNA Extraction from Saliva
- Cell-Free DNA (cfDNA) Extraction from Whole Blood
- Cell-Free RNA (cfRNA) Extraction from Plasma
- Viable PBMC Isolation
- Cerebrospinal fluid (CSF) Aliquoting

The PT Program for 2026 includes the following **combined Processing and Testing Scheme**:

- Circulating Tumor Cells (CTC) Isolation and Detection

1. “DNA Quantification and Purity” Scheme Design

The DNA used for this Scheme is extracted from whole blood obtained from a healthy donor. Three different Test Items containing DNA at a different concentration and 260/280 ratio (i.e. Tube A, Tube B and Tube C) are provided to each Participant. The Test Items are shipped at room temperature and should be stored at -80°C or lower until analysis. No processing is required at reception.

For each Test Item (Tube A, Tube B and Tube C), the Participant will need to measure the DNA concentration (ng/µl) and 260/280 ratio following his/her usual routine method. The results are collected under the following methods: Spectrophotometry, Spectrofluorometry, Microfluidic electrophoresis, Lunatic Spectrophotometry or Other (e.g. qPCR).

2. “DNA Integrity” Scheme Design

The DNA used for this Scheme is extracted from whole blood obtained from a healthy donor. Three different Test Items containing DNA at a different level of integrity (i.e. Tube A, Tube B and Tube C) are provided to each Participant. The Test Items are shipped at room temperature and should be stored at -80°C or lower until analysis. No processing is required at reception.

For each Test Item (Tube A, Tube B and Tube C), the DNA Integrity is measured following the Participant’s usual routine testing method(s). The results are collected under the following methods: Agilent TapeStation (DIN), LabChip GX (GQS), Fragment Analyzer (GQN), QIAxcel System (% above 15 kb) or Other (multiplex PCR, agarose gel), which provide the numerical value.

3. “RNA Quantification and Purity” Scheme Design

The RNA used for this Scheme is extracted from a Jurkat cell line by a Qiagen RNeasy mini kit method. Three different Test Items containing RNA at a different concentration and 260/280 ratio (i.e. Tube A, Tube B and Tube C) are provided to each Participant. The Test Items are shipped on dry ice and should be stored at -80°C or lower until analysis. No processing is required at reception.

For each Test Item (Tube A, Tube B and Tube C), the Participant will need to measure the RNA concentration (ng/µl) and 260/280 ratio following his/her usual routine method. The results are collected under the following methods: Spectrophotometry, Spectrofluorometry, Microfluidic electrophoresis, Lunatic Spectrophotometry or Other.

4. “RNA Integrity” Scheme Design

The RNA used for this Scheme is extracted from a Jurkat cell line by a Qiagen RNeasy mini kit method. Three different Test Items containing RNA at a different level of integrity (i.e. Tube A, Tube B and Tube C) are provided to each Participant. The Test Items are shipped on dry ice and should be stored at -80°C or lower until analysis. No processing is required at reception.

For each Test Item (Tube A, Tube B and Tube C) the RNA Integrity is measured following the Participant’s usual routine testing method(s). The results are collected under the following methods: Agilent Bioanalyzer (RIN), Biorad Experion (RQI), Agilent TapeStation Systems (RINe), QIAxcel System (RIS), Fragment Analyzer (RQN), Caliper LabChip (RQS), Qubit 4 Fluorometer (RNA IQ) or Other (18S:28S ratio, agarose gel),), which provide the numerical value.

5. “Cell Viability” Scheme Design

The cells used for this Scheme are a Jurkat cell line that is grown in culture in RPMI1640 10% FBS at a concentration of 5 x 10^6 to 1 x 10^7 cells/mL in T175 cm^2 in a humidified incubator at 37°C, 5% CO_2. Cells are then frozen in an animal protein-free, serum-free and defined cryopreservation medium containing 10% dimethyl sulfoxide (DMSO).

Three different Test Items containing cells at a different level of viability and early apoptosis (i.e. Tube A, Tube B and Tube C) are provided to each Participant. The Test Items are shipped on dry ice and should be stored in LN_2 until analysis. No processing is required at reception.

For each Test Item (Tube A, Tube B and Tube C), the percentage of viable cells and/or apoptotic cells is measured following the Participant's usual routine testing method(s). The results are collected under the following methods: Trypan Blue Staining or Flow Cytometry.

6. "Tissue Histology" Scheme Design

The tissues used for this Scheme are taken from tumoural and non-tumoural specific tissue types. Web access to different photos (Test Item A, Test Item B, Test Item C) is granted to each Participant.

The tissue characterization/mapping is done through the assessment of the percentage of Viable Tumor, Normal Tissue, and Other (necrotic tissue, tumor stroma).

7. "DNA Extraction from Whole Blood" Scheme Design

One PAXgene DNA tube of stabilized whole blood is shipped to the Participant. The Processing Item is shipped at room temperature and should be stored at room temperature or lower until analysis. No processing is required at reception.

DNA is extracted following the Participant's routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Salting Out or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of total and double-stranded DNA yield per mL of whole blood, DNA purity, DNA integrity (DIN) and DNA amplifiability.

8. "RNA Extraction from Whole Blood" Scheme Design

One PAXgene RNA tube of stabilized whole blood is shipped to the Participant. The Processing Item is shipped on dry ice and should be stored at -80°C or lower until analysis. No processing is required at reception.

RNA is extracted following the Participant's routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Phenol-Trizol Based or Other) and is sent back to IBBL at room temperature immediately after extraction for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of RNA yield per mL of whole blood, RNA purity, RNA integrity (RIN and DV200), mRNA quality, and DNA contamination.

9. “DNA Extraction from Buffy Coat” Scheme Design

One vial of frozen buffy coat is shipped to the Participant. The Processing Item is shipped on dry ice and should be stored at -80°C or lower until analysis. No processing is required at reception.

DNA is extracted following the Participant’s routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Salting Out or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of normalized total and double-stranded DNA yield per mL of buffy coat, DNA purity, DNA integrity (DIN) and DNA amplifiability.

10. “RNA Extraction from Buffy Coat” Scheme Design

One vial of frozen buffy coat is shipped to the Participant. The Processing Item is shipped on dry ice and should be stored at -80°C or lower until analysis. No processing is required at reception.

RNA is extracted following the Participant’s routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Phenol-Trizol Based or Other) and is sent back to IBBL at room temperature immediately after extraction for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of normalized RNA yield per mL of buffy coat, RNA purity, RNA integrity (RIN and DV200), mRNA quality and DNA contamination.

11. “DNA Extraction from FFPE Material” Scheme Design

Two sections of FFPE tonsil tissue of 10 µm thickness are shipped to the Participant. The Processing Item is shipped at room temperature and should be stored at room temperature or lower until analysis. No processing is required at reception.

DNA is extracted following the Participant’s routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Salting Out or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of total and double-stranded DNA yield per 10 µm section, DNA purity, DNA integrity (DIN), cross-linking and amplifiability.

12. “RNA Extraction from FFPE Material” Scheme Design

Two sections of FFPE colorectal tissue of 10 µm thickness are shipped to the Participant. The Processing Item is shipped at room temperature and should be stored at room temperature or lower until analysis. No processing is required at reception.

RNA is extracted following the Participant’s routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Phenol-Trizol Based or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of RNA yield per 10 µm section, RNA purity, RNA integrity (RIN and DV200), mRNA quality, and DNA contamination.

13. "DNA Extraction from Frozen Tissue" Scheme Design

One cryoExtract core of frozen pig liver tissue (10 – 30 mg) will be provided to each Participant. The Processing Item is shipped on dry ice and should be stored at -80°C or lower until analysis. No processing is required at reception.

DNA is extracted following the Participant's routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Salting Out or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of total and double-stranded DNA yield per mg tissue, DNA purity, and DNA integrity (DIN). IBBL will also assess the presence of PCR inhibitors.

14. "Total RNA Extraction from Frozen Tissue" Scheme Design

One cryoExtract core of frozen pig liver tissue (10 – 30 mg) will be provided to each Participant. The Processing Item is shipped on dry ice and should be stored at -80°C or lower until analysis. No processing is required at reception.

RNA is extracted following the Participant's routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Trizol or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of RNA yield per mg tissue, RNA purity, RNA integrity, and DNA contamination.

15. "Dual DNA/RNA Extraction from Frozen Tissue" Scheme Design

One cryoExtract core of frozen pig liver tissue (10 – 30 mg) will be provided to each Participant. The Processing Item is shipped on dry ice and should be stored at -80°C or lower until extraction. No processing is required at reception.

DNA and RNA are extracted following the Participant's routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Salting Out or Other) and are sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of total and double-stranded DNA yield per mg tissue, DNA purity, and DNA integrity (DIN). IBBL will

also assess the presence of PCR inhibitors. For the RNA samples, results will be displayed in terms of total RNA yield per mg tissue, RNA purity, RNA integrity, and DNA contamination.

16. "Microbial DNA Extraction from Saliva" Scheme Design

One Omnigene.Oral OM-501 tube of stabilized saliva will be provided to each Participant. The Processing Item is shipped at room temperature and should be stored at room temperature or lower until analysis. No processing is required at reception.

DNA is extracted following the Participant's routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Salting Out or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of total and double-stranded DNA yield per mL saliva, and DNA purity. IBBL will also conduct a qPCR for bacterial DNA and for human DNA and will assess the presence of PCR inhibitors.

17. "Microbial DNA Extraction from Stool" Scheme Design

One Zymo Fecal Collection Tube of stabilized stool will be provided to each Participant. The Processing Item is shipped at ambient temperature and should be stored at ambient temperature until analysis. No processing is required at reception.

DNA is extracted following the Participant's routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Salting Out or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of total and double-stranded DNA yield per mg stool, and DNA purity. IBBL will also conduct a qPCR for bacterial DNA and for human DNA and will assess the presence of PCR inhibitors.

18. "Circulating Cell-Free DNA (cfDNA) Extraction from Whole Blood" Scheme Design

One PAXgene Blood ccfDNA of stabilized blood spiked with mononucleosomes will be provided to each Participant. The Processing Item is shipped at room temperature and should be stored at room temperature or lower until extraction. No processing is required at reception.

cfDNA is extracted following the Participant's routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Salting Out, or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of cfDNA yield per mL whole blood. IBBL will also assess the size distribution by microfluidics electrophoresis, the presence of High Molecular Weight DNA Amplification and the cfDNA extraction efficiency by digital PCR .

19. “Circulating Cell-Free RNA (cfRNA) Extraction from Plasma” Scheme Design

One double-spun EDTA plasma will be provided to each Participant. The Processing Item is shipped on dry ice and should be stored at -80°C or lower until extraction. No processing is required at reception.

cfRNA is extracted following the Participant’s routine procedures (Magnetic Bead-Based, Silica Membrane-Based, Trizol, or Other) and is sent back to IBBL at room temperature for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of cfRNA yield per mL plasma, relative quantification expressed as Ct value of two microRNA targets amplified from all extracted cfRNA samples.

20. “Viable PBMC Extraction” Scheme Design

The Participant will proceed to the collection of one blood tube (any anti-coagulant permitted) from a healthy donor. The Participant will then extract the PBMC following his/her routine procedure. The Participant will measure the number of PBMC (cells/mL) and prepare PBMC aliquots.

The Participant will proceed to the freezing of the PBMC aliquots following his/her routine procedure. As soon as possible, the Participant will send all the aliquots generated to IBBL on dry ice for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of number of viable PBMC extracted per mL of blood, PBMC viability (%) and early apoptosis/necrosis (%), and PBMC functionality (ELISPOT).

21. “CSF Aliquoting” Scheme Design

One tube of human cerebrospinal fluid (CSF) will be provided to each Participant. The Processing Item is shipped on dry ice and should be stored at -80°C or lower until processing. No processing is required at reception.

The Processing Item is aliquoted following the Participant’s routine procedure, and is sent back to IBBL at room temperature. All aliquots are transferred to the Laboratory for Clinical Neurochemistry and Neurochemical Dementia Diagnostics, Universitätsklinikum in Erlangen for isochronous testing.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of concentrations of amyloid β peptide 1-40 (Aβ1-40), amyloid β peptide 1-42 (Aβ1-42), Tau and phosphorylated Tau 181 (pTau181).

22. “Circulating Tumor Cells (CTC) Isolation and Detection” Scheme Design

This is a combined processing and testing/analytical scheme.

One Transfix tube of freshly collected blood, spiked-in with Colorectal Cancer derived cell line as CTC mimic, will be provided to each Participant. The Processing Item is shipped at room temperature and should be stored at room temperature until processing.

The CTCs are isolated or enriched, and enumerates following the Participant's routine procedure. The number of CTCs counted will be reported in the PT website.

Each Participant will receive a performance report with summary statistics highlighting his individual results, in terms of CTC recovery rate.

Criteria for Participation

1. General Requirements

Participation is entirely voluntary, provided the following requirements are met:

- The required facilities to perform the test/processing are in place at the Participant site. You can check what facility/equipment you require by reviewing the relevant PIIS (Processing Item Information Sheet) and TIIS (Test Item Information Sheet), which contain basic information on the sample preparation, safety and handling instructions. PIIS and TIIS for each scheme are shipped along with the Items, and are downloadable on LIH website (https://www.lih.lu/en/translational-medicine/translational-medicine-operations-hub/integrated-biobank-of-luxembourg-ibbl/biospecimen-proficiency-testing-2/).
- The laboratory operator at the site has the technical competence to perform the test/processing, or has been appropriately delegated to conduct the test/processing. Your institution will ensure the technical competence is covered.
- The test/processing shall be conducted under the Participant routine conditions. Directions will not be provided on the method to use for processing or analysis to avoid any deviation from your normal processing or testing conditions. Recommendations on conditions to perform the test may be available on certain Schemes.

2. Registration Instructions

Register directly online on the website http://biospecimenpt.ibbl.lu/. Registration for the programme 2026 will be open between May 18th and August 31st, 2026.

No registration will be accepted outside these dates.

2.1. Participant Coding System

Once registered in the PT platform, the participants are being assigned a specific code to ensure confidentiality of the data they are providing. The coding is structured as follows:

- The Laboratory Number is the letter L followed by a three-digit number (L015...), unique to each Participant. Only authorized LIH/IBBL staff members (programme coordinator, project manager and logistic department) know the link between the Laboratory Number and the Participant identity.
- The Password is assigned to every individual from an Organisation. You will use your email address and the password to log in to the website (see Section 5) to submit your results for the specific Round/Scheme.

NOTE: In case of recurrent participation, Participant will use the login information received during the original registration in the PT platform. Using the same account every year will allow a history of z-scores to be established, enabling the Participant to monitor consistently his/her performance over time.

NOTE: when no connection to the account is detected for at least 5 years, the account will be deleted from the online platform.

2.2. Instructions for Participants

For all Schemes, a detailed "Test Item Information Sheet" (TIIS) or "Processing Item Information Sheet" (PIIS) is provided to all Participants along with the shipment of the PT Items and is also on LIH website (https://www.lih.lu/en/translational-medicine/translational-medicine-operations-hub/integrated-biobank-of-luxembourg-ibbl/biospecimen-proficiency-testing-2/). TIIS and PIIS describe all relevant information related to the preparation of the samples, testing conditions, biohazard information and all administrative aspects to consider.

Participants must read these instructions carefully before undertaking any operation on the Items.

Please note that concentration of the Test Items and/or nature of the samples are not provided to the Participants to avoid any bias in the performance of the test. Those details may be disclosed along with the Participant Report.

2.3. Timelines

Each Scheme will follow specific timelines for the shipment of PT Items, the testing phase of the Items, the return of the results by each Participant and the availability of the reports. Those timelines are indicated in the relevant PIIS and TIIS that is provided along with the Processing Items and Test Items, respectively.

Failure to comply with those timelines will result in inability to perform statistical analysis of Participant results. Results cannot be submitted after the deadline set-up for each Scheme.

2.4. Withdrawal

Participants can withdraw at any time from the Proficiency Testing programme. Partial refunds are available for cancellation requests received in writing prior to the end of the registration period, after an administrative cancellation fee of 100€ (EUR) is applied. No refunds are available after the registration deadline.

3. Subscription Fees

The 2026 fees for each Scheme are indicated below in EUR. You can participate in one or more PT Schemes, at the following prices:

Scheme	Code	Fee
DNA Quantification and Purity*	DNAQ26	629€
DNA Integrity*	DNAI26	629€
RNA Quantification and Purity*	RNAQ26	629€
RNA Integrity*	RNAI26	629€
Cell Viability*	CELL26	629€
Tissue Histology	THIS26	519€
CSF Aliquoting	CSAL26	519€
DNA Extraction from Whole Blood	DNABLD26	399€
DNA Extraction from FFPE Material	DNAFFC26	399€
DNA Extraction from Buffy Coat	DNABFF26	399€
RNA Extraction from Whole Blood	RNABLD26	399€
RNA Extraction from FFPE Material	RNAFFC26	399€
RNA Extraction from Buffy Coat	RNABFF26	399€
DNA Extraction from Frozen Tissue	DNAFRT26	399€
Total RNA Extraction from Frozen Tissue	RNAFRT26	399€
Dual DNA/RNA Extraction from Frozen Tissue	DUAFRT26	399€
Microbial DNA Extraction from Saliva	DNASAL26	399€
Microbial DNA Extraction from Stool	DNASTL26	399€
cfDNA Extraction from Whole Blood	cfDNA26	399€
cfRNA Extraction from Plasma	cfRNA26	399€
Viable PBMC Isolation	PBMC26	519€
Circulating Tumor Cells (CTC) Isolation and Detection	CTC26	399€

For the schemes with *, you may test multiple methods in the same run according to the lists of accepted methods. For all testing schemes, namely DNAQ26, RNAQ26, RNAI26, DNAI26, CELL26 and THIS26, you may enter up to 10 replicate measurements.

Prices are subject to change. Terms and conditions apply.

In order to receive the member discount, Organizational members will need to have their assigned delegate or alternate register. The number of Organizational member discounts will be limited to the total number of delegates and alternates held by the Organization.

Consecutive year registration is discontinued. However, previously registered participants retain the right to use their remaining rounds within a maximum period of three consecutive years. More details will be shared to the participants directly.

No refunds are available after the registration deadline. Partial refunds are available for cancellation requests received in writing prior to the end of the registration period, after an administrative cancellation fee of 100€ (EUR) is applied.

After registration closure, schemes with low number of registrations will not be conducted for statistical reasons.

For **Testing Schemes** (except the THIS26R1 scheme), you may test multiple methods in the same run according to the lists of accepted methods. You will however only be able to submit one result per method. For all testing schemes, you may enter replicate measurements in order to assess the within-laboratory variability.

For **shipments of PT schemes from/to IBBL:**

- For participants outside EU and US/Canada: the shipment effective cost of PT schemes from IBBL to participants will be covered by the participants.
- For the shipment of PT derivatives to IBBL, the cost will be covered by the participants.
- The street address on the registration form will be used as the SHIPPING address. If the samples should be shipped to a different address, please send that address to **IBBLPT@lih.lu.**

Shipment of PT Items

1. Shipment Organization

IBBL is responsible for the preparation of the Processing Items and Test Items that will be shipped to each Participant.

Once the registration is complete and Subscription fees are received at LIH, the PT Items required for the Scheme participation that have been requested will be prepared for shipment. Once materials are ready, Participants will be informed about the date of shipment and the estimated delivery date.

Processing Items and Test Items are prepared and packed according to the ICAO/IATA regulations and any additional local regulation applicable in the country where the Participant is located. Transporter airway-bill numbers for tracking purposes may be requested if needed.

Test Items are shipped along with the relevant TIIS. Processing Items are shipped along with the relevant PIIS.

Participants will be notified when shipping will commence so they know approximately when the PT Items will arrive. It is essential that the Participant communicate immediately to IBBL if any delay occurs in the delivery of the PT Items.

2. Shipment Temperatures

Depending on the conditioning of the samples to be shipped, the Schemes are categorized as either RT (Room Temperature) or DI (Dry Ice):

- DNA Quantification and Purity: RT or DI
- DNA Integrity: RT or DI
- RNA Quantification and Purity: DI
- RNA Integrity: DI
- Cell Viability: DI
- Tissue Histology: Shipment Temperature Not Applicable
- DNA Extraction from Whole Blood: RT
- RNA Extraction from Whole Blood: DI
- DNA Extraction from Buffy Coat: DI
- RNA Extraction from Buffy Coat: DI
- DNA Extraction from FFPE Material: RT
- RNA Extraction from FFPE Material: RT
- DNA Extraction from Frozen Tissue: DI
- Total RNA Extraction from Frozen Tissue: DI
- Dual DNA/RNA Extraction from Frozen Tissue: DI
- Microbial DNA Extraction from Saliva: RT
- Microbial DNA Extraction from Stool: RT

- Circulating Cell-Free DNA (cfDNA) Extraction from Whole Blood: RT
- Circulating Cell-Free RNA (cfRNA) Extraction from Whole Blood: DI
- CSF Aliquoting: DI
- Viable PBMC isolation: Shipment Temperature Not Applicable
- Circulating Tumor Cells (CTC) Isolation and Detection: RT

3. Import/Export License

For some countries (e.g. Australia, China, South Africa, Egypt), an import/export licence is required to receive/send biological samples. When registering to the PT programme, the Participant has to verify with their competent national authority whether such import/export license is required.

In such cases, the Participant has to apply him/herself to obtain this import/export permit. Once the application is complete, the Participant provides a copy or the references of his/her import/export permit to IBBL.

NOTE: The application process for an import/export license can take several months.

Results Submission & Reports

1. Online Submission of Results

Each Participant will need to login into the PT website http://biospecimenpt.ibbl.lu/ with the email address and password used during registration.

Each Participant will complete the form on the website as accurately as possible, within indicated timelines.

The number of significant figures required by Participants is:

- Zero for the Tissue Histology (i.e. "0.", no figure after the delineator);
- One for the DNA/RNA concentration (i.e. "0.1", 1 figure after the delineator);
- One for the Cell Viability (i.e. "0.1", 1 figure after the delineator)
- Zero for the Circulating Tumor Cells (CTC) Isolation and Detection (i.e. "0.", no figure after the delineator);
- Two for the DNA/RNA Integrity (i.e. "0.01", 2 figures after the delineator);
- Three for the DNA/RNA ratio (i.e. "0.001", 3 figures after the delineator).

Failure to comply with the timelines will result in inability to perform statistical analysis of Participant results. Results cannot be submitted after the deadline set-up for each Scheme, and detailed in the TIIS/PIIS.

2. Availability of Performance Reports

2.1. Statistical Analysis Approach

Statistical procedures used are those proposed by the International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories (IUPAC technical Report 2006).

All results provided by Participants will be analysed with the same statistical method and individual results are assessed against an assigned value.

For quantitative Schemes (i.e. DNAQ, DNAI, RNAI, RNAQ, CELL, THIS, PBMC, DNABLD, RNABLD, DNABFF, RNABFF, DNAFFC, RNAFFC, DNASAL, DNASTL, DNAFRT, RNAFRT, cfDNA, cfRNA, CSAL, DUAFRT, and CTC), the mean, median, standard deviation and range are provided.

For qualitative Schemes, the modes (most common responses) and range (lowest and highest response) are provided. In both cases, graphs are produced with the results from all Participants.

2.2. Evaluation of Performance

A Participant's result x is converted into a z-score according to the equation $z=(x-x_a)/\sigma_p$, where x_a is the Assigned Value and σ_p is the fitness-for-purpose based "standard deviation for inter-laboratory assessment".

The standard deviation for PT was determined by the PT Advisory Group based on approval of the following coefficients of variation:

- DNAQ26R1:
  - DNA Concentration: 25% for spectrophotometry (Lunatic)
  - DNA Ratio: 16% (Lunatic)
- DNAI26R1: 20%
- RNAQ26R1:
  - RNA Concentration: 25% for spectrophotometry (Lunatic)
  - RNA Ratio: 16% (Lunatic)
- THIS26R1: 30% for normal tissue and 15% for viable neoplasm
- CTC26R1: Observational

For the following schemes and methods, the Assigned Values will be the robust mean of the Participants and the PT standard deviation will be calculated based on Participants' standard deviation:

- "**DNA Quantification and Purity"** (Spectrophotometry, Spectrofluorometry, Microfluidic electrophoresis),
- **"RNA Quantification and Purity"** (Spectrophotometry, Spectrofluorometry, Microfluidic electrophoresis),
- **"DNA Integrity"** (Agilent TapeStation, QIAxcel System and Fragment Analyzer),
- **"RNA Integrity"** (Agilent Bioanalyzer, Biorad Experion, Agilent TapeStation Systems, Fragment Analyzer, Caliper LabChip GX and Qubit 4 Fluorometer),
- **"Cell Viability"**

For the following schemes and methods, the Assigned Values will be defined by the reference laboratories and the standard deviations will be calculated based on the above CV values :

- **"DNA Quantification and Purity**" (Lunatic Spectrophotometry),
- "**RNA Quantification and Purity"** (Lunatic Spectrophotometry),
- **"DNA Integrity"** (LabChip GX),
- "**RNA Integrity**" (LabChip GX),
- **"Tissue Histology**"

For **Processing Schemes** (PBMC, DNABLD, RNABLD, DNABFF, RNABFF, DNAFFC, RNAFFC, DNASAL, DNASTL, cfDNA, DNAFRT, RNAFRT, cfRNA, CSAL, DUAFRT, CTC), the Assigned Values are the average obtained by all the Participants. The standard deviation is the standard deviation of all the Participants. Results are analysed globally (all extraction methods) and also by individual extraction method. The scoring system is based on distance from the Assigned Value.

For most of the parameters measured, the following scoring system is used:

Deviation from assigned value	Consensus Score	Interpretation
< 1 standard deviation	0	"Accurate" or "Very Satisfactory"
≤ 2 standard deviation	1	"Acceptable" or "Satisfactory"
> 2 standard deviation	2	"Questionable"
> 3 standard deviation	3	"Requiring Action"

When the Assigned Value corresponds to the consensus mean of Participants, it can be required to highlight the proficiency of a participant to obtain better results than the Participants mean.
For certain parameters (e.g. nucleic acid extraction yield, RNA integrity…), better results correspond to results higher than the mean. In such cases, the scoring system applied is:

Deviation from assigned value	Consensus Score	Interpretation
< –3 standard deviation	3	"Requiring Action"
> -3 and < –2 standard deviation	2	"Questionable"
> -2 and < –1 standard deviation	1	"Acceptable" or "Satisfactory"
> -1 and < +1 standard deviation	0	"Accurate" or "Very Satisfactory"
> +1 standard deviation	0	"Accurate" or "Very Satisfactory"

For other parameters (e.g. cell apoptosis/necrosis…), better results correspond to results lower than the mean. In such cases, the scoring system applied is:

Deviation from assigned value	Consensus Score	Interpretation
< –1 standard deviation	0	"Accurate" or "Very Satisfactory"
> -1 and < +1 standard deviation	0	"Accurate" or "Very Satisfactory"
> +1 and < +2 standard deviation	1	"Acceptable" or "Satisfactory"
> +2 and < +3 standard deviation	2	"Questionable"
> +3 standard deviation	3	"Requiring Action"

The PT Advisory Group will review in details all the results falling into the "Questionable" and "Requiring Action" performance outcome, to provide additional advice to Participants.

2.3. Performance Reports

Reports provided to all Participants include the following: summary on the design of the Scheme, recommendations based on the outcome of the Scheme, statistical procedure used, Participant results, statistical data and summaries, including assigned values and ranges of acceptable results, procedures used to establish the standard deviation and comments on Participant performance. History of z-scores is also provided.

Once the statistical analysis and the evaluation of performance are completed, Participants will be able to find their report(s) in their account on the online PT platform.

Classification or ranking of Participants on the basis of their z-scores will not be done.

Please note that according to ISO/IEC 17043, only administrative corrections (e.g., institute or instrument name, operator etc.) could be changed after data entry has been closed and/or the PT reports have been

released. Any data that could impact group assignment and alter the final evaluation even slightly, cannot be modified as ISO/IEC 17043 considers correct identification of the method and results as part of the participant's competence assessment.

2.4. Use of Results

Upon reception of the report, the Participant can decide to use his/her PT results for publication and/or for method validation. IBBL can also use the global results for a publication in specialized international journals. Participant identity will never be disclosed to third parties, and performance data will be kept strictly confidential unless a specific request is made by the Participant (to be released, for example, to an accrediting agency).

2.5. Certificate of Participation

All Participants that submit results will receive a Certificate of Participation to the Scheme(s), which they have participated in. In case of participation in a Scheme with multiple methods, one Certificate of Participation will be issued per method.

When **all** the results are "Very Satisfactory", the Certificate of Participation includes a comment specifying "Results Were Very Satisfactory".

2.6. Label of Participation

All Participants that submit results to any of the Scheme(s) will receive a Label of Participation. All participants may use the provided label on printed or digital media to showcase their participation in IBBL's Biospecimen Proficiency Testing (PT) programme, according to the guidelines provided along with the label.

Participant Feedback and Complaints

1. Use of Comment Section Online

While submitting the results of Participant's tests on the samples directly on the website (http://biospecimenpt.ibbl.lu/), comments on the performance of the test may be added in the comment section. Any comment on specific process and/or material used, as well as any issue, technical or logistic that a Participant may have encountered in this phase, will be reviewed carefully.

2. Advisory Service on Demand

For any technical issue that a Participant may encounter and/or for any clarification needed during the testing phase, IBBL support can be contacted at IBBLPT@lih.lu.

3. Customer Satisfaction Survey

IBBL seeks Participant's feedback, both positive and negative, to be used and analysed to improve its management system, future Schemes, and customer service. At the end of the PT Scheme, Participants are encouraged to complete the Customer Satisfaction Survey, available online. The Project Manager will send the link to the survey to each Participant once Reports have been issued and received by Participants.

4. Complaints

IBBL welcomes the opportunity to discuss informally any problem or query that a Participant may have. A formal complaint regarding the service provided within the PT Programme should be sent by email (IBBLPT@lih.lu), fax or letter and will be acknowledged in writing by the same means of communication as used to contact us.

All complaints are reviewed formally and corrective actions will be taken to resolve the complaints. A specific procedure is in place to ensure all complaints are brought to resolution.

Confidentiality

1. General Policy

All data related to Participant's subscription, results and performance assessment will be kept confidential and will not be disclosed to individual Participants and/or anyone else outside LIH/IBBL office members involved in the PT Program. Performance data may be shared with regulatory and/or accreditation bodies where appropriate and necessary, but only with explicit written permission from the Participant.

As mentioned previously, Participant identity and performance results are protected through a specific coding system, which will also avoid any unintentional disclosure of information.

2. Data Protection

When processing identification and contacts' data pertaining to the Participant, in the scope of the provision of the Proficiency Testing services, the Participant and LIH-IBBL, acting as independent controllers, are solely responsible for their own compliance with the Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data ("GDPR") and the Luxembourgish Law of 1st of August 2018 implementing the GDPR into national law; and any relevant guidance issued by supervisory authorities ("Data Protection Legislation").

As per article 13 of EU GDPR, the Participants are informed that LIH-IBBL will manage their identification and contact details, for the purpose of executing the Proficiency Testing Program. The lawful basis for such processing is the existence of a contract between LIH and the Participant as well as LIH's legitimate interest in carrying out the PT Programme. The Data Protection Officer (DPO) of LIH may be contacted by email at dpo@lih.lu or by post mail at 1A-B rue Thomas Edison L-1445 Strassen, Luxembourg.

Further information about the processing of personal data by LIH-IBBL in the context of the PT Programme can be found in the Data Protection Notice: Processing of Personal Data in the Scope of LIH-IBBL's Proficiency Testing Program (Data Protection Notice: https://www.lih.lu/wp-content/uploads/2022/06/ProficiencyTestingProgram_DataProtectionNotice.pdf).

3. Data Meta-Analysis

Aggregated data from all participants and from all previous IBBL PT programs can be analysed to provide further information on specific method performance characteristics (method precision, robustness, method comparison), either in the form of a technical report to participants or in the form of an open-access publication [PMID: 36049650 DOI: 10.1016/j.nbt.2022.08.006].

Proficiency Testing Provider

IBBL (Integrated BioBank of Luxembourg)
1, rue Louis Rech
L-3555 Dudelange
Luxembourg

Contact us:
Tel: +352 26970-520 (Mon-Fri, 9 am - 5 pm CET)
Email: IBBLPT@lih.lu
Web: www.lih.lu