

Proficiency Testing Program 2011 - 2012

PARTICIPANT'S MANUAL

Proficiency Testing Provider:

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1. INTRODUCTION

1.1 Who we are

The provider of this Proficiency Testing Program is ISBER, the International Society for Biological and Environmental Repositories, based at 9650 Rockville Pike, Bethesda, Maryland 20814-3993, USA. **ISBER is the only international forum that addresses the technical, legal, ethical, and managerial issues relevant to repositories of biological and environmental.** ISBER was founded in 1999 as an educational forum for discussion of repository management and dissemination of information on operational issues. Careful management ensures that specimen collections are available for study, as new biomarkers emerge and more sensitive measurement technologies become pertinent. ISBER has more than 850 institutional and individual members worldwide, and is a Division of the American Society for Investigative Pathology (ASIP), a 501(C)3 nonprofit educational organization.

ISBER is implementing this Program internationally in collaboration with IBBL, the Integrated BioBank of Luxemburg, based in 6 rue Nicolas-Ernest Barblé, L-1210 Luxembourg, Luxembourg. The 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. It also provides these research platforms and engages in collaborative research with partners in academia and industry. The major focus for IBBL's in-house research is Biospecimen Research.

IBBL will work in partnership with ISBER, and is in charge preparing and shipping the testing materials to all Proficiency Testing Participants.

1.2 Scope

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 characterization to researchers, industry, or even 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.

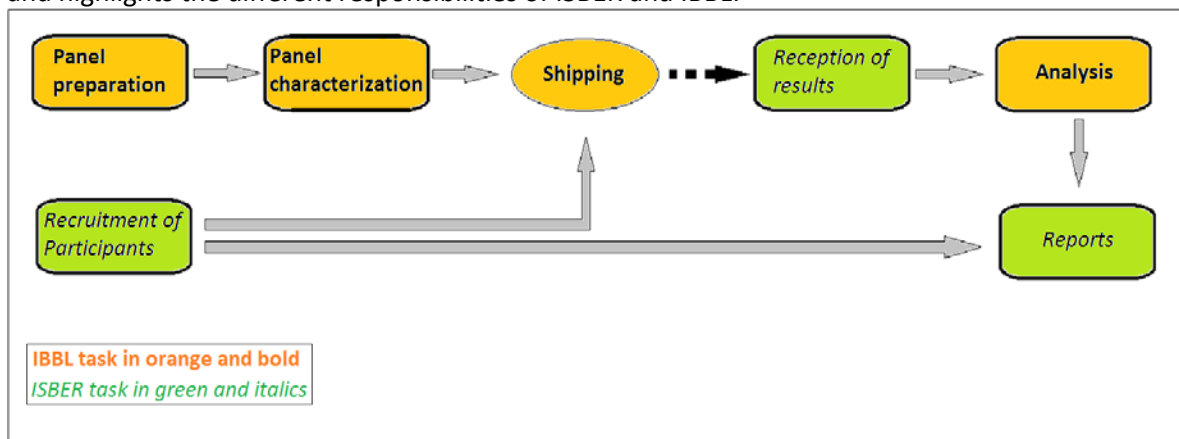
The scope of this Program is to develop, coordinate and implement PT Programs for QC assays and biomolecular characterization of biospecimens. The PT Programs include assays performed by repositories and/or end-users for the validation/characterization of biospecimens, and their cellular and molecular derivatives. This goal is in consonance with one of the National Center for Research Resources award (Biomedical Technology Research Awards) mission, as well as with the mission of ISBER.

1.3 Vision

This Program is expected to improve the quality management systems of repositories through PT of their Quality Control (QC) assays. PT Programs 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 Program here proposed represents an essential infrastructural development in the field of biomarker identification and validation, and consequently will improve health care.

1.4 Inter-laboratory Proficiency Testing

This PT Program 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 Test Items) are being distributed simultaneously to Participants for concurrent testing. After the completion of the testing, the Participants' results are returned to the Proficiency Testing provider (ISBER) and compared with the assigned value(s) derived from the reference laboratories to give an indication of the performance of the individual Participants and of the group as a whole. This flow chart outlines the whole process, and highlights the different responsibilities of ISBER and IBBL:



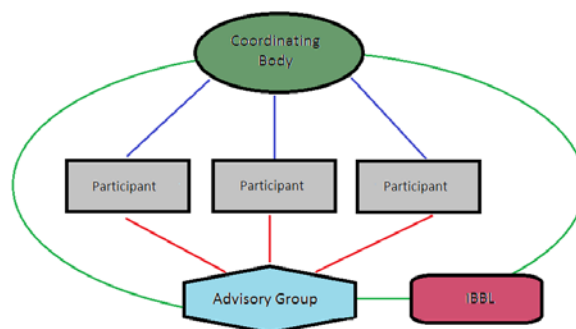
A “split-level” design is implemented in some quantitative Schemes, which means that similar (but not identical) analyte concentration levels are included in two separate aliquots of Test Items. This is used to assess Participant’s analytical accuracy.

1.5 How we’re organized

ISBER and its subcontractor IBBL have created an organizational structure to implement the PT Program. Three groups belong to this structure, and all together constitute the PT Team: the Coordinating Body (at ISBER), the Advisory Group (at ISBER), and the IBBL staff. Those groups will between them have the competencies necessary for compliance with standard ISO/IEC 17043:2010. The **Coordinating Body** acts as the PT Provider and has the responsibility for coordinating all of the activities involved in the operation of the PT Programs and Schemes.

Personnel with detailed technical knowledge and experience are part of the **Advisory Group**, which supports the operations of the PT Programs and Schemes

This diagram illustrates how the different working groups will interact in the implementation of the PT Program:



To prevent any confidentiality issues, the IBBL staff will never communicate directly with the Participants. IBBL will only ship Test Items directly to all Participants (not in the diagram).

2. CRITERIA FOR PARTICIPATION

2.1 General requirements

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

- The required facilities to perform the test are in place at the Participant site. You can check what facility/equipment you require by reviewing the relevant TIIS (Test Item Information Sheet), which contains basic information on the sample preparation, safety and handling instructions.
- The laboratorian at the site has the technical competence to perform the test, or has been appropriately delegated to conduct the test. Your Institution will ensure the technical competence is covered, and details on technical requirements must be indicated in the Registration Form while you subscribe to one or more Schemes.
- The test shall be conducted under the Participant routine conditions. Directions will not be provided on the method to use for analysis, to avoid any deviation from your normal testing conditions.

2.2 Registration Instructions

Register online directly at the ISBER website at http://www.isber.org/proficiency_testing/. If you are an ISBER member or have previously attended an ISBER event, you will need your ISBER User ID and password to register online. The registration page also contains instructions for creating a new account if you do not have a User ID and password. Alternatively, you may download a PDF of the Proficiency Test (PT) Registration Form from the ISBER website at http://www.isber.org/proficiency_testing/. Potential Participants can complete this form to be emailed (as electronic scan), faxed, or mailed to ISBER to be able to register to the desired Scheme(s).

2.2.1 Participant coding system

Participants are assigned a specific code to ensure confidentiality of the data they are providing. The coding is structured as follows:

- The Participant Code is a five- or six--digit number (59432, 101746...), unique to each Participant. Only ISBER staff knows the link between the Participant Code and the Participant identity.
- The Login ID is a number assigned to every individual from an Organization. You will use the Participant Code, the Login ID and a password to login into the website to submit your results, access your report and the global statistical analysis done on all results for the specific Round/Scheme.
- When Participants submit their results electronically, a Result ID number is given. A Result ID is a sequential number which is linked to the results you submit. The Result ID is used to protect the Participant's identity and to ensure that no bias occurs during the evaluation of performance. IBBL has no means of deducing the identity of a Participant via its pattern of subscriptions.

2.2.2 PT Program for 2011-2012

The following 4 Schemes are planned for the 2011-2012 PT Program, and 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 (2011): RT
- RNA Integrity (2011): RT
- Cell Viability (2012): DI
- Tissue Antigenicity (2012): RT

For the 2011 Schemes, a detailed “Test Item Information Sheet” (TIIS) is provided in Appendix 1, which describes all relevant information related to the preparation of the samples, testing conditions, bio-hazard information and all administrative aspects to consider. 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 global Participant results, at the end of the PT.

2.3 Subscription to multiple Schemes and/or methods

The current fees for each Scheme are indicated below in USD, and are also indicated on the PT Registration Form and in the Frequently Asked Questions. In 2011, two Schemes are available: “DNA quantification and purity” and “RNA integrity.” You can participate in one or more proficiency testing Schemes. Depending on the required preparation of the samples to be shipped, Schemes are categorized under RT (Room Temperature) or DI (Dry Ice). The 2011 and 2012 Programs will include the following Schemes:

SCHEMES	SHIPMENT TYPE	PRICE (USD)
DNA Quantification and Purity	RT	\$500
RNA Integrity	RT	\$500
Cell Viability (*not available in 2011)	DI	\$600
Tissue Antigenicity (*not available in 2011)	RT	\$500

For each Scheme you may test up to 3 methods of your choice in the same run. Different fees will be applied if you participate in more than one Scheme (5% discount for additional Schemes), and if you test more than one method within the same Scheme (\$50 US per additional method). ISBER Members will receive a 20% discount on the initial Scheme (in addition to the above discounts). 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.

3. SHIPMENT OF TEST ITEMS

IBBL will be in charge of the preparation of the Test Items that will be shipped to each Participant according to the information provided in the PT Registration Form. IBBL will then be aware of the identity of the Participants, but confidentiality of the data collected is maintained through the Result ID as described in Section 2.2.1.

Once the registration is complete and Subscription fees are received at ISBER, the samples required for the Scheme participation which 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.

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 purpose, may be requested to ISBER if needed.

Test Items are shipped along with the relevant TIIS.

4. ONLINE SUBMISSION OF RESULTS

Each Scheme will follow specific timelines for the shipment of Test Items, the testing phase of the sample, the return of the results by each Participants and the availability of the reports. Those timelines are indicated in the relevant TIIS which is provided along with the samples to test.

Each Participant will need to login in to the PT website www.kpmd.co.uk/isber/, with the Participant Code, Login ID and password (provided after the registration period is completed).

Each Participant will then complete the form on the website as accurately as possible, within indicated timelines. Failure to comply with those timelines will result in inability to perform statistical analysis of Participant results. If the results are submitted after the deadline set-up for each Scheme, the Participant will be unable to receive the performance report, and no refund will be possible.

5. AVAILABILITY OF PERFORMANCE REPORTS

5.1 Statistical analysis approach

The minimum number of Participants foreseen for each Scheme is 30. If the number of subscriptions is less than 30, the Scheme will have to be repeated, and you will be promptly informed by ISBER.

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 (like DNA, RNA and Cells), the mean, median, standard deviation and range will be provided. For qualitative Schemes (like Tissues) the modes (most common responses) and range (lowest and highest response) will be provided. In both cases, graphs will be produced with the results from all Participants.

5.2 Performance assessment

A Participant's results 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".

5.3 Performance Reports

Reports provided to all Participants will 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.

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

5.4 How results can be used

Upon reception of the Performance Report, the Participant can decide to use the PT results for publication. ISBER 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).

6. CERTIFICATE OF PARTICIPATION

All Participants will receive a Certificate of Participation to the Scheme in which they have participated.

7. CONFIDENTIALITY

7.1 General policy

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

As mentioned in section 2.2.1, Participant identity and performance results are protected through a specific coding system, which will also avoid any unintentional disclosure of information to ISBER partners (such as IBBL).

7.2 Data Protection

ISBER will prevent the misuse of personal data held on computers and will conform to all applicable standards, e.g. Data Protection laws in force.

8. PARTICIPANT FEEDBACK AND COMPLAINTS

8.1 Use of comment section online

While submitting the results of Participant's tests on the samples directly on the website, the 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.

8.2 Advisory service on demand

For any technical issue that a Participant may encounter, and/or for any clarification needed during the testing phase, ISBER support can be contacted at +1 301 634 7949 and/or ptisber@asip.org.

8.3 Complaints

ISBER 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 Program should be sent by email (ptisber@asip.org), fax (+1 301-634-7990) or letter (to ISBER address indicated on page 1 of this manual), and will be acknowledged in writing by the same means of communication as used to contact us.

All complaints are reviewed formally and reported to the Coordinator of the PT Program. Corrective actions will be taken to resolve the complaints.

A specific procedure is in place to ensure all complaints are brought to resolution.