IPT

Immunosuppressant Scheme

Scheme Description

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Notes:
Where this document has been translated, the English version shall remain the definitive version

Scheme Aims and Organisation

The primary aim of the Immunosuppressant proficiency testing scheme (IPT) is to enable laboratories performing the analysis of immunosuppressant drugs to monitor their performance and compare it with that of their peers. The IPT scheme also aims to provide information to participants on technical issues and methodologies.

The IPT scheme year operates from January to December. Further information about IPT, including test material availability, round despatch dates and reporting deadlines, are available on the current IPT application form.

The operation of all schemes is supported by an Advisory Group consisting of members of the professional bodies, scheme participants, and others experienced in the field.

Test Materials

Details of test materials available in IPT are given in Appendix A. The test parameters are continually reviewed to ensure they meet the needs of current laboratory testing and regulatory requirements.

Samples are prepared using pre-screened human blood and plasma. Patient pooled samples are also used- these pools have not been pre-screened.

The commercially available human blood and plasma is pooled and is obtained from donors who have verbally declared themselves drug free, it has been tested and found negative for:

- HEP B antigen
- HEP C antigen
- Combo HIV 1 and 2
- Syphilis
- Alanine transferase

Certificates of Analysis are retained at LGC.

Note: All test materials provided are intended for use as proficiency testing materials only and are not to be used for any other purposes.

Some aspects of the scheme, such as test material production, homogeneity testing and stability assessment, can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and LGC is responsible for this work. The planning of the scheme, the evaluation of performance and the authorisation of the final report will never be subcontracted.

Statistical Analysis

Information on the statistics used in IPT can be found in the General Protocol and in the Scheme Report. Methods for determining assigned values and the values for SDPA used for individual samples are given in Appendix A.

Methods

Methods are listed in PORTAL. Please select the most appropriate method from the list. If none of the methods are appropriate, then please report your method as 'Other' and record a brief description in the Comments Section in PORTAL.

Results and Reports

IPT results are returned through our electronic reporting software, PORTAL, full instructions for which are provided by email. However, participants may request result submission forms on which to report and return results if they are unable to report through electronic means. This will incur an additional charge.

IPT reports will be available on the website within 10 working days of round closure. Participants will be emailed a link to the report when it is available.

APPENDIX A - Description of abbreviations used

Assigned Value (AV)

The assigned value may be derived in the following ways:

- From the robust mean (RMean). This is the median of participant results after the removal of test results that are inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors. Generally, the assigned value will be set using results from all methods, unless the measurement is considered method-dependant, in which case the assigned value will be set by method as illustrated in the report tables.
  For some analytes, where there is a recognised reference method for that type of measurement, this may be used as the assigned value for a particular analyte i.e. it would be applied to results obtained by any method.

  Traceability: Assigned values which are derived from the participant results, or a sub-set of the results are not traceable to an international measurement standard. The uncertainty of assigned values derived in this way is estimated from the participant results, according to ISO 13528.

- From a formulation value (Formulation). This denotes the use of an assigned value derived from sample preparation details, where known and exact quantities of analyte have been used to prepare the sample.

  Traceability: Assigned values calculated from the formulation of the test sample are traceable, via an unbroken metrological traceability chain, to an international measurement standard. The measurement uncertainty of the assigned value is calculated using the contributions from each calibration in the traceability chain.

- From a qualitative formulation (Qual Form). This applies to qualitative tests where the assigned value is simply based on the presence/absence of the analyte in the test material.

  Traceability: Assigned values calculated from the qualitative formulation of the test sample are traceable to a certified reference standard or a microbiological reference strain.

- From expert labs (Expert). The assigned value for the analyte is provided by an 'expert' laboratory.

  Traceability: Assigned values provided by an 'expert' laboratory may be traceable to an international measurement standard, according to the laboratory and the method used. The uncertainty of measurement for an assigned value produced in this way will be provided by the laboratory undertaking the analysis. Details of traceability and the associated uncertainty will be provided in the report for the scheme/round.

Range

This indicates the concentration range at which the analyte may be present in the test material.

SDPA
SDPA represents the 'standard deviation for proficiency assessment' which is used to assess participant performance for the measurement of each analyte. Wherever possible, the SDPA is based on a concentration dependent model derived from historic data. Otherwise the SDPA is based upon the RobustSD.

Units
This indicates the units used for the assessment of data. These are the units in which participants should report their results. For some analytes in some schemes participants may have a choice of which units to report their results, however, the units stipulated in this scheme description are the default units to which any results reported using allowable alternative results will be converted to.

DP
This indicates the number of decimal places to which participants should report their measurement results.

CDM
Concentration Dependent Model

Sample: CIC/TAC **Ciclosporin and Tacrolimus**
Participants will receive: 3 x 1ml samples of liquid human blood (A, B and C)

Analyte	Method	Range (mass)	AV	SDPA	Units	DP
Ciclosporin	All	0 to 2000	RMean	RobustSD	µg/L	2
Tacrolimus	All	0 to 25	RMean	RobustSD	µg/L	2

Sample: SIR **Sirolimus**
Participants will receive: 3 x 1ml samples of liquid human blood (A, B and C)

Analyte	Method	Range (mass)	AV	SDPA	Units	DP
Sirolimus	All	0 to 30	RMean	RobustSD	µg/L	2

Sample: EVE **Everolimus**
Participants will receive: 3 x 1ml samples of liquid human blood (A, B and C)

Analyte	Method	Range (mass)	AV	SDPA	Units	DP
Everolimus	All	0 to 25	RMean	RobustSD	µg/L	2

Sample: MPA **Mycophenolic acid**
Participants will receive: 2 x 1ml liquid human plasma (A and B)

Analyte	Method	Range (mass)	AV	SDPA	Units	DP
Mycophenolic acid	All	0 to 12	RMean	RobustSD	mg/L	2

<u>Note:</u> The above ranges refer to spiked samples. Patient pooled samples are also used as samples in this scheme and these may fall outside of these ranges.