



# **General Accreditation Criteria**

## **ISO 15189 Standard Application Document**

### **Medical Testing Field Application Document**

**November 2013**



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## Table of Contents

<b>Medical Testing Field Application Document (Interpretation of NPAAC Requirements and ISO 15189)</b> .....	<b>4</b>
<b>Application of ISO 15189 and NPAAC Requirements</b> .....	<b>4</b>
<b>4 Management requirements</b> .....	<b>4</b>
4.1 Organisation and management responsibility .....	4
4.2 Quality management system .....	4
4.4 Service agreements .....	4
4.5 Examination by referral laboratories .....	5
4.7 Advisory services .....	5
4.13 Control of records.....	5
4.14 Evaluation and audits.....	6
4.15 Management review.....	6
<b>5 Technical requirements</b> .....	<b>6</b>
5.1 Personnel .....	6
5.3 Laboratory equipment, reagents and consumables.....	7
5.4 Pre-examination processes .....	9
5.5 Examination processes .....	11
5.6 Ensuring quality of examination results .....	14
5.7 Post-examination processes .....	25
5.8 Reporting of results .....	25
5.9 Release of Results .....	27
<b>References</b> .....	<b>28</b>
NPAAC publications .....	28
Standards .....	28
NATA Publications.....	28
Other references.....	28
Further Reading.....	29
<b>Amendment Table</b> .....	<b>30</b>

# Medical Testing Field Application Document

This document provides interpretative criteria and recommendations for the application of ISO15189 and the NPAAC standards for both applicant and accredited facilities.

The clause numbers in this document follow those of *ISO 15189 Medical laboratories - Particular requirements for quality and competence* but since not all clauses require interpretation the numbering may not be consecutive.

## Application of ISO 15189 and NPAAC Requirements

### 4 Management requirements

#### 4.1 Organisation and management responsibility

Specific requirements for supervision are described in the *NPAAC Requirements for Supervision of Pathology Laboratories*. Laboratories seeking approval from Medicare Australia must comply with the requirements for the relevant NPAAC category.

- (i) Where full-time equivalent (FTE) supervision of Category GY laboratories is achieved through a roster of pathologists, sufficient evidence must be available to substantiate that full-time supervision is being maintained.
- (ii) Records detailing the specific activities undertaken at both supervisory visits (to the Category B laboratory) and reciprocal visits (to the Category G laboratory) must be kept. Such records must be available for review at the assessment of the Category B laboratory.
- (iii) Supervisory visits must have appropriate technical content relative to the scope of accreditation and interaction with laboratory staff. Appropriate supervisory activities may include:
  - general technical discussion;
  - continuing education sessions; and
  - internal audits performed by medical/scientific staff with an appropriate technical background.

**4.1.2.5** The laboratory must document relief arrangements where specific supervision requirements have been stipulated by NPAAC Requirements.

#### 4.2 Quality management system

**4.2.2.2** Quality documentation must include or reference the scope of accreditation and a policy on the use of the NATA/RCPA endorsement.

#### 4.4 Service agreements

**4.4.1** Examples of contracts within a medical laboratory may include but not be limited to:

- request forms signed by the requesting clinician;
- contracts or tenders with customer groups;
- add-on requests (verbal or written);

- consultancy arrangements; and
- arrangements where the supervision is provided by a person who is not employed by the laboratory or laboratory organisation.

#### **4.5 Examination by referral laboratories**

**4.5.1** A competent referral laboratory is generally considered to be a laboratory accredited by NATA or one of NATA's mutual recognition partners for the tests referred. Where reports are obtained from an accredited facility, these must be endorsed.

**Note:** Information on accreditation status and scope of accreditation may be found at the NATA website or by contacting one of NATA's offices.

**4.5.1 b)** The competency, and where appropriate the accreditation status, of referral laboratories should be regularly reviewed to ensure currency.

**4.5.2** There must be a procedure for the follow-up of results not received in a timely fashion.

#### **4.7 Advisory services**

- (i) It is acknowledged that refrigeration equipment (refrigerators / freezers) used for the storage of blood and blood products may be outside the control or ownership of the laboratory. Where this is the case, the hospital or clinic that owns the refrigeration is responsible for ensuring compliance with AS 3864 and other relevant requirements e.g. those relating to the accreditation of the hospital. The laboratory shall provide advice and education to the users of the service regarding the appropriate transport and storage conditions of blood and blood products. This advice must also include appropriate monitoring and/or audit of equipment and procedures.
- (ii) Laboratories performing semen analysis must advise users of the service of the minimum collection requirements. These include:
  - a) a record of the time of ejaculation;
  - b) the optimal storage temperature (20-35°C) of the sample between collection and receipt into the laboratory;
  - c) a record of the number of days of abstinence;
  - d) the use of lubricants or condoms is contraindicated; and
  - e) a record of whether the collection was complete.

#### **4.13 Control of records**

All records must include the identity of the person making the record.

It is recognised that a number of staff may be involved in test processes or other laboratory procedures. It is the laboratory's responsibility to identify the critical step(s) in the procedure and ensure that the identities of the staff concerned are recorded.

See also 5.5.1.1

As far as practicable, all records must be indelible and data or observations recorded in such a manner that prevents amendment or loss of the original.

Minimum retention times (including raw data) must be in accordance with those specified by the NPAAC Requirements. Legislative or contractual obligations may prescribe longer retention times. Dictaphone recordings of microscopic and macroscopic descriptions of tissue biopsies do not need to be retained where the transcribed report is authorised by a pathologist.

All quality management system records must be retained for a minimum of three years.

The records system must include a copy of each report that contains results of testing covered by the scope of accreditation, or must allow them to be reproduced, including details such as the endorsement (if applicable) and identification of the person who authorised the report.

With reference to the list of records under 4.13 a) – v) the following records must also be retained:

- the date on which the test was performed;
- original test observations and calculations;
- the identity of the person performing the test;
- the identity of the person reviewing quality control results;
- an indication that calculations and manual data transfers have been checked; and
- any other information specified in the test method, other contractual documents or relevant statutory regulations.

#### **4.14 Evaluation and audits**

**4.14.5** The internal audit schedule must cover both the management and technical requirements of ISO 15189.

#### **4.15 Management review**

The effectiveness of the quality management system shall be reviewed by management at least once every year.

## **5 Technical requirements**

### **5.1 Personnel**

**5.1.1** Staff who work only 'out-of-hours' must have regular contact with routine and in particular, supervisory staff. The time allocated must be sufficient for the staff member to update all skills required for the out-of-hours service. Records of the time spent in the laboratory during routine hours must be kept and must be sufficiently detailed to demonstrate compliance.

#### **5.1.8**

- (i) Continuing education must be provided for pathologists, scientists and any staff involved in testing. Any education program must include in-house and external components and there must be access to appropriate reference texts and journals.

Components of in-house education may include:

- regular educational presentations;

- journal article reviews;
- case presentations;
- review of QAP educational material; and
- review of interesting or abnormal blood films, cultures etc.

Components of external continuing education may include:

- membership of relevant professional societies; and
  - attendance at meetings, conferences and workshops with evidence maintained.
- (ii) At least one appropriate journal and current text book (electronic or hardcopy) should be made available by the laboratory for each area in which testing is undertaken.

**5.1.9** Training records must be sufficiently detailed to demonstrate competence in individual tests and tasks. Proof of qualifications, membership of professional societies and hours of attendance at the laboratory may be requested as part of the assessment process. Evidence of recognition of overseas qualifications must be available.

### **5.3 Laboratory equipment, reagents and consumables**

#### **Immunohaematology – specific requirements**

The maintenance and monitoring provisions for blood bank refrigerators are as stated in *AS 3864 Medical refrigeration equipment - For the storage of blood and blood products*. User -related requirements for care, maintenance, performance verification and calibration. The requirements of this standard apply to users of such equipment.

It is recognised that there is a large variation in age, design and construction of blood bank refrigerators in use. For some refrigerators it is not always possible to access the temperature probes and consequently strict adherence to this aspect of AS 3864 may be impractical. In these circumstances equipment must be retrofitted with stand alone recording devices which will allow compliance with the standard.

Where a laboratory is using off-site or external refrigerators to store blood intended for transfusion purposes, it should ensure that the blood units are stored and handled appropriately. A procedure must be in place to confirm and monitor the suitability of the off-site storage locations to ensure that the refrigerators used for storing blood and blood products for transfusion are being maintained in accordance with AS 3864 (also refer to Clause 4.7: Advisory services). These records must be available for review at assessment.

#### **5.3.1.4 Measurement traceability**

**Note:** For calibration activities or reported results intended to be used in support of the further dissemination of metrological traceability, the criteria provided in the Calibration ISO/IEC 17025 Appendix must also be applied.

#### **General**

The results of all tests, measurements and calibrations that have a significant effect on the reported result and associated uncertainty of measurement must be traceable, where possible, to national or international standards. Facilities must,

therefore, ensure that equipment or instruments are calibrated by one (or more, if relevant) of the organisations below:

- a) a NATA accredited calibration facility and the results reported on a NATA endorsed document.
- b) a calibration facility accredited by one of NATA's mutual recognition arrangement (MRA) partners, when the MRA recognition covers calibration and the results reported on an endorsed document.

For details of NATA's current MRA partners, refer to the NATA website.

- c) Australia's National Measurement Institute (NMI) or a national metrology institute that is a signatory to the Comité International des Poids et Mesures (CIPM) MRA

**Note:** The calibration and/or measurement must actually be done by the NMI. Unendorsed reports from organisations claiming traceability to a NMI or those bearing only an ISO 9000 series certification logo are not acceptable.

- d) Calibration reports issued as a Regulation 13 certificate in accordance with Section 10 of the National Measurement Act 1960.

**Note:** National Measurement Act

Where measurement traceability in accordance with Section 10 of the National Measurement Act 1960 is required, facilities performing such measurements must have Regulation 13 Certificates for their reference standards. Regulation 13 Certificates are issued by calibration facilities appointed as Verifying Authorities under the National Measurement Regulations. Further information can be obtained from the National Measurement Institute (NMI).

The National Measurement regulations contain schedules listing the maximum permissible variations and maximum permissible uncertainties that are required for various reference standards and measuring instruments.

### Specific requirements

#### In-house calibrations

A facility performing its own calibrations will also be subject to technical assessment of these calibrations. The assessment team will determine if the in-house calibrations are fit for the purpose for which they are being used and that a reasonable estimate of the associated measurement uncertainty has been made. Fees will be charged where significant additional assessment effort is required (i.e. time or additional assessors). Specialist calibration assessors will only be used when either the calibration is outside the area of expertise of the technical assessor(s) who would normally conduct the assessment, or if it would be more time or cost effective.

**Note:** Refer to NATA's *Equipment Assurance, in-house calibration and equipment verification* for additional information.

#### Testing

Reference standards and equipment shall be calibrated over the range and to the appropriate level of accuracy specified in relevant methods.

Accreditation cannot be given for extremes of the test or measurement range based on extrapolation beyond the minimum and maximum calibration points.

A facility performing its own calibrations may also be subject to proficiency testing and technical assessment for these activities to ensure that all the relevant



requirements of ISO/IEC 17025 are met (e.g. adequately documented procedures, procedures to estimate the uncertainty of measurement and complete records of calibration data).

**Note:** Refer to NATA's *Equipment assurance, in-house calibration and equipment verification*.

Reference standards and reference materials

Reference materials

Facilities must demonstrate suitable traceability of assigned values of reference materials, where possible, through:

- a) a NATA accredited reference material provider and the results reported on a NATA endorsed document.
- b) a reference material provider accredited by one of NATA's mutual recognition arrangement (MRA) partners, when the MRA recognition covers reference material providers and the results are reported on an endorsed document.

For details of NATA's current MRA partners, refer to the NATA website.

- c) Australia's National Measurement Institute (NMI) or a national metrology institute that is a signatory to the Comité International des Poids et Mesures (CIPM) MRA.

**Note:** The calibration and/or measurement must actually be done by the NMI. Unendorsed reports from organisations claiming traceability to a NMI or those bearing only an ISO 9000 series certification logo are not acceptable.

- d) a competent supplier who can demonstrate traceability of its reference material(s) using specified methods and/or consensus standards that are clearly described and agreed by all parties concerned. This option applies when there are no readily available reference material providers as described in a) to c) above.

## 5.4 Pre-examination processes

**5.4.2** Documented instructions should be available for self-collect samples (e.g. midstream urine, semen) in languages appropriate for the patient population.

**5.4.4.3** The laboratory's collection procedures must include 'order of draw'.

**Note:** Blood collection tubes must be drawn in a specific order to avoid cross contamination of additives between tubes.

**5.4.4.3 a)** On presentation for collection, all patients must be positively identified by the collector e.g. by asking 'What is your name?'

**Note:** Where identification of the patient by the above means is not possible (e.g. unconscious patients, non-English speakers etc.), other mechanisms are required to ensure correct identification.

### 5.4.4.3 e)

- (i) When identifying the patient, three identifiers must be used on the request form.
- (ii) Whilst 3 identifiers are preferable, unidentifiable and unconscious patients must be allocated a minimum of two unique identifiers, e.g. a medical record number and a further descriptor such as male, motorbike accident.

- (iii) When labelling the patient's Specimen, three identifiers should be used where practicable (two must be used if three cannot be accommodated). Samples which are not labelled with two identifiers are considered to be inadequately labelled.
- (iv) There must be concordance between the identifiers on the request form and the Specimen label.
- (v) The Specimen must be labelled in the presence of the patient, and if possible, the patient identifiers should be confirmed by the patient.
- (vi) The identifiers must include full name and at least one of either date of birth or unique medical record number. Additional identifiers may be the unique Laboratory number or patient address. Alternative identifiers may be used in special circumstances such as patients who wish to remain anonymous.
- (vii) Where point-of-care testing is performed, labelling requirements may be relaxed, however, where a delay in testing occurs there must be labelling of the syringe or tube as above.
- (viii) Sample collection containers must not be labelled before collection.

#### 5.4.6

- (i) Samples and associated records (worksheets, slides etc.) must be uniquely identified during all stages of testing.

**Note:** This may be achieved by the use of a unique laboratory number. This is usually the most practical option especially where large numbers of samples are processed. Alternatively, samples and associated records can be uniquely identified by the use of two patient identifiers (e.g. patient's full name and either date of birth or medical record number). The uniqueness of a numbering system should take into consideration the sample storage time and ensure two samples with the same number cannot be in the laboratory at the one time.

- (ii) The following should be recorded when a semen sample is received for infertility studies:
  - a) the time of ejaculation;
  - b) an indication of the sample storage conditions between collection and receipt into the laboratory;
  - c) the number of days of abstinence;
  - d) the use of lubricants or condoms; and
  - e) whether the collection was complete.
- (iii) Sample reception procedures must cover all sample types received by the laboratory.

#### 5.4.6 a)

- (i) There may be special circumstances where the identity of the patient will not be revealed to the laboratory. In such cases, adequate precautions must be taken to maintain unique identification of the sample at all stages.
- (ii) The patient identification information on samples must match the patient identification information provided in the test request.

#### 5.4.6 b)

Documented sample reception procedures must include the action to be taken in the event that an unsuitable sample is received.

#### 5.4.6 c)

- (i) Where inadequately labelled samples are received and accepted for testing, the laboratory must assure itself of the identity of the sample. If samples that do not meet minimum acceptability criteria are accepted and tested, a record must be kept of any subsequent action taken.
- (ii) Samples that are received unlabelled, mislabelled or insufficiently labelled must not be relabelled after receipt in the laboratory.

### 5.5 Examination processes

#### 5.5.1.1

- (i) Where a test can be performed by more than one method there must be documented criteria for method selection. Where relevant, the degree of correlation between the methods must be established and documented. Further, where appropriate, the method selected should be identified on the test report.
- (ii) Examination of blood films for malarial parasites must include evaluation of both thin and thick films.
- (iii) Criteria for referral of blood films to a pathologist must be documented.
- (iv) Supplemental testing is required for reactive screening tests for infectious diseases including HIV antibody, hepatitis C antibody and hepatitis B surface antigen in persons not already known to be infected.
- (v) Where automated semen analysers are used as the primary and/or sole technique for semen analysis appropriate validation / verification must be performed against the *WHO Laboratory Manual for the Examination and Processing of Human Semen Cervical Mucus Interaction, 5th Edition World Health Organisation*. Calibration of such analysers must be performed against the three principal sperm parameters i.e. count, motility and morphology, not just count with bead suspensions. Quality Control procedures must be appropriate to the technology used.
- (vi) Where laboratories are performing drugs of abuse testing for clinical use the cut-off levels must be in-line with Australian standards. Where cut-offs other than those prescribed in Australian standards are used justification for use must be provided.

#### 5.5.1.2 and 5.5.1.3 Validation and verification of procedures/methods

**Note:** The terms verification and validation are not interchangeable.

Validation studies provide objective evidence that an in-house method or modified standard method is fit for the purpose and satisfies the particular requirements for its specific intended use. Commercial applications designated by the manufacturer 'for research purposes only' are considered in-house methods.

Verification studies are typically less extensive and demonstrate the user's ability to achieve the published performance characteristics of a method under the user's own test conditions.

- (i) There must be a policy for the introduction of new methodology. Appropriate records of validation/verification (whichever is relevant) studies must be kept and be available for review at assessment. The documentation of the validation/verification process must include the following:
- Proposed sample types;
  - Source of reference material;
  - Sample acceptance/rejection criteria;
  - Formal evaluation of the data collected;
  - Minimum sample number requirements;
  - Final summary of results including recommendations, for example, the suitability of the method for use in the laboratory and any relevant limitations of the method, etc.; and
  - Formal authorisation (sign-off) by supervisory staff.
- (ii) Verification of methods prior to use must include statistical correlation with existing validated methods. Graphical representation of the data could be of benefit. A statistically significant number of samples must be used in the evaluation process and these must cover the full range of results for the intended use of the assay. The accuracy and precision must be determined for methods that yield a quantitative result. For qualitative and semi-quantitative methods concordance studies with existing validated methods are required. Clinical sensitivity and specificity should also be evaluated in specific, local patient populations (e.g. hospital, community patients) wherever possible.
- (iii) While it is acknowledged that time required to validate in-house molecular assays may be lengthy, accreditation cannot be granted to incompletely validated assays. Where the results of such assays are reported, the following comment, or similar, must be included in the test report:
- “This assay is still undergoing development and is not yet fully validated. Results should be interpreted in association with all other information (clinical and laboratory) on the patient. Reports based on this assay are not currently NATA/RCPA endorsed.”

### 5.5.1.2

#### **Verification and comparison of blood gas analysers (BGA)**

##### Initial comparison

- (i) If the BGA is replacing an existing analyser:
- Patient comparison studies must be performed at the time of installation. Often the old and new analysers will be co-located during this time thereby allowing active comparison and limiting concerns about sample stability.
  - For branch laboratories installing a new analyser, the comparison studies may be performed in the central laboratory before relocation of the analyser to the branch site.
  - Where multiple new instruments are being installed within a multi-site organisation, the comparison studies may involve the comparison of one

new analyser against one old analyser and these data may then be taken as representative of the overall comparison and not be replicated for every installation.

- The findings of any comparison study must be available for review at the assessment of the branch laboratory and these studies must show evidence of review and authorisation.
- (ii) If the BGA is new, and there is no previous instrument or central laboratory for comparison:
- Exchange of patient samples with another facility is difficult due to the lability of blood gas samples. There may be comparison data in the literature or the manufacturer of the analyser may be able to provide information.
  - The findings of such reviews/studies must be available for review at the assessment and this information must show evidence of review and acceptance.
  - Alternatively, where this is not available the laboratory must establish appropriate internal QC limits and demonstrate satisfactory performance in internal QC and QAP. The appropriateness of these measures will be reviewed at assessment.

#### On-going comparison of blood gas analysers

- (i) For laboratory having a number of blood gas analysers at one geographical site:
- Where analysers are closely located (e.g. multiple analysers at one hospital site) a single sample should be analysed on a number of analysers within a given time (taking into account the lability of the sample), allowing comparison with patient samples. The use of patient samples will eliminate any matrix issues with internal QC and QAP material. These comparisons are a useful adjunct to daily QC testing and are recommended as part of good laboratory practice.
- (ii) For blood gas analysers that are not located at one geographical site:
- Where analysers are not closely located (e.g. at different laboratory sites) the lability of patient samples makes on-going comparison difficult. Where internal QC and QAP results suggest there may be performance problems with a particular analyser, the laboratory must investigate the possible impact on patient results. Where internal QC and QAP results demonstrate acceptable performance on-going patient comparisons are recommended as part of good laboratory practice but are not mandatory.

#### Comparison of blood gas analysers against main chemical pathology analysers

- (i) Where the blood gas analysers and main chemistry analysers are located at one geographical site:
- Where a laboratory performs serum/plasma electrolytes on the main chemistry analyser and blood electrolytes on a blood gas analyser, the laboratory should assess ongoing comparison between the platforms. It is acknowledged that the two platforms may not measure the same thing (e.g. direct ISE versus indirect ISE, different sample types etc.) and that there may be a bias, however the bias should be relatively small and

stable. The comparison can be performed by measuring a serum/plasma sample on each instrument at defined intervals and assessing the level of agreement.

- (ii) Where the blood gas analysers and main chemistry analysers are not located at one geographical site
- On-going comparison studies would be good practice however it is appreciated that logistics may complicate or preclude the performance of such studies.
  - Provided adequate comparison is demonstrated at the time of analyser implementation and QC and QAP performance is satisfactory, these comparisons are not mandatory.

#### **5.5.1.4 Uncertainty of measurement / results**

The estimation of uncertainty of measurement (MU) applies at present to quantitative tests only. This includes those tests where a numerical value is reported as a qualitative result, such as serological assays with a 'cut-off' value where the numerical result is reported as 'detected' or 'not detected'.

MU must be estimated for all applicable analytes. MU estimations must be reviewed when assay performance changes significantly.

**5.5.2** The sources of biological reference intervals and/or medical decision points must be documented and include references to the information used in deciding the intervals, any statistical processes used, literature studies considered and the personnel involved in deciding the intervals. Where possible and relevant, customers of the laboratory with appropriate expertise should also be involved in the determination of reference intervals. Consideration should be given to adopting intervals/decision points consistent with those in other laboratories, where possible and appropriate.

Age, gender and other relevant information must be considered when establishing reference intervals.

A record must be kept when changes to reference intervals are made.

**5.5.3** Method documentation must be regularly reviewed to ensure currency

### **5.6 Ensuring quality of examination results**

#### **5.6.2 Internal quality control**

Guidance on QC issues should be sought from publications of the relevant professional societies.

- (i) The QC material used must cover the analytical concentrations found in patients. As far as possible these should cover the critical clinical action points. Low/ /high, normal/abnormal, positive/negative, reactive/non-reactive controls, as appropriate for the test, must be performed.
- (ii) Controls independent of those produced by the manufacturer of the test or analyser should be used.

Mean, standard deviations (SD) and ranges supplied by manufacturers may not always provide adequate control of assays. See (iv)

If independent commercial QC material is unavailable the following approaches should be considered:

- a) where QC material is obtained from the manufacturer of the reagents or calibrator, information on the production of QC material should be sought from the manufacturer to determine the extent of independency from the kit calibration process. This should include the source of the QC material, traceability (including value assignment) and matrix matching.
  - b) pooled patient samples.
- (iii) Where calibration of an assay is required, appropriate material must be used as a calibrator. If the material selected is not intended for use as a calibrator, assigned calibration values must be substantiated.
  - (iv) Acceptance ranges (confidence limits) must be defined for internal quality control material. As far as practicable laboratories must define ranges based on the current analytical performance. Where ranges are set to limits other than +/- 2SD based on current analytical performance, the rationale for the limits must be documented.
  - (v) Numerical QC results should be presented graphically to assist in the early detection of trends.
  - (vi) The laboratory must have a system of long-term monitoring of internal quality control results to assess method performance.
  - (vii) Records must be available to demonstrate that internal quality control results have been reviewed.
  - (viii) A protocol for action to be taken where QC results fall outside acceptance ranges must be documented. This must include consideration as to whether test results should be withheld and whether previously issued results should be recalled.
  - (ix) Where available tests which incorporate immunochromatographic methodology such as D-dimer and  $\beta$ -hCG, must use additional control material. It is acknowledged that these assays incorporate an internal check to validate the integrity of the reagent and cartridge; however, ambiguity may arise in the interpretation of faint bands.

Additional discipline-specific QC requirements are detailed below.

### **Cartridge-based instruments**

These may be of the type where:

- a) the complete analytical process occurs within the cartridge and the instrument functions solely as a detector and reporter of the test signal from the cartridge; or
- b) the cartridge contains some or all required reagents, and the instrument participates in the generation of the test signal.

Electronic check: Where the detector is provided with an electronic means of regularly assessing satisfactory performance, such checking should be carried out at least at the frequency recommended by the manufacturer. A record of checks must be kept.

**Storage of cartridges:** Cartridges must be transported and stored according to manufacturer's instructions. For each refrigerated storage site, the NATA requirement for maintaining temperature records applies.

**QC & QA of Cartridges:** For the purpose of QC and QA, regardless of the number of instruments using the cartridges, the same batch/lot number of cartridges may be treated as a single entity, providing:

- the cartridges are used at the same geographic site;
- the same batch/lot number is received from the supplier in the same delivery;
- the above conditions of instrument checking and cartridge transport and storage are met;
- all storage sites are appropriately temperature monitored;
- sufficient quality control is undertaken on each batch/lot number of cartridges to demonstrate that analytical performance is satisfactory throughout the stated shelf life; and
- a record is kept of the instrument(s) and cartridge source(s) used for performing the checks.

### **Point of care testing (PoCT)**

The Australasian Association of Clinical Biochemists' position statement on PoCT is applied in relation to cartridge-based instruments and is also considered to be relevant to the disciplines of haematology, microbiology and immunology.

QC testing must be performed on all PoCT devices and for every analyte/test for which the PoCT device is being used. This is additional to the statement in the AACB guidelines. Electronic QC testing is a check of the device's measurement signal only and does not check the analytical pathway.

There are two main types of PoCT devices: low and medium complexity.

**Low complexity:** devices using strip technology (e.g. glucose or coagulation meters), a minimum of one liquid QC sample must be tested per month unless a higher frequency is suggested by the manufacturer. Where only one QC sample is tested, it should have a concentration in the clinically relevant range for the analyte being measured. If two levels of QC are available, then QC samples with both a normal and abnormal level should be tested.

**Medium complexity:** devices using cartridge-based technology (e.g. blood gas analysers, glycohaemoglobin meters) shall have a minimum of two liquid QC samples tested per month unless a higher frequency is suggested by the manufacturer. These two QC samples should contain both normal and abnormal levels.

In addition to the above QC program, QC testing should also be undertaken when:

- The lot number of the consumables changes;
- There is a new delivery of consumables;
- An operator lacks confidence in a patient result;
- The health care professional does not believe that the PoCT result fits the patient's clinical picture;



- Substantial maintenance procedures have been carried out on the device; and
- The device has suffered a physical insult (e.g. dropped, temperature extremes – hot or cold, etc.).

It is also recommended that:

- all INR results significantly above the therapeutic range should undergo confirmatory testing in an accredited laboratory; and
- at least once per week, one INR patient result should be repeat tested in an accredited laboratory and the results compared.

### **Chemical pathology**

Control material must be matrix matched where available.

**Note:** It is acknowledged that this may not always be possible for analyses which have specific QC requirements as detailed above (e.g. cartridge-based instruments).

The minimum requirement for blood gas and CO-oximetry QC is a daily assay of control material at two or more control levels, performed concurrently. For instruments with a calibration factor this procedure should take place following a full calibration cycle and before any subsequent testing of patient samples.

**Note:** The above requirement does not apply to cartridge-based instruments or those employing Intelligent Quality Management (iQM), or equivalent processes. Quality control for these systems will be reviewed at assessment.

### **Cytopathology**

A documented program must be established correlating non-gynaecological cytopathology reports with any subsequent histopathological findings, where available. Records of correlation must be kept.

The RCPA position on the examination and reporting of non-gynaecological cytopathology samples is as follows:

If the sample is either:

- voided urine; or
- sputum

AND the screening outcome is:

- 'no malignant, atypical or other abnormal cells'

the report may be issued by a scientist or senior cytotechnologist who is appropriately trained, under the supervision of an appropriately trained pathologist.

**Note:** 'Appropriately trained' is defined as having a relevant degree in science or applied science together with a minimum of 2 years full-time experience/training in a laboratory accredited by NATA/RCPA for general cytology. A senior cytotechnologist is a person with the equivalent of 5 years full time experience in cytology and holding a qualification which designates competence in cytology.

In all other circumstances, the sample together with the request, including the clinical notes, and the opinion(s) of the cytotechnologist(s) must be submitted to an appropriately qualified and trained pathologist, who will examine the case and finalise and sign out the report.

## Haematology

Multi-level controls must be run concurrently at least once per day for haemostasis testing, excluding point of care testing, and on automated cell counters. The open and closed mode of testing of automated cell counters must be considered. Additional single level controls must be run throughout the working day, giving consideration to the laboratory workload.

Where a positive control is not intrinsic to the test sample, positive controls must be performed with special stains. Control slides must be retained so that they can be retrospectively linked to the patient slides to which they pertain.

## Histopathology

Where control material is not intrinsic to the test sample, control slides must be tested with special stains. Control slides must be retained so that they can be retrospectively linked to the patient slides to which they pertain.

The identification of samples must be secure through all stages of processing. Examples of procedures that may be employed to minimise the risk of sample mix-up are:

- checking of stained sections against the corresponding block prior to reporting;
- checking slides and blocks against the details on the request form prior to reporting;
- handling one case at a time (e.g. at microtomy); and
- labelling slides and cassettes for one case at a time.

## Immunohaematology

Refer to NPAAC *Requirements for Transfusion Laboratory Practice*.

In addition, the following apply:

- QC must be performed upon opening each grouping reagent vial. If a vial remains in use after a period of seven days then QC must be repeated on each subsequent day of use; and
- If a reagent is close to the expiry date when opened, consideration should be given to performing daily QC depending on the knowledge of the performance and stability of the reagent.

The above may not apply to Micro-Column Techniques (MCT). All MCT reagents must be quality controlled in accordance with the manufacturer's instructions.

## Immunology

A positive and negative reaction must be demonstrated as a minimum on every immunofluorescence run and as an optimum with every immunofluorescence slide. Optimally, borderline positive controls and/or controls titring to a known endpoint should also be used.

**Note:** Controls may be either from previous patient samples or commercially obtained samples with known staining characteristics.

Reactive controls with defined immunofluorescence patterns for the antibodies under investigation must be tested as a minimum on every new batch of slides. Optimally, they should be tested on every run.

**Note:** Once the specificities detected by the substrate have been confirmed and the slides are stored under monitored appropriate conditions, and are within the expiry date, it is not essential to repeat for every run.

As a minimum, the appropriate working concentration of each new batch of fluorescein-labelled anti-human immunoglobulin conjugate must be determined by checkerboard titration with each different substrate with which it will be used. Optimally, this should also be performed for every new batch of individual substrate.

**Note:** If using commercial kits this should have already been done by the manufacturer. If conjugates and slides are purchased separately from the same manufacturer, however, the assay will still need to be validated. If using conjugate from one manufacturer and slides from another or in-house slides then the conjugate dilution will need to be optimised for individual substrates.

Appropriate controls must be run with each ELISA plate. Optimally, non-kit controls should be included to monitor performance over time and enable the determination of inter-lot batch variation. Appropriate negative controls should be included on each ELISA plate. This is also applicable to serological testing utilising this methodology.

## **Microbiology**

### Media (Solid, semi solid and diluents)

Each facility is responsible for ensuring that an appropriate level of quality control is performed on the media it uses. This is achieved through an effective media preparation and quality control program designed to suit the scope of testing.

Details of the procedures for preparation and quality control of media and diluents must be documented as part of the facility's management system consistent with the relevant current versions of the Australian Society for Microbiology (ASM):

*Guidelines for Assuring Quality of Medical Microbiological Media; and*

*Guidelines for Assuring Quality of solid media used in Australia for cultivation of Medically important Mycobacteria.*

### Shelf life

Shelf life of all media must be evaluated in accordance with the guidelines provided in the ASM Guidelines for Assuring Quality of Medical Microbiological Media and Guidelines for Assuring Quality of solid media used in Australia for cultivation of Medically important Mycobacteria and prepared media marked accordingly.

#### 1. Media produced in-house for distribution to satellite laboratories

In general, all facilities, including satellite laboratories receiving media from a parent facility that does not hold accreditation for media quality control (Class 8.15) will be required to carry out a full quality control evaluation on each batch of each medium made. Alternatively, facilities preparing media for distribution to satellite laboratories are encouraged to seek NATA accreditation for media quality control.

It is, however, recognised that under special circumstances facilities may be required to produce a small amount of media in-house (e.g. specialised media used by reference laboratories). Generally, this type of media will not be available for purchase from commercial accredited manufacturers. In this situation, satellite laboratories receiving specialised media from a non-accredited parent facility will not be required to perform full QC provided the following criteria are met:

- a) The parent facility carries out quality control evaluation on each batch of each medium made. A copy of the media preparation details and QC results must be made available to the satellite laboratory;
- b) The receiving satellite laboratory must demonstrate that the media have not been adversely affected by transit, storage and change in environmental conditions;
- c) The laboratories must be part of the one organisation; and
- d) The media must not be sold or provided to other facilities outside the organisation.

If any of the above is not met, the requirement for full QC at the satellite laboratory will apply.

## 2. Media purchased from accredited manufacturers

Accredited media manufacturers are those holding ISO/IEC 17025 accreditation for quality control testing of media they produce. Facilities must assure themselves that such accreditation is held by checking the current scope of the manufacturer's accreditation. The scope of accreditation will specify the classes of media for which the manufacturer can issue endorsed reports or certificates.

All media must be initially assessed for suitability to the particular requirements of the facility prior to purchase. This assessment should take into account the nature of the media and the type of test for which it is used, etc. It must be assured that QC organisms testing conditions (time and incubation temperature) are relevant to the testing for which the media are to be used. Where this is not the case the facility is responsible for undertaking additional QC if this cannot be undertaken by the manufacturer.

On an ongoing basis, some media will require only visual examination whereas other types of media require the monitoring of all batches produced until sufficient data have been generated to assure the user of the reliability of the product. At such time, the frequency of testing may be reviewed and reduced.

When a manufacturer issues a product, the product must be labelled with the product name, batch number, date manufactured and expiry date. The customer must also be provided with details of:

- a) name and code of media;
- b) reference to test methods and sterility protocol;
- c) the results of quality control (e.g. Organisms tested, pH, recovery, etc.) and expected results;
- d) shelf life.

The report or certificate issued by the manufacturer should include the NATA endorsement.

Media must be stored and used in accordance with the manufacturer's instructions and include inventory control.

Facilities must periodically review the reliability of purchased media against acceptance criteria and record the results of this review. Records relating to media quality control must be retained in compliance with NATA's record retention requirements.

3. Media purchased from non accredited suppliers

Facilities purchasing media from non-accredited suppliers are required to perform complete quality control testing on all media.

4. Media from suppliers holding ISO 9001 certification only

Certification of the operations of a manufacturer to ISO 9001 does not equate to technical accreditation. Facilities purchasing media from suppliers certified to the ISO 9001 series only or equivalent will be required to perform complete quality control testing on all media.

Maintenance of Microbiological Reference Culture Collections (MRCC)

MRCCs consist of biologically active cultures that may change their original characteristics as a result of genetic changes during manipulation over time, e.g. when passaged. MRCCs include all microbiological collections, including bacteria, viruses, fungi, protozoa etc.

**Note:** A passage is defined as the transfer of microorganisms to a new growth medium, or host, and subsequent growth to create a fresh viable culture (which may represent several generations of organism). The following examples represent one passage: *Escherichia coli* subcultured into a Nutrient Broth and incubated overnight; or cells infected with Poliovirus transferred to a flask of uninfected cells in a suitable growth medium and incubated.

Facilities must:

- hold and maintain MRCC of organisms necessary to perform, but not limited to, validation and verification of test methods, performance checks on test kits, reagents and prepared media and for use as method performance indicators as part of routine testing;
- define and document the characteristics of the reference cultures maintained as fit for purpose for their intended use, e.g. morphology and biochemical reactions;

**Note:** Characterisation may be subcontracted, where a competent subcontractor is for example, an appropriately accredited NATA facility.

- establish a program of performance checks to confirm the key characteristics of each culture are expressed as expected, and that the cultures continue to remain suitable for their intended purpose;
- maintain the following records:
  - identity, source and history of the culture;
  - date of acquisition;
  - conditions of resuscitation, preservation and storage;
  - results of purity and performance checks against defined characteristics;
  - dates of subculturing and passage number;
  - conditions used to maintain working cultures.

**Note:** The records for identity should include, where relevant, the organism name e.g. *E coli*, and a unique identification e.g. laboratory number and the catalogue number e.g. ATCC/NCTC.

Wild strains may be used when no reference strain is specified for a method or to supplement the reference strains specified. These should be confirmed by a

recognised reference laboratory, where possible, or alternative methodologies e.g. 16S gene sequencing. Where an organism is required for a particular characteristic only, the key characteristic(s) only need be confirmed.

**Note:** It is recognised that in some cases, e.g. fungi, full characterisation by a reference laboratory is not possible or feasible.

Facilities should ensure that the total number of passages is minimised, where possible, in line with current published literature and supplier's recommendations

#### Identification tests/kits

QC must be performed on microbiological identification kits (e.g. API) using relevant test organisms from a recognised type culture collection. QC should be performed when commencing the use of a batch of kits with a new production lot number, using one or more of the strains of organism recommended by the manufacturer (preferably in rotation).

#### Antibiotic susceptibility testing

Zone sizes for QC results must be recorded numerically (i.e. in millimetres).

The results of direct antibiotic susceptibility testing of urine may be reported provided that:

- the method used by the laboratory is fully documented and the conditions for its use defined;
- the method has been validated by comparison with a standard method and relevant records retained;
- the laboratory's method, if based on published data, has been verified for its own patient population and performance by staff within the laboratory; and
- a standardised method is available for use in circumstances where direct results are equivocal or there is uncertainty about reliability.

#### **Reproductive medicine**

As a minimum, a positive control must be run with every sperm antibody assay. This may be achieved by the use of QC material or by confirming, and recording, the presence of the bead clumping. As a minimum this must be performed upon opening a new kit and fortnightly thereafter to ensure appropriateness.

#### **Virology**

ASM recommends that commercial suppliers of viral culture media be accredited. Laboratories should purchase media only from accredited suppliers.

The laboratory must test each new batch of cell culture medium to ensure:

- the medium grows the cell lines which would be expected to grow;
- it produces normal densities (e.g. monolayer);
- it grows within an appropriate time frame;
- it produces normal cell morphology;
- 'cells and medium' support the growth of viruses or other intracellular organisms of interest; and
- uninoculated and inoculated controls are used.

Different controls may be used for different viruses. The laboratory must be able to demonstrate that appropriate controls are being used.

Laboratories should monitor the growth of viral cell lines by the following:

- recording of split ratios for both primary and continuous cell lines;
- testing for *Mycoplasma* yearly; and
- setting up uninoculated controls (cell culture only) and inoculated positive controls (cell culture with known virus) routinely with all viral assays.

### 5.6.3 External Quality Assurance Programs (QAPs) (Proficiency Testing)

- (i) Where available, a program which includes other laboratories in the country / region is preferred as this optimises the opportunity to reduce between-laboratory variation such as may be seen in a patient using multiple laboratories.
- (ii) Where analysers (e.g. blood gas analysers) are located outside the laboratory these must be enrolled separately in a QAP unless they meet the requirements as detailed below (QAP enrolment requirements for multiple same-analyte instruments).
- (iii) Regular submission of results to the program organisers is required whether or not the timing coincides with the testing of patients' samples.
- (iv) Participants must test QAP samples in a manner similar to patient samples. The following must be ensured:
  - Where duplicate testing is routinely performed, the laboratory must also perform duplicate testing on QAP samples;
  - Participants who perform tests on QAP samples must not engage in any inter-laboratory communications pertaining to the results of QAP samples until after the due date for return of results;
  - participants who perform tests on QAP samples may only engage in intra-laboratory communications when collaborative discussion or referral is part of the routine reporting protocol e.g. histopathology, cytopathology, haematology blood films;
  - The primary laboratory must not refer QAP samples or portions of samples to another laboratory for any analysis if the primary laboratory is accredited to perform the test.
- (v) On receipt of returns from the program organisers it must be ensured that:
  - QAP performance is reviewed and discussed by all relevant staff;
  - There is evidence that the review has taken place; and
  - The implication of unsatisfactory QAP performance for patient results is considered and a record of the considerations and action taken kept.
- (vi) QAP results should not be resubmitted where the original results were discordant with those returned from the QAP organisers.

### Chemical pathology

Enrolment in the CSF program for glucose and protein is not required if the laboratory is enrolled in a urine chemistry QAP for protein and a serum chemistry QAP for glucose where testing is performed on the same analyser.

## **Cytopathology**

In addition to the cytopathology QAP, Australian laboratories performing gynaecological cervical cytopathology must participate in the *Performance Measures* set by the National Cervical Screening Program. Results from the program organisers must be reviewed and acted upon in the same way as QAP results.

## **Immunology**

Where testing of specific allergens and allergen mixes are performed, the laboratory must participate in external QAPs for each specific allergen and the allergen mixes.

## **Immunohaematology**

All staff involved in blood banking must participate in external QAP on a rotational basis (as outlined in the NPAAC document). Where a large number of staff may preclude regular individual participation in the QAP, the laboratory must develop a replicate testing program to supplement QAP participation.

## **QAP enrolment requirements for multiple same-analyte instruments**

Diagnostic clinical chemistry testing devices routinely generate in-house quality control data that reflect the variable biochemical, electro-mechanical and human factors that combine to define their current in-service analytical performance. External QAPs additionally offer medical testing facilities the opportunity of checking the performance of their in-house quality control program, additional data to assist in identifying the causes of unacceptable performance, and independent audits of the analytical quality of the testing services through comparison against self and an external peer group over time.

Considerations of clinical need, workload, patient population, costs etc., may necessitate a laboratory employing more than one of the same, or different, analytical systems to measure the same analyte at the same or different locations. Quality assurance data demonstrate that even with identical methods and instrumentation, a variable such as location can impact measurably on analytical performance, presumably through factors such as differing work and equipment maintenance practices, staff skills, and environmental and reagent storage conditions. Therefore, in principle, every in-service analytical system should be individually enrolled in an appropriate external QAP so as to provide an independent audit of its unique analytical performance.

However, in the situation where a laboratory employs more than one semi-automated instrument to measure the same analyte(s) in the same sample type, a request for waiver of the requirement for enrolment of each such instrument in an external QAP may be approved under the following conditions.

The analysers should be of the same manufacture, employ the same analytical principles, reagent formulations and calibrators, and be located within the same laboratory site.<sup>1</sup>

For blood gas analysers, different models of the same manufacture must employ the same sampling and sample pathway system<sup>2</sup>, and must be located at the same laboratory or hospital site.

One of the analysers in the waiver group must be enrolled in the QAP for the analytes subject to waiver.



The non-enrolled instrument(s) in the waiver group must be subject to quality control, correlation and any other appropriate procedures sufficient to continuously demonstrate that its (their) quality assurance performance does not differ significantly from that of the enrolled instrument.

A waiver will apply only to the analytes replicated across the instruments in the group.

It is the responsibility of the laboratory to demonstrate that the analytical quality of each analyte measured by each instrument in the waiver group is continuously traceable to a recognised QAP.

The adequacy of the compliance arrangements will be evaluated at assessment. Additional time taken to evaluate correlation data will be at cost to the laboratory in accordance with NATA's fee schedule current at the time.

Please note that whilst the above applies specifically to clinical chemistry, application may be appropriate in other disciplines. The above criteria must be met, however, for all requests to waiver individual QAP enrolment.

### Notes

- 1 The prime purpose of quality assurance is the independent assessment of analytical performance by a discrete system for the measurement of an analyte and comparison of the performance with an external peer method group. As evidenced by end-of-cycle summaries, significant variability to the bias and imprecision in the measurement of an analyte is introduced by the use of instruments of different manufacture, of methods of different analytical principle, of different reagents and calibrators. Extreme differences may especially be observed with the use of different antibodies for the measurement of the same analyte. Significant variability in analytical performance may also be introduced into identical analytical systems by different laboratory environments where consumable storage conditions, staff training and operational practices may differ.

It is a current requirement that each Approved Pathology Laboratory (APL) be individually enrolled in appropriate quality assurance programs.

- 2 Blood gas analysers, including different models from the same manufacturer, may utilise different methods for accessing samples e.g. by drawing and by injection. Analysers may also employ different sample path-lengths between sample accession and gas measurement. Such differences can cause significant variations in reported  $pO_2$  tensions at the point of measurement.

Regardless of the number of instruments, a single enrolment in an appropriate QAP is satisfactory, providing the conditions detailed under Quality Control are met.

## 5.7 Post-examination processes

5.7.2 Laboratories must store inoculated and uninoculated viral media separately.

## 5.8 Reporting of results

### 5.8.3

#### General

In addition to those points covered in ISO 15189, test reports must include:

- (i) The test sample's laboratory number (e.g. accession number) or other unique identifier, where applicable;

- (ii) If applicable, the details of the point of care testing device, i.e. brand and model.
- (iii) Each page of a multi-page document shall bear a statement of the page number and the total number of pages.

Reports on results from tests covered by the scope of accreditation must include the name in which accreditation is held and the accreditation number.

In instances where results of tests not covered by the scope of accreditation are included on reports, the notation 'NATA/RCPA accreditation does not cover the performance of this service' shall be applied.

Laboratories should apprise themselves of any statutory requirements concerning additional information to be included on test reports.

### **5.8.3 c) Reports from other laboratories**

A test report may include results of tests performed by another laboratory provided that the source of those test results is clearly identified on the test report. Where testing is performed within a laboratory group, the group must be able to identify the laboratory in which testing was performed.

**Note:** A 'laboratory group' is defined as a group of laboratories with the same name and/or the same corporate accreditation number.

**5.8.3 f)** The time of sample receipt by the laboratory need not appear on the test report if it is traceable through the laboratory information system.

**5.8.3 g)** It is recognised that the sample type may be referred to in the test name or test system specified on the report (e.g. full blood count, faecal occult blood, semen analysis). In such circumstances it is not necessary to specify the sample type on the test report.

Where different sample types are used interchangeably (e.g. serum and plasma) the sample type can be indicated as serum/plasma on the report. If a single or predominant sample type is employed (e.g. plasma) this can be shown on the report so long as there are mechanisms in place to identify exceptions where this may impact on result interpretation.

The source of the sample must be noted where this is necessary for interpretation of results (e.g. source of stone) or source of blood sample (e.g. catheterisation studies).

### **5.8.3 l)**

- (i) A comment regarding sample labelling must be included on the test report where an unlabelled, mislabelled or insufficiently labelled sample has been accepted for testing, except when labelling requirements have been relaxed in a point of care testing environment.
- (ii) Reporting of drugs of abuse by primary screen (e.g. immunoassay or chromatography etc.) which has not been confirmed by GCMS must include a comment that the result is a screening test only and unless confirmation by GCMS is performed the result may have cross reaction and false positive results. The test method and cut off values used must also be included in the test report. Where the point of care test report format does not permit additional information, these must be included as information accompanying the report.

## 5.9 Release of Results

### 5.9.1

- (i) The laboratory must have a documented protocol for the verbal release of results.
- (ii) Test reports may be electronically issued (including from a site other than the accredited laboratory) provided that the reports have been appropriately authorised for release. The following must be satisfied and the adequacy of arrangements will be reviewed at assessment.
  - (a) Copies (hard copy or computer records) of test reports must be retained at the accredited laboratory including any handwritten comments added to issued reports.
  - (b) The laboratory must be able to demonstrate appropriate controls over the electronic generation, access, storage and backup of results and reports and program controls such as password protection. If the report is to be accessed from a website by the client there must be an appropriate control in place to ensure the report can only be downloaded in a protected format.
  - (c) Any information normally included in a hardcopy report must be included on the electronically transmitted version and appear in any hardcopy printed by the recipient. (Flexible pagination to accommodate formatting changes when printed by the recipient, may also be required).

#### 5.9.1 a)

Where the laboratory receives samples from a non-accredited collection agency for drugs of abuse testing in accordance with AS/NZS 4308 a statement reflecting this must be included in the test report. Where the point of care test report format does not permit additional information, this statement must be included as information accompanying the report.

#### 5.9.1 d) Preliminary reports

The laboratory must have a document policy for issuing preliminary reports (however named).

Preliminary reports may be issued when components of a test or suite of tests have not yet been completed. However, those results which are reported must be checked and authorised and the status of the report evident (i.e. preliminary). This includes reports which are accessible to an enquirer via a computer terminal or by other electronic means.

Where an accredited facility issues a preliminary report prior to the final report, the final report shall contain a reference to the preliminary report.

No report, whether preliminary or final, shall include results not authorised for release.

## References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

### NPAAC publications

[www.health.gov.au/npaac](http://www.health.gov.au/npaac)

### Standards

- AS 3864            *Medical refrigeration equipment*
- AS/NZS 4308:    *Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine*
- ISO 15189        *Medical laboratories - Particular requirements for quality and competence*
- ISO/IEC 17025   *General Requirements for the competence of testing and calibration laboratories*

### NATA Publications

- General Accreditation Criteria    *Equipment assurance, in-house calibration and equipment verification*
- General Accreditation Guidance   *Validation and Verification of Quantitative and Qualitative Test Methods*
- Specific Accreditation Criteria    *Calibration ISO/IEC 17025 Appendix*

### Other references

- Assessment of Bias with Emphasis on Method Comparison AACB Analytical Quality Supplement (Clin Biochem Rev, Vol 29, Suppl (i), August 2008)
- Guidelines for Assuring Quality of solid media used in Australia for cultivation of Medically important Mycobacteria. Australian Society for Microbiology
- Guidelines for Assuring Quality of Medical Microbiological Culture Media. Australian Society for Microbiology
- Guidelines for conducting quality control and quality assurance for PoCT Australasian Association of Clinical Biochemists (AACB)
- National Measurement Act 1960
- WHO Laboratory Manual for the Examination and Processing of Human Semen Cervical Mucus Interaction, 5th Edition World Health Organisation
- Guidance documents covering the implementation of specific accreditation requirements are also available from the ILAC ([www.ilac.org](http://www.ilac.org)) and APLAC ([www.aplac.org](http://www.aplac.org)) websites.

## Further Reading

*Antibiotic Susceptibility Testing by the CDS Method. A manual for Medical and Veterinary Laboratories 2009.* S.M.Bell, J.N. Pham, I.W.Carter.

*A Standardised Framework for the Validation and Verification of Clinical Molecular Genetic Tests* European Journal of Human Genetics, 18, 1276-1288 (28 July 2010)

*Recommended Principles and Practices for Validating Clinical Molecular Pathology Tests* Archives of Pathology and Laboratory Medicine, Vol 133, Issue 5, 743-755 (May 2009)

*Uncertainty of Measurement in Quantitative Medical Testing – A Laboratory Implementation Guide.* Australasian Association of Clinical Biochemists (AACB).

*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline - 5th Edition* Clinical and Laboratory Standards Institute

*Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - 6th Edition* Clinical and Laboratory Standards Institute

*Procedures for the Handling and Processing of Blood Specimens; Approved Guideline - 3rd Edition* Clinical and Laboratory Standards Institute

*The RCPA Manual* The Royal College of Pathologists of Australasia

*Guidelines for Pretransfusion Laboratory Practice* ANZSBT 5<sup>th</sup> Ed

## Amendment Table

The following amendments were made to the Medical Testing Field Application Document – July 2012.

Please refer to this sheet in conjunction with the NATA Procedures for Accreditation and the associated Medical Testing Field Application Document and Annexes to ensure that you are familiar with these amendments.

AMENDMENT TABLE			
Section	Title	Clause or Class of test amended	Amendment
	Title page		The title of the document has been changed to reflect consistency within NATA.
1	Introduction	All	Reissued as NATA Procedures for Accreditation
2	Accreditation procedures	All	Reissued as NATA Procedures for Accreditation
3	Application of ISO 15189 and NPAAC Requirements		
	Management requirements		
		4.1	Name change
		4.1.5 j)	Re-numbered to 4.1.2.5
		4.2.1	Re-numbered to 4.2.2.2
		4.4	Clause name change
		4.5	Reference renumbered to 5.8.1
		4.5.2	Re-numbered to 4.5.1 b
		4.5.4	Re-numbered to 4.5.2
		4.6	Text removed.
		4.11	Text removed.
		4.13	Title name change
		4.13.1	Sub-clause number removed
		4.13.1	Text removed.
		4.13.2	Sub-clause number removed
		4.13.3	Sub-clause number removed
		4.14	Clause name change
		4.14.1	Re-numbered to 4.14.5
	Technical Requirements		
		5.1.2	Re-numbered to 5.1.9
		5.1.9	Re-numbered to 5.1.8
		5.1.11	Text removed
		5.2.1 and 5.2.2	Text removed
		5.3	Title amended
		5.4.3 i)	Re-numbered to 5.4.4.3
		5.4.3 ii)	Re-numbered to 5.4.2
		5.4.3 c)	Re-numbered to 5.4.4.3 e)
		5.4.4.3 e	Amended
		5.4.5 i)	Re-numbered to 5.4.4.3 a)
		5.4.5 ii)	Re-numbered to 5.4.4.3 e)
		5.4.5 iii)	Re-numbered to 5.4.6 c)
		5.4.5 iv)	Re-numbered to 5.4.6 a) (i)
		5.4.5 v)	Re-numbered to 5.4.6 c) (ii)
		5.4.5 vi)	Re-numbered to 5.4.6 a) (ii)
		5.4.5 vii)	Re-numbered to 5.4.6 a) (iii)
		5.4.8	Re-numbered to 5.4.6 b)

<b>AMENDMENT TABLE</b>			
<b>Section</b>	<b>Title</b>	<b>Clause or Class of test amended</b>	<b>Amendment</b>
		5.5.1	Re-numbered to 5.5.1.1
		5.5.1 (v)	Deleted
		5.5.1 (vi)	Amended
		5.5.2	Re-numbered to 5.5.1 (also included in 5.5.1.3)
		5.5.5	Re-numbered to 5.5.2
		5.5.7	Sub-clause number removed
		5.6	Title change
		5.6.1	Re-numbered to 5.6.2
		5.6.1 (i)	Amended
		5.6.1 (ix)	Amended
		5.6.1	Microbiology Media text inserted
		5.6.1	Duplicated text removed
		5.6.2	Re-numbered to 5.5.1.4
		5.6.2	Reworded
		5.6.6	Re-numbered to 5.5.1.2
		5.6.4	Re-numbered to 5.6.3
		5.6.3	Re-numbered to 5.3.1.4
		5.6.2 (vi)	Reworded
		5.7	Title change
		5.8.12	Re-numbered to 5.8.3 c)
		5.8.3 e)	Re-numbered to 5.8.3 f)
		5.8.3 k)	Re-numbered to 5.8.3 l)
		5.8.3 (iii)	Deleted
		5.8.5	Re-numbered to 5.9.1 a)
		5.8.9	Re-numbered to 5.9.1 d)
		5.8.14	Re-numbered to 5.9.1
Annex 3.1	Clinical non-human specimen testing		Reissued as Medical Testing Annex A - Clinical non-human specimen testing
Annex 3.2	Safety		Deleted
Section 4	Equipment calibration and check intervals		Reissued as stand alone documents <ul style="list-style-type: none"> <li>• General Equipment Table</li> <li>• Reference Equipment Table</li> </ul>
Section 5	Classes of test		Reissued as a stand alone document
Section 6	References		Revised and updated
	Amendment table		Included