General Accreditation Criteria

ISO 15189:2022 Standard Application Document

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Table of Contents

Purpose

This document provides interpretative criteria and recommendations for the application of ISO 15189:2022 *Medical laboratories – Requirements for quality and competence* for both applicant and accredited facilities.

Facilities must comply with all relevant documents in the ISO 15189 NATA *General Accreditation Criteria* (NAC), in addition to the relevant NPAAC standards, for the activities for which accreditation is held or being sought (refer to *NATA Procedures for Accreditation*).

The clause numbers in this document follow those of ISO 15189, however, as not all clauses require interpretation the numbering may not be consecutive.

5 Structural and governance requirements

Specific requirements for supervision are described in the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for Medical Pathology Services* and associated documents. Facilities seeking approval from Services Australia (Medicare Australia) as an Approved Pathology Laboratory (APL) for the purposes of claiming Medicare reimbursement must comply with the requirements for the relevant NPAAC category as described in the applicable NPAAC documents.

Non-APLs

Facilities seeking NATA/RCPA accreditation for Human Pathology testing who are not intending to seek approval as an APL are also required to comply with all the relevant National Pathology Accreditation Advisory Council (NPAAC) standards.

As a minimum the *Requirements for Medical Pathology Services* and the *Requirements for the Supervision in the Clinical Governance of Medical Pathology Laboratories* Section 1 and Appendix A apply.

5.3 Laboratory activities

5.3.1 General

Facility documentation must include or reference the scope of accreditation and the policy on the use of the NATA/RCPA endorsement.

5.4 Structure and authority

5.4.1 General

The facility must document relief arrangements where specific supervision requirements have been stipulated in the regulatory framework.

6 Resource requirements

6.2 Personnel

6.2.2 Competence requirements

Proof of qualifications, membership of professional societies and hours of attendance at the laboratory must be provided (upon request) as part of the NATA assessment process.

Evidence of acceptance and recognition of overseas qualifications must be available.

6.3 Facilities and environmental conditions

6.3.1 General

Pathologists seeking to report specimens outside of a traditional laboratory environment must adhere to the RCPA Position statement *Reporting of Specimens outside the Laboratory*.

6.5 Equipment calibration and metrological traceability

6.5.1 General

Equipment shall be calibrated over the range and with an appropriate level of accuracy specified in relevant methods.

Note: Refer to the NATA document, *General Accreditation Criteria: Equipment assurance, in-house calibration and equipment verification.*

Where calibration of an assay is necessary and the material selected is not intended for use as a “calibrator”, values assigned must be substantiated and the material demonstrated as fit-for-purpose.

In-house calibration

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 (MU) has been made. Fees will be charged where significant additional assessment effort is required (i.e. time or additional assessors). Specialist calibration assessors may 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 a non-standardised calibration method is adopted, or if it would be more time or cost effective.

A facility performing its own calibrations may also be subject to proficiency testing or measurement audits where non-standard calibration methods are used.

Note: Refer to the NATA document, *General Accreditation Criteria: Equipment assurance, in-house calibration and equipment verification,* for additional information.

6.6 Reagents and consumables

6.6.3 Reagents and consumables - Acceptance testing

The facility must determine the extent of acceptance testing necessary to demonstrate ongoing performance of reagents and consumables prior to use. This should consider the stability of the method and whether transport and storage conditions, as documented by the manufacturer, are maintained.

6.8 Externally provided products and services

6.8.2 Referral laboratories and consultants

A competent referral laboratory is generally considered to be a laboratory accredited by NATA for the tests referred or a laboratory accredited by a signatory to a Mutual Recognition Arrangement.

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

Facilities should seek approval from the referral laboratory to report excerpts from the referral laboratory's report and ensure under no circumstances excerpts are misleading.

The facility should ensure that extracted results are not misleading by themselves or in conjunction with other associated results or opinions.

Note: It may be appropriate to seek a single approval to report all services provided by a referral laboratory.

7 Process requirements

7.2 Pre-examination processes

7.2.2 Laboratory information for patients and users

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

7.2.4 Primary sample collection and handling

7.2.4.2 Instructions for pre-collection activities

The collection procedures must include 'order of draw'.

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

Where point-of-care testing (POCT) is performed, labelling requirements can be relaxed, but where a delay in testing occurs and/or there are multiple patients tested at the same time, the sample must be labelled appropriately.

7.2.6 Sample receipt

7.2.6.1 Sample receipt procedure

Samples and associated records (worksheets, slides etc.) must be uniquely identified during all stages of testing to allow traceability of all necessary information.

Sample reception procedures must cover all types of samples received.

Where the facility's reception data entry processes are handled by another body in a different jurisdiction (e.g. outside of Australia), the security and confidentiality requirements of ISO 15189 and NPAAC still apply.

The facility's sample reception data entry processes must be included in the internal audit and evaluation cycle.

7.2.6.2 Sample acceptance exceptions

Where inadequately labelled samples are received and accepted for testing, the facility must assure itself of the identity of each sample. If samples that do not meet minimum acceptability criteria are accepted and tested, a record must be kept of any subsequent action taken.

Note: The facility retains responsibility for the testing and reporting of inadequately labelled samples even where the identity is confirmed by the collector.

Samples that are received unlabelled, mislabelled or insufficiently labelled must not be relabelled after receipt or sent back to the collector for relabelling. The exception is for irreplaceable specimens (e.g. histology specimens). In such cases the original specimen label must remain unaltered and visible. However an additional label may be added to the container to aid traceability through the laboratory. The person applying the additional label must be identifiable in the records and the original labelling issue must be included as a comment in the final test report.

The facility must document how it defines irreplaceable specimens.

Histology

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 include:

- 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;
- separating cases of similar type at cut-up so they are non-sequential;
- handling one case at a time (e.g. at microtomy); and
- labelling slides and cassettes for one case at a time.

7.3 Examination processes

7.3.1 General

Where a test can be performed by more than one method, there must be documented criteria for method selection.

AS/NZS 4308 and AS/NZS 4760

Facilities seeking accreditation, or who hold accreditation, for AS/NZS 4308 *Procedures for the specimen collection and detection and quantitation of drugs of abuse in urine* and/or AS/NZS 4760 *Procedures for the specimen collection and the detection and quantification of drugs in oral fluid,* must ensure that all requirements of either or both standards are satisfied at all times when reference to NATA accreditation is claimed.

The cut-off levels for drugs of abuse testing must be in-line with the Standards unless justification for different cut-off levels is provided.

Haematology

Where performed the examination of blood films for malarial parasites must include evaluation of both thin and thick films.

Criteria for referral of blood films to a pathologist must be documented.

Microbiology

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.

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

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

Manual reading of antimicrobial disc diffusion susceptibilities

Laboratories must not rely on visual estimation (eyeballing) when interpreting antimicrobial disc diffusion susceptibility plates. Where antibiotic zones are measured to determine if the organism is sensitive or resistant, these must be recorded.

Calibrated Dichotomous Susceptibility Testing (CDS Method)
The Antibiotic Susceptibility Testing by the CDS method, Nineth edition (2018), Chapter 2

- zone sizes must be measured from the back of the plate whenever possible;
- measurements must be documented;
- interpretation is based on standard criteria as follows:
  - annular radius ≥ 6 mm = susceptible
  - annular radius < 6 mm = resistant

European Committee on Antimicrobial Susceptibility Testing (EUCAST)
There are three acceptable methods listed below. The preferred methods are manual measurement or the use of an automated reader; however, a template may be used if these options are not feasible.

- manual measurement and documentation of the zone diameter from the back of the plate where possible;
- use of an automated zone reader;
- use of a template, with documentation when zone size is close to the cut-off;
- interpretation is based on the current breakpoint tables.

Clinical and Laboratory Standards Institute (CLSI)

- the diameter of zones showing complete inhibition (judged by the unaided eye), including the disc diameter, must be measured to the nearest whole number;
- this is performed using sliding calipers or a ruler held against the back of the inverted petri plate, with all measurements documented;
- interpretation is based on the current breakpoint tables.

7.3.2 Verification of examination methods

Analyser verification across a laboratory network

The following information applies where the same analyser make and model is employed across a network and a primary verification is performed at a Principal site.

"Wet chemistry" analyser verification

The principal site must undertake a complete evaluation of the analytical system which is to be used across the network. This must include evaluation against the existing analyser (if being replaced) and must demonstrate that the analyser type meets the needs in terms of performance parameters.

There must be a documented process to verify that when the same analytical system is introduced at all subsequent sites within the network that the results are compatible. Thus, an evaluation of the method's precision and accuracy is required to include correlations between methods and comparison studies with statistical analysis (e.g. Z test) between the principal site and the other site(s), particularly where common reference intervals are used. The level of verification at subsequent sites need not be as extensive as that performed at the principal site.

"Cartridge based" reader systems.

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/or the instrument participates in the generation of the test signal.

Where it can be demonstrated that the analytical system is contained within an enclosed “cartridge” [(a) above] and the instrument acts as a reader (voltmeter), only the Principal site must undertake a complete evaluation of the analytical system as for “wet chemistry” analysers above.

For all subsequent installations across the laboratory network, each site must perform the electronic/reader check as required by the manufacturer and in addition perform quality control on the batch of cartridges to be used. Further verification prior to initial use of the cartridges at each site is not required.

7.3.5 Biological reference intervals and/or clinical decision points

Consideration should be given to adopting intervals/decision points consistent with those used by other laboratories and/or those endorsed by professional peak bodies, where possible and appropriate.

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

Published reference intervals (e.g. in test reports) must match those included in the laboratory information management system and all other quality documentation.

7.3.7 Ensuring the validity of examination results

7.3.7.2 Internal quality control (IQC)

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

A system must be established for the long-term monitoring of internal quality control results to assess method performance.

Records must be available to demonstrate that internal quality control results have been reviewed.

Additional discipline-specific QC requirements are detailed below.

Cartridge-based instruments

Electronic check:	Where the detector is provided with an electronic means of regularly assessing satisfactory performance, such checking must 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 requirement for maintaining temperature records applies.
QC of Cartridges:	As per the definition of cartridge-based instruments above (refer to 5.5.1.2 a), regardless of the number of instruments using the cartridges, for QC purposes, the same batch/lot number of cartridges may be treated as a single entity, providing transport and storage are within manufactures requirements.

QC must be initially performed on each lot number of cartridges.

Ongoing QC at each geographical site where testing is performed must demonstrate that the integrity of analytical performance is satisfactory throughout the stated shelf life of the cartridges.

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

There must be a system of follow-up for correlating the results of non-gynaecological cytopathology with relevant histopathology. Records of correlation must be kept.

Attention is drawn to the fact that different Liquid based cytology (LBC) systems exist and that vials from different manufacturers are generally not interchangeable.

Haematology

Multi-level controls must be run concurrently at least once per day or on each day that testing is performed:

- for haemostasis testing, excluding POCT; and
- on automated cell counters.

Controls must be performed using open and closed modes of testing of automated cell counters where different sample probes and sample paths exist.

Where single sample probe and sample paths exists with a single calibration factor for both analytical modes QC material is required to be analysed using closed mode sampling only.

For special stains, positive control slides must be performed and 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 patient test sample, control slides must be used with special stains. Control slides must be retained so that they can be retrospectively linked to the patient slides to which they pertain.

Ideally, immunohistochemistry controls should be cut onto the test slide to ensure validity of staining. Generic "sausage" controls (multi-tissue punch controls) can be a useful way to facilitate this.

Immunopathology

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 titred to a known endpoint should also be used. 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 on every new batch of slides as a minimum. Optimally, they should be tested on every run. Once the specificities detected by the substrate have been confirmed and the slides are stored under appropriate monitored conditions and are within the expiry date, it is not essential to repeat for every run.

If commercial conjugates and slides are purchased separately from the same manufacturer (i.e different batches), or where conjugate is purchased from one manufacturer and slides from another, or in-house slides are used, then the assay must be validated, and the conjugate dilution will need to be optimised for individual substrates.

For non-commercial or in-house fluorescein-labelled anti-human immunoglobulin conjugates, the appropriate working concentration of each new batch of 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.

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

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).

For antibiotic susceptibility testing, zone sizes for QC results must be recorded numerically (i.e. in millimetres).

7.3.7.3 External quality assessment (EQA)

As described in the NPAAC *Requirements for Medical Pathology Services,* Quality Assurance Programs (QAP) must cover all testing methods performed where such programs exist.

QAP samples must be tested in the same, or similar, manner as patient samples. Accordingly, the following must be ensured:

- where duplicate testing is routinely performed, duplicate testing on QAP samples must also be performed;
- participants may only engage in intra & inter-laboratory communications when collaborative discussion or referral is part of the routine reporting protocol (e.g. histopathology, cytopathology, haematology blood films);
- QAP samples, or portions of samples, must not be referred for testing if the facility is accredited to perform the test;
- results are required to be submitted for every QAP sample sent by the provider for each program the facility is enrolled in;
- regular submission of results to the program provider is required whether or not the timing coincides with the testing of patients' samples;

Point of Care Testing (POCT)

Where analysers (e.g. blood gas analysers) are not located within the facility premises, these must be enrolled separately in a QAP unless they meet the requirements as detailed below:

- the analysers are of the same manufacture, employ the same analytical principles (e.g. same sampling and sample pathway system), reagent formulations and calibrators, and are located within the same site;
- one of the analysers in the group must be enrolled in the QAP for the analyte(s);
- the non-enrolled analyser(s) in the group must be subject to quality control, correlation and any other appropriate procedures sufficient to continuously demonstrate that their quality assurance performance does not differ significantly from that of the enrolled analyser;
- it is the responsibility of the facility to demonstrate that the analytical quality of each analyte measured by each analyser is continuously traceable to a recognised QAP.

7.3.7.4 Comparability of examination results

Verification and comparison of blood gas analysers (BGA)

On-going comparison of blood gas analysers

- More than one blood gas analyser at one geographical site:

  Where analysers are closely located (e.g. multiple analysers at one hospital site) a single specimen should be analysed on a number of analysers within a given time (considering the lability of the sample). The use of patient specimens 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.

- For blood gas analysers that are not located at one geographical site:

  Where analysers are not closely located (e.g. at different premises) the lability of patient specimens makes on-going comparison difficult. Where internal QC and

QAP results suggest there may be performance problems with a particular analyser, the possible impact on patient results must be investigated.

Comparison of blood gas analysers against main chemical pathology analysers

- Where the blood gas analysers and main chemistry analysers are located at one geographical site:

  Where serum/plasma electrolytes are performed on the main chemistry analyser and blood electrolytes on a blood gas analyser, ongoing comparison between the instrument platforms should be determined. It is acknowledged that the two platforms may not measure the same thing (e.g. direct ISE versus indirect ISE, different specimen 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 serum/plasma specimens on each instrument at defined intervals and assessing the level of agreement.

- 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.

7.4 Post-examination processes

7.4.1 Result reporting

7.4.1.1 General

Refer to *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation.*

7.4.1.2 Result review and release

Where the facility receives samples from a non-accredited collection facility for drugs of abuse testing for AS/NZS 4308 and/or AS/NZS 4760, a statement reflecting this must be included in the test report.

Preliminary reports (however named) 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).

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

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

7.4.1.7 Additional information for reports

In instances where results of testing not covered by the scope of accreditation are included in reports covering accredited testing, the notation 'NATA/RCPA

accreditation does not cover the performance of this service', or similar wording, must be applied.

Where testing is performed within the same laboratory network, reports do not need to identify which specific site conducted the testing, so long as it can be identified within the records which site performed the testing.

Note: A 'laboratory network' is as defined by NPAAC. Definitions described in regulation (e.g. TGA IVD regulations) may also apply.

The time of sample receipt need not appear on the test report if it is traceable through the laboratory information management system.

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 POCT environment.

Reporting of drugs of abuse by primary screen (e.g. immunoassay or chromatography etc.) which has not been confirmed by an appropriate chromatography coupled mass spectrometry method must include a comment that the result is for a screening test only.

Any handwritten comments included on issued reports must also be included in the copy of reports retained by the facility.

8 Management system requirements

8.1 General requirements and options

8.1.2 Fulfilment of management system requirements

Certified Quality Management System

A facility seeking accreditation to ISO 15189 may establish a Quality Management System (QMS) (e.g., in accordance with ISO 9001). In such a case, the system may not be assessed in full by NATA subject to all of the following:

- the management system being certified by a certification body accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA). The certification body must be accredited to certify QMS schemes (e.g., to ISO 9001). NATA will request the facility to provide evidence of the certification body's scope of accreditation; and
- copies of the most recent certification audit reports being made available to NATA for review, including confirmation from the certification body of the close out of any non-conformities raised; and
- evidence the QMS satisfies the requirements of ISO 15189, clause 8.1.2; and
- the management system supports and demonstrates the consistent fulfilment of the requirements of ISO 15189 for the activities covered (or proposed to be covered) by the NATA scope of accreditation.

The required extent of assessment will depend on the evidence provided.

Where nonconformities are identified with the management system, these will be reported against the relevant clause (i.e., 8.2 to 8.9).

The facility shall notify NATA within 14 days when a change occurs in its QMS certification status.

Non-certified Quality Management System

NATA will assess the management system in full against the requirements of clauses 8.2 to 8.9 when the facility has adopted a QMS which has not been independently certified by a certification body recognised under the IAF MLA.

8.4 Control of records

8.4.1 Creation of records

It is recognised that a number of staff may be involved in laboratory activities. It is the facility's responsibility to identify the critical step(s) and ensure that the identities of the staff concerned are recorded.

Records must include information specified in the method, other contractual documents or relevant statutory regulations.

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.

8.4.3 Retention of records

Minimum retention times (including raw data) must be in accordance with those specified by NPAAC requirements. Legislative or contractual obligations may prescribe longer retention times.

8.8 Evaluations

8.8.3 Internal audits

The internal audit schedule must cover all the requirements of ISO 15189 ideally within a twelve-month period.

8.9 Management reviews

8.9.1 General

The effectiveness of the quality management system must be reviewed by management at least once per year. It is recognised that facilities have different organisational structures. Accordingly, various items covered by management review may be considered at different times and at different organisational meetings.

Newly established facilities should consider a shorter interval between management reviews until there is sufficient evidence to indicate the quality management system is functioning as required/expected.

Management review processes must be structured in such a way that they include all aspects of the pathology service provided as they relate to patient care, including pre-analytical, analytical, and post-analytical processes across the organisation as a whole.

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

https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards

Standards

AS/NZS 4308	*Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine*
AS/NZS 4760	*Procedures for specimen collection and the detection and quantification of drugs in oral fluid*
ISO 15189	*Medical laboratories - Requirements for quality and competence*

NATA Publications

General Accreditation Criteria	*Equipment assurance, in-house calibration and equipment verification*
General Accreditation Criteria	*Use of the NATA emblem, NATA endorsement and references to accreditation*

Other references

Reporting of pathology specimens outside the laboratory (RCPA, 2024)

Antimicrobial susceptibility testing - EUCAST disk diffusion method (2025)

CLSI M02 Performance Standards for Antimicrobial Disk Susceptibility Tests (Fourteenth edition 2024)

Further Reading

Antibiotic Susceptibility Testing by the CDS Method. A manual for Medical and Veterinary Laboratories 2018. S.M.Bell, J.N. Pham, D.L.Rafferty, J.K.Allerton, P.M.James

A Standardised Framework for the Validation and Verification of Clinical Molecular Genetic Tests, European Journal of Human Genetics, 2010 Dec;18(12):1276-1288

Guidelines for Assuring Quality of Medical Microbiological Culture Media. Australian Society for Microbiology

Guidelines for Assuring Quality of Solid Media used in Australia for the cultivation of Medically important Mycobacteria. Australian Society for Microbiology

National Measurement Act 1960

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

The RCPA Manual, The Royal College of Pathologists of Australasia

Uncertainty of Measurement in Quantitative Medical Testing – A Laboratory Implementation Guide, Clin Biochem Rev. 2004 Nov; 25(4): S1-S24

WHO Laboratory Manual for the Examination and Processing of Human Semen, 6th Edition

Guidance documents covering the implementation of specific accreditation requirements are also available from the ILAC and APAC websites.

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
7.3.1	Updated to include clarification on the manual reading of antimicrobial disc diffusion susceptibilities.
References	Reporting of pathology specimens outside the laboratory document date updated. Additional CLSI and EUCAST references included.