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A Guide to Fulfillment of DAP Comparability Standards at a Regional or Organizational Level

This document from the Diagnostic Accreditation Program (DAP) provides guidance for organizations on fulfilling the 2015 Laboratory Medicine Accreditation Standards.

If you have questions about items in the standards please email them to:
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Introduction

Standards addressing comparability of laboratory results within a single facility in BC have been established for many years. Incorporation of ISO 15189 into the 2015 Laboratory Medicine Accreditation Standards requires health authorities and organizations to ensure comparability of laboratory results across all sites within their jurisdiction. During regional accreditation assessments it became apparent that laboratories were struggling to establish and maintain comparability from site to site. To assist laboratories with the regional requirements for comparability, the DAP held a multidisciplinary meeting with representation from various health authorities and the private laboratory sector to discuss models that will fulfill the criteria addressing regional comparability. Comparability in anatomical pathology was not addressed at that time. The general and discipline-specific information from this meeting was used to create the following guidance on comparability verification for laboratories in British Columbia.

Comparability requirements

There are six criteria used to evaluate the laboratory's verification of the comparability of patient results within the region or organization. They are as follows:

QUA3.1.1	**M**	There are procedures to establish the comparability of procedures, equipment and methods used, and establishing the comparability of results for patient samples. This is applicable to the same or different procedures, equipment, different sites or all of these.
QUA3.1.2	**M**	Comparability encompasses the entire range of clinically relevant values. *Guidance: Freshly obtained patient samples are the preferred comparability material as commercial materials have had their matrices modified in ways that may significantly affect commutability with native clinical samples.*
QUA3.1.3	**M**	Acceptability criteria are defined for comparability of procedures, equipment and methods.
QUA3.1.4	**M**	The laboratory documents, records and acts upon results from comparability. Any identified problems or deficiencies are addressed and records of action are retained.

QUA3.1.5	**M**	The laboratory notifies users of any differences in comparability of results and discusses any implications for clinical practice when examination systems provide different reference intervals for the same measurand and when examination methods are changed.
QUA3.1.6	**M**	Instruments and methods are checked against each other at least twice a year for comparability of results.

Assessment

During the regional assessment, regional personnel from each discipline or area of the laboratory:

- will be asked about the regional process to verify the comparability of results including the frequency of comparability testing and triggers for special cause comparability testing
- will provide and discuss the procedures to verify the comparability of results; the procedures should include the examinations subject to comparability, acceptability criteria, and any procedures to act on problems or deficiencies
- will provide records of the verification of comparability within the region or organization for a minimum of the previous two years; the records must include:
    - all comparability verification performed between specific methods, instruments and sites
    - demonstrate comparability verification at the defined frequency
    - demonstrate comparability through the entire range of clinically relevant values
    - any identified problems and deficiencies and subsequent follow-up

Guidance on examinations that require verification of the comparability of results

The multidisciplinary group identified that the following examinations should be subject to comparability verification. Moving forward, comparability verification will be assessed for the following examinations at both the regional and facility assessments. Organizations must determine which examinations are subject to comparability verification in addition to:

Chemistry

Comparability verification should be performed for almost all examinations. Examinations **not** subject to comparability verification include:

- body fluids
- less frequent special chemistry testing
- trace metals
- urinalysis
- results based on calculations from measured parameters for which comparability is already assessed

Hematology

- complete blood counts/differentials and any reportable results thereof
- reticulocytes
- coagulation testing including: INR, PTT, D-dimer, fibrinogen, thrombin

Examinations **not** subject to comparability verification include:

- Results based on calculations from measured parameters for which comparability is already assessed

Microbiology

- bacteria/yeast identification including automated vs. manual methods
- antimicrobial susceptibility testing including automated vs. manual methods
- primary vs. backup methodology/instruments
- molecular testing
- serology

Transfusion medicine

- ABO/Rh, antibody screening and identification
- crossmatch methods
- direct antiglobulin testing

Further examinations to consider for comparability verification:

- reaction grading
- phenotyping
- antibody titration

Guidance on the range of comparability verification

Ideally, all values throughout the reportable range would be checked during comparability testing, but that is not possible. The laboratory must establish the number and value of points checked during comparability testing. The range of values tested will be specific to individual examinations with a range equivalent to the analytical measurement range or reference interval and include all clinical decision points.

Guidance on suitable samples for comparability verification

The preferred samples for comparability verification are individual patient samples, pooled patient samples, laboratory prepared (spiked) material, proficiency testing material and QC material.

While vendors' summary reports of proficiency testing (PT) cannot be used for comparability testing, PT data can be used if the laboratory develops a mechanism to demonstrate comparability.

Manufacturers' QC material can be used to demonstrate comparability of identical instrumentation and methodology.

Manufacturers' QC material can be used to demonstrate comparability between differing measuring systems if:

- the numeric relationship between the means for QC results from the differing measuring systems is known
- the results for native clinical have been verified to be comparable
- the performance of the measuring systems remains unchanged
- the above remain comparable following lot changes

It may be more practical to perform comparability monitoring using native patient samples than to conduct the validation required for QC results.

Guidance on acceptability criteria

Laboratories must determine the limits of acceptable variability for results produced by different methods and analyzers for the same measurand. Acceptability criteria may need to be defined for each measurand. Evaluation of comparability may be based on published professional recommendations, based on goals set by external bodies or based on laboratory generated data. Individual discipline-specific groups identified the following for consideration when establishing acceptability criteria:

- CLIA total allowable error
- biological variation data
- standard deviation/coefficient of variation
- lot to lot reagent variability
- examination sensitivity issues (molecular vs. manual)
- PT provider guidelines
- clinical requirements
- expert opinion
- statistical methodology

Guidance on the frequency of comparability verification

There is no absolute answer to the question "How often should verification of results comparability be performed?" Although the standards state that comparability verification should be performed at least twice a year, the laboratory should determine the risk for non-comparable results along with cost considerations and operational viability. Initially a laboratory should perform comparability verification more frequently until confidence in comparability is established. Once the actual comparability performance has been established the laboratory can evaluate the risk and reduce comparability testing appropriately. Laboratories should also consider those situations where special cause comparability verification is performed in addition to routinely scheduled comparability verification in instances of major maintenance, software update, clinician inquiry regarding results accuracy or resolution of other problems.

References

For further information consult the following documents:

- College of American Pathologists. All common checklist. Northfield, IL: College of American Pathologists; 2016. 52 p.
- Clinical and Laboratory Standards Institute. Verification of comparability of patient results within one health care system; approved guideline (interim revision). Wayne, PA: Clinical and Laboratory Standards Institute; 2012. 84 p. CLSI document: EP31-A-IR
- International Standards Organization. Medical laboratories – requirements for quality and competence. Geneva, Switzerland: ISO; 2012. 53 p. ISO Standard: 15189:2012