FIVE YEARS OF EXPERIENCE WITH ISO15189 ACCREDITATION IN BELGIAN MOLECULAR DIAGNOSTICS LABORATORIES

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Introduction and Purpose

Since 2007, International Organization for Standardization (ISO) 15189 accreditation has been required for Belgian molecular diagnostic laboratories to be reimbursed for performing diagnostic tests. In response, the MolecularDiagnostics.be working group (MD.be) was founded to discuss the practical implementation of ISO 15189 for accreditation. This resulted in a publication offering practical guidelines to laboratories wanting to achieve ISO 15189 accreditation. The 2012 update of ISO 15189 provided an excellent opportunity to review and evaluate the non-conformities received by MD.be members during past external audits.

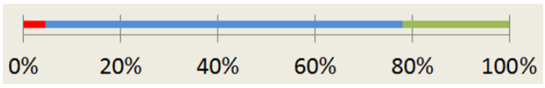
Methods

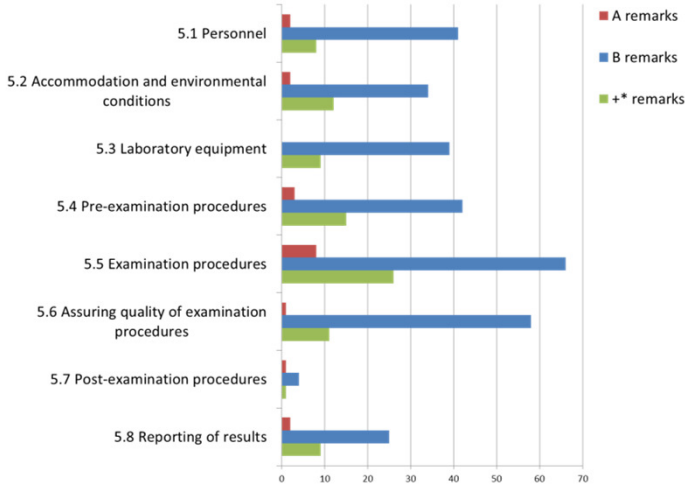
MD.be organized a survey of Belgian molecular laboratories and a gap analysis between ISO 15189:2007 and ISO 15189:2012 was performed. 17 laboratories performing molecular diagnostics in microbiology, hematology or pathology participated in this survey.
Non-conformities were subdivided:

- **A remarks:** major non-conformities immediate action
- **B remarks:** minor non-conformities – resolve within reasonable timeframe
- **+* remarks:** recommendations

Results (1)

421 non-conformities were received in view of the new ISO 15189:2012 requirements all belonging to chapter five of the standard.





§5.1 Personnel

- **Training documents not available**
- **Not enough staff doing technical supervision**
- Continuous training of personnel
- Permanent evaluation
- No backup

§5.2 Accommodation and environmental conditions

- **No good separation of different PCR activities (Contamination Risk)**

Results (2)

- Temperature monitoring
- Access control
- Maintenance

§5.3 Laboratory equipment

- Release equipment after maintenance or repair
- Incomplete equipment records
- Acceptance testing of reagents prior to use
- Use kits according to current version of kit insert

§5.4 Pre-examination procedures

- **Absence or incomplete labguide**
- **Labelling of daughter tubes problematic**
- **Stored samples can be accessed by unauthorized persons**
- Absence of sample collection instructions
- Inaccurate request forms

§5.5 Examination procedures

- **Insufficient validation (mostly in-house tests)**
  - **pre-analytical steps (pathology)**
  - **extraction procedure**
  - **sensitivity**
  - **different matrices**
- Lack of acceptance criteria
- Invalid sample type
- Not enough patient samples tested
- Cut-off: true positive – false positive
- No re-evaluation after change of procedure
- No structured validation plan
- Validation report was not approved

§5.6 Assuring quality of examination procedures

- **No independent positive control**
- QC not at clinically relevant concentration
- Control not similar to patient material
- Regular review of QC data
- Test new QC lot vs. current lot
- Consider retesting patient samples if clinically significant error has occurred
- No inter laboratory comparisons for test
- QC samples not handled in same way as patient material
- No action plan for faulty external QC
- Spreadsheets not validated or secured

§5.7 Post-examination procedures

- **Procedure for technical and medical validation of results**
- No clinical interpretation in report
- Unclear whether analysis is done externally

§5.8 Reporting of results

- **Turnaround time is clinically inappropriate**
- TATs not monitored
- TATs not reviewed
- No action when failing to meet TAT criteria
- Insufficient info on report
- Verification of manually entered results

GAP analysis ISO15189:2012 vs. ISO15189:2007

- **Reporting of results (§5.8)** of ISO 15189:2007 has been split into the requirements: **Reporting of results (§5.8) and Release of results (§5.9)**
- **New paragraph: Laboratory information Management (§5.10):** more emphasis on software validation
- Improved layout, beter ordering and more words

Conclusions

- **Many laboratories received similar audit non-conformities during the last five years.**
- **A gap analysis between ISO 15189:2007 and ISO 15189:2012 revealed some new requirements demanding changes in laboratory procedures.**
- **This study can help molecular diagnostic laboratories prepare for ISO 15189:2012 accreditation.**