Five years of experience with ISO15189 accreditation in Belgian molecular diagnostics laboratories

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on behalf of MolecularDiagnostics.be

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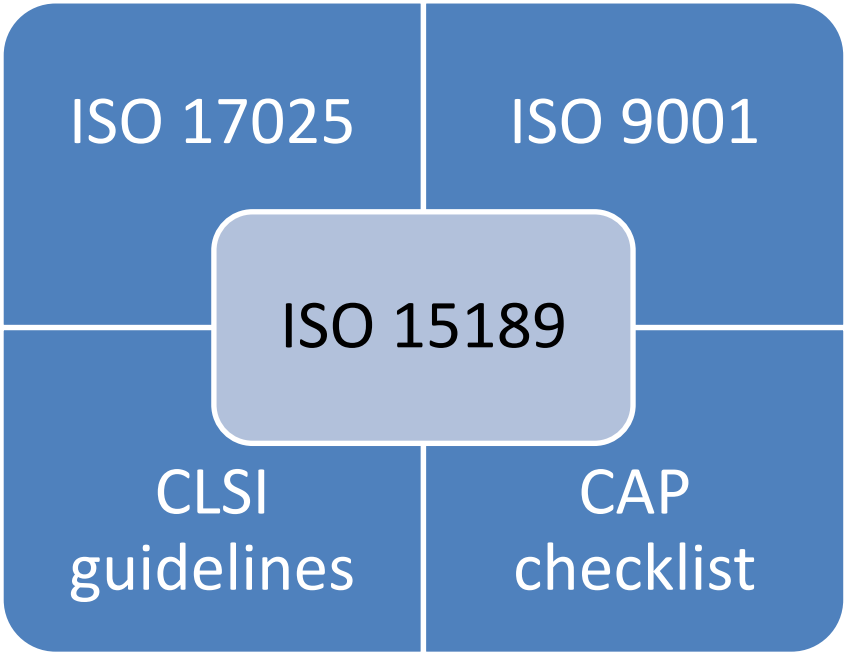
ISO 15189

Medical laboratories — Particular requirements for quality and competence

International **S**tandard **O**rganization

1st version ISO15189: 2003

Latest version ISO15189: 2012



ISO 17025 General requirements for the competence of testing and calibration laboratories
ISO 9001 quality management system
Clinical and Laboratory Standards Institute (CLSI)
College of American Pathologists (CAP)

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Situation Belgium

- Royal Decrees published in 2007 (hemato-oncology) and 2008 (microbiology):
  ISO15189 obligation for **molecular diagnostics**

- Working group **MolecularDiagnostics.be (MD.be)** founded
  to discuss the practical implementation of ISO 15189 accreditation

REFLECTIONS AND PROPOSALS TO ASSURE QUALITY IN MOLECULAR DIAGNOSTICS

Raymaekers M[1], Bakkus M[2], Boone E[3], de Rijke B[4], El Housni H[5], Descheemaeker P[6], De Schouwer P[7], Franke S[8], Hillen F[1], Nollet F[6], Soetens O[9], Vankeerberghen A[10], on behalf of the MolecularDiagnostics.be working group

Acta Clinica Belgica, 2011; 66-1

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- Groups clinical and molecular biologists working in
  molecular diagnostics in microbiology, hematology-oncology, and pathology.

  - Discussion forum
  - Test directory on website
  - Ring controls
  - Training days
  - Study days (NGS, Risk Assessment, QC in MD, ISO15189,…)
  - Biannual Scientific Meeting

6th Scientific Meeting MolecularDiagnostics.be
Antwerp – Belgium
October 18th 2016

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Current study

- New version of ISO15189 (2012)

- Collect all **non-conformities** of Technical Requirements section of ISO15189
    - focused on **Molecular Diagnostics** (microbiology, hematology & pathology)
    - period **2008-2013** (ISO15189:2007)
    - 17 Belgian laboratories participated
    - >400 non-conformities reported

Chapter 5	5.1 Personnel
	5.2 Accommodation and environmental conditions
	5.3 Laboratory equipment
	5.4 Pre-examination procedures
	5.5 Examination procedures
	5.6 Assuring quality of examination procedures
	5.7 Post-examination procedures
	5.8 Reporting of results

- **GAP analysis** new version of ISO15189:2007 vs. ISO15189:2012

- Based on these data a paper with **recommendations** is currently being written

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ISO15189 audits in Belgium

- Accreditation body = **BELAC**

- Performed by peers

- Non conformities are subdivided

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

- **421 remarks** received by 17 participating laboratories

19	A remarks	4,5%
309	B remarks	73,4%
93	+* remarks	22,1%

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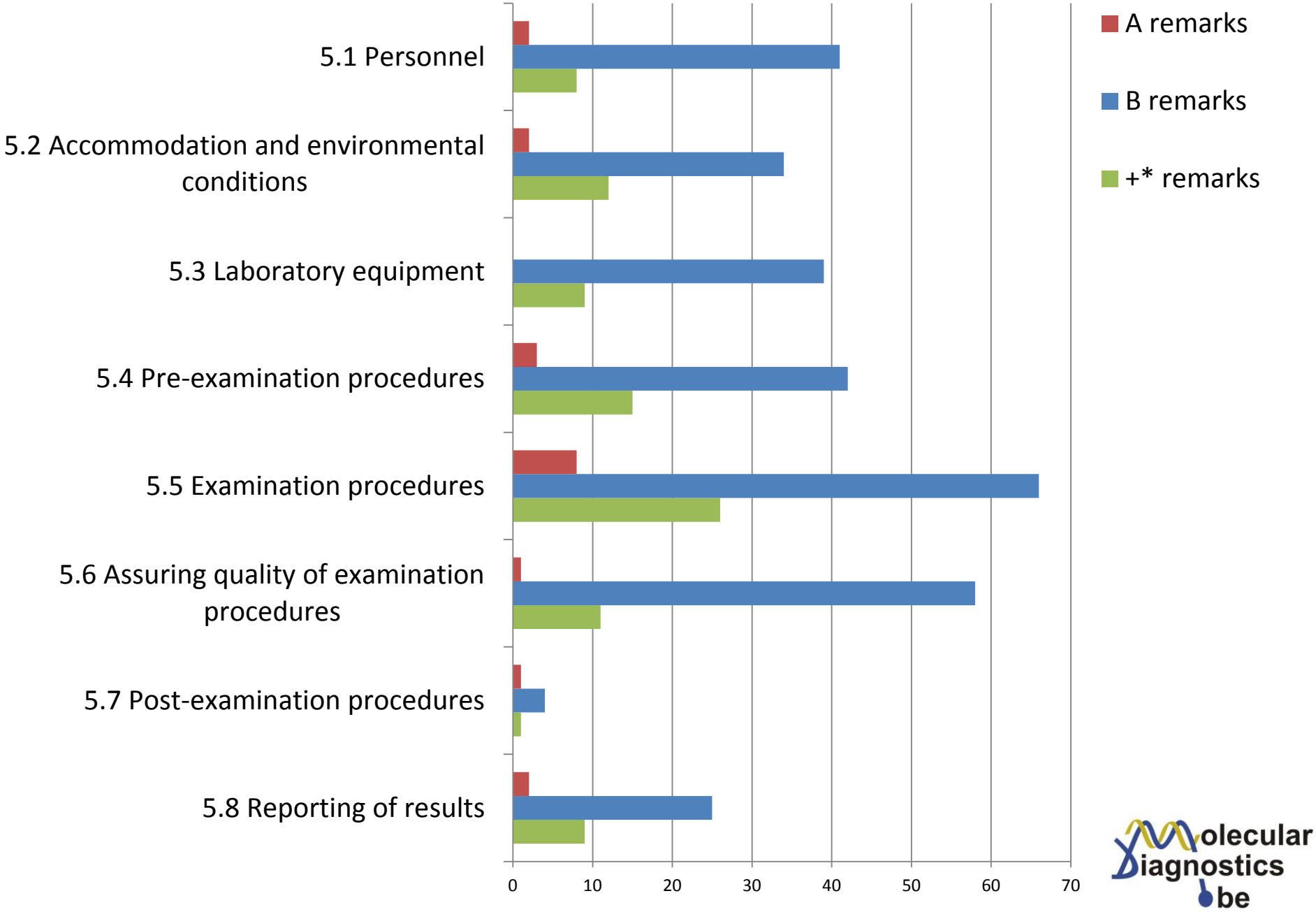
ISO15189 non-conformities (n=421)



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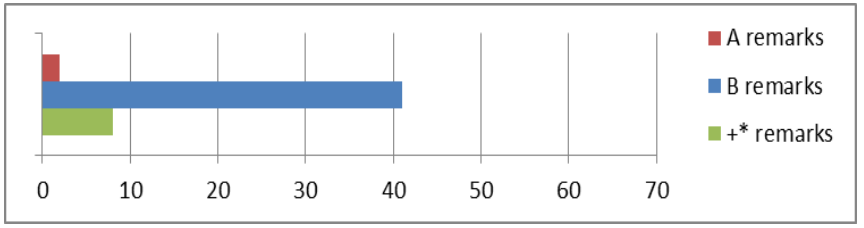
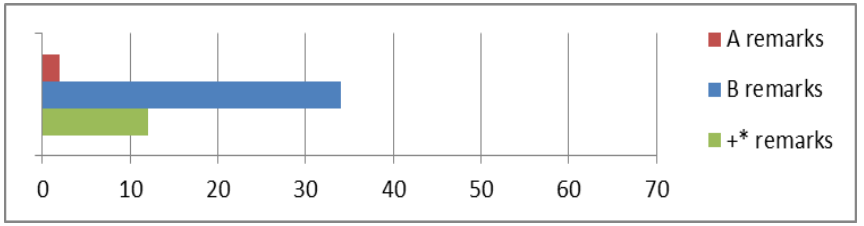
5.1 Personnel

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



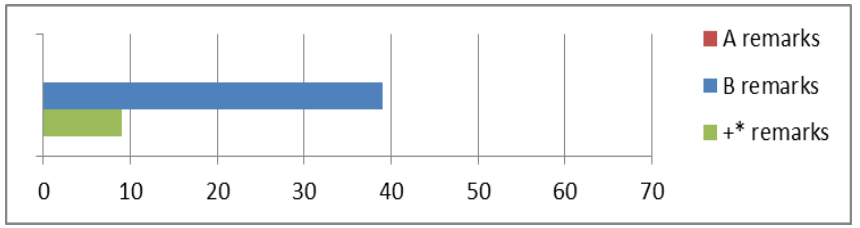
5.2 Accommodation and environmental conditions

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



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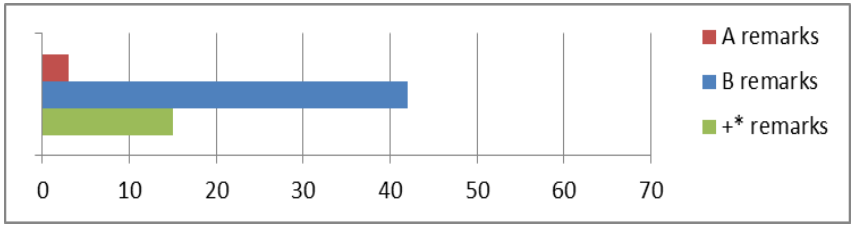
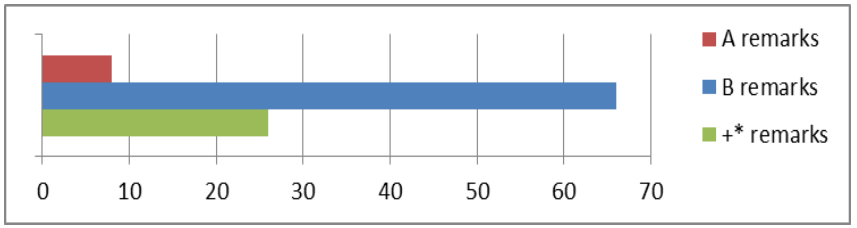
5.4 Pre-examination procedures



- **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

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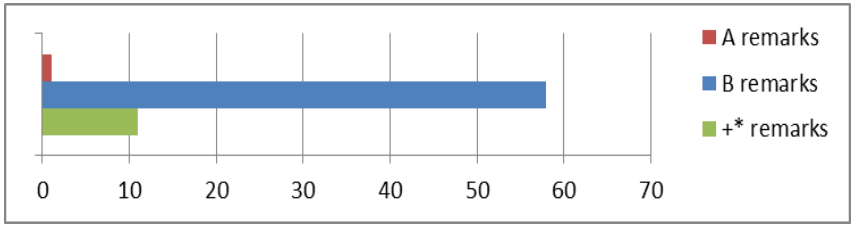
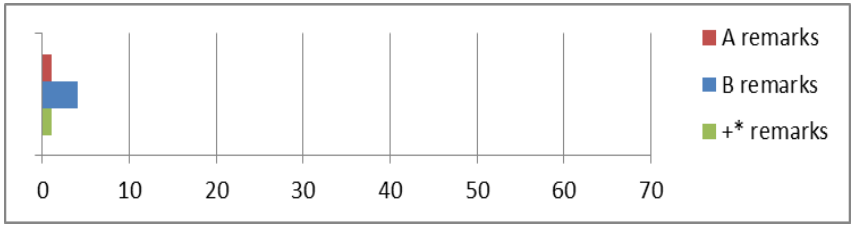
5.6 Assuring quality of examination procedures



- **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

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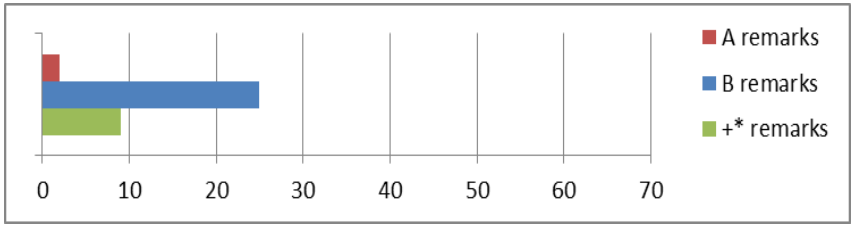
5.8 Reporting of results

- **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



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GAP analysis ISO15189:2012 vs. ISO15189:2007

- Paragraph **Reporting of results (5.8)** of ISO 15189:2007 has been split into the requirements:
  - **Reporting of results (5.8)**
  - **Release of results (5.9)**

- New paragraph: **Laboratory information Management (5.10)**

  (previously informative annex)

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5.9 Release of results
5.10 Laboratory information management

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GAP analysis ISO15189:2012 vs. ISO15189:2007

- More words:
  - Section 4 Management Requirements:
    - ISO15189:2007 - 3,700 words
    - ISO15189:2012 - 5,200 words
  - Section 5 Technical Requirements:
    - ISO15189:2007 - 5,600 words
    - ISO15189:2012 - 7,900 words
- Improved layout, better ordering
- More emphasis on software validation
- ISO15189 still offers freedom on how to achieve goals
- ‘ common sense’

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Acknowledgements

Thanks to all paricipating laboratories:

AZ Damiaan, Oostende
AZ Middelares, Gent
Clinique St-Pierre, Ottignies
GZA, Wilrijk
Imelda, Bonheiden
ITG, Antwerpen
Jessa Ziekenhuis, Hasselt
OLV, Aalst
St-Jan, Brugge
St-Lucas, Gent
UA, Wilrijk
UMC Sint-Pieter, Brussel
UZ, Brussel
UZ, Gent
UZ, Leuven
ZNA, Antwerpen
ZOL, Genk

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