Quality Assurance for Laboratories

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Quality Assurance and Quality Performance in medical laboratories

Quality of care and patient safety
Quality of care and laboratory testing

Expectations:

The physician / patient / family expects
• a correct test result
• delivered within a reasonable time
• a correct interpretation that allows clinical decision-making

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Angelina Jolie
“I had double mastectomy because of high breast cancer risk”
Quality Assurance and Quality Performance in diagnostic laboratories

Quality = “the degree to which a set of inherent characteristics fulfils requirements”. (ISO definition)

Example: Angelina Jolie has a family history of breast cancer, and requests to be tested for being carrier of a genetic mutation.

requirement :
• the availability of a carrier test
‘inherent characteristics’:
• appropriate analytical testing method
• sample
• turn-around-time (TAT)
• proper interpretation
Predictive biomarker testing

→ better clinical management
→ more effective treatment of the patients

New molecular and diagnostic technologies can be used to match select groups of patients with treatments that may give them the best results

http://www.pfizer.ie/personalized_med.cfm
State of the art: danger for patient safety

- False-positive results
- False-negative results
- Denial of treatment
- Superfluous use of high-priced therapeutic agents
- Unnecessary side effects

E. Bellon et al, Oncologist (2011) 16:467-78
Quality of care and laboratory testing

Tools to ensure quality in the laboratory

- Quality Management System
- Accreditation
- External Quality Assessment
Medical laboratories

- Laboratory of Clinical Biology
- Laboratory of Pathological Anatomy
- Laboratory associated with a Human Genetic Center
Laboratory of Clinical Biology

- Recognition Decree (KB December 3, 1999)
- Practice guideline for the setup of a quality manual in recognized clinical laboratories active within the RIZIV framework ('Praktijkrichtlijn voor het opzetten van een kwaliteitshandboek in erkende klinische laboratoria werkzaam binnen het kader van het RIZIV')
- Mandatory participation in external quality assessment (EQA) programs organized by the Institute of Public Health
- Implementation of a quality management system
- No requirement for accreditation except for some reference laboratories and tests
Laboratory of Clinical Biology

- Requirement for **BELAC accreditation** imposed by the RIZIV

  ✓ **AIDS** Reference Laboratories (KB October 6, 1996)

  ✓ Reference Laboratory for the diagnosis and the treatment of **tropical and infectious diseases** (KB January 20, 1998)

  ✓ National Reference Centers for **human microbiology** (KB February 9, 2011)
Laboratory of Pathological Anatomy

• Recognition Decree (KB December 5, 2011)
• Practice guideline for the setup of a quality system in recognized laboratories for pathological anatomy that are active in the framework of the Recognition Decree (‘Praktijkrichtlijn voor het opzetten van een kwaliteitssysteem in de erkende laboratoria voor pathologische anatomie werkzaam binnen het kader van het Erkenningsbesluit’)

• Mandatory participation in **external quality assessment** (EQA) programs
• Implementation of a **quality management system**
• No requirement for accreditation except for some tests
Laboratory of Clinical Biology / Pathological Anatomy

• Requirement for **BELAC accreditation** imposed by RIZIV / INAMI

• To perform some specific tests
  ✓ Molecular Oncology (art. 33bis)
  ✓ Human Papilloma Virus (HPV) testing (art. 24bis & art. 32)
Laboratories related to a Center of Human Genetics

• Recognition Decree (KB November 28, 2012)

• ISO 15189 Medical laboratories – Requirements for quality and competence

• Art. 33bis – Molecular Oncology

• Implementation of a quality management system and a BELAC accreditation

• Mandatory participation in external quality assessment (EQA) programs
Elements of a quality management system

• Qualified personnel – continuous education
• Standard operating procedures (SOPs) & Quality Manual
• Document control
• Reagents & equipment (maintenance and calibration)
• Accommodation
• Non conformities, corrective and preventive actions
• Internal audit, Management review
• Validation of tests, including participation to EQA

Key messages:
traceability & demonstrate competence
To improve patient safety and quality of care we need to work together.
Elements of a quality management system

Qualified personnel

*How can diagnostic industry help?*

- Offer documented training of new technology / test / instruments
- Award a training certificate (which includes information on training topic(s) / name of trainee(s) / date of training)
- Offer training material for train-the-trainer
- Provide educational material (e.g., movie on website, ..)
- ...
Elements of a quality management system

Document control

How can diagnostic industry help?

Identification of documents

e.g. instruction manuals should include

- a unique identifier,
- date of the current edition,
- edition number,
- total number of pages.
Elements of a quality management system

Document control (2)

*How can diagnostic industry help?*

**Communication of document changes**

- a new edition of a document (higher number)
- information on what was changed? What is the influence on the test (if any)?
- Information on the validation / verification experiments
- In-time communication to customers
Elements of a quality management system

Reagents and equipments

How can diagnostic industry help?

Inserts of the reagents and kits

- Acceptable conditions for transport and storage
- Expiry date(s) (preferable all the same for one kit)
- Labelling of expiry date on each component of the kit
- MSDS / safety information
Elements of a quality management system

Reagents and equipments (2)

*How can diagnostic industry help?*

**Inserts of the reagents and kits**

- Clear description of the protocol and instruction for use
- Intended purpose of the kit
- Information on expected performance and validation (see further)
Elements of a quality management system

Reagents and equipments (3)

*How can diagnostic industry help?*

**Manual of equipment** (document)

- Operating instructions for correct use
- Maintenance and calibration requirements and related technical specifications and criteria
Elements of a quality management system

Reagents and equipments (4)

*How can diagnostic industry help?*

**Installation of equipment**

- Documented installation report which evidences that equipment works conform the technical specification. A ‘declaration of conformity and the verification of the functionality of the instrument’ is provided.
- Tracebility of calibration to IS (metrological traceability)
Elements of a quality management system

Reagents and equipments (5)

How can diagnostic industry help?

**Intervention / maintenance / calibration of equipment**

- Tracebility of activities! (date, person, what is done, ...)
- Report should contain a list of what exactly is done and the results of intervention / maintenance / calibration
- This list is not a check box only – it includes measurement values and criteria for correct performing
  - Temperature verified
Elements of a quality management system

Validation

*How can diagnostic industry help?*

**CE-IVD labeled kits**
- Clear description of the expected performance characteristics:
  - Sensitivity
  - Specificity
  - Accuracy
  - Repeatability
  - Reproducibility
  - Limits of detection
  - Measurement range
  - ...
Elements of a quality management system

Validation (2)

*How can diagnostic industry help?*

**CE-IVD labeled kits**

- Clear description of the instruments used for validation,
- Matrix of samples that were included in the validation process,
- Limitations / known interference of the kit,
- Reference values,
- Background biographic references and/or reference to manuscript of validation study
Elements of a quality management system

Validation (3)

*How can diagnostic industry help?*

**Software**

- Version number of the software used during the validation of instrument / kit
- Upgrade of software
  - Communication before upgrade
  - Description of what is changed and impact on test results / instrument
Elements of a quality management system

Accommodation

*How can diagnostic industry help?*

- Inform and respect the internal rules of the laboratory related to
  - Identification (badge),
  - Entrance of the laboratory,
  - Personnel protection material (lab coat, ...)
- ...
Elements of a quality management system

Non conformities, corrective and preventive actions

How can diagnostic industry help?

- Requirement from ISO 15189 and different KBs
- Requirement from ISO 9001, ISO 13485 and IVD directive

Work together
Elements of a quality management system

Internal and external quality controls

How can diagnostic industry help?

Internal control sample(s)
- Include / provide internal control material
- If internal controls are integrated in the software, it should be described and evidenced that no additional control is needed during installation of instrument / kit

External Quality Assessment program
- If needed discussed in advance with EQA providers
Elements of a quality management system

- Qualified personnel – continuous education
- Standard operating procedures (SOPs) & Quality Manual
- Document control
- Reagents & equipment (maintenance and calibration)
- Accommodation
- Non conformities, corrective and preventive actions
- Internal audit, Management review
- Validation of tests, including participation to EQA

Key messages:
- traceability & demonstrate competence
Added value

- Easier implementation of new technology / kits
- Work load related to requests for additional information will decrease because all information is already available
- Less non-conformities during external audits
- Positive performance evaluation of suppliers
Patient Safety starts with all of us