Quality Assurance

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A diagnostic test for an infectious agent can be used to demonstrate the presence or absence of infection (and persistence), or to detect evidence of a previous infection (for example, the presence of antibodies).

Valid laboratory results are essential for diagnosis, surveillance and trade.
PRACTICAL FEATURES OF DIAGNOSTIC METHODS

- To be useful, diagnostic methods must be:
  - accurate, simple and affordable for the population for which they are intended.
  - They must also provide a result in time to institute effective control measures, particularly treatment.
  - For some infections, early diagnosis and treatment can have an important role in preventing the development of long-term complications or in interrupting transmission of the infectious agent. (decision-making for the national authority)
A FACT:

- The recent and rapid advances in molecular tools, *(High throughput sequencing)* has changed the way to screen for new organisms in environmental samples.

- As a result, novel organisms can be achieved *de novo*, that is to say, without prior knowledge of their genetic makeup.

- This provides an invaluable tool to understand variability in pathogens.

- Notwithstanding, diagnosticians should continue to focus on the primary aim of infectious diagnostic procedures:
  - Determination of the primary cause of the clinical signs in an animal and, if occurs, the cause of a mortality event.

In order to achieve this, laboratories should always be exposed to Quality Assurance Excercises *(QAE)*
Quality Assurance Exercises (QAE)
Quality Assurance (QA) is a way of preventing mistakes or defects in manufactured products and avoiding problems when delivering solutions or services to customers.

Quality Assurance refers to administrative and procedural activities implemented in a quality system so that requirements and goals for a product, service or activity will be fulfilled.

It is the systematic measurement, comparison with a standard, monitoring of processes and an associated feedback loop that confers error prevention. This can be contrasted with quality control, which is focused on process output.

Quality Assurance is any systematic process of checking to see whether a product or service being developed is meeting specified requirements.
QUALITY ASSURANCE VS. QUALITY CONTROL

The terms “quality assurance” and “quality control” are often used interchangeably to refer to ways of ensuring the quality of a service or product.

The terms, however, have different meanings.

**Assurance:** The act of giving confidence, the state of being certain or the act of making certain.

**Quality Assurance:** The planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled.

**Control:** An evaluation to indicate needed corrective responses; the act of guiding a process in which variability is attributable to a constant system of chance causes.

**Quality Control:** The observation over techniques and activities used to fulfill requirements for quality.
VALIDATION AND ASSESSMENT OF QUALITY ASSURANCE (AQA/QA)

Meaning, differences, and relationship between the two terms.

**VALIDATING A METHOD** is investigating whether the analytical purpose of the method is achieved, which is obtaining analytical results with an acceptable uncertainty level.

- **ANALYTICAL METHOD VALIDATION:** first level of QA in a laboratory.
- **AQA:** is the complete set of measures a laboratory must undertake to ensure that it can always achieve high-quality data.

Besides validation/standardized methods, these measures are:

- **Effective IQC (Internal Quality Control) procedures** (use of reference materials (RMs)).
- **Participation in PT (Proficiency Testing) schemes**
- **Accreditation to an international standard, (ISO/IEC 17025)**
* Formal recognition that a testing laboratory is competent to carry out the tests identified within the scope of accreditation

* Accreditation ensures that:

**Testing labs are:**
- Competent and
- Credible to specific tests.

**Results are:**
- Accurate,
- Reproducible,
- Traceable.

LIB-ISO 17025
The ultimate aim is to ensure that the quality of laboratory diagnostic methodology and strategy at the participants' laboratories is adequate and conforms to ‘best practice’.

Expectations from a QA Process
REFERENCES


- DESIGN AND EVALUATION OF A UNIQUE RT-qPCR ASSAY FOR DIAGNOSTIC QUALITY ASSESSMENT THAT IS APPLICABLE TO PATHOGEN DETECTION IN THREE SPECIES OF SALMONID FISH. Sepulveda et al., BMC Veterinary Research, 9:183. 2013.
Interesting References to be:

◆ **Diagnostic Quality Assurance Conference.**
  Sheraton Pentagon City Hotel- Arlington, USA - 28-29 Jul 2014

◆ **2nd Rapid Methods to Assess Quality & Stability of Biologics. Improving Prediction and Screening.**
Thank you.....

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