Department: Quality of Laboratories

VETERINARY PROFICIENCY TESTING BY INTERLABORATORY COMPARISON ORGANIZED BY SCIENSANO: MANUAL FOR THE PARTICIPANT

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1 INTRODUCTION

Laboratories that are approved by the Belgian Federal Agency for the Safety of the Food Chain (FASFC) to perform diagnostic tests within the framework of the official animal disease surveillance and monitoring programs must participate to the veterinary proficiency tests organized by Sciensano through a collaboration between the department “Quality of laboratories” and the Scientific Directorate “Infectious Diseases in Animals” (Royal Decree of 15 April 2005). Other laboratories can participate to the proficiency tests organized by Sciensano after agreement and signature of a contract (registration form).

Administrative coordinates for the proficiency tests:
Sciensano
Quality of laboratories
Juliette Wytsmanstraat 14
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The coordinator of the proficiency tests (Department Quality of laboratories) has the final responsibility for all aspects concerning the proficiency tests. He/she is assisted by an advisory committee composed of:

- the coordinator of veterinary diagnosis,
- the technical manager(s) of the reference laboratories of the Scientific Directorate Infectious Diseases in Animals of Sciensano related with the specific proficiency tests.

This advisory committee is consulted for all issues concerning the proficiency tests. If necessary, the coordinator may be assisted by other experts as required.

2 AIM

The primary objective of the veterinary proficiency tests organized by Sciensano (organization according to ISO 17043) is to determine the performances of individual laboratories for specific tests or measurements and to monitor the continuing performances of laboratories by interlaboratory comparisons. Laboratories consistently obtaining reliable results during proficiency tests are able to demonstrate the reliability of their results obtained in daily routine, which is of major importance for laboratory customers. As a secondary objective, the proficiency tests will be used to compare and evaluate the different methods/kits/protocols used by the participating laboratories. Based on this information, laboratories can decide to change or standardize their methods/kits/protocols.

The veterinary proficiency tests organized by Sciensano foresee a split-level (different levels of “the measurand”) and a split-sample (different aliquots of the same sample) design. Consequently, this proficiency testing scheme allows the assessment of the accuracy (comparing results with the assigned value) and the precision (variability) at different levels.

3 PROCESS

3.1 Collection, status, selection and homogeneity of the samples

3.1.1 COLLECTION OF THE SAMPLES

Samples for the veterinary proficiency tests are collected by the concerned reference laboratory of the Scientific Directorate Infectious Diseases in Animals of Sciensano.

3.1.2 STATUS OF THE SAMPLES

Different types of veterinary proficiency testing schemes exist depending on the nature of the test item (sample), the method in use and the number of participating laboratories. Most types of veterinary proficiency testing schemes possess the common feature of comparing results obtained by one laboratory (controlling, coordinating or reference laboratory) with those obtained by other participating laboratories (=accuracy).
In the veterinary proficiency tests organized by Sciensano, a (qualitative) value will be assigned to each sample based on the historical background information and all relevant test results provided by the concerned reference laboratory (=the assigned value or status of the sample).

3.1.3 SELECTION OF THE SAMPLES

The veterinary proficiency tests organized by Sciensano foresee a split-level (different levels of "the measurand") and a split-sample (different aliquots of the same sample) design, allowing to show or to estimate the laboratory accuracy and/or precision at different levels. Furthermore, samples can be included that are close to the cut-off level and use different acceptation criteria for these samples in order to gather information about the sensitivity of the used assays and/or participating laboratories.

3.1.4 HOMOGENEITY OF THE SAMPLES

Criteria for suitable homogeneity are based on the qualitative results obtained by repetitive testing of the samples. To ensure that every participant receives comparable proficiency test items, a homogeneity check will be performed before the start of the proficiency test on ten aliquots of each sample. Hereby, the same qualitative result should be obtained for all ten aliquots of the same sample. In addition, when also a quantitative result is required to evaluate a laboratory's performance during a proficiency test, criteria for homogeneity will be applied.

Exceptions concerning the determination of sample homogeneity:

- Samples with limited shelf life: the homogeneity check is performed during the proficiency test and not before the start of the proficiency test.
- The proficiency tests for the identification of genotypes associated with scrapie and the detection of antigens associated with transmissible spongiform encephalopathies (e.g. BSE): due to limited amounts of material, no homogeneity check is performed; the samples are tested at least once before and once after the proficiency test.

3.2 Transport of the samples

Before the samples are sent to the participating laboratories, they are identified with a unique code according to instructions specific to each proficiency test and then randomized for each participating laboratory.

Transport of the samples occurs by national courier (Sciensano) for participating laboratories located in Belgium and Luxembourg, and by international courier (e.g., DHL, World Courier, FedEx) for participating laboratories located in other countries.

When transport occurs by national courier, the samples are accompanied by a delivery order and a document containing specific instructions for the proficiency test, including:

- type of proficiency test,
- type (matrix) of sent samples,
- number of sent samples,
- storage method of the samples,
- relevant instructions (SOPs),
- deadline to perform the analysis,
- data to be sent and to whom,
- deadline to submit the results to the department Quality of laboratories of Sciensano.

When transport occurs by international courier, the participating laboratories will receive a copy of the document containing specific instructions for the proficiency test by e-mail at the moment of sending out the samples. These participating laboratories have to inform the coordinator of the proficiency tests by e-mail (EQA.toolkit@sciensano.be) when the proficiency test samples have been received, hereby mentioning whether the samples have been received in good conditions (e.g. still frozen, intact vials). At the moment of sending out the samples, each participating laboratory will receive by e-mail the notification of the samples sending, an answer form and the instruction to introduce the results online.

3.3 Execution of the proficiency test

The totality of a proficiency test must be carried out according to the instruction(s) into force and by a qualified analyst who routinely performs this analysis. If participating laboratories encounter problems during the proficiency test with performing the assays for one or more samples, a motivated request for new proficiency test samples can be sent by e-mail to the coordinator of the proficiency tests (e-mail: EQA.toolkit@sciensano.be).

3.4 Reporting the results

The online submitting of the results via the Toolkit (https://eqatoolkit.sciensano.be) before a defined deadline is recommended, but a blank answer form is also provided to the participants in case of problems with the online Toolkit system. In case this blank answer form is used to return the results, it should be submitted by e-mail to EQA.toolkit@sciensano.be.

3.5 Stability of the samples

In order to check the stability of each sample throughout the course of the proficiency test, a post-verification analysis will be performed by the concerned reference laboratory of the Scientific Directorate Infectious Diseases in Animals of Sciensano on at least one aliquot of each sample unless the concerned reference laboratory has provided evidence, on the basis of published or observed and validated data, that the samples are stable over a long period.
During this post-verification analysis, which is performed after the proficiency test results have been received from all participating laboratories or when the deadline for analysis of the samples has been exceeded, all samples should have the same qualitative result as before the start of the proficiency test. In addition, when also a quantitative result is required to evaluate a laboratory's performance during a proficiency test, criteria for stability as described in Annex B of ISO 13528 will be applied.

4 (STATISTICAL) DATA ANALYSIS

Qualitative data analysis is performed in order to determine the level of agreement between the (qualitative) results obtained by the participating laboratories and the status of the samples determined as described in 3.1.2. The minimal required criteria for the qualification of a participating laboratory are described in Table 1.

Table 1. The minimal required criteria for the qualification of a laboratory participating to the proficiency tests organized by the Scientific Directorate Infectious Diseases in Animals of Sciensano.

Test	Criteria for qualification
SAW-EDTA	Assigned quantitative value of the sample ± 1 titre
ELISA: AUJgB, IBRgB	Qualitative result (positive, negative, doubtful): ≥ 95% of agreement between the results of the participating laboratory and the qualitative value (status) of the samples determined as described in 3.1.2
Bacteriology *Salmonella* (isolation)	Strong positive samples: no mistakes allowed (100% of agreement); Negative samples: 1 mistake allowed; Weak positive samples: 1 mistake allowed
Tests with only five samples	Qualitative result (positive, negative, doubtful): 100% of agreement between the results of the participating laboratory and the qualitative value (status) of the samples determined as described in 3.1.2
Other	Qualitative result (positive, negative, doubtful; genotype): ≥ 90% of agreement between the results of the participating laboratory and the qualitative value (status) of the samples determined as described in 3.1.2

For proficiency tests where besides qualitative data also quantitative data (e.g. optical density) are available, the report can be accompanied by an annex containing a quantitative data analysis of the results (box plots). This quantitative data analysis is performed in order to communicate and discuss (educational comments) the quantitative results, which can be useful for the participating laboratories in order to evaluate their performance and/or to standardize their different diagnostic tests.

If during data management and/or statistical data analysis discrepancies (transcription errors such as discordance between quantitative and qualitative results) are detected, the coordinator of the proficiency tests will contact the concerned participating laboratory to verify the cause of these discrepancies.

5 REPORTS

5.1 Definitive individual report

Within four weeks after the deadline for submitting the results, a definitive individual with the expected results is provided to the participants via e-mail. This report contains information required to allow the participant to evaluate their proficiency.

5.2 Global report

Within sixteen weeks after the deadline for submitting the results, an English written report will be prepared following ISO17043. The report will be available online on our webpage, the participants will be informed via e-mail. If the deadline for the report will be exceeded, an e-mail will be sent to the participating laboratories. If it is necessary to amend a report, a new version will be sent to the participants and the FASFC clearly announcing that the preceding report is cancelled. The corrections (changes) made in the report will be indicated in the new version. The report cannot be partially reproduced or used for commercial or other purposes without the written permission of the coordinator of the proficiency tests of Sciensano.

5.3 FASFC report

An FASFC report will be produced for each FAFSC certificated laboratory indicating their global proficiency following the defined criteria (Table 1).

5.4 Annual global report

A global annual report will be produced to summarize the main information about the organised proficiency tests during the year (parameters, schedule, number of participants, global proficiency,…).

6 COMPLAINTS

Complaints concerning the proficiency tests schedule or the contents of the reports must be addressed to the coordinator of the proficiency tests (e-mail: EQA.toolkit@sciensano.be). The decision to amend a report or to cancel a proficiency test falls within the competence of the coordinator of the proficiency tests in agreement with the other members of the advisory committee.

7 EVALUATION

Once a year, all participating laboratories are invited to a meeting organized by the proficiency test provider (communication group proficiency tests) in order to present and discuss (i) the results of the proficiency tests organized during the last year, and (ii) the planning and set-up for the next round of proficiency tests. For the proficiency test provider, this meeting is used as feedback meeting and may result in adaptations of the procedure in use (corrective and preventive actions to improve quality according to ISO 17025 & ISO 17043).

For proficiency tests organized by one of the European or international reference laboratories of the Scientific Directorate Infectious Diseases in Animals of Sciensano the evaluation will be carried out according to the rules set up by the competent organization.

Ynse Van de Maele
Coordinator of the veterinary proficiency tests