

How to investigate poor performance in proficiency testing

Introduction

A laboratory will occasionally have a poor performance in a PT scheme. When this occurs, the laboratory should acknowledge it, carry out an investigation and document a review of possible causes, even if it decides not to take any specific action. The purpose of this leaflet is to advise laboratories on how to best address such events. A good management of the poor performance in a PT can save you time and money.

Evaluation of poor performance

Every unsatisfactory performance score indicates a problem which needs to be investigated. In addition the laboratory should set its own criteria for launching an investigation with regards to other indicators of possible poor performance, such as questionable performance scores or observed trends.

Root cause investigation

The depth of the investigation will depend on several factors, such as the importance of the analysis, the frequency of unsatisfactory results and evidence of trends.

The laboratory should check whether the PT report gives an explanation for the unsatisfactory performance. If no reason is provided, a stepwise approach is preferable to maximize the chances of determining the root cause of the problem. This approach is described in **Annex B of the Eurachem Guide** [1].

The investigation should consist of the following steps and involve the personnel that performed the analysis and where appropriate, also involve the laboratory management:

1. Analyse the raw data, internal quality control data, any trend from previous PT rounds and the overall performance of the participants in that round;
2. After investigation is complete, make a plan for corrective action and consider implications for previous test results;
3. Execute and record the corrective action(s);
4. Check whether the corrective action(s) was effective.

Causes for poor performance

The causes of poor performance can be grouped into three categories:

1. Clerical errors are not directly linked to the laboratory's technical competence, but can underline that the laboratory may have a potential problem when reporting results to its customers. Clerical errors can include transcription errors, mislabelling, incorrect units and decimal point errors. Identifying them is an important first step of an investigation. If such errors are a regular cause of poor performance, the investigation should focus on the related aspects of the quality management system.
2. Technical problems can occur at any step of the analytical procedure. If the investigation does not enable the laboratory to identify the root cause, it may be necessary to review the method validation.
3. Problems related to the PT scheme. Poor performance could also be due to the PT scheme not being entirely appropriate. The Eurachem Guide [1] provides information on selecting an appropriate PT scheme. In other cases, a problem may have occurred with the PT items. The laboratory is encouraged to discuss its findings with the PT provider.

The "Fishbone diagram" or "5 Whys" are useful tools to investigate the root cause of a problem.

Annex B - Investigating unsatisfactory or questionable results reported in a PT

Technical investigation

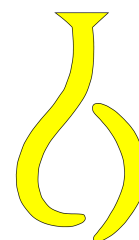
- Was the PT item received in a satisfactory condition?
- Was the PT item equivalent to a routine sample?
- ...

Clerical investigation

- Was there an error in recording the results from the instrument?
- Was there an error in reporting the results to the PT provider?
- Was the wrong units used for reporting the results to the PT provider?
- ...

Technical investigation

- Was the staff properly trained?
- Were the PT items stored and handled appropriately?
- Were the PT items preparation instructions followed?
- Was there a problem with the equipment?
- Was there a problem with the reagents?
- Was there a problem with the measurement performance?
- Was there a problem with the QC samples?
- Was there any issue with the environmental conditions?

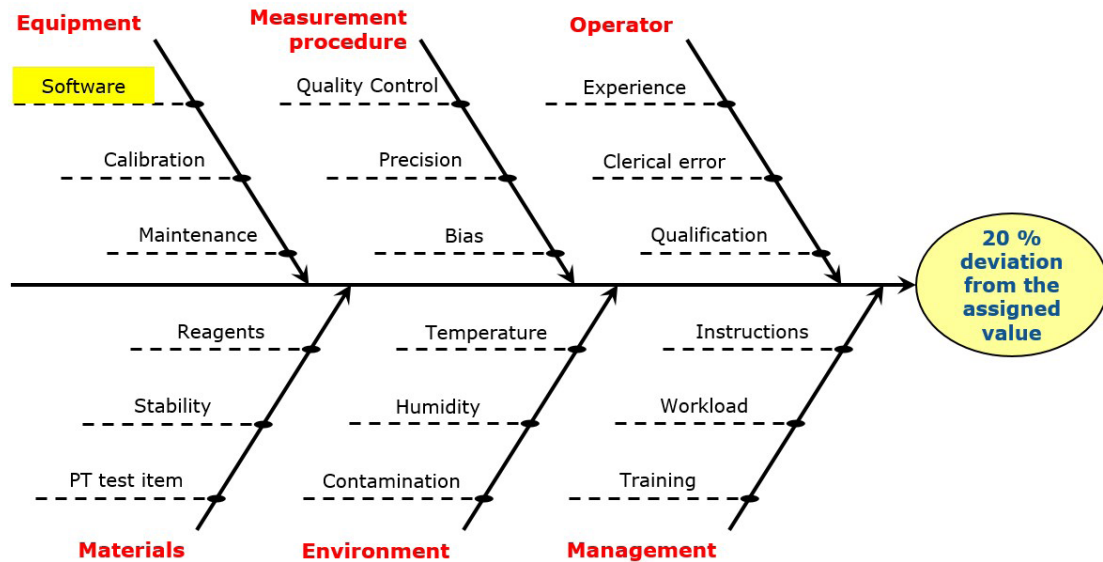


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Case studies

Example 1: A medical laboratory has provided results in a PT scheme for tumor markers in serum with a 20 % deviation from the assigned value, although the daily internal controls performed well. The laboratory investigates the process and discovers the mistake was due to an incorrect unit conversion factor being introduced for PT results when the IT system was last updated. Since patient results are reported in a different unit than the one used by the PT provider no patient results were affected.



Example 2: A laboratory performing food and feed analyses obtained poor performance scores on *Listeria monocytogenes* enumeration, because the number of microorganisms found was underestimated. Laboratory investigations showed an issue in incubation time and temperature applied by the analyst. The laboratory found that the analyst used an out-of-date procedure.

1. **Poor growth** of *Listeria monocytogenes* *why?*
2. Incorrect incubation time and temperature *why?*
3. The applied test procedure contained a mistake ... *why?*
4. An out-dated version of the procedure was used .. *why?*
5. The revised procedure was not distributed *why?*

→ **Workload of the person in charge of document control**

More information / further reading

[1] B. Brookman and I. Mann (eds.) Eurachem Guide: Selection, Use and Interpretation of Proficiency Testing (PT) Schemes (3rd ed. 2021). Available from www.eurachem.org.

Information about PT providers and schemes can be obtained from your national accreditation body, from the EPTIS website (www.eptis.org) or from other national or international organizations.