HANDLING OF UNTESTABLE/DEVIATING SAMPLES

Definition

Untestable/deviating samples are items which have been received by a laboratory, but which are not in an appropriate condition to truly reflect the original sample. This could be due to the samples not being handled correctly during transport or in the way prescribed in the relevant standard or that lack essential information for a quality analysis to be undertaken. Consequently, the validity of the reported results may be jeopardized.

Such a sample might:

- not been preserved adequately (e.g. not cooled, not acidified),
- have exceeded its maximum preservation time,
- in the case of microbiological analyses, lack the date and time of sampling,
- be denatured through heat, light or humidity,
- have rotted or suffered microbiologically, or
- have become cross contaminated.

Background [1]

In the past assessment teams of the Dutch Accreditation Council (RvA) identified major problems regarding the handling of untestable/deviating samples by ISO/IEC 17025 accredited environmental testing laboratories. In each case these findings were recognized as major non-conformities by RvA.

At the end of 2003, the Dutch EUROLAB organisation FeNeLab conducted a "blind" inter-comparison on the handling of untestable samples by ISO/IEC 17025 accredited laboratories. None of the laboratories included a clear disclaimer in their reports and on only 2 occasions a vague statement was included.

Consequently, RvA informed the EA Laboratory Committee about these results and requested that the National Accreditation Bodies (NABs) should take corrective action. In the meantime, most of the accreditation bodies in Europe have reacted, often by informing their assessors accordingly.

Requirements of ISO/IEC 17025:2017 [2]

Clause 7.4.3 of ISO/IEC 17025 [2] requires:

"Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation."

Clause 7.8.1 requires in general that *"the results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling) and shall include all the information agreed with the customer and necessary for the interpretation of the results"*.

However, the standard also sets requirements regarding the competence of laboratory personnel to evaluate the significance of deviations (clause 6.2.3).

Recommendations

When a sample is taken by the customer or on the customer’s behalf by an external provider and transferred to the laboratory, the laboratory cannot be responsible for verifying if the sample was taken in accordance with the relevant requirements. Nevertheless, a competent laboratory must not ignore any obvious observations concerning any adverse condition of the sampling process which might jeopardise the validity of the results. Just a statement that the results relate to the item tested/analysed as received, which is used by many laboratories is certainly not enough. In such a case, the laboratory shall contact the customer, inform them of the problem and ask for further instructions. Clause 7.1.4 has to be considered in this context.

When the customer requires the sample to be tested as the laboratory received it, it is the responsibility of the laboratory to perform the test. In such cases, the report shall include a disclaimer which clearly notices that deviations from the relevant standard were observed and that the validity of the results can be affected by these deviations. This general finding could be further specified e.g. by stating that the sample was supplied in packing which was inappropriate for the relevant analysis or that the sampling date was unknown or that the sample condition had deteriorated. By such an action the laboratory complies with the requirements and the intentions of ISO/IEC 17025.

Example

Disclaimer

*The sample/item (ID: xy) showed a deviation from the normal/original state (description of the state). Therefore, the validity of the corresponding test results (marked with “**”) can be affected.*

Conclusions

When a competent laboratory receives an untestable/deviating sample it shall ask the customer for further instructions. This action offers support to customers concerning sampling and the transfer of samples and may reduce the occurrence of untestable/deviating samples considerably.

The use of disclaimers in a test report in cases when the customer requires the testing of untestable samples might cause competitive disadvantages for an individual laboratory. Preferably, it should be subject to an agreement within the laboratory community of a specific branch or in a specific region. Such an agreement should clearly be supported by the respective national accreditation body or by notifying authorities.

References

[1] EA Laboratory Committee, Handling of deviating samples by ISO/IEC 17025 accredited laboratories – Final Report February 2006, EA LC (06)27

[2] ISO/IEC 17025:2017, “General requirements for the competence of testing and calibration laboratories”