HANDLING OF UNTESTABLE/DEVIATING SAMPLES

Definition

Untestable/deviating samples are items which have been received by a laboratory but do not adequately reflect the original sample. This could be due to the fact that the samples were not handled properly during the transport or not, as stated in the relevant standard, or that basic information is missing for a proper analysis. Consequently, this may jeopardize the validity of the reported results.

Such a sample can:

- be improperly preserved (e.g. not cooled, not acidified),
- have exceeded its maximum storage period,
- have missing information on place and time of sampling in microbiological analyses,
- be denatured by heat, light or moisture,
- be spoiled or microbiologically damaged, or
- be contaminated with other substances.

Background [1]

In the past, assessment teams from the Dutch Accreditation Council (RvA) identified major problems with environmental testing laboratories accredited to ISO/IEC 17025 regarding the handling of untestable/deviating samples. In each of these cases, RvA rated these findings are critical non-conformities.

At the end of 2003, the Dutch EUROLAB member FeNeLab conducted a "blind" test on the handling of untestable/deviating samples with laboratories accredited to ISO/IEC 17025. None of these laboratories had added a clear disclaimer in their test reports and on only in two cases has this fact been vaguely pointed out.

As a result, RvA informed the EA Laboratory Committee accordingly and requested that the National Accreditation Bodies (NABs) should take corrective action. In the meantime, most of the accreditation bodies in Europe have responded, 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 that the sample was taken in accordance with the relevant requirements. Nevertheless, a competent laboratory must not ignore any unusual observations concerning inappropriate sampling process conditions that could jeopardise the validity of the results. Just a statement that the results relate to the item tested/analysed as received, as used by many laboratories, is certainly not sufficient. In such a case, the laboratory shall contact the customer, inform them of the problems and ask for further instructions. Clause 7.1.4 has to be considered in this context.

If a customer requires the sample to be tested as supplied, the laboratory is required to conduct the analysis accordingly. In such cases, the report shall include a disclaimer that clearly states that deviations from the relevant standard were observed and that the validity of the results may 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 was spoiled. By doing so, the laboratory follows 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 provides customers with assistance in sampling and the transferring the samples and can significantly the occurrence of untestable/deviating samples.

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*”

TABLE OF COMMENTS RECEIVED

Author of comment	Comment	Response of resp. person (Mr. Erik Dahm)
Luca Boniardi	*the definition of "unstable" is not detailed but I do not know if it was a choice;*	*Unstable samples: My definition is rather simple: “Samples that obviously do not reflect the original sample”. I have sticked to a simple definition, because the laboratory does not know much about the sampled consignment and have therefor not the knowledge to evaluate this. The laboratory can only be suspicious and react if the sample seems to have changed due to instability.* *I don’t think that the laboratory can be responsible for evaluating all aspects of instability. Therefore this simple definition.*
Luca Boniardi	*the sentence "The laboratory must never just state that the sample was tested or analysed as received" concerns a formula that is expressly required by ISO/IEC 17015: 2018 - § 7.8.2.2. The meaning of this sentence should therefore be more*	*Tested as received: Correct but I often see that laboratories uses this sentence, which is not correct according to ISO 17025. The meaning is that the laboratory must specify if the sample was changed in any way. The analytical report shall always*

	detailed;	*include a description of the received sample. Which is explained in the next sentence.*
Luca Boniardi	*the form in which the customer is informed of the non-conformity of the sample and the way in which the customer consents to the analysis being carried out does not seem to be made explicit. Similarly, notification of the inclusion of the exclusion clause should be made in writing;*	*Information to the customer: This shall always be in writing. The reaction of the customer shall also always be in writing.*
Luca Boniardi	*I think it might be questionable, if not better explained, the point "but nevertheless the laboratory must validate the sample and identify any unusual observations concerning improper sampling process..." when just before it stated that the laboratory which did not carry out the sampling cannot therefore be held responsible for verifying that the sample was taken in accordance with the requirements.*	*"but nevertheless the laboratory must validate the sample and identify any unusual observations concerning improper sampling process...": Good idea.*