AORC Guidelines for Referee Analysis

Objective

1. The objective of referee analysis (also known as B-sample analysis or split-sample analysis) is to ensure that the findings of the first analysis are correct by conducting a confirmatory analysis on the split or remaining portion of the sample, by an independent laboratory. It is not intended to be a *de novo* analysis requiring screening and confirmatory testing for unnamed substances.

Pre-analytical Procedures

2. The referee sample should at all times be the property of the regulatory authority. Referee sample analysis must be carried out in compliance with the relevant rules of the regulatory authority and any documented regulatory authority policies or protocols for such analyses. These should include protocols for the storage and handling of referee samples, and procedures and time frame for the approval and selection of referee laboratories.

3. Approved referee laboratories should be accredited to ISO/IEC 17025, and must be member laboratories of either the Association of Official Racing Chemists (AORC) or the World Anti Doping Agency (WADA). Their supervising chemists should be professional or fellow members of the AORC or WAADS (World Association of Anti-Doping Scientists). The referee laboratory has the right to decline to accept the analysis for any reason without explanation.

4. The regulatory authority should decide beforehand whether, under what conditions, and to what extent the analytical data of the first analysis may be made available to the referee laboratory.

5. The regulatory authority must inform the referee laboratory of any requirements for any part of the analysis to be witnessed by any person representing the connections of the animal from which the sample was obtained.

6. The regulatory authority must inform the referee laboratory beforehand if additional negative samples will be sent together with the referee sample and whether these will be coded so that the referee sample cannot be identified.

7. The regulatory authority should agree with the referee laboratory beforehand on (i) the format of the test report, (ii) the scope of the analytical data to be furnished either automatically or upon request, (iii) to whom the report is to be sent and (iv) who is responsible for meeting the costs of the analysis, including the cost of any requested compliance with 5 and 6 above

8. The name of the substance to be confirmed or quantified, the type of matrix and the gender of the animal providing the sample (where relevant) must be disclosed in writing to the referee laboratory. In some cases the referee laboratory may need to seek further information (such as the approximate order of concentration) to determine whether or not it has the capability to conduct the requested analysis. However, once the referee laboratory has agreed to carry out the analysis, any further communication between the laboratory which performed the first analysis and the referee laboratory should take place only with the agreement of the regulatory authority.

Analytical Procedures

9. The referee laboratory must be advised in writing by email or facsimile as soon as the sample is dispatched. The referee laboratory must acknowledge receipt of the sample(s) as soon as possible. Any concern with respect to sample integrity (such as broken seal or sign of tampering) must be immediately reported to the regulatory authority or its agent.

10. If allowed by the relevant rules of racing or competition or by regulatory authority protocols, the connections of the animal may request that an expert witness be present during the referee analysis. However, the selection and admission of an expert witness and the timing of the witnessed analysis must be agreed beforehand by all parties during the pre-analytical phase according to the authority's rule or documented protocols. An admitted expert witness must agree to abide by all instructions of the referee laboratory and must not interfere with the referee analysis.

11. The referee laboratory will only need to analyse the submitted sample(s) for the presence or otherwise of the requested substance(s) and, in the case of a threshold substance, will determine the concentration or range of concentration of that substance. There is no requirement to screen for the presence of other prohibited substances, nor is the referee laboratory required to determine the concentration of a non-threshold substance found to be present.

12. The same sensitivity of analysis must be applied to all samples, referee or negative, submitted for the same case. However, to allow for possible sample degradation the referee laboratory is not compelled to use a similar sensitivity as for the first analysis.

13. The calibration range for quantitative analysis must bracket the threshold concentration. If the concentration of a threshold substance is found to be higher than the highest calibration point it may be reported as greater than that point. For the analysis of a threshold substance, the referee laboratory must report the relevant measurement uncertainty.

14 If the submitted sample(s) are negative to the reported substance, the referee laboratory must demonstrate its capability to confirm the analyte of interest by concomitant analysis of a positive control sample containing the reported substance at an appropriate concentration in the same matrix.

15. The referee laboratory should employ criteria as described in Part B of the ILAC-G7 document to establish whether or not the reported substance is present in the referee sample and, in the case of a threshold substance, the concentration or range of concentration of that substance. Where appropriate, the AORC *Guidelines for the Minimum Criteria for Identification by Chromatography and Mass Spectrometry* should be followed.

16. A certificate of analysis must be provided. If the reported substance is not detected or if a quantitative measurement shows the regulatory threshold has not been exceeded, this must also be reported but no explanation is required. However, sample observations which affect the analysis must be reported.

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