# RMTC Guidelines for Split Sample Analysis

*Preface*

1. Split sample analysis (also known as B-sample analysis or referee sample analysis) is a targeted confirmatory analysis by an independent laboratory on the split sample for the purpose of affirming or refuting the analytic results of the primary laboratory. Split sample analysis is not a de novo analysis requiring screening and confirmatory testing for unnamed substances.

*Pre-analytical Procedures*

2. The split sample and any sample artifacts are the property of the regulatory authority. Split 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, as well as procedures and time permitted for the approval and selection of referee laboratories.

3. Approved referee laboratories shall be accredited by the Racing Medication and Testing Consortium (RMTC). Supervising chemists shall be professional or fellow members of the AORC or WADA (World Anti-Doping Agency). If an RMTC accredited laboratory is not available, a laboratory accredited to the ISO 17025 standard shall be used. An RMTC Accredited referee laboratory has the right to decline to accept the analysis but must provide an explanation.

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

5. The regulatory authority shall specify the following:

A. the unambiguous chemical name of the analyte for confirmation;
B. the matrix to be analyzed;
C. the estimated concentration of the substance and, if a threshold substance the regulatory threshold;
D. whether it is qualitative or quantitative analysis,
E. the timeframe for completion of the analysis and issuance of report;
F. the scope of the analytical data to be furnished the person whom the report is to be issued, and

G. whether the trainer, horsemen's association, racing authority or other person is responsible for meeting the costs of the analysis, including the cost of any requested compliance with 4 above.

*Communication*

6. Primary Laboratory and Split Sample Laboratory: In some cases the referee laboratory may need additional information (such as the methodology) to determine if it has the capability to conduct the requested analysis. However, once the referee laboratory has agreed to perform the analysis, any further communication between the primary laboratory, that performed the first analysis, and the referee laboratory should take place only with advance consent of the regulatory authority.

7. Other Communications with Split Sample Laboratory: Communications between the regulatory authority representative or the individual requesting the split sample analysis and the referee laboratory should cease when the sample has been received by the referee laboratory. An exception shall be made for commission-initiated communications to address administrative issues.

*Analytical Procedures*

8. The laboratory shall be notified that is has been selected for the analysis prior to sample shipment. The referee laboratory must also be advised 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 upon receipt. Any concern with respect to sample integrity (such as broken seal, evidence of tampering, or poor sample condition) must be immediately reported to the regulatory authority's contact as designated in the solicitation. The individual or agency submitting the sample is responsible for tracking of the shipment through to its delivery.

9. If allowed by the relevant rules of racing 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 in advance 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. The referee laboratory shall have the right to exclude an expert witness that fails to abide by instructions or interferes with the analysis of any sample.

10. The referee laboratory will analyze the submitted sample(s) for the presence of the requested substance(s) and, in the case of a threshold substance, will determine the estimated concentration of that substance. Any additional analysis beyond that outlined above is prohibited unless approved by the regulatory authority and with notice given to the trainer. Any expanded analysis may require additional payment prior to completion. .

11. 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 must employ methodologies with a similar or greater sensitivity as used the first analysis.

12. 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 concentration at the highest calibration point it may be reported as greater than that concentration. For the analysis of a threshold substance, the referee laboratory must comply with ISO 17025 requirements for the reporting of measurement uncertainty.

13 If the referee laboratory does not identify the reported substance, it must demonstrate its capability to detect the target analyte by concomitant analysis of a positive control sample containing the reported substance at an appropriate concentration in the same matrix.

14. 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.

15. A certificate of analysis shall be provided under the agreement with the regulatory authority. 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 and conditions which may have affected the analysis must be reported.

16. If a data packet is requested from the referee laboratory, such request must be made through the regulatory authority and an additional fee for preparation and production of the data packet will apply.

- End -