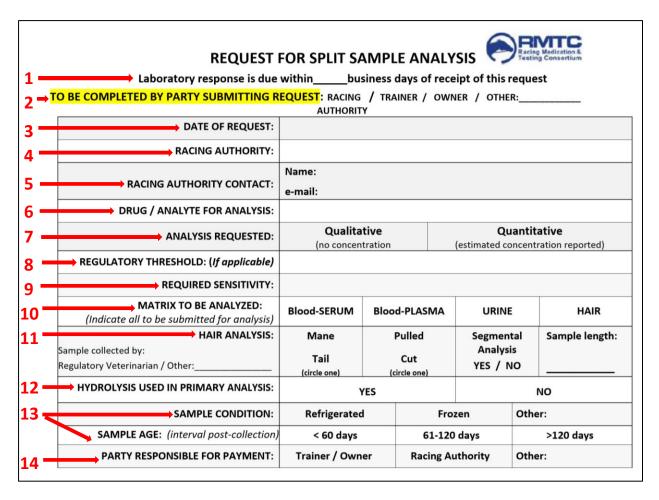
USER GUIDE: SPLIT SAMPLE ANALYSIS SOLICITATION FORM (v 2.0)

The process for solicitation of split samples varies considerably between racing jurisdictions and has resulted in frustration for regulatory authorities, laboratories, and horsemen. The standardization of the request and response process is intended to improve communications between the solicitor and the responding laboratories by clearly defining the expectations and requirements of all parties. The solicitor completes the upper section of the form and distributes it electronically to the candidate laboratories. The responding laboratories complete the lower portions and return their responses electronically. This creates a complete record of the solicitation process that can be produced upon request. The different sections of the solicitation form are explained below.

I. TO BE COMPLETED BY PARTY SOLICITING THE ANALYSIS

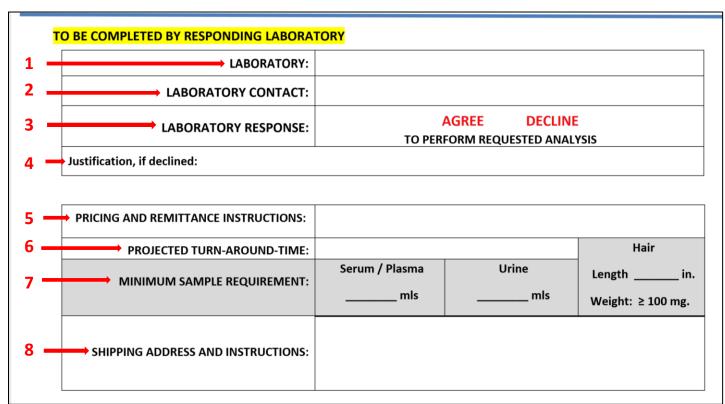


1. <u>Laboratory Response deadline</u>: Regulatory agencies may have different requirements for the length of time in which laboratories respond to a request for split samples. This allows for jurisdiction-

- specific determination of response deadlines and avoids the uncertainty of whether or not a lab's response may still be forthcoming.
- 2. <u>To be completed by party submitting request</u>: This information is useful to the laboratory should a question arise about the information included in the request.
- 3. <u>Date of request:</u> This may be important in some jurisdictions in which regulations prescribe an interval from issuance of a Report of Finding from the laboratory to the solicitation of a split lab. Further, this defines the start of the laboratory response period.
- **4.** Racing Authority: Laboratories should be informed of the jurisdiction in which the sample will be adjudicated. In the solicitation It is not be appropriate to provide the name of the racetrack, the date of sample collection, or the specific race from which the sample originated or any other information that could be used to identify the affected horse, trainer, or owner. This information may be provided after a laboratory has been selected, but not before.
- 5. Racing Authority Contact: Laboratories frequently report being contacted by multiple individuals from a Racing Authority as a split sample laboratory is solicited. It is preferable that a single person be designated for communication with the lab. This may be a regulatory veterinarian, racing official, or other Commission employee. Communications related to laboratory solicitation should be conducted via e-mail so that a record exists of the solicitation request and the responses received. It is not necessary for the designated individual to be proficient in matters related to drug testing. Technical information needed to complete the solicitation form can easily be acquired from the primary testing laboratory.
- 6. <u>Drug / Analyte for Analysis</u>: This is the substance for which the laboratory will perform a targeted analysis. In some cases this will be a metabolite of the actual substance regulated. An example is 2-1 hydroxyethylpromazine sulfoxide (HEPS) which is a metabolite of acepromazine. For the regulatory authority, the substance of interest is acepromazine. The laboratory, however, should be informed that the substance detected was HEPS; that will the substance targeted in the analysis. To inform a laboratory that split sample analysis is required for acepromazine is inaccurate and misleading. Racing authorities may wish to require their primary laboratories to submit concurrent with the issuance of a Report of Finding, a partially completed copy of this form including the analyte name, concentration (where applicable) and if hydrolysis was performed in the primary analysis
- 7. Analysis Requested: Substances associated with a numerical regulatory threshold (i.e. Flunixin, 20 ng/ml in serum or plasma) will require Quantitative Analysis that results in a report that includes the concentration detected in the test sample. The determination of the concentration is required in order to affirm or refute the finding of the primary laboratory. For substance associated with a regulatory threshold that is the laboratory's limit of detection, Qualitative Analysis is indicated. Either the substance is detected, or it is not; the amount detected is not relevant to the reporting of the finding. In some cases, the affected trainer or his representative will request Quantitative Analysis for a non-threshold substance as a component of a defense argument. This request should be considered by the Regulatory Authority and the analysis performed only with its prior consent.
- **8.** Regulatory Threshold: If the substance is associated with a threshold—a concentration specified by regulation—the split sample laboratory should be advised at the time of the solicitation. While many thresholds are consistent between racing jurisdictions, others are not. Therefore, it is

- preferable to provide the information rather than to assume that the laboratory knows the relevant regulatory threshold.
- 9. Required Sensitivity: For substances associated with a threshold concentration, this will be the concentration reported in the sample by the primary laboratory. For substances regulated by the laboratory's limit of detection this value may either be the estimated concentration of the substance in the sample OR the laboratory's lower limit of detection. Either is sufficient information for responding laboratories to know if their analytical method is sufficiently sensitive.
- 10. Matrix to be Analyzed: If the regulated substance was detected in serum, then that will be the matrix submitted for analysis, not 'blood.' Laboratories typically analyze either serum or plasma, not both. It is important to identify what type of blood sample will be submitted for analysis. It is not unusual for the affected trainer or his representative to request analysis of additional matrices despite the Report of Finding's issuance for the detection of a substance in a single matrix (serum or plasma, urine, or hair). This request should be considered by the Regulatory Authority and the requested analysis performed only with its prior consent. If, for example serum and urine are both to be analyzed, this represents two analyses and should be expected to be priced accordingly.
- **11.** <u>Hair Analysis:</u> The specifics of the hair analysis performed by the primary laboratory are critical to the split sample laboratory performing a comparable analysis.
- **12.** <u>Hydrolysis used in Primary Analysis:</u> This informs the split sample laboratory of the sample preparation they will apply to the sample to perform an analysis consistent with the method utilized by the primary laboratory. This is rarely disclosed in the primary laboratory's Report of Finding, but can easily be ascertained by a phone call or e-mail to the laboratory.
- **13.** <u>Sample Condition and Sample Age:</u> This helps to inform the laboratory of the risk of sample degradation which could impact the results of a split sample analysis. It is preferable that split sample analysis be solicited and performed as promptly as is possible after the issuance of the primary laboratory's Report of Finding to minimize the impact of sample degradation during storage.
- 14. Party Responsible for Payment: While it is inappropriate to identify the affected individual to the laboratory during the solicitation process, it is helpful for the lab to know what party will be responsible for submitting payment. This information aids the laboratory in providing remittance instructions in its response to the solicitation. Laboratories may not initiate analysis until payment is received, so it is important for the Regulatory Authority to confirm that payment has been received and that sample analysis is scheduled to proceed.

II. TO BE COMPLETED BY RESPONDING LABORATORIES



- **1.** Laboratory: This identifies the responding laboratory.
- 2. <u>Laboratory Contact</u>: The name and e-mail address of the individual designated by the laboratory to respond to split sample solicitations and subsequent related communications. The designation of a single individual will reduce redundant communications and establish an appropriate chain of communication within the laboratory. As noted above, communications related to split sample solicitation should be archived. Therefore, e-mail is the recommended method for communications between responding laboratories and the solicitor.
- 3. <u>Laboratory Response</u>: The laboratory will indicate if it agrees or declines to accept the sample.
- 4. <u>Justification, if declined:</u> RMTC-accredited laboratories are required to provide justification if the solicitation is declined. RMTC-accredited laboratories are expected to agree to accept split sample analyses associated with Controlled Therapeutic Medications, as listed in the RCI Schedule of Controlled Therapeutic Medications. As a condition of their RMTC accreditation laboratories are required to have validated methods for the controlled therapeutic medications at concentrations relevant to the thresholds in the specified matrices. An example of an exception that would permit an RMTC-accredited laboratory to decline the analysis of a Controlled Therapeutic substance would be where the laboratory's scope of ISO 17025 accreditation is for analysis in plasma but the sample for which split sample analysis is requested is serum.
- **5.** <u>Pricing and Remittance Instructions:</u> The laboratory specifies its pricing for the requested analysis. This pricing is inclusive of the issuance of a Certificate of Analysis. It should be expected

- that the production of a litigation packet will result in additional cost. The laboratory will identify approved methods of payment. (i.e. cashier's check, credit card, electronic transfer of funds). Sample shipment should not occur until payment arrangements have been made to the satisfaction of the recipient laboratory.
- 6. Projected Turn-Around-Time: The laboratory will provide an estimate of the time from sample receipt to anticipated reporting. This interval can be quite variable based on multiple factors that may include a laboratory's need to acquire Certified Reference Material to perform the analysis, validate the analytical method for the substance, or the existing queue of substances designated for targeted confirmatory analysis. When a laboratory is selected, the Racing Authority's contact may find it helpful to enter the laboratory's projected date for issuance of its report in Outlook or other digital reminder system. This will remind the Authority's contact when the report is expected and allow for a timely inquiry if the report is not received.
- 7. <u>Minimum Sample Requirement:</u> The laboratory will specify the minimum amount of sample that it requires to perform the analysis. If a laboratory's minimum sample volume is greater than the amount of sample retained, that laboratory will likely be unable to complete the requested analysis and thus should be excluded from consideration. For hair samples, the 100 mg minimum weight requirement is the equivalent of a hair bundle approximately the diameter of a #2 pencil and no less than 4" in length.
- **8.** <u>Shipping Address and Instructions:</u> The laboratory will provide an accurate shipping address (which may differ from the payment remittance address). It will also identify any constraints on receipt of samples (e.g. The laboratory is unable to receive shipments on Saturdays).