



Laboratory Guidelines

***TUE* Enquiries**

Version 4.0

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[For the purpose of these Laboratory Guidelines, *Code* definitions are in *Italics* and *International Standard* definitions are Underlined.]

1.0 Objective

These Laboratory Guidelines have been developed to ensure a harmonized approach to Laboratory reporting procedures based on the requirements of the *International Standard* for Laboratories (ISL) ^[1]. These Laboratory Guidelines were produced to assist the Laboratories in processing Presumptive Adverse Analytical Findings (PAAF) in compliance with ISL 2021 Art. 5.3.6.2.2 ^[1].

2.0 Scope

These Laboratory Guidelines follow the rules established in the ISL ^[1] and relevant *Technical Documents* regarding the Analytical Testing of Samples. The requirements therein are still fully applicable and shall be respected. These Laboratory Guidelines contain additional recommendations to facilitate the correspondence between Laboratories and Testing Authorities (TAs) (or Results Management Authorities (RMAs), where different) and allows for the harmonized recording of such decisions in ADAMS. Therefore, these Laboratory Guidelines also provide guidance on how to maintain traceability in Analytical Testing and reporting decisions until such time that specialized reporting modules are available in ADAMS.

3.0 TUE Enquiry Requirements

The ISL provides the option for Laboratories to contact the relevant TA or RMA (if different) to enquire if an approved TUE is on file for human Chorionic Gonadotrophin (hCG), human Growth Hormone (hGH; Biomarkers Test), Beta-2 Agonists, Diuretics, Amphetamine, Methylphenidate, Glucocorticoids or Beta-blockers. If a TUE Enquiry is sent by the Laboratory, it shall be sent to the TA (or RMA, if different) to request guidance, in writing, as to whether, on the basis of a valid TUE (as determined by the TA or RMA, if different), the TA (or RMA, if different) wishes the Laboratory to confirm the PAAF or report the test result as a Negative Finding as detailed in these Laboratory Guidelines.

It is strongly recommended that the Laboratory utilizes the template form (Appendix A) in these Laboratory Guidelines (or a Laboratory form containing similar descriptive elements) to receive documented and signed evidence of the TA's (or RMA's) instructions.

4.0 Reporting Requirements

In order to ensure full traceability of the TA's (or RMA's, if different) authorization to confirm the PAAF or to report the test result as a Negative Finding, the following guidance shall be followed in order to have traceability in the Sample's ADAMS record.

4.1. TUE Statement

The Laboratory shall record a statement in the comments section of the ADAMS record that clearly includes the key words “TUE Enquiry” and describes that the TA (or RMA, if different) confirmed the existence of an approved TUE and that the test result may be reported as a Negative Finding.

The following statement should be included in the *ADAMS* Analysis Details/Explanation/Opinion text field:

“**TUE Enquiry**: The TA (or RMA, if different) confirmed that a valid *TUE* is on file for **[substance]** and has authorized the reporting of this *Sample*’s test result as a Negative Finding. The *TUE* Enquiry record is on file in the Laboratory”.

The Laboratory shall produce the *TUE* Enquiry form if requested by the TA, RMA (if different) or *WADA*.

4.2. Uploading of *TUE* Enquiry Form

In addition to the statement above, the Laboratory may, optionally, upload the TA (or RMA, if different) - approved *TUE* Enquiry Form into the *Sample*’s *ADAMS* record:

- Upload and attach the signed *TUE* Enquiry instructions (in pdf format) through the “Activities” Tab in the *ADAMS* record (see Appendix B);
- Save the *ADAMS* record and submit.

It is noted that the *TUE* enquiry form may be uploaded as described in Appendix B without the need for the TA (or RMA, if different) to “un-match” the *ADAMS* record.

5.0 Bibliography

[1] *WADA International Standard for Laboratories (ISL)*.

[Comment: The current versions of *WADA ISL* may be found at <https://www.wada-ama.org/en/what-we-do/science-medical/laboratories>]

Appendix A: TUE Enquiry Form

Date:	Sample Code:
<u>TA</u> (or <u>RMA</u> , if different):	Sport/Discipline:
Mission Code/Batch ID/Event:	

The Initial Testing Procedure(s) (ITPs) applied to the Sample identified the following Presumptive Adverse Analytical Finding(s) (PAAF), which may be linked to an approved TUE.

<u>PAAF(s)</u>	Estimated concentration¹
<input type="checkbox"/> S.2 hCG	
<input type="checkbox"/> S.2 hGH (Biomarkers Test)	
<input type="checkbox"/> S.3 Beta-2 Agonist [specify substance(s)]:	
<input type="checkbox"/> S.5 Diuretic [specify substance(s)]:	
<input type="checkbox"/> S.6a Amphetamine	
<input type="checkbox"/> S.6b Methylphenidate	
<input type="checkbox"/> S.9 Glucocorticoid [specify substance(s)]:	
<input type="checkbox"/> P.1 Beta-blocker [specify substance(s)]:	

¹ The concentration value is a non-confirmed estimate based on a qualitative ITP result.

Section below to be completed by the relevant TA (or RMA, if different)

As per the ISL 2021 Art. 5.3.6.2.2, please indicate below whether the Laboratory shall perform a Confirmation Procedure (based on the existence or absence of a valid TUE for this Prohibited Substance / Prohibited Method related to the Sample identified above).

<input type="checkbox"/>	Do not confirm the <u>PAAF</u> and report the test result as a <u>Negative Finding</u>. A valid TUE, in compliance to the <u>TUE International Standard</u> , is on file ² .
<input type="checkbox"/>	Confirm the <u>PAAF</u> and report the <u>Confirmation Procedure</u> result.

² It is the responsibility of the TA (or RMA, if different) to ensure that the nature of the Prohibited Substance(s) found in the Sample is/are commensurate with the prescription indicated on the granted TUE. If not proceeding with the Confirmation Procedure, then the TA (or RMA, if different) shall provide WADA with a copy of the approved TUE or the associated ADAMS TUE number.

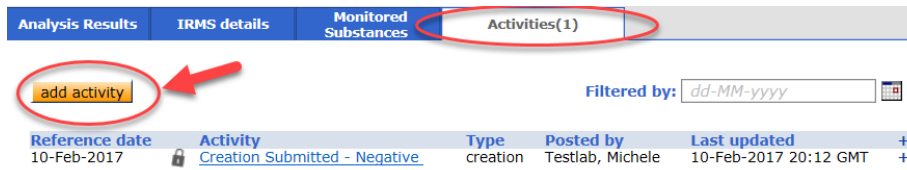
Name and title of responsible <i>Person</i> :	
Signature of responsible <i>Person</i> :	
Organization:	Date:

Please forward this completed form to the Laboratory at:

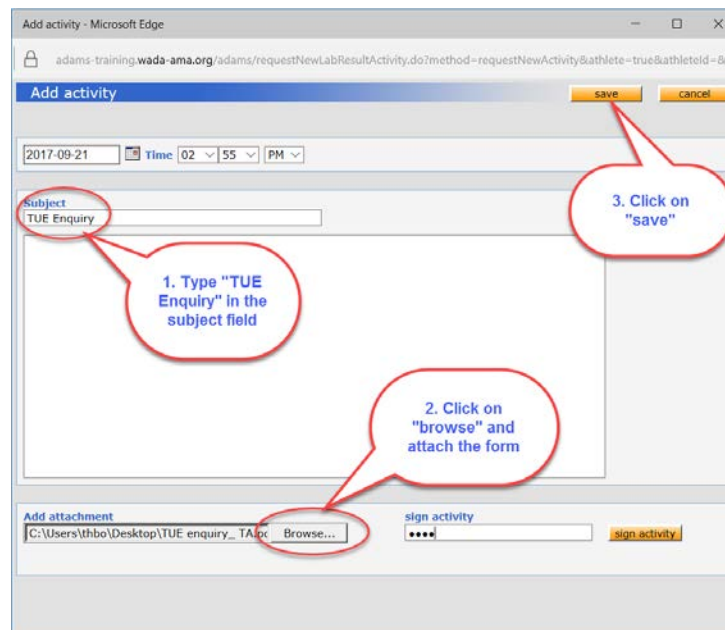
Fax: 123-456-7890 or email scientist@laboratory.org

Appendix B: Attaching a TUE enquiry form to an ADAMS record

1. Note that the ADAMS record will not need to be unmatched by the Testing Authority (TA).
2. The Laboratory shall click on the “Activities” Tab in ADAMS record of the relevant Sample code and then click on the “Add Activity” button.



3. Type the description of the activity in the Subject line (see example below for attaching Test Reports).
4. Under “Add Attachment”, click on “Browse” to retrieve and attach the TA's (or RMA's, if different) forwarded TUE enquiry document (in pdf format) and click on “Save”.



5. The TUE enquiry will be accessible to the TA (and RMA, if different).

