WORLD ANTI-DOPING AGENCY

World Anti-Doping Program

GUIDELINES

TUE ENQUIRIES BY ACCREDITED LABORATORIES

Version 2.0

June 2018

Objective

The following guideline is the result of continuing efforts to harmonize Laboratory reporting procedures based on the requirements of the *International Standard for* Laboratories (ISL) [1], as well as on the observations and recommendations made by the *WADA* Laboratory Expert Group (LabEG).

This guideline was produced to assist the Laboratories in reporting Presumptive *Adverse Analytical Findings* (P*AAF*) exclusively for the S.3. Beta-2 Agonists and S.9. Glucocorticoids drug classes and enquiring with the relevant Testing Authority (TA) and/or Results Management Authority (RMA) about the existence of an approved *Therapeutic Use Exemption (TUE)* before performing confirmation analyses. In accordance with ISL (provision 5.2.4.3.1.1), the decision to confirm the PAAF or report the finding as negative shall be made by the TA and/or or Results Management Authority (RMA) and it shall be retained by the Laboratory as part of the *Sample* record. The form below is an example of how this requirement may be met. It is recommended that all Laboratories refer to this form when contacting TAs or RMAs for the existence of an approved *TUE*.

1. Scope

This guideline follows the rules established in the *World Anti-Doping Agency's (WADA)* ISL [1] and relevant Technical Documents regarding the Analytical Testing of *Sample*s. These requirements are still fully applicable and shall be respected. This Guideline contains additional recommendations to facilitate the correspondence between Laboratories and TAs and allows for harmonized recording of such decisions into *ADAMS*. Therefore this guideline also provides guidance on how to maintain traceability in reporting such decisions until such time that specialized reporting modules are available in *ADAMS*.

2. *TUE* enquiry Requirements

The ISL article 5.2.4.3.1.1 provides the option for Laboratories to contact the relevant TA or RMA to enquire if an approved TUE is on file for a PAAF for beta-2-agonists or glucocorticoids detected in the Initial Testing Procedure. In addition, the Laboratory shall request guidance as to whether, on the basis of the valid *TUE*, the TA wishes the Laboratory to confirm the PAAF or report the finding as "Negative".

It is strongly recommended that the Laboratory utilizes the template form in the Annex to this guideline (or a Laboratory form containing similar descriptive elements) to receive documented and signed evidence of the TA's instructions.

3. Reporting Requirements

In order to ensure full traceability of the TA's instructions to confirm the PAAF or to report the *Sample* as Negative for the beta-2 agonist or glucocorticoid PAAF, the following guidance shall be followed in order to incorporate the TA's authorization into the *ADAMS* record.

It is noted that the *TUE* enquiry form may be uploaded as described below without the need for the TA to "un-match" the *ADAMS* record.

The Laboratory shall record the decision of the TA into ADAMS. Two methods are acceptable to update the *ADAMS* record:

1. Attach the TA-approved *TUE* Enquiry Form to *ADAMS* record:

- Add a statement in the comments section of the *ADAMS* record that clearly identifies that instructions have been received from the TA based on a *TUE* enquiry. For example, enter the statement in the Analysis Details/Explanation/Opinion text field:

  "TUE enquiry: refer to attached document under activities tab"

- Upload and attach the signed *TUE* enquiry instructions (in pdf format) through the "Activities" Tab in the *ADAMS* record (see Appendix 2):
  - Select "add activity";
  - Then "browse" under Add Attachment;
  - Select the appropriate pdf document and "open";
  - Add the statement to subject field "*TUE* Enquiry"; and
  - Click on save.

- Save the *ADAMS* record and submit.

2. Add a comment to *ADAMS* record:

- Add a statement for the comments section of the *ADAMS* record that clearly describes that the TA confirmed the existence of an approved TUE and that the test result may be recorded as Negative. Enter the statement in the Analysis Details/Explanation/Opinion text field:

  "***TUE Enquiry****: The Testing Authority confirmed that a proper TUE is on file for [substance] and has authorized the reporting of this sample as "Negative". TUE Enquiry record is on file in the Laboratory*".

Laboratory Name
Laboratory Address (or Letterhead)

TUE Enquiry Form

Date:			
TA or RMA:			
Sample Code:		**Lab Code:**	
Sport/Discipline:			
Mission Code/Batch ID/Event :			

The Laboratory Initial Testing Procedure applied to the sample above identified a Presumptive Adverse Analytical Finding that may fall under an approved *Therapeutic Use Exemption* status within the following drug class identified in the *WADA Prohibited List*:

Presumptive Analytical Finding:		
Drug Class	☐ S.3 Beta-2 agonists	☐ S.9 Glucocorticoids
Estimated concentration[1] based on initial test:		

[1] the concentration value is a non-confirmed estimation based on a qualitative initial test result.

Name and Title of responsible person:	
Signature:	*Date:*

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Section below to be completed by the relevant Results Management Authority:

Please indicate below whether the Laboratory is to perform a confirmatory analysis (based on the existence or absence of a valid TUE for this substance related to the sample identified above)

☐	Do not confirm the Presumptive *Adverse Analytical Finding* and report sample as Negative. (An acceptable *TUE*, in compliance to the *TUE* Standard, is on file[2]).
☐	Confirm the Presumptive *Adverse Analytical Finding* and report confirmation result.

[2] It is the role of the Testing Authority or Results Management Authority to ensure that the nature of the substance(s) found in the sample is/are commensurate with the prescription as indicated on the granted *TUE*.

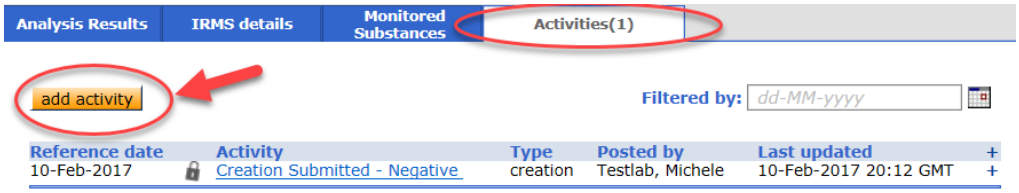
Name and title of responsible person:	
Signature of responsible person:	
Organization:	*Date:*

Please forward this completed form to the *[name]* Laboratory at
Fax: *123-456-7890* or email *scientist@laboratory.org*

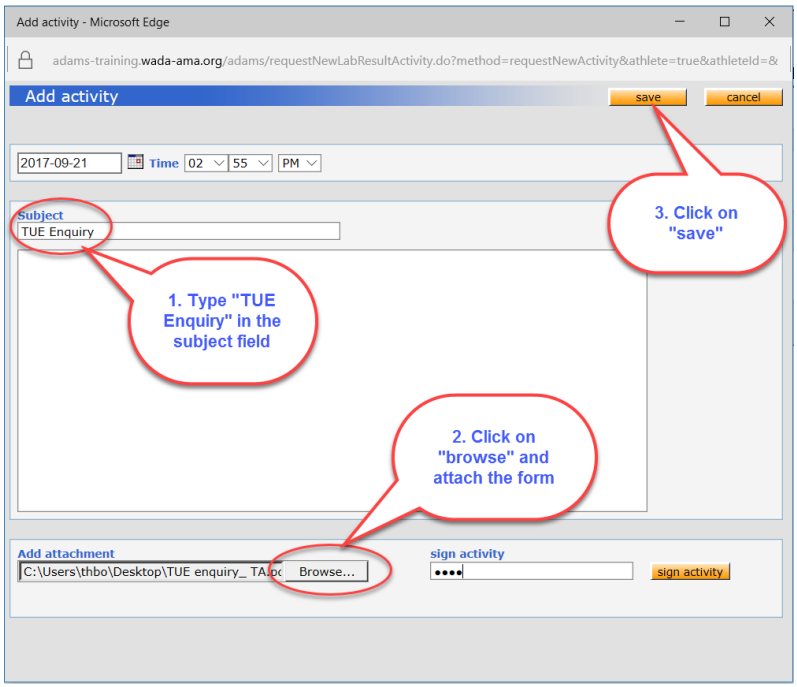
Appendix: *TUE* Enquiries by Accredited Laboratories Version 2.0 June 2018

Attaching a *TUE* enquiry form to *ADAMS* records via the "Activities Tab"

1. Note that the *ADAMS* record will not need to be unmatched by the 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 forwarded *TUE* enquiry document (in pdf format) and click on "Save".



5. The *TUE* enquiry will be accessible to the TA and RMA.