

WORLD ANTI-DOPING PROGRAM

LABORATORY GUIDELINES

TUE ENQUIRIES

BY LABORATORIES

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



1. Objective

The following <u>Laboratory Guidelines</u> are the result of continuing efforts to harmonize <u>Laboratory</u> reporting procedures based on the requirements of the *International Standard* for Laboratories (ISL)¹. These <u>Laboratory Guidelines</u> were produced to assist the <u>Laboratories</u> in addressing <u>Presumptive</u> <u>Adverse Analytical Findings</u> (PAAF) in compliance with ISL Art. 5.3.4.5.4.7.3.

In accordance with this Art. of the ISL, the decision to confirm a <u>PAAF</u> or to report the test result as a <u>Negative Finding</u> shall be made by the <u>Testing Authority</u> and shall be retained by the <u>Laboratory</u> as part of the <u>Sample</u> record. The form included as an appendix to these <u>Laboratory Guidelines</u> is an example of how this requirement may be met.

2. Scope

These <u>Laboratory Guidelines</u> follow the rules established in the ISL and relevant *Technical Documents* regarding the <u>Analytical Testing</u> of Samples. The requirements therein are still fully applicable and shall be respected. These <u>Laboratory Guidelines</u> contain additional recommendations to facilitate the correspondence between <u>Laboratories</u> and <u>Testing</u> Authorities and allows for the harmonized recording of such decisions into ADAMS. Therefore, these <u>Laboratory Guidelines</u> also provide guidance on how to maintain traceability in <u>Analytical Testing</u> and reporting decisions until such time that specialized reporting modules are available in ADAMS.

3. *TUE* Enquiry Requirements

The ISL provides the option for <u>Laboratories</u>, if practicable, to contact the relevant <u>Testing Authority</u> to enquire if an approved *TUE* is on file for Amfetamine, Methylphenidate, Beta-2 Agonists, Diuretics, Glucocorticoids, Beta-blockers or for any other *Prohibited Substance* or *Prohibited Method* whose *Use* has been declared by the *Athlete* on the DCF when a <u>PAAF</u> is detected in the <u>Initial Testing</u> <u>Procedure</u>. If a *TUE* Enquiry is sent by the <u>Laboratory</u>, it shall be sent to the <u>Testing Authority</u> to request guidance, in writing, as to whether, on the basis of a valid *TUE* (as determined by the <u>Testing Authority</u>), the <u>Testing Authority</u> wishes the <u>Laboratory</u> to confirm the <u>PAAF</u> or report the test result as a Negative Finding as detailed in these Laboratory Guidelines.

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

¹ https://www.wada-ama.org/en/resources/laboratories/international-standard-for-laboratories-isl



4. Reporting Requirements

In order to ensure full traceability of the <u>Testing Authority</u>'s instructions to confirm the <u>PAAF</u> or to report the test result as a <u>Negative Finding</u>, the following guidance shall be followed in order to have traceability to the <u>Testing Authority</u>'s authorization into the ADAMS record.

 The <u>Laboratory</u> shall record a statement in the comments section of the *ADAMS* record that clearly includes the key words "*TUE* Enquiry" and describes that the <u>Testing Authority</u> confirmed the existence of an approved *TUE* and that the test result may be reported as a <u>Negative Finding</u>. The following statement should be included in the *ADAMS* Analysis Details/Explanation/Opinion text field:

"*TUE* Enquiry: The <u>Testing Authority</u> confirmed that a valid *TUE* is on file for [substance] and has authorized the reporting of this Sample's test result as a <u>Negative Finding</u>. *TUE* Enquiry record is on file in the <u>Laboratory</u>".

The <u>Laboratory</u> shall produce the *TUE* Enquiry forms if requested by the <u>TA</u> or *WADA*.

- 2. In addition to the statement above, the <u>Laboratory</u> may, optionally, upload the <u>Testing Authority</u>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 *Testing* Authority to "un-match" the *ADAMS* record.



Appendix A: *TUE* Enquiry Form

Date:	Sample Code:
Testing Authority:	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), which may be linked to an approved TUE.

Presumptive Adverse Analytical finding	Estimated concentration ¹
S.6a Amfetamine	
S.6b Methylphenidate	
S.3 Beta-2 Agonist [specify substance(s)]:	
S.5 Diuretic [specify substance(s)]:	
S.9 Glucocorticoid [specify substance(s)]:	
P.1 Beta-blocker [specify substance(s)]:	
Other Prohibited Substance or Prohibited Method declared on the DCF [specify substance(s)/method(s)]:	

¹ the concentration value is a non-confirmed estimate based on a qualitative <u>ITP</u> result.

Section below to be completed by the relevant <u>Testing Authority</u>

As per the ISL v.10.0 Art. 5.3.4.5.4.7.3, please indicate below whether the <u>Laboratory</u> shall perform a <u>Confirmation Procedure</u> (based on the existence or absence of a valid *TUE* for this *Prohibited Substance* / *Prohibited Method* related to the *Sample* identified above).

Do not confirm the <u>Presumptive Adverse Analytical Finding</u> and report the test result as a <u>Negative Finding</u> .
A valid TUE, in compliance to the TUE International Standard, is on file ² .
Confirm the <u>Presumptive Adverse Analytical Finding</u> and report the <u>Confirmation Procedure</u> result.

² It is the responsibility of the <u>Testing Authority</u> 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 <u>Confirmation Procedure</u>, then the <u>Testing Authority</u> shall provide *WADA* with a copy of the approved *TUE* or the associated *ADAMS TUE* number.

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

Please forward this completed form to the <u>Laboratory</u> 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 <u>Testing Authority</u>.
- 2. The <u>Laboratory</u> shall click on the "Activities" Tab in *ADAMS* record of the relevant *Sample* code and then click on the "Add Activity" button.

Analysis Results	IF	MS details	Monitored Substances	Activit	ies(1)		
add activity					Filtered by:	dd-MM-уууу	
Reference date		Activity		Туре	Posted by	Last updated	+
10-Feb-2017	ĥ	Creation Sub	mitted - Negative	creation	Testlab, Michele	10-Feb-2017 20:12 GMT	+

- **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 <u>Testing Authority</u>'s forwarded *TUE* enquiry document (in pdf format) and click on "Save".

Add activity - Microsoft Edge -		×
adams-training.wada-ama.org/adams/requestNewLabResultActivity.do?method=requestNewActivity&athlete=true	ie&athletel	id=&
Add activity save	canc	el
2017-09-21		$ \square$
	ick on ave"	
1. Type "TUE Enquiry" in the subject field		
2. Click on "browse" and attach the form		
Add attachment sign activity C:\Users\thbo\Desktop\TUE enquiry_TApc Browse sign activity sign a	ctivity	

5. The TUE enquiry will be accessible to the <u>Testing Authority</u> and <u>Results Management Authrority</u>.

nalysis Results	IRM		4onitored Ibstances	Activiti	es(2)		
add activity					Filtered by:	dd-MM-yyyy	
Reference date		c tivity JE Enguiry	~	Type User Activity	Posted by Boghosian, Thierry	Last updated 21-Sep-2017 20:00 GMT	+++++++++++++++++++++++++++++++++++++++
21-Sep-2017	/ IU						