

Laboratory Guidelines

Conducting and Reporting Subcontracted Analysis and Further Analysis for *Doping Control*

Version 3.0

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

1.0 Objective

These Laboratory Guidelines have been developed to ensure a harmonized approach in the analysis and reporting of (i) Samples which are shipped to another Laboratory for subcontracted analyses, or (ii) long-term stored Samples which undergo Further Analysis (as described in ISL 2021 Article 5.3.6.3 ^[1]). These Laboratory Guidelines also provide direction when there is a need to ship a Sample between Laboratories, including how to report the results into ADAMS. These principles may also apply to Samples that need to be transported to another Laboratory as a result of cessation of Laboratory Analytical Testing activities, e.g. by Suspension, Analytical Testing Restriction or Revocation of a Laboratory's WADA accreditation.

2.0 Scope

These Laboratory Guidelines follow the rules established in the *WADA International Standard for Laboratories (ISL) 2021* ^[1] and relevant *Technical Documents (TDs)* ^[2, 3] regarding the Analytical Testing of Samples and contain additional recommendations to facilitate the implementation of subcontracted analyses and Further Analysis of Samples in long-term storage. It should be noted that all mandatory reporting parameters of ADAMS may not be applicable to the Analytical Testing typically involved in subcontracted analysis and Further Analysis. Therefore, this document also provides guidance to ensure traceability in the subcontracted and Further Analysis(es) results until such a time that specialized reporting modules are available in ADAMS.

3.0 Subcontracted Analysis Requirements

The ISL Article 5.2.6 provides the conditions for which an analysis may be subcontracted to another Laboratory. In cases where a Laboratory lacks the analytical capacity to conduct a test, Samples may need to be transported to another Laboratory to complete the test menu originally requested by an *Anti-Doping Organization (ADO)*. For example:

- Technical failure of relevant instrumentation, which will be out of service during the reporting timeline required by the *ADO* [e.g. Gas Chromatography / Combustion / Isotope Ratio Mass Spectrometry (GC/C/IRMS)];
- Required analysis (which is not mandatory for all Laboratories) is not available in the Laboratory that received the Sample [e.g. GC/C/IRMS analysis for 19-norandrosterone; analysis for human Growth Hormone (hGH) biomarkers; confirmation analyses for intact human Chorionic Gonadotropin (hCG)].

For the purposes of these Laboratory Guidelines:

- “Lab1” will refer to the Laboratory that originally received the Sample from the Testing Authority (TA); however, in compliance with ISL Article 5.2.6, must ship the Sample(s) to another Laboratory to complete the requested test menu;
- “Lab2” will refer to the subcontracted Laboratory that receives the Sample(s) to perform a specified Analytical Testing Procedure(s) necessary to complete the requested test menu.

The TA shall be informed as soon as possible by Lab1 regarding the lack of analytical capacity that will impact the reporting timeline of the requested test results. The decision to arrange for the subcontracted analysis shall be made with the TA's approval. Written approval from the TA for subcontracting shall be kept as part of the *Sample* record.

Lab1 shall be responsible for transport of the *Sample(s)*, chain of custody up to *Sample* reception by the Lab2 and for the reporting of results into ADAMS, including the results produced by Lab2.

If the subcontracted analysis of the "A" *Sample* by Lab2 results in an *Adverse Analytical Finding (AAF)*, the "B" *Sample* container shall also be transferred to Lab2 in order to comply with ISL Article 5.3.6.2.3. The TA shall be consulted before shipping the "B" *Sample*.

3.1. Costs

If the need for subcontracting is related to a Test Method which is within Lab1's scope of ISO/IEC 17025 accreditation (but temporarily unavailable), or due to Suspension, Analytical Testing Restriction or Revocation of a Laboratory's WADA accreditation, then Lab1 shall be responsible for the transportation and analysis costs associated with the subcontracted analysis of the *Sample(s)*.

If the need for subcontracting is related to a Test Method for which Lab1 does not have the analytical capacity, and the Test Method in question is not mandatory for all Laboratories (as determined by WADA), the costs for transport and analysis(es) shall be the responsibility of the TA.

3.2. Chain of Custody

Lab1 shall be responsible for the recording of chain of custody (in compliance with TD LCOC ^[2]) that records the removal of the *Sample* "A" and/or "B" containers from storage, packaging and transfer to the courier or other responsible shipping body. Lab1 is responsible for the maintenance of the chain of custody up to *Sample* reception by Lab2. A copy of the Laboratory Internal Chain of Custody shall also be included in the shipment, be signed by Lab2 upon receipt and a copy sent to the Lab1 to acknowledge the reception.

Lab1 shall be responsible for the integrity of the *Sample(s)*, which can be addressed either by resealing individual containers with a tamper-evident system or by sealing the box in which the *Sample(s)* are transported in a manner which ensures *Sample* integrity and proper maintenance of chain of custody.

[*Comment: For example, Sample(s) may be resealed with resealing systems (e.g. new bottlecaps) produced by the manufacturer of an appropriate Sample collection equipment that replicates the security and tamper-evident functionality of the original seal. The resealing system of shipped "A" Sample(s) shall be tamper evident.*]

3.3. Documents

Lab1 shall send a copy of the relevant TA documentation (e.g. *Doping Control Form (DCF)*, external Chain of Custody) to the Lab2, as well as a written request for the subcontracted analysis.

3.4. “A” Sample Analysis

Lab2 shall only perform the analysis requested by Lab1 and produce a Test Report with a descriptive statement such as “Subcontracted Analysis”, which specifies the Test Method(s) applied to the *Sample(s)* and the test result(s) in compliance with ISL Article 5.3.8.4. The Test Report shall be forwarded to Lab1.

Lab1 shall enter all test results into the *ADAMS* record of the *Sample*:

- Check all relevant [Test Method] tickboxes (conducted by both Lab1 and Lab2);
- Add a statement in the Comments Section of the *ADAMS* record that clearly identifies the subcontracting arrangement.

[For example: Enter the statement “Subcontracted Analysis: [Lab2] conducted the [Test Method], see attached Test Report under activities tab” in the Analysis Details/Explanation/Opinion text field.]

- Upload and attach Lab2’s hardcopy Test Report (in pdf format) through the “Activities” Tab in the *ADAMS* record (Select “add activity”, “Browse” under Add attachment, select Lab2 Test Report and “open”, add statement to subject field “[Lab2] Test Report” and save). See Appendix A;
- If necessary, update the final test result (Negative Finding, *ATF* or *AAF*);
- Save the *ADAMS* record and submit.

The submission will be traceable within the audit trail of the *ADAMS* record and the Lab2 Test Report can be downloaded by the TA and/or Results Management Authority (RMA). See Appendix A.

3.5. “B” Sample Analysis

If Lab2’s subcontracted analysis of the “A” *Sample* results in an *AAF*, then Lab2 shall conduct the “B” *Sample Confirmation Procedure (CP)*, if requested (unless otherwise approved by *WADA* for exceptional circumstances). The *Athlete* or the *Athlete’s* representative shall have the right, upon being notified by the TA, to attend the “B” *Sample* opening (and to the analysis of “B” *Sample* aliquot) in Lab2 as per ISL Article 5.3.6.2.3 ^[1].

- Lab2 conducts the “B” *Sample CP*;
- The TA provides access to the associated *ADAMS* DCF record to Lab2;
- Lab2 submits the “B” *Sample CP* test result(s) directly into *ADAMS*;

3.6. “B” Sample Splitting Procedure

If necessary (for example, due to insufficient “A” *Sample* volume), Lab2 may also split the “B” *Sample* based on the procedure described in ISL Article 5.3.3.2 ^[1]. The procedure to analyze and report the split “B” *Sample* shall be made with the input of Lab1 and the TA as described below:

- Lab2 conducts the “B1” *Sample Initial Testing Procedure (ITP)* (and *CP*, if necessary);
- The TA provides access to the associated *ADAMS* DCF record to Lab2;

- Lab2 reports its test results by submitting the “B1” *Sample* test result(s) directly into ADAMS;
- If an AAF is reported on the basis of the “B1” analysis, then Lab2 shall conduct the “B2” *Sample CP* and report the results directly into ADAMS.

*[Comment: For the purposes of these Laboratory Guidelines, the first bottle of the split “B” *Sample*, which is to be used as the “A” *Sample* (see ISL Article 5.3.3.2) is referred to as “B1”. The second bottle of the split “B” *Sample*, which is to be used for the “B” *CP*, is referred to as “B2”.]*

3.7. Multiple AAFs

Lab1 confirms an AAF but must forward the “A” *Sample* to Lab2 to complete the test menu, which in turn identifies an additional AAF.

[Example:

A specified stimulant is identified by Lab1; however, the *Sample* is shipped to Lab2 for a subcontracted analysis for Erythropoietin Receptor Agonists (ERAs), which also produces an AAF.

In this case, Lab2 shall conduct the analysis for ERAs and, in addition, repeat the “A” *CP* for the specified stimulant in order to maintain compliance with the ISL Article 5.3.6.2.3 ^[1]. If there is a Presumptive Adverse Analytical Finding (PAAF) for the ERA(s), then both *Prohibited Substances* should be confirmed by Lab2 in both the “A” *Sample* and the “B” *Sample* (if requested).

Alternatively, Lab1 may conduct the “B” *CP* for the specified stimulant, reseal the “B” container (by *Athlete*, *Athlete’s* representative or Independent Witness) and send to Lab2 to conduct the ERA “B” *CP*. This procedure shall take into consideration the “B” *Sample’s* volume and the *Athlete’s* right to attend the opening of the resealed “B” *Sample* by Lab2. The appropriate action may depend on several factors and, if necessary, WADA may be contacted for further guidance.]

3.8. Laboratory Documentation Package

If a Laboratory Documentation Package is requested by the TA and/or RMA on the basis of an AAF or ATF from a subcontracted analysis, then Lab1 (which originally received the *Sample*) will be responsible for providing the required Laboratory Documentation Package (in compliance with TD LDOC ^[3]) to the TA or RMA. Each Laboratory involved (*i.e.* Lab1 and Lab2) shall provide documentation relevant to the Analytical Testing steps conducted.

[Comment: For example, Lab2 shall provide Lab1 with the necessary Laboratory Internal Chain of Custody documents and any relevant analytical documentation that will result in a complete and coordinated record. Lab1 shall include their own documentation and incorporate the information provided by Lab2 into a complete Laboratory Documentation Package (in compliance to the TD LDOC ^[3]) to be provided to the TA or RMA. Documentation related to the arrangement of the subcontracted analysis shall be included in the Laboratory Documentation Package.]

Each Laboratory will be responsible for defending the specific Analytical Testing steps they conducted if there is a case before a hearing body.

4.0 Further Analysis Requirements

There are several possible scenarios for the conduct of Further Analysis on Samples that have been already analyzed and reported by a Laboratory (see also ISL 2021 Article 5.3.6.3):

- Lab1 has the analytical capacity and conducts the requested Further Analysis (see Article 4.1); or
- Lab1 does not have the analytical capacity to conduct the requested Further Analysis and must ship the *Sample(s)* to Lab2 (see Article 4.2) for analysis, after informing the TA or *WADA* (as applicable) and receiving written approval; or
- Lab1 is requested to send the *Sample(s)* for long-term storage in Lab2 (Laboratory as *Sample Custodian*) or in an external *Sample* storage facility (TA as *Sample Custodian*) (see Article 4.2). Lab2 is then requested to conduct Further Analysis on the stored *Sample(s)*.

4.1. Further Analysis in the same Laboratory

In this case, the Laboratory that conducted and reported the results of the original analysis prior to storing the *Sample(s)* (Lab1) is requested to conduct Further Analysis. The request for Further Analysis may be based on the availability of a new or improved Test Method in the Laboratory, or the application of a Test Method that was not part of the original test menu. The TA or *WADA*, as applicable, shall provide guidance on whether to conduct Analytical Testing on the volume remaining in the “A” *Sample* or to split the “B” *Sample*. Such a decision should include the input of the Laboratory with particular attention on *Sample* volume and Analytical Testing strategy.

4.1.1. Costs

All costs associated with the storage and analysis conducted by Lab1 shall be borne by the relevant TA or *WADA*, as applicable.

4.1.2. Documents

Lab1 shall maintain the relevant TA documentation (e.g. DCF, external Chain of Custody), proper Laboratory Internal Chain of Custody and storage records for the *Sample(s)* as per the TD LCOC ^[2].

4.1.3. Reporting an “A” *Sample* or split “B” (B1) *ATF* or *AAF* into *ADAMS*

Lab1 shall perform the analysis requested by the TA or *WADA* and then produce a hardcopy Test Report with a descriptive such as “Further Analysis”, which clearly specifies the Test Method(s) that were applied to the *Sample(s)*, including a test result which is in compliance with ISL Article 5.3.8.4 ^[1].

Lab1 records all relevant results into the *ADAMS* record:

- Check all relevant [test method] tickboxes;

- Add a statement in the comments section of the *ADAMS* record that clearly identifies which Test Method(s) was conducted at the request of the TA or *WADA* for Further Analysis.

[Comment: For example, enter the statement “Further Analysis: [Test Method(s)] was conducted, see attached test report under activities tab” in the Analysis Details/Explanation/Opinion text field];

- Upload and attach Lab1’s hardcopy Test Report (in pdf format) through the “Activities” Tab in the *ADAMS* record (Select “add activity”, “Browse” under Add attachment, select Lab1 Test Report and “open”, add statement to subject field “[Lab1] Further Analysis Test Report” and save). See Appendix A;
- If necessary, update the final test result (e.g., *ATF*, *AAF*);
- Save the *ADAMS* record and submit.

The submission is recorded within the audit trail in *ADAMS* and the Lab1 Further Analysis Test Report can be downloaded by the TA and *WADA*.

4.1.4. Reporting a “B” or split “B” (B2) *Sample ATF* or *AAF* into *ADAMS*

If Lab1’s analysis of the “B” *Sample* or the split “B” (B2) *Sample* results in an *ATF* or *AAF*, then Lab1 reports the results of the “B” or “B2” *Sample* analysis into *ADAMS*.

4.1.5. Reporting an “A” or “B” *Sample* or split “B1” or “B2” *Sample* as a Negative Finding

If Lab1’s analysis of the “A” or “B” *Sample* or split “B1” or “B2” *Sample* results in a Negative Finding, then Lab1 may utilize the following procedure to update all relevant results into the *ADAMS* record(s):

- Lab1 may utilize the electronic batch update functionality in *ADAMS* to report all relevant Negative Finding test results via .csv or .xml file format;
- The TA shall un-match the relevant *ADAMS* records from the DCF, if necessary;
- The mandatory items for the .csv or .xml file are necessary for the batch update and shall include the update comment below and the new analysis information;
- Check all relevant [Test Method] tickboxes;
- Add a statement for the comments section of the *ADAMS* record that clearly identifies the Test Method(s) conducted at the request of the TA or *WADA* for Further Analysis;

Enter the statement “Further Analysis: [Lab1] conducted the [Test Method(s)] which resulted in a Negative Finding. The test report can be requested from the Laboratory” in the Analysis Details/Explanation/Opinion text field;

[Comment: If the original reporting included any comments, then these comments shall be included in the .csv or .xml file and updated with the additional new comments. The file will overwrite the original comments in ADAMS.]

- Upload the .csv or .xml file.

4.1.6. Laboratory Documentation Package

Lab1 will be responsible for providing the required Laboratory Documentation Package (in compliance with TD LDOC ^[3]).

4.2. Further Analysis in a Different Laboratory

Several *Sample* storage scenarios may be involved:

Laboratories as *Sample* Custodians:

- If the Laboratory that conducted and reported the original analysis (Lab1) is requested, by the TA or *WADA*, to ship the “A” and “B” *Samples* to a different Laboratory (Lab2) to conduct Further Analysis, the instructions below are applicable;
- If the Laboratory that conducted and reported the original analysis (Lab1) is requested, by the TA or *WADA*, to ship the “A” and “B” *Samples* to a different Laboratory (Lab2) for long-term storage of *Samples* and Lab2, or any other Laboratory other than Lab1, is selected by the TA to conduct the Further Analysis, then the instructions below are applicable.

TA as *Sample* Custodian:

- *Samples* may also be transported for long-term storage to an external Fit-for-Purpose Sample storage facility, which is under the responsibility (or delegated responsibility) of the TA that has ownership over the *Samples*. If Lab2, or any other Laboratory other than Lab1, is selected by the TA to conduct the Further Analysis, then the instructions below are applicable.

The TA or *WADA*, as applicable, shall provide guidance to Lab2 on whether to conduct the Further Analysis on the volume remaining in the “A” *Sample* or to split the “B” *Sample*. Such a decision should include the input of the Lab2 with particular attention on *Sample* volume and Analytical Testing needs.

4.2.1. Costs

All costs associated with the long-term storage, *Sample* transport and Further Analysis shall be borne by the relevant TA or *WADA*.

4.2.2. Documents

As per ISL Article 5.3.11.3, Lab1 shall maintain proper Laboratory Internal Chain of Custody and storage records for the storage and shipment of the *Samples* to Lab2 or the TA Sample storage facility. Lab2 or the TA Sample storage facility shall maintain the relevant TA documentation (e.g. DCF, external Chain of Custody), proper chain of custody (in compliance to TD LCOC) for the *Sample* storage upon receipt and shipment records for the shipment to another Laboratory, if applicable. A Laboratory performing Further Analysis shall maintain proper Laboratory Internal Chain of Custody throughout the analysis of the *Samples* and subsequent storage in their facilities.

4.2.3. Reporting an “A” *Sample* or split “B” (B1) *ATF* or *AAF* into *ADAMS*

Lab2 shall perform the analysis requested by the TA or *WADA* and then produce a hardcopy Test Report with a descriptive statement such as “Further Analysis” and which clearly specifies the Test Method(s) that were applied to the *Sample(s)* including a test result which is in compliance with ISL Article 5.3.8.4 ^[1]. The hardcopy Test Report shall be forwarded to Lab1.

Lab1 shall submit all relevant results into the *ADAMS* record:

- Check all relevant [Test Method] tickboxes;
- Add a statement in the comments section of the *ADAMS* record that clearly identifies the Test Method(s) conducted at the request of the TA or *WADA* for Further Analysis.

[Comment: For example, enter the statement “Further Analysis: [Lab2] conducted the [Test Method], see attached Test Report under activities tab” in the Analysis Details/Explanation/Opinion text field];

- Upload and attach Lab2’s hardcopy Test Report (in pdf format) through the “Activities” Tab in the *ADAMS* record (Select “add activity”, “Browse” under Add attachment, select Lab2’s Test Report and “open”, add statement to subject field “[Lab2] Further Analysis Test Report” and save). See Appendix A;
- If necessary, update the final test result (e.g., *ATF*, *AAF*);
- Save the *ADAMS* record and submit.

If necessary (for example, due to a lack of “A” *Sample* volume) Lab2 may also split the “B” *Sample* based on the procedure described in ISL Article 5.3.3.2 ^[1]. The procedure to split the “B” *Sample*, as described below, shall be made in consultation with Lab1 and the TA or *WADA*:

- Lab2 conducts the “B1” *Sample* ITP(s) and CP(s), if necessary;
- The TA provides access to the associated *ADAMS* DCF record to Lab2;
- Lab2 submits the “B1” *Sample* result(s) directly into *ADAMS*;
- If an *AAF* is reported on the basis of the “B1” analysis, then Lab2 shall conduct the “B2” CP and report the results into *ADAMS*.

The submission is recorded within the audit trail in *ADAMS* and the Lab2 Further Analysis Test Report can be downloaded by the TA and *WADA*. Lab2 may also simultaneously provide the hardcopy Test Report to the TA and/or *WADA* upon request.

4.2.4. Reporting a “B” or split “B” (B2) test result into *ADAMS*

In this case, an *ADAMS* record for the “B” or split “B” (B2) test result does not exist before Lab2’s analysis.

- The TA provides access to the associated *ADAMS* DCF record to Lab2;
- Lab2 submits the “B” or “B2” *Sample* test result(s) directly into *ADAMS*.

4.2.5. Reporting an “A” *Sample* or split “B” (B1) *Sample* as a Negative Finding into ADAMS

If Lab2’s analysis of the “A” or split “B1” *Sample* results in a Negative Finding, then Lab1 may utilize the following procedure to update all relevant results into the ADAMS record(s):

- Lab 2 shall provide a hard copy Test Report for the results of their analyses to Lab1.
- Lab1 may utilize the electronic batch update functionality in ADAMS to report all relevant Negative Finding results via .csv or .xml file format;
- The TA shall un-match the relevant ADAMS records, if necessary;
- The mandatory items for the .csv or .xml file are necessary for the batch update and shall include the update comment below and the new analysis information;
- Check all relevant [Test Method] checkboxes;
- Add a statement for the comments section of the ADAMS record that clearly identifies the Test Method(s) conducted at the request of the TA or WADA for Further Analysis.

Enter the statement “Further Analysis: [Lab2] conducted the [Test Method(s)] which resulted in a Negative Finding. [Lab2’s] test report is on file in [Lab1]” in the Analysis Details/Explanation/Opinion text field;

[Comment: If the original reporting included any comments, then these comments shall be included in the .csv or .xml file and updated with the additional new comments. The file will overwrite the original comments in ADAMS.]

- Upload the .csv or .xml file.

4.2.6. Laboratory Documentation Package

If a Laboratory Documentation Package is requested by the TA and/or RMA on the basis of an AAF from Further Analysis, then Lab2 (which conducted the Further Analysis and reported the AAF) will be responsible for providing the required Laboratory Documentation Package (in compliance with TD LDOC ^[3]). Each Laboratory and TA involved (i.e. Lab1, TA as *Sample* custodian, and Lab2) shall provide documentation related to the steps they conducted. For example, Lab1 shall provide Lab2 with the necessary Laboratory Internal Chain of Custody documentation and any relevant analytical documentation that will result in a complete and coordinated record. Lab2 shall incorporate the documentation provided by Lab1 as an appendix and deliver the complete Laboratory Documentation Package to the requesting TA and/or RMA.

5.0 ADAMS Reporting

Refer to appendix A for further details on reporting the results of a subcontracted analysis and Further Analysis into ADAMS until such time that ADAMS is configured to accept, record and link these analyses to the original ADAMS record and DCF.

In the case of Further Analysis, the original ADAMS record test result may require an update from Negative Finding to “*Adverse Analytical Finding*” or “*Atypical Finding*”.

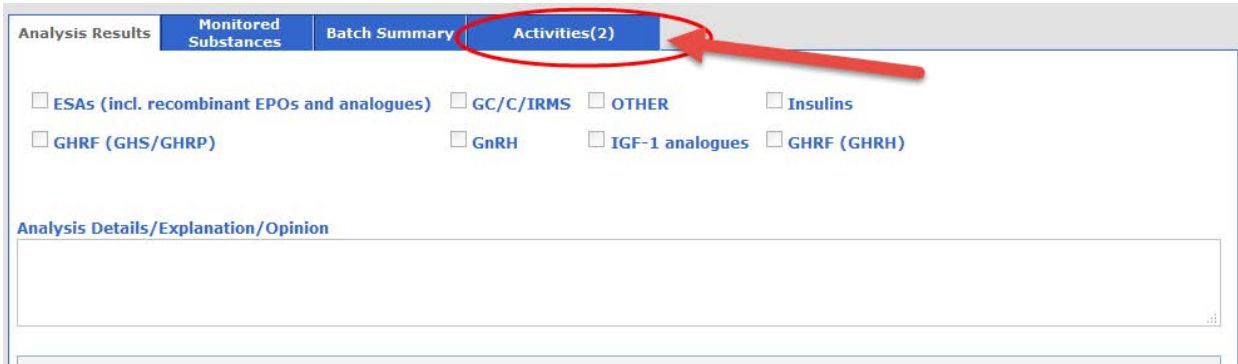
6.0 Bibliography

- [1] *WADA International Standard for Laboratories (ISL)*.
- [2] *WADA Technical Document on Laboratory Internal Chain of Custody (TD LCOC)*.
- [3] *WADA Technical Document on Laboratory Documentation Packages (TD LDOC)*.

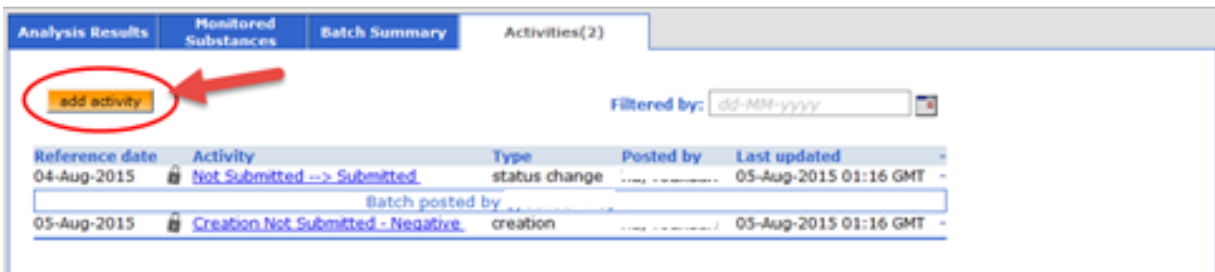
[Comment: Current versions of WADA ISL and Technical Documents may be found at <https://www.wada-ama.org/en/what-we-do/science-medical/laboratories>]

Appendix A: Attaching Documentation to *ADAMS* Records through “Activities Tab”

1. Each relevant *ADAMS* record will need to be unmatched by the Testing Authority;
2. The original Laboratory (associated with the *ADAMS* record) shall click on the “Activities” Tab;

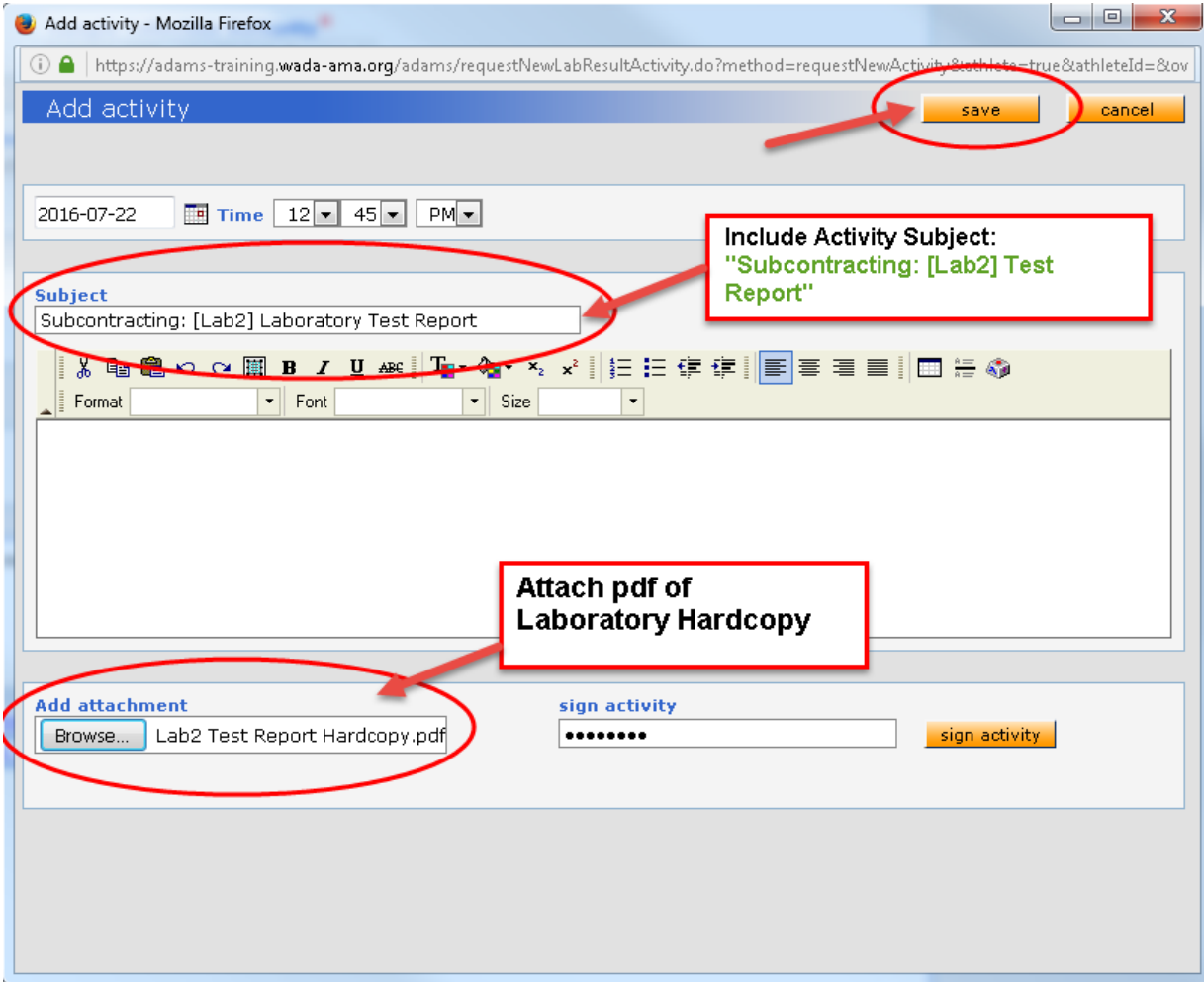


3. Click on the “Add Activity” button.



Reference date	Activity	Type	Posted by	Last updated
04-Aug-2015	Not Submitted --> Submitted	status change		05-Aug-2015 01:16 GMT
05-Aug-2015	Creation Not Submitted - Negative	creation		05-Aug-2015 01:16 GMT

4. Type the description of the activity in the Subject line (see example below for attaching Test Reports).
5. Under “Add Attachment”, click on “Browse” to retrieve and attach the Laboratory Test Report (in pdf format) and click on “Save”.



Add activity - Mozilla Firefox
 https://adams-training.wada-ama.org/adams/requestNewLabResultActivity.do?method=requestNewActivity&include=true&athleteId=&ov

Add activity save cancel

2016-07-22 Time 12:45 PM

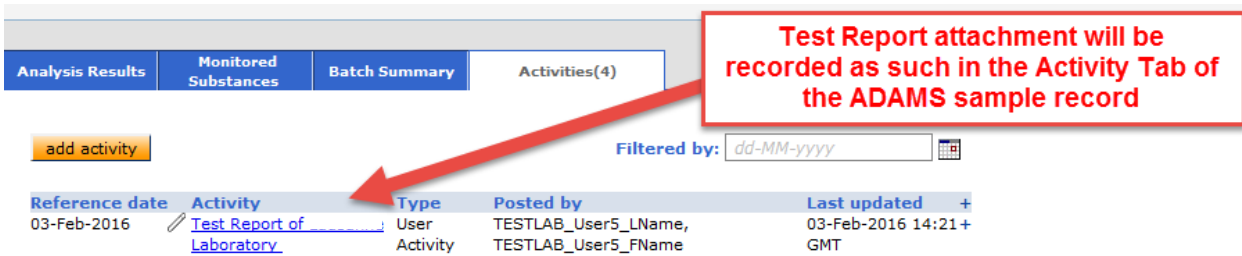
Subject
 Subcontracting: [Lab2] Laboratory Test Report

Attach pdf of Laboratory Hardcopy

Add attachment
 Browse... Lab2 Test Report Hardcopy.pdf

sign activity
 sign activity

6. Test Report will be accessible to the Testing Authority and WADA.



Analysis Results | Monitored Substances | Batch Summary | **Activities(4)**

add activity Filtered by: dd-MM-yyyy

Reference date	Activity	Type	Posted by	Last updated
03-Feb-2016	Test Report of Laboratory	User	TESTLAB_User5_LName,	03-Feb-2016 14:21+
		Activity	TESTLAB_User5_FName	GMT

Test Report attachment will be recorded as such in the Activity Tab of the ADAMS sample record