Creating a Lab Result - EN

ADAMS Release 7 May 2019 - What's new?

- point 7:
  - Labs are able to specify the Sample Specific Gravity (Confirmation Procedure) for Urine samples; this field is different from and functionally NOT related to the existing field Confirmed specific gravity that is exclusively associated with the Steroid Profile.
  - The existing field Specific Gravity is renamed into Sample Specific Gravity (Initial Testing Procedure).

ADAMS Release June 2018 - What's new?

- point 18: Labs are able to provide the LH-Analysis details for Urine samples

ADAMS 4.7.0 - What's new?

- point 15: Labs are able to indicate a dedicated Overall IRMS conclusion irrespective and independent from the overall Lab test result.

ADAMS 4.1/4.1.1 - What's new?

- point 3: Sample collection date mandatory
- point 7: Validity is automatically calculated based on the Microbial contamination markers
- point 15: new tab "IRMS details" to facilitate the IRMS-reporting on Target compounds and Endogenous Reference compounds
- point 21: Steroid Profiling data - also provide information on the Microbial contamination and the Confounding factors
- point 21: Allowing the value '-2' for the steroid variable epitestosterone, if the date received of the sample is after 1 January 2016

1. Go to the Search area.

2. Click on the New lab result button.
3. Fill in the **Sample Code**, **Sample Collection Date**, select the **Sample type** and **SampleAB**. These fields are mandatory at all times.

**ADAMS 4.0**

Since ADAMS 4.0 - effective 1 Jan 2015 - the SampleAB can assume the values A, B, B1 and B2. In conformance with the Code 2015 - clause 2.1.2, ADAMS needs to account for the possibility of splitting an athlete’s B sample into two bottles – a B1 & B2 sample – and to allow the Labs to differentiate and to report the results accordingly after their analysis.

**FAQ**

*Is it possible that two (or more) different laboratories are entering the exact same sample code/type in ADAMS? How can I enforce the creation in that case?*

Yes, nowadays it is very well possible in practice that duplicate sample codes exist, since there are different manufacturers who have their own numbering system. It could occur that coincidentally the same number is used by one or more of these manufacturers.

ADAMS checks on duplicate entries of analytical results whenever they are created. Upon entering a sample code in ADAMS where this code already exists in ADAMS, a “possible duplicate”- warning will be displayed, as in the example:

The duplication check is made on a combination of the 5 parameters: Sample Code, Sample type (urine/blood), Sample AB (since release 4.0 A, B, B1 and B2), Lab name and Date received by Lab (since release 3.0). In case the sample code, sample type and sampleAB are the same, but the Lab name or only the Date received by Lab is different, it is possible to enforce the data-entry of your result. Simply clicking on the Save-button on top of the page and disregarding the warning message would suffice.

Data-entry will be hampered though and prevented by ADAMS if the same lab enters the same sample code/type and same Date received (assuming it is not the B, B1 or B2 sample).

**Analysis contracted to 2 Labs - how to report?**

It is possible that a TA has contracted the analysis of the sample to 2 different Lab, for example lab A performs the routine
4. If a corresponding DCF exists in ADAMS for this sample, then using the **Auto-complete** button automatically retrieves certain data from this DCF and populates this into the lab result form. Verify that the data copied is accurate and add other additional information.

(fields copied are: Mission order #, Sample collection date, country/region/city, Lab, TA, SCA, RMA, Test type (in/out of competition), Sport/discipline, Gender)

If no Auto-complete is used:

5. Enter a Lab reference number (this could be the Client's Batch ID#) and Mission Order number if relevant.

6. Fill in the country, region and city for the sample collection.

7. Fill in the **Sample Specific Gravity (Initial Testing Procedure)**, **Sample Specific Gravity (Confirmation Procedure)**, **pH** and **validity**.

**ADAMS Release 7 May 2019:**

- the field **Specific gravity** is renamed into **Sample Specific Gravity (Initial Testing Procedure)**
- the field **Sample Specific Gravity (Confirmation Procedure)** is added: when a Urine Lab/EQAS result is Saved in the Submitted or Partially submitted status with a date_received that is equal to or greater than **1 March 2019** with a Test result = AAF/ATF, it is mandatory to provide a value in the field Sample Specific Gravity (Confirmation Procedure) for that result. In all other cases it is optional to provide a value in the field Sample Specific Gravity (Confirmation Procedure). This applies to all Urine A/B/B1/B2 samples.
- the field **Sample Specific Gravity (Confirmation Procedure)** is different from and functionally NOT related to the existing field **Confirmed specific gravity** that is exclusively associated with the Steroid Profile.

**ADAMS 4.1/4.1.1**

For samples with a date received after **16 March 2016** the validity will be calculated automatically based on the microbial contamination markers

8. Enter the date the sample was received at the Lab, and (optionally) the Date Results reported and the Analysis Date & time.

(The **Date Results reported** indicates the date of your submission through ADAMS and thus the date that the sample analysis results were reported to the TA. So it does not refer to the date the entry was made in ADAMS (this date of entering the record into ADAMS can be verified from the Activities tab). The **Analysis date** relates to the date when the initial analysis of the sample starts).

9. Specify the **mandatory Testing Authority (TA)** and the **optional Result Management Authority (RMA)**.

**ADAMS 4.0**

As of Release 4.0 - effective 1 Jan 2015 - in pursuance of the International Standard for Laboratories 2015 (ISL) clause 5.2.6.6, the field Result Management Authority is to be added on the Lab pages in ADAMS (Lab result/EQAS/BPLR) as an optional field and the Testing authority as a mandatory field to allow Labs to report this information. In addition, the IST 2015 dictates that the RMA should become a mandatory field on the Doping control form (DCF). The TA is already a mandatory field on the DCF.

The RMA's role in the process and access rights are re-instated in order to follow up as per their results management duties. They will receive the ADAMS notification(s) for all laboratory results: Adverse Analytical Finding (AAF), Atypical Finding (ATF) and Negative laboratory results The TA is the organization that authorized the test(s) and will retain view-rights to the results as well as the right to receive the notifications. International Federations are notified automatically for AAFs based on the sport, as in previous versions of ADAMS.

The field Creator is a READ-only field displaying the organization that created the Lab Result record.

**If the client organisation is not listed and selectable in the Testing Authority pick list, whom should be contacted?**

Whenever you deal with an IF, NADO or NF as Testing Authority that has not been recorded in ADAMS, please let us know at adams@wada-ama.org, so we could add this organization in ADAMS allowing you to proceed with the reporting of the results.
10. Specify the **Sample Collection Authority (SCA)** which has become **mandatory** as of ADAMS 3.1.

The IST states that both the SCA and TA fields are mandatory and therefore your clients will be expected to provide TA and SCA designations on their DCFs and/or ADAMS. It is our understanding that the SCA is always known based on the physical sample and DCF received.

11. Select who should be notified with the results in the **Send Notification of results to** box. [WADA, TA are automatically notified; IF as per ISL only for AAF results]. Click on the magnifying glass icon to search.

12. Select the **test type** – In or Out of Competition and the **Gender**. If In-Competition is selected, a text box for the Competition Name appears.

13. Fill in the **Sport/discipline**. This field is populated by searching for the relevant sport/discipline from the database. Enter at least three letters from the desired sport name. Click on the magnifying glass icon to search. Select your Sport/Discipline from the pop up window.

14. Fill in the **Test result**. The **Test result reason** text box can be used to detail an explanation, e.g. in case the sample has not been analyzed (status entered as "not analyzed") or when an ATF turns into an AAF.

   Possible values for a **Test result**:
   - **Negative**: The analysis did not reveal a prohibited substance or high T/E ratio.
   - **AAF**: Adverse Analytical Finding. A prohibited substance or metabolite or maker was found
   - **ATF**: Atypical Finding. When further investigation is needed
   - **Not analyzed**

15. Specify the **Type of analysis**.

**ADAMS 4.0/4.1**

For Blood – GH Isoforms, GH Biomarkers, Blood Transfusions, HBOCS, ESAs (incl. recombinant EPOs and analogues), Insulins, IGF-1 analogues, Other;

For Urine - ESAs (incl. recombinant EPOs and analogues), GC/C/IRMS, Insulins, GHRF (GHS/GHRP), GHRF (GHRH), IGF-1 analogues, GnRH, OTHER.

For Urine samples with a date received **before** 1 Jan 2016: When a GC/C/IRMS analysis is done, the user will have to declare if the results are consistent with the administration of exogenous steroids.

- [ ] The GC/C/IRMS results are consistent with the exogenous origin of the target compound(s)
- [ ] The GC/C/IRMS results are inconclusive or do not indicate an exogenous origin of the target compound(s)

[When importing lab results: If the result is AAF or ATF then the first checkbox will be ticked automatically. If the status is negative, then the 2nd checkbox will be ticked.]

**ADAMS 4.1/4.1.1**

Labs are able to provide more information on the IRMS-reporting for samples with a date received **after 1 Jan 2016**:

- **values of IRMS Target Compounds, and associated uc**: this information is mandatory for at least one Target Compound

- **values of Endogenous Reference Compounds, and associated uc**: one is mandatory (preferentially PDiol)

- **IRMS Comments**: free text (optional); if as a TC the option "Other (specify in comments)" is selected, the description can be stated here

  - TC = ERC – TC: is automatically calculated and displayed
Labs are able to indicate a dedicated **Overall IRMS conclusion** irrespective and independent from the overall Lab test result.

This to address the following problem cases: Lab has detected a prohibited substance (e.g., S1.1A Exogenous AAS/clostebol) and intends to report this finding as an AAF in ADAMS. In addition, an IRMS analysis was performed and values for the TC/ERC were determined. The IRMS-conclusion however was Negative or ATF (inconclusive). Similar for other combinations such as Negative or ATF for the Lab result, whereas the IRMS proves to be an AAF.

If one of the first three options (Negative, AAF, ATF) is ticked, it becomes **mandatory** for the user to enter at least one TC/ERC value in the dedicated section. When the Lab result is Saved in the (Partially) submitted status, the system will check if the selected Overall IRMS-conclusion matches the ‘highest level’ of result inferred from the TC/ERC (precedence of severity is AAF>ATF>Negative). Otherwise an error message will be prompted.
16. If applicable, enter details about the analysis in the **Analysis Details/Explanation/Opinion** text box.

17. On the Lab result/EQAS page the Lab user may indicate the **capabilities and methods** that were used when analyzing the sample.

Select the **Capability and method(s) used**: 

In the selection list the table will appear of the Lab capabilities/methods with their ISO Code and Description as they are pre-defined from the Admin-backend (see **1. Configuration ADMIN BACKEND** on how to pre-define these). A free-text comments field “*The sample was analysed using Laboratory test method(s):*” is also available:

18. For **Urine** samples the details regarding the **LH-Analysis** can be provided:

**Release June 2018**

According to the section 5.2 of WADA’s Technical documents for Labs - **TD2018CG/LH** - “The Laboratory shall report the measured concentration of total LH when the Initial Testing Procedure produces a Presumptive Adverse Analytical Finding (PAAF), i.e. if the total LH concentration (after adjustment if urine SG is greater than 1.020) is greater than 60 IU/L when using the Immulite assay or greater than 40 IU/L when applying the Delfia assay. In cases when LH is not detectable, the Laboratory shall report the finding as “the concentration of LH was less than the limit of detection (LOD)” and specify the applicable LOD”.

This LH-reporting takes effect on 1 March 2018 for the Labs (in ADAMS as per Release June 2018).
The default value is No LH-Analysis performed. In the PDF Test report the LH-Analysis states No LH-Analysis performed.

- If Negative is selected, either the 'Concentration (iU/L)' or the 'LOD (iU/L)' can be entered or none. A value entered for the LOD implies that the "concentration of LH was less than this specified LOD" - in the PDF Test report the LH-Analysis states Negative - below LOD. For a value entered in the 'concentration' the PDF Test report states Negative - xx IU/L for the LH-Analysis. If no values are entered in neither the 'Concentration' nor the 'LOD, the PDF Test report states Negative for the LH-Analysis.

- If PAAF is selected, a 'Concentration (iU/L)' is mandatory when the result is saved in the Partially submitted or Submitted status. The PDF Test report states ATF - xx IU/L for the LH-Analysis.

- If ATF is selected, a 'Concentration (iU/L)' is mandatory when the result is saved in the Partially submitted or Submitted status. The PDF Test report states ATF - xx IU/L for the LH-Analysis.

- The input value for concentration or LOD has to be numeric: a positive integer or a number with 1 digit after decimal point. E.g. 3, 2.0

- Applicable to Urine samples of all Sample AB types A, B, B1 and B2

- Locked results: LH-Analysis details can be added on locked results if they didn’t exist before (existing details however can not be modified)

19. To add a metabolite and/or prohibited substance click on the Add Substance button, and select the required Class. The substance is mandatory when a substance class is selected. Click on the Add Metabolite to detail possible associated metabolite(s), and enter the appropriate information. If more than one prohibited substance and/or metabolite is to be reported, then click on the Add Substance and/or Add Metabolite button to detail each finding.

The Only metabolite(s) checkbox can be checked to indicate that only metabolite(s) were detected during the analysis (not the parent). This will be explicitly reflected as such and clearly stated in the pdf Test report (produced by dint of the Print analysis result record button). When the box is checked, at least one metabolite in combination with a substance/class has to be specified at the time of (partial) Submission.
20. If a specific so-called **Threshold substance** (e.g. “morphine > DL of 1.2 µg/mL”) is selected when Adding a substance in the previous step, then automatically the concentration/uncertainty section appears, which can be completed:

21. For the reporting of **Steroid Profiling** data (endogenous steroids) on Urine samples a dedicated section can be used. It allows for reporting on the:

- Presence of **microbial contamination**
- **Steroid Profile Variables**
- Presence of **Confounding Factors**
22. To enter data for the Monitoring program use the indicator *Analysed for Monitoring program* and enter the substances and estimated values. Multiple substances can be added, as well as the *Comments to the sample* which relates to the sample as a whole.

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**Steroid Profile Data**

<table>
<thead>
<tr>
<th>Microbial contamination</th>
<th>Initial values</th>
</tr>
</thead>
<tbody>
<tr>
<td>5αAND/A</td>
<td></td>
</tr>
<tr>
<td>5βAND/Etio</td>
<td></td>
</tr>
</tbody>
</table>

**Steroid Profile Variables**

<table>
<thead>
<tr>
<th>Steroid</th>
<th>Initial values</th>
</tr>
</thead>
<tbody>
<tr>
<td>5α-androstenediol</td>
<td>ng/mL</td>
</tr>
<tr>
<td>5β-androstenediol</td>
<td>ng/mL</td>
</tr>
<tr>
<td>androsterone</td>
<td>ng/mL</td>
</tr>
<tr>
<td>epitestosterone</td>
<td>ng/mL</td>
</tr>
<tr>
<td>etiocholanolone</td>
<td>ng/mL</td>
</tr>
<tr>
<td>T/E</td>
<td></td>
</tr>
<tr>
<td>testosterone</td>
<td>ng/mL</td>
</tr>
</tbody>
</table>

**Presence Confounding Factors**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Initial values</th>
<th>Est. concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Glucuronid</td>
<td>○ Y ○ N</td>
<td></td>
</tr>
<tr>
<td>Ketoconazole or similar</td>
<td>○ Y ○ N</td>
<td></td>
</tr>
<tr>
<td>5α-reductase inhibitors</td>
<td>○ Y ○ N</td>
<td></td>
</tr>
<tr>
<td>Heterodimetric hCG</td>
<td>○ Y ○ N</td>
<td></td>
</tr>
<tr>
<td>Anabolic Steroids</td>
<td>○ Y ○ N</td>
<td></td>
</tr>
<tr>
<td>Masking agents and diuretics</td>
<td>○ Y ○ N</td>
<td></td>
</tr>
</tbody>
</table>

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**ADAMS 4.1 and 4.1.1**

- The Urine lab results validity is automatically calculated based on *microbial contamination markers 5αAND/A and 5βAND/Etio*: these fields are **mandatory** if the date received of the sample is after 16 March 2016.
- As per ITP, the *presence/absence of confounding factors* can be indicated; this information is **mandatory** for Urine samples *if the date received of the sample is after 1 January 2016*. When mandatory, the information has to be indicated for all confounding factors. If the Estimated concentration of the confounding factor *Ethyl Glucuronid* is above 5 ug/mL, this concentration value should be stated.
- If the gender in a Urine Lab result is Female or X (non-Male), the confounding factor hCG should not be mandatory for A, B, B1 and B2 samples. This holds for both the Initial and Confirmed value. If the hCG initial = yes for the Female athlete, there is no need to provide a confirmed value.
- For the **Confirmation Procedure** for the steroid profile, the values for the *microbial contamination markers* and those *confounding factors* that were detected during the initial testing procedure, have to be confirmed. Also see Lab Result Confirmation Procedure.
The right to enter Monitored data needs to be included in your user account profile (see the section Appendix B - Reporting Monitoring data).

23. The default Status when creating a new lab result, is "Not Submitted".

Possible values for the Status:

- **Not submitted**: This means that the result can be saved in ADAMS, but is not yet available to the Testing Authority. Mandatory fields can be left blank when saving, except for the Sample code field.
- **Submitted**: Once all analysis' are complete and ready to be submitted to the Testing Authority. All mandatory fields need to be filled out.
- **Partially Submitted**: Not all analysis' are completed [e.g. some tests are in practice so expensive that the lab waits until there are enough tests to run for the economy-of-scale]. All mandatory fields need to be filled out.
- **Cancelled**: nothing can be changed

In the Status reason field the actual reason and need for modifying the value should be entered (for new records there is no relevance). The main idea of having a 'reason' to be entered is for safety purposes to ensure that neither a test result nor a record status value can be selected by mistake and then saved. The consequences of an accidentally wrongly selected 'AAF/ATF' or 'submitted' could be far-reaching, more so in legal disputes.

24. If you are ready to record the result, click on the **Save** button.

25. Using the **Print Analysis Results record** button prints a PDF report of the analysis results that is formatted like a test report. You may use this function for: printout for your own records or QC, a full test report to include in Documentation Packages, a print out to send to clients not yet utilizing ADAMS. It indicates who/when has submitted the results and performed the print: Submitted on; submitted by.

26. If desired, Use the **Notify** button to notify other ADAMS-users within or outside your Lab

27. If desired, use the **Print**-button to print the entire sample information, in other words to create a hardcopy of the Lab result record as it is shown on the screen (page being displayed, related data in the database including data under the Tabs). It is recommended to print in View-mode and not the Edit-mode.

When you save a Lab result for the first time, the **Activities tab** will be enabled.

Via this Activities tab you can attach any files, i.e. reference documents or publications for the attention of the TA client. For full details see the section Attaching Files in ADAMS.

This Activities tab also tracks the creation of and amendment to each record in the system, so that by clicking on an Activity tab you can get an overview of the history of a specific lab result record. The Activity tab only stores one entry per day and it will reflect the last activity to a record for each day that there was activity to track.

Please note that the Lab results entry form does accept ASCII inputs for , Ø, ß, <, etc. You may verify the relevant ASCII codes in any word processing program. For example in MS-Word you could look under Insert – Symbol — subset Basic Greek. You could simply use the copy/paste operation.

**Standard urine test and EPO urine test are usually reported at different times. How should I report in ADAMS?**

If Standard urine test and EPO and IRMS results are available at the same time then the findings can be reported into ADAMS all at once (both EPO and IRMS checkboxes can be ticked - they are not mutually exclusive). If reporting the findings separately, e.g. standard results first and EPO and/or IRMS later, then choose Partially Submitted until all data is in. It is recommended that the Laboratory includes the reason for the partially submitted data in the test reason field (e.g. awaiting EPO test results to be reported at a later date). When 'Partially submitted' and Saved, the TA in question gets an automatic notification upon the result matching with the DCF. In second instance, after the match, when you would like to modify the result for the EPO-result, simply use the Edit-button and add the EPO-result. Set the status to 'Submitted' and Save. Again the TA gets automatically notified.
Where do I provide comments on the result in ADAMS?

- Analysis details/Explanation/Opinion

Any specific details on the analysis activities. Examples include the ISO methods utilized, integrity statement etc. It is a free text box to allow flexibility for the labs to enter additional and perhaps unique data required by their clients on the sample or general comments on the analysis. This comment is also printed on the Test Result Report. One Example below:

```
Analysis Details / Explanation / Opinion
Details de l'analyse / Explication / Opinion:
- The sample was correctly sealed
- The sample was analyzed using validated methods. (ANAL-09, ANAL-12, ANAL-15, ANAL-37, ANAL-35, ANAL-108, ANAL-42, ANAL-97)
```

- Details concerning the finding

A free text box to allow flexibility for the labs to enter additional analysis details for e.g. each AAF (especially in cases of multiple findings). This can include MU details, statements about metabolites and possibilities of administrations, for IRMS can include the specific analyte (ERC, A, E, etc) findings, etc. This comment is not part of the Test Result Report.

When printing or creating a pdf, even when we reduce the format of the page to 80%, the right side of the page does not appear?

If you select the "Page Setup" option from the Internet Explorer "File" menu, it will open a window where you can define your left and right margins (in the "Margins" section). It is preferable to set your margins 10 millimeters. This should avoid truncation of the right part of the page; otherwise you may need to change the settings of your printer.