	Standard Operating Procedure Data and Audit Trail Review in Agilent OpenLabs Software		SOP Number D-804	Revision 1
			Effective Date 06/02/25	Page Page 1 of 6
Written by/ Date MSM 01/16/25		Reviewed by/ Date AJS 01/17/25		Approved by/ Date Jec 01/27/25
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1.0 Purpose

The purpose of this procedure is to define the process and criteria for reviewing audit trails in Agilent Open Labs data collection software. This SOP also defines how electronic data is stored and archived.

2.0 Scope

The procedure governs electronic data and audit trails created by Open Labs software used in the Quality Control Laboratory.

3.0 Responsibility

- 3.1 It is the responsibility of QC analysts to ensure all generated data meet GMP requirements.
- 3.2 It is the responsibility of data review analysts or other qualified individuals to review data and sign notebooks/electronic data and/or audit trails.
- 3.3 It is the responsibility of QC Laboratory Management to keep this procedure current with the latest Ion Labs Practices.

4.0 Definitions

- 4.1 **Data Integrity** – completeness, consistency, and accuracy of data
- 4.2 **Audit Trail** – a secure, computer-generated, time-stamped electronic record that allows for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record. Audit trails include those that track creation, modification, or deletion of data (such as processing parameters and results) and those that track actions at the record or system level (such as attempts to access the system or rename or delete a file)

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4.3 **Agilent OpenLabs Software** – chromatographic data acquisition system (CDS)

5.0 References

5.1 D-807, HPLC Operation Maintenance and Qualification

5.2 D-808, SOP, Use of OpenLab for HPLC and GC Data Acquisition and Reporting

6.0 OpenLabs Audit Trails and Electronic Data Review

6.1 OpenLabs Audit Trails are only to be reviewed by qualified personnel.

6.2 OpenLabs Audit Trails are to be reviewed for each analytical run, regardless of data disposition.

6.3 OpenLabs Electronic records should be reviewed for all settings used to acquire data along with settings for data processing.

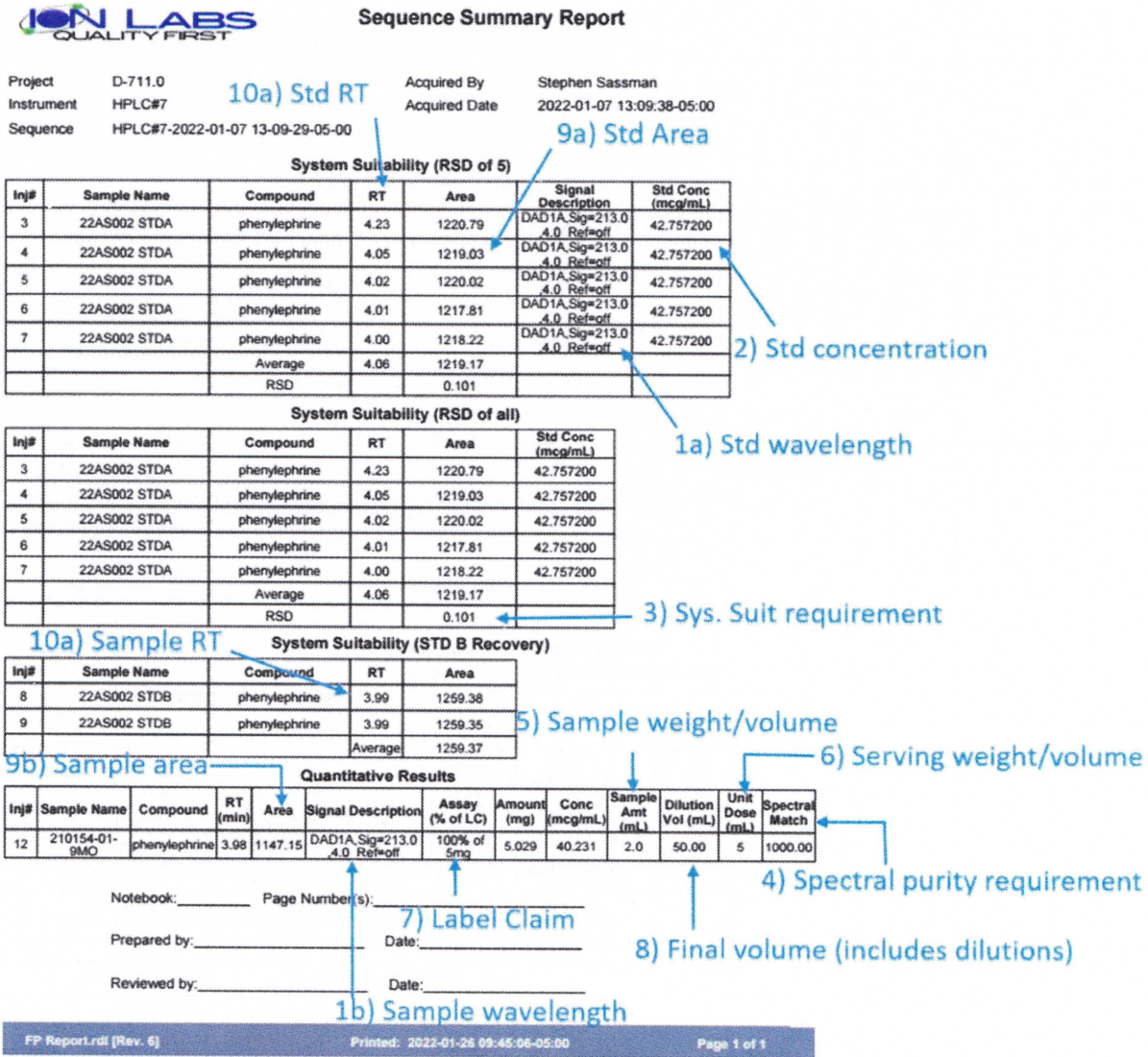
6.3.1 Acquisition settings should be reviewed against the appropriate testing methods to ensure all method settings were followed.

6.3.2 Settings used for data processing should be evaluated to ensure data integrity was not compromised and no data was manipulated, i.e. are the integration events justified.

6.3.3 Manually entered data such as dilution factors, sample weights, standard concentrations, etc, should be evaluated against notebook write-ups for accuracy.

6.3.4 OpenLabs data reports should also be reviewed for accuracy prior to approving. Figure 1 shows a sample summary report from Open Labs.

Figure 1 Example OpenLabs Data Report



6.4 System Audit trails

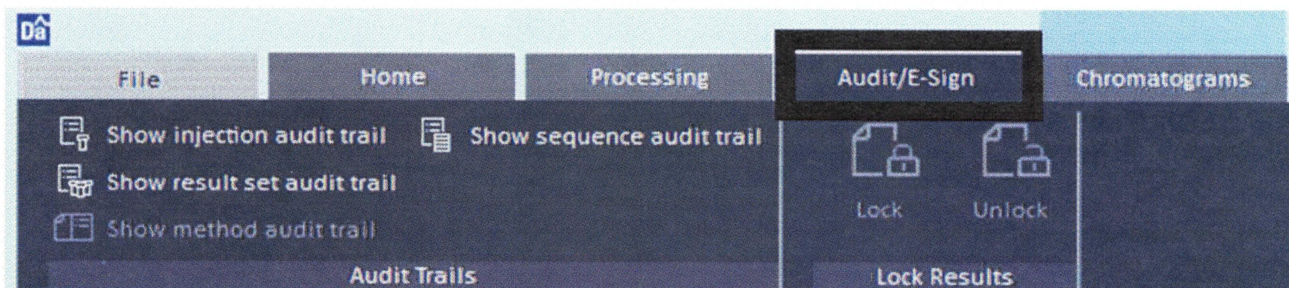
6.4.1 A “global” audit trail exists in the content management server. This collects information on a broad scale such as:

6.4.1.1 System logins, opening of projects, creation of projects and other global transactions

6.4.1.2 These can be accessed by logging in to the content management system and clicking on “Activity Log.”

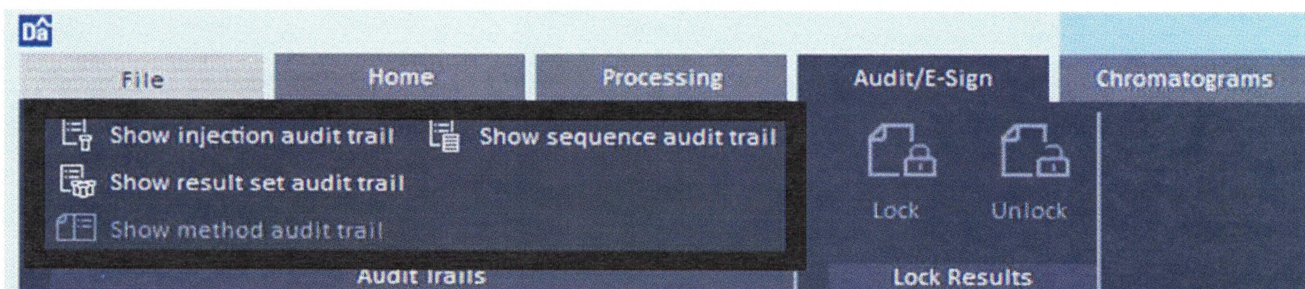
6.4.2 Method audit trails exist in the data analysis window of the open lab application.

6.4.2.1 After opening the project and data set that is to be reviewed, click on the Audit/E-Sign tab at the top of the page.



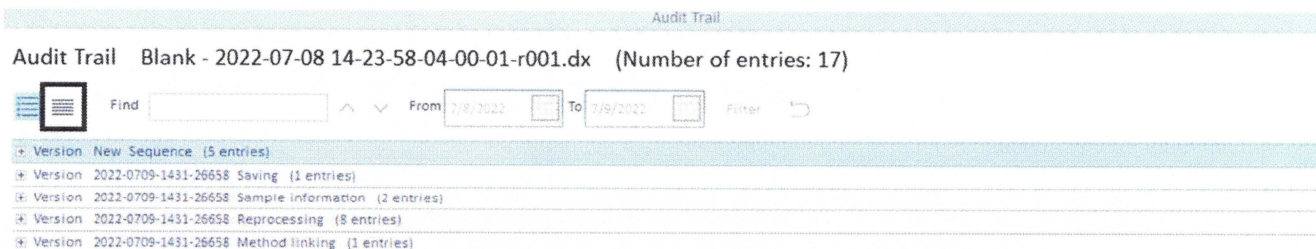
6.4.3 Result audit trails are mandatory and will always be included however depending on the method set up parameters audit trails may include:

1. Injection audit trail
2. Sequence audit trail
3. Result audit trail
4. Method audit trails.

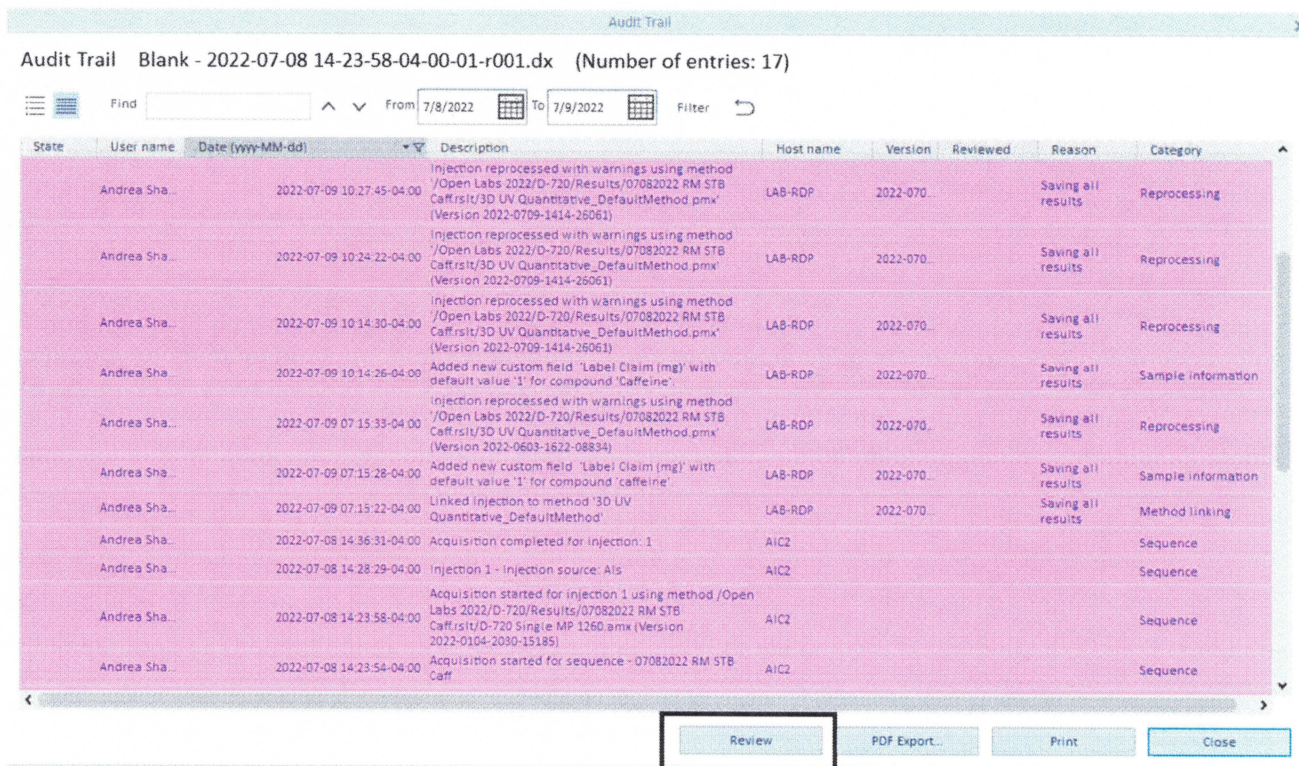


6.5 Reviewing audit trails

6.5.1 After loading the audit trail to be reviewed, click on the detailed view list.



6.5.2 Review audit trails by individually inspecting each entry, scrolling down to the bottom of the list. Click review at the bottom of the list to notate the audit trail as reviewed.



6.5.3 Audit trail review should include evaluation of what process occurred and the rationale for each process.

6.5.4 Audit trails that are reviewed change from pink to gray.

7.0 Creating Projects, enabling audit Trails

7.1 Projects in the Open Lab software can be created by following these steps:

7.1.1 Open the control panel and navigate to the projects tab

7.1.2 Right click on the project icon and select create project

7.1.3 Alternatively, you can click on the create project icon on the top left hand corner of the screen.

7.1.4 In properties, enter project name and desired project folder path. If desired, add a description.

7.1.5 In CDS settings under audit trail settings, click the box next to “Allow users to type in their own reason when saving”).

7.1.6 In each sub-section in audit trail, click the boxes to enable audit trail and allow users to type their own reasons when saving results

8.0 Archiving OpenLabs Data

8.1 Open Labs data will be archived at regular intervals, minimally every two years.

8.2 New Data Acquisition Projects should be created on an annual basis.

9.0 Revision History

Revision	Date	Description of Changes	CCR	By
0	09/23/22	New procedure.	N/A	J. Sassman
1	01/16/25	Updated flow and section names of document for clarity Removed Form D-804-F1	CC-25-0021	M. Maples