COLLEGE of AMERICAN PATHOLOGISTS

Laboratory Quality Solutions

In Vitro Diagnostic (IVD) Test Data Coding Quality Assurance Program

User Guide

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1. INTRODUCTION

1.1 About the IVD Test Data Coding Quality Assurance Program

Background

The clinical laboratory community recognizes that there is a need to improve test result data representation and help achieve clinical interoperability.

To address this need, the College of American Pathologists (CAP), in partnership with the Food and Drug Administration (FDA), created the In Vitro Diagnostic (IVD) Test Data Coding Quality Assurance Program (the QA Program). The program is based on the work of the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) initiative and utilizes the Laboratory Interoperability Data Repository (LIDR).

About SHIELD

SHIELD is a public-private initiative to develop policies and models to overcome laboratory test result interoperability barriers.

SHIELD's vision is to describe the same test, the same way, everywhere in the healthcare ecosystem. This includes:

- Consistent identification and description of IVD laboratory data and their attributes.
- Secure description of patient information that allows effective use while protecting patient privacy.
- Consistent interoperability across all applicable information technology systems from the point of order through all downstream uses.
- Understandable, reproducible, and usable results for both human and computerized systems.

About LIDR

LIDR is a centralized database housing codes that outline the precise attributes of every IVD test. It acts as a resource for the standardized digital depiction of laboratory tests offered by IVD manufacturers. Moreover, it facilitates mapping to standard coding systems such as Systematized Medical Nomenclature for Medicine–Clinical Terminology (SNOMED CT®), Logical Observation Identifiers Names and Codes (LOINC®), and Unified Code for Units of Measure (UCUM), serving as a crucial reference for test mapping procedures.

The QA Program will monitor a laboratory's test compendium encoding by comparing it to LIDR for their tests and methods.

1.2 QA Program Data Flow

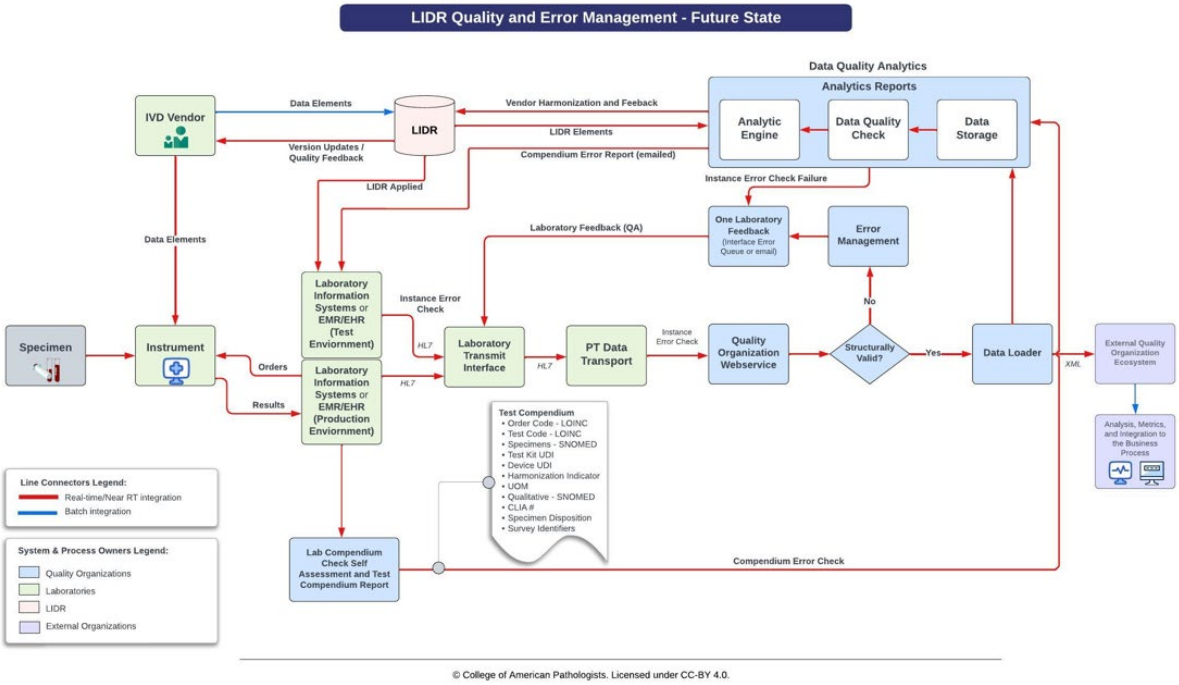
The data flow in the program follows these basic steps:

1. The IVD vendor provides test coding: The IVD vendors provide specific and unique coding for any test being performed in a clinical laboratory to the LIDR Administrator. LIDR is curated and serves as a resource, storing the data elements for all clinical laboratory tests. It is based on the input from the IVD manufacturers who are experts on their tests and methods.
2. Laboratory encodes LIDR data elements: The laboratory applies LIDR data element coding to the laboratory information system (LIS), so when any test results are entered into the LIS, unique data elements exist and are embedded in the Health Level Seven (HL7®) message when results are electronically transferred to an outside system.

3. Laboratory performs the Instance Error Check: Working in the test environment of the laboratory's LIS, the laboratory orders and results a test simulating a proficiency test (PT) sample. Once the result is entered in the LIS, the results are sent from the LIS to the laboratory transmit interface.
4. Laboratory transports results to quality organization: The laboratory interface engine transmits the results to the quality organization interface engine.
5. Quality organization checks encoding accuracy: The quality organization checks the accurate encoding of tests by receiving HL7 messages and test compendium reports from QA Program enrolled laboratories, which are validated for accuracy by comparison to LIDR. Validation will identify any issues and return an error to the performing laboratory that will include any of the elements that do not match what is expected.

Figure 1 illustrates the data flow of the QA Program.

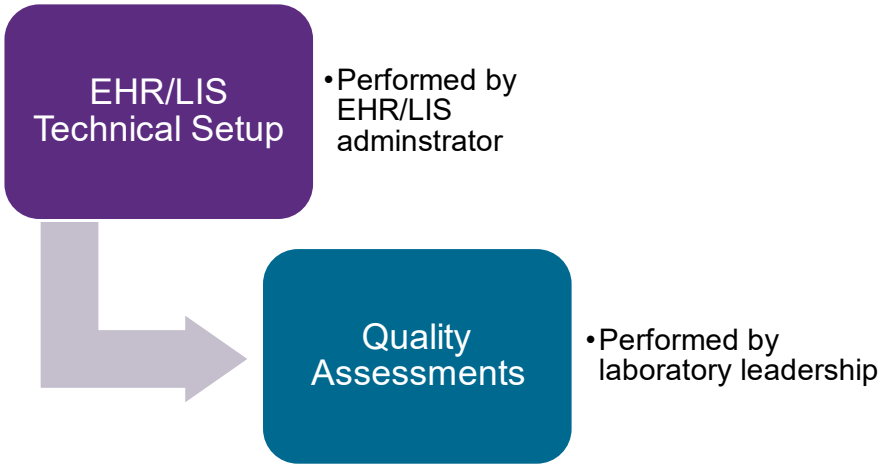
Figure 1: LIDR Quality and Error Management – Future State



1.3 QA Program Responsibilities

Figure 2 shows the two areas of responsibility for the QA Program.

Figure 2: Areas of Responsibility



1.4 About This Guide

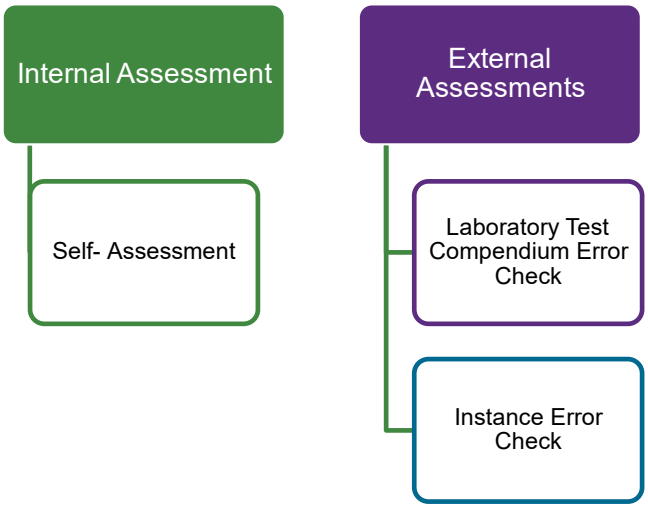
This user guide contains instructions for performing quality assessments. An e-learning course is available to support the contents of this user guide. A technical guide is available for electronic health record / laboratory information system (EHR/LIS) technical setup required for participation in the QA Program.

2. QUALITY ASSURANCE (QA) ASSESSMENTS

2.1 Overview of QA Assessments

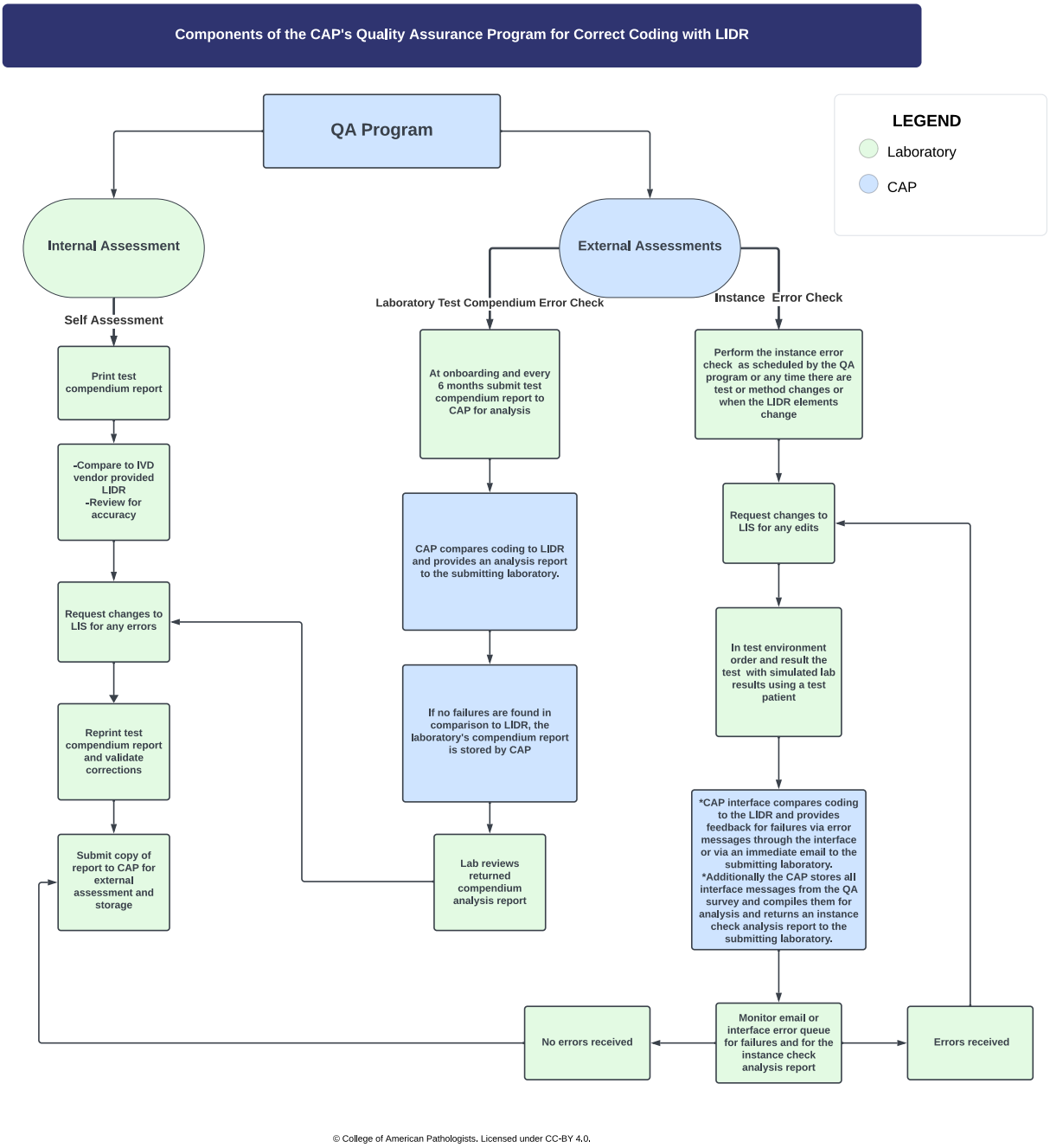
After the laboratory administrator has encoded the LIDR data elements and created the new test result interface, the laboratory leadership team should perform QA assessments to ensure that the system has been configured correctly. As illustrated in Figure 3 below, there are two categories of QA assessments: internal and external.

Figure 3: QA Assessments



A laboratory performs its own internal assessment (i.e., self-assessment). A quality organization (e.g., the CAP) performs external assessments as part of the laboratory's QA Program subscription plan. Figure 4 below illustrates the detailed workflow for the different quality assessments.

Figure 4: QA Assessment Workflow

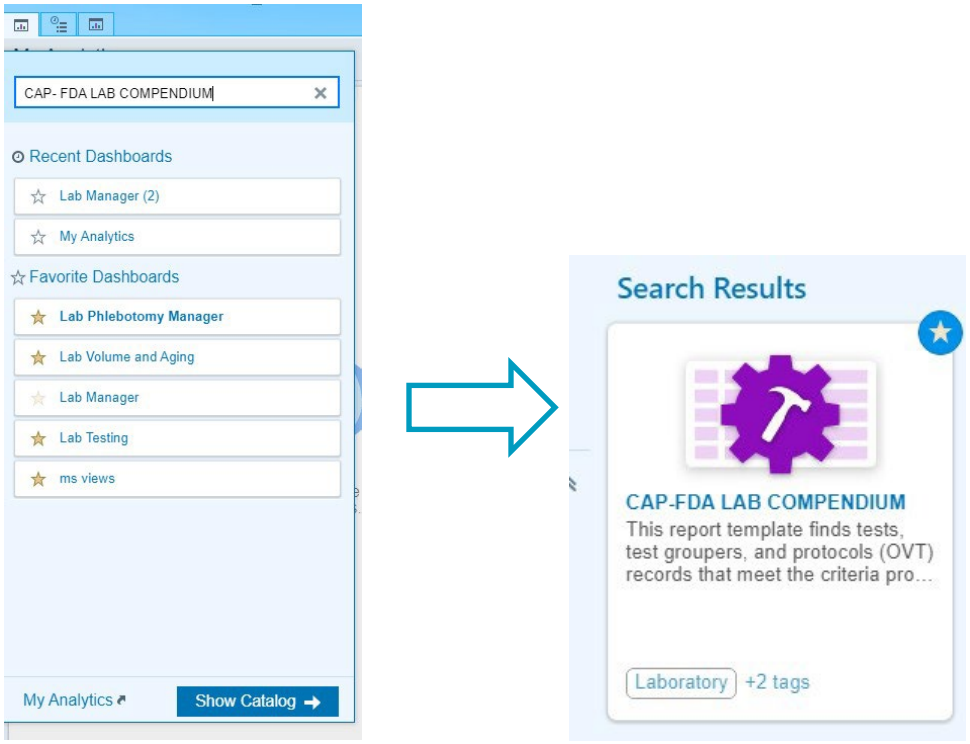


2.2 Self-Assessment

To perform a self-assessment, the laboratory first generates a LIDR Test Compendium Report, then validates that the LIDR data elements have been correctly encoded. A LIDR Test Compendium Report will be pulled by the laboratory as part of the QA process to assess the accuracy of coding in the LIS and EHR as compared to the expected coding from the LIDR files. The purpose of the compendium check is to ensure that the codes are valid and updated when new LOINC and SNOMED CT versions are released. Minimally, the self-assessment should be performed every six months for the QA Program and then submitted to the CAP.

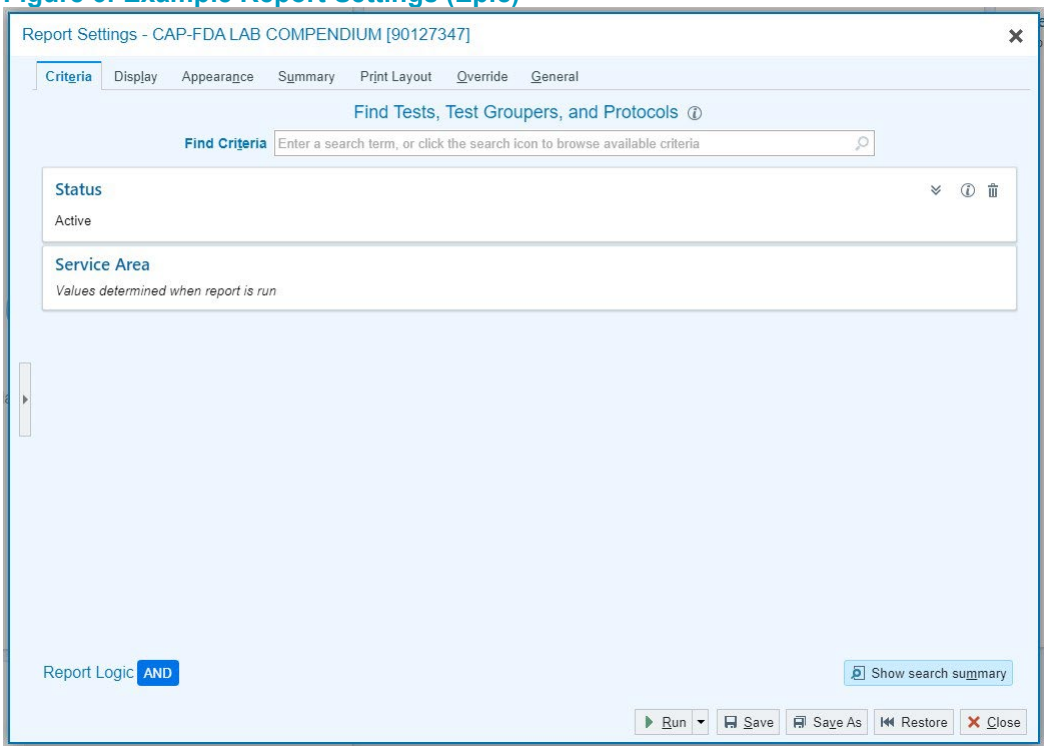
Step #	Instructions
1	Search for the LIDR Test Compendium Report in your laboratory's LIS. The example in Figure 5 below shows a report named "CAP-FDA LAB COMPENDIUM" in an Epic® system. The search method and name of the report may be different in your laboratory system.
2	Edit the report as needed.

Figure 5: Example Report Search (Epic)



Step #	Instructions
3	In the report settings, update the search criteria before selecting “Run”. See Figure 6.

Figure 6: Example Report Settings (Epic)



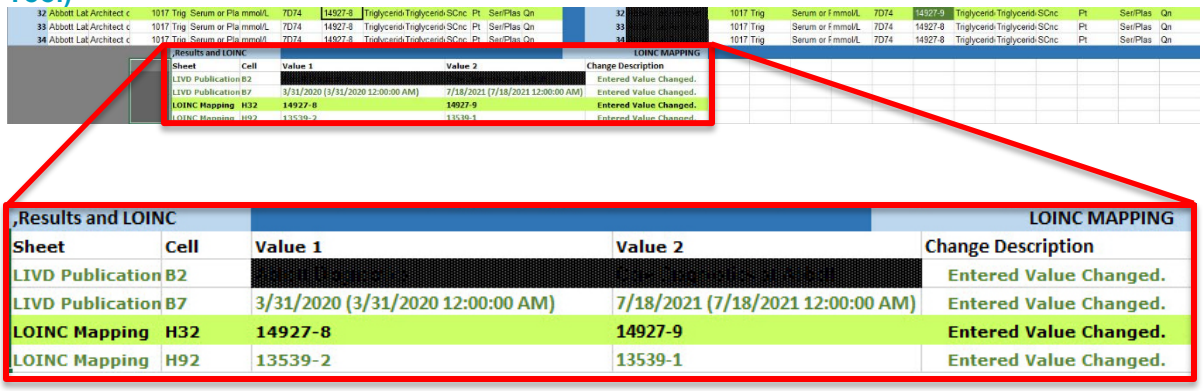
Validate the LIDR Data Elements and Modify

After generating the report, the laboratory should validate that the LIDR elements have been encoded correctly for each test resulted by the laboratory. This step should be completed by the laboratory staff responsible for submitting the LIDR elements to the LIS analysts for build.

Step #	Instructions
1	Compare the report to the IVD vendor supplied LIDR. Validate that the report matches the IVD vendor-supplier LIDR coding for the entire test compendium of the laboratory.

Step #	Instructions
2	It may be possible to automate the comparison by utilization of the Excel "Compare" tool if the format of LIDR and the laboratory generated LIDR Test Compendium Report are formatted exactly the same way (e.g., the column headers and rows contain the same information in both Excel spreadsheets). See Figure 7. As you can see, there is a discrepancy in the LOINC code mapping.
3	If there is a discrepancy, request modifications by an LIS analyst following your organization's request process.

Figure 7: Example Comparison of LIDR and LIDR Test Compendium Report (Excel "Compare" Tool)



,Results and LOINC				LOINC MAPPING
Sheet	Cell	Value 1	Value 2	Change Description
LIVD Publication	B2	[redacted]	[redacted]	Entered Value Changed.
LIVD Publication	B7	3/31/2020 (3/31/2020 12:00:00 AM)	7/18/2021 (7/18/2021 12:00:00 AM)	Entered Value Changed.
LOINC Mapping	H32	14927-8	14927-9	Entered Value Changed.
LOINC Mapping	H92	13539-2	13539-1	Entered Value Changed.

If your lab does not have an automated comparison method, it will have to compare the two documents manually.

2.3 Laboratory Test Compendium Error Check

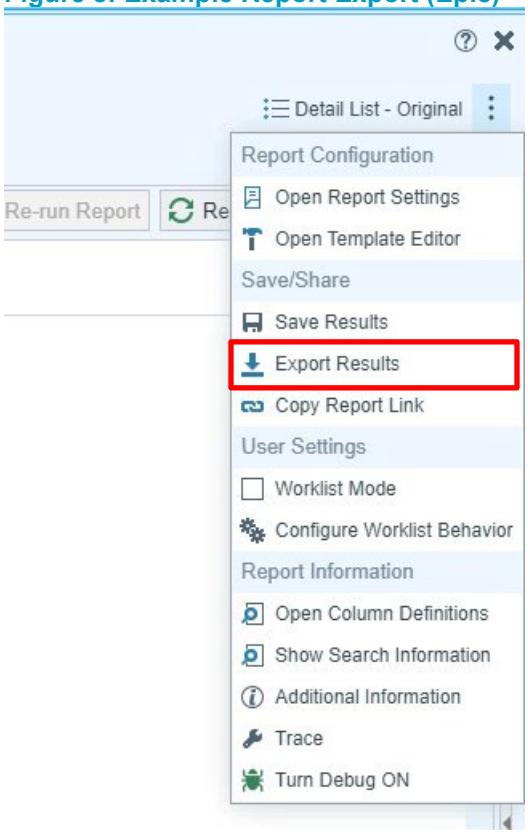
Upon completion of the self-assessment, the laboratory should request an external Laboratory Test Compendium Error Check by the quality organization (e.g., the CAP). A Laboratory Test Compendium Error Check is one of two external assessments the laboratory may request via a QA Program subscription.

Submit the LIDR Test Compendium Report to the Quality Organization for Analysis

The first task is to submit a copy of the LIDR Test Compendium Report to the quality organization for analysis and comparison to LIDR.

Step #	Instructions
1	Export the LIDR Test Compendium Report from the LIS. See Figure 8.

Figure 8: Example Report Export (Epic)



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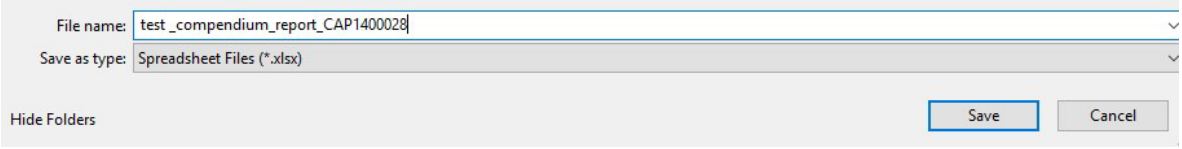
Step #	Instructions
2	Name the file using this format: **test_compendium_report_CAPXXXXXXX**. (The Xs represent the laboratory CAP number). Be sure to use underscores between each word (no spaces). Save the report in Excel spreadsheet format. See Figure 9. **Figure 9: Name and Save File** 
3	Generate an email to FDATestCompendium@cap.org. Include the laboratory CAP number in the subject of the email (i.e., Test Compendium Report CAP #XXXXXXX). Attach the LIDR Test Compendium Report to the email.

Review the QA Analysis Report and Resolve Issues

Through a web-based portal, the quality organization will provide a QA analysis report to the laboratory. The laboratory manager and medical director/pathologists should review this report to ensure that the submitted LIDR codes from the LIDR Test Compendium Report were successful. If there are any issues, the laboratory should resolve them. For more information about using the portal and interpreting reports, see Appendix sections 3.1 “QA Analysis Reports from the CAP” and 3.2 “How to Interpret Your Test Compendium QA Analysis Report.”

Step #	Instructions
1	Evaluate the QA analysis report to ensure that the submitted LIDR codes from the LIDR Test Compendium Report were successful and to determine if any laboratory tests have been encoded incorrectly.
2	Request corrections in the LIS build for unsuccessful test elements (correction requests should be directed to the LIS analysts for resolution).
3	Once corrections are completed, regenerate a new LIDR Test Compendium Report.
4	Resubmit the new LIDR Test Compendium Report to the CAP for reassessment.
5	Repeat Steps 1-4 until all test data elements have been successfully encoded.

2.4 Instance Error Check

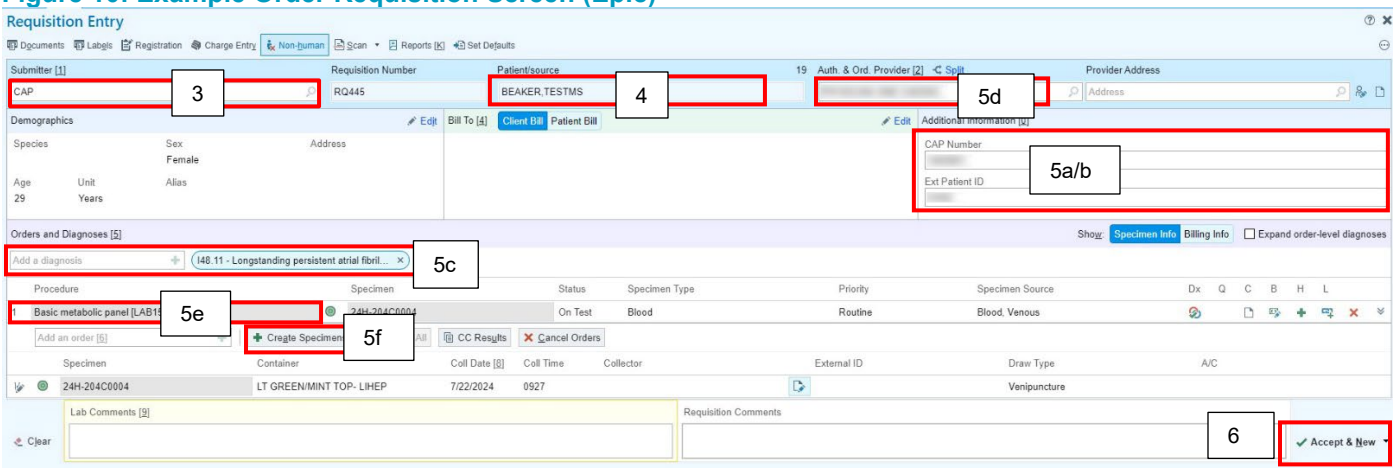
As part of the QA Program offering, the laboratory may subscribe to an Instance Error Check program. On a rotating basis, the laboratory tests are ordered and resulted in the test environment of the laboratory to validate the correct interface mapping, coding, and transmission of their tests. Additionally, before submitting a proficiency testing survey – such as when a new test method or test is added to the laboratory compendium – the laboratory can test their LIDR configuration against the expected LIDR codes curated by the quality organization. This can be done by submitting simulated test results in the test environment.

Register and Order the Test in the Test Environment

The laboratory registers and orders a simulated proficiency test for a test patient within the test environment of the LIS and places an order using the same test orders as they would for a patient sample. In Epic Beaker®, this process involves generating orders using requisition entry. Use the laboratory specific quality organization submitter and a laboratory specific test patient.

Refer to Figure 10 when following the instructions below (the numbers correspond to the steps).

Figure 10: Example Order Requisition Screen (Epic)



Step #	Instructions
1	In Epic Beaker, log in to the appropriate laboratory department in which the proficiency testing is being performed.
2	Open “Requisition Entry”: **Lab** > **Requisition Entry.**
3	In the “Submitter” field, select the submitter for CAP proficiency testing. Use the specific department’s laboratory submitter (e.g., the CAP). Additional fields become available: CAP Number, Specimen ID, and Kit ID (to be completed in step 5 a and b).
4	Search for the laboratory’s proficiency testing patient by name or MRN.

Step #	Instructions
5	Populate requisition fields to generate the order: a. **CAP Number** – The CAP ID associated with the laboratory. b. **CAP Kit ID** – The eight-digit Kit ID specific to the survey. Note: The display example is a generic image and does not show a CAP KIT ID or CAP NUMBER but could have these fields in the area designated as 5 a/b. c. **Diagnosis Code** – You may leave this empty or enter a generic code. d. **Authorizing Provider** – Enter the name of laboratory director. e. **Procedure** – Enter the appropriate orderable test for the PT being performed. Multiple tests can be ordered on this sample if the PT survey utilizes the same specimen for more than one test. f. Select "**Create Specimen"** – Enter the collection details (date/time/collector).
6	Select "Receive/Accept & New".
7	After the order is generated, the "specimen" will be on the laboratory outstanding list and ready to be resulted. Result with any results as you would for a normal patient sample.
8	Once the laboratory results the test in the LIS, the encoded results are sent via an HL7 interface to the quality organization (e.g., the CAP).
9	The results will be evaluated by the quality organization for correct LIDR coding. If there are errors, an email will be returned to the laboratory indicating the failure (see section 3.3 "How to Interpret Your Instance Error Check QA Analysis Report" in the Appendix). In addition, Instance Error Check survey results are stored and compiled with previous submissions to determine progress of correctly encoding laboratory tests with the LIDR data elements.

Resolve Failures from the Instance Error Check

The quality organization compares the test results to the expected LIDR coding previously submitted during onboarding. If there are missing or incorrect codes, an error message may be sent to the interface error queue for that particular interface. Indications of failure may also be sent as an email to the laboratory subscriber with details on the status and any errors detected which need correction.

Step #	Instructions
1	Review the CAP evaluation of your laboratory test results. Figure 11 shows a sample email from the CAP.
2	The expected follow-up from the laboratory is to correct their coding to match LIDR. Send modification requests to the LIS analyst following your organization's request procedures.
3	If the change is due to a new or updated test, file a new LIDR Test Compendium Report to the quality organization for storage and then repeat the Instance Error Check.
4	Repeat the Instance Error Check as needed.

Figure 11: Sample Instance Error Check QA Analysis Email Notification

We have evaluated your kit test result and our findings are below:

Test Ordered LOINC code: 24321-2
Test Ordered Name: Basic metabolic 2000 panel - Serum or Plasma
Date Processed: May 28, 2024
CAP #: 10000
Kit #: 333333

Field	Status	Message
Test Ordered LOINC Code	PASS	
Specimen Collection SNOMED	PASS	
Specimen Source SNOMED	PASS	
Specimen Type SNOMED	PASS	
Test Performed: 2345-7 (Glucose)		
Test Performed LOINC Code	PASS	
CLIA Number	PASS	
SNOWMED	PASS	
UDI Instrument	PASS	
UDI Kit	FAIL	UDI Kit was missing.
Unit of Measure	PASS	
Test Performed: 2951-2 (Sodium)		
Test Performed LOINC Code	PASS	
CLIA Number	PASS	
SNOWMED	PASS	
UDI Instrument	PASS	
UDI Kit	PASS	
Unit of Measure	FAIL	For Unit of Measure, expected 'mmol/L' but was 'mmol/cL'.

For further inquiries, please contact FDATechnicalteam@cap.org .

Step #	Instructions
5	See the Appendix for information on evaluating the Instance Error Check QA analysis report.

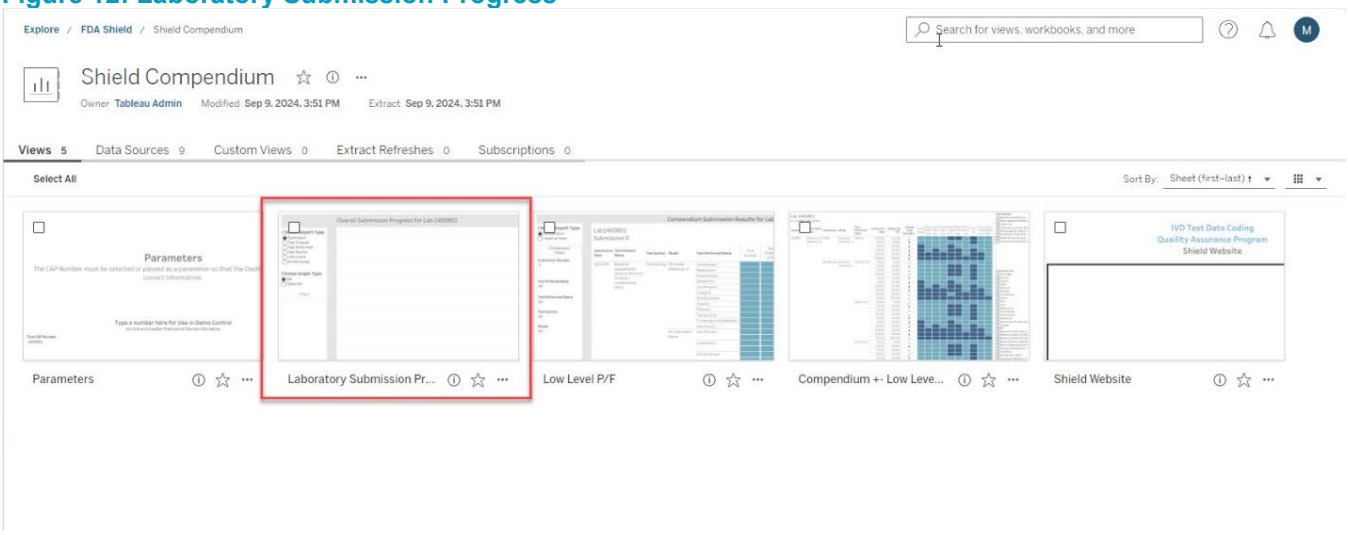
3. APPENDIX

3.1 QA Analysis Reports from the CAP

QA analysis reports for the LIDR Test Compendium Error Check and the Instance Error Check are available via a web portal provided by the CAP. The reports are interactive and accessible through the QA Analysis Dashboard (FDA SHIELD). Access to the reports is available to the participating laboratories. The reports provide an analysis of the performance of the laboratory over time and have the capacity to provide comparison data of the individual laboratory to peer groups reporting the same tests and methods. The reports are models at this time and may be limited in some functionality due to the datasets utilized to create them. While the peer group analysis feature is built into the system, it cannot be used effectively without peer group data. Current reports only compare data from within a single laboratory.

From the main menu, select “Laboratory Submission Progress” (see Figure 12).

Figure 12: Laboratory Submission Progress

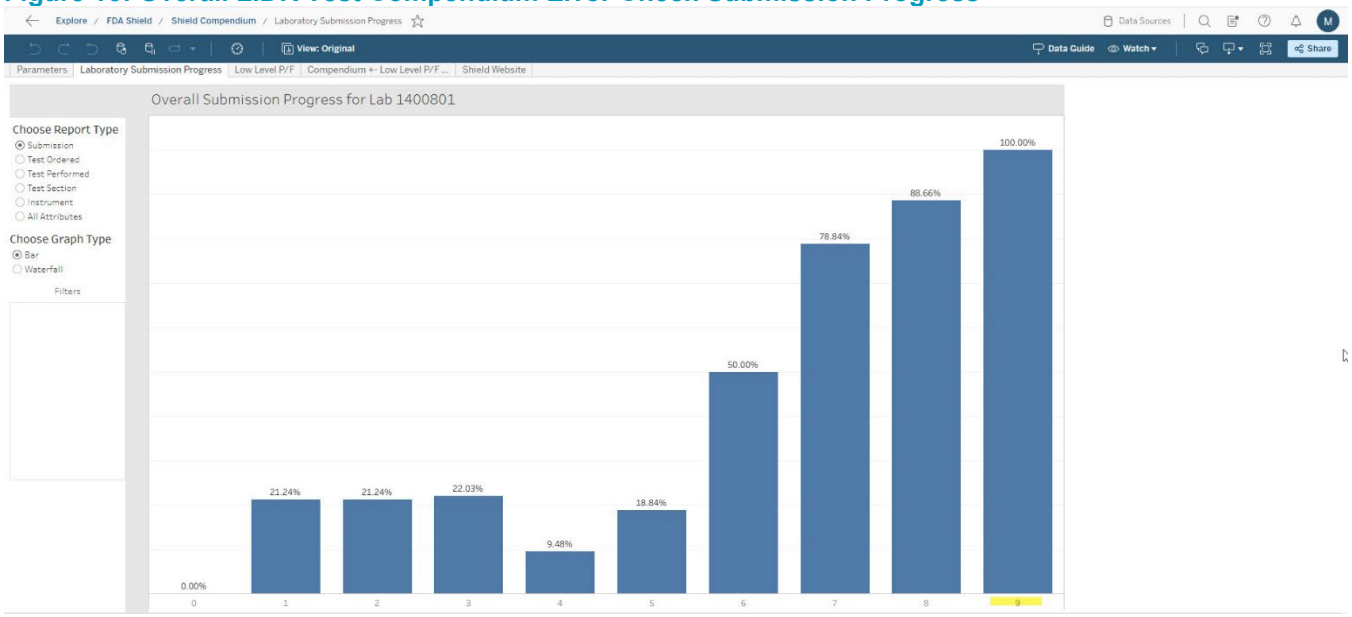


3.2 How to Interpret Your Test Compendium QA Analysis Report

LIDR Test Compendium Error Check QA Analysis Reports

Once the dashboard is accessed, the view will open with a graphical representation of the laboratory’s performance for recent LIDR Test Compendium Error Check submissions to the QA Program (Figure 13). The most recent submission would be the ninth submission in the image below.

Figure 13: Overall LIDR Test Compendium Error Check Submission Progress



Filtering options are available to obtain information on the performance of the laboratory based on the test ordered, test performed, test section, or instrument by making a choice using the radio buttons to the left of the graph (Figure 14). In this figure, the graph is filtered by “Test Ordered”, displaying the overall performance of each compendium submission for ordered tests.

Figure 14: LIDR Test Compendium Error Check Submission Progress Filtered by Test Ordered

In this figure, all tests (by Ordered Test LOINC code) had 100% correct LIDR elements reported by the ninth LIDR Test Compendium Error Check submission, except for the “Staphylococcus aureus DNA [Presence] by NAA with non-probe detection in Positive blood culture” ordered test.

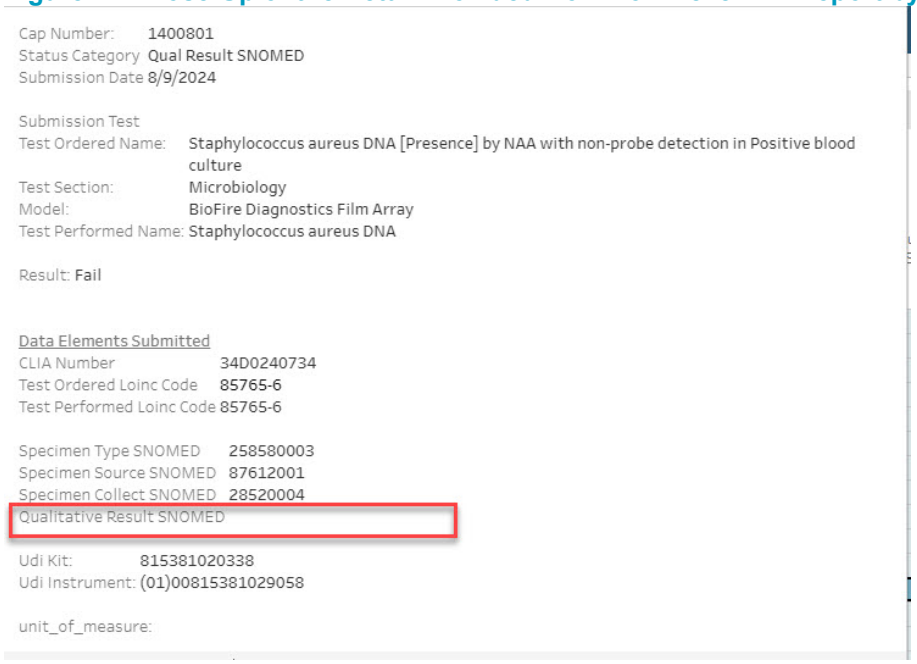
To further investigate the failure of this test, go to the alternate tab “Compendium +- Low Level P/F” to review the submissions included so far. As shown in Figure 15, this was selected with appropriate filtering options on the right side of the page.

Figure 15: LIDR Test Compendium Error Check Low Level P/F Tab with Filtered Options

In this view, the dates of submission and an indication of performance from the previous submission are visible. To identify why the previous submission was scored at 80% passing, the row for the 09/28/24 submission should be evaluated. Dark blue cells indicate passing and the light blue cells indicate failure. Hovering over cells provides further information. In the example below (Figure 16 and 17), the failure is related to a missing Qualitative Result SNOMED CT code for the performed test Staphylococcus aureus DNA.

Figure 16: LIDR Test Compendium Error Check Low Level P/F Tab with Progress Indicator and Additional Information

Figure 17: Close-Up of the Detail Provided from Low Level P/F Report by Hovering Over a Cell



The expected follow-up from the laboratory would be to review their LIDR Test Compendium Report for the reported test to ensure that the qualitative results reported are encoded with SNOMED CT. Once the LIS has been updated with the correct coding, the laboratory should perform an interim Instance Error Check for immediate validation that the correction was made and then submit another LIDR Test Compendium Report to the CAP at the next scheduled evaluation period.

3.3 How to Interpret Your Instance Error Check QA Analysis Report

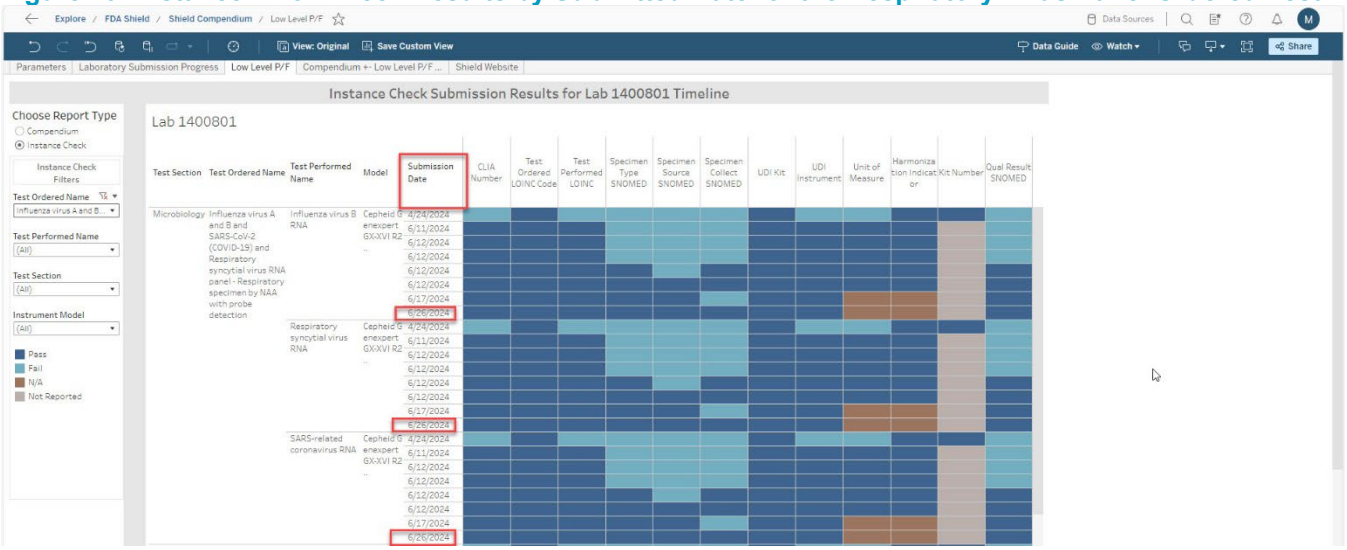
Instance Error Check QA Analysis Reports

To view Instance Error Check QA analysis reports, use the tab labelled “Low Level P/F” (see Figure 18). Select the radio button to view Instance Error Check reports. This view provides pass and fail results for the correct LIDR element for each performed test in submitted HL7 result messages. It also displays information on the performance of a laboratory over several submissions. In this report, filters can be selected to drill down to specific Instance Error Check results by test ordered name, test performed name, test section, and instrument model. The legend displays the meaning of the colored cells. A result of “N/A” indicates that the particular LIDR element is not applicable to the reported test. For instance, a test that is resulted with qualitative results would not include units of measure. A result of “Not Reported” indicates that an element that is not required was not included in the result transmission. For example, kit number is not a required LIDR data element but is an optional CAP element used to determine if the submission is part of a QA survey.

Figure 18: Low Level P/F for Instance Error Check Results

In Figure 19, the filter is set to the Respiratory Virus Panel ordered test. The laboratory wants to view the results of the most recent submission from 6/26/2024. Based on this view, the laboratory has passed for all required LIDR elements for each of the three tests performed in the ordered panel.

Figure 19: Instance Error Check Results by Submitted Date for the Respiratory Virus Panel Ordered Test



If the laboratory wants to see what was submitted for a particular data element, hovering over that cell will provide more detail. In Figure 20 and 21, the detail indicates the resulted test being viewed is the Influenza Virus B RNA performed on the Cepheid Genexpert®. The qualitative result SNOMED CT was 260373001 which was correct and resulted in a pass grading.

Figure 20: Low Level P/F Report Showing Detailed Information by Hovering Over a Cell

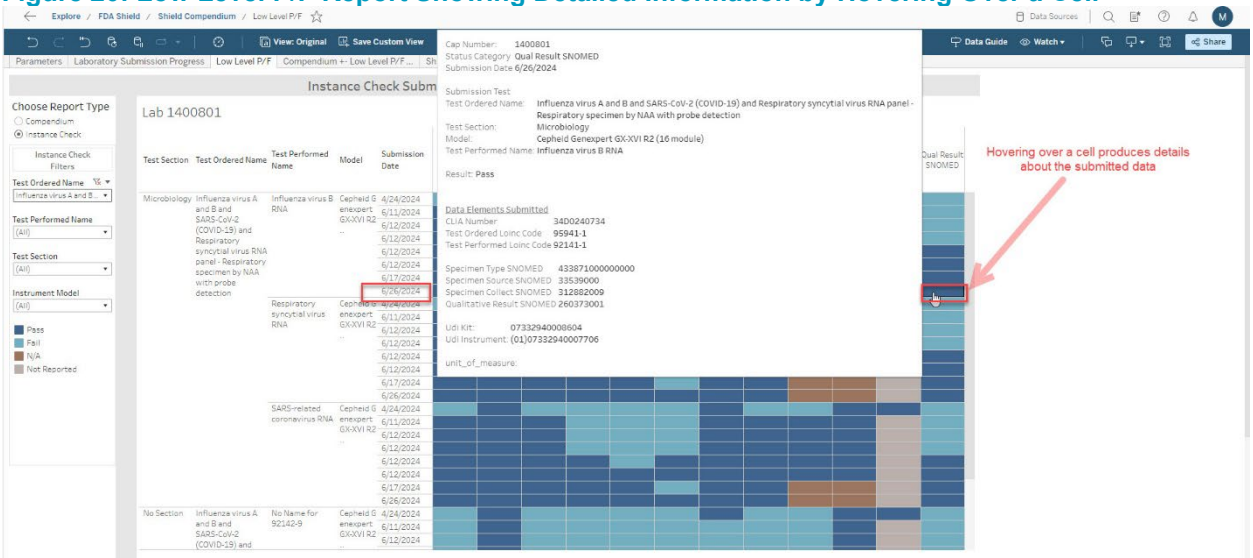


Figure 21: Close-Up of the Detail Provided from Low Level P/F Report by Hovering Over a Cell

In Figure 22 and 23, the detail indicates the resulted test being viewed is the Glomerular Filtration Rate (GFR) performed on the Beckman Coulter DxC 860i®. The Specimen Collect SNOMED was 73416001 which was incorrect and resulted in a failed grading.

Figure 22: Low Level P/F Report Showing Detailed Information by Hovering Over a Cell

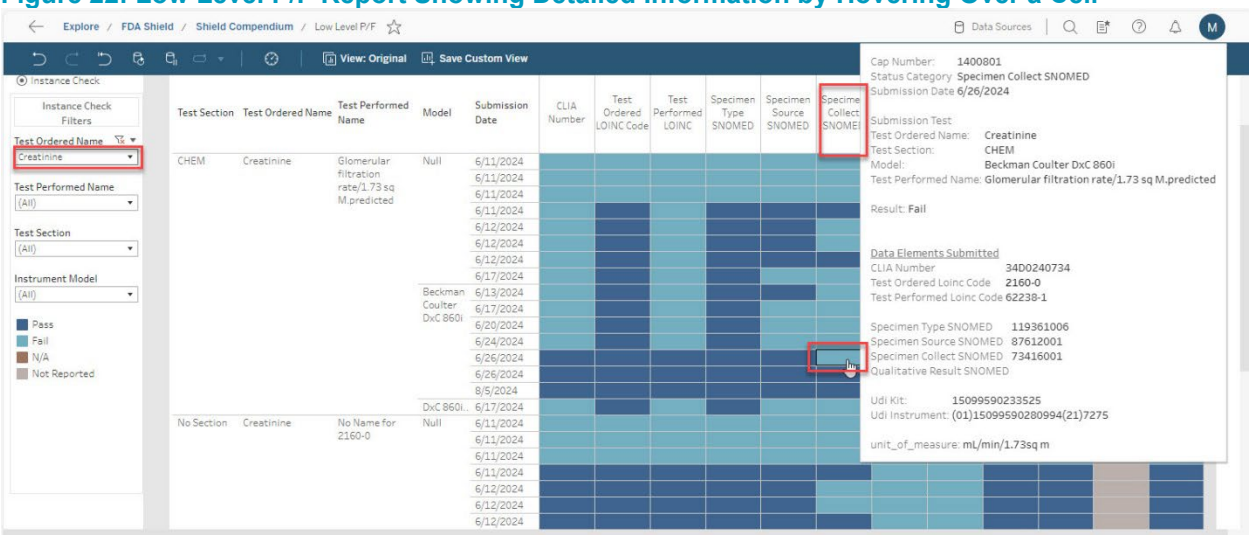
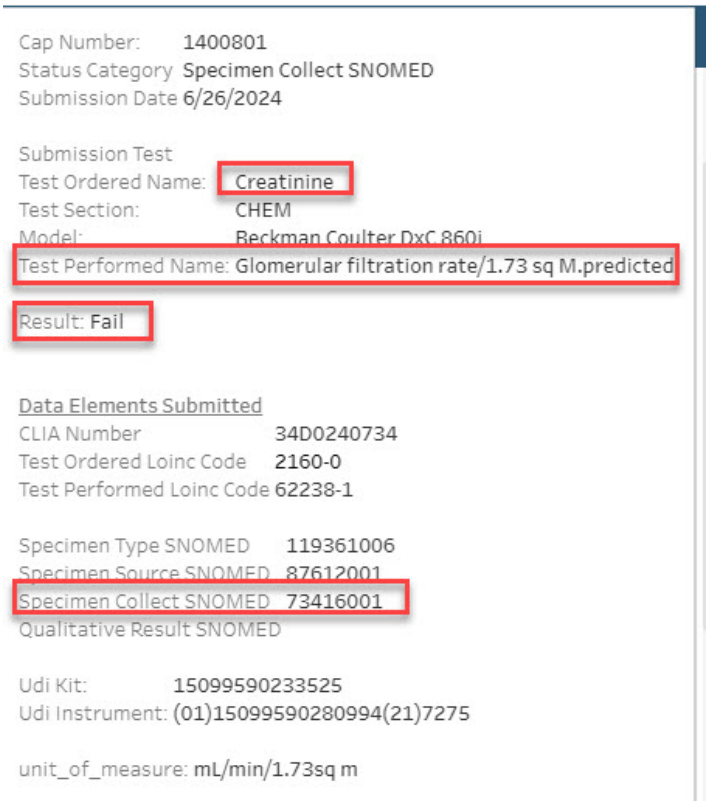


Figure 23: Detailed Information from Hovering Over Failed Cell for the Glomerular Filtration Rate (GFR) Resulted Test



While this display shows this data element failed, the report includes a subsequent submission of the test which then passed on the same day. The laboratory would have received an emailed notice of the initial failure and made a correction to the Specimen Collect SNOMED data element when the Instance Error Check was performed. The next submission shows the correction and a passing status (Figure 24 and 25).

Figure 24: Low Level P/F Report Showing Detailed Information by Hovering Over a Cell

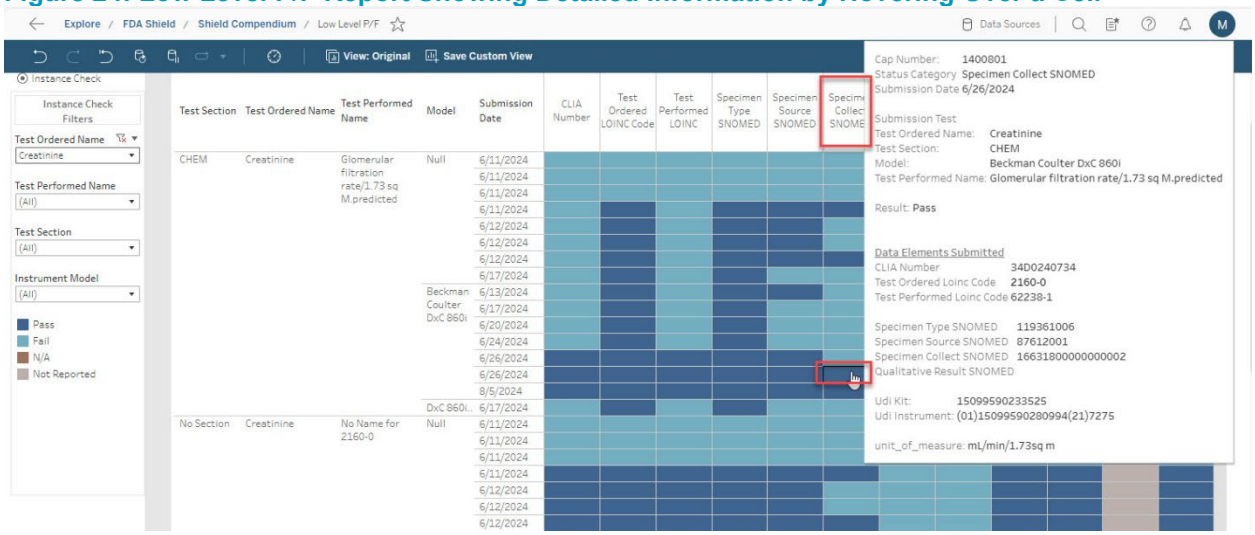


Figure 25: Detailed Information from Hovering Over Passed Cell for the Glomerular Filtration Rate (GFR) Resulted Test