Testing in the Client Self Test (CST) Environment

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1.0 Introduction

1.1 Purpose

The purpose of this document is to provide an overview of the Ontario Laboratories Information System (OLIS) Client Self Test (CST) environment. This document defines the process that Adopters are required to follow in order to test the functionality of their Laboratory Information System (LIS) to the OLIS HL7 Interface built by the Adopter's Development team or 3rd party company. When this process is complete Adopters will be able to perform Conformance Testing.

This document provides information on the steps required to schedule and access the CST environment and a description of data elements for each stage of OLIS implementation (eg. Orders and Results, Referrals In and Out, Order Retrieval, Walk-Ins and 3rd Party Viewer.

1.2 Audience

The audience for this document includes all individuals that are involved during testing of the LIS to OLIS interface in the OLIS CST environment. These individuals can include: Project Manager, Nomenclature, LIS and Information Technology Subject Matter Experts, Vendor, Project Sponsor, IT Department Director, Interface Analysts, System Testers and other interested members of the Adopter's OLIS implementation team.

1.3 Scope

1.3.1 In Scope

- The Adopter is required to fully and extensively test the functionality of the Laboratory Information System to OLIS Interface against the OLIS HL7 specification requirements .

- Adopters must test the OLIS Nomenclature mappings for all the laboratory tests for which they report clinical results from all sections of the laboratory Adopters must throughly test all of the scenarios that they intend to submit to OLIS before Conformance Testing. An appropriate sample of these scenarios (as determined by the OLIS Adoption Coordinators) must be forwarded to the OLIS Adoption Coordinator for review. The Adopter may want to use the Conformance Testing scenarios provided in "Conformance Test Scenarios(Current Version)"for developing testing scenarios for each discipline and sub-discipline. The Adoption Coordinator will review the submitted scnearios and provide feedback to the Adopter on whether the messages sent are in compliance with the OLIS HL7 specifications or require changes. This review is not the same as the review following the submission of Conformance Tests.

1.3.2 Out of Scope

- Any testing or modifications to a Hospital Information System (HIS) and/or LIS that is not related to the LIS to OLIS Interface

1.4 Acronyms & Abbreviations

The following table provides a list of acronyms and abbreviations that will be used in this guide.

Acronyms and Abbreviations	Definition
CCO	Cancer Care Ontario
CPDB	Corporate Providers Data Base
HIS	Hospital Information System
HL7	Health Level Seven
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers Names and Codes
LRA	Local Registration Authority
MOHLTC	Ministry of Health and Long Term Care
OLIS	Ontario Laboratory Information System
OLIS HL7 Specifications	Current OLIS HL7 Specification: Version 1.05: 2009-11-30
OLTP	Online Transaction Processing
PKI	Public Key Infrastructure
RA	Registration Authority
RELMA ®	Regenstrief LOINC Mapping Assistant
RPDB	Registered Persons Data Base

2.0 Overview on Client Self Test Environment

2.1 What is Self-Testing

To ensure the integrity and accuracy of all data the OLIS Program Team provide a Self-testing and Conformance Testing service for use by all organizations to verify system compliance with OLIS. For an LIS, HIS, or CMS to be authorized to interact with the OLIS Production environment, it must be successfully conformance tested.

Self-testing is the stage in which Adopters test their systems in the Client Self Test (CST) environment in order to prepare for Conformance Testing (Refer to the Conformance Test Guide for more information). Testing in the CST environment is meant to ensure the LIS to OLIS interface functions as specified in the OLIS HL7 specification. Self-testing can be performed by any stakeholder who is an authorized OLIS user (is registered and has a PKI test certificate for OLIS).

2.2 What is the OLIS Client Self Test Environment?

Client Self Test (CST) is a testing environment provided by OLIS to Adopters for the purpose of testing the functionality of the LIS to OLIS HL7 Interface. The CST environment provides an equivalent-to-production OLIS environment to support systems developers and other stakeholders who adapt software that will interface with OLIS. It's purpose is to allow functional testing of the various aspects of laboratory-related business processes, including testing the HL7 message interactions with OLIS, SOAP(Simple Object Access Protocol[1]) message interactions at the transport protocol level, as well as compliance with the Test Request Nomenclature and Test Result Nomenclature.

Within the CST environment there are "managed" and "open" areas. CST has an open environment where Adopters can test their software at any time with minimal restrictions, Referred to as the "sandbox". In the "open" area, multiple users may interact in a shared-mode with OLIS, testing their system's capability to send to and receive messages from OLIS. Activity logs will not be maintained in this "open" area. The "sandbox" area is available at any time (24 hours a day, 7 days a week, 365 days a year) and requires no scheduling. Conformance testing takes place in the "managed" areas. The managed areas allow up to Ten stakeholders to practice concurrently for conformance testing where the user has control of a session in the environment. In the "managed" area, activity logs will be maintained. At the request of the

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1.   [1] SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the practice of using XML and HTTP as a method invocation mechanism.

stakeholder, these logs can be reviewed to assist in problem resolution. The "managed" areas are also available at any time but scheduling is required as a limited number of sessions can operate concurrently.

The CST environment allows the OLIS Adopter's implementation team to:
- set up and test their LIS to OLIS interface (Troubleshoot connnectivity (i.e. PKI))

- become familiar with the use of OLIS;

- refine the setup of their LIS;

- prepare for Conformance Testing – testing and review of HL7 messsages, error handling, reportable test flags and blocking patient test information;

- Repeat conformance tests when changes are made to an Adopter's LIS (or HIS) which could affect the compliance of the required OLIS HL7 messages format, or the content of the OLIS HL7 messages;

- Test changes made by the OLIS Program Team to OLIS functionality or when enhanced or previously untested functionality is introduced

2.2 Why is Self Testing Important?

- Quality assurance: To confirm that patient information sent to OLIS is the same as it is in reports to practitioners

- Meet validation needed for internal Quality Assurance,CAP, QMPLS/OLA accreditation.

- Define business process changes for client registration, error handling, practitioner set-up, etc.

- Validation of nomenclature mapping and specimen mapping. Nomenclature changes due to changes in methodology, addition of new tests and/or updates to the OLIS Nomenclature require validation in the CST environment

- Training support staff and teams on the use of OLIS. Staff involved in nomenclature maintenance and implementing business changes will change over time. The CST environment provides a medium in which new individuals can become familiar with OLIS.

2.3 What is the difference between Self Testing and Conformance Testing?

The differences between Self Testing and Conformance Testing are outlined the table below:

Characteristic	Self Testing	Conformance Testing
Registration required	Yes	Yes
PKI certificate required	Yes	Yes

Testing as pre-requisite for OLIS Production use	Required to proceed to CT	Yes
Stakeholder is required to schedule time in session	Yes to practice conformance tests; No, to test in "open" area	Yes
Stakeholder is required to use published test data	Yes (with exception, stakeholder can use acceptable alternative patient identifiers and other patient data)	Yes
Number of concurrent users supported	10+	10
Session is monitored (activity logs are reviewed)	Only at request of stakeholder	Yes
Testing scripts available	No (conformance test scripts available for practice)	Yes
Certification following successful completion of testing	Yes	Yes
Help Desk support available	Yes	Yes

3.0 Accessing the CST Environment

3.1 Registration and Enrolment Requirements

Organizations and individuals will need to register (via the Local Registration Authority (LRA) if one exists) with the eHealth Ontario Service Desk in order to obtain access to the CST environment. If an LRA does not exist one must be established so that the LRA can initiate the registration process. Prior to registration of nominated individuals, Adopters must ensure:

1) A ONE ID Direct and Masters Service Agreement is signed;

2) A network connection is established;

3) A organizational setup and service enrolment form is completed;

4) A PKI Agreement is signed and a PKI certificate is installed; and

5) A Registration Authority or Local Registration Authority is registered.

For more information on these steps, refer to the OLIS Adoption Toolkit.

3.1.1 Request for PKI Certificate

To request a PKI Certificate, a Computer Application Registration Form and an Application Owner Registration Enrolment form must be completed (Refer to the OLIS Adoption Toolkit). These forms indentify the application owner with whom eHealth Ontario will correspond with in regards to issuance of the PKI Certificate and subsequent renewals of the certificates. (Note: PKI Certificates currently expiry every 3 years. The application owner will be contacted prior to expiry to allow time to renew the certificate without service interruption). Please note that each system connecting to OLIS requires its own PKI certificate. For example, if you have a Hospital Viewer and a LIS System, a separate PKI certificate must be obtained for each system.

3.1.2 Registration of Individuals for Access to OLIS Web Communities

The following steps are required for the registration of OLIS users:

- Two separate registration forms need to be completed for both OLIS environments (CST/CT and/or Production). These forms include:
  - o Individual Registration and Enrolment Form - OLIS Operations) – Refer to Forms Section.
  - o Individual Registration and Enrolment Form - OLIS Web App HC Providers – Refer to Forms Section.
- The RA or LRA fills in the form on behalf of the registering user. The signing officer, RA/LRA, Sponsor and user sign the form;
- The form is then faxed by the Adopter to the eHealth Ontario Registration group to be processed . The Fax number is located on the Registration Form);
- If the form is completed as required, it will be processed by the eHealth Ontario over a period of approximately 5 business days;
- If the form is not completed as required, a ticket will be opened by eHealth Ontario. The signing LRA/RA will be notified via email of the issue and the steps to resolve the issue;
- After the form is processed, a registration package is provided to the RA/LRA for use by the new user;
- The new user logs onto the eHealthOntario Portal (www.eHealthOntario.ca) with their registration package, and fills in the 'self –complete' questions. They then need to log out and back in again to complete the registration process;
- After the initial log in, the user can go to www.eHealthOntario.ca, log in, and access the OLIS link on the page.

3.1.3 Access to the OLIS Program Collaboration Portal and OLIS Viewer

The OLIS Program Collaboration Portal is an Internet based forum for communicating with sites that have, or which are in the process of implementing interfaces from their LIS to OLIS. OLIS communications to Adopters is facilitated through this Portal. This Portal is loaded with updates to RPDB, CPDB and Nomenclature for Adopters.

The eHealth Ontario portal also provides access to the OLIS Viewer. Adopters will require access to the OLIS Viewer sometimes referred to as the "Web App" or "Web Application" in the CST environment to view data that has been submitted by the Adopter to OLIS to validate transactions[2]. By logging into the OLIS Viewer, Adopters can verify that the results have been submitted and displayed in the desired format. For more information on subscribing to this Portal refer to the document entitled "OLIS Program Collaboration Portal" in the OLIS Adoption Toolkit.

3.2 Scheduling Access to the CST Environment

There are a limited number of CST instances in the CST environment available to OLIS Adopters. There is one shared instance that can be accessed by all Adopters (referred to as the Sandbox) and other instances of the OLIS environment which are assigned to OLIS Adopters during specific phases of their development and testing cycle. The shared environment (Sandbox) is refreshed at regular intervals so the databases containing a standard dataset of patients and test results are available at all times. The other instances of the CST environment are scheduled on an as needed basis. They can be used during the development cycle and for testing the LIS to OLIS interface. A dedicated CST instance of the CST environment will be used to perform Conformance Testing. This environment will be refreshed prior to the Adopter commencing their Conformance Tests.

Scheduling of a dedicated CST environment can be arranged through the OLIS Adoption Coordinator assigned to support your implementation or through the OLIS Business Support Desk once the implementation is completed. The environment will be accessible for a specified period based on the Adopter's project implementation plan or an Adopter's needs and availability. If an OLIS Adopter is not able to complete specific phases of a project in the time period scheduled, it may be necessary to move to a different CST instance to complete the development and testing of the LIS to OLIS interface or to the sandbox until an instance becomes available.

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[2]The OLIS Adoption and Stakeholder Management Team has access to the CST Environment

4.0 Testing in Client Self Test

4.1 Testing Scenarios

OLIS has developed a library of Test scenarios that will be used to ensure a new OLIS Adopter is able to send HL7 messages that meet the OLIS HL7 specifications These test scenarios are designed to identify key data fields that must be validated to:

- Demonstrate the ability of the laboratory to submit transactions to OLIS;
- Assess the ability of the laboratory to handle transaction errors;
- Designate reportable tests; and
- Demonstrate the ability to transmit a patient's data blocking requests.

The testing scenarios should be used by each site as a templates for developing their own test scripts during the set up and testing phases of their implementation (Refer to the OLIS Testing Scenarios Manual for all test scenarios). It is up to each site to determine what testing they feel meets the needs of their organizations quality requirements.

Some Testing Scenarios test each of the HL7 message segments and processes that require special handling of specific message segments. There are also supplemental test scenarios that can be used for more comprehensive testing when required. OLIS has developed Testing scenarios for:

- OLTP (Orders and Results generated by the Adopter's laboratory);
- Referred-In Requests from other laboratories;
- Referred-Out Requests to other laboratories;
- Order Retrieval from OLIS for walk in patients; and
- 3rd Party Viewer or Query and Display capability (when applicable).

Contact an OLIS Coordinator for the Testing Scenarios.

4.2 Data Elements

Adopters will submit data or queries on fictitious patients into an OLIS CST environment based on information supplied by OLIS Business Support Desk. This includes the following type of information:

- Patient Data
- Health Card Number
- Health Card Version Code
- Name, Last, Given, Middle
- Date of Birth
- Gender
- Practitioner Data (Medical Doctor, Dentist, Nurse Practitioner, Midwife)
- Provider Data (Hospitals, Laboratories, Specimen Collection Centres)

All other data required to test the LIS/OLIS functionality (e.g. results, dates and times, units of measurements, reference intervals) are provided by the Adopter.

4.3 Review Process

Once an OLIS Adopter has completed the execution of their test menu and test scenarios, the HL7 messages and their acknowledgements must be forwarded to their OLIS Adoption and Management Team Coordinator for review. This includes screen images and internal and external laboratory reports. This review will be used to identify that the potential points of failure have all been tested and handled satisfactorily (Refer to the current version of the Conformance Test Guide for examples). This review is not the same as the review following the submission of a Conformance Test.

4.4 Client Signoff

Before proceeding to Conformance Testing an Adopter must submit a form indicating that they have successfully tested all of their nomenclature mapping their business practices in the Client Self Test environment that are related to OLIS and:

- Testing was completed for the entire laboratory information system (LIS) test menu for each modality indicated above;

- Submission of test requests and results by the organization OLIS Interface meets the requirements defined in the OLIS HL7 Interface Specifications;

- Error conditions encountered during processing of test requests and results are logged by the organization's OIS Interface for follow up and correction by support personnel;

- The organization has defined and tested business processes which support the on-going submission of test requests and results via the OLIS Interface;

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4.5 Repeat Testing

When changes are made to an Adopter's LIS, the Adopter site must notify the OLIS Business Support Desk of the timing and provide release notes outlining the scope of change that is planned. Based on the extent of the changes documented in the software release notes, the Business Support Desk will determine which conformance test scenarios will be required to recertify the LIS to OLIS interface. This may range from a single conformance test scenario to the full comprehensive set of conformance tests. The same process applies in a situation when there is a OLIS upgrade. Again the Adopter can use these conformance test scenarios, if they wish, to formulate their own testing scenarios.

5.0 Types of OLIS Interactions

5.1 Orders and Results

The test scenarios used by the Adopter for testing the Orders and Results phase of OLIS implementation should include:
- Discipline (Laboratory Section) Specific Cases; and
- Error Handling Cases.

It is important to ensure that all laboratory test procedures (both insured and non-insured) can be transmitted to the CST OLIS repository without any errors and that the data submitted to OLIS, mirrors data provided by the laboratory via their HIS/LIS to practitioners.

For each Order and Result HL7 transaction, there are two HL7 messages that must be reviewed together: a message generated by the Adopter's interface which contains the patient identification, order information and test results; and an acknowledgement message generated by OLIS. The acknowledgement message confirms that the transaction was received and reports any errors that might have occurred when the message was processed (Figure 1).

If a laboratory test result must be corrected, a second HL7 message must be submitted with specific controls over key data fields so the original test results will be invalidated and replaced with the new test results. When this corrected test result is transmitted, OLIS will generate a matching acknowledgement message to report the transaction was successfully processed, or to report errors that occurred during processing.

**Figure 1: On Line Transaction Process – Orders and Results**
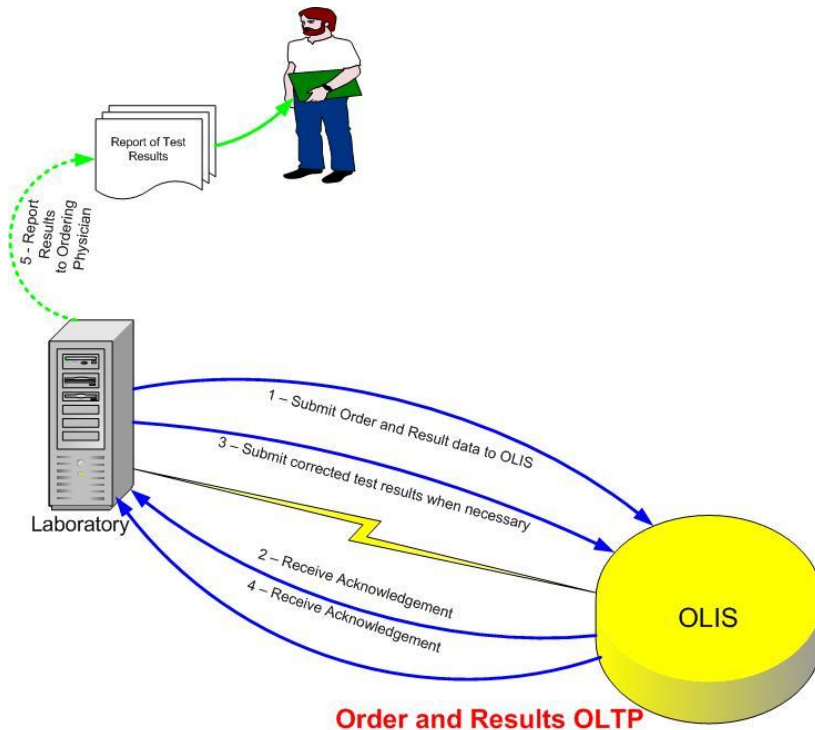
5.2 Referred In and Referred Out Testing

Testing of Referred In and Referred Out Testing is complex. In the case of *referred out testing*, testing involves assessing the ability of a sending laboratory *(Referring Laboratory)* to submit HL7 messages to order tests that are referred to another laboratory, then to retrieve the results, incorporate them in their own LIS, and report the final results through OLIS. Specimen identification must also be transmitted as part of the ordering process so the Receiving laboratory (*Reference laboratory)* will be able to match the order with specimens that are transmitted to their facility for testing. Therefore, Referred In and Referred Out Testing is performed in two stages, one for the *Referring Laboratory* and one for the *Reference Laboratory* (Refer to Figure 2).

For OLIS Adopters that receive specimens from other laboratories for testing, the test scenarios are designed to show they are able to query OLIS to retrieve details of orders that are directed to their laboratory, and to process the order (making use of the specimen identification transmitted with the order retrieved from OLIS). The test scenario is also designed to assess how the order is handled in the *reference laboratory's* LIS and how the results are reported to the OLIS repository.

Figure 2: Referrals In/Out
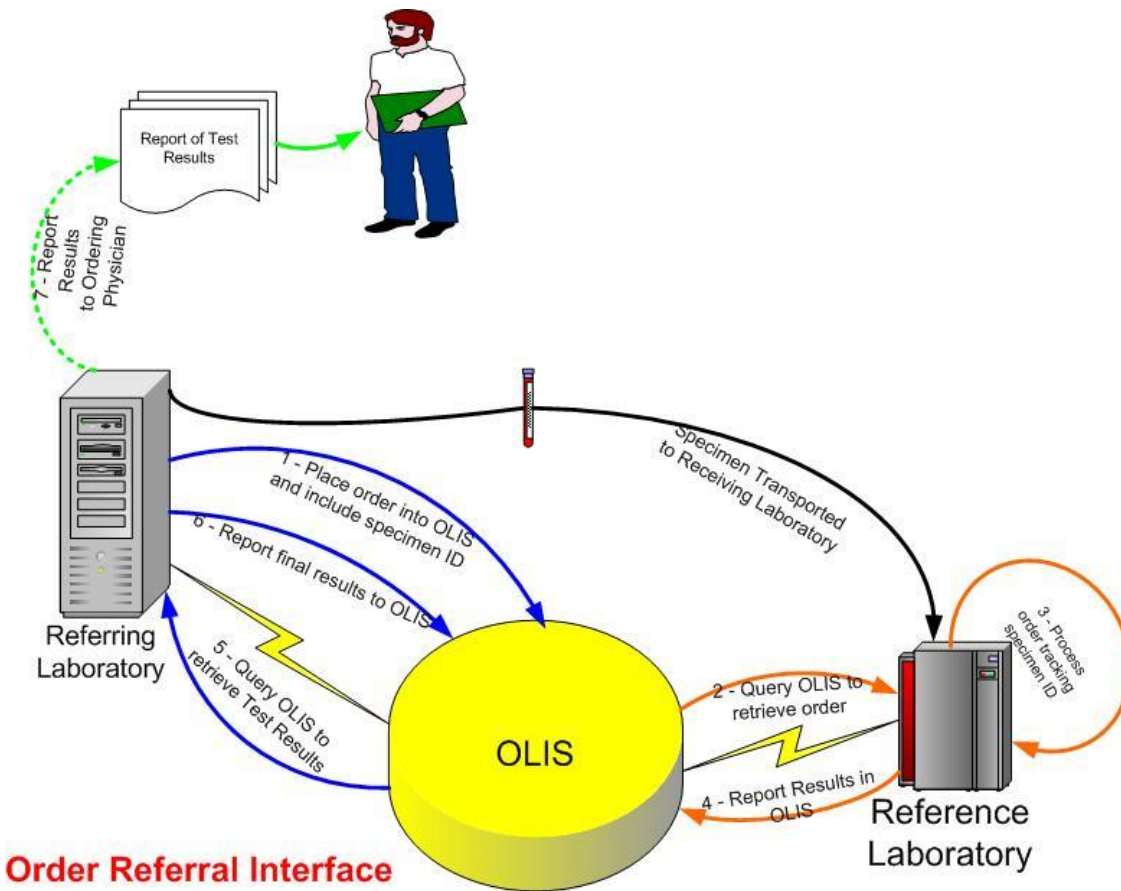
The mechanics of performing Referred In and Referred Out Testing is similar to what is done for Orders and Results. Testing scenarios can be obtained from the OLIS coordinator and provide direction on how to submit data. The Adopter can use these conformance test scenarios, if they wish, to formulate their own testing scenarios. One test scenario is for laboratories that send specimens to other laboratories for testing (*Referred Out testing*) and the other test scenario is for laboratories that receive orders from other laboratories for testing (*Referred In testing*). Laboratories that will use OLIS to refer out specimens to another laboratory must go through Referred Out Conformance testing. Laboratories that receive specimens from other laboratories for testing must go through the Referred In testing. Laboratories that sends specimens to another laboratory for testing and also receives specimens from outside laboratories for testing are required to complete both Referred In and the Referred Out Conformance testing.

Testing must be performed for each laboratory module that is used to generate referred out testing orders (or to receive referred in test requests). If an OLIS Adopter has a separate LIS for different laboratory sections, or if the LIS has unique modules that handle referred out or referred in specimens, each LIS module must be subjected to testing. There are a variety of variables that can be altered when submitting test scenarios to simulate the actual practices that will be followed as the OLIS Adopter starts to make use of OLIS to automate the process for placing orders, querying OLIS to retrieve orders and reporting results through OLIS. This allows the testing scenarios to vary in order to provide a realistic test of the practices that will be followed when referring specimens to another laboratory.

5.3 Orders Retrieval (Walk-Ins)

Order Retrieval is a process in which a physician places an order into OLIS. This can occur through their Clinical Management System (CMS) or Web Application. When a patient arrives at a specimen collection centre, the centre can query OLIS for the order. The centre then collects the sample from the patient and sends it to the laboratory. The laboratory performs testing on the sample and submits the result into OLIS. The results can be retrieved by the physician from OLIS (Figure 3). Please note, that although this functionality is available in OLIS some hospitals and laboratories are reluctant to accept walk-in patients.

Figure 3: Order Retrieval
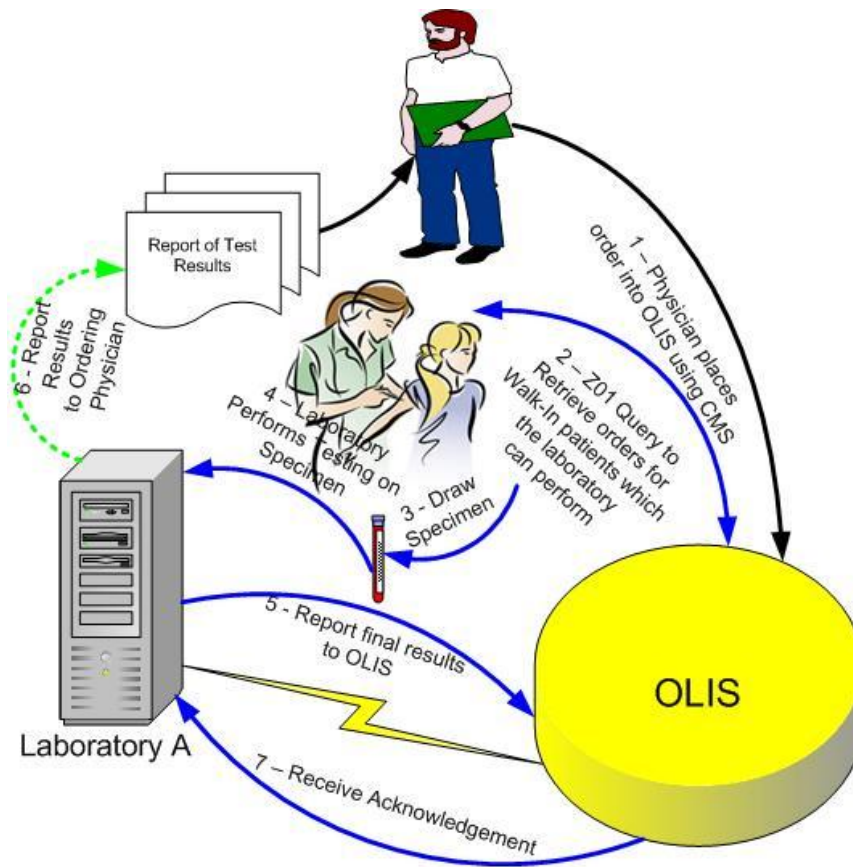
Order Retrieval (Walk-Ins)

Testing of Order Retrieval is more complex than the tests that are performed for Order and Results. It involves assessing the business processes that are followed within the laboratory, not simply scrutinizing the computer generated HL7 messages and laboratory reports related to a variety of testing scenarios. Test scenarios must be assessed both individually and collectively to ensure the work processes that are followed are robust and complete enough to detect and correct potential failures, and to ensure only valid information is transferred to the OLIS Repository.

The mechanics of performing testing for Order Retrieval is similar to what is done for Orders and Results. There are eight categories of test scenarios used for testing Orders Retrieval phase of the OLIS implementation:

- Errors in Response
- No Orders in Response

- Answer Simple Order with Ancillary Information
- Answer Order w/ Multiple Test Requests
- Answer Order w/ Unknown Practitioner
- Answer Separate Orders on Same Specimen
- Walk-In orders for Non-OHIP Patients
- Test Not Performed

5.4 Third Party Viewer

For OLIS Adopters that develop a Viewer for retrieving and displaying results stored in the OLIS repository, it is necessary to complete Testing scenarios to validate that their system is capable of:

- placing specific queries to OLIS;

- displaying the results in a clinically appropriate manner; and

- providing appropriate warnings to the user

When OLIS receives an HL7 query messages submitted by a Third Party Viewer it generates an HL7 message with the appropriate information and sends this query to the Viewer (Figure 4).

Figure 4: OLIS Viewer
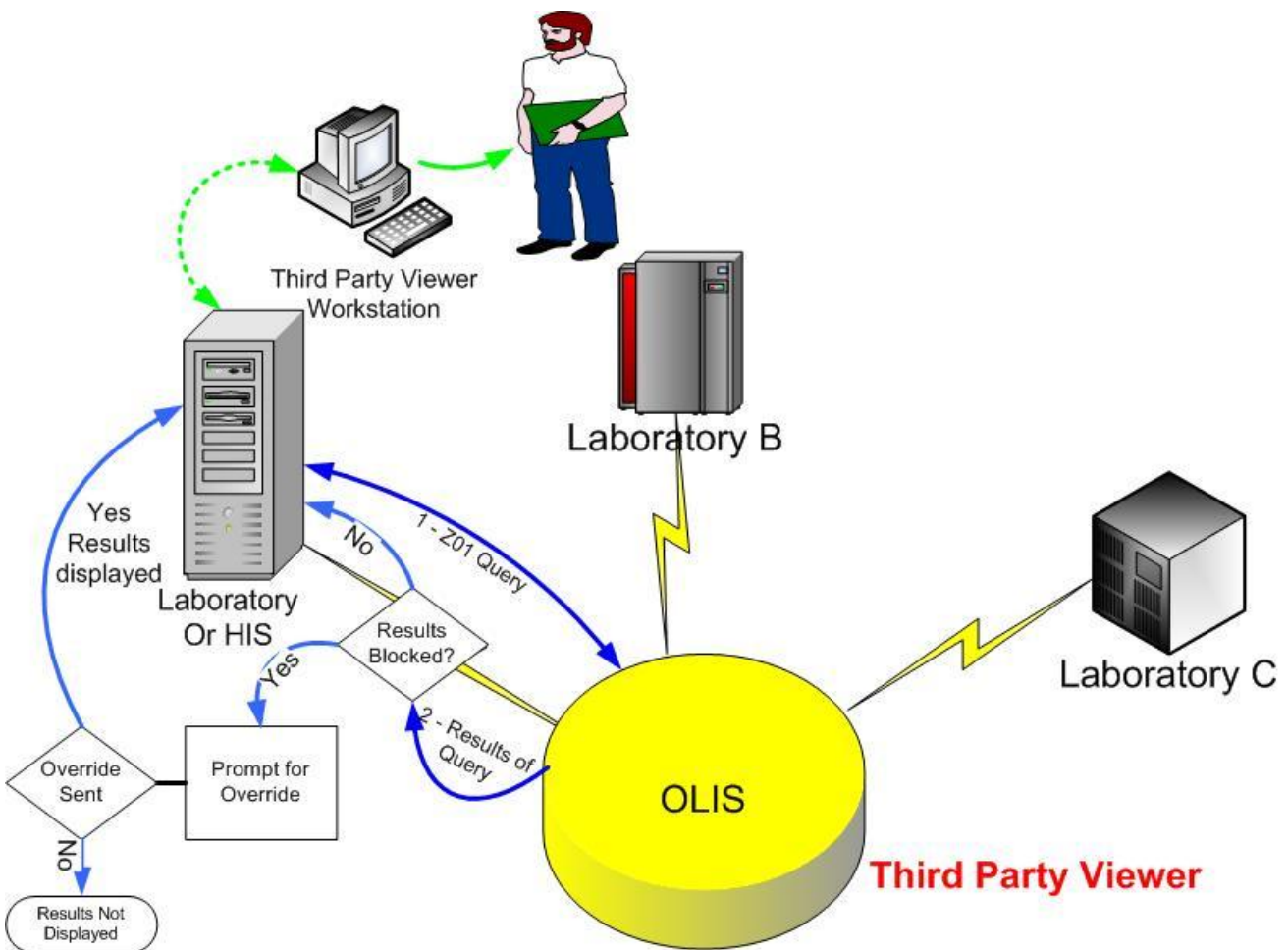
The testing scenarios provide steps the Adopter through each of the stages of placing the query and displaying test results. Scenarios have been developed to demonstrate how the third party viewer functions when:

- Data is found for the query

- No data is found for the query

- Patient information has been blocked

- Some patient information has been blocked, but other data is accessible.

- One of the three overrides has been employed to view blocked data

Scenarios for a Third Party Viewer are designed to validate the query message sent to OLIS meets HL7 specifications. Test scenarios are also designed to test whether the Viewer is able to provide appropriate notification to users when: a patient is not found in OLIS; no test results for the timeframe are specified; the patient has blocked their personal health information from being displayed; and overrides are used to view blocked information.

6.0 Getting Help during Client Self Testing

During CST there are a number of topics that the Adopter may require assistance with in order to complete testingContact the OLIS Coordinator or the Business Support Desk for help.