SCC SoftComputer
2025 Real World Testing Test Plan

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only] _____

Developer Name: _SCC SoftComputer_____

Product Name(s): _SoftLab_____

Version Number(s): _4.0.7, 4.0.8, 4.0.9, 4.5.4, 4.5.5, 4.5.8_____

Certified Health IT: _170.315(f)(3): Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results, 170.315(b)(10): Electronic Health Information export_____

Product List (CHPL) ID(s): _15.07.04.2287.SL40.07.01.1.230209, 15.07.04.2287.SL40.08.02.1.230209, 15.07.04.2287.SL40.09.03.1.230209, 15.07.04.2287.SL45.05.03.1.230209, 15.07.04.2287.SL45.04.04.1.230209, 15.99.04.2287.SL45.04.05.1.230606_____

Developer Real World Testing Page URL: _https://www.softcomputer.com/regulatory-affairs/_____

170.315(f)(3): Transmission to Public Health Agencies - Reportable Laboratory Tests

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

The criterion 170.315(f)(3) is satisfied through implementation of an ELR interface that transmits reportable lab results to a receiving system such as a state DOH. SCC SoftComputer's stock ELR interface has been designed, tested, and demonstrated to be capable of transmitting messages in accordance with the standards referenced in the criterion. Although the Implementation Guide upon which the criterion is dependent includes references to many vocabulary items, the criterion specifically calls out and focuses on the use of LOINC and SNOMED CT codes. Conformance is established not only by the mechanics of the interface, but also by data input to the system by users and by other systems. Users of SoftLab must define and maintain data dictionaries and must utilize the system appropriately while ordering and resulting in order to capture the necessary data. External HIS, EMR, and CIS systems must transmit the necessary data to SoftLab to be captured and re-sent through the ELR interface.

During each interface implementation at a client site, the ELR interface is validated with the client and with the state DOH to meet the particular needs of the state for interoperability and function. Typically, each reportable test is validated between the client and the state before the interface is used for live data transmission. In addition, each installed ELR interface is validated during implementation to conform to the referenced Implementation Guide. Sample messages are captured and input to the same NIST testing tool that is used for certification testing. The interface as implemented at each client is thus verified to be conformant at the time of installation and is expected to remain so throughout its use.

The goal of this Real World Test is to measure observations of interoperability and data exchange. Ideally, ongoing interoperability is best verified by continually obtaining confirmation from each receiving system (typically a state Department of Health) that the transmitted information has been received and successfully utilized. But, although electronic acknowledgement of message transmission can be considered as an implicit indicator of successful transmission, many state DOH's do not employ a mode of message exchange that includes acknowledgement. Thus to avoid the impracticality of conducting testing by polling state Departments of Health and requiring client participation in the installation and re-validation of the very interface to be tested, SCC instead will focus on a non-intrusive

method of regularly querying client systems for information about the history of reporting by ELR interface. Such queries will provide meaningful, quantitative statistical data regarding use of the ELR interface in the field in the form of number of tests qualified for reporting vs. number of tests reported with a focus on inclusion of LOINC and SNOMED CT codes.

Privacy and Security aspects of the measure are established by the particular mode of transport (VPN, sftp, etc.) chosen by the receiving state DOH, and are therefore not subject to change without the express involvement of the receiving state DOH.

Ideally, all SoftLab clients using an ELR interface in the United States will contribute, producing a breadth of data. A high degree of capture and transmission of reportable results with LOINC codes as required by standards and for certification is deemed a good indication of maintenance of functionality of the Certified Health IT in real world settings. In addition, a tally of complaints regarding conformance to certification requirements over the same period of time will supplement conclusions regarding maintenance of interoperability and functionality. An observation of inclusion of SNOMED CT codes will be included as well.

SoftLab may be installed equally in any laboratory care or practice setting, and is designed to perform uniformly across all settings. The requirements for using SoftLab's ELR interface to meet criterion 170.315(f)(3) are not differentiated by care setting, therefore testing will not be separated and results will not be distinguished by care or practice setting.

STANDARDS UPDATES

N/A

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

Measurement/Metric	Description
Sample size	Total number of ELR interfaces contributing to data set
Number of results qualified for ELR	Total number of results qualified for ELR across the sample size
Number of ELR results sent	Total number of ELR results transmitted across the sample size
Number of ELR results with LOINC	Total number of ELR results sent with LOINC codes across the sample size
Number of ELR results with SNOMED	Total number of ELR results that included SNOMED codes in results across the sample size
Results sent/Results qualified (%)	Ratio of Results sent/Results qualified expressed as a percentage
Results with LOINC/Results sent (%)	Ratio of Results with LOINC/Results sent expressed as a percentage
SNOMED results/Results sent (%)	Ratio of SNOMED results/Results sent expressed as a percentage
Number of complaints registered	Total number of complaints registered over the course of the testing period.

SCC SoftComputer
2025 Real World Testing Test Plan

ASSOCIATED CERTIFICATION CRITERIA

Measurement/Metric	Associated Certification Criteria
Sample size	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.
Number of results qualified for ELR	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.
Number of ELR results sent	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.
Number of ELR results with LOINC	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.
Number of ELR results with SNOMED	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.
Results sent/Results qualified (%)	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.
Results with LOINC/Results sent (%)	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.
SNOMED results/Results sent (%)	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.
Number of complaints registered	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

Measurement/Metric	Justification
Sample size	Raw data
Number of results qualified for ELR	Raw data
Number of ELR results sent	Raw data
Number of ELR results with LOINC	Raw data
Number of ELR results with SNOMED	Raw data
Results sent/Results qualified (%)	The ratio indicates degree of adherence to requirements to send ELR results when qualified.
Results with LOINC/Results sent (%)	The ratio indicates degree of adherence to requirements to send LOINC codes with ELR reportable results.
SNOMED results/Results sent (%)	It is required to send SNOMED CT codes as results when applicable. Not all results are reportable in SNOMED form.
Number of complaints registered	Complaints are registered by clients when expected data is not received by their respective Department of Health. The number of complaints indirectly reflects complaints about interoperability with ELR receivers.

SCC SoftComputer
2025 Real World Testing Test Plan

CARE SETTING(S)

Care Setting	Justification
All settings	The plan is agnostic of facility size or setting. SCC SoftComputer does not market or install ELR capability differently per care setting. The system is expected to function equally in all care settings, at facilities of all sizes. Results from all care settings will be combined and reported in total.

EXPECTED OUTCOMES

Measurement/Metric	Expected Outcomes	Interpretation
Sample size	Raw data	None
Number of results qualified for ELR	Raw data	None
Number of ELR results sent	Raw data	None
Number of ELR results with LOINC	Raw data	None
Number of ELR results with SNOMED	Raw data	None
Results sent/Results qualified (%)	~ 100%	A high percentage reflects adherence to requirements to send ELR results when qualified.
Results with LOINC/Results sent (%)	~ 100%	A high percentage reflects adherence to requirements to send LOINC codes with ELR reportable results.
SNOMED results/Results sent (%)	Any value	Any quantity is acceptable. Not all results are reportable in SNOMED form. Data is offered for information only.
Number of complaints registered	~ 0	Complaints are registered by clients when expected data is not received by their respective Department of Health. A low number of complaints indirectly reflects successful interoperability with ELR receivers.

RELIED UPON SOFTWARE

SCC Soft Computer SoftLab and associated ELR Interface (all versions).

SCC SoftComputer
2025 Real World Testing Test Plan

170.315(b)(10): Electronic Health Information export

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

The export of EHI associated with a particular patient is a method of sharing information with an external organization. Export is typically used when there is a need to gather a complete patient record. This metric will provide information on the data exported for a single patient and the frequency of usage.

The criterion 170.315(b)(10) is met via two methods: a specialized user-driven utility that may be used on demand by an authorized user to export a single patient's historic results, and a specialized utility that is coordinated with SCC resources to export a population's historic results. The population export may be used to pre-load data to another information system, or for research or quality purposes to look for specific trends on patient population. The use case for each is occasional, as needed, and the output is file-based in a standardized HL7 format. Real World Testing data is gathered by observing the incidental use in the field of these utilities over time.

SoftLab may be installed equally in any laboratory care or practice setting, and is designed to perform uniformly across all settings. The requirements for using the SoftLab to meet criterion 170.315(b)(10) are not differentiated by care setting, therefore testing will not be separated and results will not be distinguished by care or practice setting.

CARE SETTING(S)

The plan is agnostic of facility size or setting. SCC SoftComputer does not market or install capabilities differently per care setting. The system is expected to function equally in all care settings, at facilities of all sizes. Results from all care settings will be combined and reported in total.

STANDARDS UPDATES

N/A

MEASURES USED IN OVERALL APPROACH

TEST METHODOLOGY

SINGLE PATIENT EXPORT

Client system logs will be reviewed periodically to determine the occurrence and frequency of use. Log files obtained during Real World Testing will be de-identified and analyzed to validate the proper operation of the export, with data recorded for future reporting.

PATIENT POPULATION EXPORT

As SCC resources are involved in execution of any Patient Population export due to the potential for negative impacts to the system, SCC staff will monitor the progress and success of the export in real-time, noting any issues that are encountered.

EXPECTED OUTCOME(S)

SINGLE PATIENT EXPORT

It is expected that logs will confirm that authorized users are able to use the export utility to produce files for transfer and sharing. Usage and any subsequent errors will be tracked and trended over time.

PATIENT POPULATION EXPORT

It is expected that export functions will be completed successfully, and authorized users will be able to share EHI for a patient population. Errors in export will be identified and analyzed.

METRICS

SINGLE PATIENT EXPORT

Number of successfully generated Single Patient Exports for the sampled client set during 2025.

PATIENT POPULATION EXPORT

Number of successfully generated Patient Population Exports for the sampled client set during 2025.

Schedule of Key Milestones – 170.315(f)(3) and 170.315(b)(10)

Key Milestone	Care Setting	Date/Timeframe
Verify implementation of RWT queries for active participant clients.	All settings	November 1, 2024
Submit proposed 2025 RWT Testing plan to ACB.	All settings	November 1, 2024
Publication of 2025 Real World Testing plan.	All settings	December 15, 2024
Begin collection of 2025 information as laid out by the plan.	All settings	January 1, 2025
Evaluate data collection to address any concerns.	All settings	Monthly, 2025
Data collection and review.	All settings	Monthly, 2025
End of 2025 Real World Testing period/final collection of all data for analysis.	All settings	January 2026
Analysis and report creation.	All settings	January 15, 2026
Submit 2025 Real World Testing report to ACB.	All settings	February 1, 2026
Publication of 2025 Real World Testing report.	All settings	March 1, 2026

SCC SoftComputer
2025 Real World Testing Test Plan

ATTESTATION

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

Authorized Representative Name: _Kenton Smith_

Authorized Representative Email: _Kentons@softcomputer.com_

Authorized Representative Phone: _727-789-0100_

Authorized Representative Signature: _[signature]_

Date: _5 November, 2024_