

SCC Soft Computer

2022 Real World Testing Test Plan

GENERAL INFORMATION

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

Developer Name: SCC Soft Computer

Product Name(s): SoftLab

Version Number(s): 4.0.7, 4.0.8, 4.0.9, 4.5.4, 4.5.5

Certified Health IT: 170.315(f)(3): Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results

Product List (CHPL) ID(s): 15.07.07.2287.SO03.01.00.1.170515, 15.07.07.2287.SO03.02.01.1.170706, 15.07.07.2287.SO03.03.02.1.210325, 15.07.07.2287.SO03.04.02.1.180909, 15.07.07.2287.SO03.03.03.1.181116

Developer Real World Testing Page URL: <https://www.softcomputer.com/regulatory-affairs/>

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 Soft Computer'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 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

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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 the 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 (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

No standards updates have been made that affect measure *170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results*.

SVAP references as standards *170.205(g) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September, 29, 2011* and *170.205(g) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012*. Currently, neither of these standards has new versions.

USCDI is not currently applicable to *170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results*.

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

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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.

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

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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.

CARE SETTING(S)

Care Setting	Justification
All settings	The plan is agnostic of facility size or setting. SCC Soft Computer 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.

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SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Validate approach to collect data for Real World Testing Plan.	All settings	November, 2021
Activation of queries on client systems.	All settings	December, 2021
Publication of Real World Testing plan.	All settings	December 15, 2021
Begin collection of information as laid out by the plan.	All settings	January 1, 2022
Evaluate data collection to understand and address any concerns.	All settings	Monthly, 2022
Data collection and review.	All settings	Monthly, 2022
End of Real World Testing period/final collection of all data for analysis.	All settings	January 2023
Analysis and report creation.	All settings	January 15, 2023
Submit Real World Testing report to ACB (per their instructions).	All settings	March 1, 2023

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: _____

Authorized Representative Email: _____

Authorized Representative Phone: _____

Authorized Representative Signature: _____

Date: _____