



Mayo Clinic Lab Registry

Real World Test Plan 2025

November 1, 2024

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GENERAL INFORMATION

Developer Name: Mayo Clinic

Product Name: Mayo Clinic Lab Registry

Version Number(s): 5.00.00

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2792.Mayo.05.00.1.240429

Developer Real World Testing Plan Page URL: <https://www.mayoclinic.org/about-mayo-clinic/disclosures/real-world-test>

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Laboratory data coming out of Mayo Clinic's Laboratory Information System (LIS) into a public health interface is processed by Mayo Clinic Lab Registry and data is consolidated and reported to each applicable state's public health agency. All of Mayo Clinic's laboratory data is filtered through this stand-alone product that is a rule-based engine that applies SNOMED and LOINC to reportable findings. The application assigns reportable test results and produces Electronic Laboratory Reporting (ELR) data to meet the interoperability standards per certification criteria in 170.315(f)(3). Laboratory data comes from Mayo Clinic Hospitals, Clinics and Mayo Clinic Laboratories reference laboratory. Real World Testing will be conducted on all modes of incoming data for compliance of output to the implementation guidance.

Laboratory data is provided by other systems, Mayo Clinic Lab Registry adds applicable LOINC and SNOMED codes and formats messages to interoperability standards. LOINC and SNOMED codes will be evaluated for inclusion on the outbound message to monitor continued functionality of the system. Transmission rates will be monitored to ensure messages are transmitted through proper modes of transmission to state agencies for notification of reportable diseases.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	N/A
Date of ONC ACB notification	N/A
Date of customer notification	N/A

Conformance method and measurement/metric(s)	N/A
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MEASUREMENT(S)/METRIC(S) USED IN OVERALL APPROACH

Description of Measurement/Metric

Measurement/Metric	Description
OBX-3 LOINC values	% complete, number of LOINC values reported/number of total reports sent
OBX-5 SNOMED values	% complete, number of SNOMED values reported/number of total reports sent
Transmission success rate	% complete, number of records transmitted successfully to public health/number of total reports
Request fulfillment	Time to complete and respond to requests for EHI export

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
OBX-3 LOINC values	170.315(f)(3) Transmission to public health agencies - reportable laboratory tests and value/results.	Oracle Cloverleaf Integration Engine
OBX-5 SNOMED values	170.315(f)(3) Transmission to public health agencies - reportable laboratory tests and value/results.	Oracle Cloverleaf Integration Engine
Transmission success rate	170.315(f)(3) Transmission to public health agencies - reportable laboratory tests and value/results.	Oracle Cloverleaf Integration Engine
Request fulfillment	170.315(b)(10) Electronic Health Information export	

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
OBX-3 LOINC values	Adherence to requirements to send LOINC codes with ELR reportable results.
OBX-5 SNOMED values	SNOMED CT codes are provided for results when applicable. Not all results are reportable in SNOMED form.
Transmission success rate	Transmissions of reportable messages successfully sent to public health agencies
Request fulfillment	Requirement expects the user to have the ability to create a report in a timely fashion (business hours 7:00am-4:00pm)

Care Setting(s)

Care Setting	Justification
All settings	Provides reportable ELR test results from all laboratory testing performed to public health partners. Results from all care settings will be combined and reported in total.

Expected Outcomes

Measurement/Metric	Expected Outcomes
OBX-3 LOINC values	95% complete
OBX-5 SNOMED values	75% complete, structured numeric results will be excluded as they are not expected to contain SNOMED.
Transmission success rate	90% success rate
Report fulfillment	Completion and response to request within 8 business hours of request receipt.

Quarterly report cards from public health agencies may be utilized to validate data.

SCHEDULE OF KEY MILESTONES

Key Milestone	Date/Timeframe
Submit proposed 2025 Real World Testing plan	November 1, 2024
Begin collection of 2025 information as laid out by the plan	January 1, 2025
Evaluate data collection to address any concerns	Monthly 2025
Data collection and review	Monthly 2025
End of 2025 Real World Testing period/final collection of data	January 2026
Analysis and create report	January 15, 2026
Submit 2025 Real World Testing report to ACB	February 1, 2026
Publication of 2025 Real World Testing report.	March 1, 2026

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.

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ⁱ Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

<https://www.federalregister.gov/d/2020-07419/p-3582>