clinisys™

# Real World Testing Report 2025

**Developer Name:** Clinisys™

**Product Names:**

- Clinisys™ Harvest® (formerly Clinisys™ Orchard Harvest®)
- Clinisys™ Orchard® (formerly Clinisys™ Orchard Enterprise Lab®)

**Version Numbers:**

- Clinisys™ Harvest® v14, v15
- Clinisys™ Orchard® v11, v12

**CHPL IDs:**

- Clinisys™ Harvest® v14 – 15.07.09.2825.OR02.14.02.0.230518
- Clinisys™ Harvest® v15 – 15.07.09.2825.OR02.15.03.0.250101
- Clinisys™ Orchard® v11 – 15.11.09.2825.ENLB.11.00.0.240618
- Clinisys™ Orchard® v12 – 15.11.09.2825.ENLB.12.01.0.250513

## Standards Version Advancement Process (SVAP) Standards Update

**Standards Updates** (including STANDARDS VERSION ADVANCEMENT PROCESS [SVAP] and UNITED STATES CORE DATA FOR INTEROPERABILITY [USCDI])

| | |
|---|---|
| NO | I have products certified with voluntary SVAP or USCDI standards. |
| YES | None of my products include these voluntary standards. |

**Real World Testing Plan URL:** Clinisys™ ONC Health IT Certification

## Changes to Original Plan

| 45 CFR 170.317(f)(3) | | |
|---|---|---|
| **Summary of Change** | **Reason** | **Impact** |
| Counts provided are for a 30-day period rather than a full quarter. | Timing constraints delayed the initiation of data collection at the outset of Q3. | None. Use of a smaller dataset allowed sufficient volume to ensure compliance. |
| Data was obtained from clients utilizing Clinisys™ Harvest® v15 and Clinisys™ Orchard® v12. | | Clinisys™ Harvest® v15 and Clinisys™ Orchard® v12 were inherited from prior certified versions and no changes were made to their codebases; real-world testing of these iterations was sufficient to validate conformance across all products for calendar year 2025 (Clinisys™ Harvest® v14 and Clinisys™ Orchard® v11.) |

**Changes,** continued

| 45 CFR 170.315(b)(10) | | |
|---|---|---|
| **Summary of Change** | **Reason** | **Impact** |
| Clients did not want real patient data to be exported from the application. | Clients did not want real patient data to be exported from the application. | None. Use of test patient data allowed successful determination of exporting patient results. |
| Data was obtained from clients utilizing Clinisys™ Harvest® v15 and Clinisys™ Orchard® v12. | | Clinisys™ Harvest® v15 and Clinisys™ Orchard® v12 were inherited from prior certified versions and no changes were made to their codebases; real-world testing of these iterations was sufficient to validate conformance across all products for calendar year 2025 (Clinisys™ Harvest® v14 and Clinisys™ Orchard® v11.) |

## Real World Testing Overview

Clinisys™ provides an Electronic Laboratory Results (ELR) interface that sends reportable laboratory results to appropriate public health agencies. Here we provide evidence that interfaces in use transmit data that meets certification criterion 45 CFR 170.317(f)(3).

Over a 30-day period in Q3 of 2025, Clinisys™ collected counts of the number of results that qualified as reportable results and the number of results transmitted to the public health agency of two laboratories using:

- Clinisys™ Harvest® v15, CHPL ID: 15.07.09.2825.OR02.15.03.0.250101
- Clinisys™ Orchard® v12, CHPL ID: 15.11.09.2825.ENLB.12.01.0.250513

## Outcomes

**Clinisys™ Orchard®:** The care settings represented are physician laboratory settings.

| Measurement/ Metric | Associated Criterion(a) | Relied Upon Software | Outcomes | Challenges Encountered | Remediation |
|---|---|---|---|---|---|
| Count of reportable results sent via the ELR interface | 170.317(f)(3) | N/A | Qualified Results Lab 1: 718<br><br>Transmitted Results lab 1: 716 | From Lab 1, the Outbound Queue showed 718 messages delivered to the State of Florida in the date range.<br><br>A SQL query of results flagged send to host returned 716 SIDs. | The two-message discrepancy was due to the ELR interface configuration, which sends one OBR per message.<br><br>Two orders had multiple reportable orderables, accounting for the difference, and confirming the counts aligned. |

**Clinisys™ Orchard®,** continued

| Measurement/ Metric | Associated Criterion(a) | Relied Upon Software | Outcomes | Challenges Encountered | Remediation |
|---|---|---|---|---|---|
| Count of reportable results sent via the ELR interface | 170.317(f)(3) | N/A | Qualified Results<br>Lab 2: 22<br><br>Transmitted Results<br>lab 2: 12 | From Lab 2, the Outbound Queue showed 12 messages delivered.<br><br>A SQL query of results flagged as PHA initially returned 22. | Of the 22 messages, 8 were QC order choices ineligible for state reporting, and 2 were duplicate SIDs that would have been sent in a single message.<br><br>After accounting for these, the total aligns with the correct number of 12 messages. |

**Clinisys™ Harvest®:** The care settings represented are hospital laboratory settings.

| Measurement/ Metric | Associated Criterion(a) | Relied Upon Software | Outcomes | Challenges Encountered | Remediation |
|---|---|---|---|---|---|
| Count of reportable results sent via the ELR interface | 170.317(f)(3) | N/A | Qualified Results Lab 1: 132<br><br>Transmitted Results lab 1: 132 | The Clinisys™ Harvest® data browser for the same date range showed 421 records. | From Lab 1, we confirmed that 132 messages were generated and sent to the state via the SFTP interface during the review period.<br><br>After filtering for unique SID/orderable pairs, the counts matched exactly, reflecting the client's high volume of STD and microbiology testing where multiple rows consolidate into single messages.<br><br>No further investigation is required. |

**Clinisys™ Harvest®,** continued

| Measurement/ Metric | Associated Criterion(a) | Relied Upon Software | Outcomes | Challenges Encountered | Remediation |
|---|---|---|---|---|---|
| Count of reportable results sent via the ELR Interface | 170.317(f)(3) | N/A | Qualified Results Lab 2: 114<br><br>Transmitted Results lab 2: 114 | The Clinisys™ Harvest® data browser for the same date range showed 124 records. | After reviewing the Mapper scripts, the reason for the 10-result difference was quickly identified.<br><br>*No growth* results were being flagged in the system to be sent to the state, but the Mapper was configured to remove those results.<br><br>This accounted for the 10 fewer results observed. |

## Real World Testing Overview

Clinisys™ provides an electronic health information export interface that enables clients to export results for either a single patient or an entire patient population. The evidence below demonstrates that the interfaces in use successfully export data in compliance with certification criterion 170.315(b)(10).

Clinisys™ partnered with clients to confirm that the export specifications—whether for individual patients or entire populations—consistently produce accurate, compliant, and successful outputs.

- Clinisys™ Harvest® v15, CHPL ID: 15.07.09.2825.OR02.15.03.0.250101
- Clinisys™ Orchard® v12, CHPL ID: 15.11.09.2825.ENLB.12.01.0.250513

**Clinisys™ Orchard®:** The care settings represented are hospital laboratory settings.

| Measurement/ Metric | Associated Criterion(a) | Relied Upon Software | Outcomes | Challenges Encountered | Remediation |
|---|---|---|---|---|---|
| EHI export – Single patient population EHI report | 170.315(b)(10) | N/A | Single export field data content matches HL7 specifications. | Client requested that no live data be exported. | A single test patient was utilized because the client requested that no live data be exported. |

**Clinisys™ Orchard®,** continued

| Measurement/ Metric | Associated Criterion(a) | Relied Upon Software | Outcomes | Challenges Encountered | Remediation |
|---|---|---|---|---|---|
| EHI export – patient population EHI report | 170.315(b)(10) | N/A | Patient population export field data content matches HL7 specifications. | Client requested that no live data be exported. | Multiple test patients were utilized because the client requested that no live data be exported |

**Clinisys™ Harvest®:** The care settings represented are hospital laboratory settings.

| Measurement/ Metric | Associated Criterion(a) | Relied Upon Software | Outcomes | Challenges Encountered | Remediation |
|---|---|---|---|---|---|
| EHI export – Single patient population EHI report | 170.315(b)(10) | N/A | Single export field data content matches HL7 specifications. | Client requested that no live data be exported. | A single test patient was utilized because the client requested that no live data be exported |

**Clinisys™ Harvest®,** continued

| Measurement/ Metric | Associated Criterion(a) | Relied Upon Software | Outcomes | Challenges Encountered | Remediation |
|---|---|---|---|---|---|
| EHI export – Patient population EHI report | 170.315(b)(10) | N/A | Patient population export field data content matches HL7 specifications. | Client requested that no live data be exported. | Multiple test patients were utilized because the client requested that no live data be exported |

## Milestones

| Key Milestone | Dates |
|---|---|
| Identification of participants | July 14, 2025 |
| Collection of data begins | September 1, 2025 |
| Final collection and data analysis | November 19, 2025 |

Per current Enforcement Discretion guidance, submission of this results report is not required.

## Overall Outcome

The Clinisys™ Electronic Laboratory Results (ELR) interface identified all results qualified for reporting to the agency and, following remediation, successfully transmitted them in a format accepted by the agency. The process is fully compliant with the certification criterion 45 CFR 170.317(f)(3).

The Clinisys™ EHI patient export process identified all fields qualified for the patient export and successfully exported them in a format accepted by the agency. This process is fully compliant with the certification criterion outlined in 45 CFR 170.315(b)(10).