

# ELINCS v1.1 to HL7R1 Change Summary

The California HealthCare Foundation (CHCF) has produced this document to provide Laboratory and EHR implementers of the ELINCS HL7-R1 implementation guide a means of estimating the level of effort involved in developing a new ELINCS HL7-R1 interface or upgrading an existing ELINCS v1.1 interface to the new HL7-R1 specification. Access to the new ELINCS HL7-R1 implementation guide is limited to members of HL7 and so may not be readily available to all parties wishing to immediately implement the specification. This document provides a high-level summary of the changes that have been made to the ELINCS specification since version 1.1. In addition to this document, a supporting document, "ELINCS v1.1 to HL7-R1 Change Details.doc", provides a more technical listing of the field-by-field changes that have been made to the ELINCS specification. The document also provides more details about certain new requirements of the implementation guide. The combination of these two documents should provide the reader with the information necessary to develop an estimate of the level of effort required to implement a fully conformant ELINCS HL7-R1 interface.

This document assumes that the reader is fully familiar with the ELINCS v1.1 specification. If this is not the case, you may download a free version of the ELINCS v1.1 specification from the CHCF ELINCS website (<http://www.elincs.org>).

This document (and the related detail document) is intended to provide the reader with high level information about the changes to the ELINCS specification. It is not intended to take the place of ELINCS HL7-R1 specification and does not contain information sufficient to implement a fully conformant ELINCS interface. For that, the official HL7 document is required.

## **Change Summary**

This section describes each of the major changes that have been incorporated into the ELINCS HL7-R1 implementation guide. In summary, these changes include:

- Change from HL7 v.2.4 to HL7 v.2.5.1 (New required and optional segments/fields)
- Full support for the structured reporting of microbiology Culture/Sensitivity results
- Special rules for reporting the identifiers of ordered tests, depending on whether the ordering system and the reporting system support unique identifiers for each test ordered on a requisition.
- Full support for sending copies of lab results to other providers
- A broader set of lab tests for which LOINC coding is required

In addition to those items listed above, this document also addresses concerns that have been raised about certain coding requirements of the guide.

## **HL7 v2.4 → HL7 v2.5.1 & New Segments/Fields**

One of the most sweeping changes to the ELINCS specification is the change from HL7 v.2.4 to HL7 v2.5.1. This change impacts almost every segment of the message structure, although most of these impacts are minor and require little-to-no alteration of an existing interface. However, there are a few notable exceptions which are described in this section.

The change from v2.4 to v2.5.1 was implemented for two primary reasons. First, it keeps the ELINCS specification in harmony with other emerging laboratory specifications and matches the

certification criterion set forth by CCHIT for ambulatory EHR certification in 2008. Second, the move to v.2.5.1 allows for the use of new fields that were created specifically to meet certain requirements of the ELINCS specification that were not supported in v.2.4 (specifically, OBR-50, OBX-23, OBX-24, and OBX-25).

## **Data Type Changes**

A number of HL7 data types have changed between v.2.4 and v.2.5.1. In some cases, new components have been added to certain data types. In other cases, the use of some components has been deprecated. For the most part, the HL7 ELINCS project team has attempted to minimize the required use of new components and has continued the use of previously supported required components. However, in some cases, changes to the component and sub-component usage could not be avoided. Additionally, the data types of certain entire fields have changed as of HL7 v2.5.1. In some of these cases the actual implementation of the field has not changed at all (e.g., the specification does not use any of the newly defined components of the new data type and the components that are used are compatible with the old data type.). In other cases implementation changes will be necessary (e.g., OBR-26 Parent Result and OBR-29 Parent). See **Section 1: ELINCS HL7-R1 Segment & Field Usage Changes** of the change details document (blue highlighted text) for details on some of the changes to field data types. Where possible, this section also notes the fields where the field components have changed.

## **TQ1 (Timing/Quantity) Segment Support**

The TQ1 segment is a new segment, introduced in HL7 v2.5. The ELINCS HL7-R1 implementation guide supports the optional use of this segment. This segment is used in place of the OBR-27 Quantity Timing field that was supported in ELINCS v1.1 but has since been deprecated by HL7. The segment is used in ELINCS messages to identify the earliest or latest date/time a test may be performed. If the segment is present, TQ1-7, TQ1-8, or both fields must be populated. For field usage details, see **Section 1: ELINCS HL7-R1 Segment & Field Usage Changes** of the change details document.

## **SPM (Specimen) Segment Support**

The SPM segment is a new segment, introduced in HL7 v2.5. The ELINCS HL7-R1 implementation guide supports the use of this segment. Only the SPM-4 Specimen Type field is required to be populated when the SPM segment is present. However, a number of other fields are optionally available to be used to report back other information about the collected specimen. The ELINCS specification does not provide guidance beyond that provided by the HL7 standard for these optional fields. Labs are not required to populate the optional fields of the SPM segment and EHRs are not required to capture or display any data sent in these optional fields.

Should data be present in SPM-21, 22, or 23, an NTE segment must also be present under the same OBR segment as the SPM that contains these fields. The NTE segment must contain the same information that is present in SPM-21, 22, and 23. This requirement ensures that EHRs which do not have the ability to capture the coded data provided in these fields can alternatively display the information as a note on the OBR segment. For field usage details, see **Section 1: ELINCS HL7-R1 Segment & Field Usage Changes** of the change details document.

## **ORC Segment Support**

Although it is not a new segment as of HL7 v2.5, the ELINCS HL7-R1 implementation has added the required use of the ORC segment to clearly group ordered tests within a given

requisition. The required use of this segment has been added to support another new feature of the ELINCS HL7-R1 implementation guide, specific rules for ordered test and requisition identification, discussed later in this document. For field usage details, see **Section 1: ELINCS HL7-R1 Segment & Field Usage Changes** of the change details document.

### ERR Segment Support

The Accept/Acknowledgement method has changed in ELINCS HL7-R1 from “SU” (Successful completion only) to “AL” (Always). This means that an EHR system that receives an ELINCS result message must send an acknowledgment to the sending lab system if the message is accepted and also if the message is rejected. To support this change, the ERR segment of the MT-ACK-1 Acknowledgement message type has been added to allow EHR systems to report back to the sending laboratory the specific errors found in a result message. The segment usage is “RE”, indicating that the EHR shall include error information when available and appropriate. For field usage details, see **Section 1: ELINCS HL7-R1 Segment & Field Usage Changes** of the change details document.

### New Fields

ELINCS HL7-R1 has added support for a small number of new “required”, “required-or-empty”, and “conditional-or-empty fields”. These fields are displayed in the table below. For additional details, see **Section 1: ELINCS HL7-R1 Segment & Field Usage Changes** of the change details document (green highlighted text).

Segment	Seq	Element Name	Usage
OBR	50	Parent Universal Service Identifier	CE
OBX	23	Performing Organization Name	R
OBX	24	Performing Organization Address	R
OBX	25	Performing Organization Medical Director	RE

### Removed Fields

A small number of fields have been de-supported since ELINCS v1.1. Fields were de-supported if HL7 had deprecated the use of the field in the original standard or if the field was not being implemented correctly in the previous specification. These fields are displayed in the table below. For additional details, see **Section 1: ELINCS HL7-R1 Segment & Field Usage Changes** of the change details document (red highlighted text).

Segment	Seq	Element Name
OBR	14	Specimen Received Date/Time
OBR	15	Specimen Source
OBR	27	Quantity/Timing
OBX	15	Producer’s ID
OBX	19	Date/Time of the Analysis

### Field Implementation Changes

In addition to the newly added segments and fields discussed in the previous sections, a number of existing fields have had changes made to the way they are implemented. Some fields have had their static value changed and others have had the rules for how to implement the field modified. There are approximately 15 fields that have had changes made to their

implementation specification. These changes are listed in **Section 1: ELINCS HL7-R1 Segment & Field Usage Changes** of the change details document (blue and red highlighted text).

## Culture/Sensitivity Reporting

Laboratories are required to report culture results and antimicrobial sensitivity reflex results per the rules described by the ELINCS HL7-R1 Implementation Guide. The rules defined in the implementation guide give guidance on how to report culture results and how to unambiguously relate an antimicrobial sensitivity result to the culture result that spawned it.

Some fields require the use of standardized coding systems (e.g., OBX-3 must be populated with LOINC codes to identify an organism identification result and a colony count for culture results). Other fields merely need to be coded but the specification does not go so far as to mandate a particular coding system (e.g., for Culture results, OBX-5 must be a coded entity but a standard coding system, such as SNOMED-CT, is not required to be used as the coding system).

The following fields are of particular importance in reporting culture and antimicrobial sensitivity result reporting and the implementation guide provides detailed guidance on the population of these fields. For additional details on culture and antimicrobial sensitivity reporting, see **Section 2: Reporting of Culture Results and Antimicrobial Sensitivities** in the change details document.

Segment	Seq	Element Name
OBR	2	Placer Order Number
OBR	3	Filler Order Number
OBR	26	Parent Result
OBR	29	Parent
OBR	50	Parent Universal Service Identifier
OBX	3	Observation Identifier
OBX	4	Observation Sub-ID
OBX	5	Observation Value

## Ordered Test Identification

Clinicians often order multiple lab tests on a single requisition for a single patient. In the ambulatory setting, labs typically report all of the results for such a requisition as a single message. For these “multi-test requisitions,” two alternative paradigms exist for assignment of unique identifiers to the requisition and to its constituent tests: *Requisition-Only Identification* and *Test-Specific Identification*. Because both paradigms are used today by EHRs and laboratory information systems, the ELINCS HL7-R1 implementation guide includes both models and requires that conformant systems support both models. This requirement and the details of its implementation are important, because it allows EHRs and labs that do not use the same model to interoperate nevertheless, subject to certain rules and constraints.

In *Requisition-Only Identification* (“RO”), a single identifier is assigned to the entire requisition and no unique identifiers are assigned to the individual tests (although unique service codes do indicate the *type* of each test, such as “4356-BLCx” or “2849-Tox Screen”). Some EHRs use this model to generate test requisitions: They assign an identifier to the entire requisition, but assign no unique identifiers to the constituent tests. Some labs use this model to report test

results: They capture only the requisition identifier and report all of the constituent tests using that single identifier.

In *Test-Specific Identification* (“TS”), a unique identifier is assigned to each individual test in the requisition and another identifier is assigned to the entire requisition itself. As with *Requisition-Only Identification*, a unique service code is also assigned to each test to indicate its type. Some EHRs use this model to generate test requisitions: They assign a pair of identifiers to each ordered test, one denoting the requisition in which the test appears and one denoting the test itself. Some labs are able to accommodate this model when reporting test results: They capture the requisition identifier and the test-level identifiers and include back both identifiers in each reported result.

Depending on which model is used, certain elements in the OBR segment are populated differently (as described in **Section 3: Ordered Test Identification** in the detail document). When both the lab and the EHR use the same model, interoperability is straightforward (regardless of which model is used). When the lab and the EHR use different models, interoperability is more complex, but still possible if both systems are conformant with this specification.

Conformance with the ELINCS HL7-R1 implementation guide does not require EHRs and labs to implement Test-Specific Identification in their systems. Specifically, labs are not required to capture or report unique test-specific identifiers and EHRs are not required to generate them (although the specification accommodates EHRs and labs that already use test-specific identifiers). Rather, conformance requires only that EHRs and labs recognize that messages from their trading partners may or may not contain test-specific identifiers, and be able to adjust their processing accordingly.

**Note:** Future versions of the ELINCS implementation guide will require EHRs and labs to implement test-specific identification, but a transition period is required to achieve widespread implementation of this specification.

## Copy-To Messaging

Copy-to messaging is fully supported in ELINCS HL7-R1. Laboratories that support copy-to messaging use two fields, ORR-21 “Filler Field 2” and OBR-28 “Result Copies To,” when reporting a message copy. OBR-21 is used to indicate to the receiving EHR system whether the message is the original message delivered to the ordering provider (“ResultCopiesRequest”) or whether the message is a copy of a message meant for another provider (“ResultCopyEnclosed”). OBR-28 contains the provider information, including provider identifiers, of the providers for whom copies were requested to be sent. The following table describes the use of OBR-21 and OBR-28

Intended Recipient of Result	OBR-21 Value	OBR-28 Contents
Ordering Provider (No copies requested)	Empty	Empty. When OBR-21 is empty, OBR-28 may not be populated.
Ordering Provider (Copies requested)	“ResultCopiesRequested”	The provider information of all of the providers to whom copies were requested to be sent. A maximum of five repeats is supported for this field.
Other Providers	“ResultCopiesEnclosed”	The provider information of the physician the copy is intended to be delivered to. Only a single provider element is allowed in this case.

Result copies are only supported in MT-ORU-2 messages (e.g., preliminary, final, correction messages, etc.). OBR-21 is not supported for MT-ORU-1 message types.

## LOINC Coding Requirements

The ELINCS HL7-R1 implementation guide has increased the requirements for the tests that must be LOINC coded from the top 80% to the top 95% of laboratory tests performed by frequency. This has resulted in an increase in the total number of tests that must be LOINC coded from 94 to 155 distinct tests. In addition, the implementation guide has changed the manner in which the LOINC codes that may be used to identify these commonly reported tests are specified. As a result, the number of LOINC codes that may potentially be reported in an ELINCS message has increased from approximately 300 to 550 unique codes.

In ELINCS v1.1, the LOINC codes that could be used to identify the top 80% of performed laboratory tests were listed explicitly in the specification. In ELINCS HL7-R1, instead of listing each of the LOINC codes that can be used to identify one of the top 95% of performed laboratory tests, the LOINC *parameters* that define the laboratory test (e.g., Component, System, Time Aspect, Property, Scale Type, and Method) are listed in a table of tests. The LOINC codes that correspond to these tests (given the provided parameters) can then be determined by querying the most recent version of the LOINC database with the provided parameter values for the test.

An example comparison of the previous approach (a predetermined list of LOINC codes) to the current approach (a list of LOINC codes queried from the LOINC database given certain test parameters) is provided below. The codes that match between the two approaches are highlighted.

### ELINCS v.1.1 Codes for LDL-Cholesterol Test

Test	Test Desc	Sample LOINC Codes
LDL-Cholesterol	LDL Cholesterol, patient serum/plasma quantitative	<b>2089-1, 12773-8, 13457-7, 18262-6, 22748-8</b>

### ELINCS v.HL7-R1 Test Parameters for LDL-Cholesterol Test

Test	Test Desc	Component	System	Time Aspect	Property	Scale Type	Method
LDL-Cholesterol	LDL Cholesterol, patient serum/plasma quantitative	CHOLESTEROL.IN LDL	SER/PLAS	PT	ACNC, MCNC, MSCNC, SCNC	QN	*
<b>LOINC Codes that result from a LOINC database query, given the above parameters:</b>							
<b>2089-1, 12773-8, 13457-7, 18262-6, 22748-8, 35198-1, 39469-2, 49132-4</b>							

As you can see, the newer approach has identified a few additional codes that were not present in the previous version of ELINCS. Laboratories should choose the appropriate code from among these and use it whenever the test is reported (typically only one code would be appropriate for the lab to use when reporting a particular test). EHR systems must be prepared to accept any of the valid codes derived from the test parameters provided in the table and correctly map these codes to EHR's internal representation for the test concept.

## Coding Requirements

One commonly voiced concern is the coding requirements that are specified in the implementation guide. Coding systems such as SNOMED-CT and UCUM have the potential to improve the quality and automated computability of data transmitted via a standardized laboratory message, such as ELINCS HL7-R1. However, many EHR and laboratory systems are not yet ready to fully support all of the standardized coding systems used in electronic lab reporting.

The ELINCS HL7-R1 has taken the pragmatic approach of specifying limited requirements for standardized medical coding systems. In most cases, a standard coding system is strongly recommended, although not required in the current version of the implementation guide. The following table indicates the fields in the ELINCS HL7-R1 implementation guide that have recommendations or requirements for coding and the circumstances in which the code is used.

Field	Coding System	Recommended/ Required	Usage Comment
OBX-3 Observation Identifier	LOINC	Required	The usage of the LOINC coding system is required for those tests identified in section 9 of the ELINCS HL7-R1 implementation guide.
OBX-5 Observation Value	SNOMED-CT	Recommended	The usage of SNOMED-CT to identify an identified microorganism in a culture result is strongly recommended, but not required.
OBX-6 Units	UCUM	Recommended	The usage of the UCUM coding system for units of measure is recommended when units apply to the test result. A local unit value may also be reported in the same field.