Integrating the Healthcare Enterprise



5 IHE Pathology and Laboratory Medicine Technical Framework Supplement

10 Laboratory Clinical Communications (LCC)

Rev. 1.0 – Draft for Public Comment

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Foreword

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This is a supplement to the IHE Pathology and Laboratory Medicine (PaLM) Technical

Framework V8.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on November 29, 2017 for public comment. Comments are invited and can be submitted at http://ihe.net/PaLM Public Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by January 26, 2018.

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This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

- 40 Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **bold strikethrough**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.
- General information about IHE can be found at www.ihe.net. 45

Information about the IHE Pathology and Laboratory Medicine domain can be found at http://www.ihe.net/IHE Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://www.ihe.net/IHE Process and http://www.ihe.net/Profiles.

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The current version of IHE Pathology and Laboratory Medicine Technical Framework can be found at http://www.ihe.net/Technical Frameworks.

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Introduction to this Supplement

The current order-result paradigm supported under HL7^{®1} V2 includes ordering, order cancellation, unsolicited replacement of issued orders by the Order Placer or Order Filler, and result reporting. It does not encompass other clinically-important interactions related to ordering

- 100 and resulting laboratory tests, such as recommendations for order replacement by the Order Filler or additional work after resulting required for fulfillment of the original clinical need. The former occurs when an Order Filler such as a clinical laboratory has information indicating that one or more orders (such as an order for laboratory tests) may be inappropriate due to patient characteristics or impossible to complete, but does not have prior permission to replace that order 105 without clinical input. The latter occurs when a result may need to be verified or interpreted
 - before being acted upon.

Communications satisfying these needs are typically carried out by phone, fax, or other manual methods, which are inefficient for Order Fillers and ordering clinicians, are not amenable to automation and decision support, prevent Order Fillers from communicating through the EHR as

- 110 a full member of the patient's care team, and do not create structured documentation useful in quality assurance and process improvement. The Laboratory Clinical Communication (LCC) Profile defines workflows, messages, and data elements to support automated communications between Order Filler and Order Placer/EHR systems about orders and results. It is intended to carry enough information about existing orders or results that systems can implement
- 115 streamlined, convenient methods to support requesting replacement of orders or issuing new orders for additional work related to particular results.

The LCC Profile also enables improved Order Filler quality assurance. The communication and resolution of needs for order replacement, result confirmation, and, if appropriate, result interpretation are integral parts of service quality that are currently managed on an *ad hoc* basis

120 outside of information systems. Communications can be delayed or lost and summary data about ordering and resulting problems is difficult to compile. Thus recognition and correction of the acute and/or systemic problems indicated by these communications is time consuming and error prone. This new profile will enable rapid, standardized, automated capture of and response to problems related to orders and questions about results, and will allow this information to be logged, tracked, and included in QA studies and process improvement projects.

The LCC Profile was developed from a clinical laboratory and anatomic pathology perspective and will benefit interactions in both of those specialties. The use cases cited in this document are laboratory-oriented. However, the problems the profile addresses are general to ordering and resulting workflows, and thus these communication patterns should be useful to any clinical services that respond to orders and/or create clinical information that may require further action

130 services that respond to orders and/or create clinical information that may require further action.

¹ HL7 is the registered trademark of Health Level Seven International.

Open Issues and Questions

None.

Closed Issues

- OO CR-855 (V2.10) modified the REL segment in order to describe the type of objects
- 135 linked by the REL segment identified in REL-4 and REL-5 respectively by adding two new fields (REL-17 and REL-18). This approach is pre-adopted for use in LAB-7.

General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

140 Appendix A – Actor Summary Definitions

N/A

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

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Transaction	Definition
LAB-6	Proposal for Order Replacement
LAB-7	Request for Fulfillment (e.g., verification of a result)

Glossary

N/A

Volume 1 – Profiles

Copyright Licenses

150 N/A

Domain-specific additions

N/A

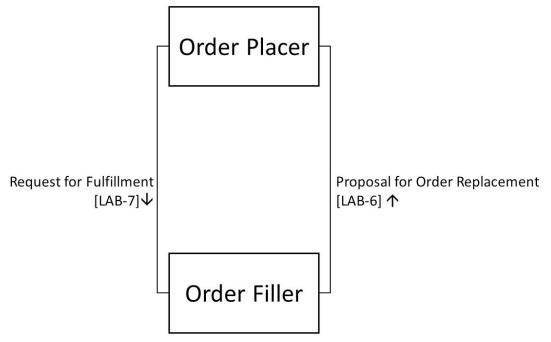
X LCC (Laboratory Clinical Communications) Profile

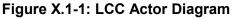
- 155 The Laboratory Clinical Communications (LCC) Profile supports further information exchanges between clinicians and laboratories in the context of a set of test orders. This profile covers use cases, workflows and transactions for additional information exchange after placing an order or receiving a result. This additional clinical communication may include recommending replacement orders when the submitted orders are not optimal or inappropriate for the type of
- 160 specimen or clinical setting, or requesting follow up on a specific result that does not fully meet the clinical need or does not fit the clinical presentation of the patient.

X.1 LCC Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at <u>http://ihe.net/Technical_Frameworks/#GenIntro</u>.

Figure X.1-1 shows the actors directly involved in the LCC Profile





The LCC Profile defines two transactions occurring between the Order Filler representing the laboratory application, and the Order Placer representing the application used in the clinical care setting.

Table X.1-1 lists the transactions for each actor directly involved in the LCC Profile. To claim
 compliance with this profile, an actor shall support all required transactions (labeled "R") and
 may support the optional transactions (labeled "O").

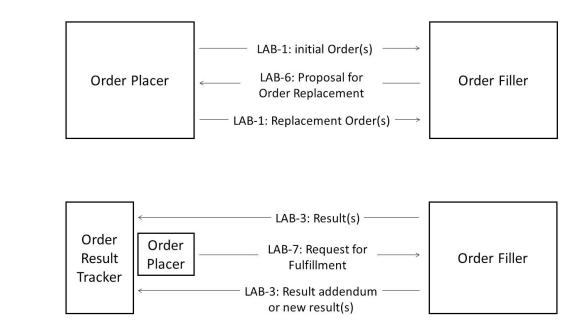
Actors	Transactions	Optionality	Reference
Order Filler	Proposal for Order Replacement [LAB-6]	R	PaLM TF-2:3.6
	Request for Fulfillment [LAB-7]	R	PaLM TF-2:3.7
Order Placer	Proposal for Order Replacement [LAB-6]	R	PaLM TF-2:3.6
	Request for Fulfillment [LAB-7]	R	PaLM TF-2:3.7

Table X.1-1: LCC Profile - Actors and Transactions

X.1.1 Actor Descriptions and Actor Profile Requirements

180 Requirements are documented in Transactions (Volume 2a). There are no additional requirements on the profile's actors imposed by LCC transactions.

Transactions Proposal for Order Replacement [LAB-6] and Request for Fulfillment [LAB-7] integrate into the transaction flow of the LTW Profile of the PaLM TF.





Note that communication between Order Placer and Order Result Tracker is assumed to take place one way or the other: These two actors might be grouped in a single application, or have information exchanges, or be used separately by two distinct applications used by the clinician.

190 X.2 LCC Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options when applicable are specified in notes.

Actor	Option Name	Reference
Order Filler	No options defined	
Order Placer	No options defined	

Table X.2-1: LCC - Actors and Options

195 X.3 LCC Required Actor Groupings

Section not applicable.

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X.4 LCC Overview

The LCC Profile introduces two feedback loops between the clinicians placing the orders and receiving the results on one side, and the laboratory performing the orders and sending the results on the other side. The first feedback loop (order replacement) operates between the Order Placer and Order Filler systems. The second feedback loop (result fulfillment) is triggered by a result and requires coordination between the Order Result Tracker and the Order Placer systems so that a follow-up order from the Order Placer to the Order Filler may refer to the previous result. This

205 The LCC Profile works in tandem with the Laboratory Testing Workflow (LTW) Profile in support of the use cases described below.

coordination is represented by grouping the Order Placer and Order Result Tracker.

The LTW Profile defines five transactions (LAB-1 to LAB-5) that flow between four actors to support laboratory test ordering and resulting (see PaLM TF-1: 3). These transactions support standard ordering and resulting but are insufficiently flexible to support the range of

- 210 communications related to orders and results that typically occur between clinicians and ancillary services such as laboratories. For example, orders that cannot or should not be carried out may be refused or cancelled directly, or the Order Filler may contact the Order Placer outside the system and ask that replacement orders be issued. Also, when results do not completely fill the clinical need there is no facility within systems to request additional work related to that order or result.
- 215 The LCC Profile defines two additional transaction types (LAB-6 and LAB-7) for the LTW with new triggers that increase the flexibility of the order-result interaction within the system and meet these needs.

Prior to the LCC Profile, Order Placers were able to send replacements for existing orders to Order Fillers as part of the LAB-1 transaction (referred to in the IHE PaLM TF as "order

- 220 update"). Order Fillers could create new orders and send them to Order Placers for order number assignment using the LAB-2 transaction, but this transaction does not allow association of the new orders with previous Order Placer orders as would be required to express and document order replacement. The LTW Profile "order update" concept is derived from the HL7 V2.5.1 order replacement pattern, which includes order replacement by either the Placer or the Filler,
- 225 though as noted the latter is not included in the LTW Profile. The new LAB-6 transaction blends elements of these existing transactions and uses new order control and status codes to support a transaction starting with the Filler that recommends replacement of one or more specific existing orders with one or more new orders. The transaction uses the message structure of the HL7 Filler order replacement message, identifying the orders to be replaced and defining replacement
- 230 orders. This message structure is similar to the Placer order update currently covered by the LTW Profile. It differs from these previous messages by using new control codes to indicate that the replacement is a recommendation rather than a completed act. The Placer may accept, decline, or modify the replacement orders and return an order replacement message to the Filler with control codes indicating those responses.
- 235 Transaction LAB-6 also introduces a time window during which orders with pending recommendations are held by the Filler and recommendation responses can be accepted from the Placer. If no responses are received by the end of the window, order processing by the Filler proceeds as it would have without the transaction. This hold status is represented by Order Status code, on hold (HD), Order Status Modifier, expires on time (EOT), and the beginning and end times for the hold status in a new field, Order Status Date Range (ORC-36).

Orders for additional work on one or more results are carried in a new LAB-7 transaction. This additional work may include, for example, confirmation or interpretation, follow up of a process problem, an assertion of error, or a request for annotation, from the Order Placer to the Order Filler. The order includes the patient identity and results to be interpreted or annotated, and may

- 245 incorporate results from multiple tests as well as observations entered at order time. The transaction does not assume that the Order Filler system originally provided the results to be interpreted. Because the LAB-7 order may require information from a result, a LAB-7 implementation would be most convenient when the Order Placer and Order Results Tracker are integrated in a single system, allowing automatic incorporation of the result information into the
- 250 new order. The response by the Order Filler may be in the form of an addendum or amendment to the original result and/or a report or other result associated with the LAB-7 order. These orders are called "fulfillment orders" because the requested additional work is required for the result to fulfill its intended clinical purpose.

Transaction LAB-7 establishes a target relationship between the new order and a previous
 information instance (such as an order or result) by incorporating the REL segment into the order message with a new relationship type, Service Target (SVTGT, REL-2), and two new fields (REL-17 and REL-18) to identify the types of the source and target information instances.

In addition to communicating recommendations and orders, LAB-6 and LAB-7 messages allow replaced and replacement orders to be linked, or results to be linked with fulfillment orders, so

260 that the frequency, context, and performance quality of recommendation and fulfillment activities can be monitored.

This LCC Profile incorporates and extends concepts from the HL7 V3 laboratory ordering behavioral model into HL7 V2 so that they may be available to the laboratory community prior to broad implementation of HL7 V3. The V3 behavioral modeling is ongoing and the LCC

- 265 Profile will track that work as it continues. The current IHE PaLM Technical Framework and the ONC laboratory ordering and reporting initiatives are based on HL7 V2.5.1. LCC development initially focuses on repurposing existing HL7 V2.5.1 messages and data elements to carry the data that LCC transactions require. Where extension of field definitions, new fields, new codes, or new messaging patterns are required, they are proposed for the next version of the HL7 V2 in
- 270 cooperation with the HL7 Orders & Observations (OO) workgroup, and approved new features are "pre-adopted" individually into the overall HL7 V2.5.1 environment of the PaLM Technical Framework.

The intent of this work is to create a communication standard for use by separate LIS and EHR/order entry systems. LCC Profile development does not modify the LTW and other

275 profiles, except for the definition of a limited number of new codes/terms/fields and minor modifications of code and segment usage specifications affecting only LCC messages. As such it sits within the framework defined by the LTW. In addition, the workflow and use cases from this project should be beneficial to integrated LIS/EHR systems through the definition of a more comprehensive order-result workflow that addresses clinical needs.

280 X.4.1 Concepts

See PaLM TF-1: 3.4.

X.4.2 Use Cases

The following paragraphs describe the use cases for the LCC Profile. They can be divided into two sub-categories:

- 285 1. Proposal for order replacement prior to testing
 - 2. Result fulfillment and follow up after testing

X.4.2.1 Use Case #1: Proposal for Order Replacement

After receiving an order from clinical practice and identifying some issues, the laboratory creates an order replacement message and sends it to the clinician with a suggestion of a replacement for all or some of the ordered tests, before testing begins.

X.4.2.1.1 Proposal for Order Replacement Description

PreCondition:

An order group (or single order) is created by the Order Placer and sent as a "New Order" message to the Order Filler.

295 Initial Part:

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The receiving Order Filler identifies that the test(s) as ordered cannot be performed for several reasons:

- 1. **Test prioritization.** A set of laboratory tests is ordered but the patient is a difficult draw and inadequate volume is obtained to run all tests. The selection of the most useful of the ordered tests depends on the patient's clinical status. An LCC message is returned to the ordering EHR that provides notice of the volume problem and presents a suggested prioritization of tests with an option to modify the priority. Using the message display, the clinician quickly prioritizes the tests to run immediately and schedules a follow up blood draw to provide specimens for the remaining tests. The information is returned to the LIS where the initial order is amended, the follow up blood draw is scheduled as a new procedure, and the problem and its resolution are captured into a QA database.
- 2. **Optimizing diagnostic yield for individual patients.** A set of orders is received by the laboratory that is expected to have poor diagnostic yield for the patient based on an individualized Bayesian analysis including demographics, prior diagnoses, and prior testing results. The laboratory issues an LCC message recommending replacement of some or all of the ordered tests with tests that are expected to have a higher diagnostic yield in this context, and includes explanations in the message along with the recommendations. The clinician can consider the recommendations and either accept or decline them in the returned message.
- 315
 3. Reference laboratory order modification. Specimens are drawn by a local clinical laboratory and shipped to a reference laboratory, with a testing order transmitted via their reference laboratory interface. On arrival it is found that the specimen is inadequate (incorrect type, volume, tube type, etc.). An LCC message is returned to the local laboratory via the interface that indicates the problem, the tests that can be carried out on the available specimen, and the amount and type of additional specimen needed. If appropriate specimens are available, the local lab can elect to ship them immediately to complete the original order. Otherwise, the laboratory can pass the message back to the ordering EHR for amendment of the original order and/or additional sampling.
- 4. Proactive follow-up of inconclusive testing. A fine needle biopsy is sent to pathology but proves to be inconclusive. Rather than report an essentially negative result with a recommendation for resampling, an LCC message is sent to the clinician indicating that the sample was inadequate for diagnosis and presenting an order for repeat sampling. If the clinician chooses to repeat the test, the results of both tests are reported together with a definitive diagnosis. If no further specimen is provided, the results of the initial specimen are reported. *This potential use of the LCC with inconclusive specimens in AP allows initial and follow up specimens to be reported together rather than reporting potentially misleading negative results.*
 - 5. **Handling future order timeout.** A physician seeing a patient for hyperlipidemia writes a future order for a lipid panel in 4 months and asks the patient to return in 6 months for follow up. When the patient has not visited the lab by 5 months, the order expires and an

LCC message is returned to the physician's EMR indicating no-show expiration and allowing replacement of the original order with a new order having a longer time frame and notification to the patient, or cancellation of the order. *It often matters clinically whether a test has expired due to a no-show or has been canceled for other reasons. Current systems do not do a good job of providing this information to clinicians and queuing up their likely responses.*

6. **Proactive correction of incorrect test orders.** A laboratory receives an order for an expensive genetic test. Other test results and a check of the clinical history indicate that a different genetic test is indicated. An LCC message is returned to the clinician with the correct test presented for ordering and an explanation for the substitute order. The clinician can quickly order the replacement test. *Incorrect test orders are not uncommon and the problem is especially acute with new genetic tests according to studies in the past two years by academic centers and major reference laboratories. These errors yield unnecessary cost, delays in diagnosis, and incorrect diagnoses. Currently there is no good way to communicate this information within the order/result transactions.*

7. **Promotion of test utilization goals and guideline adherence.** A laboratory receives an order for an expensive confirmatory test without a history of the appropriate screening test. An LCC message is returned to the physician that recommends replacement of the ordered test with the screening test and provides the option to order the latter or confirm the previous order. The physician quickly orders the screening test from within the message display. *Though this is a simple example, a similar mechanism might provide decision support related to test utilization and testing guidelines. In settings where a lab supports multiple small ambulatory EHRs, maintenance of decision support rules individually in those EHRs may be difficult. Future standardization of decision support rule format will help, but certain forms of sophisticated or laboratory-specific decision support may be best managed in the LIS. The LCC will provide one mechanism for the results of LIS-based order filtering or decision support to be communicated back to the EHR and ordering physicians.*

8. **Capture or correction of data required for testing.** A test is ordered with required data that is missing or erroneous. An LCC message is returned to the ordering system indicating the omission or error and requesting replacement with a similar order that contains the required data. The message display queues up the order with a heading describing the problem and the missing or incorrect fields easily accessible for correction. The physician quickly enters the new data and submits the replacement order. *Limited rules-based processing of orders received in the lab might be used to detect errors, omissions, and other data problems that could be followed up quickly for correction.*

9. **Results-dependent test ordering in extended testing algorithms.** At some locations, clinician orders are required for all tests in a complex reflex algorithm, where the nature of the downstream testing is unknown at the time of the initial order. This situation may occur in AP or CP; a typical AP example might be ER/PR/HER2 testing in evaluation for breast cancer, which may extend over multiple specimens (see published ASCO/CAP guidelines). The communication process around these algorithms is currently awkward;

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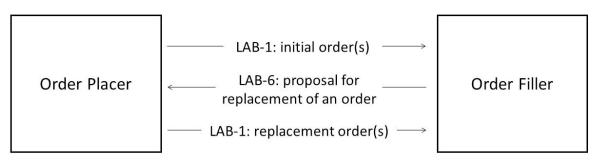
the availability of the LCC would allow intermediate orders based on "results so far" to be queued up for the clinician, with an explanation. The official result would be optimally communicated as a single report at the end of the algorithm. *This use case can be addressed currently using pending and final results, but that approach requires the clinician or pathologist to switch to the order entry module and manually find the correct follow up order. The LCC allows the order to be queued up by the lab with all necessary details (e.g., specific tissue block to test) so that it is ready to execute in the context of the preliminary result. This supports accurate reflex ordering and compliance needs of healthcare organizations, allowing the ordering provider to approve and authorize the additional testing.*

In all these scenarios, the Order Filler creates a Proposal for Order Replacement message and sends it to the Order Placer.

390 Middle Part and Final Part follow the Use Case #1 in PaLM TF-1: 3.4.2.1.1.

X.4.2.1.2 Proposal for Order Replacement Process Flow

In the UML diagram below the LAB-1 transactions are pre-and post-conditions respectively of the LAB-6 transaction.



Continues per Process Flow PalmTF-1 (3.2.2.1-1)

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Figure X.4.2.1.2-1: Proposal for Order Replacement Process Flow

X.4.2.2 Use Case #2: Request for Fulfillment

The clinician reviews received results against the clinical history or current presentation of the patient and needs some clarification or follow up on one or more results and sends a request for follow up to the laboratory.

400 X.4.2.2.1 Request for Fulfillment Description

Pre-Condition:

A full cycle of order and result reporting has already occurred – see PaLM TF-1: 3.4.2.1; the Order Result Tracker has received results from the Order Filler.

Initial Part:

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405 The clinician requests a follow up review of a specific order or result in the Order Placer application. The Order Placer creates a New Order to the Order Filler that contains reference to the respective order or result in question.

Here are several scenarios that could trigger a Request for Fulfillment:

- 1. Identification and follow-up of results with unusual patterns or lack of clinical 410 support. A patient in the ER with substernal chest pain and a non-diagnostic EKG initially has a cardiac Troponin I (cTnI) below the level of detection but the second value is elevated, prompting the patient's admission to the acute cardiology service. The third cTnI value is again undetectable. Confirmation of the previous elevated value and the current normal value are requested through the EHR via an LCC message, yielding a corrected result of "undetectable" for the previously elevated specimen. The patient is 415 discharged without catheterization. Routine monitoring of confirmation requests reveal an elevated number for cTnI since a new test formulation was deployed several months previously. Reports of these results to the test vendor from multiple sites lead to reformulation of the assay with improved performance. This scenario is derived from 420 actual events and is representative of multiple examples of feedback to test kit vendors from practical use settings. Such test performance monitoring is currently done manually with significant effort, cost, and delay in reporting.
 - 2. **Interpretation of unusual or complex results.** A patient with joint pain, fever, and sudden onset deep venous thrombosis showed an elevated PT and PTT with otherwise normal coagulation tests. An interpretation was requested of the PT and PTT results from the EHR via an LCC message. The interpretation added as an addendum to the test panel indicated that the results were consistent with a lupus anticoagulant and recommended the appropriate evaluation strategy.
- 3. Identification of local test performance problems. A mechanical problem develops in an analyzer such that the next scheduled recalibration results in inappropriately low cortisol values in patients while controls and other parameters remain within defined ranges. Physicians receiving results that seem clinically inconsistent can easily request confirmation of those results directly from results review, yielding faster recognition of problems and correction of results. *This scenario is derived from actual events in which the analyzer had an unrecognized mechanical problem and all check parameters were within specifications. The discrepancy was phoned in by a single endocrinologist who was known to be a demanding client. Confirmation on a second analyzer revealed the problem. Multiple results required correction.*
- 4. **Identification of test performance problems across populations.** An endocrine service that performed IGF-1 testing for pituitary evaluation found occasional instances where mildly-to-moderately elevated levels of IGF-1 occurred in patients who did not have

pituitary disease. This discrepancy between lab and clinical findings was reported on an ongoing basis when it occurred, with a brief LCC message that could be sent from the EHR to the LIS with only a couple of clicks to note the lack of clinical correlation. No technical problems with the test were found locally, but ongoing statistical analysis of these responses across multiple tests revealed a higher-than-expected rate for IGF-1 and this was reported to the test vendor. Similar performance monitoring reports from multiple locations led the vendor to review the use of a reference range established in Scandinavian populations with US patients, and design a reference range study for the US. *This scenario is derived from actual events. A standard method to simply and easily capture clinical assessment of test performance would allow automated performance monitoring and much faster reporting and response to performance issues than is currently possible. Ultimately, this capability would promote performance improvement at both the local laboratory and national vendor levels.*

- 5. Local process improvement. A local quality or process problem in testing, for example, the wrong test was done, the turnaround time was excessive, the interaction with the patient or ordering physician was problematic, etc., is noted as a request for follow up by the physician at results review, yielding a coded and/or free text problem flag attached to the original order and result. The outcome of quality assurance follow up can be reported as a result of this request. *This capability allows development of data sets that directly support and monitor local laboratory performance improvement. The ability to flag a result quickly for a quality issue would encourage reporting of problems, as opposed to the more typical incident reports which are handled externally and are awkward to manage within the clinical workflow, and the ability to return a result on quality assessment follow up could improve collaboration between a laboratory and its clients.*
- 6. Request for storage or banking of residual specimen for future use. Test results and clinical characteristics of a patient indicate that a particular specimen would be useful for research or quality-related work. At results review, a physician or pathologist may request that a specimen be captured for these purposes. *This mechanism may be useful to identify particular specimens for specialized follow up, e.g., heterophile antibody analysis, quality activities, e.g., creating quality control specimen pools, or research. Such specimens are often lost to follow up due to lack of ability to annotate them for capture during their residence in the lab.*
- Annotation of interesting test results. An endocrinologist with a busy practice sends testing to an academic center in a nearby city, and collaborates with faculty there in clinical research studies. When a patient displays an interesting result suggesting benefit from future research follow up, or inclusion in a clinical trial, the clinician can quickly flag the result with a pre-defined code that allows it to be retrieved easily in subsequent searches. The academic center scans their results on a regular basis and takes appropriate action for flagged results (e.g., inclusion in registries or follow up for trial participation). *This mechanism repurposes the fulfillment mechanism to allow arbitrary annotation of results*.

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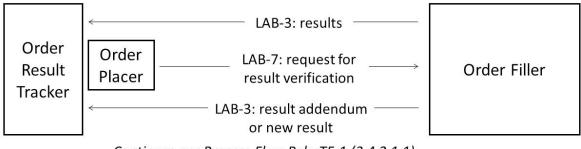
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In all these scenarios the Order Placer creates a Request for Fulfillment message and sends it to the Order Filler.

Middle Part and Final Part follow the Use Case #1 in PaLM TF-1: 3.4.2.1.1.

X.4.2.2.2 Proposal for Order Replacement Process Flow

490 The UML diagram below the LAB-3 transactions are Pre-and Post-Condition, respectively, of the LAB-7 transaction.



Continues per Process Flow PalmTF-1 (3.4.2.1.1)



X.5 LCC Security Considerations

495 The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus the LCC messaging extensions fit within LTW security requirements. Because local software implementations may allow selection of replacement orders or initiation of fulfillment orders in the context of results review, those implementations would need to make sure that order entry security is correctly incorporated into these streamlined order entry views.

X.6 LCC Cross Profile Considerations

N/A

Appendices

N/A

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Volume 2 – Transactions

Add Section 3.6

3.6 Proposal for Order Replacement [LAB-6]

3.6.1 Scope

This transaction is used to communicate Order replacement recommendations.

- 510 This transaction occurs when the Order Filler receives testing orders and has information about either the specimen or the patient indicating that one or more of the orders may be impossible to carry out or may not represent optimal care. The purpose of the transaction is for the Filler to recommend to the Placer one or more replacement orders for one or more existing orders (see Use Cases, Order Replacement), and it may occur any time from immediately after the order is
- 515 placed until the initiation of the technical testing workflow. Replacement orders must be returned within a defined recommendation time window to be accepted. LAB-6 differs from existing Filler order replacement in that it solicits replacement orders from the Placer instead of canceling the Placer's orders and creating new orders without Placer input. Thus, it supports collaborative agreement between the Placer and Filler on a final order set in a variety of contexts where order
- 520 selection may be challenging. Recommended orders, replaced orders, accepted recommendations, and declined recommendations are denoted with specific order control codes so that they may be archived and tracked to evaluate the performance and impact of order recommendation. While LAB-6 is intended to be consistent with and an optional addition to the LTW, some extension of HL7 V2.5.1 is required and is pre-adopted from later versions of the standard into the IHE profile, as outlined below.

3.6.2 Actor Roles

Actor:	Order Placer
Role:	In addition to roles defined in Palm TF-2a: 3.1.2:
	Receives replacement suggestion from the order filler
	Sends accept or reject transaction for one or more of the suggested replacement orders to the order filler
Actor:	Order Filler

Role:	In addition to roles defined in PaLM TF-2a: 3.1.2:
	Sends replacement suggestion to the order placer with specified time window
	Receives the accept or reject transactions to one or more of the suggested replacement orders from the order placer, or initiates default processing if the time window closes before a transaction is received.

3.6.3 Referenced Standards

- Order replacement (LAB-6):
- HL7 V2.5.1, Ch. 4 Order Entry
 - HL7 V2.8.2, Ch. 4 Order Entry
 - HL7 V2.8.2, Ch. 2C, Code Tables (Tables 38 and 119) LOINC (Universal Service Identifiers for identification of replacement orders)

3.6.4 Interaction Diagram

530

535 LAB-6 Order Replacement Recommendation is shown in red within the LAB-1 sequence diagram below, based on Figure 3.1.4-1 in the PaLM Technical Framework, Vol. 2a.

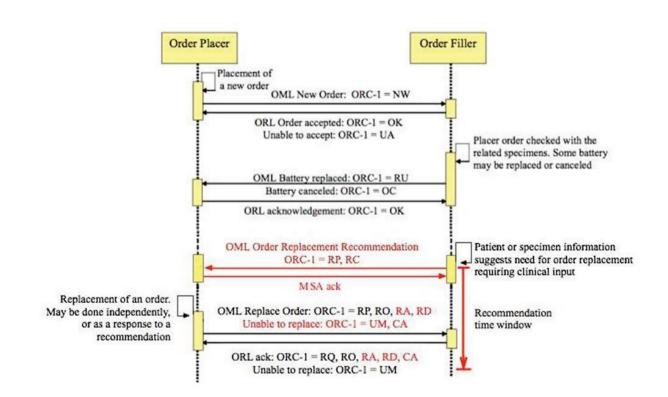


Figure 3.6.4-1: Proposal for Order Replacement transaction within the LAB-1 ordering sequence

540 LAB-6 consists of 4 interactions:

545

- 1. an order replacement recommendation sent from Filler to Placer
- 2. an immediate acknowledgement of the recommendation, sent from Placer to Filler
- 3. a later order replacement message sent from Placer to Filler, which must be received within the recommendation time window to be valid and which may accept, reject, or modify the replacement recommendation, and
- 4. an acknowledgement of the order replacement message from the Filler to the Placer.

The last two interactions are similar to the current order replacement interactions except for the addition of several order control codes (shown in red).

3.6.4.1 Proposal for Order Replacement [LAB-6] Messages

550 Order replacement recommendation and response extends the previous order replacement messaging pattern to allow an Order Filler to recommend order replacement and wait a defined period for a response from the Order Placer. Order replacement recommendations use the previous Filler-to-Placer unsolicited replacement message except that modified and new codes for order control, order status, and order control code reasons identify the original orders,
 recommended replacements, and responses to the recommendations. The recommendation hold time window is specified by codes in Order Status (ORC-5) and Order Status Modifier (ORC-25), and timestamps in Order Status Date Range (ORC-36). The ORC-36 field with the associated value set and the expanded set of codes for ORC-25 field are pre-adopted from HL7 V2.10.

560 **3.6.4.1.1 Trigger Events**

LAB-6 is triggered in the Order Filler after ordering but prior to initiating order fulfillment, when an order cannot or should not be carried out based on information available. It will carry information to the Order Placer on why the order cannot be completed, a recommendation for one or more replacement orders and/or order cancellation, a wait (hold) time for a response to the recommendation, and an indication that the hold status expires based on that time. The response to LAB-6 is carried in the current LAB-1 Placer Order Management unsolicited order "update" transaction defined by the LTW (essentially returning the completed message, with or without modification to the replacement orders, to the Filler).

3.6.4.1.2 Message Semantics

- 570 This profile is based on the existing order replacement patterns defined in HL7 V2.7.1 Ch. 2C, Table 0119, pp. 34-37 (in HL7 V2.5.1 this material is in Ch. 4, pp. 30-32). The transaction has four components (also see the example message fragments in **Figures 3.6.4.1.2-1 to Figure 3.6.4.1.2-3** below):
- Replacement recommendation. When the Order Filler receives orders (or identifies pending orders) from the Order Placer that it wishes replaced, the Filler sends a replacement recommendation to the Placer in which the orders to be replaced have the control code "RP" (ORC-1) and the recommended replacement orders have the new control code "RC". This replacement request is generally similar in structure to the unsolicited and solicited replacement messages (OML^O21) that are currently supported between the Filler and Placer, with the following features:
 - 1. As in the existing order replacement messages the ORC/OBR of the original orders are grouped first, followed by the ORC/OBR of the recommended replacement orders. This pattern supports 1:1, 1: many, many:1, and many:many order replacements.
- 585
 2. An "RP" ORC-1 Order Control code is used in the original orders to be replaced. Currently unsolicited replacement notifications (Filler to Placer) use RU in the original orders and solicited replacement requests (Placer to Filler) use RP in the original orders. The use of RP here in the Filler to Placer direction is logically consistent with the prior use and extends it to indicate a replacement recommendation rather than notification. The original orders are expected to have both Placer and Filler order numbers.
 - 3. The ORC-5 Order Status of the original orders is set to status code "HD" (on hold).

595		4. The ORC-16 Control Code Reason may contain a code indicating the general reason for the replacement recommendation drawn from code system HL7-0949 and extended with IHE specific codes as described under ORC-16. Additional information may be provided in an NTE segment associated with the original orders.
		5. The ORC-25 Order Status Modifier (with code EOT, expiration on time) is used to indicate that the hold expires after the time specified in ORC-36 (see below).
600		6. Start and stop times for the "HD" (on hold) status are contained in a new ORC-36 Order Status Date Range field (DTM^DTM). This interval represents the time window during which the Filler will wait for a response to the replacement recommendation message.
605		7. A new "RC" ORC-1 Order Control code is used in the recommended replacement orders rather than RO. The recommended replacement orders do not contain placer or filler order numbers.
	2.	Immediate acknowledgement. The Placer responds immediately with an acceptance acknowledgement (MSA) to indicate that the replacement recommendation has been received.
610	3.	Replacement request. After consideration of the recommendation, the Placer issues a replacement request with a structure similar to the replacement recommendation (OML^O21) and also to the current solicited replacement request, with the following features:
		1. The ORC/OBR of the original orders are grouped first, followed by the ORC/OBR of the recommended replacement orders.
615		2. The original orders contain control codes RP (replace), UM (do not replace), or CA (cancel) depending on the Placer's desired outcome.
		3. The recommended replacement orders contain control codes RA (replacement accepted) or RD (replacement declined) based on the Placer's desired outcome. Orders with control code RA contain Placer order numbers.
620		4. Additional orders may be added by the Placer to the replacement order list. These additional replacement orders contain control code RO and Placer order numbers. They are handled as solicited replacements that are in addition to the recommended replacements.
625		5. If the placer wishes to cancel the original orders without replacement, the original orders should be returned with control code CA and the replacement orders with control code RD.
		6. Placer systems should issue replacement requests only for orders with status HD that are within the date range specified in ORC-36.
630	4.	Replacement confirmation. If a replacement request is received from the Placer before the HD Order Status stop time, the Filler responds with an ORL^O22 confirmation

message similar in structure to the confirmation of a solicited order replacement, with the following features:

- 1. The ORC/OBR of the original orders are grouped first, followed by the ORC/OBR of the accepted replacement orders. Declined replacement orders are not included in the confirmation.
- 2. The original orders contain RQ (replaced as requested) Order Control codes, similar to the response to a solicited order replacement.
- 3. Accepted replacement orders echo their RA or RO Order Control codes, are assigned both Placer and Filler order numbers, and have an appropriate Order Status such as IP (in process).
- 4. Any Placer-specified replacement orders (RO) that cannot be executed are included in the replacement order list with an Order Control code UA (unable to accept).

If the HD Order Status Date Range stop time is passed without a replacement request from the Placer, a status update message is transmitted from the Filler to the Placer changing the HD Order Status to an appropriate value, and the recommendations are canceled.

Specimens. If specimens are available and appropriate for analysis, order recommendations (Filler to Placer) may include SPM segments referring to those specimens. If more than one order can be fulfilled by a specimen, its SPM segment must be repeated for each order to be assigned to it. It is the responsibility of the Filler to ensure that the assigned specimens are

- 650 appropriate and have the capacity (e.g., volume) to support the proposed testing. The replacement request message (Placer to Filler) must include the SPM segment to confirm use of that specimen for replacement orders. If a proposed order does not contain an SPM segment or if the replacement request does not confirm the SPM segment, the accepted replacement order(s) will require a new specimen. Because order replacement is inherently an order-centric process,
- 655 specimen- and container-centric ordering patterns (O33 and O35 events) are not supported by the LCC. Instead, the message should be oriented around the orders, and specimens should be assigned to them as noted above.

660

665

635

640

```
Initial message from Placer to Filler (Lab order OML^O21):

...
ORC|NW|1234||...
New order with Placer order number
OBR|...
...
```

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Replacement recommendation -- Filler recommends a change in this order (Filler to Placer OML^021): ... (1) (5) (16) (25) (36) Field numbers 670 ORC|RP|1234|5678||HD|||||||||||||||||||||||EOT|...|<start>^<end>| Order to be replaced OBR ... NTE ... Opt. additional information ORC | RC | | | |... Replacement order 675 OBR NTE ... Opt. additional information ••• SPM||4321|... Specimen available ••• 680 Immediate acceptance acknowledgement (Placer to Filler MSA) If the Placer does not send an acceptance or rejection message within the required 685 time, a status update message is sent changing ORC-5 HD to IP and continuing processing according to default procedures, otherwise... Replacement request within the time window (Placer to Filler OML^021): ... (1) (16) (25) Field numbers (36) 690 ORC|RP|1234|5678|||||||||||||||||||||||EOT|...|<start>^<end>| Confirm replace this order OBR ... ORC | RA | 1504 | | | |... Accepted replacement with Placer order number OBR 695 ••• SPM||4321|... Use proposed specimen Replacement confirmation (Filler to Placer ORL^022): 700 OBR

```
      ORC|RA|1504|5679||IP|...
      Replacement order now with Filler order number and status change

      OBR|...
      OBR|...

      705
      ...

      SPM||4321|...
      Use proposed specimen
```



710	Placer sends three new orders (not shown)
	Filler recommends replacing the three orders with two orders (Filler to Placer OML^021):
715	(1) (5) (16) (25) (36) Field numbers ORC RP 1234 5678 HD EOT <start>^<end> Order to replace</end></start>
	OBR
	ORC RP 1235 5679 HD EOT <start>^<end> Order to replace</end></start>
	OBR
	ORC RP 1236 5680 HD EOT <start>^<end> Order to replace</end></start>
720	OBR
	ORC RC Replacement order
	OBR
	NTE Optional information
	ORC RC Replacement order
725	OBR
	NTE Optional information
	No SPM segment is included indicating that a new specimen must be drawn.
730	
	Placer returns immediate acceptance acknowledgement (MSA) …
	Placer returns the replacement request, accepting replacement of two of the three
	original orders and rejecting replacement of one of the original orders. Of the

735 recommended orders, one is accepted, one is declined, and an additional order is added to the recommendations (Placer to Filler OML^021): ... (1) (16) (25) (36) Field numbers ORC|RP|1234|5678|||||||||||||||||||||||||EOT|...|<start>^<end>| Order to replace 740 OBR ORC|RP|1235|5679|||||||||||||||||||||||||||||EOT|...|<start>^<end>| Order to replace OBR ... ORC|UM|1236|5680|||||||||||||||||||||||||||||EOT|...|<start>^<end>| Do not replace this order 745 OBR ... ORC | RA | 2236 | |... Accepted recommendation with Placer order # OBR ... NTE ... ORC | RD | | |... Declined recommendation 750 OBR ... NTE ... ORC | RO | 2238 | | | |... New order added by Placer OBR NTE ... 755 •••• Filler confirms replacement (Filler to Placer ORL^022): ••• 760 OBR Second replaced order OBR | ... ORC | RA | 2236 | 5690 | | IP | ... Accepted recommendation with Filler order # and IP status 765 OBR NTE ... ORC | RO | 2238 | 6123 | | IP | ... New order with Filler order # and IP status OBR ... NTE ... 770 ORC | SC | 1236 | 5680 | | IP | ... Retained original order with IP status

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OBR | ...

••••

775

Figure 3.6.4.1.2-2 Multiple Order Replacement, Partially Declined Replacement, and Added Replacement Orders IHE PaLM Technical Framework Supplement –Laboratory Clinical Communications (LCC)

```
Placer places the initial order (not shown) ....
       Filler recommends replacement of the order (Filler to Placer OML^021):
780
                                                                 (36)
       ... (1)
                          (5)
                                        (16)
                                                    (25)
                                                                              Field numbers
       ORC|RP|1234|5678||HD|||||||||||||||||||||||||||EOT|...|<start>^<end>| Order to replace
       OBR ...
       ORC | RC | | | |...
                                                                        Replacement order
       OBR ...
785
       NTE ...
       •••
       Placer declines replacement, original order stays in effect (Placer to Filler
       OML^021):
790
       ...
       ORC|UM|1234|5678||||||||||||||||||||||||||||||EOT|...|<start>^<end>| Do not replace
       OBR ...
       ORC | RD | | | ....
                                                                        Recommendation declined
       OBR ....
795
       NTE ...
       •••
       Filler confirms return of original order to active status (Filler to Placer ORL^022):
       ....
800
       ORC | SC | 1234 | 5678 | | IP | | | | | | | | | | | | ...
                                                                                 Status change to
       in process
       OBR ...
```

Figure 3.6.4.1.2-3 Declined Replacement

805 LCC uses the same segment definitions as described for LAB-1 in PaLM TF-2a: 3.1.3.2 Constraints on OML Message Structures added by Transaction LAB-1.

3.6.4.1.3 Expected Actions

LAB-6 defines three new interactions, the replacement recommendation from Filler to Placer, the replacement request from Placer to Filler, and the replacement confirmation from Filler to

810 Placer. These transactions support new communications capabilities between the Placer and Filler, but they do not define specific implementation requirements for the Placer and Filler systems. The Actions described here are based on reasonable implementations, but others are possible.

Replacement Recommendation

- 815 1. The Filler system reviews incoming and pending orders automatically or manually to detect those requiring replacement
 - 2. The Filler system constructs a Replacement Recommendation message using automated rules or a user interface supporting a laboratory expert, including a time limit for a Placer response
- 820 3. The Replacement Recommendation is transmitted to the Placer system.

Replacement Request

825

835

- 1. The Placer system immediately sends an acknowledgement of receipt of the Replacement Recommendation to the Filler system.
- 2. The Placer system follows a locally-defined report and escalation process to notify a responsible party of the Replacement Recommendation within its time limit, usually the care provider responsible for the original order or a covering provider
 - 3. The Placer system displays the order and replacement recommendations to the provider, and offers a convenient method to accept or reject the recommendations and optionally add new orders or cancel the original orders
- 4. The Placer system transmits the accepted, rejected, and new orders to the Filler system in a Replacement Request

Replacement Confirmation

- 1. The Filler system receives the Replacement Request and transmits a Replacement Confirmation message to the Placer system, updating the status of all orders to in progress, replaced, or canceled as appropriate
- 2. If the Placer does not send a Replacement Request by the required time limit, the Filler sends a status update message changing the status of the existing orders to reflect the final filler action

3.6.5 Security Considerations

840 The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus, the LCC messaging extensions fit within LTW security requirements.

3.6.5.1 Security Audit Considerations

The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus the LCC messaging extensions fit within LTW auditing requirements.

3.6.5.1.(z) <Actor> Specific Security Considerations

Not applicable.

3.7 Request for Fulfillment [LAB-7]

850 **3.7.1 Scope**

This transaction is used to streamline the ability of the Order Placer/Order Result Tracker application to issue follow up orders on results that do not meet expectations, either clinically or operationally.

LAB-7 is triggered when test results are clinically or operationally problematic. It yields a new fulfillment order that is created in the context of an existing result in the Order Result Tracker. The new order automatically includes references to that result and its order, and allows additional information to be entered by the clinician. Additional results may be included in the transaction. The message is sent from the Order Placer/Order Results Tracker to the Order Filler as an unsolicited order message. The response from the Order Filler is returned to the Order

860 Result Tracker in the current LAB-3 Order Results Management transaction as an addendum or amendment to the original result, and/or as a separate result of the fulfillment order.

3.7.2 Actor Roles

Actor:	Order Placer grouped with Order Result Tracker
Role:	In addition to roles defined in PaLM TF-2a: 3.1.2:
	Sends a fulfillment request to the order filler, referencing an existing result. Receives an updated result for the requested fulfillment from the order filler
Actor:	Order Filler
Role:	In addition to roles defined in PaLM TF-2a: 3.1.2:
	Receives the fulfillment request from the order placer
	After completion of the fulfillment request, sends an appended result transaction and/or a new result to the order placer

Table 3.7.2-1: Actor Roles

3.7.3 Referenced Standards

- 865 Results fulfillment [LAB-7]:
 - HL7 V2.5.1, Ch. 4 Order Entry
 - HL7 V2.8.2, Ch. 4 Order Entry
 - HL7 V2.8.2, Ch. 7 Observations (OBX-21)
 - HL7 V2.8.2, Ch. 12 Patient Care (REL segment)
- LOINC (Universal Service Identifiers for fulfillment actions like confirmation and interpretation)
 - SNOMED CT (Universal Service Identifiers for fulfillment actions like quality review and specimen storage)

3.7.4 Interaction Diagram

875 LAB-7 interaction appears in red in the sequence of LAB-3 reporting in the diagram below.

The LAB-1 blue and dashed interactions appear only when Order Placer and Order Result Tracker are not grouped together.

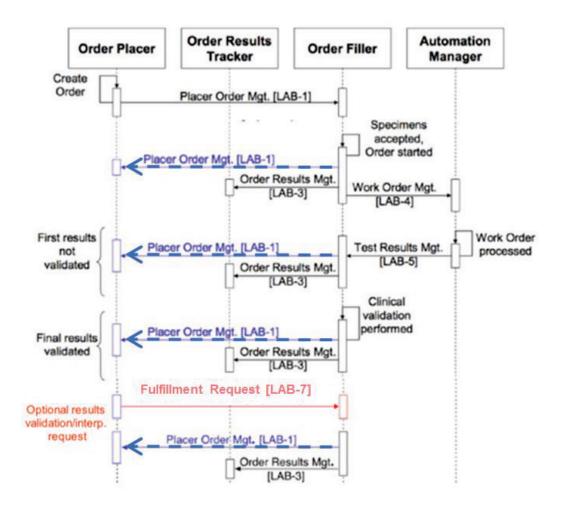


Figure 3.7.4-1. Request for Fulfillment within the LAB-3 reporting sequence

880 3.7.4.1 Message Request for Fulfillment [LAB-7]

LAB-7 supports the ability of clinicians to issue orders for further work on a result that by itself may not be understandable or fully meet the clinical need, or may appear to be in error. This workflow may be most convenient in a combined Order Placer/Order Results Tracker application in which new orders may be issued in the context of clinical results review, though other

885 implementations are possible. In an abstract sense, LAB-7 asks that an existing result be annotated with the outcome of additional work. That annotation may be an amendment, addendum, or correction to a previous result, or may be expressed as the result of the LAB-7 order itself. These annotations are necessary for the result to fulfill a clinical purpose and thus the LAB-7 order created by the Tracker application is referred to below as a *fulfillment order*. 890 The primary result of interest for the fulfillment order is referred to as the *target result* and the original order that produced this result is called the *target order*. LAB-7 accommodates settings that include multiple targets such as concurrent interpretation of several results in context.

3.7.4.1.1 Trigger Events

- The LAB-7 transaction is normally triggered by the clinical staff during results review, when results do not fully meet the clinical need, are inconsistent or confusing, or indicate a process problem. LAB-7 may also provide a general mechanism for attaching annotations to results for a variety of purposes. A primary goal of the transaction is to allow a request for additional work related to an existing order/result to be issued quickly from the results review workflow and to automatically incorporate a reference to the patient and targeted order/result. This capability
- avoids the current disruption in workflow required to issue orders for interpretation or results review (exit results review, open order entry, create order, describe which order/result to target, describe problem). A LAB-7 transaction creates a fulfillment order that targets a particular result, and it may include other results for additional context. The target result may or may not have been created by the Filler of the fulfillment order. The fulfillment order may yield an addendum, amendment, correction, or annotation of the target result, and it may also yield its own result or a
 - reference to the update of the target.

The service ID for fulfillment orders may represent concepts such as *result confirmation, result interpretation, service process problem, inconsistent with clinical findings,* or *incorrect test done,* which are applied to the target result. Since the presence of the fulfillment order itself

- 910 linked to the parent result represents a form of annotation, the mechanism could be used with an Ask at Order Entry and a generic *annotate* service ID for arbitrary annotation of results from Tracker/Placer systems. In the future, LOINC will be the usual source for standard service IDs and it should be reviewed to determine whether useful service IDs for these concepts exist or whether new concepts should be submitted for coding.
- 915 The results of LAB-7 orders yield information useful in the clinical management of patients. In addition, LAB-7 is intended to enable aggregate queries that support process monitoring and process improvement. For example, an unexpectedly high rate of confirmation requests for a particular test result might prompt a review of that test's performance under conditions associated with the requests. To support this capability, fulfillment orders are linked to the target results and their orders in a consistent way such that the targets can be retrieved in either the Filler or the
- Placer/Tracker system using structured data contained in the fulfillment order.

3.7.4.1.2 Message Semantics

3.7.4.1.2.1 OML^O21 Static Definition

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[11]	2
[PATIENT begin	RE	[01]	

Table 3.7.4.1.2.1-1: OML^O21 Message Static Definition

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Segment	Meaning	Usage	Card.	HL7 chapter
PID	Patient Identification	R	[11]	3
[PATIENT_VISIT begin	RE	[01]	
PV1	Patient Visit	R	[11]	3
]	PATIENT_VISIT end			
]	PATIENT end			
{	ORDER begin	R	[1*]	
ORC	Common Order (for one battery)	R	[11]	4
[{	TIMING begin	RE	[01]	
TQ1	Timing Quantity	R	[11]	4
}]	TIMING end			
	OBSERVATION REQUEST begin	R	[11]	
OBR	Observation Request	R	[11]	4
[{NTE}]	Notes and Comments	0	[0*]	2
[{REL}]	Relationship Segment*	0	[0*]	12
[{	OBSERVATION begin	0	[0*]	
OBX	Observation Result	R	[11]	7
[{NTE}]	Comment of the result	0	[0*]	2
}]	OBSERVATION end			
[{	SPECIMEN begin	0	[0*]	
SPM	Specimen	R	[11]	7
[{SAC}]	Container	RE	[0*]	13
}]	SPECIMEN end			
[SGH]	Segment Group Header**	0	[01]	
[{	PRIOR_RESULT begin	0	[0*]	
PV1	Patient Visit – previous result	R	[11]	3
{	ORDER_PRIOR begin	R	[1*]	
ORC	Common Order - previous result	R	[11]	4
OBR	Order Detail - previous result	R	[11]	4
{[NTE]}	Notes and Comments - previous result	0	[0*]	2
{	OBSERVATION_PRIOR begin	R	[1*]	
OBX	Observation/Result - previous result	R	[11]	7
{ [NTE] }	Notes and Comments - previous result	0	[0*]	2
}	OBSERVATION_PRIOR end			
}	ORDER_PRIOR end			
] }	PRIOR_RESULT end			
[SGT]	Segment Group Trailer**			
	OBSERVATION REQUEST end			
}	ORDER end			

925 * Pre-adopted form HL7 V2.10 – per OO CR-851

** Pre-adopted from HL7 V2.8

The fulfillment order for the LAB-7 transaction message is carried in a modified OML^O21 laboratory order message that includes information that makes a link to the prior order, order group or result using one or more clinical relationship segment (REL) segments (HL7 V2.7

- 930 Chapter 12) pre-adopted from HL7 V2.10 per OO CR-851. The REL segment establishes a service target relationship between the order segments in the message and the previous orders/results that are to be acted upon. The prior target order and/or target result are included in the prior results section of the order message, and other results may be included in this section for context. The acknowledgement of the fulfillment order from the Filler is a standard
- 935 ORL^O22. The result of the fulfillment order may be coded or text, and the order may trigger confirmation, correction, or amendment of the previous result. If the annotation use case is supported, the fulfillment order could also result in addition of an arbitrary annotation to a previous result.

Figure 3.7.4.1.2.1-2, below, is a simplified fulfillment order. The ORC and OBR are the new
fulfillment order requesting review of a previous result. The REL segment establishes a target
relationship between the new order and a previous order requiring additional action such as
confirmation or interpretation. The REL segment includes a variety of fields defining a clinical
relationship and the identity of the asserting party. For this use, the required fields are the
Relationship Type (REL-2), the Source Identifier (REL-4), used to carry the new order number,

- 945 and the Target Identifier (REL-5, used to carry the previous order group (ORC-4), order (OBR-2), or result identifier (OBX-21). When using order (OBR-2, Placer Order Number) or order group (ORC-4, Placer Group Number) identifiers as targets, the target encompasses the entire order or order group and all related results; when the target is restricted to the specific result the result identifier (OBX-21, Observation Instance Identifier) is sent. In cases where a single order
- targets several orders or results, an REL segment is included for each target, and these segments are numbered sequentially beginning with "1" in REL-1 (Set ID).

Clinician working from order review requests review of a blood test result (OML^021): ORC | NW | 1567 | ... New fulfillment 955 order OBR | 1567 | 21026-0^Pathologist interpretation of blood tests ^LN | ... LOINC code for review (2) REL field number (17) (18)REL||SVTGT|9999|1567|1234|...|PLAC|PLAC| Fulfillment Target 960 link to existing placer order nmbr ••• ORC | PR | 134 | ... Prior order

965

970

975

980

OBR | 1567 | 55231-5^Electrolytes panel - Blood^LN | ...

LOINC code of order to be reviewed

Figure 3.7.4.1.2.1-2: Example Fulfillment Order (REL segment)

Notes:

- REL-2 contains the relationship type code drawn from Relationship Type codes system HL70948 introduced in v2.9 1. and REL-3 carries the EI for this relationship.
 - The REL segment uses EI datatypes for the source and target of the link, which carry a single identifier. REL-4 2. (Source) will carry the Placer Order Number (OBR-2) for the current order (ORC-1 of that Order group is 'NW') and REL-5 (Target) will carry either the Placer Group Number (ORC-4), Placer Order Number (OBR-2), or Observation Instance Identifier (OBX-21) for the prior order group, order, or result respectively (ORC-1 of the order group of these identifiers is valued 'PR').
 - 3. The OML message is modified to add one or more REL segments as the last segment of each OBR group.
 - 4. If the fulfillment message is sent to the Filler who processed the prior order, the prior order does not need to be included in the message. If the message is sent to a third party Filler, the pertinent orders and results must be included in the message as prior results with Placer group, order, or result EIs matching the EI named as the target of the relationship.

Order fulfillment action

Codes that might be used as Universal Service Identifiers (OBR-4, CWE) in LAB-7 are listed 985 below in Table 3.7.4.1.2.1-3. Additional codes might be identified for other types of fulfillment actions or annotations.

Table 3.7.4.1.2.1-3: Possible service codes for use with the LCC Profile LAB-7 transaction (Universal Service Identifier, OBR-4, CWE)

Code	Code System	Description		
21026-0	0 LOINC Pathologist interpretation of blood tests			
386344002	SNOMED CT	Laboratory data interpretation (Procedure)		
80970002	SNOMED CT	Medical evaluation, quality of care, review of exception case (Procedure)		
C93374	NCI Thesaurus/BRIDG	Defined specimen storage		

990 Fulfillment actions and result annotations are likely to be specified by a limited number of Universal Service Identifiers as above. More information about the purpose of a fulfillment request that could be useful for identifying particular types of quality problems or specific specimen handling instructions might be communicated as structured data in OBR-31 Reason for Study, using the following proposed codes. The code system Reason for Study HL70951 995 supporting OBR-31 was added in HL7 v2.9.

Code	Context	Description				
CR	Lab review	Confirm results value; requests verification of previously reported results				
IN	Lab review	Interpret results, requests interpretation of previously reported results				
IR	Lab review	Review clinically inconsistent results, requests comparison of previously reported results amongst themselves				
SI	Lab review	Suspected interference, requests verification of previously reported results due to suspected interference				
OP	Quality of care	Test ordering problem, for process improvement work this code can be used to identify orders and the respective results, where problems occurred during ordering				
SP	Quality of care	Sampling problem, for process improvement work this code can be used to identify orders, where problems occurred during sample collection				
TP	Quality of care	Specimen transport problem, for process improvement work this code can be used to identify orders, where problems occurred during sample transport				
TT	Quality of care	Turnaround time problem, for process improvement work this code can be used to identify results with excessive reporting delay				
IT	Quality of care	Incorrect test performed, for process improvement work this code can be used to identify when an incorrect test was performed for the target order				
PI	Quality of care	Patient identification problem, for process improvement work this code can be used to identify when a patient identification issue has occurred on the target order				
XR	Quality of care	Incorrect results, for process improvement work this code can be used to identify when incorrect result were reported for the target order				
BS	Specimen storage	Bank residual specimen, requests that the specimen should be stored long term, provides instructions for specimen storage in OBR-46				
TS	Specimen storage	Transfer residual specimen, requests that the specimen should be moved to a different location, provides instructions for specimen storage in OBR-46				
FP	Specimen storage	Store residual specimen pending follow up, requests that the specimen should be saved for a short duration until a follow up contact, provides instructions for Specimen storage in OBR-46				

Table 3.7.4.1.2.1-4: Reason for Study codes (OBR-31, CWE, HL70951)

3.7.4.1.3 Expected Actions

LAB-7 defines one new transaction, the fulfillment request from Placer to Filler. This transaction supports new communication capabilities between the Placer and Filler, but they do not define specific implementation requirements for the Placer and Filler systems. The Actions described here are based on reasonable implementations, but others are possible.

Fulfillment Request

1005

- 1. The Filler system reviews incoming orders automatically or manually to detect those requesting fulfillment
- 2. The Filler system identifies the target(s) of the fulfillment order, either in existing data or in the prior results group in the incoming message.

3. The Filler system evaluates if it can perform the request and creates an appropriate acknowledgement message and sends it to the placer.

1010 3.7.5 Security Considerations

The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus the LCC messaging extensions fit within LTW security requirements.

3.7.5.1 Security Audit Considerations

1015 The LCC message transactions take place in the context of existing LTW transactions, and the data content of order replacement and fulfillment messages is of the same nature as existing LTW transactions. Thus the LCC messaging extensions fit within LTW auditing requirements.

3.7.5.1.z <Actor> Specific Security Considerations

Not applicable

1020 C Common HL7 Message Segments

Profiling conventions, messaging details, and segments that have common definitions across the LCC transactions are discussed below.

Update the ORC segment definitions in PaLM TF Vol 2.x C.5 as follows

1025 C.5 ORC – Common Order Segment

HL7 V2.5: chapter 4 (4.5.1). The ORC and OBR segments contain a number of duplicate fields. The Technical Framework is defined in such a way that fields in the OBR segment will be used in preference over their equivalents in ORC. If a field is listed as being optional in ORC, its equivalent in OBR may well be mandatory.

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Table	C.5-1:	ORC	Segment
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SEQ	LEN	DT	Usage	Card. TBL #		ITEM#	Element name
1	2	ID	R	[11]	[11] <u>0119</u>		Order Control
5	2	ID	С	[01]	<u>0038</u>	00219	Order Status
16	250	CE	θ <u>C(RE/O)</u> <u>CP: When</u> <u>MSH-21 is</u> valued "LAB-6"	[01]		00230	Order Control Code Reason
25	250	CWE	<u>X C(RE/X)</u> <u>CP: When</u> <u>ORC-5 is valued</u> <u>"HD"</u>	[0 <u>θ1</u>]	[0 <u>01]</u> <u>0950*</u> 01		Order Status Modifier
<u>32*</u>	<u>8</u>	<u>DT</u>	<u>0</u>	<u>[01]</u>	<u>[01]</u> <u>023</u>		Advanced Beneficiary Notice Date
<u>33*</u>		<u>CX</u>	<u>0</u>	<u>[0*]</u> <u>03300</u>		<u>03300</u>	<u>Alternate Placer Order</u> <u>Number</u>
<u>34*</u>	<u>250</u>	CWE	<u>0</u>	<u>[0*]</u>	0*] 0934 03387 Order		Order Workflow Profile
<u>35*</u>		ID	<u>0</u>	<u>[01]</u>	[01] 0206 00816 <u>Action Code</u>		Action Code
<u>36**</u>		<u>DR</u>	<u>C(RE/X)</u> <u>CP:When ORC-</u> <u>5 is valued</u> <u>"HD"</u>	<u>[01]</u>		<u>TBD</u>	<u>Order Status Date Range</u>

* Pre-adopted from HL7 V2.9

** Pre-adopted from HL7 V2.10 per OO-CR852

ORC-1 Order Control (ID), required.

1035 This field may be considered the "trigger event" identifier for orders. Many order control codes are defined in the *HL7 table 0119 – Order Control Codes*. The Technical Framework allows only the following subset:

Value	Description of use				
NW	"New Order". Event request in OML message sent by the Order Placer in transaction LAB-1 or in OML message sent by the Order Filler in transaction LAB-4.				
OK	"Notification or request accepted". Event notification in OML message. Event acknowledgement in ORL message				
UA	"Unable to accept order/service". Event notification in OML message. Event acknowledgement in ORL message sent by the Order Filler in transaction LAB-1 or in ORL message sent by the Automation Manager in transaction LAB-4.				
SC	"Status changed". Event notification in OML, ORU and OUL messages				
СА	"Cancel order/ service request". Event request in OML message sent by the Order Placer in LAB-1, or by the Order Filler in LAB-4.				
CR	"Canceled as requested". Event acknowledgement in ORL message responding to OML (CA)				
UC	"Unable to cancel". Event acknowledgement in ORL message responding to OML (CA)				
OC	"Order service canceled". Event notification in OML message sent by the Order Filler in transactions LAB-1 and LAB-3.				
SN	"Send order/service number". Event request in OML message sent by the Order Filler in transaction LAB-2				
NA	"Number assigned". Event acknowledgement in ORL message sent by the Order Placer in LAB-2, responding to OML (SN)				
RP	"Order/service replace request". Event request in OML message sent by the Order Placer in transaction LAB-1 or in OML message sent by the Order Filler in transaction LAB-4. Orders to be replaced in Replacement Request messages.				
RQ	"Replaced as requested". Event acknowledgement in ORL message responding to OML (R <u>QP</u>)				
UM	"Unable to replace". Event acknowledgement in ORL message responding to OML (RQP). Replacement Request messages for orders that should not be modified (declined replacement)				
RU	"Replaced unsolicited". Event notification in OML message (LAB-1) and OUL message (LAB-3) sent by the Order Filler.				
XO	"Change order/service request". Used by the Order Placer in LAB-1				
XR	"Changed as requested". Used by the Order Filler in LAB-1 in response to XO				
UX	"Unable to change" Used by the Order Filler in LAB-1 in response to XO				
PR	"Previous results with new order/service". Used in LAB-1, LAB-4, LAB-21 and LAB-22 to provide some previous results with the order or work order or wok order step that is requested by the sender.				
<u>RC*</u>	"Recommended change". Identifies that this OBR represents a recommended replacement order; used in the Replacement Recommendation message sent from the Filler to the Placer.				
<u>RA*</u>	 <u>"Recommendation accepted". Identifies that this previously recommended replacement order has been accepted.</u> <u>Placer application: Used in the Replacement Request message; includes the assigned placer order number for the accepted replacement order.</u> Filler application: Used in the Replacement Confirmation message in response to the Replacement 				
	Request message, when it was accepted.				

Value	Description of use				
	<u>"Recommendation declined". Identifies that this previously sent recommended replacement order</u> has been declined by the Placer.				
<u>RD*</u>	Placer application: Used in the Replacement Request message.				
	<u>Filler application: Used in the Replacement Confirmation message in response to the Replacement</u> <u>Request message, when it was declined.</u>				
<u>RO</u>	<u>"Replacement order". Used in Replacement Request messages for replacement orders that were</u> not recommended by the Filler but added by Placer (existing HL7 code)				

* Pre-adopted from HL7 V2.9

1040 ORC-5 Order Status (ID), conditional.

Condition predicate: This field shall be valued in all OML messages sent by the Order Filler. It represents the status of the order. This field shall not be valued in OML messages sent by the Order Placer.

The allowed values for this field within the Technical Framework are a subset of *HL7 table 0038* 1045 - Order Status:

Value	Description	Comment
А	Some, but not all, results available	
СА	Order was canceled	
СМ	Order is completed	
IP	In process, unspecified	
SC	In process, scheduled	
HD	<u>Order is on hold</u>	Indicates that the order is not currently being worked on but has been placed on hold waiting for additional communication. Filler application: used in the recommendation message sent to the Placer. Placer application: used in the replacement request message in response to the recommendation message from the Filler.

HL7 Table 0038 - Order Status: IHE Subset for all Transactions

Note: For the conditions of use of these values, please read PaLM TF-2.x: C10 "Correlations of status between ORC, OBR and OBX".

ORC-16 Order Control Code Reason (CE), optional conditional

1050 <u>Predicate: Usage is required, but may be empty, when MSH-21 (Message Profile ID is valued "LAB-6", else it is optional.</u>

HL7 definition: This field contains the explanation (either in coded or text form) of the reason for the order event described by the order control code (HL7 Table 0119).

In the LCC LAB-6 it may be used to communicate the reason for an order replacement recommendation (see table below).

Value	Description	<u>Comment</u>			
<u>SV*</u>	Specimen Volume	Specimen volume inadequate for requested testing, recommend a subset of tests appropriate for available volume			
<u>ST*</u>	<u>Specimen Type</u>	Incorrect specimen type for requested testing, recommend testing that can use the submitted specimen type			
<u>UN*</u>	<u>Unavailable</u>	Requested test unavailable, alternative testing proposed			
<u>CO*</u>	Cost	Lower cost testing strategy proposed			
<u>(SR)</u>	<u>Screening</u> <u>Required</u>	Screening test required prior to confirmatory test			
<u>(IT)</u>	Indicated testing	Indicated follow up testing based on initial results			
<u>(FO)</u>	Future Order	Future order timed out without specimen			
<u>(IN)</u>	<u>Inappropriate</u>	Requested testing not appropriate in this patient			
<u>(KI)</u>	<u>Known</u> Interference	The requested testing will yield inaccurate results in this patient			
<u>(IY)</u>	Improved Yield	Recommended testing improves diagnostic yield			

HL7 Table 0949 – Order Control Code Reason: IHE Subset for all Transactions

* Pre-adopted from HL7 V2.9

() IHE Extension of HL7 user defined table

1060 ORC-25 Order Status Modifier (CWE), optional conditional.

Predicate: Usage is required, but may be empty, when ORC-5 (Order Status) is valued "HD", else it is not supported.

HL7 definition: This field is a modifier or refiner of the ORC-5-Order status field. This field may be used to provide additional levels of specificity or additional information for the defined order status codes. Unlike the Order Status field, which is controlled by an HL7 defined table, this 1065 field is a CE data type allowing applications to support an unlimited library of Order Status Modifier codes.

The Technical Framework does not constrain the usage of this field. In the LCC LAB-6 transactions it uses the code "EOT" (expiration on time) to indicate that the hold expires after the time specified in Order Status Date Range (ORC-36).

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<u>Value</u>	Description	Comment
EOT	<u>Expiration on</u> <u>time</u>	The order status is timed and will auto-expire once the prescribed time interval has passed. For example this code would be used to indicate that the order is not currently being worked on but has been placed on a time limited hold awaiting a replacement order. If the hold time expires, default processing will resume. Usage Note: Filler Applications: In an order replacement setting, sent in a Replacement Recommendation message

HL7 Table 0950 – Order Control Code Modifier: IHE Subset for all Transactions

<u>Value</u>	Description	Comment
		(OML), where ORC-5 = HD, indicating that the hold for a response to the recommendation is timed.

ORC-32 Advanced Beneficiary Notice Date (DT), optional

HL7 Definition: This field contains the date the patient gave consent to pay for potentially
 uninsured services or the date that the Advanced Beneficiary Notice Code (ORC-20) was
 collected.

The Technical Framework does not constrain the usage of this field.

ORC-33 Alternate Placer Order Number (CX), optional

<u>HL7 Definition: This field enables a shorter number to be communicated that is unique</u> within other identifiers.

The Technical Framework does not constrain the usage of this field.

ORC-34 Order Workflow Profile (EI), optional

<u>HL7 Definition: The Order Workflow Profile references/represents the information</u> necessary to define the workflow variant when that is not fully described through the use of

1085 ORC-1 Order Control and MSH-21 Message Profile. This enables contributing systems to apply locally agreed to rules. See User-defined Table 0934 - Order Workflow Profile for a list of suggested values.

The Technical Framework does not constrain the usage of this field.

ORC-35 Action Code (ID), optional

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1090 <u>HL7 Definition: This field reveals the intent of the message. Refer to HL7 Table 0206 -</u> Segment Action Code for valid values.

The action code can only be used when an ORC is uniquely identified according to Chapter 2, Section 2.10.4.2.

The Technical Framework does not constrain the usage of this field.

1095 <u>ORC-36 Order Status Date Range (DR), conditional</u> <u>Predicate: Usage is required, but may be empty, when ORC-5 (Order Status) is valued</u> <u>"HD", else it is not supported.</u>

HL7 Definition: This field allows the sending application to identify the time span over which the order status described by ORC-5 (Order Status) and, if used, ORC-25 (Order

1100 Status Modifier) is effective. For example, this will be used by the filler in the case of an order replacement recommendation to indicate the start and end time the original order that is proposed to be replaced will be on hold while waiting for a response to the recommendation (ORC-5 = 'HD' and ORC-25 = 'EOT'). When the status is outside of the specified date range, it should be considered an unspecified status.

1105

Add a new section for the REL segment definition in PaLM TF-2x as follows

C.X REL Segment

Pre-adopted base definition from V2.10 v per OO CR-855:

	HL7 Auribule Table - REL – Chincal Relationship Segment							
SEQ	LEN	DT	Usage	Card.	TBL#	ITEM #	ELEMENT NAME	
1	14	SI	С			02240	Set ID – REL	
2		CWE	R		HL7094 8	02241	Relationship Type	
3		EI	R			02242	This Relationship Instance Identifier	
4		EI	R			02243	Source Information Instance Identifier	
5		EI	R			02244	Target Information Instance Identifier	
6		EI	0			02245	Asserting Entity Instance ID	
7		XCN	0			02246	Asserting Person	
8		XON	0			02247	Asserting Organization	
9		XAD	0			02248	Assertor Address	
10		XTN	0			02249	Assertor Contact	
11		DR	0			02250	Assertion Date Range	
12	11	ID	0		0136	02251	Negation Indicator	
13		CWE	0			02252	Certainty of Relationship	
14	5=*	NM	0			02253	Priority No	
15	5=*	NM	0			02254	Priority Sequence No (rel preference for consideration)	
16	11	ID	0		0136	02255	Separability Indicator	
17		ID	R		0203	TBD	Source Information Instance Object Type	
18		ID	R		0203	TBD	Target Information Instance Object Type	

HL7 Attribute Table - REL – Clinical Relationship Segment

1110 *Is conformance length (CLEN)

REL-1 Set ID - REL (SI), required (conditional in HL7 V29, but condition predicate is not defined, so using required here).

Contains the Set ID of the specific relationship record – shall increment sequentially starting with the value '1' for each occurrence in the message or for each Order_Observation Group

1115 **REL-2 Relationship Type (CWE)**, required

Contains the type of the relationship for the instance identified in REL-3 between the source identified in REL-4 and the Target identified in REL-5. The values are drawn from user defined table HL70948.

Value	Description	Comment
SVTGT	Service target	Target universal service identifier is the object of the service identified by the source universal service identifier. Example: An order requests clarification or interpretation of a previous clinical laboratory test result.

Constrained HL7 Table 0948 - Relationship Type

1120

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REL-3 This Relationship Instance Identifier (EI), required

HL7 Definition: This field contains the instance identifier of this relationship.

REL-4 Source Information Instance Identifier (EI), required

HL7 Definition: This field contains the Instance ID of the Source Segment – for LCC it will carry the Placer order number for the current order.

REL-5 Target Information Instance Identifier (EI), required

HL7 Definition: This field contains the Instance ID of the Target Segment – for LCC it will carry either the Placer Group Number (ORC-4), Placer Order Number (ORC-2/OBR-2), or Observation Instance Identifier for the prior order group, order, or result, respectively. This is the object of interest for the fulfillment request.

REL-17 Source Information Instance Object Type (ID), required

HL7 Definition: This field contains the identifier type code drawn from coding system HL70203 describing the object identified by the Source Information Instance Identifier (REL-4).

REL-18 Target Information Instance Object Type (ID), required

1135 HL7 Definition: This field contains the identifier type code drawn from coding system HL70203 describing the object identified by the Target Information Instance Identifier (REL-5).

Value	Description	Comment
FILL	Filler Identifier	An identifier for a request where the identifier is issued by the person, or service, that produces the observations or fulfills the request.
OBI	Observation Identifier	Unique and persistent identifier for an observation instance; e.g., OBX-21 (Observation Identifier) of the result for which a clarification is requested
PLAC	Placer Identifier	An identifier for a request where the identifier is issued by the person or service making the request.

Constrained HL7 Table 0203 - Identifier Type Code

Appendices

N/A

1140

Volume 2 Namespace Additions

N/A

1145

Volume 3 – Content Modules

N/A

Volume 4 – National Extensions

1150 Add appropriate Country section

4 National Extensions

N/A