# EHR-Laboratory Interoperability and Connectivity Specification

("ELINCS")

## Overview

Sept. 29, 2006

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# ELINCS Project Overview

- A national project sponsored by the California HealthCare Foundation (www.chcf.org)
- Motivation
  - Streamline the implementation of electronic data interfaces between labs and ambulatory EHRs
  - Expand the electronic delivery of laboratory results to clinicians in the office setting
  - Promote the adoption of EHRs among ambulatory-care providers
- Initiated in February, 2005

# The Problem: No EHR is an Island

"The practice was told that the EHR would interface with a national lab; that turned out to be untrue, says Dr. Gutman, because the lab does not have uniform systems throughout the country, or even on Long Island. The lab interface has been operational for a year, but the practice still hasn't hooked up its internal lab; they've had to hire an outside programmer to write that interface. The practice also had difficulty interfacing to its scheduling system, necessitating manual entry.

“As a result of all this, says Gutman, the EHR has created extra work for the staff, rather than savings. So, in his view, the group isn't seeing any return on the $150,000 it paid for the system initially or on the extra costs for additional licenses, computers, and interfaces."

*["Why EHRs Falter". Medical Economics, April 7, 2006]*

# Lab Connectivity Matters

## Desired EHR Capabilities Ranked by Physicians*

| Rank | Feature |
|---|---|
| 1 | Displays a summary of patient's clinical condition (problem list, med list, etc.) |
| 2 | Allows documentation of progress notes |
| 3 | Displays patient's demographic and insurance information |
| 4 | Captures billing codes and transmits them to billing system |
| 5 | Allows access to EMR system from home or another office |
| **6** | **Imports and displays lab results** |
| 7 | Imports and displays radiology reports |
| 8 | Displays clinical notes from consulting or referring physicians |
| 9 | Displays history of immunizations, screening tests, and other preventive procedures |
| *10* | *Alerts to interactions and contraindications in prescriptions* |
| *11* | *Documents and prints prescriptions* |
| 12 | Can incorporate information originating with patient (intake questionnaires) |
| 13 | Documents and prints orders for lab tests |
| 14 | Provides secure e-mail communication with patients and colleagues |
| 15 | Provides administrative reports on clinical practice |
| … | |
| *19* | *Sends prescriptions electronically to the pharmacy* |
| … | |
| *21* | *Electronically transmits orders for lab tests* |
| … | |
| *23* | *Displays disease management guidelines and other references* |

* Survey of 376 MDs in small (< 11) practices – California HealthCare Foundation, 2004 [unpublished]

# The Vision: ELINCS in the Practice

A four-physician practice in a suburban community recently purchased an EHR system. During installation of the system, the vendor called the local hospital lab and the local reference lab and confirmed that they offer electronic result reporting using the ELINCS messaging specification. Following two days of configuration and testing by the vendor, the four physicians began seeing test results from both labs appear in their EHR.

Several months later, the lead physician received an alert from the EHR that a patient she had recently placed on Lisinopril had had no serum creatinine monitoring performed at either lab since the prescription, a variance from best practices and pay-for-performance criteria. She forwarded the alert to her staff to arrange a follow-up appointment for the patient.

# The Vision: ELINCS in the Lab

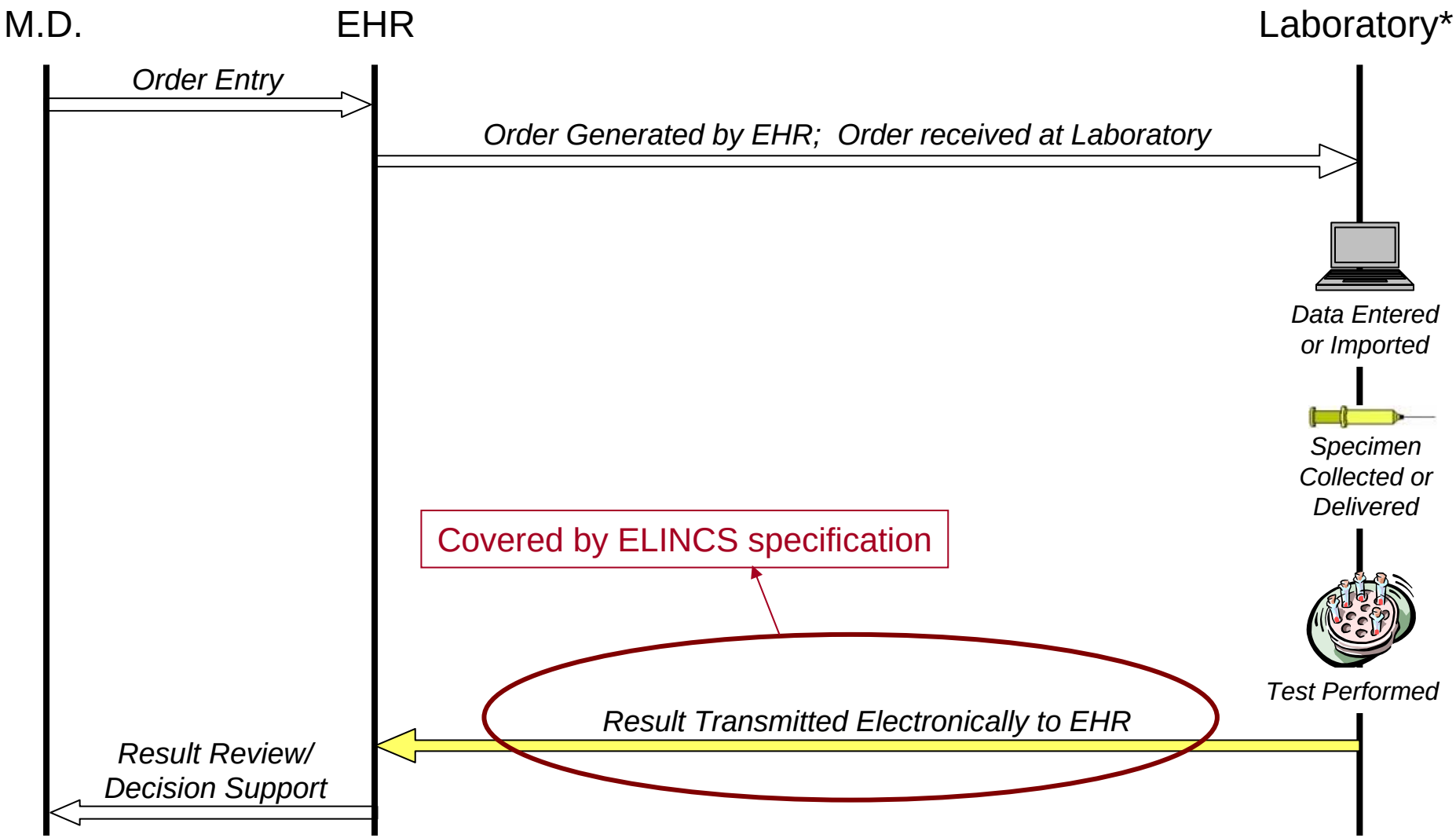
Lakeville hospital provides outpatient lab testing in a community also served by a larger hospital lab and a reference lab. Lately, physicians in the community have been purchasing various EHR systems and requesting that Lakeville report lab results to them electronically.

Because of product-certification requirements for EHRs, all of the purchased EHR systems accept results formatted in the ELINCS specification. Lakeville lab implements a single ELINCS interface and begins sending electronic results to 17 local practices.

# ELINCS Project Goals

- An *standard interoperability specification* for the electronic reporting of lab results to EHRs
  - Detailed specification of the format and coding of lab-result messages
  - Detailed interaction rules for laboratory information systems and EHRs
  - Based on requirements of varied stakeholders
    - EHR vendors, commercial labs, L.I.S. vendors, clinician users, government bodies, standards organizations
  - Balance of ideal requirements and practical capabilities => enable widespread near-term adoption
  - *Support for objective conformance testing*

# ELINCS Use Case: Outpatient Lab Testing






* Hospital, Reference, or Clinic

# ELINCS Development Process

- Multi-disciplinary technical working group
- Consensus-based decision making
  - Discussion and consensus in work group
  - Public comment period to collect wider industry input
  - Thorough documentation of process
- Guidance from external steering committee

# Technical Working Group Representation

**Commercial Laboratories**

Ameripath
LabCorp
Quest Diagnostics

**EHR Vendors**

AllScripts
Emdeon (WebMD)
e-MDs
NextGen

**Hospital L.I.S. Vendors**

GE Medical Technologies
Misys

**Government**

CDC
CMS
V.A.

**Other Organizations**

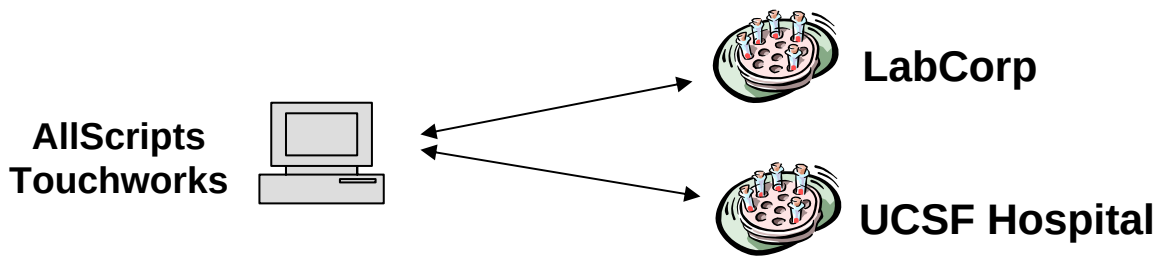
American College of Physicians
eHealth Initiative
Indiana Health Information Exchange

# ELINCS Status

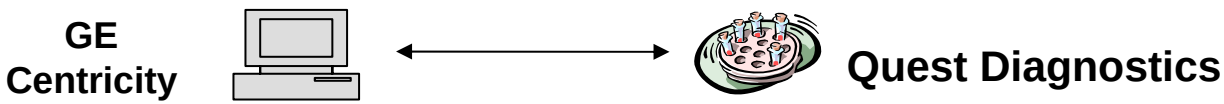
- Version 1.0 completed and published July 2005
  - Available at www.elincs.org
- Version 1.0 pilot projects initiated Feb. 2006
  - Goal: Reference implementations of ELINCS v1.0
  - 5 projects in California
  - Include physician groups, EHR vendors, and laboratories
  - Testing underway; go-lives in Sept/Oct 06

# ELINCS Pilot Project Grantees

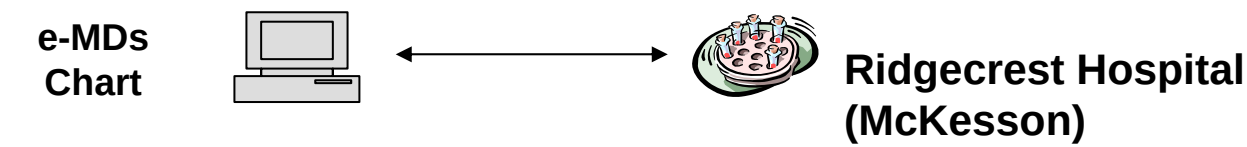
1. Brown & Toland Medical Group




2. Cedars-Sinai Medical Foundation

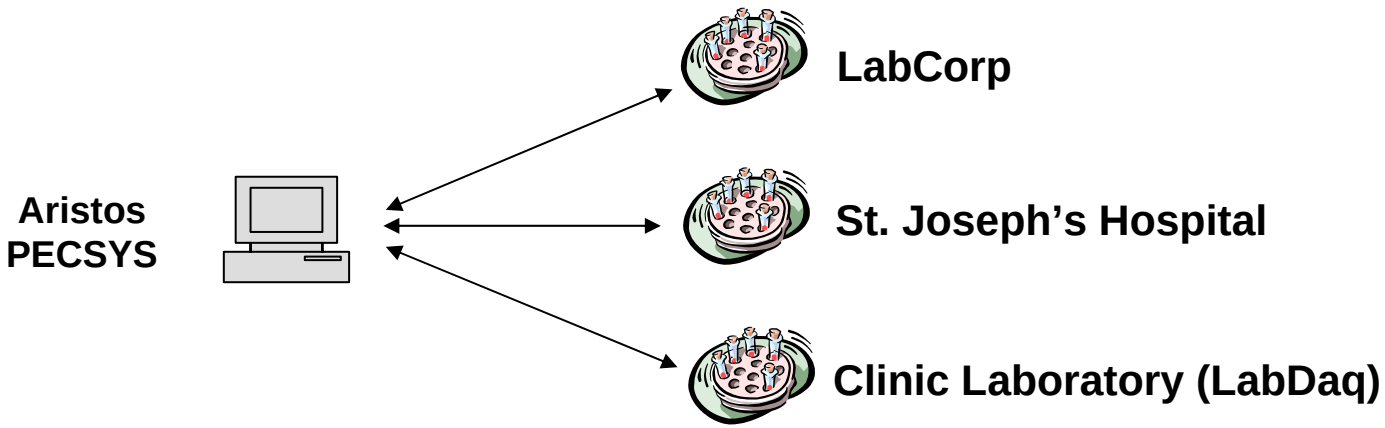



3. Southern Sierra Medical Clinic

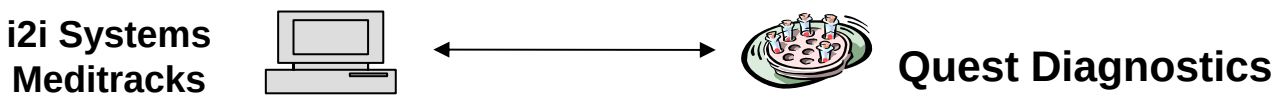


# ELINCS Pilot Project Grantees

4. Humboldt Del Note IPA




5. Redwood Community Health Coalition



# ELINCS Roadmap

- ELINCS v1.1 (Summer 2006)
  - Minor modifications to incorporate learnings from pilot implementations and ensure backward compatibility for v2.0
  - LOINC coding for 80% most common tests
  - Envisioned widespread adoption in 2007
- ELINCS v2.0 (Fall 2006)
  - Standardized structure for microbiology results
  - LOINC coding for 95% most common tests
  - Envisioned adoption in 2008
- ELINCS Orders (2007 ?)
  - Standardized interaction and message format for electronic orders
- ELINCS v3.0 (2008 ?)
  - SNOMED coding, units coding
  - Structured pathology reporting

# ELINCS and CCHIT

- Certification Commission for Healthcare Information Technology (CCHIT)
  - EHR-certification body funded by HHS
  - See www.cchit.org/about/overview.htm
- CCHIT has proposed that ELINCS v1.1 be a certification criterion for ambulatory interoperability by May 2007
  - See www.cchit.org/work/criteria.htm
- ELINCS is working with CCHIT to support its certification process

# *Caveat*

- CCHIT to use interoperability specifications created by *Health Information Technology Standards Panel* (HITSP)
  - Contracted by HHS to develop interoperability specifications for health data (including lab)
  - See www.hitsp.org
- HITSP has not yet published its interoperability specifications
  - Deliverable date: Sept. 29, 2006
- HITSP's specification for lab interoperability may be different than ELINCS v1.1

# Checklist for Labs Implementing ELINCS v1.1

- ✓ Ability to report test results, cancellations, and corrections electronically
- ✓ Ability to report tests using HL7 v2.4 messaging
- ✓ Ability to report tests using “ORU” message type
- ✓ Ability to populate ELINCS required segments and fields
  - ✓ 4 required segments (out of the 16 in ORU message)
  - ✓ 37 required fields (out of the 106 in ORU message)
  - ✓ Limited optionality (most optional fields are omitted)
- ✓ LOINC coding for 100 most common tests
- ✓ Ability to capture, store, and report the required data elements from test orders
- ✓ Ability to receive and process acknowledgement messages sent by EHRs

# Questions

# Comments

# Feedback

www.ELINCS.org

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# Additional Slides

# ELINCS Format and Content: Message Structure

## ORU message type (HL7 v2.4)

| Segment ID | Usage | Cardinality | Segment Name |
|---|---|---|---|
| MSH | R | [1..1] | Message Header |
| { | R | [1..*] | Message Content Block |
| PID | R | [1..1] | Patient Identification |
| [PD1] | X | [0..0] | Additional Demographics |
| [{NK1}] | X | [0..0] | Next of Kin/Associated Parties |
| [{NTE}] | X | [0..0] | Notes and Comments |
| [ | X | [0..0] | |
| PV1 | X | [0..0] | Patient Visit |
| [PV2] | X | [0..0] | Patient Visit - Additional Info |
| ] | | | |
| { | R | [1..*] | Test Order Block |
| ORC | X | [0..0] | Order Common |
| OBR | R | [1..1] | Observations Report ID |
| {[NTE]} | RE | [0..*] | Notes and comments |
| [CTD] | X | [0..0] | Contact Data |
| { | ** | ** | Test Result Block |
| OBX | R | [1..1] | Observation/Result |
| {[NTE]} | RE | [0..*] | Notes and comments |
| } | | | |
| {[FT1]} | X | [0..0] | Financial Transaction |
| {[CTI]} | X | [0..0] | Clinical Trial Identification |
| } | | | |
| } | | | |
| [DSC] | X | [0..0] | Continuation Pointer |

**R**: Required Always
**RE**: Required if data available
**X**: Not supported

# ELINCS Format and Content: Segment Structure

Example: OBX

| SEQ | ELEMENT NAME | LEN | DATA TYPE | Usage | Cardinality |
|---|---|---|---|---|---|
| **1** | **Set ID - OBX** | **4** | **SI** | **O** | **[0..1]** |
| **2** | **Value Type** | **2** | **ID** | **C** | **[0..1]** |
| **3** | **Observation Identifier** | **250** | **CE** | **R** | **[1..1]** |
| **4** | **Observation Sub-ID** | **20** | **ST** | **O** | **[0..1]** |
| **5** | **Observation Value** | **65536** | ***** | **C** | **[0..*]** |
| **6** | **Units** | **250** | **CE** | **RE** | **[0..1]** |
| **7** | **References Range** | **60** | **ST** | **RE** | **[0..1]** |
| **8** | **Abnormal Flags** | **5** | **IS** | **RE** | **[0..5]** |
| 9 | Probability | 5 | NM | X | [0..0] |
| 10 | Nature of Abnormal Test | 2 | ID | X | [0..0] |
| **11** | **Observation Result Status** | **1** | **ID** | **R** | **[1..1]]** |
| 12 | Date Last Observation Normal Value | 26 | TS | X | [0..0] |
| 13 | User Defined Access Checks | 20 | ST | X | [0..0] |
| 14 | Date/Time of the Observation | 26 | TS | X | [0..0] |
| **15** | **Producer's ID** | **250** | **CE** | **R** | **[1..1]** |
| **16** | **Responsible Observer** | **250** | **XCN** | **RE** | **[0..*]** |
| 17 | Observation Method | 250 | CE | X | [0..0] |
| 18 | Equipment Instance Identifier | 22 | EI | X | [0..0] |
| **19** | **Date/Time of the Analysis** | **26** | **TS** | **RE** | **[0..1]** |

**R**: Required Always
**RE**: Required if data available
**O**: Optional
**C**: Conditional
**X**: Not supported

# ELINCS Format and Content: Field Definitions

## Example: OBX-3 Observation Identifier

ELINCS Specification: For the tests listed in Appendix A, the LOINC coding system *must* be used to represent the observation (analyte) reported. In these cases, the LOINC code for the reported analyte must appear in the 1st, 2nd, and 3rd components of OBX-3. For tests that are not listed in Appendix A, LOINC codes need not be reported in OBX-3 and the first three components of the field may be left blank. However, LOINC codes *may* be reported for any tests and their use is encouraged. In any case, *the first three components of OBX-3 are reserved for LOINC codes only.*

For all tests, the 4th, 5th, and 6th components of OBX-3 must be populated with the laboratory's internal codes for the reported analytes. In most cases, the lab's internal codes will be its proprietary codes for analytes, but this is not necessarily the case, and the nature of these codes is outside the purview of the ELINCS specification.

**Note:** The labs' internal codes are required even when LOINC codes are reported. This is to provide backward compatibility with result data that was received prior to the adoption of the ELINCS specification.

Field: OBX-3 Observation Identifier

| Component/Sub-Component | Usage |
|---|---|
| identifier (ST) | RE |
| text (ST) | RE |
| name of coding system (IS) | RE |
| alternate identifier (ST) | R |
| alternate text (ST) | R |
| name of alternate coding system (IS) | R |

ELINCS Sample Values:

```
2089-1^LDL Cholesterol^LN^576X^LDL Chol^99Lab
```

[LOINC code for LDL Cholesterol, plus the lab's internal code; note that LDL Cholesterol appears among the tests listed in Appendix A.]

```
^^^7564ZZ^Hep B SAg^99Lab
```

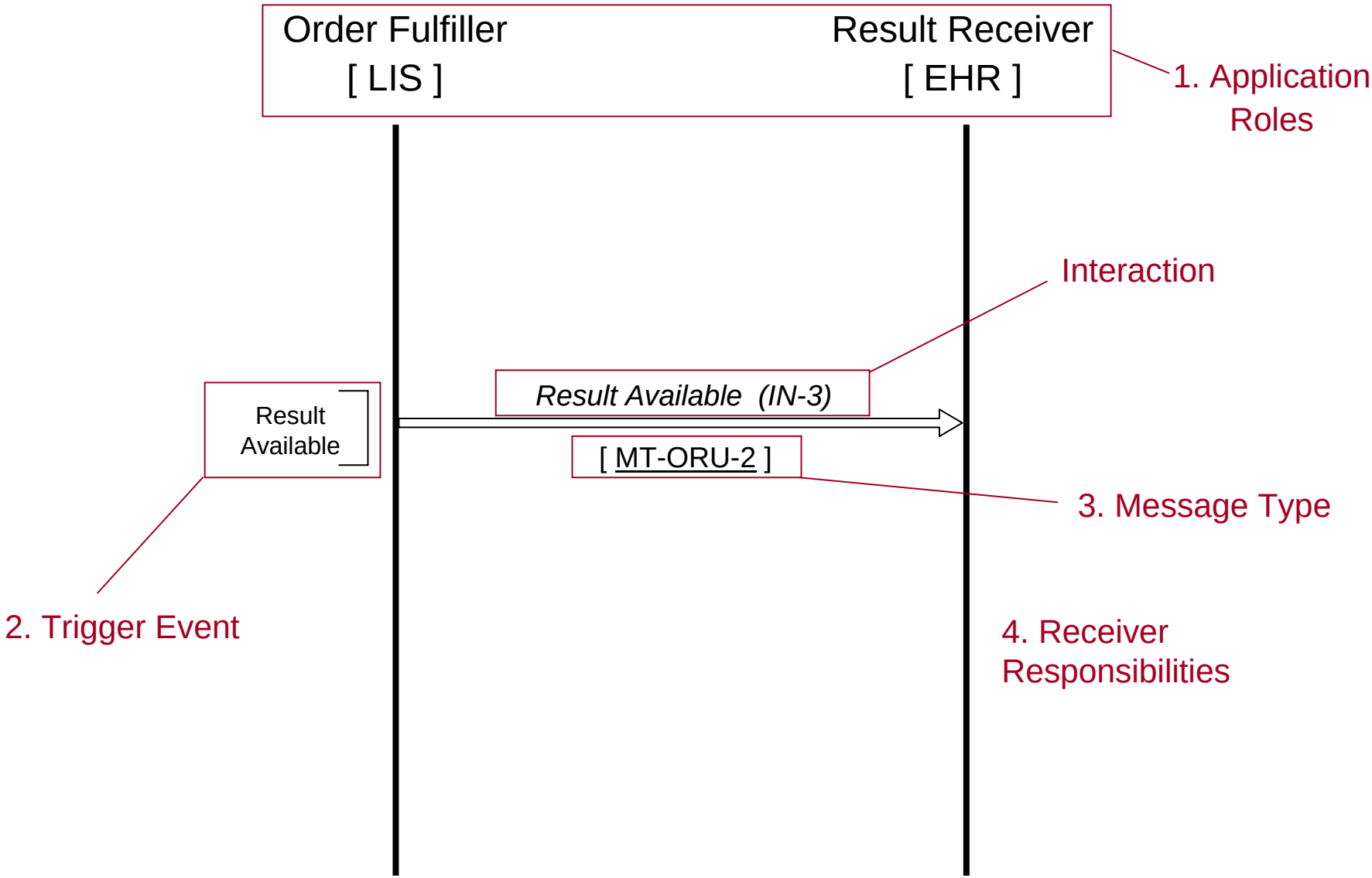
[Lab's internal code for Hep B surface antigen, coded per lab's proprietary coding system; note that Hep. B surface antigen does not appear among the tests listed in Appendix A.]

# Standard coding for Common Tests

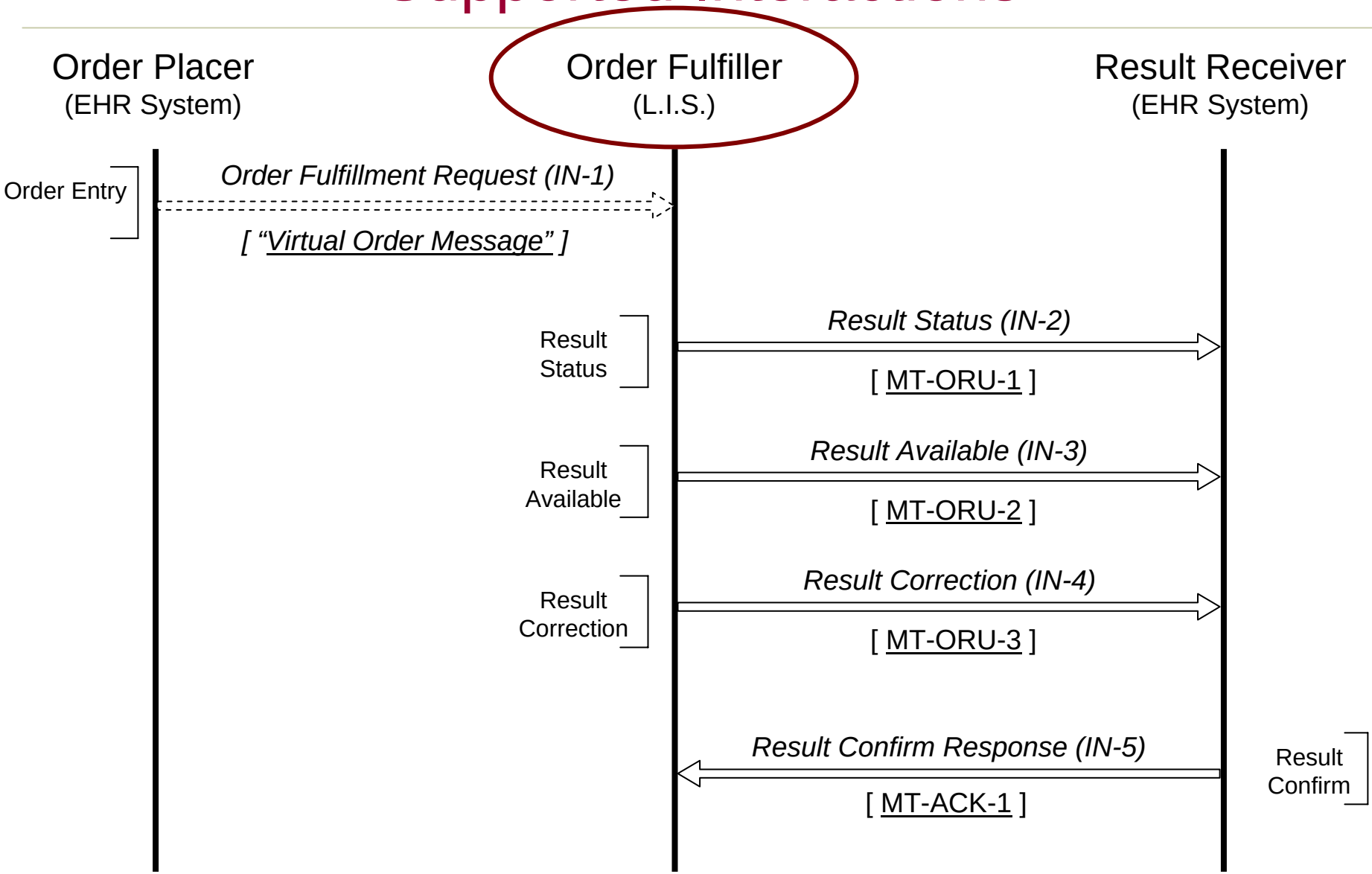
- LOINC codes required for top 80% of tests (by frequency)
  - ~ 100 tests;  Based on data from 3 large CA provider groups
- Tests enumerated in ELINCS specification
- Examples:

| Test Category | Test | Test Description | LOINC Code(s) | Sample Values |
|---|---|---|---|---|
| Common blood cell count and differential WBC count analytes | | | | |
| | RBC | Red Blood Cells (Erythrocytes), patient blood | 790-6, 789-8, 26453-1 | 4.41 M/uL |
| | WBC | White Blood Cells (Leukocytes), patient blood | 6690-2, 26464-8, 804-5 | 7.3 K/uL |
| | PLATELETS | Platelets, patient blood quantitative | 778-1, 777-3, 26515-7 | 400 K/uL |
| | HEMOGLOBIN | Blood count, hemoglobin | 30350-3, 718-7 | 12.2 g/dL |
| | BANDS | Neutrophil bands, patient blood, quantitative | 26507-4. 30229-9, 763-3 | 1.14 K/uL |
| | BANDS % | Neutrophil bands as percent of total leukocytes | 26508-2, 35332-6, 764-1 | 7% |
| | ... | | | |

# ELINCS Interaction Model: Based on HL7 v3.0



# ELINCS Interaction Model: Supported Interactions



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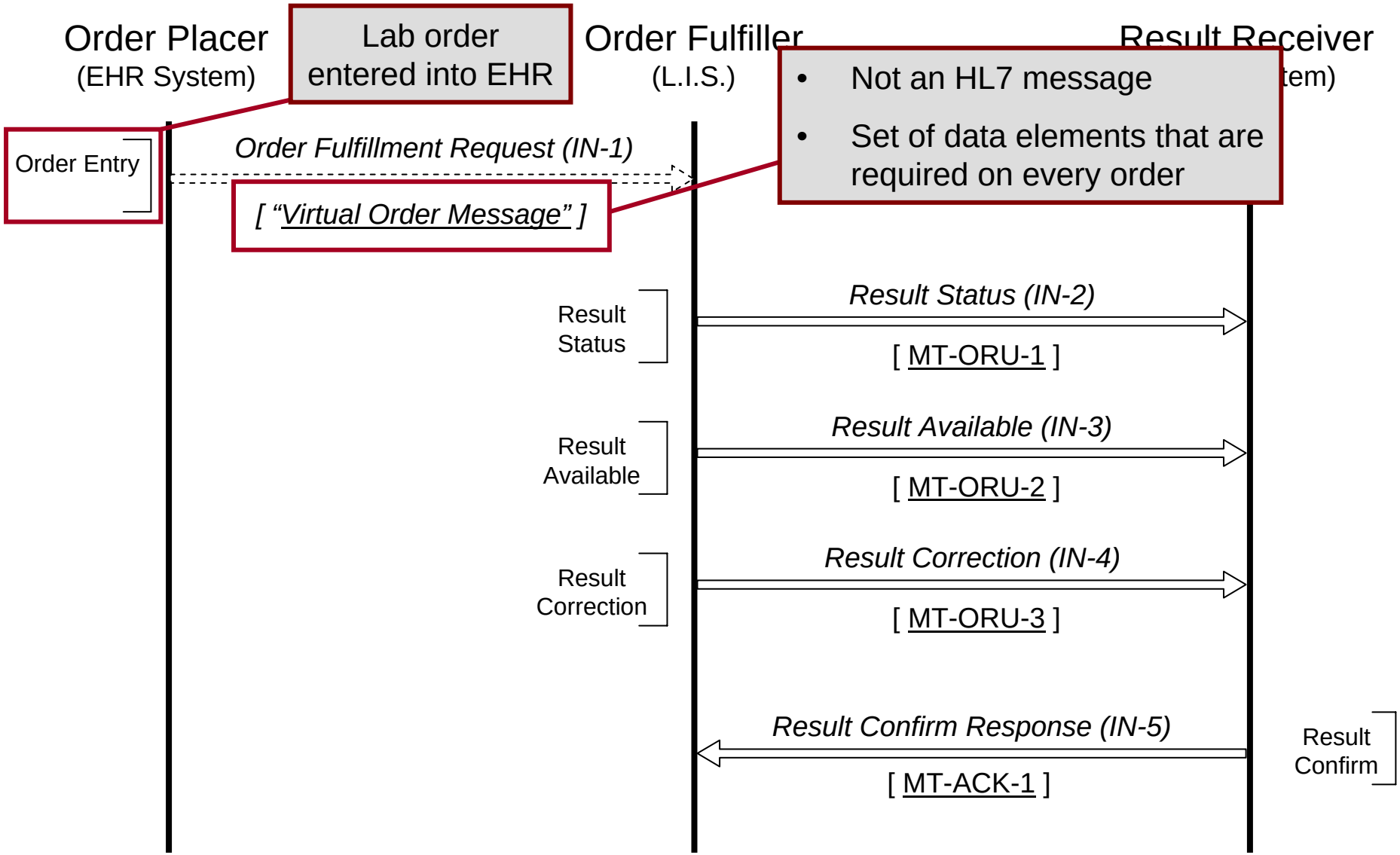
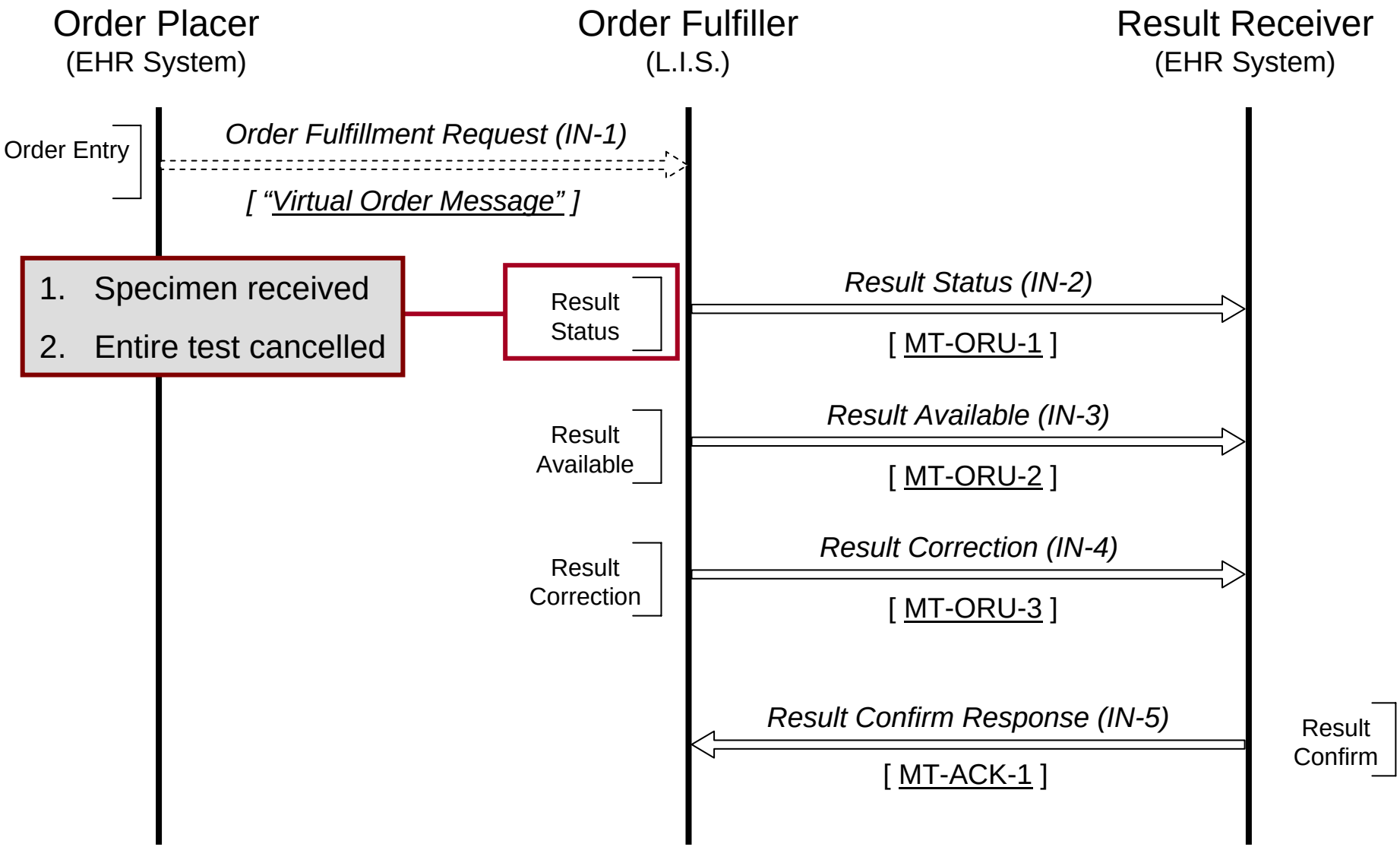


# Virtual Order Message

- EHR Responsibilities
  - Include required data elements on all orders
  - Examples:  Requisition ID, Ordering Provider, Patient Name, Ordered Test IDs, etc.…
- Lab Responsibilities
  - Record required data elements on the order
  - Store data elements during lifetime of the order
  - Include data elements in all ELINCS status/result messages
- Example:  Requisition ID

# ELINCS Interaction Model: Supported Interactions



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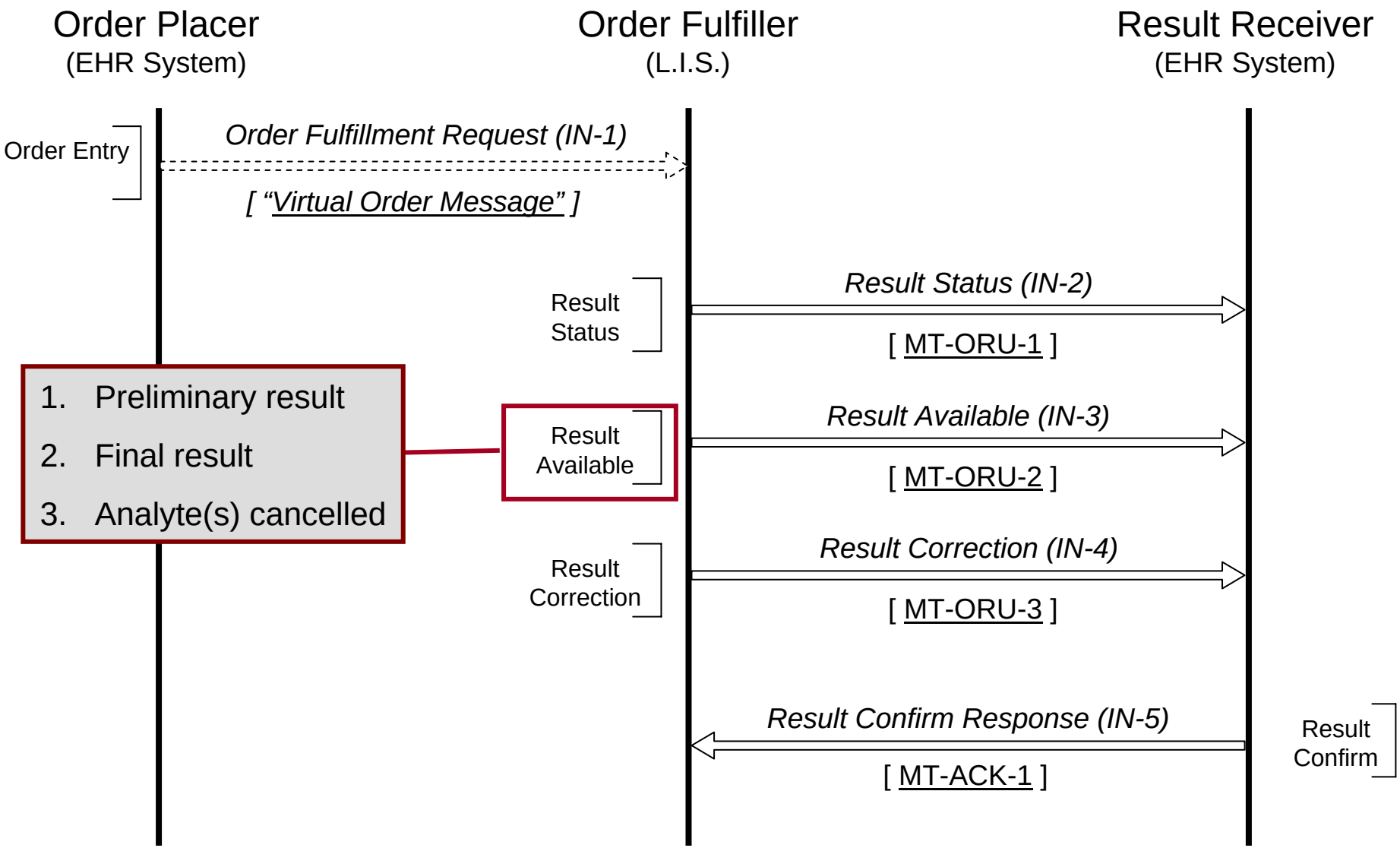

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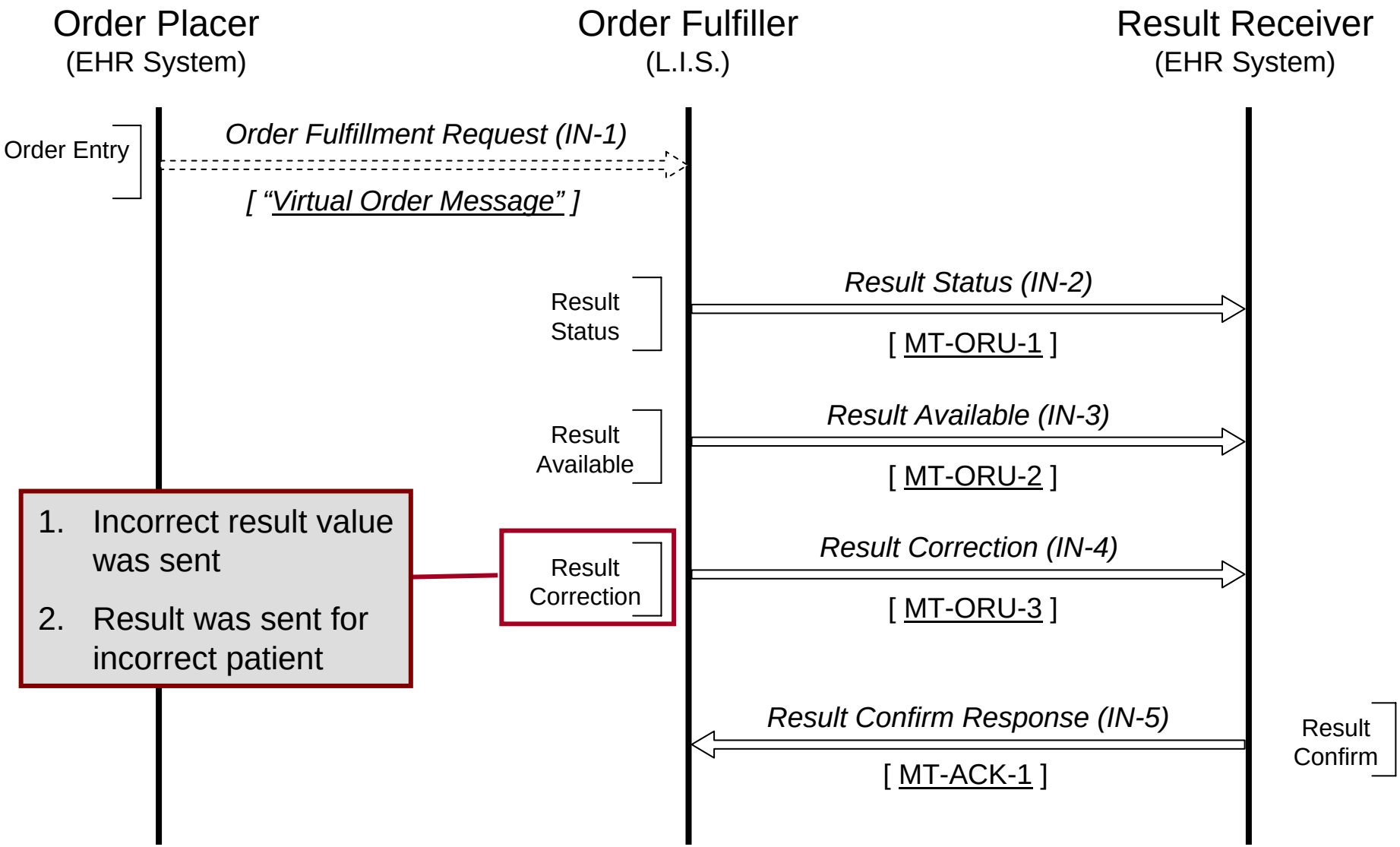

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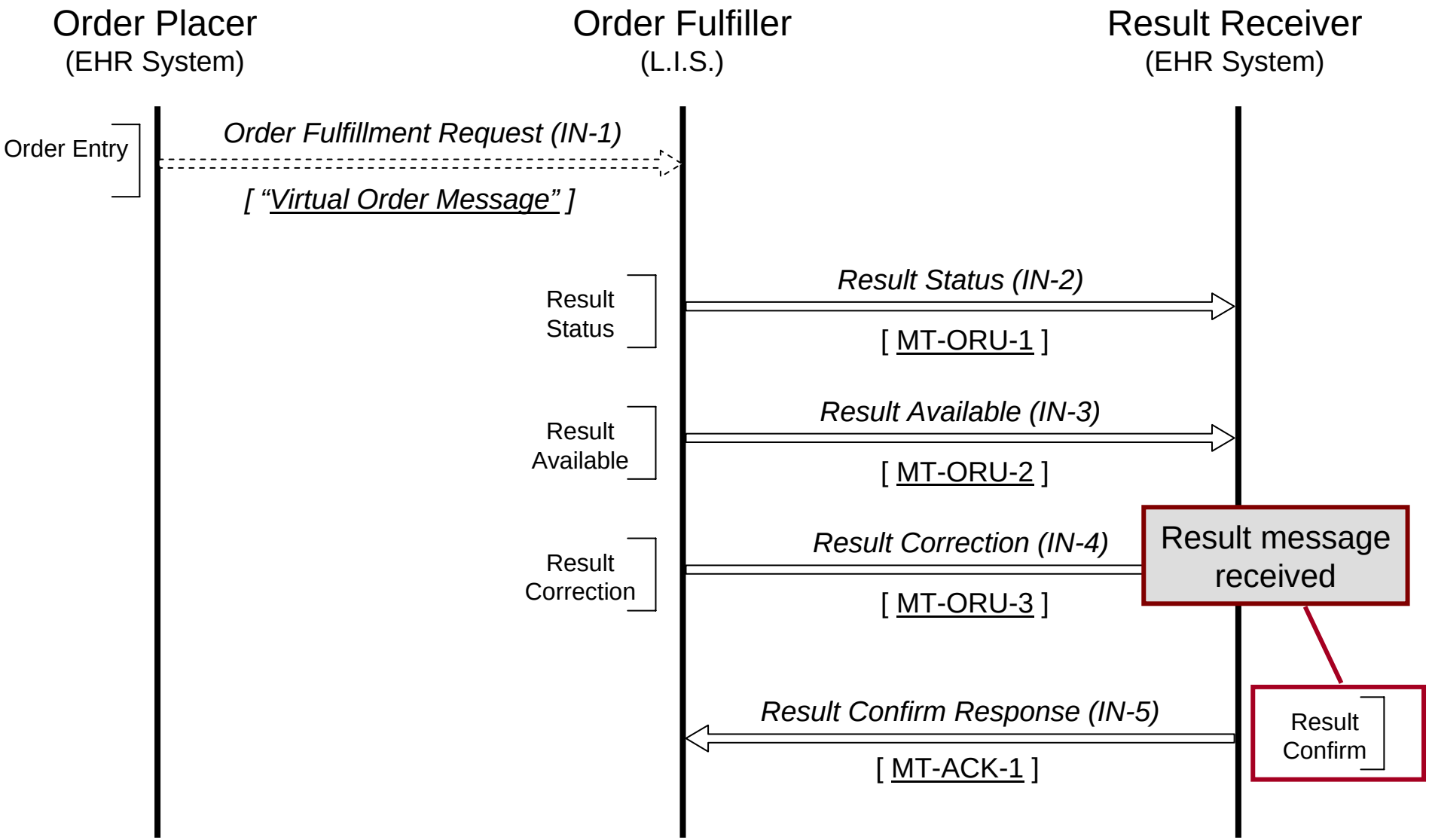

# EHR Receiver Responsibilities

- Acknowledging receipt of lab messages
  - Releases lab from need to resend message
- Storing and displaying certain information
  - Test cancellations
  - Identity of the lab performing the test
  - Required to assure labs of CLIA conformance (Clinical Laboratory Improvement Amendments)