Newborn Screening (NBS)
Lab Order Technical Specifications

HL7 2.5.1

Based on HL7 Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1, STURelease 3 - US Realm

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REVISION HISTORY

Release	Date	Revised By:	Description
1	06/05/2023	GDSP	Initial Version

California Department of Public Health (CDPH) and Genetic Disease Screening Program (GDSP) assume no liability for the information contained herein and reserves the right to make changes to this document as deemed necessary. Please refer to the CDPH HIE Gateway Website for the current document or contact the GDSP at 1-866-718-7915.

SECTION 1: OVERVIEW

The purpose of this Guide is to define an HL7 message for transmitting Newborn Dried Blood Spot (NDBS) Laboratory Orders. It provides a recommended approach for using an HL7 Version 2.5.1 OML^O21 message to send an NDBS laboratory test order from the placer, such as the physician or birth hospital, to the laboratory fulfilling the order. In the HL7 standard, the OML event O21 message is used for laboratory order messages.

The scope of this Guide is to describe the specifications and how specifications may be used for sending electronic lab orders in the current state of business process flow in Newborn Dried Blood Spot Screening. Future state or business process redesign is outside the scope of this document. Also, other use cases, such as newborn hearing screening that may be related to newborn screening in general, as well as other processes within newborn dried blood spot screening, such as sending laboratory results or follow-up of abnormal results, are outside of the scope of this document.

This guide and message format were specifically designed to allow partner facilities or vendors to claim conformance to HL7 Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1,STU Release 3 - US Realm. However, as described in this guide, the GDSP program allows flexibility where possible to accommodate exchange partners who do not wish to strictly adhere to LOI.

1.1. INTENDED AUDIENCE

This document is intended for technical staff from hospital and clinic partners, EHR vendors, LIS vendors and other entities supporting providers' specimen order submission to the State of California GDSP. The reader of this state Implementation Guide (IG) should have a solid HL7 foundation and be familiar with the contents of the HL7 Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1, STU Release 3 - US Realm. The goal of this Guide is toprovide an unambiguous specification for creating and interpreting messages exchanged between providers and the State of California GDSP.

1.2. DATA EXCHANGE REQUIREMENTS

To engage in data exchange with the GDSP, the sending partner (i.e., the provider, EHR or LIS) will need to ensure that they:

- Are a registered Newborn Screening specimen submitter with GDSP.
- Ensure that all associated facilities in their organizational hierarchy is accurate.
- Have the ability to send NBS specimen order data by constructing a valid HL7 version 2.5.1 message.
- Have the ability to interface with the GDSP using the file transportoption listed below.

1.3. TRANSPORT OPTION FOR DATA EXCHANGE

There are a few different transport methods that may be considered to securely submit newborn screening orders, formatted as HL7 messages, to the GDSP NBS Lab. The current supported method of submitting HL7 messages is HTTP REST Web Services.

Interface Type	Endpoint URL	Connection Details
Orders - Inbound to GDSP	**TEST Environment:** https://dataexchangetrain.cdph.ca.gov:9010/PostNBSOrder **PROD Environment:** https://dataexchange.cdph.ca.gov:9010/PostNBSOrder	**GDSP webservices Details** SSL/TLS protocols: TLSv1.2. SSL/TLS Cipher Suites: The SSL cipher suite determines which algorithms are used for key exchange, encryption, and message integrity. Due to the SSL handshake, the client and server negotiate which cipher suite should be used for the connection, and the connection can only be established if the client and server have a cipher suite in common. Supported: FIPS cipher suites. This includes AES 128-bit and AES 256-bit cipher suites. **Client Authentication:** Trusted Certificates are used to authenticate the HTTPS clients. In order to successfully connect, an HTTPS client must present the ITSD issued certificate while handshake

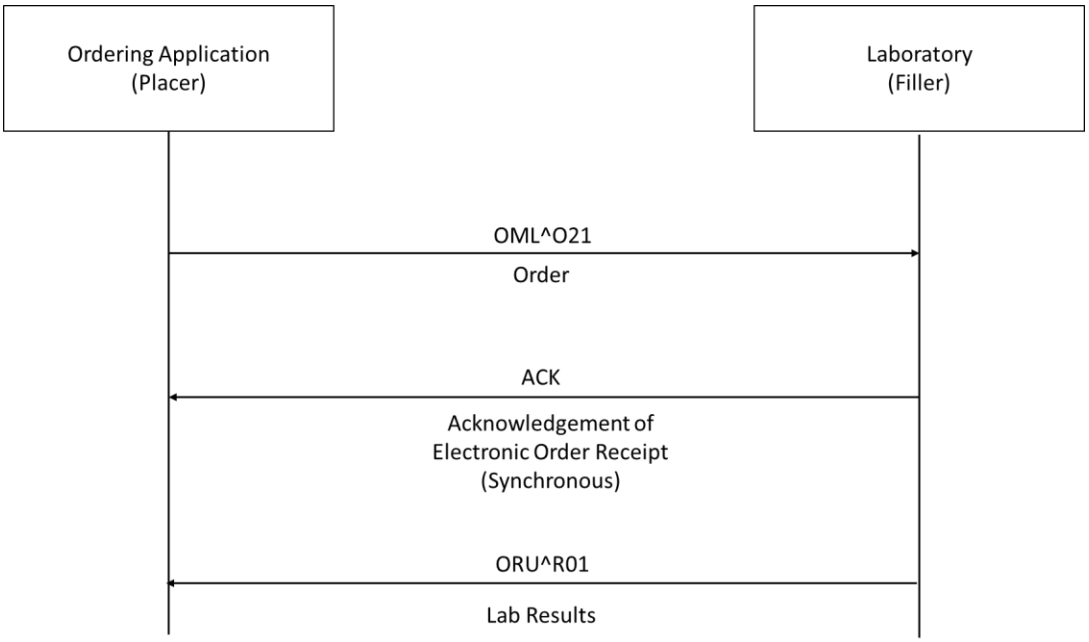
1.4. ASSUMPTIONS

- Electronic health record systems and laboratory systems are in place at the submitter end that allow for the electronic messaging of laboratory orders.
- The data specified and agreed upon for data exchange is available. The electronic health record system contains sufficient information for the placer to construct the lab order message properly.
- Each OML^O21 message contains laboratory order information for a single Newborn Dried Blood Spot card (the specimen).

1.5. ACTORS, GOALS, AND MESSAGING TRANSACTIONS

The following diagram illustrates where the OML^O21 message fits into an order interaction between the GDSP and the entity submitting the newborn screening specimen.

Figure 1.1: Use Case and Goal

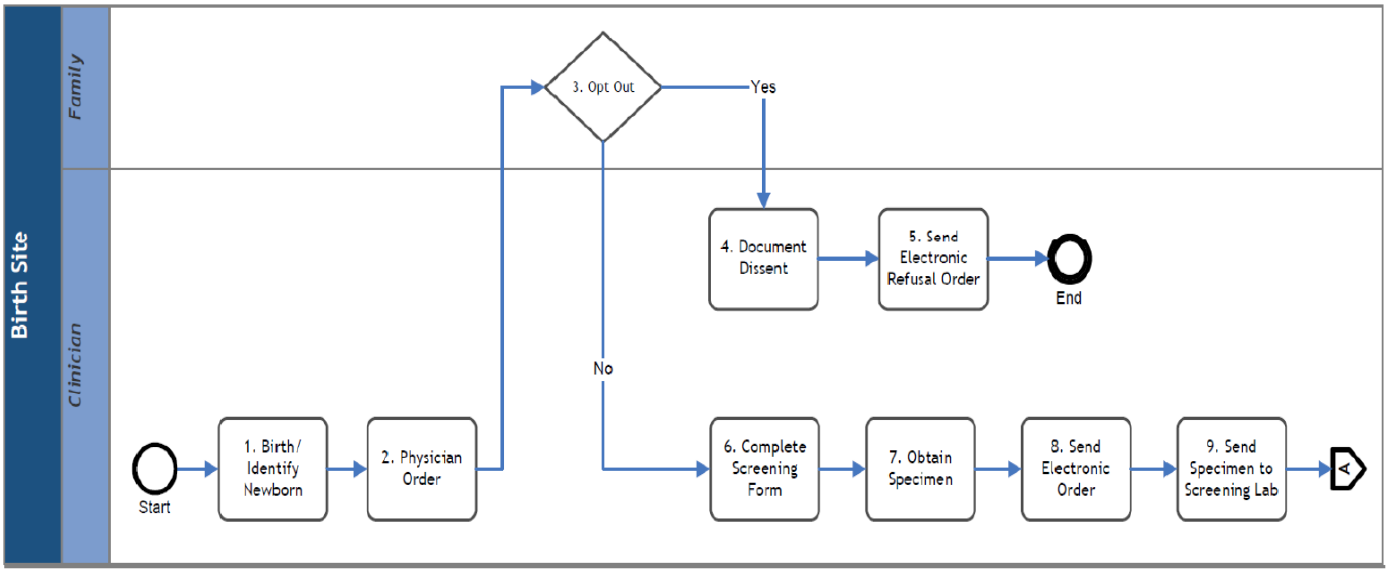


This guide outlines the appropriate messaging format to send an electronic order for a newborn screening specimen to the GDSP.

Table 1.1: Use Case and Goal – Orders

Use Case	Message Type	Goal
Send Newborn Screening Specimen Order	OML^O21	To send newborn screening specimen and associated patient demographic information to the GDSP.
Acknowledge Receipt	ACK^O21	To acknowledge receipt of a message.
Report Error	ACK^O21	To send error messages related to submitted messages. These errors could result in rejection of the message.

Figure 1.2: Task Flow Diagram for Newborn Screening Orders



SECTION 2: HL7 MESSAGING INFRASTRUCTURE

This section will contain a basic description of the terms and definitions, which are used in this document to understand the HL7 standard as it applies to the GDSP information systems.

2.1 HL7 DEFINITIONS

The terms below are organized to move from the message to subsequently more granular components. The details of how HL7 messages are structured for the GDSP purposes will be explained later in this document.

2.1.1 MESSAGE

A message is the entire unit of data transferred between systems in a single transmission. It is a series of segments in a sequence defined by the message specifications.

2.1.2 SEGMENT

A segment is a logical grouping of data fields. Segments within a defined message may be required or optional, may occur only once, or may be allowed to repeat. Each segment is named and is identified by a segment ID, a unique 3-character code.

2.1.3 FIELD

A field is a string of characters delimited by field separators (|). Each field has an element name and is identified by the segment it is in and its position within the segment, e.g., PID-5 is the fifth field of the PIDsegment.

2.1.4 COMPONENT

A component is an element within a composite field and is delimited within the field by component separators (^). Within a field having several components, not all components may be required. Leading empty components must be represented by a delimiter (^); trailing empty components may be eliminated from the field. A component is referenced by the 3-character segment code, followed by the field position, and the component position with that field, e.g., OBX-5.2 denotes the second component of the fifth field of the OBX segment.

2.1.5 NULL AND EMPTY FIELDS

The null value is transmitted as two double quote marks “”. A null-valued element differs from an empty element. The null value means that the receiving system voids any previous value. An empty element remains unchanged. The empty element does not overwrite previously entered data.

2.1.6 DATA TYPE

A data type restricts the contents and format of the data field. Data types are given a 2- or 3-letter code that is specified by HL7. Some data types are coded or composite types with several components.

The applicable HL7 data type is listed and defined in each field definition.

2.1.7 CODE SETS

The GDSP associates most data elements with a list of acceptable values. Where applicable, this guide lists code values expected by GDSP. The GDSP may not use all the HL7 permitted values.

2.1.8 DELIMITERS

Delimiter characters are used to separate segments, fields, and components in an HL7 message. The delimiter values are given in MSH-2 and used throughout the message.

|	Field Separator (ASCII 124)
^	Component Separator (ASCII 094)
&	Sub-component Separator (ASCII 038)
~	Repetition Separator (ASCII 126)
\	Escape Character (ASCII 092)

2.1.9 MESSAGE SYNTAX

Several segments form each message. Each segment begins with a three-letter code that identifies the segment category. Segments must be a single line and end with a segment terminator. Square brackets, [], enclose required but may be empty segments. Braces, {}, enclose segments that may be repeated.

2.1.10 SEGMENT TERMINATOR

Only the ASCII 013 carriage return is allowed. Throughout this document, this character is represented as <CR>. This value cannot be changed by implementers.

2.2 RULES FOR SENDING SYSTEMS

The following rules are used by sending systems to construct HL7 messages for submission to GDSP Laboratory.

- Encode each segment in the order specified in the message format.
- Begin the segment with the 3-letter segment ID (for example “PID”).
- Precede each field with the data field separator (“|”).
- Use the HL7 recommended encoding characters (“^~\&”).
- Encode the data fields in the order given in the table defining the segment’s structure.
- Encode the data field according to its HL7 data type format. Less restrictive data types may be allowed if it is formatted correctly and in the required location within the data type.
- Do not include any characters for fields are not present in the segment. Since later fields in the segment are encoded by ordinal position, fields that are not present do not reduce the number of field separators in the segment. For example, when the second and third fields are not present, the field separators maintain the ordinal position of the fourth field (as in MSG|field1|||field4).
- Trailing separators may optionally be omitted. For example, |field1|field2 is equivalent to |field1|field2|||||, when field3 and all subsequent fields are not present.
- End each segment with the default HL7 segment terminator, carriage return character (ASCII 013)

2.3 FIELD SPECIFICATIONS & USAGE

A key attribute to HL7 fields, components, and sub-components is the Usage Code. In the table below arethe acceptable Usage Codes used in this specification document.

Table 2.3.1: Usage Codes

Usage Code	Interpretation	Comment
R	Required	A conforming sending application shall populate all “R” elements with a non- empty value. The absence of a required element will result in an error.

RE	Required but may be empty	A conforming sender should be capable of providing all "RE" elements. If the conforming sender knows the required values for the element, then it must send that element. If the conforming sender does not know the required values, then that element may be omitted.
C	Conditional	This usage has an associated condition predicate. The associated condition predicate is specified in the HL7 message definition. **If the predicate is satisfied:** A conformant sending application must always send the element. A conformant receiving application must process or ignore data in the element. It may raise an error if the element is not present. **If the predicate is NOT satisfied:** A conformant sending application must NOT send the element. A conformant receiving application must NOT raise an error if the condition predicate is false and the element is not present, though it may raise an error if the element IS present
O	Optional	The GDSP allows exchange partners to send optional elements to meet LOI or partner internal requirements. This guide specifies fields that will be returned to the submitter upon receipt. Optional fields may be sent but will not be consumed by GDSP or returned to the submitting facility.
X	Not Supported	The element is not supported. Sending applications should not send this element. A receiving application may raise an error if it receives an unsupported element.

SECTION 3: OML^O21 ORDER SEGMENT DETAILS

This section will contain specifications for each segment used in the OML^021 order message. It will indicate which fields are supported or required and describe any constraints on these fields.

Table 3.1: OML^O21 Segments

Segment	Definition	GDSP Usage	Note
MSH (Message Segment Header)	The MSH segment defines the intent, source, destination, and some specifics of the syntax of a message.	R	This begins every message and includes information about the type of message, how to process it, and by whom it was created.
PID (Patient Identifier Segment)	The PID segment contains permanent patient identifying and demographic information that, for the most part, is not likely to change. Used by all applications as the primary means of communicating patient identification information frequently.	R	Used to carry information about the patient/client.
PD1 (Patient Additional Demographic)	The PD1 segment contains information about the patient's Primary Care Provider (Post-Discharge provider) information. For newborn screening purposes, a PD1 segment is required that transmits information on the patient's pediatrician name and ID.	R	Used to carry information about the pediatrician of the newborn. Important for GDSP in situations of abnormal result follow-up.
NK1 (Next of Kin Segment)	The NK1 segment contains information about the patient's next-of-kin or other related parties. For newborn screening purposes, an NK1 is required that transmits information on the patient's mother.	R	Used to carry information about the mother of the newborn. Important for GDSP in situations of abnormal result follow-up, patient matching, Medicaid billing, and linkage of multiple newborn screening specimens.
ORC (Common Order Segment)	The ORC segment is used to transmit fields that are common to all orders (all types of services that are requested).	R	Used to give information about the newborn screening order.

Segment	Definition	GDSP Usage	Note
OBR (Observation Request Segment)	The observation request (OBR) segment is used to capture information about one test being performed on the specimen. Most importantly, the OBR identifies the type of testing to be performed on the specimen and ties that information to the order for the testing.	R	Used to identify an order for results to the newborn screening testing panel.
OBX (Observation Result Segment)	The OBX segment has many uses. It carries observations about the object of its parent segment. In the OML^O21, it is associated with the OBR and ORC pair. The basic format is a question and answer.	R	Used to transmit various ask-at-order entry and/or ask-at-specimen entry responses.

3.1 MSH: MESSAGE SEGMENT HEADER

The MSH segment is required at the beginning of each message sent. It contains information used to identify the intent, source, and destination of the message, as well as certain specifics about the syntax of the message. There is only one MSH segment per message.

Example MSH Segment:

MSH|^~\&|ApplicationName|R777|SISHIERECEIVER|SISGDSP|20000102000000||OML^O21|1|P|2.5.1

Table 3.1.1: Message Segment Header (MSH)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Field Separator	ST	R			|
2	Encoding Characters	ST	R			^~\&
3	Sending Application	HD	R			ApplicationName
4	Sending Facility	HD	R		GDSP provided Hospital Code	R777
5	Receiving Application	HD	R		SISHIERECEIVER	
6	Receiving Facility	HD	R		SISGDSP	
7	Date/Time of Message	TS	R		yyyymmddHHMMSS	20000102000000

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
9	Message Type	MSG	R			OML^O21
10	Message Control ID	ST	R			1234
11	Processing ID	PT	R			P – Production
						T-Testing
12	Version ID	VID	R		HL7 Version	2.5.1

3.2 PID: PATIENT IDENTIFIER SEGMENT

The Patient Identifier segment is used by all applications as the primary means of communicating patient identification information. This segment contains permanent patient identifying and demographic information.

Example Patient Identifier (PID) Segment:

PID|1|12345|3000678^^^EPI||TEST^BABYGIRL|MotherMaidenName|22220201000000|F||2106-3^White~1002-5^American Indian or Alaska Native|1234 HOLLMAN RD^^MONTEREY^CA^91234||||SP^SPANISH||||000000000|||2135-2^Hispanic or Latino||Y|1

Table 3.2.1: Patient Identifier Segment (PID)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – PID	SI	R			1
2	Patient ID	CX	O			12345
3	Patient Identifier List	CX	R		Hospital MRN	3000678^^^EPI
5	Patient Name	XPN	R		Name should not contain a suffix	TEST^BABYGIRL
6	Mother's Maiden Name	XPN	O		The mother's full legal name appears in the NK1 segment.	MotherMaidenName
7	Date/Time of Birth	TS	R		yyyymmddhhmmss	22220201000000
8	Administrative Sex	IS	R	See Appendix		F - Female

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
				Table(A.1) for possible accepted values		
10	Race	CE	R	See Appendix Table (A.2) for possible accepted values		2106-3^White
11	Patient Address	XAD	R			1234 HOLLMAN RD^^MONTEREY^CA^91234
15	Primary Language		O	See Appendix Table (A.3) for possible accepted values	Mother's language	spa
19	Patient SSN Number	NM	O		9 numeric digits	123456789
22	Ethnicity	CE	R	See Appendix Table (A.4) for possible accepted values		2135-2^Hispanic or Latino
24	Multiple Birth Indicator		R	Yes, Y, No, N		Yes
25	Birth Order	NM	C		If PID.24 is Yes, then we need a value in this field	1

3.3 PD1: PATIENT PRIMARY CARE PROVIDER INFORMATION

The PD1 segment contains information about the patient's primary care provider. For newborn screening purposes, a PD1 is required where PD1.4 field is valued with baby's post discharge care provider, which is typically the pediatrician.

Example PD1 Segment:
PD1||||1234567890^Lastname^FirstName^^^^^^^^^^NPI|

Table 3.3.1: Patient Primary Care Provider (PD1)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
4	Patient Primary Care Provider Name and ID No.	XCN	R		Post Discharge Care Provider Information	PD1||||1234567890^Lastname^ FirstName^^^^^^^^^^NPI|
4.1	Id Number	ST	R		Need NPI in this field	
4.2	Provider Last Name	ST	R			
4.3	Provider First Name	ST	R			
4.13	Identifier Type Code	ST	R		NPI	

3.4 NK1: NEXT OF KIN SEGMENT

The NK1 segment contains information about the patient's next-of-kin or other related parties. For newborn screening purposes, a NK1 is required where NK1-3 Relationship is valued MTH. This information about the mother of the newborn is important to GDSP for abnormal result follow-up, patient matching, Medicaid billing, and linkage of multiple newborn screening specimens. In uncommon scenarios where the birth mother is not the primary contact for the baby (e.g.,ward of the court or foster care), the alternate contact information should still be sent in the required NK1 where NK1-3 is valued 'MTH'.

Example NK1 Segment:

NK1|1|TEST^GBS|MTH^Mother|1234 HOLMAN RD^^MONTEREY^CA^91234^USA^^^MONTEREY|1234567890^^^ Gbs.test@email.com ||||||||||19970201000000|||||||||||||||888888888

Table 3.4.1: Next of Kin Segment (NK1)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID - NK1	SI	R			1
2	NK Name	XPN	R			TEST^GBS

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
3	Relationship	CE	R			MTH^Mother
4	Address	XAD	RE			1234 HOLMAN RD^^MONTEREY^CA^91234^USA^^^MONTEREY
5	Phone Number	XTN	O		Primary Phone #	1234567890
5.4	Email Address	ST	O		Mother's email	Gbs.test@email.com
6	Business Phone Number	XTN	O		Alternate Emergency #	1234567890
16	Date/Time of Birth	TS	RE			19970202000000
33	Next of Kin/Associated Party's Identifiers	CX	O		Mother's SSN	888888888

3.5 ORC: COMMON ORDER SEGMENT

The Common Order segment (ORC) is used to transmit fields that are common to all orders (all types of services that are requested). There will be only one ORC segment for this message.

Example ORC Segment:

ORC|NW|200373582^EPC|||||||||1515151515^DoctorLast^DoctorFirst|||||||| Hospital Name^^^^^^^^^R777|||1111 First St.^^Richmond^CA^9000

Table 3.5.1: Order Request Segment (ORC)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Order Control	ID	R		New order/service	NW
2	Placer Order Number	EI	R			200373582^EPC
12	Ordering Provider	XCN	R			1515151515^DoctorLast^DoctorFirst

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
12.1	Ordering Provider NPI	ST	R		This can be a repetitive field with NPI / license number	1515151515
12.2	Ordering Provider Last Name	ST	R			DoctorLast
12.3	Ordering Provider First Name	ST	R			DoctorFirst
21	Ordering Facility Name	XON	R			Hospital Name^^^^^^^^^R777
21.1	Ordering Facility Name	XON	R			Hospital Name
21.10	Ordering Facility code	ST	R		GDSP provided Hospital Code	R777
24	Ordering Provider Address	XAD	R			1111 First St.^^Richmond^CA^9000
24.1	Street Address	SAD	R			1111 First St.
24.3	City	ST	R			Richmond
24.4	State or Province	ST	R			CA
24.5	Zip or Postal Code	ST	R			9000

3.6 OBR: OBSERVATION REQUEST SEGMENT

The observation request (OBR) segment identifies the type of testing to be performed on the specimen. For the newborn screening panel test order, the value required in OBR-4 (Universal Service Identifier) is 54089-8^Newborn screening panel AHIC^LN.

Example OBR Segment(s):
OBR|1|200373582^EPC |10003866^HOSP LAB |54089-8^NEWBORN SCREEN^NBSEAP|||20220207150719||| RL6240^LuceyLast^RichelFirst

Table 3.6.1: Order Request Segment (OBR)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID - OBR	SI	R			1
2	Placer Order Number	EI	R		The GDSP Laboratory will return this value in the result message.	200373582^EPC
3	Filler Order Number	EI	O		Filler Order Number is typically the LAB Accession No.	10003866^HOSP LAB
4	Universal Service Identifier	CE	R			54089-8^NEWBORN SCREEN^NBSEAP
4.1	Identifier		R		LOINC Code	54089-8
4.2	Text		R		Desc	NEWBORN SCREEN
4.3	Name of coding system		R			NBSEAP
7	Observation Date/Time	TS	R		Specimen collected Date and Time in yyyymmddHHMMSS format	20230101123045
10	Collector Identifier	XCN	O		This field will identify the person, department, or facility that collected the specimen. If received in the order message, the GDSP Laboratory will return this value in the result message	RL6240^LuceyLast^RichelFirst

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
10.1	Collector Identifier Number	ST	O		Id of the person collecting the specimen	RL6240
10.2	Collector Family Name	ST	O		Family Name of the person collecting the specimen	LuceyLast
10.3	Collector Given Name	ST	O		Given Name of the person collecting the specimen	RichelFirst

3.7 OBX: OBSERVATION RESULT SEGMENT

The observation/result (OBX) segment contains information regarding a single observation result. This includes identification of the specific type of observation, the result for the observation, and when the observation was made. The basic format is a question (OBX-3) and an answer (OBX-5).

3.7.1. FORM NUMBER (TRF) OBX Segment

Example: OBX|1|NM|57716-3^State printed on filter paper card [Identifier] in NBS card^LN||3500009433

Table 3.7.1: Form Number Observation Result Segment (OBX 3.1= 57716-3)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			1
2	Value Type	ID	R		Numeric	NM
3	Observation Identifier	CE	R			57716-3^State printed on filter paper card [Identifier] in NBS card^LN
3.1	Identifier	ST	R		LOINC Code	57716-3
3.2	Text	ST	R		Observation Description	State printed on filter paper card [Identifier] in NBS card

3.3	Name of Coding System	ID	R		This is the coding system	LN
5	Observation Value	Varies	R		TRF Form No. that can be scanned from the paper	3500009433

3.7.2. REASON FOR TEST & REASON FOR SPECIMEN NOT COLLECTED OBX Segment

Example: OBX|2|ST|57721-3^Reason for lab test in Dried blood spot^LN||LA12421-6^Initial Screen^LN

Table 3.7.2: Reason For Test Observation Result Segment (OBX 3.1= 57721-3)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			2
2	Value Type	ID	R			ST
3	Observation Identifier	CE	R			57721-3^Reason for lab test in Dried blood spot^LN
3.1	Identifier	ST	R		LOINC Code	57721-3
3.2	Text	ST	R		Observation Description	Reason for lab test in Dried blood spot
3.3	Name of Coding System	ID	R		This is the coding system	LN
5	Observation Value	Varies	R	See Appendix Table (A.5a) & (A.5b) for acceptable values in this field		LA12421-6^Initial Screen^LN
5.1	Observation Identifier	ST	R			LA12421-6
5.2	Observation Value	ST	R			Initial Screen

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
5.3	Name of Coding System	ST	R			LN

3.7.3. FEEDING TYPE OBX Segment:

Example: OBX|3|ST|67704-7^Feeding Types^LN||LA16914-6^Breast milk^LN

Table 3.7.3: Feeding Type Observation Result Segment (OBX 3.1= 67704-7)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			3
2	Value Type	ID	R			ST
3	Observation Identifier	CE	R			67704-7^Feeding Types^LN
3.1	Identifier	ST	R		LOINC Code	67704-7
3.2	Text	ST	R		Observation Description	Feeding Types
3.3	Name of Coding System	ID	R		This is the coding system	LN
5	Observation Value	Varies	R	See Appendix Table (A.6) for acceptable values in this field		LA16914-6^Breast milk^LN
5.1	Observation Identifier	ST	R			LA16914-6
5.2	Observation Value	ST	R			Breast milk
5.3	Name of Coding System	ST	R			LN

3.7.4. COLLECTION METHOD OBX Segment:

Example: OBX|4|ST|79566-6^Collection method - DBS^LN||LA25402-1^Heel Stick^LN

Table 3.7.4: Collection Method Observation Result Segment (OBX 3.1= 79566-6)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			4
2	Value Type	ID	R			ST
3	Observation Identifier	CE	R			79566-6^Collection method - DBS^LN
3.1	Identifier	ST	R			79566-6
3.2	Text	ST	R			Collection method - DBS
3.3	Name of Coding System	ID	R			LN
5	Observation Value	Varies	R	See Appendix Table (A.7) for acceptable values in this field		LA25402-1^ Heel Stick^LN
5.1	Observation Identifier	ST	R			LA25402-1
5.2	Observation Value	ST	R			Heel Stick
5.3	Name of Coding System	ST	R			LN

3.7.5 INFANT FACTORS AFFECTING NEWBORN SCREENING OBX Segment:

Example: OBX|5|ST| 57713-0^Infant factors that affect newborn screening interpretation^LN||LA137-^None^LN\n

Table 3.7.5: NICU Observation Result Segment (OBX 3.1= 57713-0)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			5
2	Value Type	ID	R			ST

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
3	Observation Identifier	CE	R			57713-0^Infant factors that affect newborn screening interpretation^LN
3.1	Identifier	ST	R			57713-0
3.2	Text	ST	R			Infant factors that affect newborn screening interpretation
3.3	Name of Coding System	ID	R			LN
5	Observation Value	Varies	R	See Appendix Table (A.8) for acceptable values in this field		LA137-2^None^LN
5.1	Observation Identifier	ST	R			LA137-2
5.2	Observation Value	ST	R			None
5.3	Name of Coding System	ST	R			LN

3.7.6 PLACE OF BIRTH OBX Segment:

Example: OBX|6|ST|73766-8^Place where birth occurred^LN||LA6218-7^Hospital^LN

Table 3.7.6: Place of Birth Observation Result Segment (OBX 3.1= 73766-8)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			5
2	Value Type	ID	R			ST
3	Observation Identifier	CE	R			73766-8^Place where birth occurred

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
3.1	Identifier	ST	R			73766-8
3.2	Text	ST	R			Place where birth occurred
3.3	Name of Coding System	ID	R			LN
5	Observation Value	Varies	R	See Appendix Table (A.9) for acceptable values in this field		LA6218- 7^Hospital^LN
5.1	Observation Identifier	ST	R			LA6218- 7
5.2	Observation Value	ST	R			Hospital
5.3	Name of Coding System	ST	R			LN

3.7.7 GESTATIONAL AGE OBX Segment:

Example: OBX|7|NM|57714-8^Obstetric estimation of gestational age^LN||39|wk^weeks

Table 3.7.7: Gestational Age Observation Result Segment (OBX 3.1= 57714-8)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			7
2	Value Type	NM	R			NM
3	Observation Identifier	CE	R			57714-8^Obstetric estimation of gestational age^LN
3.1	Identifier	ST	R			57714-8
3.2	Text	ST	R			Obstetric estimation of gestational age
3.3	Name of Coding System	ID	R			LN

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
5	Observation Value	Varies	R			39
6.1	Units	ST	R			weeks

3.7.8 BIRTH WEIGHT OBX Segment:

Example: OBX|8|NM|8339-4^Birthweight^LN||4256|g^gram

Table 3.7.8: BirthWeight Observation Result Segment (OBX 3.1= 8339-4)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			8
2	Value Type	NM	R			NM
3	Observation Identifier	CWE	R			8339-4^Birthweight^LN
3.1	Identifier	ST	R			8339-4
3.2	Text	ST	R			Birthweight
3.3	Name of Coding System	ID	R			LN
5	Observation Value	Varies	R			4256
6.1	Units	ST	R			gram

3.7.9 NEWBORN PHYSICIAN ADDRESS OBX Segment:

Example: OBX|9|ST|62327-2^Post-discharge provider practice address^LN||5901 Lakeside Avenue^^Richmond^CA^94804

Table 3.7.9: Pediatrician Address Observation Result Segment (OBX 3.1= 62327-2)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			9
2	Value Type	ST	R			ST

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
3	Observation Identifier	CWE	R			62327-2^Post-discharge provider practice address^LN
3.1	Identifier	ST	R			62327-2
3.2	Text	ST	R			Post-discharge provider practice address
3.3	Name of Coding System	ID	R			LN
5	Observation Value	Varies	R		Newborn Physician Address	
5.1	Street Address					5901 Lakeside Avenue
5.2	City					Richmond
5.3	State					CA
5.4	Zip					94804

3.7.10 NEWBORN PHYSICIAN PHONE NUMBER OBX Segment:

Example: OBX|10|ST|62328-0^Newborn Physician Phone Number^LN||8316498788

Table 3.7.10: Pediatrician Phone number Observation Result Segment (OBX 3.1= 62328-0)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			9
2	Value Type	ST	R			ST
3	Observation Identifier	CWE	R			62328-0^Newborn Physician Phone Number^LN
3.1	Identifier	ST	R			62328-0
3.2	Text	ST	R			Newborn Physician Phone Number
3.3	Name of Coding System	ID	R			LN

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
5	Observation Value	Varies	R		Newborn Physician number	8316498788

3.7.11 RBC TRANSFUSION OBX Segment:

This is an optional segment, only to be sent when there is a RBC transfusion.

Example: OBX|11|ST|79569-0^RBC transfusion^LN||LA25396-5^RBC

Table 3.7.11: RBC Transfusion Observation Result Segment (OBX 3.1= 79569-0)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			9
2	Value Type	ST	R			ST
3	Observation Identifier	CWE	R			79569-0^RBC transfusion^LN
3.1	Identifier	ST	R			79569-0
3.2	Text	ST	R			RBC transfusion
3.3	Name of Coding System	ID	R			LN
5	Observation Value	Varies	R			LA25396-5^RBC
5.1	Observation Identifier	ST	R		LOINC Code	LA25396-5
5.2	Observation Value	ST	R			RBC

3.7.12 RBC TRANSFUSION DATE OBX Segment:

This is an optional segment, only to be sent when there is a RBC transfusion. This segment sends the RBC transfusion date.

Example: OBX|12|ST|62317-3^RBC transfusion Date^LN||20230314063821

Table 3.7.12: RBC Transfusion Date Observation Result Segment (OBX 3.1= 62317-3)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Set ID – OBX	SI	R			9
2	Value Type	ST	R			ST
3	Observation Identifier	CWE	R			62317-3^RBC transfusion Date^LN
3.1	Identifier	ST	R			62317-3
3.2	Text	ST	R			RBC transfusion Date
3.3	Name of Coding System	ID	R			LN
5	Observation Value	Varies	R		yyyymmddHHMMSS	20230314063821

3.7.13 BABY WARD OF COURT OBX Segment:

This is an optional segment. Only send it if the baby is a ward of court.

Example: OBX|13|ST|GDSPWOC^BABY WARD OF COURT^GDSP

Table 3.7.13: Ward of Court Observation Result Segment (OBX 3.1= GDSPWOC)

SEQ	Data Element	Data Type	GDSP	Value Set	Comments	Example
			Usage			
1	Set ID – OBX	SI	R			6
2	Value Type	ID	R			ST
3	Observation Identifier	CE	R			GDSPWOC^BABY WARD OF COURT^GDSP

SECTION 4: ACK: ACKNOWLEDGEMENT SEGMENT

This section will contain specifications for each segment used in the ACK^021 message. It will indicate which fields are supported or required and describe any constraints on these fields.

Table 4.1: ACK^O21 Message Segments

Segment	Definition	GDSP Usage	Note
MSH (Message Segment Header)	The MSH segment defines the intent, source, destination, and some specifics of the syntax of a message.	R	This begins every message and includes information about the type of message, how to process it, and by whom it was created.
MSA **(Message Acknowledgement Segment)**	The MSA segment is included in the acknowledgement (ACK) message.	**R**	Contains information used to identify the receiver's acknowledgement response to an identified prior message.
ERR (Error Segment)	The ERR segment reports information about errors in processing the message. The segment may repeat. Each error will have its own ERR segment.	RE	Used to return information about errors.

4.1.1. ACK : ACKNOWLEDEGEMENT (ACK) MESSAGES AND ERROR SEGMENTS

The GDSP will provide each order transaction with a success or failure response. This messagewill include an application-level response to indicate the success (MSA-1 = AA) or failure (MSA-1 = AR) of the transaction to meet the standards for this guide or to meet application requirements as specified below. Hard errors (MSA-1 = AR) are communicated using the appropriate ERR segment elements (ERR-3 and/or ERR-5).

Table 4.1.1: Message Acknowledgement Segment (MSA)

SEQ	Data Element	Data Type	GDSP Usage	Value Set	Comments	Example
1	Acknowledgement Code	ID	R	See Appendix Table (A.10) for the codes sent		AA
2	Message Control ID	ST	R		This field echoes the Message Control ID sent in MSH-10 by the initiating system	
3	Text Message		X			
4	Expected Sequence Number		X			
5	Delayed Acknowledgement		X			
6	Error Condition		X			

i. ACCEPTED (AA ACK)

Message successfully transmitted and accepted, allowing associated demographic information to be imported.

Example ACK Message (Successful):
MSH|^~\\&|SISHIERECEIVER|SISGDSP|EPIC|R150|20230510104956634-0700||ACK|364965|T|2.5.1
MSA|AA|2442

ii. REJECTED (AR ACK)

Hard errors (MSA-1 = AR) will result in a complete rejection of the electronic order. Unless replaced with a valid order, the demographic information will not be imported into the GDSP newborn screening information system and results will not be sent electronically for the specimen.

Example ACK Message (Unsuccessful):
MSH|^~\&|1231300009|R356|EPIC|MONTAGE|202204111117065000700||ACK|4020|D|2.5.1
MSA|AR|1245
ERR|||EO13^Facility Name Missing|

The following is a list of Newborn Screening application specific hard errors that will result in the rejection of the message.

Table 4.1.1.2: Hard Errors Specific to Genetic Screening Lab

Reason for Rejections	Field name	Negative ACK Messages to EHR
OBX.5 value is missing on the OBX segment with OBX.3 = 57716-3	Form Number	Form number missing
OBX.5 value greater or lesser than 10 characters in the OBX segment with OBX.3 = 57716-3	Form Number	Invalid form number (Less than 10 digits or more than 10 digits)
If the Order with the same TRF is sent again	Form Number	Duplicate Form number
Value in PID.5.1is missing	Baby's Last Name	Last Name Missing
Value in PID.5.2 is missing	Baby's First Name	First Name Missing
Value in PID.11 is missing	Baby's Address	Address Missing
Value in PID.7 is missing	Baby's Date of Birth	DOB Missing
Value in PID.7 is missing	Baby's Birth Hour	DOB Missing
	Baby's Birth Weight	Birth Weight Missing
Value in PID.8 is missing	Baby's Sex	Sex Missing
Value in PID.2 is missing	Baby's Medical Record/EHR#	MR Number Missing
Value in ORC.2 is missing	Baby's Hospital Order #	Hospital Order Number Missing
Value in ORC.21.10 is missing	Hospital Submitter Code	Hospital Submitter code missing
Value in ORC.12.2 is missing	Inpatient/Ordering Physician Last Name	Ordering Physician Missing
Value in ORC.12.3 is missing	Ordering Physician First Name	Ordering Physician Missing
Value in OBR.7 is missing	Date Specimen Collected	Specimen Collection Information Missing
Value in OBR.7 is missing	Date Specimen Collected Time	Specimen Collection Information Missing
Value in ORC.12.1 is missing	Physicians NPI# or Medical License	Ordering Physician ID Missing

SECTION 5: SPECIMEN LABELS

To accept and import an electronic order into the newborn screening information system, the GDSP must have a means to verify that the electronic order matches the physical specimen. In addition, user errors or technical issues may disrupt the adequate transfer of electronic information from the facility to GDSP. For these reasons, GDSP requires the physical specimen demographic form to include on the approved label. Only GDSP approved labels will be accepted by the laboratory. Specimens received with inadequate information on the demographic form may be rejected even if an electronic order is also received.

To improve patient safety and submitter efficiencies, interfacing partners are highly encouraged to implement a GDSP approved label. An example of an approved label is demonstrated below.

5.1 LABEL SPECIFICATIONS

An ideal label includes the following:

- Font size should be maximized.
- Section and field order should match example above.
- Time must be displayed in military time
- The following are the required field labels:
  - TRF Number: 3367701336
  - Hospital Code: R356
  - MRN: 1000635
  - Name: Test, Baby Girl
  - DOB: 11/11/2021
  - TOB: 1700
  - Sex: F
  - Collected: 11/12/2021 1300
  - Collected by: RL6240
  - Birth Weight: 3175

Label Fields	Description
TRF #	10-digit TRF Number from the form
MR#	Hospital Medical Record Number for the baby
Name	First Name Last Name

Label Fields	Description
DOB \Time of Birth	MM/DD/YYYY HHMM
Gender	M/F/U
Birth Weight	In Grams
Collection Date/Time	MM/DD/YYYY HHMM
Collector Initials	2 or 3 letter initials
Hospital Code	Code provided by GDSP

SECTION 6: EXAMPLE MESSAGE

MSH|^~\&|EPIC|R356|SISHIERECEIVER|SISGDSP|20220207150825|RL6240|OML^O21|121121|D|2.5.1

PID|||3000657^^^EPI||SURROGATEEVENT^BABYBOY|BLUEBERRY|20220203182821|M||2054-5^Black or African American|4040 CENTRAL AVE^^PACIFIC GROVE^CA^93950||||E^ENGLISH|||||||2186-5^Not Hispanic|||A

PD1||||1234567890^PCPLASTNAME^PCPFIRSTNAME^^^^^^^^^^NPI^^

NK1|1|SURROGATEEVENT^NORMA|||8315550909^^^GBS@nomail.com||||||||||19980131|||||||||||||||123-09-8555

ORC|NW|3492201783|20035610^EPC|||||||||1518194786^RALLABANDI^SRUJANA||||||||||12345 Hwy.^^MONTEREY^CA^93333

OBR|1|3492201783^EPC|20035610^EPC||||20220207150719|||^TESTLASTNAME^TESTFIRSTNAME

OBX|1|NM|57716-3^State printed on filter paper card [Identifier] in NBS card^LN||3477701755

OBX|2|ST|57721-3^Reason for lab test in Dried blood spot^LN||LA12421-6^Initial Screen^LN

OBX|3|ST|67704-7^Feeding Types^LN||LA16917-9^NPO^LN

OBX|4|ST|79566-6^Collection method - DBS^LN||LA25402-1^Heel Stick^LN

OBX|5|ST|57713-0^Infant factors that affect newborn screening interpretation^LN||LA137-2^None^LN

OBX|6|ST|73766-8^Place where birth occurred^LN||LA6218-7^Hospital^LN

OBX|7|NM|57714-8^Obstetric estimation of gestational age^LN||39|wk^weeks

OBX|8|NM|8339-4^Birthweight^LN||5555|g^gram

OBX|9|ST|62327-2^Post-discharge provider practice address^LN||5901 Lakeside Avenue^^Richmond^CA^94804

OBX|10|ST|62328-0^Newborn Physician Phone Number^LN||8316498788

OBX|11|ST|79569-0^RBC transfusion^LN||LA25396-5^RBC

OBX|12|ST|62317-3^RBC transfusion Date^LN||20230314063821

OBX|13|ST|GDSPWOC^BABY WARD OF COURT^GDSP

APPENDIX A – CODE TABLES

The following tables define the valid values for the segments described above.

Table A.1 - Sex

Sex			
Type	**HL7 Code**	**Value**	**Description**
HL7	Sex	F	Female
		M	Male
		U	Unknown/Undifferentiated

Table A.2 - Race

Race			
Type	**HL7 Code**	**PID 10.1**	**PID 10.2**
HL7	Race	2054-5	Black or African American
		2106-3	White
		2028-9	Asian
		1002-5	American Indian or Alaska Native
		2034-7	Chinese
		2039-6	Japanese
		2040-4	Korean
		2047-9	Vietnamese
		2033-9	Cambodian
		2041-2	Laotian
		2028-9	Other S.E. Asia
		2036-2	Filipino
		2118-8	Middle Eastern or North African
		2029-7	Asian Indian
		2076-8	Native Hawaiian or Other Pacific Islander
		2087-5	Guamanian
		2080-0	Samoan
		2131-1	Other Race

Table A.3 - Primary Language

Primary Language			
Type	**HL7 Code**	**PID 15.1**	**PID 15.2**
HL7	Primary Language	eng	English
		spa	Spanish
		oth	Other

Table A.4 - Ethnicity

Ethnicity			
Type	**HL7 Code**	**PID 22.1**	**PID 22.2**
HL7	Ethnicity	2135-2	Hispanic
		2186-5	Not Hispanic

Table A.5a- Reason for test

Reason for test			
OBX 3.1	**OBX 3.2**	**OBX 5.1**	**OBX 5.2**
57721-3	Reason for test	LA12421-6	Initial screen
		LA12426-5	Repeat of inadequate or early (<12hrs initial specimen)

Table A.5b - Reason for Specimen not collected

Reason for specimen not collected			
OBX 3.1	**OBX 3.2**	**OBX 5.1**	**OBX 5.2**
57721-3	Reason for specimen not collected	LA14132-7	No sample collected due to parental refusal
		LA19826-9	Infant Deceased
		LA19822-8	Urgent Transfer

Table A.6 - Feeding Types

Feeding Types			
OBX 3.1	**OBX 3.2**	**OBX 5.1**	**OBX 5.2**
67704-7	Feeding Types	LA16914-6	Breast Milk
		LA16915-3	Lactose Formula
		LA14041-0	Lactose free formula (including soy or hydrolyzed)
		LA16917-9	NPO
		LA12418-2	TPN

Table A.7 - Collection Method

Collection method			
OBX 3.1	**OBX 3.2**	**OBX 5.1**	**OBX 5.2**
79566-6	Collection method	LA25402-1	Heel stick
		LA25404-7	Line draw

Table A.8 - Infant factors that affect newborn screening interpretation

Infant factors that affect newborn screening interpretation			
OBX 3.1	**OBX 3.2**	**OBX 5.1**	**OBX 5.2**
57713-0	Infant factors that affect newborn screening interpretation	LA12419-0	NICU
		LA137-2	None

Table A.9 – Place where birth occurred

Place where birth occurred			
OBX 3.1	**OBX 3.2**	**OBX 5.1**	**OBX 5.2**
73766-8	Place where birth occurred	LA6218-7	REG.NURSERY/FCC/RI
		LA20033-9	Home birth
		LA20034-7	Outpatient
		LA46-8	Other
		LA4489-6	Unknown

Table A.10 - Acknowledgement Code

Acknowledgement Code			
Type	**HL7 Code**	**Value**	**Description**
HL7	Acknowledgement Code	AA	Application Accept
		AR	Application Reject