



BUSINESS RULES FOR VACCINE-PREVENTABLE DISEASE (VPD) LABORATORY MESSAGES

BY REFERENCE CENTERS TO CDC

HL7 Version 2.5.1

Document Version ID: 2.2

March 15, 2016

REVISION HISTORY

Date	Version	Description
	1.0.1	Version 1 of the Business Rules released
7/11/2014	2.0.1	Draft of the Version 2 Business Rules released
6/30/2015	2.1	Version 2.1 Business Rules released
3/15/2016	2.2	Version 2.2 Business Rules released
5/24/2024	2.3	Version 2.3 Business Rules released

Table of Contents

Acknowledgement	v
Copyright notices	v
Introduction	1
Intended Audience.....	1
Scope	1
Abbreviations and Acronyms	2
VPD Testing	4
PCR testing.....	4
Serologic testing	4
The VPD Message	5
Key characteristics of the VPD message	5
One specimen per message.....	5
No ACK message from CDC	6
No preliminary results.....	6
Messages are sent for all specimens received.....	6
Identifiers in VPD messages	7
Patient identifiable information	7
Submitter's order number is required.....	7
Submitter's specimen ID in SPM-2.1 is required	Error! Bookmark not defined.
Snapshot processing for updated or corrected messages	8
Message Control ID in MSH-10.....	8
Message coding highlights	9
CWE fields must contain the standard code in the first triplet.....	9
CE fields must also contain the standard code in the first triplet.....	9
Milliseconds in MSH-7	9
Patient age must be sent if date of birth is not known	10
UCUM units of measure	10
SPM-2 must contain both the submitter's specimen ID and the Reference Center's ID for each specimen	Error! Bookmark not defined.
HL7 usage rules.....	12
VPD message differences.....	12

Value set differences.....	Error! Bookmark not defined.
Message profile ID in MSH-21	14
Specimens	15
Rejected specimens	Error! Bookmark not defined.
VPD Vocabulary	17
Code Systems	17
LOINC codes and PLT codes	17
SNOMED codes and APhL SNOMED extension codes	17
Other Code Systems	18
Epidemiologic important information (Epi questions)	18
Ordering and resulting Epi questions.....	19
Epi questions for patient age	20
VPD change control processes.....	21

ATTACHMENTS:

Message Spec Spreadsheet

Epi Questions

Value Sets

HL7 Tables

Acknowledgement

This publication was supported by Cooperative Agreement #U60HM000803 from CDC and/or Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or Assistant Secretary for Preparedness and Response or APHL.

Copyright notices

HL7®

This business rule document is based on underlying HL7 standards that have the following copyright: Copyright © 2015 Health Level Seven International® ALL RIGHTS RESERVED. HL7 International and Health Level Seven are registered trademarks of Health Level Seven International. APHL is an organizational member of HL7 and is using HL7 in this document according to the license agreement applicable to organizational members. Please see <http://www.hl7.org/legal/ippolicy.cfm?ref=common> for the full license terms governing the material.

LOINC®

The LOINC codes, LOINC table (regardless of format), LOINC Release Notes, LOINC Changes File, and LOINC Users' Guide are copyright © 1995-2015, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee. All rights reserved. LOINC® and RELMA® are registered United States trademarks of Regenstrief Institute, Inc.

SNOMED CT®

Copyright ©2002-2015, The International Health Terminology Standards Development Organisation (IHTSDO). All Rights Reserved. SNOMED CT® was originally created by The College of American Pathologists. SNOMED® and SNOMED CT® are registered trademarks of the IHTSDO.

Introduction

This document provides the information to support Vaccine Preventable Disease (VPD) laboratory messaging from Reference Centers to CDC. These messages are based on the *HL7 Version 2.5.1 Electronic Laboratory Reporting to Public Health Implementation Guide, Release 1.0* (hereafter the ELR 2.5.1 Guide), which is available for download on the HL7 website and the APHL SharePoint site:

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98

https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/IPMG/VPDpjt/VPD%20Vocabulary%20Resources/v251_IG_LB_LABRPTPH_R1_INFORM_2010FEB.zip

The ELR 2.5.1 Guide does not contain information specific enough to support VPD messaging. This VPD Business Rules document contains that VPD-specific information and provides further constraints on the ELR 2.5.1 message profile. This Business Rules document supplements but does not replace the ELR 2.5.1 Guide. VPD message implementers at the Reference Center should have access to the ELR 2.5.1 Guide.

Intended Audience

This Business Rules document has two intended audiences. First, project managers must understand the specifics of the message to manage the project. Second, technical groups must implement these guidelines to create messages according to the specification. The goal for this document and its associated spreadsheets is to provide information about the VPD message that is usable by both audiences.

Scope

Version 2.3 of the VPD Business Rules supports messages for the following diseases: Measles, Mumps, Rubella, Varicella zoster, Pertussis, Haemophilus influenzae, and Streptococcus pneumoniae.

Abbreviations and Acronyms

Abbreviations and Acronyms	
Term	Meaning
APHL	Association of Public Health Laboratories.
APHL SNOMED CT extension code	APHL authors code in the SNOMED CT APHL namespace for laboratory test results that do not exist yet in the International Edition or the US Edition of SNOMED CT. APHL SNOMED extension codes are used in the OBX-5 field of VPD messages. If these test results are subsequently incorporated into SNOMED, then the APHL SNOMED extension code is retired and replaced by a SNOMED code (in the International Edition or the US Edition) in the VPD vocabulary.
Assay	An assay is a laboratory test.
CCB	Change Control Board. All changes in VPD processes and vocabulary are managed by the VPD CCB.
CDC	Centers for Disease Control and Prevention. Most references to CDC in this document are to the VPD subject matter experts who are working on this project.
ELR 2.5.1	Electronic Laboratory Reporting to Public Health, as described in the ELR 2.5.1 Guide
ELR 2.5.1 Guide	The HL7 Version 2.5.1 Electronic Laboratory Reporting to Public Health Implementation Guide, Release 1
Epi questions	These are coded questions from CDC's case notification forms. The VPD message allows for about a dozen Epi questions. Example: "MUM122^Did the patient receive a mumps-containing vaccine?"
HL7	(1) Health Level Seven International (the standards development organization based in Ann Arbor, MI), (2) the HL7 family of informatics standards (e.g., the HL7 2.5.1 messaging standard). www.hl7.org .
IHTSDO	The International Health Terminology Standards Development Organisation (IHTSDO) is the standards development organization (SDO) that develops and distributes SNOMED CT. www.ihtsdo.org/snomed-ct/
LIMS	Laboratory Information Management System. The laboratory computer system, also known as Laboratory Information System (LIS).
LOINC	Logical Observation Identifiers Names and Codes. This coding standard for observations used in HL7 messages includes codes for laboratory tests, clinical measurements, and other observations. LOINC is developed by the Regenstrief Institute at the University of Indiana. www.loinc.org
NAAT	Nucleic Acid Amplification Test. NAAT copies a fragment of DNA or RNA in a specimen and, over a number of cycles, creates exponentially more copies of the fragment. When enough copies have been created, the test can determine if the fragment comes from a particular bacteria or virus. PCR tests are NAATs.
NCIRD	National Center for Immunization and Respiratory Diseases at the CDC. The VPD programs are part of NCIRD.
PCR	Polymerase chain reaction. There are many different PCR methods, including real time PCR and conventional PCR. Most of the laboratory tests in this VPD project are PCRs (see NAAT above).
PLT code	APHL maintains the Public health Lab Test (PLT) code system for lab tests that do not exist yet in LOINC. PLT codes are used in the OBR-4 and OBX-3 fields of VPD messages. Many of these test results are subsequently incorporated into LOINC. When that happens the PLT code is retired and replaced by a LOINC code in the VPD vocabulary.

Abbreviations and Acronyms	
Term	Meaning
Regenstrief Institute	The Regenstrief Institute at the University of Indiana is the SDO that develops and maintains LOINC.
SDO	Standards Development Organization. Examples include HL7, IHTSDO, and the Regenstrief Institute.
SNOMED	See SNOMED CT.
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms is a comprehensive clinical healthcare terminology. It is the most recent version of SNOMED, which has been in use since 1977. SNOMED CT was originally developed by the College of American Pathologists (CAP) and is now developed by IHTSDO. www.ihtsdo.org/snomed-ct/
SPHL	State Public Health Laboratory.
VPD	(1) Vaccine preventable disease. (2) Also refers to the VPD programs at CDC. (3) Also refers to this VPD HL7 2.5.1 messaging project.
VPD Business Rules	Vaccine Preventable Disease Business Rules for ELR 2.5.1 Messaging, Version 2.0 (this document). "VPD Business Rules" also refers to the VPD Message Specification spreadsheet that accompanies this document.
VZV	Varicella zoster virus, the virus that causes chickenpox and shingles. This virus is also known as Human herpesvirus 3 and Herpes zoster virus.

VPD Testing

PCR testing

Most of the VPD tests that the Reference Centers perform are PCRs, and all of those PCR tests are CDC-developed assays. Some laboratories do an initial non-CDC PCR to determine if a VPD agent, such as Varicella zoster virus (VZV), is present. If this initial assay detects VZV, then the laboratory follows the described CDC protocol for further testing.

Proficiency testing for VPD is currently done only by the Wisconsin Reference Center, although other labs can enroll in the proficiency testing program. In the past CDC provided the strains for the proficiency test panels although Wisconsin will now be providing its own strains.

Ct values in VPD messages

- Crossing threshold (Ct) values are required for real-time PCR bacterial test results.
- Ct values are optional for real-time viral PCRs, and VPD Reference Centers are encouraged to send them if they can.
- Targets are tested twice and both Ct values should be included in the VPD message rather than averaging them.
- Each Ct value should be reported in an OBX segment.
- In addition to the Ct values, an OBX segment with the Ct value interpretation should be sent.
- The Ct values and Ct value interpretation for one bacterial target are shown below.
 - OBX|2|SN|PLT326^Bordetella sp DNA IS481 marker XXX RT-PCR [Ct]^PLT|1|^26.22|{Ct}^CrossingThreshold^UCUM|...
 - OBX|3|SN|PLT326^Bordetella sp DNA IS481 marker XXX RT-PCR [Ct]^PLT|2|^26.37|{Ct}^CrossingThreshold^UCUM|...
 - OBX|4|CWE|PLT354^Bordetella sp DNA IS481 marker XXX RT-PCR [Ct values interpretation]^PLT|3|260373001^Detected^SCT|...

Serologic testing

Two commercial measles serology kits were approved for use in VPD testing -- the MicroImmune Measles IgM capture EIA (distributed by BluePoint Bioscience) and the Trinity Biotech Captia Measles IgM ELISA. BluePoint Bioscience has discontinued marketing the MicroImmune kit in the United States due to insufficient sales. The Trinity assay does not perform as well as the Microimmune assay. For the time being Reference Centers will not be performing VPD serologic testing.

Some Reference Centers have developed their own serologic tests for use in their in-house testing for VPDs. Currently these tests and results are not reported through this VPD project, except for the New York City lab. New York City does mostly serologic testing for VPDs and it is sending VPD messages with serologic results.

The VPD Message

The VPD message is an HL7 ORU^R01 message, which is an unsolicited message containing the results of one or more observations. "Unsolicited" means that the message is not being sent as a response to a query or some other request for information. "Observation" means any clinical test, measurement, or question that can have a result or value. Most of the observations in VPD messages are laboratory tests, although there are also some epidemiologically important information items (Epi questions), such as "MUM122^Did the patient receive a mumps-containing vaccine?".

Not all elements of the CDC testing protocol are reported by the VPD message at this time, and some elements may require alternate means of transmission. For example, completed run sheets and electrophoretic gel images depicting results still need to be submitted as PDF documents on the Reference Centers sFTP site, as defined in the SOP for RT-PCR assays for genotyping Mumps virus.

Key characteristics of the VPD message

The VPD message profile was created by modifying the existing ELR 2.5.1 message profile. A valid VPD message is a valid ELR 2.5.1 message. The VPD message profile has some additional constraints that make it more specific and more useful for VPD. This document describes the differences between the VPD message and the ELR 2.5.1 message. It also highlights some VPD message details that are important for implementers in the Reference Centers and others who work with VPD messages. Some of these key features are listed below.

VPD messages are sent for the following types of submitters

- Results for a specimen received from a submitter that has an OID assigned on the APHL look up table (by CLIA and NPI numbers), regardless of relationship to reference center's jurisdiction.
- Results for specimen received from a submitter that does NOT have an OID assigned on the APHL look up table (by CLIA and NPI numbers) and is part of the reference center's jurisdiction - in this case the reference center can replace the OBR-2 and SPM-2 with their respective numbers, as assigning authority information is not available, but the results are valid for the internal data submission use case.
- Results for specimen received from a submitter that does NOT have an OID assigned on the APHL look up table (by CLIA and NPI numbers) and is outside of the reference center's jurisdiction. These require follow up with APHL / CDC prior to including in VPD messaging.

One specimen per message

- An ELR 2.5.1 message can contain results for one patient or for many patients, but this is not true for VPD messages.
- Each VPD message must contain results for only one specimen from one patient.

No ACK message from CDC

- The VPD message is unidirectional. CDC will not send an acknowledgement (ACK) message.
- Email message reports are sent to Reference Centers in place of an ACK.

No preliminary results

- Only final and corrected results should be sent to CDC in VPD messages. CDC will reject preliminary results.
- In most cases a message will be sent when the entire order has been fulfilled.
- Sometimes, to avoid a delay in sending a positive result, the Reference Center will send a message with the final result that a VPD pathogen has been found. Then after more time intensive testing (e.g. genotyping or serotyping) has been completed, the laboratory will send a second message that includes the initial results plus the genotyping or serotyping results.
- When a corrected message is sent, it must be resent in its entirety, including all results previously transmitted for that patient order.

Messages are sent for all specimens received

- Messages will be generated for all specimens submitted to the Reference Center.
- Even if a specimen is rejected because it is inadequate or unsatisfactory in some way and testing is not done on the specimen, a VPD message should be sent for that specimen. The process for sending such a message is explained in the Specimens section of this document.

VPD message structure

The VPD HL7 message is a modified version of the ELR 2.5.1 message. Many of the message segments are allowed by the ELR 2.5.1 specification are not being used by VPD Reference Centers and they are not expected in VPD messages. The table below shows all of the message segments that have been used in VPD messages.

VPD message segments				
Segment	Segment name	Required	Cardinality	Comment
MSH	Message Header	yes	[1,1]	
SFT	Software Segment	yes	[1,1]	
PID	Patient identification	yes	[1,1]	
NTE	Notes and Comments	no	[0,*]	Notes and Comments for PID

VPD message segments				
ORC	Common Order	no	[0,1]	ORC is not required for VPD but should be include it if possible
OBR	Observation Request	yes	[1,1]	
NTE	Notes and Comments	no	[0,*]	Notes and Comments for OBR
OBX	Observation/Result	yes	[1,1]	
NTE	Notes and Comments	no	[0,*]	Notes and Comments for OBX
SPM	Specimen	yes	[1,1]	One SPM segment per message is sufficient. You can also send one SPM segment per OBR if your system is set up to do that.
OBX	Observation/Result	no	[0,*]	Observation related to the specimen

Notes regarding VPD message segments:

The ORC is not required but all VPD Reference Centers are including it in VPD messages. You should send an ORC segment if you have the information for it.

OBX related the specimen can be used to report the patient's age if PID-7 DOB is not known. However, an Epi question OBX segment is usually used for this purpose. See the section on Epi questions for more information.

Identifiers in VPD messages

Patient identifiable information

- Limited patient identifiable information will be sent in the message to CDC, including the patient's date of birth or age.
- The Reference Center should have a unique patient identifier, or can use a combination of identifiers to produce a unique patient identifier. This ID should remain traceable in the system across time.

Submitter's order number is required

- The OBR-2 field is for the "Placer Order Number" (the submitter's order number information).
- This is a required field of the VPD message. You must put the submitter's order number in the OBR-2 field.
- The Placer Order Number should uniquely identify the order, should not be associated with a group of orders, and should not be reused.
- OBR-2 is the same field as ORC-2. These two fields must contain the same information.

SPM-2 must contain both the submitter's specimen ID and the Reference Center's ID for each specimen

- SPM-2.1 (Placer Assigned Identifier) must contain the submitter's specimen ID and identify the submitter as the assigning authority.
 - SPM-2.1 is an optional field in ELR 2.5.1 messages. However, it is a required field for VPD messages.
 - If the submitter has not assigned an ID to a specimen, the Reference Center must create one and use that in SPM-2.1 – it may be the same as the filler specimen ID.
- The Reference Center must also create its own ID for each specimen and put it in SPM-2.2 (Filler Assigned Identifier), using its own OID to identify the assigning authority.

Snapshot processing for updated or corrected messages

- VPD messaging uses "snapshot" processing for updated or corrected messages. Ideally, this means updated and corrected messages contain all previously reported orders and test results for a specimen, in addition to the updated or corrected results for that specimen. The Reference Center should not send a message with only the OBX segments for the updated or corrected results.
- When CDC receives an updated or corrected message, it should contain current and complete results for that specimen.
- The updated or corrected message should be able to replace the entire data content of the original message.
- In order for snapshot processing to work correctly, key identifiers in the updated message must be the same as those in the original message, including:
 - PID-3 (Patient ID)
 - SPM-2.1 (Submitter specimen ID)
 - SPM-2.2 (Reference Center specimen ID)
- Note that the OBR-22 field (Results Report/Status Change - Date/Time) will be different in the updated message.

Message Control ID in MSH-10

- The Message Control ID is an identifier that allows the sender to uniquely identify its messages.
- When CDC sends message feedback to APHL or the Reference Center, it always refers to the message by the Message Control ID. Unfortunately, this number is rarely useful because few laboratories use it to track their messages; they tend to use the Accession number and/or the Specimen ID instead.
- To make the MSH-10 field more useful in VPD messages the APHL team recommends creating a concatenated Message Control ID out of three identifiers, separated by underscores:
 - Internal control number, such as a monotonically increasing number. Example: **100334275**
 - Accession Number from the LIMS for the order. Example: **Z10010357**
 - Filler Specimen ID (Reference Center's ID for the specimen). Example: **14VR000458**
 - The concatenated Message Control ID will be: **100334275_Z10010357_14VR000458**

- *Note: This concatenated format for the Message Control ID is not required, but it makes it much easier for the Reference Center and the APHL team to process message feedback from CDC.*

Message coding highlights

CWE fields must contain the standard code in the first triplet.

- ELR 2.5.1 messages use HL7's CWE data type for coded data like laboratory tests and test results. The CWE data type contains two triplets of data for (1) a code, (2) text, and (3) the coding system. One of these triplets is for a standard code, like LOINC, and the other triplet is for the laboratory's own local code, text, and code system. An example is shown below with the first triplet in bold.
 OBX|1|CWE|**54091-4**^RUBV RNA XXX QI PCR^LN^2204^Rubella PCR^L|
 In this example, the first triplet contains the standard (LOINC coded) laboratory test and the second triplet contains the laboratory's local code (the LN in the first triplet means LOINC and the L in the second triplet means Local.)
- Note that while the ELR 2.5.1 Guide does not require that the first triplet contain the standard code, as shown here, the VPD message profile does.
- VPD messages must have the standard code in the first triplet of CWE fields.

CE fields must also contain the standard code in the first triplet

- CE is an old HL7 data type that has mostly been replaced by the CWE data type. There are still a few instances of the CE data type in the ELR 2.5.1 message.
- The standard code must be placed in the first triplet of CE fields.

Milliseconds in MSH-7

- The MSH-7 field is for the date and time the message is created. For ELR 2.5.1 messages, the time must have a minimum granularity of seconds. For example, March 5, 2014 at 5:16 pm +37 seconds in Saint Paul, MN would be represented as follows.
 201403051716**37**-0600
- VPD messages must have a granularity of milliseconds for the time in MSH-7.
- Milliseconds in VPD messages can be expressed with either three or four digits, as shown in the examples below. These examples are for a VPD message created on March 5, 2014 at 5:16 pm +37 seconds +**249** milliseconds in Saint Paul, MN.
 20140305171637.**249**-0600 (three-digit milliseconds)
 20140305171637.**2490**-0600 (four-digit milliseconds)

Patient age must be sent if date of birth is not known

- PID-7 is for the patient's date of birth. If the patient's DOB is not known, leave PID-7 empty and add an OBX segment with the patient's age. There are two ways to do this.
 - As an Observation related to Specimen: Patient age can be sent in an OBX segment of the SPM section of the message, as described in the ELR 2.5.1 Guide.
 - As the answer to an Epi question: Patient age can be sent in an OBR segment for epidemiologically important information:
OBR|1||68991-9^Epidemiologically important info pni^LN^12345^^L^2.46|...
OBX|1|SN|35659-2^Age at specimen collection^LN||^9|a^Years^UCUM|...
- The section of this document on Epi questions contains more information about sending patient age in VPD messages.
- **Note: If the patient's DOB and age are both unknown, leave PID-7 empty and do not send an OBX segment for patient age.**

UCUM units of measure

- UCUM units of measure are used in VPD messages.
- The UCUM unit for Year is "a". The OBX-6 field below shows UCUM coded units for a nine year old patient:
OBX|2|SN|21612-7^Age - Reported^LN||^9|a^Years^UCUM|...
- The OBX-6 field below has UCUM coded units for the Ct value 24.86 in a real-time PCR test:
OBX|2|NM|PLT308^MuV RNA XXX RT-PCR [Ct]^PLT|1|24.86|{Ct}^Cycle threshold^UCUM|...
- The APHL team will provide the correct UCUM units in VPD vocabulary tables.

OBX-8, Abnormal Flags, and Test Interpretation Codes

- The ELR 2.5.1 specification has pre-adopted the HL7 2.7 version of OBX-8.
- The meaning of OBX-8 is now "Test Interpretation Code" rather than "Abnormal Flags" and the 2.7 version of HL7 table 0078 is used for OBX-8 rather than the 2.5.1 table.
- According to the ELR 2.5.1 specification OBX-8 should be valued unless OBX-11 (Observation Result Status) is valued 'X'.
- For VPD messages the following guidelines apply:
 - OBX segments for Epi questions should not have a value in OBX-8.
 - Most VPD Reference Centers are not putting a value in OBX-8. Others are putting a value in it occasionally.
 - CDC is not failing messages or flagging them with warnings if OBX-8 is empty.
 - Reference Centers are encouraged to put a value in OBX-8 where appropriate.

Ordering Provider (OBR-16 and ORC-12)

- OBR-16.1 and ORC-12.1 are for the Ordering Provider ID. This is the CLIA number or NPI ID.

- For internal testing, you might not know the submitter's CLIA or NPI.
 - Do not leave this field empty when the submitter's CLIA or NPI is not known.
 - Use the Reference Center's CLIA or NPI instead of the submitter's.
- OBR-16 and ORC-12 are for Ordering Provider information. These two fields must contain the same information.
- OBR-16.2 and ORC-12.2 are for the ordering provider's family name (surname). However, for VPD messages the individual provider's name is usually unknown. The submitting organization is used instead.
 - If the submitter is an organization, use OBR-16.2 and ORC-12.2 for the organization's name.
 - Do not leave OBR-16.2 empty if the actual provider who ordered the test is unknown.

Ordering Facility Address (ORC-22) and Ordering Provider Address (ORC-24)

- ORC-22 is for the Ordering Facility Address. This is a required field for VPD messages.
- ORC-24 is for the Ordering Provider Address, which is not available for VPD messages. There are two options for ORC-24:
 - You can put the Ordering Facility Address information in ORC-24, as well as in ORC-22.
 - You can leave ORC-24 empty.

Reason for Study (OBR-31) and Specimen Role (SPM-11)

- These two fields are only used by VPD Reference Centers that do proficiency testing for CDC. Other Reference Centers can leave these two fields empty.
- For a Reference Center that does proficiency testing, there are two possible values for OBX-31:
 - PHC1122^Routine testing^CDCPHINVS
 - PHC1127^Proficiency testing^CDCPHINVS
- If OBR-31.1 is valued PHC1127:
 - SPM-11 must be valued "F^Specimen used for testing proficiency of the organization performing the testing (Filler)^HL70369"
- If OBR-31.1 is valued PHC1122:
 - SPM-11 may be left empty, or
 - SPM-11 may be valued "P^Patient (default if blank component value)^HL70369"

HL7 usage rules

An HL7 message profile defines the usage or "optionality" of each element (field, field component, or subcomponent) in the message. The usage of a message element can be one of the following:

- Required
- Required but may be empty
- Conditional
- Optional
- Not supported

The table below describes the HL7 usage rules for the VPD message.

HL7 Usage Rules			
Usage	Description	Meaning	Comment
R	Required	The application must populate "R" elements with a non-empty value.	
RE	Required but may be empty	The application must populate "RE" elements with a non-empty value if there is relevant data.	
C(a/b)	Conditional	An element with a conditional usage code has an associated "condition predicate" that determines if the submitter needs to value the element.	Example: OBR 4.2 (Ordered test name) has a usage of C(R/X). In this case the condition predicate C(R/X) is: IF OBR 4.1 is valued THEN OBR 4.2 is R, ELSE OBR 4.2 is X.
O	Optional	The usage for this element has not been defined.	Optional elements are avoided in the VPD message profile.
X	Not supported	The application shall not populate "X" elements.	

VPD message differences

The VPD message contains several HL7 fields whose usage and other specifications have been changed from the ELR 2.5.1 message profile. In most cases, the optionality of the data element has been changed to R (Required) in the VPD message. The table below shows the details of these **changes**, which are **highlighted in bold font**.

Differences between the VPD message and the ELR 2.5.1 message							
HL7 Field	ELR 2.5.1	VPD	ELR 2.5.1 Usage	VPD Usage	Field Name	Implementation Definition	Comment
MSH-2	Length 4..5	Length 5..5	R	R	Encoding Characters	The HL7 encoding characters: ^~\&# (the # is the truncation character).	
MSH-7	granularity = seconds	granularity = milliseconds	R	R	Date/Time Of Message	For VPD, this field should be precise to the millisecond with either 3 or 4 digits of precision.	Format: YYYYMMDDHHMMSS. SSS[S]-ZZZZ
MSH-21	Cardinality [1..*]	Cardinality [2..2]	R	R	Message Profile Identifier	For VPD messages there are two profile IDs.	See "Message profile ID" in MSH-21" below
MSH-21.2			RE	R	Namespace ID	Namespace ID of the message profile.	See "Message profile ID in MSH-21" below
OBR-2	Cardinality [0..1]	Cardinality [1..1]	RE	R	Placer Order Number	The submitter's order number, namespace ID, and OID.	
OBR-16	Cardinality [0..*]	Cardinality [1..1]	RE	R	Ordering Provider	Information about the ordering provider (i.e., the submitter).	OBR-16 has components for information about the ordering provider's name, ID, and facility.
OBR-31			RE	Varies	Reason for study	Indicates if a test is for Proficiency testing or Routine testing	This is only for a state lab doing proficiency testing
OBX-5			C(RE/X)	C(R/X)	Observation value	The test result or answer to an Epi Question	If OBX.11 = X then OBX.5 must be empty
SPM-2.1			O	R	Placer Assigned Identifier	The submitter's specimen ID information	If the submitter doesn't send a specimen ID the Reference Center must create a submitter specimen ID for SPM-2.1.
SPM-11			O	C(R/O)	Specimen role	Indicates if a specimen is for a patient or proficiency testing	This is only for a state lab doing proficiency testing
SPM-24	Cardinality [0..*]	Cardinality [1..1]	O	R	Specimen Condition	Coded information about the condition of the specimen	The VPD value set for SPM-24 includes SNOMED CT codes and codes in HL7 table 0493.

Value set differences for VPD messages

Some of the value sets specified by the ELR 2.5.1 message have been changed for VPD messaging. These are shown in the table below. All these VPD-specific value sets have been provided to the Reference Centers. They are also maintained on PHIN VADS.

VPD value set changes			
Field	Field name	ELR 2.5.1 value set	VPD value set
OBR-4	Universal Service Identifier	Laboratory Order Value Set from HITSP	VPD Lab Order Identifier
OBR-31	Reason for Study	Reason for Study value set	VPD Reason for Study
OBX-3	Observation Identifier	Laboratory Observation Identifier value set	VPD Lab Test Identifiers
OBX-5	Observation Value	Coded Laboratory Observation value set	VPD Laboratory Coded Observation
SPM-4	Specimen Type	Specimen Type value set	VPD Specimen Type
SPM-7	Specimen Collection Method	Specimen Collection Method value set	VPD Specimen Collection Method
SPM-8	Specimen Source Site	Body Site value set	VPD Specimen Source Body Site
SPM-11	Specimen Role	HL70369	VPD Specimen Role
SPM-21	Specimen Reject Reason	HL70490	VPD Specimen Reject Reason
SPM-24	Specimen Condition	HL70493	VPD Specimen Condition

Message profile ID in MSH-21

The third row in the table above (MSH-21) indicates that the Message Profile field of the VPD message is different than the MSH-21 field in the ELR 2.5.1 message. VPD messages contain two message profiles, i.e., "two repetitions" of the HL7 message profile element. The first repetition contains the ELR 2.5.1 message profile ID. The second repetition contains the VPD message profile ID. This is shown in the table below.

Message Profile Identifier (MSH-21 field)					
Message Profile	MSH-21.1 Entity Identifier	MSH-21.2 Namespace ID	MSH-21.3 Universal ID	MSH-21.4 ID Type	Concatenated Profile
ELR 251 Profile	PHLabReport-NoAck	ELR251R1_Rcvr_Prof	2.16.840.1.113883.9.11	ISO	PHLabReport-NoAck^ELR251R1_Rcvr_Prof^2.16.840.1.113883.9.11^ISO
VPD Profile	VPD_Version_1.0	VPDMsgMapID	2.16.840.1.113883.9.30	ISO	VPD_Version_1.0^VPDMsgMapID^2.16.840.1.113883.9.30^ISO
The entire MSH-21 field for the VPD message contains both profiles:		PHLabReport-NoAck^ELR251R1_Rcvr_Prof^2.16.840.1.113883.9.11^ISO~VPD_Version_1.0^VPDMsgMapID^2.16.840.1.113883.9.30^ISO			
Note the tilde character in the row above (entire MSH-21 field). This is the HL7 repetition character that separates the two message profiles.					

Rejected specimens and cancelled tests

Messages are sent for all specimens received by the Reference Center, even if the test is cancelled. A test might be cancelled because the specimen is unsuitable for testing. For example, the specimen might be incorrectly labeled, or it might be damaged, etc. In these situations the Reference Center should reject the specimen and not perform the test. Rejected VPD specimens still need to be reported to CDC. Reference Centers are reimbursed based on specimens received for testing, including rejected specimens. Tests can also be cancelled for reasons other than rejected specimens.

There are two options for indicating cancelled tests in VPD messages:

- Option 1: Put "373121007^Test not done^SCT" in OBX-5
 - OBX-11 (Observation Result Status) is valued 'F'
- Option 2: Put 'X' in OBX-11 (Observation Result Status)
 - OBX-2 (Value Type) is left empty
 - OBX-5 is left empty
 - OBX-8 (Abnormal Flags) is left empty
- For both options, if a test is cancelled because the specimen was rejected, put the specimen reject reason in SPM-21.

Examples of Option 1 and Option 2 for cancelled tests are shown below.

Option 1

Rejected specimen message	
<i>Both VZV strain type and VZV genotyping were ordered. Since VZV was not detected the genotyping test was cancelled.</i>	
MSH ...	
SFT ...	
PID ...	
ORC ...	
OBR 1 PLT368^VZV strain type DNA XXX PCR^PLT ...	VZV was not detected so VZV genotyping was cancelled
OBX 1 PLT368^VZV strain type DNA XXX PCR^PLT 260415000^Not detected^SCT ...	
OBR 2 PLT359^VZV Gentyp XXX PCR^PLT ...	The genotyping OBX-5 is "Test not done" and OBX-11 is valued 'F'
OBX 1 PLT359^VZV Gentyp XXX PCR^PLT 373121007^Test not done^SCT F ...	
SPM ...	

Option 2

Rejected specimen message	
<i>The lab rejected this nasopharyngeal swab specimen because the container broke and the specimen dried out.</i>	
MSH ...	
SFT ...	
PID ...	
ORC ...	
OBR ...	
OBX 1 XXXX PLT368^VZV strain type DNA XXX PCR^PLT XXXX X ...	OBX-11 is valued 'X'. OBX-2, OBX-5, OBX-6, and OBX-8 are empty.
SPM 1 258500001^Nasopharyngeal swab^SCT 20140512 20140512 281262008^Sample broken^SCT SDO^Sample dried out^HL70493	
	SPM-21 contains the specimen reject reason.

VPD Vocabulary

Code Systems

LOINC codes and PLT codes

LOINC is the preferred code system for VPD laboratory tests. LOINC codes are used in the OBR-4 field of the HL7 message to indicate the order and in OBX-3 field to specify the test that was done. However, some VPD tests do not have LOINC codes yet. For these tests the APHL team creates and assigns a PLT code to the test.

APHL maintains its own code system of Public health Lab Test (PLT) codes for laboratory tests that are not currently in LOINC. These PLT codes are submitted to the Regenstrief Institute for inclusion in the next release of LOINC. When a PLT code is incorporated into LOINC, the PLT code is retired and the new LOINC code replaces it in the VPD vocabulary.

The table below shows example LOINC and PLT codes used in VPD messages.

LOINC and PLT codes			
OBX_3_1	OBX_3_2_long_name	OBX_3_2_short_name	OBX_3_3
48508-6	Measles virus RNA [Presence] in Unspecified specimen by Probe and target amplification method	MeV RNA XXX QI PCR	LN
PLT359	Varicella zoster virus genotype [Identifier] in Unspecified specimen by Probe and target amplification method	VZV Gentyp XXX PCR	PLT

SNOMED codes and APHL SNOMED CT extension codes

SNOMED CT is the preferred code system for coded VPD results. This includes qualitative results like Detected and Not detected, as well as names or organisms. There are many VPD results that do not exist yet in the International Edition or the US Edition of SNOMED CT. In these cases, the APHL team creates SNOMED extension codes for use in VPD messages.

The APHL SNOMED extension codes are APHL's codes for test results that are not currently in SNOMED CT. They are available in this [viewer](#). APHL submits these SNOMED extension codes to IHTSDO for inclusion in the next release of SNOMED CT. If a duplicate term is incorporated into SNOMED, the APHL SNOMED extension code is retired from the VPD vocabulary and replaced by the new SNOMED CT code.

The table below shows example SNOMED CT and APHL SNOMED extension codes used in VPD messages.

SNOMED CT and APhL SNOMED extension codes			
OBX_5_1	OBX_5_2_long_name	OBX_5_2_short_name	OBX_5_3
260373001	Detected (qualifier value)	Detected	SCT
2251000284108	Varicella-zoster virus DNA detected, unable to type (finding)	Varicella-zoster virus DNA detected, unable to type	SCT

Other Code Systems

Several other code systems are used in VPD messages. These include PHIN Questions, RxNorm, HL7 Vocabulary Tables, and HL7 NullFlavor.

Other code systems				
Code system name	Code system code	SDO	Used for	Example
PHIN Questions	PHINQUESTION	CDC	Epidemiologic information	PRT021^What antibiotic did the patient receive?^PHINQUESTION
RxNorm	RxNorm	National Library of Medicine	RxNorm provides normalized names for clinical drugs	3640^DOXYCYCLINE^RxNorm
NullFlavor	NULLFL	HL7	HL7 v.3 codes for null responses like Unknown, Other, Not asked, etc.	UNK^Unknown^NULLFL
HL7 Vocabulary Tables	HL7xxxx (e.g., HL70493)	HL7	HL7 v.2 codes various message fields. Example: HL70493 Specimen Condition	SDO^Sample dried out^HL70493

Epidemiologic important information (Epi questions)

VPD messages can contain an OBR segment and one or more OBX segments for epidemiologically important information (Epi questions). Epi questions are used in VPD messages to convey various types of information, including:

- The patient's age (if date of birth is not specified)
- When the patient became ill.
- Whether the patient was vaccinated for a particular VPD.
- The date of the patient's last vaccination for a particular VPD.
- Whether or not the patient treated with an antibiotic.

- Which antibiotic the patient received.
- The date antibiotic treatment was started.

The following table shows all of the Epi questions available for use in VPD messages.

Epi Questions			
OBX-3.1	OBX-3.2	OBX-3.3	Condition
21612-7	Age - Reported	LN	All
29553-5	Age calculated	LN	All
35659-2	Age at specimen collection	LN	All
11368-8	Illness or injury onset date and time	LN	All
VAC103	Date of last vaccination?	PHINQUESTION	All
30952-6	Date and time of vaccination	LN	All
MEA039	Did the patient receive a measles-containing vaccine?	PHINQUESTION	Measles
MUM122	Did the patient receive a mumps-containing vaccine?	PHINQUESTION	Mumps
PLT446	Date of last vaccination for measles	PLT	Measles
PLT447	Date of last vaccination for mumps	PLT	Mumps
PLT448	Date of last vaccination for pertussis	PLT	Pertussis
PRT020	Was patient treated with an antibiotic prior to specimen collection?	PHINQUESTION	Pertussis
PRT021	What antibiotic did the patient receive?	PHINQUESTION	Pertussis
PRT023	What was the date when the first antibiotic was started?	PHINQUESTION	Pertussis
PRT044	Did the patient ever receive a pertussis-containing vaccine?	PHINQUESTION	Pertussis

Ordering and resulting Epi questions

All Epi questions are ordered with a single OBR-4 LOINC code: 68991-9 (see table below).

Order code for Epi questions			
OBR_4_1	OBR_4_2_long_name	OBR_4_2_short_name	OBR_4_3
68991-9	Epidemiologically important information for public health reporting panel	Epidemiologically important info pnl	LN

One or more Epi questions and their answers can go in OBX segments below this OBR segment. In the example message below there are four Epi questions and answers under the Epi question order in the second OBR.

Epi questions in a VPD message	
MSH	^~\&# ...
SFT	...
PID	...
ORC	...
OBR	1 ...
OBX	1 ...
OBR	2 9876543^XX.State.SPHL^2.16.840.0^ISO 14ZT00953^XX.State.SPHL^2.16.840.0^ISO 68991-9^Epidemiologically important info pni^LN ...
OBX	1 SN 35659-2^Age at specimen collection^LN 1 ^9 a^year^UCUM ...
OBX	2 TS 11368-8^Illness or injury onset date and time^LN 1 20140501 ...
OBX	3 CWE MEA039^Did the patient receive a measles-containing vaccine?^PHINQUESTION 1 Y^Yes^HL70136 ...
OBX	4 TS VAC103^Date of last vaccination?^PHINQUESTION 1 20040218 ...
SPM	1 ...

An accompanying spreadsheet contains all of the details, including codes, formatting, and units for the answers to VPD Epi questions.

Epi questions for patient age

PID-7 (Date/Time of Birth) is an RE field. It is required in VPD messages if the patient's date of birth is known. Sometimes the Reference Center does not have this information, or is not allowed to specify DOB because privacy policies. In these cases the PID-7 field of the VPD message is left empty and the Reference Center must put the patient's age in an OBX segment.

There are two options for sending patient age in an OBX segment.

- As an Observation related to Specimen: Patient age can be sent in an OBX segment of the SPM section of the message, as described in the ELR 2.5.1 Guide.
SPM|1|...
OBX|1|SN|35659-2^Age at specimen collection^LN||=^9|a^Years^UCUM|...
- As the answer to an Epi question: Patient age can be sent under an OBR segment for epidemiologically important information.

OBR|1||68991-9^Epidemiologically important info pni^LN^Age^^L^2.46|...
 OBX|1|SN|35659-2^Age at specimen collection^LN||=^9|a^Years^UCUM|...

Reference Centers can choose from three LOINC codes to use in OBX-3 code for patient age, depending on how the laboratory's LIMS is set up. The table below shows the three LOINC codes for specifying patient age.

Epi questions if date of birth is unavailable		
LOINC code	LOINC Shortname	Comment
35659-2	Age at specimen collection	This is the preferred LOINC for age observation.
21612-7	Age - Reported	This is the code for age used in PHLIP Flu messages.
29553-5	Age calculated	This LOINC code should be used if the Reference Center has the patient's DOB but cannot send it in the message because of privacy policies.

Note: The Reference Center should only send patient age if the patient's date of birth is not contained in PID-7.

VPD change control processes

VPD change control processes have been added to the PHLIP Change Control Board (CCB). All changes in VPD vocabulary, testing, and messaging are overseen by the CCB, which consists of representatives from CDC, VPD Reference Centers, and APHL.

Vocabulary and coding changes are the most common types of change in the VPD program. APHL's PLT and APHL SNOMED extension codes make it possible to code laboratory tests and test results that are not currently in LOINC or SNOMED. After creating new PLT and APHL SNOMED extension codes, APHL submits them for addition to future versions of LOINC and SNOMED. Most of the PLT codes are subsequently added to LOINC, and APHL SNOMED extension codes are added to either the International Edition or the US Edition of SNOMED CT.

When a PLT code is incorporated into LOINC, the PLT code is retired from the VPD vocabulary and replaced by the new LOINC code. Similarly, when new SNOMED codes replace some of the APHL SNOMED extension codes in the VPD vocabulary, the temporary APHL SNOMED extension codes are retired. These coding changes are subject to the approval of the CCB.

Other proposed VPD changes, like changes to the HL7 message are also be reviewed by the CCB.

Business rules for the New York City PHL

The New York City Public Health Laboratory is sending test result data to CDC in VPD messages, even though it is not one of the four VPD Reference Centers. Many of the VPD tests and processes at the NYC PHL are different than the corresponding tests and processes at VPD Reference Centers.

Overview of NYC VPD testing

- Most of the NYC PHL's tests for VPDs are serology tests.
- NYC PHL does two PCRs for VPD:
 - Measles virus PCR (Using the CDC kit)
 - Mumps virus PCR (Using the CDC kit)
- NYC PHL does not do genotyping when Measles virus or Mumps virus are detected by PCR. They send the specimen to CDC or to the NY State VPD Reference Center (Wadsworth Lab) for confirmation and genotyping.
- NYC PHL sends many of the specimens it tests to the Wadsworth Lab or to CDC for confirmatory testing.

The table below contains all of NYC PHL's non-PCR tests that will be sent in VPD messages. NYC does not report quantitative results for these tests.

NYC PHL VPD tests			
Code	Text	Code System	Comment
549-6	Bordetella pertussis [Presence] in Unspecified specimen by Organism specific culture	LN	This is NYC PHL's only test for pertussis
35275-7	Measles virus IgG Ab [Presence] in Serum by Immunoassay	LN	Qualitative result for Measles IgG (Diasorin ELISA kit)
	Measles virus IgM Ab [Presence] in Serum by Immunoassay		Qualitative result for Measles IgM (Trinity BioTech ELISA kit)
6476-6	Mumps virus IgG Ab [Presence] in Serum by Immunoassay	LN	Qualitative result for Mumps IgG (Diasorin ELISA kit)
6478-2	Mumps virus IgM Ab [Presence] in Serum by Immunoassay	LN	Qualitative result for Mumps IgM (Trinity BioTech ELISA kit)
40667-8	Rubella virus IgG Ab [Presence] in Serum or Plasma by Immunoassay	LN	Qualitative result for Rubella IgG (Diasorin ELISA kit)
24116-6	Rubella virus IgM Ab [Presence] in Serum by Immunoassay	LN	Qualitative result for Rubella IgM (Diasorin ELISA kit)

NYC PHL VPD tests			
Code	Text	Code System	Comment
15410-4	Varicella zoster virus IgG Ab [Presence] in Serum by Immunoassay	LN	Qualitative result for VZV IgG (Diasorin ELISA kit)
29662-4	Varicella zoster virus IgM Ab [Presence] in Serum by Immunoassay	LN	Qualitative result for VZV IgM (Zeus Scientific ELISA kit)

In addition to the test and process differences at NYC PHL, there is one HL7 coding change to accommodate OBX-5 results formatted as strings. The following OBX segments demonstrate these string data type results.

- OBX|1|ST|PLT337^Virus identified Referral Test Send-out XXX^PLT^PLT337| |See attached report from CDC|
- OBX|1|ST|PLT337^Virus identified Referral Test Send-out XXX^PLT^PLT337| |See attached report from NY-Wadsworth lab|
- OBX|1|ST|PLT337^Virus identified Referral Test Send-out XXX^PLT^PLT337| |See attached report from reference lab|