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digene® HC2® System Software Data Interface Guide

For use with *digene* HC2 System Software version 3.4
as part of digene HC2 System Suite 4.4

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1096261EN Rev. 01

Contents

1 Introduction

Thank you for choosing the *digene* Hybrid Capture® 2 (HC2) System Software. We are confident it will become an integral part of your laboratory.

1.1 About this manual

This guide provides information needed by laboratory Information Technology (IT) personnel to program the software interface between the laboratory information system (LIS) and the *digene* HC2 System Software so that exported data can be parsed into reportable results. Submit this guide to the appropriate IT personnel at your laboratory.

1.2 General information

1.2.1 Technical assistance

At QIAGEN we pride ourselves on the quality and availability of our technical support. If you have any questions or experience any difficulties regarding the *digene* HC2 System Software or QIAGEN products in general, do not hesitate to contact us.

QIAGEN customers are a valuable source of information regarding our products. We encourage you to contact us if you have any suggestions or feedback concerning our products.

For technical assistance and more information, contact QIAGEN Technical Services or a local distributor.

1.2.2 Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

1.2.3 Version management

This document is *digene* HC2 System Software Data Interface Guide, 1096261EN, Rev. 01. This user manual is for use with the *digene* HC2 System Software version 3.4 as part of the *digene* HC2 System Suite 4.4.

2 Understanding the *digene* HC2 System Software

The *digene* HC2 System Software may be configured for unidirectional or bidirectional communication with an LIS. When configured for unidirectional behavior, only test orders sent by the *digene* HC2 System Software are supported; when configured for bidirectional communication, all LIS messages in this document are supported and are received.

As part of bidirectional communication, the *digene* HC2 System Software queries the LIS for open test orders. The query includes test orders for assays supported by the *digene* HC2 System Software, and the LIS is expected to respond with test orders matching supported assays.

Send test order messages may also be configured to save to a fixed local directory. When configured to export to file, test orders cannot be received from the LIS. Exported files are saved as text files labeled with the plate ID in the directory **C:\Users\Public\QIAGEN\HC2 System Software\data\lis**. The exported files can be saved to a removable data storage device. The exported files are automatically deleted the next time the *digene* HC2 System Software opens.

During the configuration of the *digene* HC2 System Software, the connection to the LIS is tested. If the LIS acknowledges the message, then the connection functions correctly and the cabling and settings for communication are correct.

The export of preliminary results is configurable in the *digene* HC2 System Software. Preliminary results can be excluded so that only final results are transmitted. The setting affects the number and types of records sent in a message.

Refer to digene *HC2 System Software User Manual* for additional instructions on configuring the *digene* HC2 System Software for data export.

2.1 Understanding the assigned assay protocol codes

Assay protocol codes are assigned automatically in the *digene* HC2 System Software and cannot be reconfigured for assay protocols validated by QIAGEN. Different assay protocols are available for different regions of the world. The assigned assay protocol codes and interpreted result values for all assay protocols validated by QIAGEN are described in the following tables.

2.1.1 Assay protocol codes for the United States market

These assay protocol codes are for use with the *digene* HC2 assay protocols, version 5.4A, supplied on a CD (cat. no. 1094619).

Assay protocol ID	**Assay protocol code**	**Protocol type**	**Interpreted result value**			
			Negative	**Positive**	**Retest or equivocal**	**Split**
High Risk HPV	100	Consensus	– –	High Risk	N/A	Split
Low Risk HPV	101	Consensus	– –	Low Risk	N/A	Split
RCS High Risk HPV	108	Consensus	– –	High Risk	N/A	Split
CTGC	102	Non-consensus	– –	Ver CTGC	N/A	Split
CT-ID	103	Non-consensus	– –	CT-ID+	Equiv	Split
GC-ID	104	Non-consensus	– –	GC-ID+	Equiv	Split
RCS CTGC	105	Non-consensus	– –	Ver CTGC	N/A	Split
RCS CT-ID	106	Non-consensus	– –	CT-ID+	Equiv	Split
RCS GC-ID	107	Non-consensus	– –	GC-ID+	Equiv	Split

2.1.2 Assay protocol codes for the Canadian market

These assay protocol codes are for use with the *digene* HC2 assay protocols, version 5.4C, supplied on a CD (cat. no.1094621).

			Interpreted result value			
Assay protocol ID	**Assay protocol code**	**Protocol type**	**Negative**	**Positive**	**Retest or equivocal**	**Split**
High Risk HPV	121	Consensus	– –	High Risk	N/A	Split
Low Risk HPV	122	Consensus	– –	Low Risk	N/A	Split
RCS High Risk HPV	123	Consensus	– –	High Risk	N/A	Split
CTGC	124	Non-consensus	– –	Ver CTGC	N/A	Split
CT-ID	125	Non-consensus	– –	CT-ID+	Equiv	Split
GC-ID	126	Non-consensus	– –	GC-ID+	Equiv	Split
RCS CTGC	127	Non-consensus	– –	Ver CTGC	N/A	Split
RCS CT-ID	128	Non-consensus	– –	CT-ID+	Equiv	Split
RCS GC-ID	129	Non-consensus	– –	GC-ID+	Equiv	Split

2.1.3 Assay protocol codes for other markets

These assay protocol codes are for use with the *digene* HC2 assay protocols, version 5.4B, supplied on a CD (cat. no. 1094620).

Assay protocol ID	**Assay protocol code**	**Protocol type**	**Interpreted result value**			
			Negative	**Positive**	**Retest or equivocal**	**Split**
HPV High Risk	112	Consensus	– –	High Risk	N/A	Split
HPV High Risk retest	109	Consensus	– –	High Risk	N/A	Split
HPV Low Risk	113	Consensus	– –	Low Risk	N/A	Split
HPV Low Risk Retest	110	Consensus	– –	Low Risk	N/A	Split
RCS High Risk	114	Consensus	– –	High Risk	N/A	Split
RCS High Risk Retest	111	Consensus	– –	High Risk	N/A	Split
CT-ID	116	Non-consensus	– –	CT-ID+	Equiv	Split
GC-ID	117	Non-consensus	– –	GC-ID+	Equiv	Split
RCS CT-ID	119	Non-consensus	– –	CT-ID+	Equiv	Split
RCS GC-ID	120	Non-consensus	– –	GC-ID+	Equiv	Split
HPV PS Test	130	Consensus	– –	Positive	N/A	Split

2.2 Exporting data

The *digene* HC2 System Software only exports data for specimens having a final result. The structure of the message and the records sent differ based on the assay protocol type (consensus or non-consensus) and whether the final result was derived or non-derived.

2.2.1 Understanding the assay protocol types and retest algorithm

The 2 types of assay protocols are non-consensus and consensus. A non-consensus assay protocol does not have a retest zone and all results are reported with a "Final" status. A consensus assay protocol always has constituent tests and has a retest zone with a retest algorithm that is automatically tracked, as required, in the *digene* HC2 System Software.

Consensus assay protocol results are further defined as non-derived or derived. Non-derived consensus assay protocol results did not require retesting, meaning the final result was obtained from the initial constituent test and the retest algorithm was not required. All non-derived consensus assay protocol results are reported with a status of final.

Derived consensus assay protocol results required retesting, meaning the retest algorithm was required and the specimen was tracked to a final result in the *digene* HC2 System Software. Two further constituent tests may be required to derive a final result. Until a final result is derived, the *digene* HC2 System Software assigns the results of the individual constituent tests a status of preliminary.

If a specimen is being retested, two samples of the same specimen can be run on the same plate as replicates. This allows the second and third test to be run concurrently and will derive a final result from one assay. If both results of the replicates are positive, then both results are flagged with a result status of final. Likewise, if both results of the replicates are negative, then both results are flagged with a result status of final.

If, however, one sample is positive and the other is negative, then the final derived consensus assay protocol result is positive. The positive result is flagged with a final status and the negative result is flagged with a preliminary status.

2.3 Understanding field format and restrictions

The required fields for each type of record for the *digene* HC2 System Software are defined in this document. If a field is not defined, the field will be ignored by the *digene* HC2 System Software if received and the field will not be sent as part of any *digene* HC2 System Software output.

The *digene* HC2 System Software restricts the format of certain fields as described in the following sections.

2.3.1 Patient ID

The patient ID may only contain alphanumeric characters and underscores as well as non-leading or non-trailing spaces and hyphens. The *digene* HC2 System Software will remove leading and trailing spaces. The maximum length allowed is 20 characters.

2.3.2 Patient names

The first name and last name may only contain alphanumeric characters as well as non-leading or non-trailing spaces and hyphens. The *digene* HC2 System Software will remove leading and trailing spaces. The maximum length allowed is 20 characters.

2.3.3 Specimen ID

The specimen ID may only contain alphanumeric characters and underscores as well as non-leading or non-trailing spaces and hyphens. The *digene* HC2 System Software will remove leading and trailing spaces. The maximum length allowed is 30 characters.

2.3.4 Timestamp

When formatting a timestamp value as a string, the “YYYYMMDDHHmmss” convention is used. The following table describes the components of the convention.

Component	**Description**
YY	Four-digit year
MM	Two-digit month; January is “01”, December is “12”
DD	Two-digit day of the month
HH	Two.digit hour using military time
mm	Two-digit minute of the hour
ss	Two-digit second of the minute

For example, the timestamp of “20101119153921” would be 3:39:21 p.m. on November 19th, 2010. All timestamp values are in the time zone of the *digene* HC2 System Software.

The timestamp may be truncated to only include the known values. For instance, a birthdate may include only the year, month and day, while a test result timestamp may include the year, month, day, hour and minute. Parameters not transmitted are assumed to be unknown.

3 Interfacing with an LIS Using CLSI Standards

The *digene* HC2 System Software can be configured to communicate with the LIS via a serial port connection in compliance with Clinical and Laboratory Standards Institute® (CLSI) standards LIS1-A and LIS2-A2. The *digene* HC2 System Software sends messages containing test results to the LIS. A new message is sent for each assay protocol on a plate. A message will contain the results for the quality controls, calibrators and specimens contained on the plate.

The *digene* HC2 System Software utilizes the NCCLS LIS1-A low level protocol for transmitting data over a serial port connection. When configured for file-based transport of messages, the NCCLS LIS2-2A high level protocol message is stored in the file with no additional low level formatting.

3.1 Understanding the applicable standards

The *digene* HC2 System Software conforms to CLSI standard LIS1-A, Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems, in brokering data exchanges with the LIS over a serial port connection. The CLSI standard LIS1-A is a revision of the American Society for Testing and Materials (ASTM®) standard E1381-02.

The *digene* HC2 System Software conforms to CLSI standard LIS2-A2, Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems, in the application level of messages used in communication with the LIS. The CLSI standard LIS2-A2 is a revision of the ASTM standard E1394-97.

3.1.1 Understanding references to the applicable standards in the *digene* HC2 System Software

The applicable standards are referenced in the *digene* HC2 System Software and in this user guide as **ASTM** and **E 1394-97** because the standards previously used and referenced were ASTM E1394-97 and ASTM E1381.

3.2 Understanding message structure

The LIS2-A2 high-level protocol enables 2 systems to establish a link for the transmission of remote requests and results. Messages are sent as records which consist of fields composed in a standardized form. Each field can contain components detailing additional information.

Each record has a tier assigned in the hierarchy of the message. All records with a higher tier are associated with the immediately prior lower-tier record until a record of equal or lesser tier is encountered. The following table defines the record types of the standard.

Record type	**Tier**
Message header record	0
Patient information record	1
Test information record	2
Result record	3
Message terminator record	0
Manufacturer record	0–3
Comment record	0–3

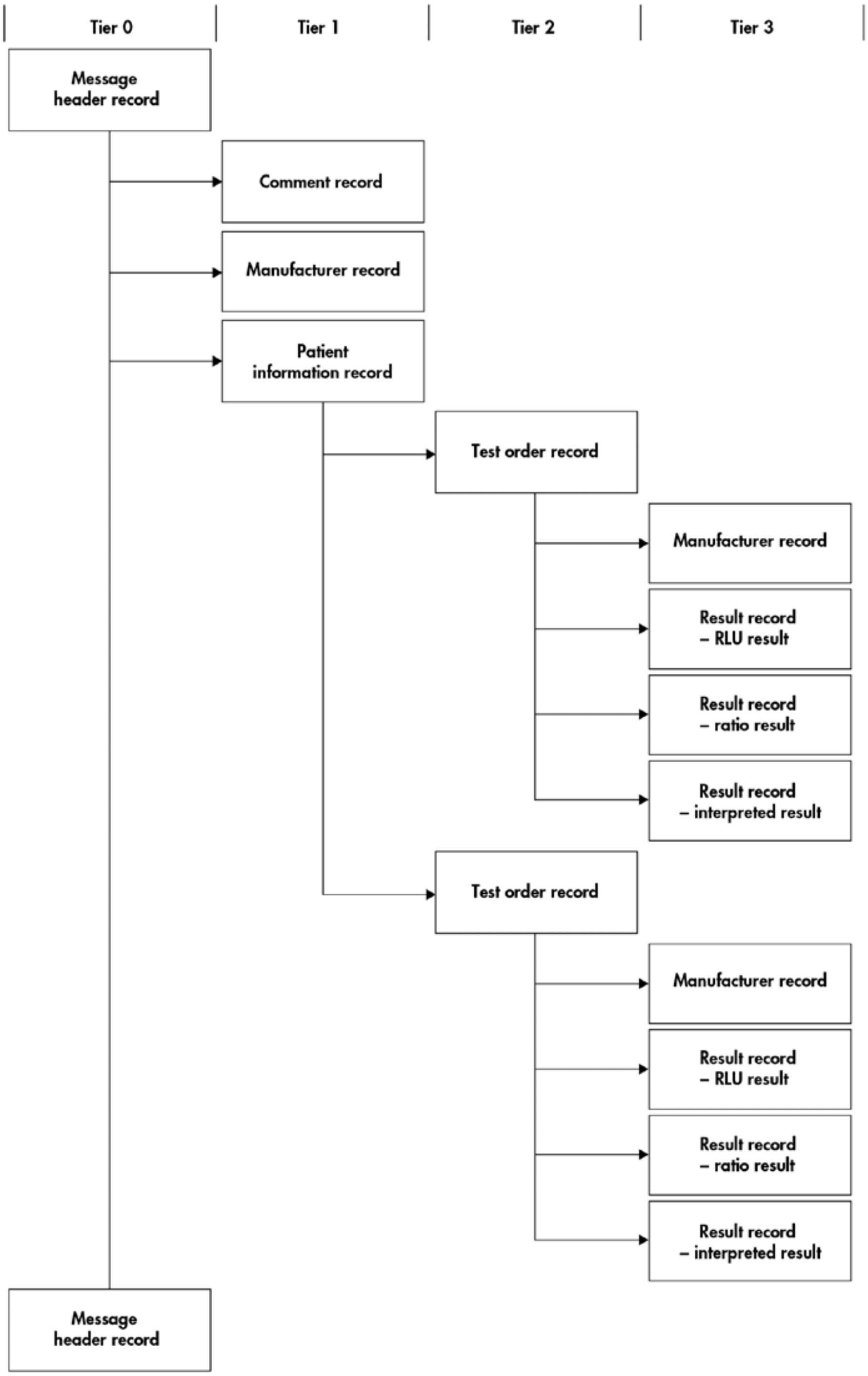
A message must contain only one message header record to start the message and only one message terminator record to end the message. A message may contain any number of patient information records, test order records, result records, comment records and manufacturer records.

Example of a message:

```
Message Header Record
  Patient Record 1
          Test Order Record 1
          Test Order Record 2
  Patient Record 2
          Test Order Record 3
                    Result Record 1
  Patient Record 3
          Test Order Record 4
Message Terminator Record
```

In the message example, test order records 1 and 2 are associated with patient record 1. Patient record 2 is at the same tier as patient record 1, so any following records of a higher tier now belong to patient record 2.

Structure of messages:



3.2.1 Understanding comment records and manufacturer records

The comment and manufacturer records may appear at any level of hierarchy in the message. A comment or manufacturer records provides information on the immediately previous record that is not a manufacturer or comment record.

Example of a message with comment and manufacturer records:

```
Message Header Record
  Patient Record 1
          Comment Record 1
          Test Order Record 1
                    Comment Record 2
                    Manufacturer Record 1
Message Terminator Record
```

In the message example, comment record 1 is providing additional information about patient record 1. Comment record 2 and manufacturer record 1 are providing additional information about test order record 1.

3.2.2 Understanding result records

The result record of a valid specimen has three parameters of the result, as follows:

- The relative light units (RLU) value as measured by the DML instrument
- The ratio of the RLU to the assay cutoff (CO)
- The interpreted result for the specimen as defined by the assay protocol:
  See "Understanding the assigned assay protocol codes," page 8, for additional information.

3.2.3 Understanding query messages

A query message is different from other messages. When sending a query message to the LIS, the *digene* HC2 System Software sends a message containing only a message header record, a query record and a message terminator record. After sending a query message, the *digene* HC2 System Software expects the next message received from the LIS to contain the result to the query. The *digene* HC2 System Software will not transmit until a response is received from the LIS or the timeout period of 30 seconds expires.

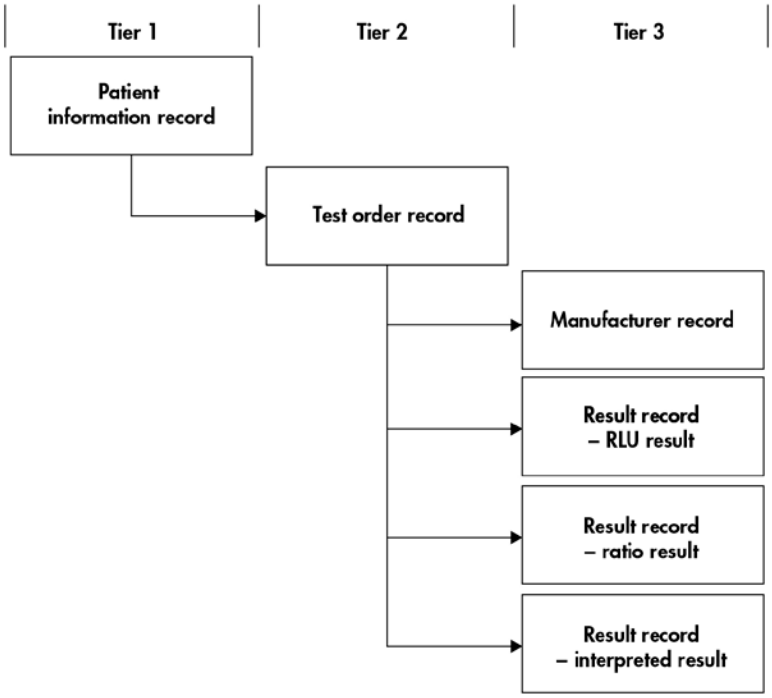
For additional details about query messages, see "Understanding query messages," page 37.

3.2.4 Exporting non-consensus assay protocol results

For specimens tested using a non-consensus assay protocol, the following records are sent for each specimen:

- Patient information record
- Test order record
- Result record for the RLU result
- Result record for the ratio result
- Result record for the interpreted result

Structure of records exported for a non-consensus assay protocol result:



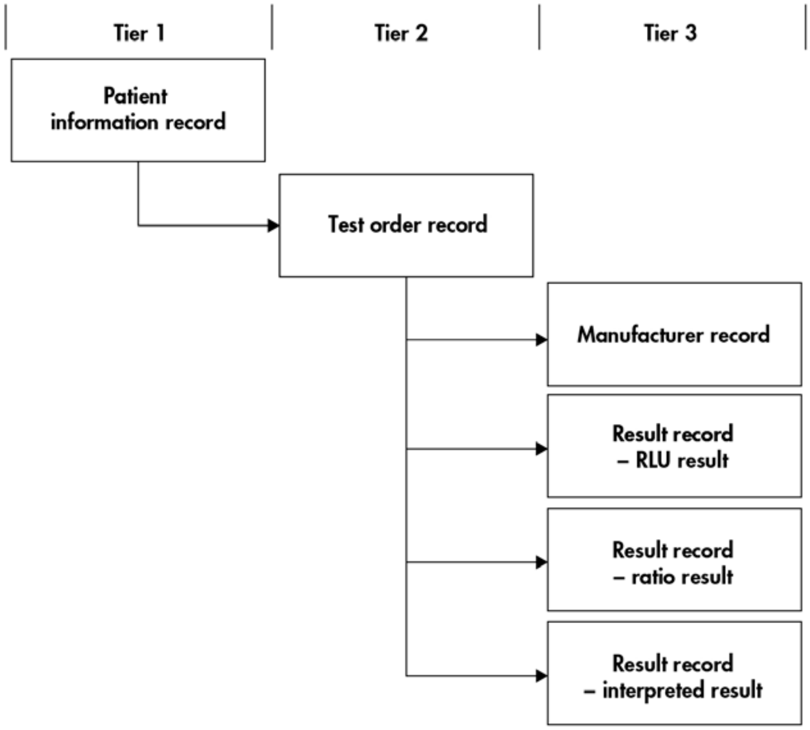
3.2.5 Exporting non-derived consensus assay protocol results

For a non-derived consensus assay protocol result, the configurable setting determining if preliminary results are transmitted affects the records sent to the LIS. If configured to not include preliminary results, the *digene* HC2 System Software transmits only the derived result and does not transmit the constituent records.

If preliminary results are not included, the following records are exported for each specimen:

- Patient information record
- Test order record
- Result record for the RLU result
- Result record for the ratio result
- Result record for the interpreted result

Structure of records exported for a non-derived consensus assay protocol results with preliminary results not included:

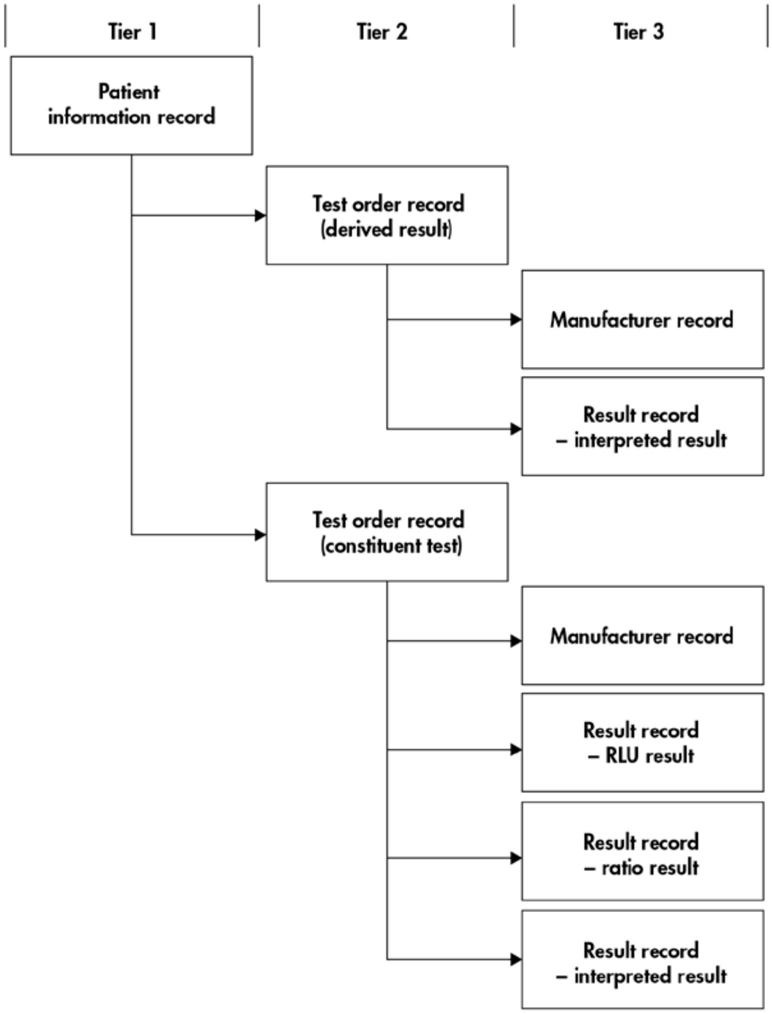


If preliminary results are included, the test order and result records are sent twice. The derived result, containing a test order and a result record for the interpreted result, is sent first. Following the derived result, the constituent measurement records, containing the test order record, result record for the RLU result, result record for the ratio result and the result record for the interpreted result, are sent.

If preliminary results are included, the following records are exported for each specimen:

- Patient information record
- Test order record (derived result)
- Result record for the interpreted result (derived result)
- Test order record (constituent result)
- Result record for the RLU result (constituent result)
- Result record for the ratio result (constituent result)
- Result record for the interpreted result (constituent result)

Structure of records exported for a non-derived consensus assay protocol results with preliminary results included:



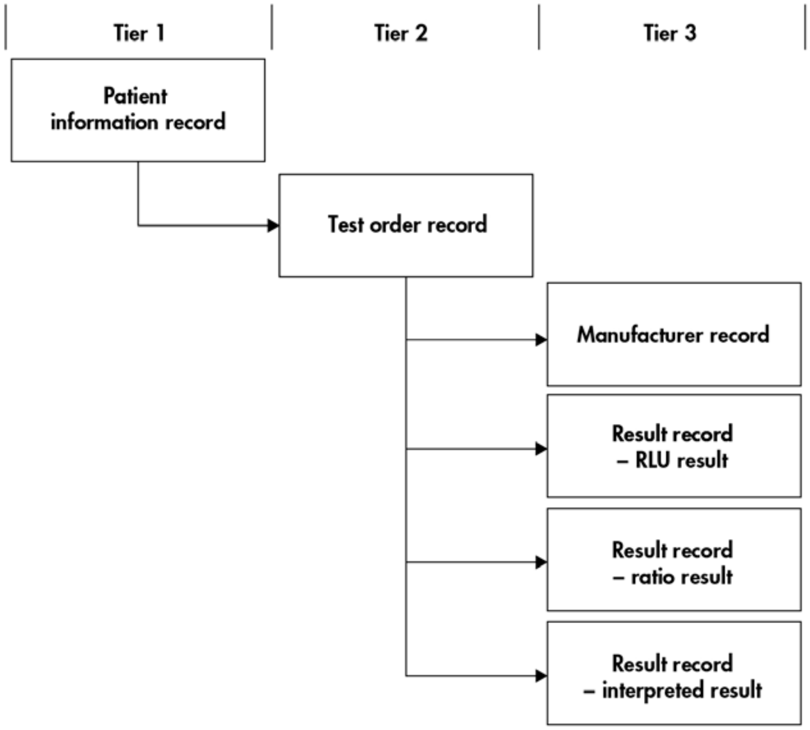
3.2.6 Exporting derived consensus assay protocol results

For a derived consensus assay protocol result, the configurable setting determining if preliminary results are transmitted affects the records sent to the LIS. If configured to not include preliminary results, the *digene* HC2 System Software transmits only the derived result and does not transmit the constituent records.

If preliminary results are not included, the following records are exported for each specimen:

- Patient information record
- Test order record
- Result record for the RLU result
- Result record for the ratio result
- Result record for the interpreted result

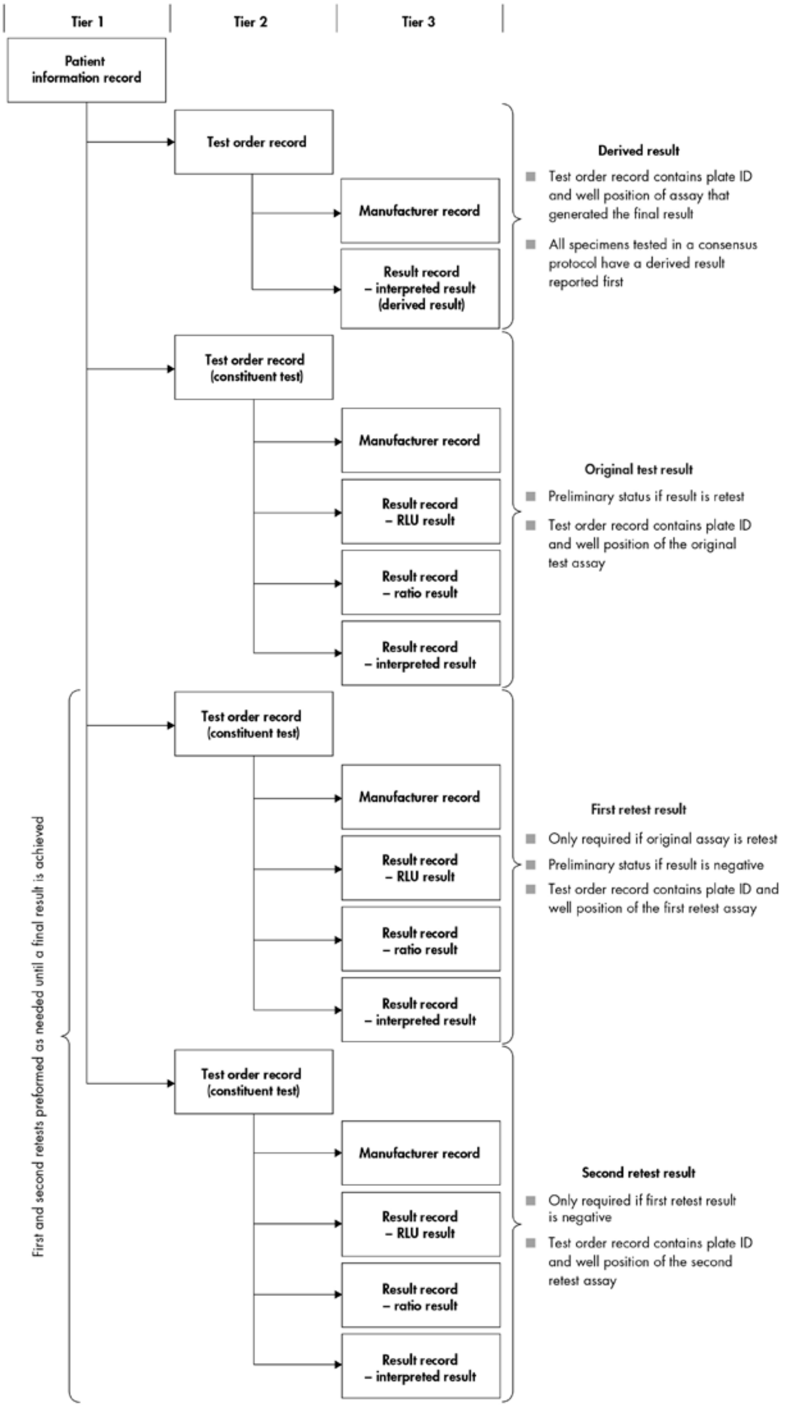
Structure of records exported for a derived consensus assay protocol results with preliminary results not included:



If preliminary results are included, the test order and result records are transmitted for each constituent test performed. The maximum number of constituent tests, as defined by the retest algorithm, is three. The following minimum records are exported for each specimen:

- Patient information record
- Test order record (derived result)
- Result record for the interpreted result (derived result)
- Test order record (constituent result)
- Result record for the RLU result (constituent result)
- Result record for the ratio result (constituent result)
- Result record for the interpreted result (constituent result)

Structure of records exported for a derived consensus assay protocol results with preliminary results included:



Derived result

- Test order record contains plate ID and well position of assay that generated the final result
- All specimens tested in a consensus protocol have a derived result reported first

Original test result

- Preliminary status if result is retest
- Test order record contains plate ID and well position of the original test assay

First retest result

- Only required if original assay is retest
- Preliminary status if result is negative
- Test order record contains plate ID and well position of the first retest assay

Second retest result

- Only required if first retest result is negative
- Test order record contains plate ID and well position of the second retest assay

3.2.7 Exporting data for replicates

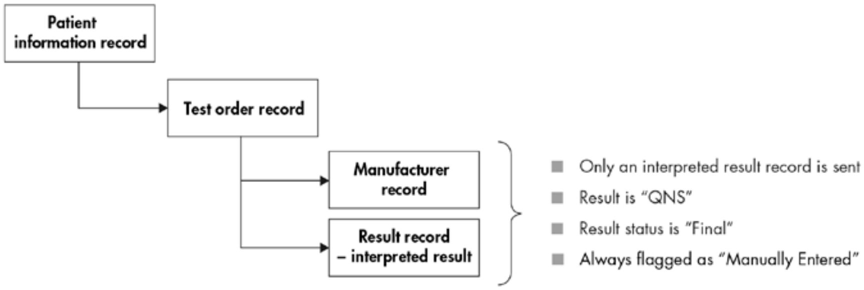
Replicates of specimens export test results separately. If the replicates are tested using a non-consensus assay protocol, both test results are final. If the replicates are tested using a consensus assay protocol, the following outcomes are possible:

- Both replicates are negative and both test results are considered final
- Both replicates are positive and both test results are considered final
- One replicate is positive and one replicate is retest; the retest result is preliminary and the positive result is final
- One replicate is positive and one replicate is negative; both results are preliminary and a third test is required to determine a final result
- One replicate is negative and one replicate is retest; both results are preliminary and a third test is required to determine a final result

3.2.8 Exporting data for QNS specimens

Specimens with a status of quantity not sufficient (QNS) will export only one result record for the interpreted result; no result records for the RLU or ratio result are sent as the well on the plate was not measured. The result is flagged as manually entered as a user set the specimen to QNS in the *digene* HC2 System Software.

Structure of records exported for a specimen with a result of QNS:



3.2.9 Exporting data of unclear or invalid specimens

If a plate was created from the output file of a pre-analytical system, specimens with a result status of unclear or invalid are not transmitted. Refer to digene *HC2 System Software User Manual* for additional information about specimens with a result status of unclear or invalid.

3.2.10 Understanding patient data

Patient data are optional fields that can be populated using the *digene* HC2 System Software or sent from the LIS as a response to a query made by the *digene* HC2 System Software. The *digene* HC2 System Software accepts the following patient data fields:

- Patient ID
- First name
- Last name
- Birth date
- Gender

Regardless of how patient data are populated, patient data are included when present. An empty patient record is transmitted for specimens without patient data.

3.2.11 Understanding quality control data

Quality control result records are sent in the same general format as specimen result records with the addition of a manufacturer record containing the lot number and expiration information. Field 8.4.12 of a test order record for a quality control contains a designation of **Q** to indicate the record is for a quality control. Several other fields have modifications specific to quality controls and these fields are detailed in the descriptions of the applicable fields. As with specimens, a separate result record is generated for each result exported.

3.2.12 Understanding calibrator data

Data for calibrators are sent as a manufacturer records. Each record contains the following for the respective calibrator:

- RLU of the calibrator
- Mean RLU of the calibrators of the same type
- %CV of the RLU of the calibrators of the same type
- Kit lot information

3.2.13 Exporting data for failed assays

An assay that does not meet the defined parameters of an assay protocol will result in a failed assay. An assay can fail by either the calibrators or the quality controls failing the defined parameters of an assay protocol. The results of specimens contained on a failed plate cannot be accepted, and consequently, the specimen results are not exported.

Whether the data of calibrators and quality controls on a failed assay are exported is determined by the settings in the *digene* HC2 System Software. To modify the setting, refer to digene *HC2 System Software User Manual* for additional instructions.

Depending on the cause of the invalid assay, different data for the calibrators and quality controls are exported. If the calibrators not meeting the defined parameters of an assay protocol are the cause of the failed assay, the calibrator data is exported. For the quality controls, only the result record for the RLU result is exported. If the quality controls not meeting the defined parameters of an assay protocol are the cause of the failed assay, all calibrator and quality control data are exported. For the quality controls, result records are sent for the RLU, ratio and interpretative results. The interpretative result will define the quality control as invalid.

If a plate was created from the output file of a pre-analytical system and the quality controls are not valid, only the interpretive result is exported. The interpretative result will define the quality control as invalid. Refer to digene *HC2 System Software User Manual* for additional information about plates created from the output file of a pre-analytical system.

3.3 Understanding records

Each type of record has a defined structure made up of fields. Each record utilized in the communication of the *digene* HC2 System Software with an LIS is defined in the following sections.

3.3.1 Message header record

Every message begins with a message header record.

LIS2-A2 field	Field name	Transmitted	Description
6.1	Record type	Character	Indicates message header record **Note**: The default setting is **H**
6.2	Delimiter definition		Delimiters are defined in this field; these are hard-coded in the *digene* HC2 System Software
	Field	|	
	Repeat	\	
	Component	^	
	Escape	&	
6.3–6.4	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
6.5	Sender name or ID		Identifies the system sending the message
	Name	String	Name of instrument **Note**: The default setting is **HC2**
	^Software version	String	Version of *digene* HC2 System Software **Note**: The default setting is **^3.4**
	^Rapid Capture s/n	String	Serial number of the Rapid Capture® System (RCS) Null if a RCS is not present
	^Luminometer s/n	String	Serial number of the DML instrument
	^Software version	String	Version of *digene* HC2 System Software **Note**: The default setting is **^3.4**

LIS2-A2 field	Field name	Transmitted	Description
6.6–6.11	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
6.12	Processing ID	Character	The setting **P** is for production operation **Note**: The default setting is **P**
6.13	Version number	String	Version of the specification in use **Note**: The default setting is **E 1394 97**
6.14	Date and time of message	String	The timestamp when the message was generated in the format of "YYYYMMDDHHmmss"; the timestamp is in the time zone of the *digene* HC2 System Software

3.3.2 Comment record

Immediately following the message header record, the *digene* HC2 System Software sends a comment record.

LIS2-A2 field	Field name	Transmitted	Description
10.1	Record type	Character	Indicates comment record The field is set to **C**
10.2	Sequence number	Integer	At most, one comment record is sent following the header record The field is set to **1**
10.3	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
10.4	Comment text	String	**Assay Protocol** [assay protocol ID] **has been encountered. Data for this assay now follows:**
10.5	Comment type	Character	A generic or free text comment The field is set to **G**

3.3.3 Calibrator manufacturer record

The *digene* HC2 System Software sends calibrator data as a manufacturer record that immediately follows the comment record.

LIS2-A2 field	Field name	Transmitted	Description
14.1	Record type	Character	Indicates manufacturer record The field is set to **M**
14.2	Sequence number	Integer	Index of the manufacturer record in a collection of manufacturer records
14.3	Calibrator name	String	From the *digene* HC2 System Software
14.4	Assay ID		From the *digene* HC2 System Software
	Local protocol code	String	Assay protocol code; see "Understanding the assigned assay protocol codes," page 8, for additional instructions
	^Protocol name	String	Assay protocol ID
14.5	Test location		From the *digene* HC2 System Software **Note**: Plates measured prior to *digene* HC2 System Software version 3.3 will have this field blank
	Plate ID	String	Capture plate ID
	^Well location	String	Location of the calibrator on the capture plate
14.6	RLU	Number	Measured RLU result
	^Average of calibrators	Number	Mean of calibrator RLU results
	^%CV of calibrators	Number	%CV of the calibrator RLU results

LIS2-A2 field	Field name	Transmitted	Description
14.7	Outlier flag	String	**Outlier** indicates a calibrator that has been excluded as an outlier If the calibrator is not an outlier, the field position is indicated with **|**
14.8	Kit lot	String	Kit lot ID of the kit used for testing
14.9	Kit lot expiration date	String	Kit lot expiration of kit used for testing in the format "YYYYMMDD"

3.3.4 Patient information record

A patient information record is transmitted as the container for test orders which contains results. All fields of the patient information record are optional except for the record type, field 7.1, and sequence number, field 7.2. For quality control results and specimens without associated patient information, the patient information record contains null fields except for the record type and sequence number fields.

LIS2-A2 field	Field name	Transmitted	Description
7.1	Record type	Character	Indicates patient information record The field is set to **P**
7.2	Sequence number	Integer	Index of the patient record among patient records within the message; increments of 1 The field is set to **1**
7.3	Practice-assigned patient ID	String	Patient ID from either an LIS test order or an ID manually entered into the *digene* HC2 System Software
7.4–7.5	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
7.6	Patient name		Patient name; the field must use the specified order; use nulls for unknown or missing values
	Last name	String	
	^First name	String	

LIS2-A2 field	Field name	Transmitted	Description
7.7	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
7.8	Birth date	String	Patient date of birth in the format of "YYYYMMDD"
7.9	Gender	Character	Use **M** for male, **F** for female or **U** for unspecified
7.10–7.13	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
7.14	Attending physician ID	String	Physician ID; included only if entered manually into the *digene* HC2 System Software
7.15–7.19	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
7.20	Patient active medications	String	Medications in use by patient; included only if entered manually into the *digene* HC2 System Software

3.3.5 Test order record for a specimen or quality control

A test order record contains the general information about a specimen or quality control and applies to the patient information record immediately prior.

LIS2-A2 field	Field name	Transmitted	Description
8.4.1	Record type	Character	Indicates test order record The field is set to **O**
8.4.2	Sequence number	Integer	Index of the test order record for the patient; resets to **1** for each patient

LIS2-A2 field	Field name	Transmitted	Description
8.4.3	Specimen ID	String	Specimen or quality control ID of the sample tested
	^Plate ID	String	Capture plate ID that contained the sample **Note**: Plates measured prior to *digene* HC2 System Software version 3.3 will have this field blank
	^Well location	String	Location of the sample on the capture plate
8.4.4	Instrument specimen ID	String	The instrument specimen ID is included when the specimen ID was created in the *digene* HC2 System Software; this indicates to the LIS that the specimen ID in field 8.4.3 may not be known to the LIS This field will be null for specimens received from the LIS; indicate field position with **|**, omit if last character of a message
8.4.5	Universal test ID	String	The first 3 components of this field are null to conform with LIS2-A2; indicate field position with **|**, omit if last character of a message
	^^^Test code	String	Assay protocol code; see "Understanding the assigned assay protocol codes," page 8, for additional instructions
	^Test name	String	Assay protocol ID
8.4.6–8.4.11	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
8.4.12	Action code	String	The action code is **Q** when sending quality control results This field is null when sending specimen results; indicate field position with **|**, omit if last character of a message
8.4.13–8.4.14	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message

LIS2-A2 field	Field name	Transmitted	Description
8.4.15	Date/time specimen received	String	Timestamp indicating when the specimen was created in the digene HC2 System Software in the format of "YYYYMMDDHHmmss" The field is null for quality controls; indicate field position with **|**, omit if last character of a message **Note**: The default setting is null
8.4.16–8.4.25	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
8.4.26	Report type	Character	Indicates the status of the result; **P** is a preliminary result status; **F** is a final result status The field is null for quality controls; indicate field position with **|**, omit if last character of a message

3.3.6 Manufacturer record for a quality control

When sending information about a quality control, the test order record for the quality control is immediately followed by a manufacturer record containing additional information about the quality control.

LIS2-A2 field	Field name	Transmitted	Description
14.1	Record type	Character	Indicates manufacturer record The field is set to **M**
14.2	Sequence number	Integer	Index of the manufacturer record among manufacturer records for the immediately prior test order record The field is set to **1**
14.3	Kit lot	String	Kit lot ID of the kit used
14.4	Kit lot expiration date	String	Expiration date of the kit lot used in the format of "YYYYMMDD"

LIS2-A2 field	Field name	Transmitted	Description
14.5	QC lot number	String	Quality control lot ID of the quality control
14.6	QC lot expiration date	String	Expiration date of the quality control in the format of "YYYYMMDD"

3.4 Result record

A valid result in the *digene* HC2 System Software has three parameters, as follows:

- The RLU value as measured by the DML instrument
- The ratio of the RLU to the assay cutoff (CO)
- The interpreted result for the specimen

The interpreted result will have a designation specific to the assay protocol used during the testing of the specimen. See "Understanding the assigned assay protocol codes," page 8, for additional instructions.

For each of the parameters of the result, a separate result record is transmitted.

LIS2-A2 field	Field name	Transmitted	Description
9.1	Record type	Character	Indicates results record The field is set to **R**
9.2	Sequence number	Integer	Index of the result record among result records sent for the immediately prior test order record

LIS2-A2 field	Field name	Transmitted	Description
9.3	Universal test ID		The first 3 components of this field are null to conform with LIS2-A2; indicate field position with **^**
	^^^Test code	String	Assay protocol code; see "Understanding the assigned assay protocol codes," page 8, for additional instructions
	^Test name	String	Assay protocol ID
	^Specimen cutoff type	String	Cutoff type; **primary**, **secondary** or **tertiary** The field is null for quality controls; indicate field position with **^**
	^Specimen type	String	Specimen type The field is null for quality controls; indicate field position with **^**
	^Result type	String	Type of result as **Rlu** for RLU, **Rat** for RLU/CO result or **I** for interpreted result
9.4	Data or measurement value	String	Value of the test result
9.5	Units	String	Unit of measure used by the result value The field is null for **Rat** and **I** results; indicate field position with **|**, omit if last character of a message
9.6	Reference range	String	Defines the specification range for a quality control to be valid The field is null for **Rlu** and **I** results; indicate field position with **|**, omit if last character of a message. The field is null for specimens; indicate field position with **|**, omit if last character of a message

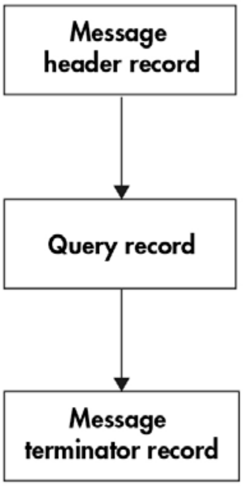
LIS2-A2 field	Field name	Transmitted	Description
9.7	Result abnormal flags	Character	The error condition for an invalid quality control; **>** for greater than the specified range or **<** for less than the specified range The field is null for specimens; indicate field position with **|**, omit if last character of a message
9.8	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
9.9	Result status	String	Result status as **Preliminary** or **Final** The field is null for quality controls; indicate field position with **|**, omit if last character of a message
9.10	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
9.11	Operator identification	String	User ID of the *digene* HC2 System Software user that added the assay to the plate
9.12	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
9.13	Date and time test completed	String	Timestamp when the test was completed in the format of "YYYYMMDDHHmmss"
9.14	Instrument identification	String	**Manually Entered** indicates the measurement value was entered by the user The field is null for normal specimen data

3.5 Understanding query messages

The *digene* HC2 System Software can send a message to the LIS to query for test orders. The *digene* HC2 System Software can have only one query outstanding. After the *digene* HC2 System Software sends a query message, the *digene* HC2 System Software blocks transmission of further messages until a response is received from the LIS or the timeout for the start of the response expires after 30 seconds. The next message received from the LIS is assumed to contain the results to the query message.

The query message contains a message header record, a query record and a message terminator record.

The structure of a query message is as follows:



3.5.1 Message header record of a query message

LIS2-A2 field	Field name	Transmitted	Description
6.1	Record type	Character	Indicates message header record The field is set to **H**
6.2	Delimiter definition		Delimiters are defined in this field; these are hard-coded in the *digene* HC2 System Software
	Field	|	
	Repeat	\	
	Component	^	
	Escape	&	

LIS2-A2 field	Field name	Transmitted	Description
6.3–6.4	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
6.5	Sender name or ID		Identifies the system sending the message
	Name	String	Name of instrument The field is set to **HC2**
	^Software version	String	Version of *digene* HC2 System Software The field is set to **^3.4**
	^Rapid Capture s/n	String	Serial number of the RCS Null if a RCS is not present
	^Luminometer s/n	String	Serial number of the DML instrument The field is set to **^**
	^Software version	String	Version of *digene* HC2 System Software The field is set to **^3.4**
6.6–6.11	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
6.12	Processing ID	Character	The setting **P** is for production operation The field is set to **P**
6.13	Version number	String	Version of the specification in use The field is set to **E 1394 97**
6.14	Date and time of message	String	The timestamp when the message was generated in the format of "YYYYMMDDHHmmss"; the timestamp is in the time zone of the *digene* HC2 System Software

3.5.2 Query record of a query message

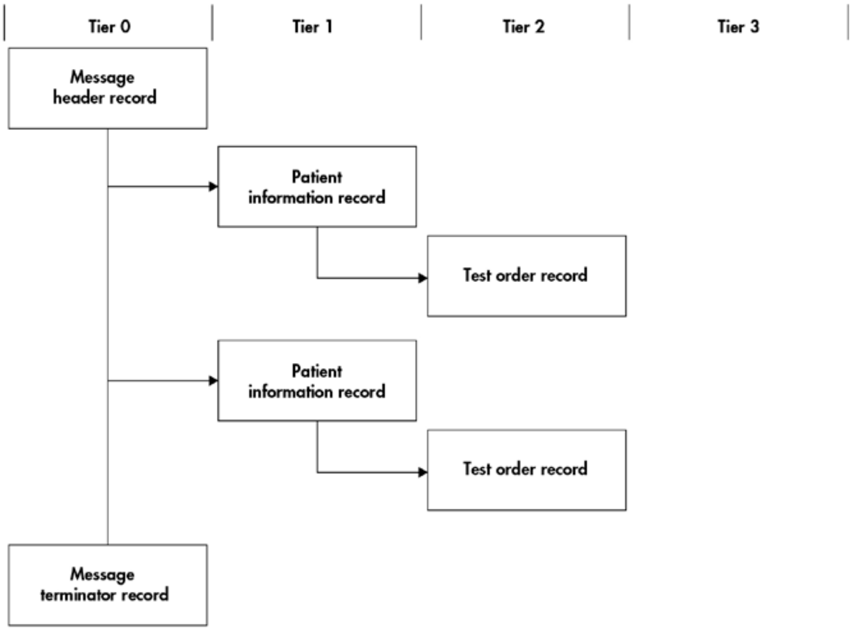
LIS2-A2 field	Field name	Transmitted	Description
11.1	Record type	Character	Indicates request record type The field is set to **Q**
11.2	Sequence number	Integer	The *digene* HC2 System Software sends only one request in a query message The field is set to **1**
11.3	Starting range ID number		
	^Sample ID	String	The field is set to **^ALL**
11.4	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
11.5	Universal test ID	String	The mapped value for the assay protocol as defined in the *digene* HC2 System Software To query for multiple assay protocols, the repeat delimiter (****) is used to request multiple assay protocols Example: **^^^^CT\\^^^^GC**
	^^^^ Test Name		
11.6	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
11.7	Beginning request results date and time	String	Beginning timestamp (7 days prior) in the format of "YYYYMMDDHHmmss" for which the LIS will return test orders
11.8	Ending request results date and time	String	Ending timestamp (current date and time) in the format of "YYYYMMDDHHmmss" for which the LIS will return test orders

LIS2-A2 field	Field name	Transmitted	Description
11.9–11.12	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
11.13	Request information status codes	Character	Indicates that only test order records and patient information records are requested The field is set to **O**

3.6 Understanding query responses

The query response from the LIS contains a message header record followed by patient information records and test order records in answer to the query message from the *digene* HC2 System Software. The query response must be delivered in a single message and may not be split across multiple messages. The query response will not include result records, manufacturer records or comment records.

The structure of a query response is as follows:



The test name field (field 8.4.5) of the test order record specifies the assay protocol to be used to test the specimen. The test name field must be mapped in the *digene* HC2 System Software to the applicable assay protocol before test order records from the LIS can be processed. The mapping of the assay protocols is applicable only to the receipt of query responses from the LIS. To configure the mapping of assay protocols, refer to digene *HC2 System Software User Manual* for additional instructions.

The query response will be acknowledged as accepted as long as the message is well formed. Upon receipt, the patient information record is checked for a practice-assigned patient ID (field 7.3) that matches an existing patient ID in the *digene* HC2 System Software. If a matching patient ID exists, the patient data in the *digene* HC2 System Software is updated with the received information.

An empty field of a patient information record is considered null and will not overwrite the applicable parameter in the *digene* HC2 System Software. A field populated with 2 double quotes (**""**) indicates that the parameter is blank and the applicable parameter in the *digene* HC2 System Software is deleted.

Once the patient information is updated, the test order record is checked for a matching specimen ID in the *digene* HC2 System Software. If a matching specimen ID exists, the specimen data in the *digene* HC2 System Software is updated and associated with the patient; any association of the specimen with a different patient in the *digene* HC2 System Software is overwritten.

If a matching specimen ID is not available, a new specimen is created in the *digene* HC2 System Software and associated with the patient.

Errors in the data of the test orders are addressed by sending a rejection message for the individual test orders. See "Understanding rejection messages," page 45, for additional information.

3.6.1 Message header record of a query response

LIS2-A2 field	Field name	Received	Description
6.1	Record type	Character	Indicates message header record The field is set to **H**
6.2	Delimiter definition		Delimiters are defined in this field; these are hard-coded in the *digene* HC2 System Software
	Field	|	
	Repeat	\	
	Component	^	
	Escape	&	
6.3–6.4	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
6.5	Sender name	String	The identifying information for the LIS
6.6–6.11	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
6.12	Processing ID	Character	The setting **P** is for production operation The field is set to **P**
6.13	Version number	String	Version of the specification in use The field is set to **E 1394 97**
6.14	Date and time of message	String	Timestamp when the message was generated in the format of "YYYYMMDDHHmmss"; the timestamp is in the time zone of the *digene* HC2 System Software

3.6.2 Patient information record of a query response

A patient information record is transmitted as the container for test order records. All fields of the patient information record are optional except for the record type (field 7.1) and sequence number (field 7.2).

LIS2-A2 field	Field name	Received	Description
7.1	Record type	Character	Indicates patient information record The field is set to **P**
7.2	Sequence number	Integer	Index of the patient information record included in the query response starting at 1 for each query response message
7.3	Practice assigned patient ID	String	Patient ID supplied by the LIS
7.4–7.5	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
7.6	Patient name		Patient name; the field must use the specified order; use nulls for unknown or missing values
	Last name	String	
	^First name	String	
7.7	N/A	N/A	Null field; indicate field position with **|,** omit if last character of a message
7.8	Birth date	String	Patient date of birth in the format of "YYYYMMDD"
7.9	Gender	Character	Use **M** for male, **F** for female or **U** for unspecified

3.6.3 Test order record of a query response

The only difference in a test order record for a query message and a query response is that the report type field (field 8.4.26) is set to **Q** to signify that the test order record is a query response.

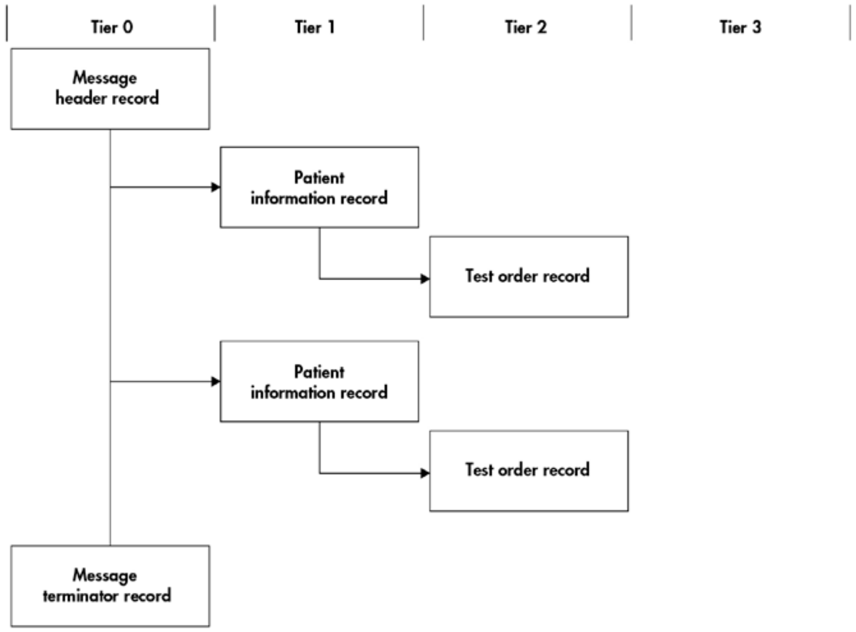
The test order record of a query response sent by the LIS will use the mapped name, as configured in the *digene* HC2 System Software, as the test name.

LIS2-A2 field	Field name	Received	Description
8.4.1	Record type	Character	Indicates test order record The field is set to **O**
8.4.2	Sequence number	Integer	Index of the test order record for the immediately prior patient information record The index starts at 1 for each new patient
8.4.3	Specimen ID	String	Specimen ID supplied by the LIS for specimen
8.4.4	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
8.4.5	Universal test ID ^^^^Test name	 String	Mapped value of the assay protocol to be used to test the specimen
8.4.6–8.4.11	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
8.4.12	Action code	Character	Use **N** for new test orders; the *digene* HC2 System Software only processes new test orders The field is set to **N**
8.4.13–8.4.25	N/A	N/A	Null fields; maintain positions using **|**
8.4.26	Report type	Character	Use **Q** to indicate the test order is provided in response to a query message

3.7 Understanding rejection messages

If a test order is rejected, the *digene* HC2 System Software sends a message to the LIS to inform the LIS of test orders that will not be processed. The rejection message begins with a message header record and ends with a message terminator record. The rejection message contains patient information records and test order records that describe the rejected test orders.

The structure of a rejection message is as follows:



Test orders are rejected at the patient information record level. If two test order records are associated with the same patient information record and one test order record contains an error, both test order records will be rejected.

Rejection messages are sent for the following reasons:

- Test order records with a test name that has not been mapped to an assay protocol in the *digene* HC2 System Software
- The requested test is not available in the *digene* HC2 System Software
- The content of a data field violates the restrictions imposed by the *digene* HC2 System Software:
  See "Understanding field format and restrictions," page 13, for additional instructions.

3.7.1 Message header record of a rejection message

LIS2-A2 field	Field name	Transmitted	Description
6.1	Record type	Character	Indicates message header record The field is set to **H**
6.2	Delimiter definition		Delimiters are defined in this field; these are hard-coded in the *digene* HC2 System Software
	Field	|	
	Repeat	\	
	Component	^	
	Escape	&	
6.3–6.4	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
6.5	Sender name or ID		Identifies the system sending the message
	Name	String	Name of instrument The field is set to **HC2**
	^Software Version	String	Version of *digene* HC2 System Software The field is set to **^3.4**
	^Rapid Capture s/n	String	Serial number of the RCS Null if a RCS is not present
	^Luminometer s/n	String	Serial number of the DML instrument The field is set to **^**
	^Software Version	String	Version of the *digene* HC2 System Software The field is set to **^3.4**
6.6–6.11	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message

LIS2-A2 field	Field name	Transmitted	Description
6.12	Processing ID	Character	The setting **P** is for production operation The field is set to **P**
6.13	Version number	String	Version of the specification in use The field is set to **E 1394 97**
6.14	Date and time of message	String	The timestamp when the message was generated in the format of "YYYYMMDDHHmmss"; the timestamp is in the time zone of the *digene* HC2 System Software

3.7.2 Patient information record of a rejection message

A patient information record is transmitted as the container for rejected test order records. All fields of the patient information record are optional except for the record type (field 7.1) and sequence number (field 7.2). The data found in the fields of the patient information record exactly match the values supplied by the LIS, except field 7.2, which is given the appropriate index within the message.

LIS2-A2 field	Field name	Transmitted	Description
7.1	Record type	Character	Indicates patient information record The field is set to **P**
7.2	Sequence number	Integer	Index of the patient information record among patient information records within the message
7.3	Practice-assigned patient ID	String	Patient ID supplied by the LIS If no patient ID was supplied by the LIS, the field is null; indicate field position with **|**, omit if last character of a message
7.4–7.5	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message

LIS2-A2 field	Field name	Transmitted	Description
7.6	Patient name		Patient name; the field must use the specified order; use nulls for unknown or missing values
	Last name	String	
	^First name	String	
7.7	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
7.8	Birth date	String	Patient date of birth in the format of "YYYYMMDD"
7.9	Gender	Character	Use **M** for male, **F** for female or **U** for unspecified

3.7.3 Test order records of a rejection message

LIS2-A2 field	Field name	Transmitted	Description
8.4.1	Record type	Character	Indicates test order record The field is set to **O**
8.4.2	Sequence number	Integer	Index of the test order record among test order records for the immediately prior patient information record
8.4.3	Specimen ID	String	Specimen ID supplied by the LIS for specimen
8.4.4	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
8.4.5	Universal test ID		Mapped value of the assay protocol to be used to test the specimen
	^^^^Test name	String	
8.4.6–8.4.11	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message

LIS2-A2 field	Field name	Transmitted	Description
8.4.12	Action code	Character	Use **C** to indicate the test order record was rejected by the *digene* HC2 System Software **Note**: The default setting is **C**
8.4.13–8.4.25	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
8.4.26	Report type	Character	Use **X** to indicate the test order is rejected by the *digene* HC2 System Software **Note**: The default setting is **X**

3.8 Example messages

The following examples are provided for the different types of messages that can be transmitted. The examples are presented in a series of messages in the order that would occur to test a CT-ID specimen and a high-risk HPV specimen. The series starts as a query message from the *digene* HC2 System Software and ends with the transmission of the results to the LIS.

Comments are included in the messages to explain the relevant or background information. Comments are bold and contained in brackets.

3.8.1 Example of a query message

The query message example is initiated by the *digene* HC2 System Software. The query message requests test orders for all assay protocols configured in the *digene* HC2 System Software. The query message requests all test orders entered into the LIS within the last 7 days.

Example of a query message:

```
H|\^&|||HC2^3.4^^^3.4|||||||P|E 1394-97|20130821172710
Q|1|^ALL||^^^^CT-ID\^^^^CTGC\^^^^GC-ID\^^^^High  Risk HPV\^^^^Low Risk HPV\^^^^
RCS CT-ID\^^^^RCS CTGC\^^^^GC-ID\^^^^RCS High Risk HPV||20130814182951|20130821
182951|||||O
L|1|N
```

3.8.2 Example of a query response

The LIS acknowledges the query message with a query response containing the requested test order records. In the example, the first 2 patients each have 2 valid orders. The third patient, Mina Murray, is an invalid order because the *digene* HC2 System Software does not have an assay protocol “UNMAPPED” installed.

Example of an LIS query response for test orders:

```
H|\^&||||||||||P|E 1394-97|20130824112209
[First patient; two test orders]
P|1|Patient01|||Harker^Jonathan||19500503|M
O|1|CTSpec-01||^^^^CTMAP|||||||N||||||||||||||Q
P|1|Patient01|||Harker^Jonathan||19500503|M
O|1|HPVSpec-01||^^^^High Risk HPV|||||||N||||||||||||||Q
[Second patient; two test orders]
P|1|Patient02|||Westenra^Lucy||19530912|F|
O|1|HPVSpec-02||^^^^High Risk HPV|||||||N||||||||||||||Q
P|1|Patient02|||Westenra^Lucy||19530912|F|
O|1|HPVSpec-03||^^^^High Risk HPV|||||||N||||||||||||||Q
[Third patient; invalid test order]
P|1|Patient03|||Murray^Mina||19530509|F|
O|1|CTSpec-04||^^^^UNMAPPED|||||||N||||||||||||||Q
L|1|N
```

3.8.3 Example of a rejection message

The *digene* HC2 System Software rejects test order records at the patient information record level if the test order record cannot be fulfilled by the *digene* HC2 System. In the example below, the assay protocol included in the query response is not available.

Example of a rejection message:

```
H|\^&|||HC2^3.4^^^3.4|||||||P|E 1394-97|20130821172710
P|1|Patient03|||Murray^Mina||19530509|F|
O|1|CTSpec-04||^^^^UNMAPPED|||||||N||||||||||||||Q
L|1|N
```

3.8.4 Example of data export for a non-consensus assay protocol

Example of data export for a non-consensus assay protocol:

```
H|\^&|||HC2^3.4^RCS_SN^9102071007^3.4|||||||P|E 1394-97|20131009222703
C|1||Assay protocol CT-ID has been encountered. Data for this assay now
follows:|G
[The following records contain information for the calibrators.]
M|1|NC|103^CT-ID|ExaPlateCT-ID^A1|22^24.00^11.79||CTKit|20141009
M|2|NC|103^CT-ID|ExaPlateCT-ID^B1|26^24.00^11.79||CTKit|20141009
M|3|NC|103^CT-ID|ExaPlateCT-ID^C1|57^24.00^11.79|Outlier|CTKit|20141009
```

```
M|4|PC CT|103^CT-ID|ExaPlateCT-ID^D1|221^212.00^6.00||CTKit|20141009
M|5|PC CT|103^CT-ID|ExaPlateCT-ID^E1|295^212.00^6.00|Outlier|CTKit|20141009
M|6|PC CT|103^CT-ID|ExaPlateCT-ID^F1|203^212.00^6.00||CTKit|20141009
```

[The following records contain information for the quality controls:]

```
P|1
O|1|CT+^ExaPlateCT-ID^G1||^^^103^CT-ID|||||||Q
M|1|CTKit|20141009|CTLot|20140804
R|1|^^^103^CT-ID^^^Rlu|546|RLU||||||Super||20131009212529
R|2|^^^103^CT-ID^^^I|Valid|||||||Super||20131009212529
R|3|^^^103^CT-ID^^^Rat|2.57||1.00 - 20.0|||||Super||20131009212529
P|2
O|1|GC+^ExaPlateCT-ID^H1||^^^103^CT-ID|||||||Q
M|1|CTKit|20141009|GCLot|20140804
R|1|^^^103^CT-ID^^^Rlu|125|RLU||||||Super||20131009212529
R|2|^^^103^CT-ID^^^I|Valid|||||||Super||20131009212529
R|3|^^^103^CT-ID^^^Rat|0.58||0.000 - 1.00|||||Super||20131009212529
```

[The following records contain information for a specimen with patient information available:]

```
P|3|Patient01|||Harker^Jonathan||19500503
O|1|CTSpec-01^ExaPlateCT-ID^A2||^^^103^CT-ID||||||||||20131009210545|||||||||||F
M|1|CTKit|20141009
R|1|^^^103^CT-ID^Primary^STM^Rlu|783|RLU||||Final||Super||20131009212529
R|2|^^^103^CT-ID^Primary^STM^Rat|3.69|||||Final||Super||20131009212529
R|3|^^^103^CT-ID^Primary^STM^I|CT-ID+|||||Final||Super||20131009212529
```

[The following records contain information for a specimen tested in replicate and missing patient information:]

```
P|4||||||20131009
O|1|NotFromOrder^ExaPlateCT-ID^B2|NotFromOrder|^^^103^CT-ID||||||||||20131009211415|||||||||||F
M|1|CTKit|20141009
R|1|^^^103^CT-ID^Primary^STM^Rlu|55|RLU||||Final||Super||20131009212529
R|2|^^^103^CT-ID^Primary^STM^Rat|0.25|||||Final||Super||20131009212529
R|3|^^^103^CT-ID^Primary^STM^I|--|||||Final||Super||20131009212529
O|2|NotFromOrder^ExaPlateCT-ID^C2|NotFromOrder|^^^103^CT-ID||||||||||20131009211415|||||||||||F
M|1|CTKit|20141009
R|1|^^^103^CT-ID^Primary^STM^Rlu|67|RLU||||Final||Super||20131009212529
R|2|^^^103^CT-ID^Primary^STM^Rat|0.31|||||Final||Super||20131009212529
R|3|^^^103^CT-ID^Primary^STM^I|--|||||Final||Super||20131009212529
L|1|F
```

3.8.5 Example of data export for a consensus assay protocol with preliminary results

Consensus assay protocols have the option of configuring whether preliminary results are included as part of data export. If preliminary results are included, the final interpreted result is transmitted followed by all of the constituent test results. All of the results are under the patient information record. In the following example, specimen **HPVSpec-01** was tested 3 times before a final result was determined.

Example of a data export for a consensus assay protocol with preliminary results:

```
H|\^&|||HC2^3.4^RCS_SN^9102071007^3.4||||||P|E 1394-97|20131009222651
C|1||Assay protocol High Risk HPV has been encountered. Data for this
assay now follows:|G
[The following records contain information for the calibrators:]
M|1|NC|100^High Risk
HPV|ExaPlateHPV_3^A1|21^22.00^6.43||HPVKit|20141009
M|2|NC|100^High Risk HPV|ExaPlateHPV_3^B1|68^22.00^6.43|Outlier|HPVKit
|20141009
M|3|NC|100^High Risk HPV|ExaPlateHPV_3^C1|23^22.00^6.43||HPVKit|201410
09
M|4|HRC|100^High Risk HPV|ExaPlateHPV_3^D1|254^250.00^6.94||HPVKit|201
41009
M|5|HRC|100^High Risk HPV|ExaPlateHPV_3^E1|265^250.00^6.94||HPVKit|201
41009
M|6|HRC|100^High Risk HPV|ExaPlateHPV_3^F1|231^250.00^6.94||HPVKit|201
41009
[The following records contain information for the quality controls:]
P|1
O|1|QC1-LR^ExaPlateHPV_3^G1||^^^100^High Risk HPV|||||||Q
M|1|HPVKit|20141009|H1Kit|20140804
R|1|^^^100^High Risk HPV^^^Rlu|57|RLU|||||Super||20131009213537
R|2|^^^100^High Risk HPV^^^I|Valid||||||Super||20131009213537
R|3|^^^100^High Risk HPV^^^Rat|0.22||0.00100 - 0.999||||Super||201310
09213537
P|2
O|1|QC2-HR^ExaPlateHPV_3^H1||^^^100^High Risk HPV|||||||Q
M|1|HPVKit|20141009|H2Kit|20140804
R|1|^^^100^High Risk HPV^^^Rlu|926|RLU|||||Super||20131009213537
R|2|^^^100^High Risk HPV^^^I|Valid||||||Super||20131009213537
R|3|^^^100^High Risk HPV^^^Rat|3.70||2.00 - 8.00||||Super||2013100921
3537
P|3|Patient01|||Harker^Jonathan||19500503
```

[The following records contain information for the final interpreted result of the specimen:]

```
O|1|HPVSpec-01^ExaPlateHPV_3^A2||^^^100^High Risk HPV||||||||||2013100
9210545|||||||||||F
```

```
M|1|HPVKit|20141009
```

```
R|1|^^^100^High Risk HPV^Tertiary^PreservCyt^I|High Risk|||||Final||Su
per||20131009213537
```

[The following records contain information for the first test result as indicated by “Primary”:]

```
O|2|HPVSpec-
01^ExaPlateHPV_1^A2||^^^100^High Risk HPV||||||||||20131009210545|||||
||||||P
```

```
M|1|HPVKit|20141009
```

```
R|1|^^^100^High Risk HPV^Primary^PreservCyt^Rlu|255|RLU||||Preliminary
||Super||20131009212859
```

```
R|2|^^^100^High Risk HPV^Primary^PreservCyt^Rat|1.02|||||Preliminary||
Super||20131009212859
```

```
R|3|^^^100^High Risk HPV^Primary^PreservCyt^I|Retest|||||Preliminary||
Super||20131009212859
```

[The following records contain the information for the second test result as indicated by “Secondary”:]

```
O|3|HPVSpec-01^ExaPlateHPV_2^A2||^^^100^High Risk HPV||||||||||2013100
9210545|||||||||||P
```

```
M|1|HPVKit|20141009
```

```
R|1|^^^100^High Risk HPV^Secondary^PreservCyt^Rlu|95|RLU||||Preliminar
y||Super||20131009213249
```

```
R|2|^^^100^High Risk HPV^Secondary^PreservCyt^Rat|0.38|||||Preliminary
||Super||20131009213249
```

```
R|3|^^^100^High Risk HPV^Secondary^PreservCyt^I|Retest|||||Preliminary
||Super||20131009213249
```

[The following records contain the information for the third test result as indicated by “Tertiary”:]

```
O|4|HPVSpec-01^ExaPlateHPV_3^A2||^^^100^High Risk HPV||||||||||2013100
9210545|||||||||||F
```

```
M|1|HPVKit|20141009
```

```
R|1|^^^100^High Risk HPV^Tertiary^PreservCyt^Rlu|765|RLU||||Final||Sup
er||20131009213537
```

```
R|2|^^^100^High Risk HPV^Tertiary^PreservCyt^Rat|3.06|||||Final||Super
||20131009213537
```

```
R|3|^^^100^High Risk HPV^Tertiary^PreservCyt^I|High Risk|||||Final||Su
per||20131009213537
```

```
L|1|F
```

3.8.6 Example of a message for a consensus assay protocol with only final results

Consensus assay protocols have the option of configuring whether preliminary results are included as part of data export. If preliminary results are not included, only the final interpreted result is transmitted. In the following example, specimen **HPVSpec-01** was tested 3 times before a final result was determined.

Example of data export for a consensus assay protocol with only the final result:

```
H|\^&|||HC2^3.4^RCS_SN^9102071007^3.4||||||P|E 1394-97|20131009222703
C|1||Assay protocol High Risk HPV has been encountered. Data for this assay now
 follows:|G
```

[The following records contain information for the calibrators:]

```
M|1|NC|100^High Risk HPV|ExaPlateHPV_3^A1|21^22.00^6.43||HPVKit|20141009
M|2|NC|100^High Risk HPV|ExaPlateHPV_3^B1|68^22.00^6.43|Outlier|HPVKit|20141009
M|3|NC|100^High Risk HPV|ExaPlateHPV_3^C1|23^22.00^6.43||HPVKit|20141009
M|4|HRC|100^High Risk HPV|ExaPlateHPV_3^D1|254^250.00^6.94||HPVKit|20141009
M|5|HRC|100^High Risk HPV|ExaPlateHPV_3^E1|265^250.00^6.94||HPVKit|20141009
M|6|HRC|100^High Risk HPV|ExaPlateHPV_3^F1|231^250.00^6.94||HPVKit|20141009
```

[The following records contain information for the quality controls:]

```
P|1
O|1|QC1-LR^ExaPlateHPV_3^G1||^^^100^High Risk HPV||||||Q
M|1|HPVKit|20141009|H1Kit|20140804
R|1|^^^100^High Risk HPV^^^Rlu|57|RLU|||||Super||20131009213537
R|2|^^^100^High Risk HPV^^^I|Valid||||||Super||20131009213537
R|3|^^^100^High Risk HPV^^^Rat|0.22||0.00100 - 0.999||||Super||20131009213537
P|2
O|1|QC2-HR^ExaPlateHPV_3^H1||^^^100^High Risk HPV||||||Q
M|1|HPVKit|20141009|H2Kit|20140804
R|1|^^^100^High Risk HPV^^^Rlu|926|RLU|||||Super||20131009213537
R|2|^^^100^High Risk HPV^^^I|Valid||||||Super||20131009213537
R|3|^^^100^High Risk HPV^^^Rat|3.70||2.00 - 8.00||||Super||20131009213537
P|3|Patient01|||Harker^Jonathan||19500503
```

[The following records contain information for the final interpreted result of the specimen:]

```
O|1|HPVSpec-01^ExaPlateHPV_3^A2||^^^100^High Risk HPV|||||||||20131009210545||
|||||||||F
M|1|HPVKit|20141009
R|1|^^^100^High Risk HPV^Tertiary^PreservCyt^Rlu|765|RLU||||Final||Super||20131
009213537
R|2|^^^100^High Risk HPV^Tertiary^PreservCyt^Rat|3.06|||||Final||Super||2013100
9213537
R|3|^^^100^High Risk HPV^Tertiary^PreservCyt^I|High Risk|||||Final||Super||2013
10092135374
L|1|F
```

4 Interfacing with an LIS Using HL7 Standards

The *digene* HC2 System Software can be configured to communicate with an LIS in accordance with the Health Level 7 (HL7) and Minimal Low Layer Protocol (MLLP) standards. The *digene* HC2 System Software can communicate with the LIS via an Ethernet network connection using messages that conform to the HL7 standard. The *digene* HC2 System Software will send messages using transmission control protocol (TCP) over the Ethernet network, utilizing the MLLP standard for defining the message transmission.

The *digene* HC2 System Software operates as a client in the client-server model for HL7 communications. The *digene* HC2 System Software initiates all communications with the LIS server and will not accept unsolicited communications.

4.1 Understanding message structure

The *digene* HC2 System Software adheres to HL7 standard version 2.5.1 for transmitting to and receiving messages from an LIS. The HL7 high-level protocol messages are comprised of segments. The segment types and order of segments are determined by the event that triggers the message and are defined in the message structure. Each segment is composed of fields that contain the data pertinent to that segment.

The following table defines the message structure utilized by the *digene* HC2 System Software.

Message structure	Message direction	Message type	Description
ACK	● *digene* HC2 System Software to LIS ● LIS to HC2	General acknowledgment	Acknowledge message receipt
OUL_R22	● *digene* HC2 System Software to LIS	Unsolicited laboratory observation	Send test order results
QBP_Q11	● *digene* HC2 System Software to LIS	Query by parameter	Query for test orders
ACK_Q11	● *digene* HC2 System Software to LIS	Query acknowledgment	Acceptance or rejection of test orders in the query response
RSP_Z90	● LIS to *digene* HC2 System Software	LIS response to query for test orders	Orders returned as a result of the query

The message structure described in the HL7 standard uses a nomenclature of segments and grouping identifiers. A set of square brackets "**[ ]**" indicates that the contained segments are optional but, when provided, must appear in exactly the manner described. A set of curly braces "**{ }**" indicates that the contained segments can be repeated in exactly the defined order. A segment or group of segments can be both optional and repeating as indicated by using both brackets and curly braces. The order of the brackets and curly braces does not matter as either order is equivalent; **{[…]}** and **[{…}]** are equivalent.

Example of a structure message:

```
MSH
PID
[{
  ORC
  OBR
  SPM
}]
```

The example message structure defines that the message must contain an MSH segment followed by a PID segment. The PID segment may optionally be followed by multiple instances of a group composed of an ORC, an OBR and a SPM segments. All members of the repeating segment must be present for each instance of the group.

Only the segments of a message that are required by the *digene* HC2 System Software are defined in this user guide, and additional segments in a message are ignored. The following table describes the segments utilized by the *digene* HC2 System Software.

Segment	Segment type	Description
ERR	Error information	Additional details for an error
MSA	Message acknowledgment	Describes the type of acknowledgment to a message
MSH	Message header	General message information
ORC	Common order	Order control number and status
OBR	Observation request	Order details including test identification
OBX	Observation result	Details the results of a test order
PID	Patient identification	Details on a patient
QPD	Query parameter definition	Contains the query parameters for new orders
QAK	Query acknowledgment	Acknowledges the query
RCP	Response control parameter	Defines the priority of the query
SAC	Specimen container detail	Contains the capture plate ID and well location
SPM	Specimen	Details about a specimen for testing
INV	Inventory detail	Details about lot number and expirations

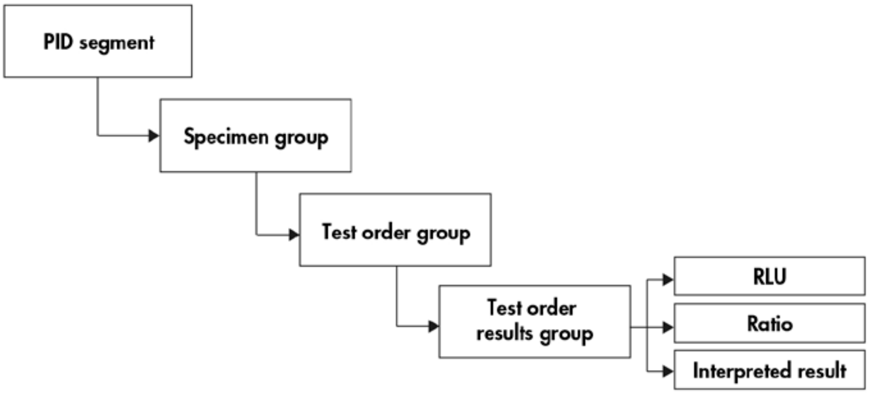
The *digene* HC2 System Software utilizes the MLLP when transmitting data over an Ethernet connection. The *digene* HC2 System Software prepends a vertical tab character (0x0B) at the start of a message transmission, and terminates a message transmission using a file separator character (0x1C) followed by a carriage return (0x0D). The LIS is expected to use the same formatting when transmitting messages to the *digene* HC2 System Software.

4.1.1 Exporting non-consensus assay protocol results

For specimens tested using a non-consensus assay protocol, the following records are sent for each specimen:

- PID segment
- Specimen group
- Test order group
- Test order results group
  - The RLU result
  - The ratio result
  - The interpreted result

Structure of records exported for a non-consensus assay protocol result:



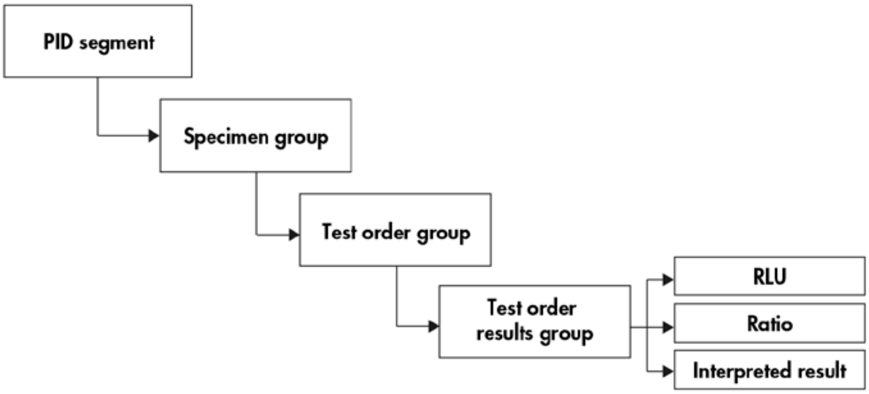
4.1.2 Exporting non-derived consensus assay protocol results

For a non-derived consensus assay protocol result, the configurable setting determining if preliminary results are transmitted affects the records sent to the LIS. If configured to not include preliminary results, the *digene* HC2 System Software transmits only the derived result and does not transmit the constituent records.

If preliminary results are not included, the following records are exported for each specimen:

- PID segment
- Specimen group
- Test order group
- Test order results group
    - The RLU result
    - The ratio result
    - The interpreted result

Structure of records exported for a non-derived consensus assay protocol results with preliminary results not included:

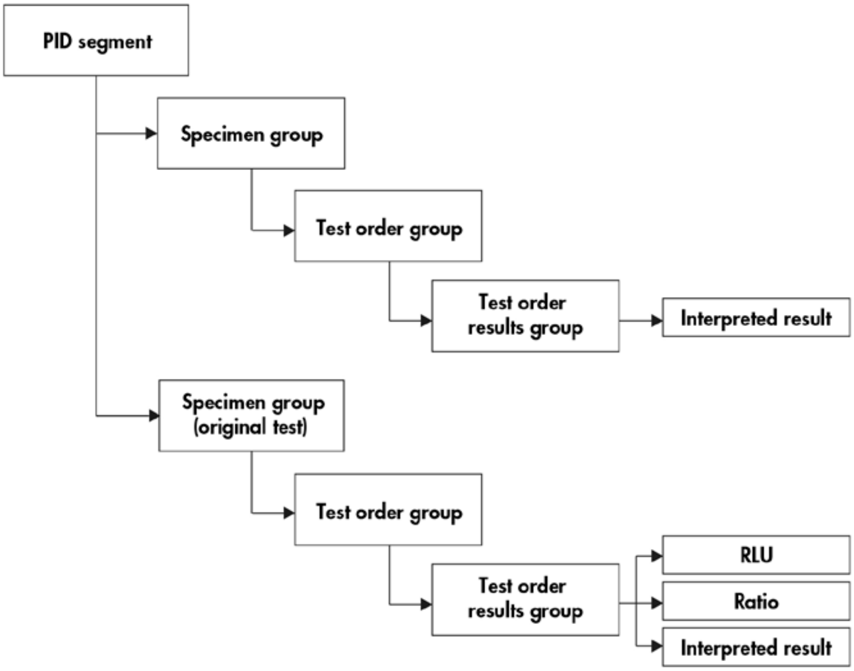


If preliminary results are included, the derived result is sent first. Following the derived result, the constituent measurement records are sent.

If preliminary results are included, the following records are exported for each specimen:

- PID segment (derived result)
- Specimen group (derived result)
- Test order group (derived result)
- Test order results group (derived result)
    - The interpreted result (derived result)
- Specimen group (constituent result)
- Test order group (constituent result)
- Test order results group (constituent result)
    - The RLU result (constituent result)
    - The ratio result (constituent result)
    - The interpreted result (constituent result)

Structure of records exported for a non-derived consensus assay protocol results with preliminary results included:



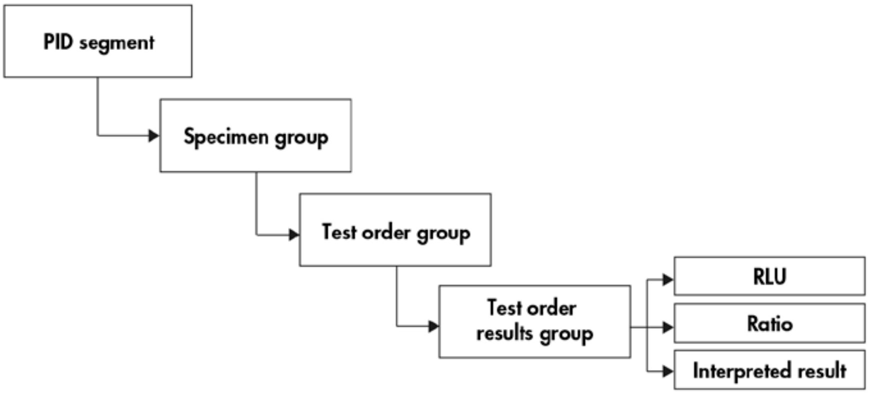
4.1.3 Exporting derived consensus assay protocol results

For a derived consensus assay protocol result, the configurable setting determining if preliminary results are transmitted affects the records sent to the LIS. If configured to not include preliminary results, the *digene* HC2 System Software transmits only the derived result and does not transmit the constituent records.

If preliminary results are not included, the following records are exported for each specimen:

- PID segment
- Specimen group
- Test order group
- Test order results group
  - The RLU result
  - The ratio result
  - The interpreted result

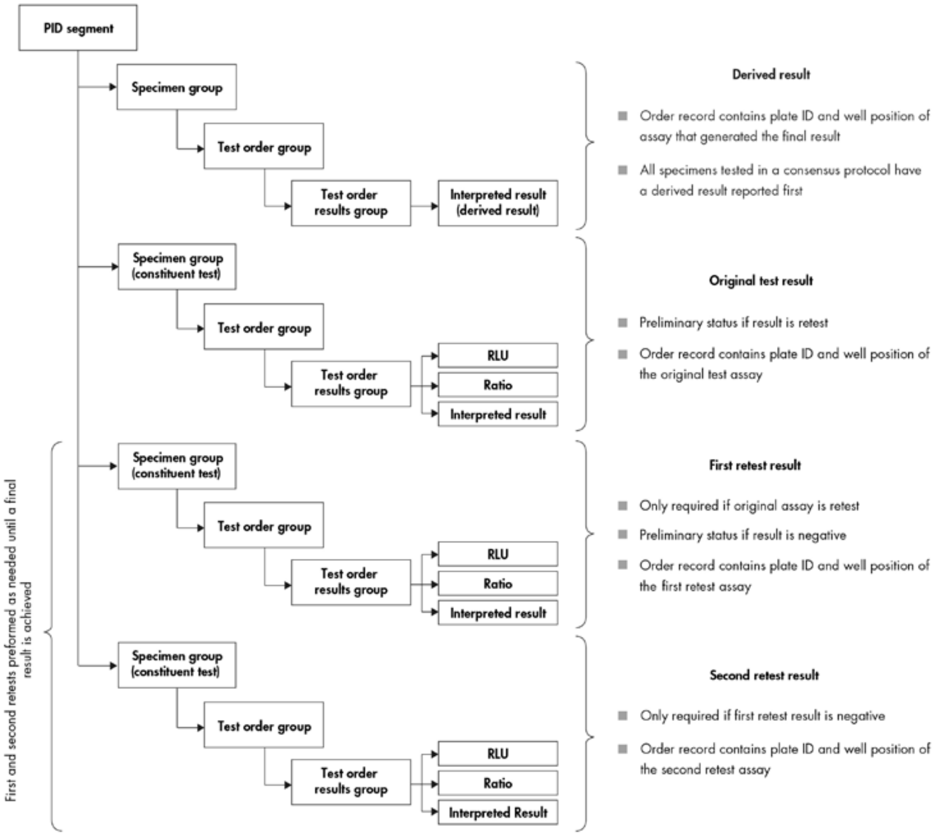
Structure of records exported for a derived consensus assay protocol results with preliminary results not included:



If preliminary results are included, the records are transmitted for each constituent test performed. The maximum number of constituent tests, as defined by the retest algorithm, is three. The following minimum records are exported for each specimen:

- PID segment (derived result)
- Specimen group (derived result)
- Test order group (derived result)
- Test order results group (derived result)
    - The interpreted result (derived result)
- Specimen group (constituent result)
- Test order group (constituent result)
- Test order results group (constituent result)
    - The RLU result (constituent result)
    - The ratio result (constituent result)
    - The interpreted result (constituent result)

Structure of records exported for a derived consensus assay protocol results with preliminary results included:



Derived result

- Order record contains plate ID and well position of assay that generated the final result
- All specimens tested in a consensus protocol have a derived result reported first

Original test result

- Preliminary status if result is retest
- Order record contains plate ID and well position of the original test assay

First retest result

- Only required if original assay is retest
- Preliminary status if result is negative
- Order record contains plate ID and well position of the first retest assay

Second retest result

- Only required if first retest result is negative
- Order record contains plate ID and well position of the second retest assay

4.1.4 Exporting data for QNS specimens

Specimens with a status of quantity not sufficient (QNS) will export only one result record for the interpreted result; no result records for the RLU or ratio result are sent as the well on the plate was not measured. The result is flagged as manually entered as a user set the specimen to QNS in the *digene* HC2 System Software.

Structure of records exported for a specimen with a result of QNS:

4.1.5 Exporting data of unclear or invalid specimens

If a plate was created from the output file of a pre-analytical system, specimens with a result status of unclear or invalid are not transmitted. Refer to digene *HC2 System Software User Manual* for additional information about specimens with a result status of unclear or invalid.

4.1.6 Understanding patient data

Patient data are optional fields that can be populated using the *digene* HC2 System Software or sent from the LIS as a response to a query made by the *digene* HC2 System Software. The *digene* HC2 System Software accepts the following patient data fields:

- Patient ID
- First name
- Last name
- Birth date
- Gender

Regardless of how patient data are populated, patient data are included when present. When transmitting test results, modifications made in the *digene* HC2 System Software are communicated to the LIS. An empty patient record is transmitted for specimens without patient data.

4.1.7 Understanding quality control data

Quality control records are sent in the same general format as specimen records in an unsolicited laboratory observation (OUL) message. Field SPM 4 of contains a designation of **QC** to indicate the record is for a quality control. Several other fields have modifications specific to quality controls and these fields are detailed in the descriptions of the applicable fields. As with specimens, a separate result record is generated for each result exported.

4.1.8 Understanding calibrator data

Calibrator records are sent in the same general format as specimen records in an unsolicited laboratory observation (OUL) message. Field SPM 4 of contains a designation of **CAL** to indicate the record is for a calibrator. Several other fields have modifications specific to calibrators and these fields are detailed in the descriptions of the applicable fields. As with specimens, a separate result record is generated for each result exported.

4.1.9 Exporting data for failed assays

An assay that does not meet the defined parameters of an assay protocol will result in a failed assay. An assay can fail by either the calibrators or the quality controls failing the defined parameters of an assay protocol. The results of specimens contained on a failed plate cannot be accepted, and consequently the specimen results are not exported.

Whether the data of calibrators and quality controls on a failed assay are exported is determined by the settings in the *digene* HC2 System Software. To modify the setting, refer to digene *HC2 System Software User Manual* for additional instructions.

Depending on the cause of the invalid assay, different data for the calibrators and quality controls are exported. If the calibrators not meeting the defined parameters of an assay protocol are the cause of the failed assay, the calibrator data is exported. For the quality controls, only the result record for the RLU result is exported. If the quality controls not meeting the defined parameters of an assay protocol are the cause of the failed assay, all calibrator and quality control data are exported. For the quality controls, result records are sent for the RLU, ratio and interpretative results. The interpretative result will define the quality control as invalid.

If a plate was created from the output file of a pre-analytical system and the quality controls are not valid, only the interpretive result is exported. The interpretative result will define the quality control as invalid. Refer to digene *HC2 System Software User Manual* for additional information about plates created from the output file of a pre-analytical system.

4.2 General message acknowledgment

Both the *digene* HC2 System Software and the LIS respond to messages with a general message acknowledgment (ACK). The ACK communicates to the sender that the message was received. The content of the ACK details if the message will be processed or rejected. The ACK must be received within 20 seconds or the transaction is cancelled.

The following table defines the segments of the ACK.

Segment	Cardinality	Segment name
MSH	1	Message header segment
MSA	1	Message acknowledgment segment
{ERR}	0..*	Error segment

4.2.1 Message header segment

The following table describes the fields of the MSH segment.

HL7 field	Field name	Transmitted	Description
MSH-1	Field separator	Character	Defines the separator used between fields The field is set to **|**
MSH-2	Encoding characters		Encoding characters used in the message; these values should always be used
	Component	Character	The field is set to **^**
	Repetition	Character	The field is set to **~**
	Escape	Character	The field is set to ****
	Subcomponent	Character	The field is set to **&**

HL7 field	Field name	Transmitted	Description
	Sending application		Uniquely identifies the sending application; for messages originating from the LIS, the LIS provides its own identifier
MSH-3.1	Namespace	String	The field is set to **QIAGEN**
MSH-3.2	Universal ID	String	The field is set to **^HC2 3.4**
MSH-4–MSH-6	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-7	Date and time of message	String	Timestamp the message was created using "YYYYMMDDHHmmss" format
MSH-8	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Message type		Indicates the message is an acknowledgment to the triggering event TTT, where TTT is the trigger event code from the originating message
MSH-9.1	Message code	String	The field is set to **ACK**
MSH-9.2	Trigger event	String	
MSH-9.3	Structure	String	The field is set to **^ACK**
MSH-10	Message control ID	String	The *digene* HC2 System Software uses a unique ID for this field to identify the message; the value is copied to the MSA-2 field of the MSA message
MSH-11	Processing ID	Character	The setting **P** is for production operation The field is set to **P**
MSH-12	Version ID	String	Version of the specification in use The field is set to **2.5.1**

HL7 field	Field name	Transmitted	Description
MSH-13–MSH-17	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-18	Character set	String	Specifies the standard used to encode the message The field is set to **UNICODE UTF-8**

4.2.2 Message acknowledgment segment

The message acknowledgment segment (MSA) details the receiving system's type of acknowledgment to the sending system. An accepted message will be processed, but it is not guaranteed that the *digene* HC2 System Software will complete the processing of the message. Messages that exceed the allowable HL7 field lengths, include unknown table values or are improperly formatted are acknowledged with an error code (AE). Messages that contain instructions that cannot be completed by the *digene* HC2 System Software are acknowledged with a reject code (AR).

HL7 field	Field name	Transmitted	Description
MSA-1	Acknowledgement code	String	Use **AA** for accept; use **AE** for message format or content error; use **AR** for message rejected The field is set to **AA**
MSA-2	Message control ID	String	Matches the MSH-10 field of the MSH message that is being acknowledged

4.2.3 Error segment

If the MSA segment indicates the sender's message contains errors or is rejected, the message will include error segments. The error segments provide further details on the reason for the message error or rejection.

The handling of errors by the *digene* HC2 System Software is divided into either protocol errors or data errors. Protocol errors describe messages that are corrupted in transmission or are unable to be parsed using the generalized HL7 message format. Examples of protocol errors include a missing segment, incorrect delimiting or corrupt packet. Data errors describe messages that are valid, but the content of one or more fields is not as expected by the *digene* HC2 System

Software. Data errors result in the message being acknowledged without an error, but an order rejection is sent. See "Reject test orders," page 92, for additional information.

HL7 field	Field name	Transmitted	Description
ERR-1–ERR-2	N/A	N/A	Null fields; indicate field positions with "|", omit if last character of a message
ERR-3	HL7 error code	Integer	Values defined according to the following: 0357 0 — Message accepted 0357 100 — Segment sequence error 0357 101 — Required field missing 0357 102 — Data type error 0357 103 — Table value not found 0357 200 — Unsupported message type 0357 201 — Unsupported event code 0357 202 — Unsupported processing id 0357 203 — Unsupported version id 0357 204 — Unknown key identifier 0357 205 — Duplicate key identifier 0357 206 — Application record locked 0357 207 — Application internal error
ERR-4	Severity	Character	Use **F** for a fatal error; the initiating message will not be processed The field is set to **F**

4.3 Sending test results

The *digene* HC2 System Software can export test results using the unsolicited laboratory observation (OUL) message. The message utilizes the OUL_R22 message structure.

A defined container message for the contents of an entire capture plate is not available. All results for a capture plate are sent as sequential, self-contained OUL messages containing information for each specimen. Preliminary and replicate specimens are transmitted in individual OUL messages; however, no results are sent until a final result is determined. The *digene* HC2 System Software is configurable to include or exclude preliminary results from being exported.

Segment	**Cardinality**	**Segment name**
MSH	1	Message header segment
[PID]	0..1	Patient Identification Segment
{	1..*	Specimen group
SPM	1	Specimen segment
{	1..*	Container group
[SAC]	0..1	Specimen container detail segment (optional)
[INV]	0..*	Inventory detail segment (optional)
{	1..*	Test order group
OBR	1	Observation request segment
ORC	1	Common order segment
{	1..*	Test order results group
{OBX}	1..*	Observation result segment(s)
}		
}		
}		
}		

4.3.1 Message header segment

The following table describes the fields of the MSH segment.

HL7 field	Field name	Transmitted	Description
MSH-1	Field separator	Character	Defines the separator used between fields The field is set to **|**
MSH-2	Encoding characters		Encoding characters used in this message; these values should always be used
	Component	Character	The field is set to **^**
	Repetition	Character	The field is set to **~**
	Escape	Character	The field is set to ****
	Subcomponent	Character	The field is set to **&**
	Sending application		Uniquely identifies the sending application
MSH-3.1	Namespace	String	The field is set to **QIAGEN**
MSH-3.2	Universal ID	String	The field is set to **^HC2 3.4**
MSH-4–MSH-6	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-7	Date and time of message	String	Timestamp the message was created using “YYYYMMDDHHmmss” format
MSH-8	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message

HL7 field	Field name	Transmitted	Description
	Message type		Indicates the message type, triggering event, and the structure of the message
MSH-9.1	Message code	String	The field is set to **OUL**
MSH-9.2	Trigger event	String	The field is set to **^R22**
MSH-9.3	Structure	String	The field is set to **^OUL_R22**
MSH-10	Message control ID	String	The *digene* HC2 System Software uses a unique ID for this field to identify the message; the value is copied to the MSA-2 field of the MSA message
MSH-11	Processing ID	Character	The setting **P** is for production operation The field is set to **P**
MSH-12	Version ID	String	Version of the specification in use The field is set to **2.5.1**
MSH-13–MSH-17	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-18	Character set	String	Specifies the standard used to encode the message The field is set to **UNICODE UTF-8**

4.3.2 Patient identification segment

When sending calibrator and control results, the patient identification (PID) segment contains no information other than the PID-1 field. The HL7 specification requires PID-3.1 and PID-3.5 fields are sent. The exclusion of those fields occurs because in the context of calibrator and control results patient identification is not applicable.

The following table describes the fields of the PID segment.

HL7 field	Field name	Transmitted	Description
PID-1	Set ID-PID	Integer	Index of the patient within the collection of patients The field is set to **1**
PID-2	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Patient identifier list		Identifier for the patient
PID-3.1	ID number	String	
PID3.2–PID3.4	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
PID-3.5	Identifier code	String	If the patient does not have a test order from the LIS the identifier code will be **U**
PID-4	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Patient name		Name of the patient
PID-5.1	Family name	String	Last name of the patient
PID-5.2	Given name	String	First name of the patient
PID-6	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
PID-7	Date of birth	String	Date of birth using "YYYYMMDD" format
PID-8	Gender	Character	Use **M** for male or **F** for female; if a code is not recognized by the *digene* HC2 System Software, null will be reported

4.3.3 Specimen segment

The following table describes the fields of the specimen (SPM) segment.

HL7 field	Field name	Transmitted	Description
SPM-1	Set ID	Integer	Index of the specimen within the collection of specimens The field is set to **1**
	Specimen ID		The LIS ID will be present and match the *digene* HC2 System Software ID for specimen IDs received or confirmed by the LIS The absence of a value for the LIS ID indicates that the *digene* HC2 System Software ID may be unknown to the LIS
SPM-2.1	LIS ID	String	For calibrators and quality controls, the LIS ID is always null
SPM-2.2	*digene* HC2 System Software ID	String	The ID for the specimen, calibrator, or quality control in the *digene* HC2 System Software
SPM-3	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Specimen type		Describes the specimen type
SPM-4.1	Identifier	Null	Null field; indicate field position with **|**, omit if last character of a message
SPM-4.2	Text	String	For calibrators use **CAL**; for quality controls use **QC**; for specimens use **specimen type** The specimen type is reported as the type defined in the *digene* HC2 System Software, which is unknown at the time the test order is received If the SPM segment is part of a query response, then the SPM 4 field should be null or will be ignored

HL7 field	Field name	Transmitted	Description
SPM-5–SPM-17	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
SPM-18	Specimen received date/time	String	The timestamp of when the specimen was entered into the *digene* HC2 System Software; null for calibrator and quality controls

4.3.4 Specimen container detail segment

The optional specimen container detail (SAC) segment describes the plate ID and well location of the test.

The following table describes the fields of the SAC segment.

HL7 field	Field name	Transmitted	Description
SAC-1–SAC-9	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
SAC-10	Carrier identifier	String	Capture plate ID
SAC-11–SAC-14	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
SAC-15	Location	String	Well location on the capture plate in the format of row first, column second

4.3.5 Inventory detail segment

The following table describes the fields of the optional inventory detail (INV) segment.

HL7 field	**Field name**	**Transmitted**	**Description**
	Substance identifier		Lot number
INV-1.1	Identifier	Null	Null field; indicate field position with **|**, omit if last character of a message
INV-1.2	Text	String	For a specimen or calibrator, it is the kit lot number; for a quality control it is the quality control lot number
INV-2	Substance status	String	Use **OK** for unexpired; use **EE** for expired
	Substance type		
INV-3.1	Identifier	Null	Null field; indicate field position with **|**, omit if last character of a message
INV-3.2	Text	String	For a specimen or calibrator, use **KIT**; for a quality control use **QC**
INV-4–INV-11	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
INV-12	Expiration date/time	String	Expiration date of the item in the format of “YYYYMMDDHHmmss”

4.3.6 Observation request segment

The following table describes the fields of the observation request (OBR) segment.

HL7 field	**Field name**	**Transmitted**	**Description**
OBR-1	Set ID	Integer	The *digene* HC2 System Software only returns one OBR segment per specimen The field is set to **1**
OBR-2	Placer order number	String	Identifies the placer of the order; originates as the OBR-2 field of the LIS response to a query for test orders message For test orders generated manually at the instrument, this field will be null
OBR-3	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Universal service identifier		The assay protocol defined in the *digene* HC2 System Software
OBR-4.1	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
OBR-4.2	Test name	String	The assay protocol ID defined in the *digene* HC2 System Software
OBR 4.3	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
OBR 4.4	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
OBR 4.5	Alternate test name	String	The mapped name from the *digene* HC2 System Software
OBR-5–OBR-21	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message

HL7 field	Field name	Transmitted	Description
OBR-22	Results report/status change date/time	String	Timestamp when the measurement was taken by the instrument in the format of "YYYYMMDDHHmmss"
OBR-23–OBR-24	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
OBR-25	Result status	Character	Use **F** for final; use null for calibrators and quality controls The field is set to **F**

4.3.7 Common order segment

The following table describes the fields of the observation request (ORC) segment.

HL7 field	Field name	Transmitted	Description
ORC-1	Order control	String	Indicates that the results of this order are ready and will appear in a following OBX segment The field is set to **RE**
ORC-2	Placer order number	String	Identifies the placer of the order; originates as the OBR-2 field of the LIS response to a query for test orders message
ORC-3–ORC-5	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
ORC-6	Response flag	Character	Only the **Exception Response** is used; the *digene* HC2 System Software will ignore all responses The field is set to **E**

4.3.8 Observation result segment

A valid specimen result in the *digene* HC2 System Software contains 3 values as follows:

- The relative light units (RLU) value as measured by the DML instrument
- The ratio of the RLU to the assay cutoff (CO)
- The interpreted result for the specimen as defined by the assay protocol:
  See "Understanding the assigned assay protocol codes," page 8, for additional information.

Each of the result values are included in a separate observation result (OBX) segment. The following table describes the fields of the OBX segment.

HL7 field	**Field name**	**Transmitted**	**Description**
OBX-1	Set ID	Integer	Index of this OBX segment in a collection of OBX segments The field is set to **1**
OBX-2	Value type	String	Use **ST** for string data; use **NM** for numerical data **ST** is used for calibrators
OBX-3	Observation ID	String	The type of result being returned; use **Rlu** for the relative light unit value, use **Rat** for the ratio of RLU/CO, use **I** for the interpreted result, use null for calibrators
OBX-4	Observation sub-ID	String	The cutoff factor class used in determining the result; either **primary**, **secondary** or **tertiary**, null for calibrators and quality controls
OBX-5	Observation value	String/numeric	The test result value; null for calibrators
OBX-6	Units	String	Use **RLU** for RLU values; not used for ratio and interpreted results
OBX-7	Reference ranges	String	Range and statics for quality controls and calibrators; null for specimens For calibrators, information is provided in **[RLU]:[Mean]:[%CV]**; example: **126:130:25.4** For quality controls, information is provided in **[low ratio] – [high ratio]**; example: **2.0 – 8.0**

HL7 field	Field name	Transmitted	Description
OBX-8	Abnormal flags	String	Flags for results; use **N** for normal, use **CO** for calibrator outlier, use **QL** for a quality control outside of limit
OBX-9–OBX-10	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
OBX-11	Observation result status	Character	Use **F** for final result; use **P** for preliminary result; null for calibrators and quality controls
OBX-12–OBX-13	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
OBX-14	Date/time of the observation	String	Timestamp when the measurement was taken by the instrument in "YYYYMMDDHHmmss" format Null for calibrators
OBX-15	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
OBX-16	Responsible observer	String	User ID of the *digene* HC2 System Software user that added the assay to the plate Null for calibrators
OBX-17	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
OBX-18	Equipment instance ID	String	Serial number of the DML instrument performing the test; contains **Manually Entered** for tests with the measurement value was entered by the user Null for calibrators

4.4 Query for test orders

A query by the *digene* HC2 System Software for test orders includes the list of tests the *digene* HC2 System is configured to test as well as a date and time range. The LIS will respond with a list of new test orders corresponding to the supported tests in the specified date and time range. The date and time range specified is with respect to the time zone of the LIS.

The query message sent to the LIS by the *digene* HC2 System Software conforms to the QBP_Q11 Query by Parameter message structure defined in the HL7 standard. The following table defines the segments of a query message.

Segment	Cardinality	Segment name
MSH	1	Message header segment
QPD	1	Query parameter definition segment
RCP	1	Response control parameter segment

4.4.1 Message header segment

The following table describes the fields of the MSH segment.

HL7 field	Field name	Transmitted	Description
MSH-1	Field separator	Character	Defines the separator used between fields The field is set to **|**
MSH-2	Encoding characters		Encoding characters used in the message; these values should always be used
	Component	Character	The field is set to **^**
	Repetition	Character	The field is set to **~**
	Escape	Character	The field is set to ****
	Subcomponent	Character	The field is set to **&**

HL7 field	Field name	Transmitted	Description
	Sending application		Uniquely identifies the sending application
MSH-3.1	Namespace	String	The field is set to **QIAGEN**
MSH-3.2	Universal ID	String	The field is set to **^HC2 3.4**
MSH-4–MSH-6	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-7	Date and time of message	String	Timestamp the message was created using "YYYYMMDDHHmmss" format
MSH-8	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Message type		Indicates the message type, triggering event and the structure of the message
MSH-9.1	Message code	String	The field is set to **QBP**
MSH-9.2	Trigger event	String	The field is set to **^Q11**
MSH-9.3	Structure	String	The field is set to **^QBP_Q11**
MSH-10	Message control ID	String	The *digene* HC2 System Software uses a unique ID for this field to identify the message; the value specified here is copied to the MSA-2 field of the response segment from the LIS
MSH-11	Processing ID	Character	The setting **P** is for production operation The field is set to **P**
MSH-12	Version ID	String	Version of the specification in use The field is set to **2.5.1**

HL7 field	Field name	Transmitted	Description
MSH-13–MSH-17	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-18	Character set	String	Specifies the standard used to encode the message The field is set to **UNICODE UTF-8**

4.4.2 Query parameter definition segment

The following table describes the fields of the query parameter definition (QPD) segment.

HL7 field	Field name	Transmitted	Description
QPD-1	Query name	String	Name of the query to run The field is set to **Z_HC2_01**
QPD-2	Query tag	String	The *digene* HC2 System Software will use a unique ID for this field to identify the message; the value will be exactly copied to the QAK-1 response segment
QPD-3	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
QPD-4	Begin date	String	The LIS will only return test orders entered on or after this date in the LIS Format of "YYYYMMDD"
QPD-5	End date	String	The LIS will only return test orders entered on or prior to this date in the LIS The *digene* HC2 System Software will provide a 7-day range with the current date as the end date

HL7 field	Field name	Transmitted	Description
	Universal service identifier		The mapped value for the requested assay protocol; for multiple assay protocols additional parameters will be specified using the repeat delimiter **~** to request multiple supported assays Example: **^CT~^GC** - CT is mapped to CT-ID, and GC is mapped to GC-ID
QPD-6.1	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
QPD-6.2	Test name	String	Mapped value for the requested assay protocol

4.4.3 Response control parameter segment

The following table describes the field of the response control parameter (RCP) segment.

HL7 field	Field name	Transmitted	Description
RCP-1	Query priority	Character	Indicates the response is requested immediately The field is set to **I**

4.5 LIS response to a query for test orders

When the *digene* HC2 System Software sends a query message, the LIS will respond with a segment pattern response using the RSP_Z90 message structure. The *digene* HC2 System Software will maintain the connection to the LIS until a response is received or the *digene* HC2 System Software is exited. The response message must be sent to the *digene* HC2 System Software on the same connection used to make the query and the *digene* HC2 System Software will timeout if a response is not received in 40 seconds.

The following table details the segments of the RSP message. The grouping of the specimen group is separate from the order group. A specimen will be created for each order contained in the order group. Additionally, all SPM segments must be after the last OBR segment, otherwise the SPM segments are considered part of an undefined patient order.

Segment	Cardinality	Segment name
MSH	1	Message header segment
MSA	1	Message acknowledgment segment
QAK	1	Query acknowledgment segment
QPD	1	Query parameter definition segment
{	0..*	Response group
PID	1	Patient identification segment
{	1..*	Order group
ORC	1	Common order segment
OBR	1	Observation request segment
}		
{	1..*	Specimen group
SPM	1	Specimen segment
}		
}		

4.5.1 Message header segment

The following table describes the fields of the MSH segment.

HL7 field	Field name	Received	Description
MSH-1	Field separator	Character	Defines the separator used between fields The field is set to **|**
MSH-2	Encoding characters		Encoding characters used in the message; these values should always be used
	Component	Character	The field is set to **^**
	Repetition	Character	The field is set to **~**
	Escape	Character	The field is set to ****
	Subcomponent	Character	The field is set to **&**
MSH-3	Sending application	String	Uniquely identifies the sending application; varies by installation
MSH-4–MSH-6	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-7	Date and time of message	String	Timestamp the message was created using "YYYYMMDDHHmmss" format
MSH-8	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Message type		Indicates the message type, triggering event and the structure of the message
MSH-9.1	Message code	String	The field is set to **RSP**
MSH-9.2	Trigger event	String	The field is set to **^Z90**
MSH-9.3	Structure	String	The field is set to **^RSP_Z90**

HL7 field	Field name	Received	Description
MSH-10	Message control ID	String	The received value is copied to the MSA-2 field of the response segment
MSH-11	Processing ID	Character	The setting **P** is for production operation The field is set to **P**
MSH-12	Version ID	String	Version of the specification in use The field is set to **2.5.1**
MSH-13–MSH-17	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-18	Character set	String	Specifies the standard used to encode the message The field is set to **UNICODE UTF-8**

4.5.2 Message acknowledgment segment

The message acknowledgment segment (MSA) details the receiving system's type of acknowledgment to the sending system. An accepted message will be processed, but it is not guaranteed that the *digene* HC2 System Software will complete the processing of the message. Messages that exceed the allowable HL7 field lengths, include unknown table values or are improperly formatted are acknowledged with an error code (AE). Messages that contain instructions that cannot be completed by the *digene* HC2 System Software are acknowledged with a reject code (AR).

The following table describes the fields of the MSA segment.

HL7 field	Field name	Received	Description
MSA-1	Acknowledgement code	String	Use **AA** for accept; use **AE** for message format or content error; use **AR** for message rejected The field is set to **AA**
MSA-2	Message control ID	String	Matches the MSH-10 field of the message being acknowledged

4.5.3 Query acknowledgment segment

The following table describes the fields of the QAK segment.

HL7 field	Field name	Received	Description
QAK-1	Query tag	String	Identifier given in the query request; must match the QPD-2 field of the QPD segment
QAK-2	Query response status	String	Indicates the result of executing the query Use **OK** for data found, no errors; use **NF** for no data found, no errors; use **AE** for application error; use **AR** for application reject
QAK-3	Message query name	String	Name of the query; must match QPD-1 of the QPD segment of the query for test orders

4.5.4 Query parameter definition segment

The following table describes the fields of the QPD segment.

HL7 field	Field name	Received	Description
QPD-1	Query name	String	Name of the query ran The field is set to **Z_HC2_01**
QPD-2	Query tag	String	Identifier specified in query for test orders
QPD-3	Begin date	String	Date specified in query for test orders Format of "YYYYMMDD"
QPD-4	End date	String	Date specified in query for test orders Format of "YYYYMMDD"

HL7 field	Field name	Received	Description
	Universal service identifier		For multiple assay protocols, additional parameters will be specified using the repeat delimiter **~**
QPD-5.1	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
QPD-5.2	Test name	String	Universal service identifier specified in query for test orders

4.5.5 Patient identification segment

The LIS response to a query for test orders message includes one or more response groups starting with a patient identification (PID) segment. The PID segment is optional, but if it is included, the PID-3.1 field is required.

The following table describes the fields of the PID segment.

HL7 field	Field name	Received	Description
PID-1	Set ID	Integer	Index of the patient in LIS response to query for test orders The field is set to **1**
PID-2	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Patient identifier list		Unique identifier for the patient
PID-3.1	ID number	String	The *digene* HC2 System Software restricts the format of this field; see "Understanding field format and restrictions", page 13,for additional information
PID-4	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message

HL7 field	Field name	Received	Description
	Patient name		Name of the patient The *digene* HC2 System Software restricts the format of this field; see "Understanding field format and restrictions", page 13, for additional information
PID-5.1	Family name	String	Last name of the patient
PID-5.2	Given name	String	First name of the patient
PID-6	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
PID-7	Date of birth	String	Date of birth using "YYYYMMDD" format If a time is given, the *digene* HC2 System Software will ignore it
PID-8	Gender	Character	Use **M** for male or **F** for female; if a code is not recognized by the *digene* HC2 System Software, null will be reported

4.5.6 Common order segment

The following table describes the fields of the ORC segment.

HL7 field	Field name	Received	Description
ORC-1	Order control	String	Use **NW** to indicate the order as new; all other values are rejected The field is set to **NW**
ORC-2	Placer order number	String	Matches the same as the OBR 2 field of the OBR segment

4.5.7 Observation request segment

The test name field of the test order specifies which assay protocol will be used in the *digene* HC2 System Software based on the configuration. Assay protocols must be mapped according to the parameters for the query to occur. Refer to digene *HC2 System Software User Manual* for additional instructions.

The following table describes the fields of the observation request (OBR) segment.

HL7 field	**Field name**	**Received**	**Description**
OBR-1	Set ID	Integer	Index of the OBR in a collection of OBR segments
OBR-2	Placer order number	String	Identifies the placer of the order
OBR-3	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Universal service identifier		The mapped value for the requested assay protocol
OBR-4.1	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
OBR-4.2	Test name	String	The mapped value for the requested assay protocol Example: **^CT** is mapped to CT-ID assay protocol

4.5.8 Specimen segment

The following table describes the fields of the specimen (SPM) segment.

HL7 field	**Field name**	**Received**	**Description**
SPM-1	Set ID	Integer	Index of the specimen within the collection of specimens The field is set to **1**
SPM-2	Specimen ID	String	Unique identifier of the specimen The *digene* HC2 System Software restricts the format of this field; see "Understanding field format and restrictions", page 13,for additional information

4.6 Reject test orders

The *digene* HC2 System Software responds to the LIS response to a query for test orders with an acknowledgment that the message is formed well. If the *digene* HC2 System Software cannot complete a test order or the test order has errors, the *digene* HC2 System Software returns a test order results message with a status of rejected.

The *digene* HC2 System Software utilizes the unsolicited laboratory observation (OUL) message to send the rejection to the LIS. The message utilizes the OUL_R22 message structure.

The following table details the segments of the OUL message.

Segment	Cardinality	Segment name
MSH	1	Message header segment
[PID]	0..1	Patient identification segment
{	1..*	Specimen group
SPM	1	Specimen segment
{	1..*	Container group
OBR	1	Observation request segment
ORC	1	Common order segment
}		
}		

4.6.1 Message header segment

The following table describes the fields of the MSH segment.

HL7 field	Field name	Transmitted	Description
MSH-1	Field separator	Character	Defines the separator used between fields The field is set to **|**
MSH-2	Encoding characters		Encoding characters used in the message; these values should always be used
	Component	Character	The field is set to **^**
	Repetition	Character	The field is set to **~**
	Escape	Character	The field is set to ****
	Subcomponent	Character	The field is set to **&**

HL7 field	Field name	Transmitted	Description
	Sending application		Uniquely identifies the sending application
MSH-3.1	Namespace	String	The field is set to **QIAGEN**
MSH-3.2	Universal ID	String	The field is set to **^HC2 3.4**
MSH-4–MSH-6	N/A	N/A	Null fields; indicate field position with **|**, omit if last character of a message
MSH-7	Date and time of message	String	Timestamp the message was created using “YYYYMMDDHHmmss” format
MSH-8	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Message type		Indicates the message type, triggering event and the structure of the message
MSH-9.1	Message code	String	The field is set to **OUL**
MSH-9.2	Trigger event	String	The field is set to **^R22**
MSH-9.3	Structure	String	The field is set to **^OUL_R22**
MSH-10	Message control ID	String	The *digene* HC2 System Software uses a unique ID for this field to identify the message; the value will be used for the MSA-2 field response segment from the LIS
MSH-11	Processing ID	Character	The setting **P** is for production operation The field is set to **P**
MSH-12	Version ID	String	Version of the specification in use The field is set to **2.5.1**

HL7 field	Field name	Transmitted	Description
MSH-13–MSH-17	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
MSH-18	Character set	String	Specifies the standard used to encode the message The field is set to **UNICODE UTF-8**

4.6.2 Patient identification segment

The patient identification segment is omitted when sending calibrator and quality control results.

The following table describes the fields of the PID segment.

HL7 field	Field name	Transmitted	Description
PID-1– PID-2	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
PID-3	Patient identifier list	String	Matches the value received in the test order
PID-4	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Patient name		Name of the patient
PID-5.1	Family name	String	Last name of the patient
PID-5.2	Given name	String	First name of the patient
PID-6	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
PID-7	Date of birth	String	Date of birth using "YYYYMMDD" format
PID-8	Gender	Character	Use **M** for male or **F** for female; if a code is not recognized by the *digene* HC2 System Software, null will be reported

4.6.3 Specimen segment

The following table describes the fields of the specimen (SPM) segment.

HL7 field	Field name	Transmitted	Description
SPM-1	Set ID	Integer	Index of the specimen within the collection of specimens The field is set to **1**
	Specimen ID		Identifier for the specimen within the assay protocol
SPM-2.1	LIS ID	String	

4.6.4 Observation request segment

The following table describes the fields of the observation request (OBR) segment.

HL7 field	Field name	Transmitted	Description
OBR-1	Set ID	Integer	Index of the OBR in a collection of OBR segments
OBR-2	Placer order number	String	Identifies the placer of the order
OBR-3	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
	Universal service identifier		The mapped value for the requested assay protocol
OBR-4.1	N/A	N/A	Null field; indicate field position with **|**, omit if last character of a message
OBR-4.2	Test name	String	The mapped value for the requested assay protocol Example: **^CT** is mapped to CT-ID assay protocol

4.6.5 Common order segment

The following table describes the fields of the common order segment (ORC) segment.

HL7 field	Field name	Transmitted	Description
ORC-1	Order Control	String	Use **UA** to indicate the order is unable to be accepted The field is set to **UA**
ORC-2	Placer order number	String	Identifies the placer of the order; originates as the OBR-2 segment of the RSP_Z90 message
OBR-3—OBR-4	N/A	N/A	Null fields; indicate field positions with **|**, omit if last character of a message
OBR-5	Order status	String	Use **CA** for canceled The field is set to **CA**
OBR-6	Response flag	Character	Only the **Exception Response** is used; the *digene* HC2 System Software will ignore all responses

4.7 Example messages

The following examples are provided for the different types of messages that can be transmitted. The examples are presented in the order that would occur to test a CT ID specimen and a high-risk HPV specimen. The series starts as a query message from the *digene* HC2 System Software and ends with the transmission of the results to the LIS.

Comments are included in the messages to explain the relevant or background information. Comments are bold and contained in brackets.

4.7.1 Example of a query message

The query message example is initiated by the *digene* HC2 System Software. The query message requests test orders for all assay protocols configured in the *digene* HC2 System Software. The query message requests all test orders entered into the LIS within the last 7 days.

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009210544||QBP^Q11^QBP_Q11|201310090905442648|P
|2.5.1 ||||||UNICODE UTF-8
QPD|Z_HC2_01|128451c9-6967-495a-a17e-bbdce255767c||20131002|20131009|^CTMAP~^Hi
gh Risk HPV
RCP|I
```

4.7.2 Example of a query response

The LIS acknowledges the query message with an acknowledgment containing the requested test order records. In the example, the first 2 patients each have 2 valid orders. The third patient, Mina Murray, is an invalid order because the *digene* HC2 System Software does not have an assay protocol **UNMAPPED** installed.

```
MSH|^~\&|Location||||20130508161109||RSP^Z90^RSP_Z90|MSG00001|P|2.5.1
MSA|AA|MSG00001
QAK|128451c9-6967-495a-a17e-bbdce255767c|OK|Z_HC2_01
QPD|Z_HC2_01|TAG|20131002|20131009|^CTMAP|^High Risk HPV
PID|1||Patient01||Harker^Jonathan||19500503|M|
ORC|NW|S01
OBR|1|S01||^CTMAP
SPM|1|CTSpec-01||ALL
PID|2||Patient01||Harker^Jonathan||19500503|M|
ORC|NW|S02
OBR|1|S02||^High Risk HPV
SPM|1|HPVSpec-01||ALL
PID|3||Patient02||Westenra^Lucy||19530912|F|
ORC|NW|S03
OBR|1|S03||^High Risk HPV
SPM|1|HPVSpec-02||ALL
PID|4||Patient02||Westenra^Lucy||19530912|F|
ORC|NW|S04
OBR|1|S04||^High Risk HPV
SPM|1|HPVSpec-04||ALL
PID|5||Patient03||Murray^Mina||19530509|F|
ORC|NW|S05
OBR|1|S05||^UNMAPPED
SPM|1|CTSpec-04||ALL
```

4.7.3 Example of a rejection message

The *digene* HC2 System Software rejects test order records at the patient level if the test order cannot be fulfilled by the *digene* HC2 System. In the example below, the assay protocol included in the query response is not available.

```
MSH|^~\&|QIAGEN^HC2 3.4|||20131009210545||OUL^R22^OUL_R22|201310090905452649|P
|2.5.1|||||UNICODE UTF-8
PID|1||Patient03||Murray^Mina||19530509|F
SPM|1|CTSpec-04
OBR|1|S05||^UNMAPPED|||||||||||||||||||||X
ORC|UA|S05|||CA|E
```

4.7.4 Example of data export for a non-consensus assay protocol

Example of data export for a non-consensus assay protocol:

[The first set of 6 messages is the data for the assay calibrators, differentiated by “CAL” in the SPM segment.]

[Negative Calibrator #1]

```
MSH|^~\&|QIAGEN^HC2 3.4|||20131009213706||OUL^R22^OUL_R22|201310090937060566|P
|2.5.1|||||UNICODE UTF-8
PID|1
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateCT-ID|||||A1
INV|^CTKit|OK|^KIT|||||||||20141009
OBR|1|||103^CT-ID|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||22:24:11.79|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060566|P|2.5.1
MSA|AA|201310090937060566
```

[Negative Calibrator #2]

```
MSH|^~\&|QIAGEN^HC2 3.4|||20131009213706||OUL^R22^OUL_R22|201310090937060567|P
|2.5.1|||||UNICODE UTF-8
PID|1
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateCT-ID|||||B1
INV|^CTKit|OK|^KIT|||||||||20141009
OBR|1|||103^CT-ID|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||26:24:11.79|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060567|P|2.5.1
MSA|AA|201310090937060567
```

[Negative Calibrator #3]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060568|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateCT-ID|||||C1
INV|^CTKit|OK|^KIT|||||||||20141009
OBR|1|||103^CT-ID|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||57:24:11.79|CO|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060568|P|2.5.1
MSA|AA|201310090937060568
```

[Positive Calibrator #1]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060569|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^PC CT||^CAL
SAC||||||||||ExaPlateCT-ID|||||D1
INV|^CTKit|OK|^KIT|||||||||20141009
OBR|1|||103^CT-ID|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||221:212:6|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060569|P|2.5.1
MSA|AA|201310090937060569
```

[Positive Calibrator #2]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060570|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^PC CT||^CAL
SAC||||||||||ExaPlateCT-ID|||||E1
INV|^CTKit|OK|^KIT|||||||||20141009
OBR|1|||103^CT-ID|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||295:212:6|CO|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060570|P|2.5.1
MSA|AA|201310090937060570
```

[Positive Calibrator #3]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060571|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^PC CT||^CAL
SAC||||||||||ExaPlateCT-ID|||||F1
INV|^CTKit|OK|^KIT|||||||||20141009
OBR|1|||103^CT-ID|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||203:212:6|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060571|P|2.5.1
MSA|AA|201310090937060571
```

[The next set of messages in this example is the data for the quality controls, differentiated by “QC” in the SPM segment.

Note: Quality controls may be interspersed in the specimen data depending on the plate layout in the *digene* HC2 System Software.]

[Quality Control #1]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060572|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|CT+||^QC
SAC||||||||||ExaPlateCT-ID|||||G1
INV|^CTLot|OK|^QC||||||||||20140804235959
OBR|1|||103^CT-ID^^^CTMAP||||||||||||||||||20131009212529|||F
ORC|RE|||||E
OBX|1|NM|Rlu||546|RLU||||||||20131009212529||Super
OBX|2|ST|I||Valid|||||||||20131009212529||Super
OBX|3|NM|Rat||2.57||1.00 - 20.0|||||||20131009212529||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060572|P|2.5.1
MSA|AA|201310090937060572
```

[Quality Control #2]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060573|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|GC+||^QC
SAC||||||||||ExaPlateCT-ID|||||H1
INV|^GCLot|OK|^QC||||||||||20140804235959
OBR|1|||103^CT-ID^^^CTMAP||||||||||||||||||20131009212529|||F
```

```
ORC|RE|||||E
OBX|1|NM|Rlu||125|RLU||||||||20131009212529||Super
OBX|2|ST|I||Valid|||||||||20131009212529||Super
OBX|3|NM|Rat||0.58||0.000 - 1.00||||||20131009212529||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060573|P|2.5.1
MSA|AA|201310090937060573
```

[The next message is the data for the order received for Jonathan Harker.]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060574|P
|2.5.1||||||UNICODE UTF-8
PID|1||Patient01||Harker^Jonathan||19500503|M
SPM|1|CTSpec-01^CTSpec-01||^STM||||||||||||||20131009210545
SAC||||||||||ExaPlateCT-ID|||||A2
INV|^CTKit|OK|^KIT|||||||||20141009235959
OBR|1|S01||103^CT-ID^^^CTMAP||||||||||||||||||20131009212529|||F
ORC|RE|S01||||E
OBX|1|NM|Rlu|Primary|783|RLU|||||F|||20131009212529||Super
OBX|2|NM|Rat|Primary|3.69||||||F|||20131009212529||Super
OBX|3|ST|I|Primary|CT-ID+||||||F|||20131009212529||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937060574|P|2.5.1
MSA|AA|201310090937060574
```

[The next message is data for an order entered using the *digene* HC2 System Software and does not exist in the LIS. The “U” in the PID segment indicates the patient was not received as part of a test order. This specimen was tested in replicate — it has 2 sets of results for the single PID segment.]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213707||OUL^R22^OUL_R22|201310090937070575|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^NotFromOrder||^STM||||||||||||||20131009211415
SAC||||||||||ExaPlateCT-ID|||||B2
INV|^CTKit|OK|^KIT|||||||||20141009235959
OBR|1|||103^CT-ID^^^CTMAP||||||||||||||||||20131009212529|||F
ORC|RE|||||E
OBX|1|NM|Rlu|Primary|55|RLU|||||F|||20131009212529||Super
OBX|2|NM|Rat|Primary|0.25||||||F|||20131009212529||Super
OBX|3|ST|I|Primary|--||||||F|||20131009212529||Super
SPM|2|^NotFromOrder||^STM||||||||||||||20131009211415
SAC||||||||||ExaPlateCT-ID|||||C2
INV|^CTKit|OK|^KIT|||||||||20141009235959
OBR|1|||103^CT-ID^^^CTMAP||||||||||||||||||20131009212529|||F
```

```
ORC|RE|||||E
OBX|1|NM|Rlu|Primary|67|RLU|||||F|||20131009212529||Super
OBX|2|NM|Rat|Primary|0.31||||||F|||20131009212529||Super
OBX|3|ST|I|Primary|--||||||F|||20131009212529||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213707||ACK|201310090937070575|P|2.5.1
MSA|AA|201310090937070575
```

4.7.5 Example of data export for a consensus assay protocol with preliminary results

Consensus assay protocols have the option of configuring whether preliminary results are included as part of data export. If preliminary results are included, the final interpreted result is transmitted followed by all of the constituent test results. All of the results are under the patient information record. In the following example, specimen **HPVSpec-01** was tested 3 times before a final result was determined.

Example of a data export for a consensus assay protocol with preliminary results:

[The first set of 6 messages is the data for the assay calibrators, differentiated by “CAL” in the SPM segment.]

[Negative Calibrator #1]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370585|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateHPV_3|||||A1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||21:22:6.43|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370585|P|2.5.1
MSA|AA|201310090940370585
```

[Negative Calibrator #2]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370586|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateHPV_3|||||B1
INV|^HPVKit|OK|^KIT|||||||||20141009
```

```
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||68:22:6.43|CO|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370586|P|2.5.1
MSA|AA|201310090940370586
```

[Negative Calibrator #3]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370587|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateHPV_3|||||C1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||23:22:6.43|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370587|P|2.5.1
MSA|AA|201310090940370587
```

[Positive Calibrator #1]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370588|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^HRC||^CAL
SAC||||||||||ExaPlateHPV_3|||||D1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||254:250:6.94|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370588|P|2.5.1
MSA|AA|201310090940370588
```

[Positive Calibrator #2]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060570|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^PC CT||^CAL
SAC||||||||||ExaPlateHPV_3|||||E1
INV|^HPVKit|OK|^KIT|||||||||20141009235959
```

```
OBR|1|||103^CT-ID|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||295:212:6|CO|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370588|P|2.5.1
MSA|AA|201310090940370588
```

[Positive Calibrator #3]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370590|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^HRC||^CAL
SAC||||||||||ExaPlateHPV_3|||||F1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||231:250:6.94|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370589|P|2.5.1
MSA|AA|201310090940370589
```

[The next set of messages is the data for the quality controls, differentiated by “QC” in the SPM segment.

Note: Quality controls may be interspersed in the specimen data depending on the plate layout in the *digene* HC2 System Software.]

[Quality Control #1]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060572|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|CT+||^QC
SAC||||||||||ExaPlateHPV_3|||||G1
INV|^HPVKit|OK|^KIT|||||||||20141009235959
OBR|1|||103^CT-ID^^^CTMAP||||||||||||||||||20131009212529|||F
ORC|RE|||||E
OBX|1|NM|Rlu||546|RLU||||||||20131009212529||Super
OBX|2|ST|I||Valid|||||||||20131009212529||Super
OBX|3|NM|Rat||2.57||1.00 - 20.0|||||||20131009212529||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370591|P|2.5.1
MSA|AA|201310090940370591
```

[Quality Control #2]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370592|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|QC2-HR||^QC
SAC||||||||||ExaPlateHPV_3|||||H1
INV|^H2Kit|OK|^QC|||||||||20140804235959
OBR|1|||100^High Risk HPV^^^High Risk HPV||||||||||||||||||20131009213537|||F
ORC|RE|||||E
OBX|1|NM|Rlu||926|RLU||||||||20131009213537||Super
OBX|2|ST|I||Valid|||||||||20131009213537||Super
OBX|3|NM|Rat||3.70||2.00 - 8.00|||||||20131009213537||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214038||ACK|201310090940370592|P|2.5.1
MSA|AA|201310090940370592
```

[The next message is the data for the order received for Jonathan Harker.]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214038||ACK|201310090940370592|P|2.5.1
MSA|AA|201310090940370592
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370593|P
|2.5.1||||||UNICODE UTF-8
```

[All the results will be grouped by the patient segment.]

```
PID|1||Patient01||Harker^Jonathan||19500503|M
```

[The following records contain information for the final interpreted result of the specimen.]

```
SPM|1|HPVSpec-01^HPVSpec-01||^PreservCyt||||||||||||||20131009210545
SAC||||||||||ExaPlateHPV_3|||||A2
INV|^HPVKit|OK|^KIT|||||||||20141009235959
OBR|1|S02||100^High Risk HPV^^^High Risk
HPV||||||||||||||||||20131009213537|||F
ORC|RE|S02||||E
OBX|1|ST|I|Tertiary|High Risk||||||F|||20131009213537||Super
```

[The following records contain information for the first test result as indicated by “Primary” in the OBX segments. The specimen was tested on 3 plates and this record is for the first plate, “ExaPlateHPV_1”.]

```
SPM|2|HPVSpec-01^HPVSpec-01||^PreservCyt||||||||||||||20131009210545
SAC||||||||||ExaPlateHPV_1|||||A2
INV|^HPVKit|OK|^KIT|||||||||20141009235959
OBR|1|S02||100^High Risk HPV^^^High Risk
HPV||||||||||||||||||20131009212859|||F
ORC|RE|S02||||E
OBX|1|NM|Rlu|Primary|255|RLU|||||P|||20131009212859||Super
OBX|2|NM|Rat|Primary|1.02||||||P|||20131009212859||Super
OBX|3|ST|I|Primary|Retest||||||P|||20131009212859||Super
```

[The following records contain information for the second test result as indicated by “Secondary” in the OBX segments. This record is for the second plate, “ExaPlateHPV_2”.]

```
SPM|3|HPVSpec-01^HPVSpec-01||^PreservCyt||||||||||||||20131009210545
SAC||||||||||ExaPlateHPV_2|||||A2
INV|^HPVKit|OK|^KIT|||||||||20141009235959
OBR|1|S02||100^High Risk HPV^^^High Risk
HPV||||||||||||||||||20131009213249|||F
ORC|RE|S02||||E
OBX|1|NM|Rlu|Secondary|95|RLU|||||P|||20131009213249||Super
OBX|2|NM|Rat|Secondary|0.38||||||P|||20131009213249||Super
OBX|3|ST|I|Secondary|Retest||||||P|||20131009213249||Super
```

[The following records contain information for the third test result as indicated by “Tertiary” in the OBX segments. This record is for the third plate, “ExaPlateHPV_3”.]

```
SPM|4|HPVSpec-01^HPVSpec-01||^PreservCyt||||||||||||||20131009210545
SAC||||||||||ExaPlateHPV_3|||||A2
INV|^HPVKit|OK|^KIT|||||||||20141009235959
OBR|1|S02||100^High Risk HPV^^^High Risk
HPV||||||||||||||||||20131009213537|||F
ORC|RE|S02||||E
OBX|1|NM|Rlu|Tertiary|765|RLU|||||F|||20131009213537||Super
OBX|2|NM|Rat|Tertiary|3.06||||||F|||20131009213537||Super
OBX|3|ST|I|Tertiary|High Risk||||||F|||20131009213537||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214038||ACK|201310090940370593|P|2.5.1
MSA|AA|201310090940370593
```

4.7.6 Example of a message for a consensus assay protocol with only final results

Consensus assay protocols have the option of configuring whether preliminary results are included as part of data export. If preliminary results are not included, only the final interpreted result is transmitted. In the following example, specimen **HPVSpec 01** was tested 3 times before a final result was determined.

Example of data export for a consensus assay protocol with only the final result:

[The first set of 6 messages is data for the calibrators, differentiated by “CAL” in the SPM segment.]

[Negative Calibrator #1]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370585|P
|2.5.1||||||UNICODE UTF-8
PID|1
```

```
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateHPV_3|||||A1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||21:22:6.43|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370585|P|2.5.1
MSA|AA|201310090940370585
```

[Negative Calibrator #2]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370586|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateHPV_3|||||B1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||68:22:6.43|CO|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370586|P|2.5.1
MSA|AA|201310090940370586
```

[Negative Calibrator #3]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370587|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^NC||^CAL
SAC||||||||||ExaPlateHPV_3|||||C1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||23:22:6.43|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370587|P|2.5.1
MSA|AA|201310090940370587
```

[Positive Calibrator #1]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370588|P
|2.5.1||||||UNICODE UTF-8
PID|1
```

```
SPM|1|^HRC||^CAL
SAC||||||||||ExaPlateHPV_3|||||D1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||254:250:6.94|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370588|P|2.5.1
MSA|AA|201310090940370588
```

[Positive Calibrator #2]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060570|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^PC CT||^CAL
SAC||||||||||ExaPlateHPV_3|||||E1
INV|^HPVKit|OK|^KIT|||||||||20141009235959
OBR|1|||103^CT-ID|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||295:212:6|CO|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370588|P|2.5.1
MSA|AA|201310090940370588
```

[Positive Calibrator #3]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370590|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|^HRC||^CAL
SAC||||||||||ExaPlateHPV_3|||||F1
INV|^HPVKit|OK|^KIT|||||||||20141009
OBR|1|||100^High Risk HPV|||||||||||||||||||||F
ORC|RE|||||E
OBX|1|ST|||||231:250:6.94|N|||F
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370589|P|2.5.1
MSA|AA|201310090940370589
```

[The next set of messages is the data for quality controls, differentiated by “QC” in the SPM segment.

Note: Quality controls may be interspersed in the specimen data depending on the plate layout in the *digene* HC2 System Software.]

[Quality Control #1]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213706||OUL^R22^OUL_R22|201310090937060572|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|CT+||^QC
SAC||||||||||ExaPlateHPV_3|||||G1
INV|^HPVKit|OK|^KIT|||||||||20141009235959
OBR|1|||103^CT-ID^^^CTMAP||||||||||||||||||20131009212529|||F
ORC|RE|||||E
OBX|1|NM|Rlu||546|RLU||||||||20131009212529||Super
OBX|2|ST|I||Valid|||||||||20131009212529||Super
OBX|3|NM|Rat||2.57||1.00 - 20.0|||||||20131009212529||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214037||ACK|201310090940370591|P|2.5.1
MSA|AA|201310090940370591
```

[Quality Control #2]

```
MSH|^~\&|QIAGEN^HC2 3.4||||20131009214037||OUL^R22^OUL_R22|201310090940370592|P
|2.5.1||||||UNICODE UTF-8
PID|1
SPM|1|QC2-HR||^QC
SAC||||||||||ExaPlateHPV_3|||||H1
INV|^H2Kit|OK|^QC|||||||||20140804235959
OBR|1|||100^High Risk HPV^^^High Risk HPV||||||||||||||||||20131009213537|||F
ORC|RE|||||E
OBX|1|NM|Rlu||926|RLU||||||||20131009213537||Super
OBX|2|ST|I||Valid|||||||||20131009213537||Super
OBX|3|NM|Rat||3.70||2.00 - 8.00|||||||20131009213537||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009214038||ACK|201310090940370592|P|2.5.1
MSA|AA|201310090940370592
```

[The next message is the data for the order received for Jonathan Harker.]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213708||ACK|201310090937070583|P|2.5.1
MSA|AA|201310090937070583
MSH|^~\&|QIAGEN^HC2 3.4||||20131009213707||OUL^R22^OUL_R22|201310090937070584|P
|2.5.1||||||UNICODE UTF-8
PID|1||Patient01||Harker^Jonathan||19500503|M
```

[The following records contain information for the final interpreted result of the specimen.]

```
SPM|1|HPVSpec-01^HPVSpec-01||^PreservCyt||||||||||||||20131009210545
SAC||||||||||ExaPlateHPV_3|||||A2
```

```
INV|^HPVKit|OK|^KIT|||||||||20141009235959
OBR|1|S02||100^High Risk HPV^^^High Risk
HPV||||||||||||||||||20131009213537|||F
ORC|RE|S02||||E
OBX|1|NM|Rlu|Tertiary|765|RLU|||||F|||20131009213537||Super
OBX|2|NM|Rat|Tertiary|3.06||||||F|||20131009213537||Super
OBX|3|ST|I|Tertiary|High Risk||||||F|||20131009213537||Super
```

[The LIS acknowledges the message with the following response:]

```
MSH|^~\&|||QIAGEN^HC2 3.4||20131009213708||ACK|201310090937070584|P|2.5.1
MSA|AA|201310090937070584
```

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