



Quidel Triage MeterPro Data Interface Specification

The data interface is designed as a serial (RS232) unidirectional interface for communication with Laboratory or other information systems. The physical interface on the instrument is a DB-9 female connector. Interface connections must utilize only pins 2, 3 and 5 on the MeterPro. All other pins shall be open (unconnected to signals, ground or each other).

Data format: 1 start bit, 8 data bits, 1 stop bit, no parity

Signals: Transmit Data (TxD), Receive Data (RxD) and Signal Ground (GND)

Transmission Baud Rate: 9600 or 38400

Connector on the instrument: DB-9 (female), Pin 2 = TxD (out), Pin 3 = RxD (in), Pin 5 = GND

The interface may be used for transferring Patient Results, QC Sample Results, QC Device Results and Miscellaneous Results from the Triage MeterPro to a Host system.

The Laboratory Information System (LIS) data transfer is implemented according to the following standards and documents: The Instrument Interface complies with legacy ASTM Interface Specifications maintained by the Clinical And Laboratory Standards Institute® (CLSI) and published as LIS1-A (formally ASTM E 1381-91) and LIS2-A (formally ASTM E1394-97).

Important Note: LIS interface functionality must be enabled in each meter using a MeterPro-specific LIS Enable Code provided by Quidel and entered into the instrument by the site Supervisor. Please contact Quidel Technical Support and have the Serial Number of the MeterPro(s) available to obtain the LIS Enable Code(s)

Notes on version specific features of LIS interface for the Quidel Triage MeterPro. All changes are cumulative. Interface for MeterPros with firmware versions lower than 4.06.062 is not supported.

- LIS6 is in the following MeterPro software versions: \geq 4.06.062, all 4.07.xxx, all 5.01.xxx and all 5.02.xxx
- LIS7 is in MeterPro software versions \geq 5.03.xxx
- LIS8 is in MeterPro software versions \geq 5.04.xxx

Changes from LIS6 to LIS7 interface versions:

AUX ID Transmission: LIS7 supports the transfer of information from the data input field of the MeterPro "Aux ID". This information is sent in field 8.1.4 of the Patient Results transmission.

LIS7 supports the new test type "Misc Test" or Miscellaneous Test. This is a new test type that can be used for Calibration Verifications, Proficiency Survey, Training etc.

Starting with LIS7, Users may recall and send individual Patient Test results to LIS. In LIS6 a recalled result sent to LIS will result in an upload of **all** Patient Test results.

Changes from LIS7 to LIS8 interface versions:

Transmission of the Control Level for QC Sample Results. For QC Sample results, the MeterPro will report whether the control used for the test is a High or Low level Control. See Field 9.4.5 in Section III; METERPRO RESPONSE (QC SAMPLE RESULTS). In LIS8, for the "Sender ID" field (field 7.1.5) the text is changed from "BIOSITE" to "TRIAGE".

Notes:

Quidel Triage Census® ATM Software does not use the interface described in this specification. This interface **should not** be enabled when MeterPros are connected to Triage Census ATM.

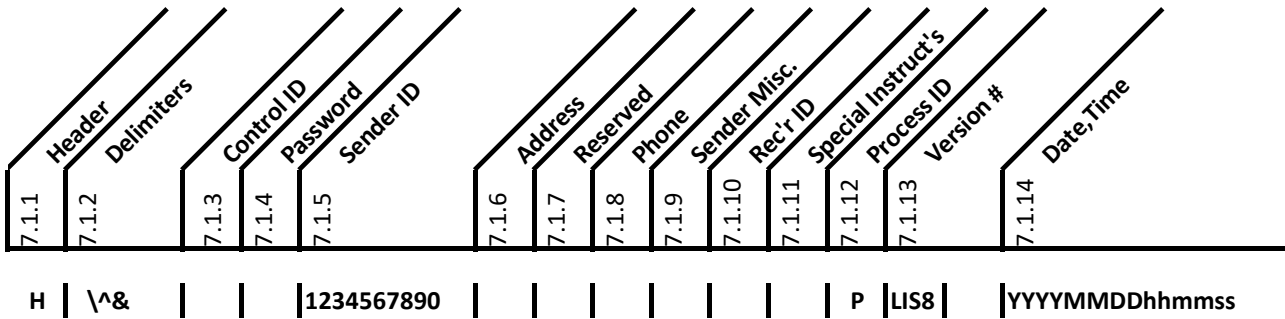
The Normalcy Flag (Result Record Field 10.1.7) description specifies those flags allowed by the industry standard: "L" (Low), "H" (High), "N" (Normal), and "A" (Abnormal). Normalcy Flags for Bi-Level tests are "L", "N", or "H", while those for Tri-Level tests (e.g. TNI) are "N" or "A".

IMPLEMENTATION OF THE LIS COMMUNICATION PROTOCOL IN THE QUIDEL TRIAGE METERPRO

Note: "Section 1, LIS HOST QUERY FOR SPECIFIC RESULTS" is the specification for querying the MeterPro for results.
 When the MeterPro is set to perform "Auto-Upload" of results (the most common mode of operation), communication is automatic and initiated by the MeterPro.
 For MeterPro initiated Auto-Upload specifications, start in "Section II, MeterPro Response" on the next page.
 Fields that contain sample data below are implemented. Empty fields are not.
 Sample data transmissions are in Section VI, pages 13 and 14.

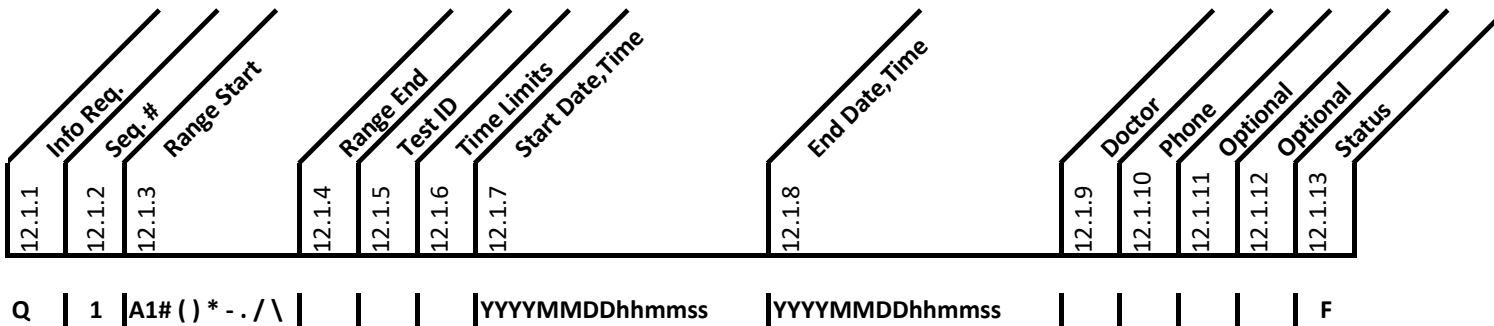
I. LIS HOST QUERY FOR SPECIFIC RESULTS

Host Query Header Record



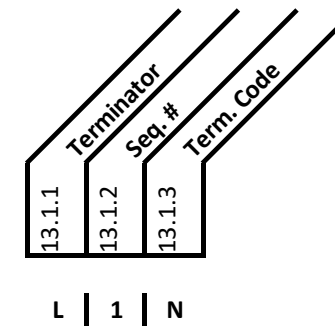
- Notes:
- 7.1.2 Delimiters: MUST use | \ ^ &
 - 7.1.12 Process ID: P (Production)

Host Query Record



- Notes:
- 12.1.3 Range Start used to specify request: All (patients), QCSample, QCDevice or MiscTest or Specific Patient ID. Supported Characters (alphanumeric and special) are listed

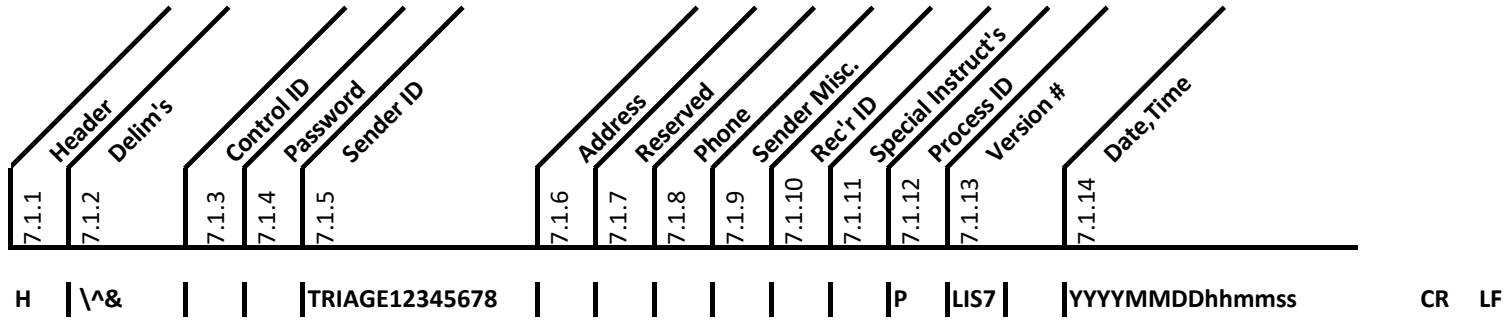
Message Terminator Record



II. METERPRO RESPONSE (PATIENT RESULTS)

Note: The following communications protocols are response to a Host Query to the MeterPro (Host ENQ / MeterPro ACK / Host Query / MeterPro upload starting with the "H" record) or by "Auto Upload" from the Meter (Meter ENQ / Host ACK / Meter upload starting with "H" Record).

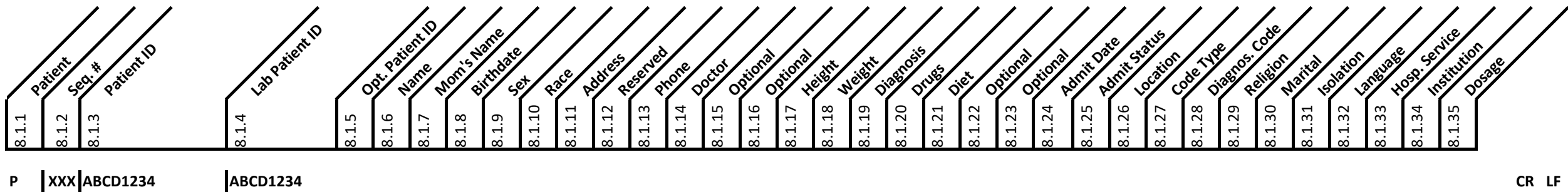
Message Header Record



Notes:

- 7.1.2 Delimiters: | \ ^ &
- 7.1.5 Sender ID: TRIAGE followed by 8-digit Instrument Serial #
- 7.1.12 Process ID: P (Production)
- Units are listed for each test separately
- CR and LF sent at end of each record

Patient Information Record



Notes:

- 8.1.3 Alphanumeric data. The MeterPro may also send any of the following special characters # () * - . / \
When using LIS Accession numbers instead of Patient ID's, the accession number is usually found in field 8.1.3 which corresponds to the "Patient ID" User Input field in the MeterPro
- 8.1.4 Contains the data entered in the "Aux ID" field of the MeterPro. Aux ID is an optional User Data Input. This field may hold up to 12 characters including special characters # () * - . / \

Test Order Record

9.4.1	9.4.2	9.4.3	9.4.4	9.4.5	9.4.6	9.4.7	9.4.8	9.4.9	9.4.10	9.4.11	9.4.12	9.4.13	9.4.14	9.4.15	9.4.16	9.4.17	9.4.18	9.4.19	9.4.20	9.4.21	9.4.22	9.4.23	9.4.24	9.4.25	9.4.26	9.4.27	9.4.28	9.4.29	9.4.30	9.4.31	
Order	Seq. #	Specimen ID	Instr. Spec. ID	Test ID	Priority	Order Date, Time	Coll. Date, Time	End Date, Time	Volume	Collection ID	Action	Danger Code	Specimen Info	Rec't Date, Time	Spec'inn Descr.	Doctor	Phone	User Field 1	User Field 2	Lab Field 1	Lab Field 2	Result Date, Time	Billing	Instrument Sect.	Report Type	Reserved	Location	Hosp. Infect'n	Spec'inn Service	Spec'inn Institut'r	
O	1	12345678	^ 12345	AAAAAA	^ 12345	S														ABCD1234		YYYYMMDDhhmmss			Q						CR LF

Patient Test Results Notes:

- (1) A separate order record is sent for each set of 3 analytes. Improves compliance with ASTM E1394 and provides encoding of Panel Type, Reagent Lot #, **flagsQC**, **Check**, **errorCode**, **IntQC**, **checksum**, and **Test Date/Time** into single record rather than having data repeated in each Result record
- (2) 9.4.4 Unique result identifier provided by 8-digit **Instrument Serial #** and 5-digit **Patient Result Serial #**, separated by Component Delimiter (^)
- (3) 9.4.5 Test ID: **Panel Type** (e.g., CARDIAC, BNP, etc.) and **Reagent Lot #** separated by Component Delimiter (^)
- (4) 9.4.21 QC result code. Either **PASS** or **E** and 7 digit result code, e.g. **E1234567**
- (5) 9.4.22 Lab Field 2 used for Patient Result Approval System: "RESULT APPROVED", "RESULT REJECTED", or empty field (if approval not requested).
- (6) 9.4.23: **Result Date,Time** put here instead of repeating 3 times in Result records
- (7) 9.4.26 Report Type: **Q** (successful response to query). **Z** (requested patient data not available)

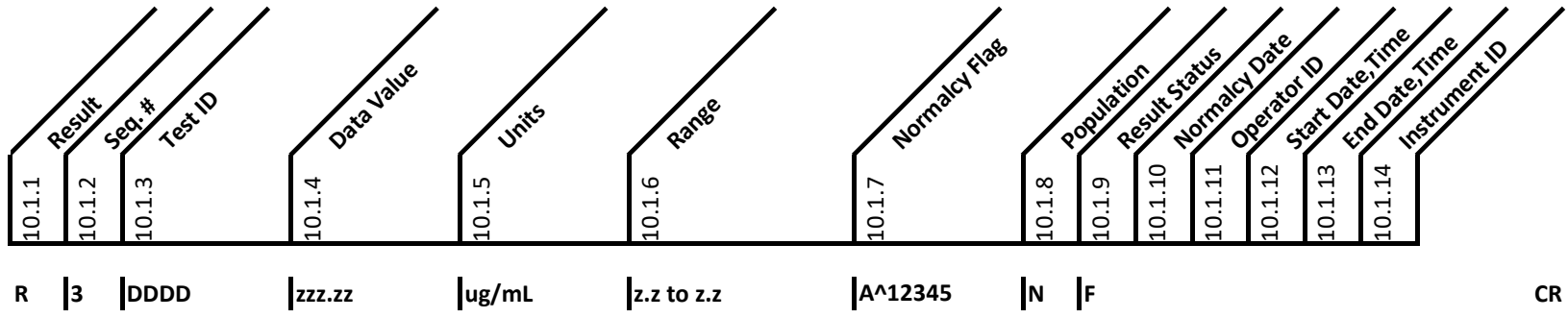
Test Result Records

10.1.1	10.1.2	10.1.3	10.1.4	10.1.5	10.1.6	10.1.7	10.1.8	10.1.9	10.1.10	10.1.11	10.1.12	10.1.13	10.1.14
Result	Seq. #	Test ID	Data Value	Units	Range	Normalcy Flag	Population	Result Status	Normalcy Date	Operator ID	Start Date, Time	End Date, Time	Instrument ID
R	1	BBBB	xxx.xx	ng/mL	x.x to x.x	A^12345	N	F	ABC123				CR LF

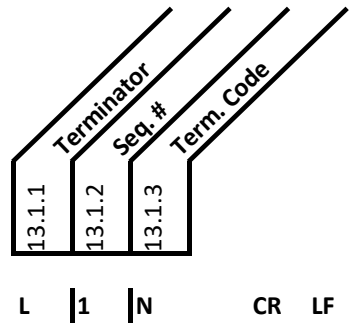
10.1.1	10.1.2	10.1.3	10.1.4	10.1.5	10.1.6	10.1.7	10.1.8	10.1.9	10.1.10	10.1.11	10.1.12	10.1.13	10.1.14
Result	Seq. #	Test ID	Data Value	Units	Range	Normalcy Flag	Population	Result Status	Normalcy Date	Operator ID	Start Date, Time	End Date, Time	Instrument ID
R	2	CCCC	yyy.yy	pg/mL	y.y to y.y	A^12345	N	F					CR LF

Continued next page

Test Result Records continued



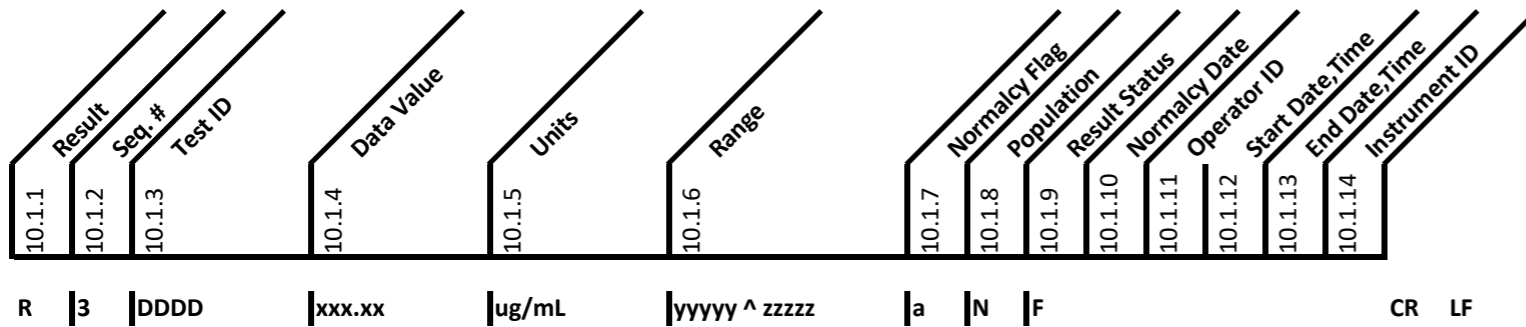
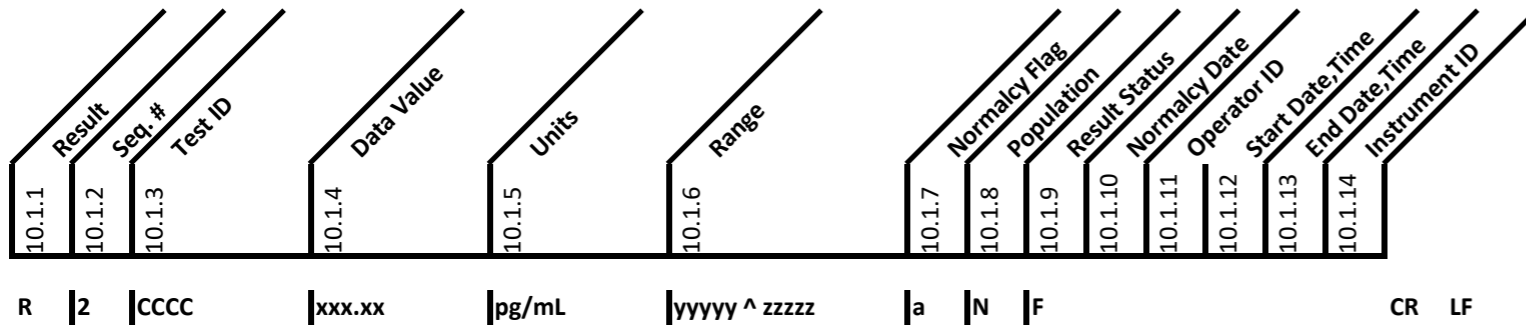
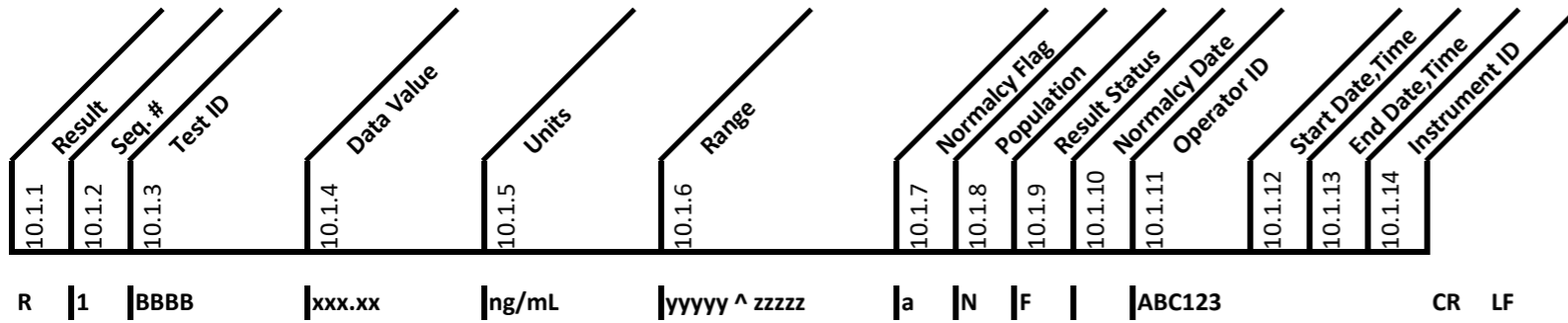
Message Terminator Record



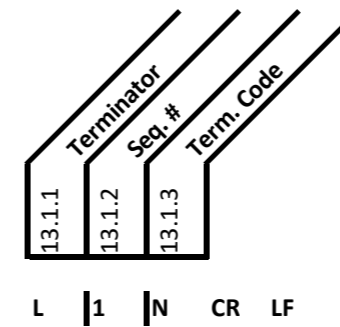
Test Result Records Notes:

- (1) 10.1.2 Seq. #: Number of Result records corresponds to # of tests in Panel, e.g. 3 for Cardiac panel, 1 for BNP. Number of result records is dependant on the Test Panel and could be as many as 15
- (2) 10.1.3 Test ID: Test names correspond to Panel Type, e.g. **CKMB**, **TNI**, and **MYO** for Cardiac panel, **BNP** for BNP panel
- (3) 10.1.4 xxx.xx, yyy.yy and zzz.zz are only examples. Actual number of leading and following decimal places is dependent on specifications of the actual test
- (4) 10.1.5 Units: Listed separately for each test. Note, prefix "u" used for "μ"
- (5) 10.1.6 x.x, y.y and z.z are only examples. Actual number of leading and following decimal places is dependent on specifications of the actual test. Range only included for qualitative test types (not POS / NEG types).
- (6) 10.1.7 Normalcy Flag: **L** (Low), **H** (High), **N** (Normal), **A** (Abnormal), followed by Component Delimiter (^) and Result Settings Flags (16-bit word)
- (7) 10.1.11 Operator ID: Left **NULL** in Seq. #2, #3 and any following result records in the same message to convey same as Seq. #1 (See 6.4.10.1)
 "1234" is only an example. Actual number of alphanumeric characters is dependent on actual instrument setting

QC Sample Result Records



Message Terminator Record

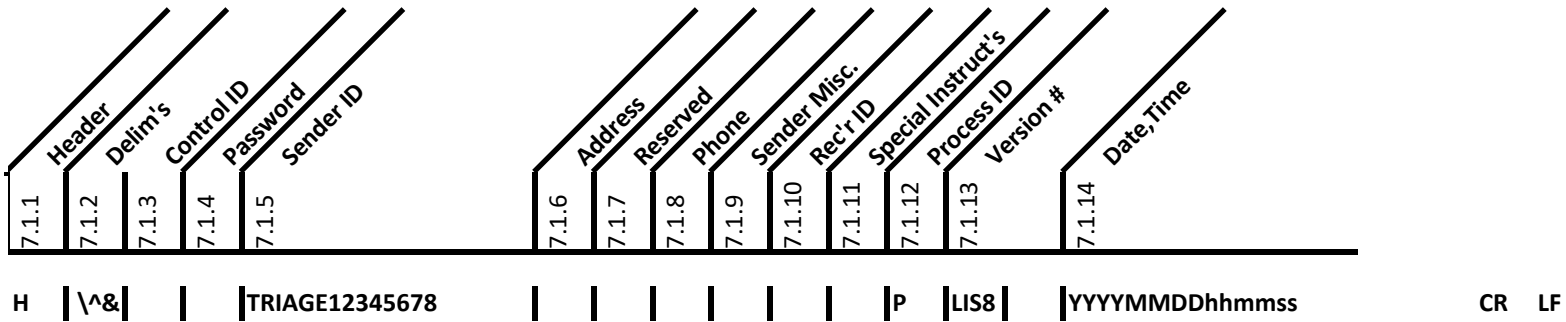


QC Sample Result Records Notes:

- (1) 10.1.2 Sequence #: Starts at 1 and increments with each assay in the Panel; e.g. 1-3 for Cardiac panel, 1 for BNP. Number of result records is dependant on the Test Panel and could be as many as 15
- (2) 10.1.4 "xxx.xx" is only an example, actual number of leading and following decimal places is dependent on specifications of the actual test
- (3) 10.1.3 Test ID: Individual assay names correspond to Panel Type; e.g. **CKMB**, **TNI**, and **MYO** for Cardiac panel, **BNP** for a BNP panel
- (4) 10.1.5 Units: Listed separately for each test. Note, prefix "u" used for "μ"
- (5) 10.1.6 Range: **Range Allowed** and **Concentration Allowed** for the analyte separated by the Component Delimiter (^)
- (6) 10.1.7 Normalcy Flag: **N** (Normal), **A** (Abnormal), followed by Component Delimiter (^) and Result Settings Flags (16-bit word)
- (7) 10.1.11 Operator ID: Left **NULL** in Seq. #2 and #3 to convey same as Seq. #1 (See 6.4.10.1)

IV. METERPRO RESPONSE (QC DEVICE RESULTS)

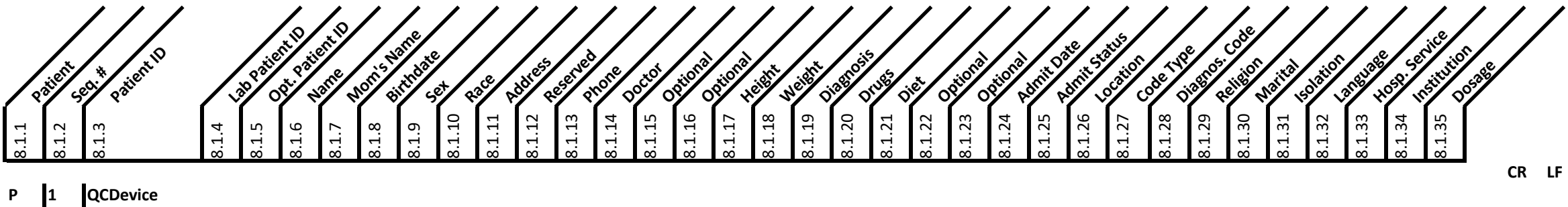
Header Record



Notes:

- (1) 7.1.2 Delimiters: | \ ^ &
- (2) 7.1.5 Sender ID: TRIAGE followed by 8-digit Instrument Serial #
- (3) 7.1.12 Process ID: P (Production)
- (4) CR and LF inserted at end of each record

"Patient Information Record"



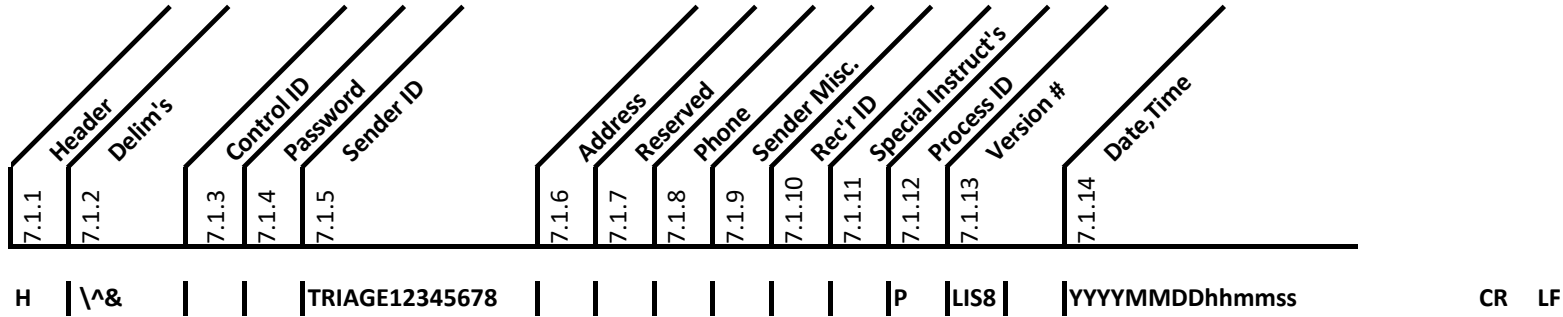
Notes:

- (1) 8.1.3 Patient ID: "QCDevice" used to indicate data to follow.

V. METERPRO RESPONSE (MISC. TEST RESULTS):

Note: The following communications protocols are response to a Host Query to the MeterPro (Host ENQ / MeterPro ACK / Host Query / Transmission) or by "Auto Upload" from the Meter (Meter ENQ / Host ACK / Meter upload starting with "H" Record).

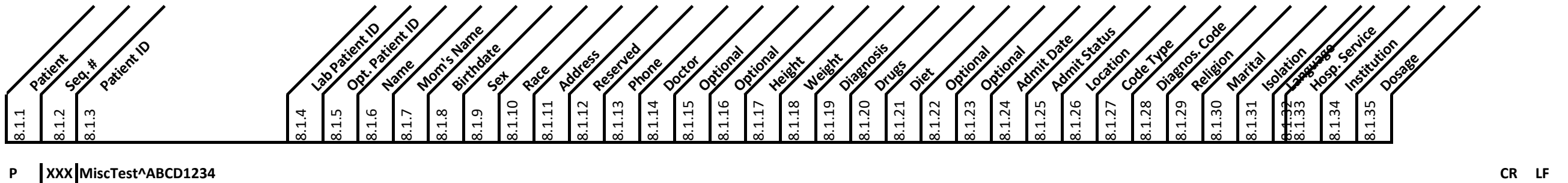
Misc Test Message Header Record



Notes:

- (1) 7.1.2 Delimiters: | \ ^ &
- (2) 7.1.5 Sender ID: TRIAGE followed by 8-digit Instrument Serial #
- (3) 7.1.12 Process ID: P (Production)
- (4) Units are listed for each test separately
- (5) CR and LF inserted at end of each record

Misc Test Information Record



Notes:

- (1) 8.1.3 "MiscTest" followed by a component delimiter (^) and up-to a 20 character Misc Test ID. Alphanumeric data. The Meter may also send any of the following supported special characters: # () * - . / \
- (2) 8.1.4 N/A for Misc Test

Misc Test - Test Order Record

9.4.1	9.4.2	9.4.3	9.4.4	9.4.5	9.4.6	9.4.7	9.4.8	9.4.9	9.4.10	9.4.11	9.4.12	9.4.13	9.4.14	9.4.15	9.4.16	9.4.17	9.4.18	9.4.19	9.4.20	9.4.21	9.4.22	9.4.23	9.4.24	9.4.25	9.4.26	9.4.27	9.4.28	9.4.29	9.4.30	9.4.31	
Order	Seq. #	Specimen ID	Instr. Spec. ID	Test ID	Priority	Order Date, Time	Coll. Date, Time	End Date, Time	Volume	Collection ID	Action	Danger Code	Specimen Info	Rec't Date, Time	Spec'mn Descr.	Doctor	Phone	User Field 1	User Field 2	Lab Field 1	Lab Field 2	Result Date, Time	Billing	Instrument Sect.	Report Type	Reserved	Location	Hosp. Infect'n	Spec'mn Service	Spec'mn Institut'r	
O	1	12345678	^ 12345	AAAAAA	^ 12345	S														ABCD1234		YYYYMMDDhhmmss			Q						CR LF

Patient Results Notes:

- (1) A separate order record is sent for each set of 3 analytes. Improves compliance with ASTM E1394 and provides encoding of Panel Type, Reagent Lot #, **flagsQC**, **errorCodeIntQC**, **checksumm**, and **Test Date/Time** into single record rather than having data repeated in each Result record
- (2) 9.4.4 Unique result identifier provided by 8-digit **Instrument Serial #** and 5-digit **Misc Test Result Serial #**, separated by Component Delimiter (^)
- (3) 9.4.5 Test ID: **Panel Type** (e.g., CARDIAC, BNP, etc.) and **Reagent Lot #** separated by Component Delimiter (^)
- (4) 9.4.21 QC result code. Either **PASS** or **E** and 7 digit result code, e.g. **E1234567**
- (5) 9.4.23: **Result Date,Time** put here instead of repeating 3 times in Result records
- (6) 9.4.26 Report Type: **Q** (successful response to query). **Z** (requested patient data not available)

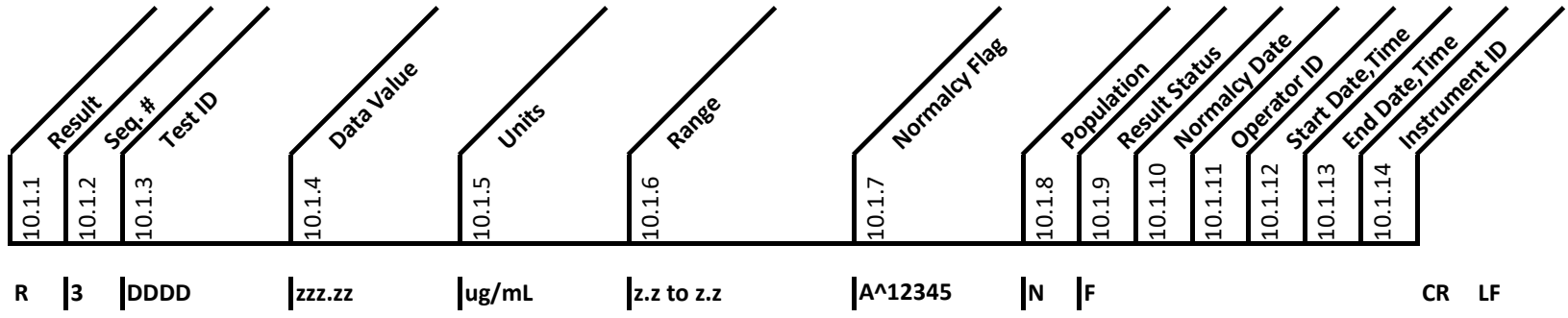
Misc Test - Test Result Records

10.1.1	10.1.2	10.1.3	10.1.4	10.1.5	10.1.6	10.1.7	10.1.8	10.1.9	10.1.10	10.1.11	10.1.12	10.1.13	10.1.14
Result	Seq. #	Test ID	Data Value	Units	Range	Normalcy Flag	Population	Result Status	Normalcy Date	Operator ID	Start Date, Time	End Date, Time	Instrument ID
R	1	BBBB	xxx.xx	ng/mL	x.x to x.x	A^12345	N	F	ABC123				CR LF

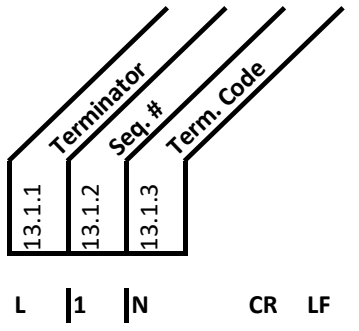
10.1.1	10.1.2	10.1.3	10.1.4	10.1.5	10.1.6	10.1.7	10.1.8	10.1.9	10.1.10	10.1.11	10.1.12	10.1.13	10.1.14
Result	Seq. #	Test ID	Data Value	Units	Range	Normalcy Flag	Population	Result Status	Normalcy Date	Operator ID	Start Date, Time	End Date, Time	Instrument ID
R	2	CCCC	yyy.yy	pg/mL	y.y to y.y	A^12345	N	F					CR LF

Continued next page

Misc Test - Test Result Records continued



Message Terminator Record



Test Result Records Notes:

- (1) 10.1.2 Seq. #: Number of Result records corresponds to # of tests in Panel, e.g. 3 for Cardiac panel, 1 for BNP. Number of result records is dependant on the Test Panel and could be as many as 15
- (2) 10.1.3 Test ID: Test names correspond to Panel Type, e.g. **CKMB**, **TNI**, and **MYO** for Cardiac panel, **BNP** for BNP panel
- (3) 10.1.4 xxx.xx, yy.yy and zzz.zz are only examples. Actual number of leading and following decimal places is dependent on specifications of the actual test
- (4) 10.1.5 Units: Listed separately for each test. Note, prefix "u" used for "μ"
- (5) 10.1.6 x.x, y.y and z.z are only examples. Actual number of leading and following decimal places is dependent on specifications of the actual test. Range only included for qualitative test types (not POS / NEG types).
- (6) 10.1.7 Normalcy Flag: **N** (Normal), **A** (Abnormal), followed by Component Delimiter (^) and Result Settings Flags (16-bit word)
- (7) 10.1.11 Operator ID: Left **NULL** in Seq. #2, #3 and any following result records in the same message to convey same as Seq. #1 (See 6.4.10.1)
"1234" is only an example. Actual number of alphanumeric characters is dependent on actual instrument setting
- (8) 10.1.13: **Result Date,Time** put in Order record

Example Transmissions - Continued from previous page

LIS Host Query for Specific Patient Test Result (Patient ID LLH-000-56E)

Note: LIS Host Query for results is uncommon for LIS interfacing.

"Auto-Upload" of test results is the most commonly implemented method.

LisPC: [ENQ]
Meter: [ACK]
LisPC: [STX]0H|\^&|||1234567890|P|20180815133200[CR][ETB]E7[CR][NL]
Meter: [ACK]
LisPC: [STX]1Q|1|LLH-000-56E|||20180815010001|20180815112937||D|F[CR][ETB]36[CR][NL]
Meter: [ACK]
LisPC: [STX]2L|1|N[CR][ETX]05[CR][NL]
Meter: [ACK]
LisPC: [EOT]
Meter: [ENQ]
LisPC: [ACK]
Meter: [STX]1H|\^&|||TRIAGE00078347|P|LIS8|20180815113102|[CR][ETB]CF[CR]
LisPC: [ACK]
Meter: [STX]2P|001|LLH-000-56E|229ASX[CR][ETB]AE[CR]
LisPC: [ACK]
Meter: [STX]3O|1||00078347^00001|CARDIAC^01000|S|||||||PASS||20180815105832||Q[CR][ETB]3C[CR]
LisPC: [ACK]
Meter: [STX]4R|1|CKMB|1.2|ng/mL|0.0 to 4.3|N^09B7|N|F||ROGER-19[CR][ETB]BC[CR]
LisPC: [ACK]
Meter: [STX]5R|2|MYO|14.0|ng/mL|0.0 to 107|N^09B7|N|F[CR][ETB]7D[CR]
LisPC: [ACK]
Meter: [STX]6R|3|TNI|0.10|ng/mL|0.00 to 0.40|N^0DB7|N|F[CR][ETB]B6[CR]
LisPC: [ACK]
Meter: [STX]7L|1|N[CR][ETX]0A[CR]
LisPC: [ACK]
Meter: [EOT]
LisPC: [ACK]