Alere Afinion 2 – HL7 Connectivity Protocol

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1 ABOUT THIS DOCUMENT

This document describes the Data Connectivity Protocol (patient and control records) for LIMS connectivity based on the HL7 (health level 7) protocol for the Alere Afinion 2 Analyzer.
It describes the protocol and the format of the records returned from the Analyzer 2 (including the acknowledgement message received from the LIMS). It also gives examples and highlights issues to be especially addressed; all needed by the programmer that shall interface to this protocol on the LIMS side.

1.1 Abbreviation

LIMS	Laboratory Information Management System
LIS	Laboratory Information System

2 PHYSICAL TRANSMISSION OF MESSAGES

2.1 HL7 Socket transfer

Each HL7 message will be transmitted as follows:

Sender (Alere Afinion 2 Analyzer)	Direction	Receiver (LIS)
<VT>HL7-ORU-O01-message<FS><CR>	-->	
	<--	<VT>HL7-ACK-message<FS><CR>

wherein:
<VT> … ASCII 0x0B
<FS> … ASCII 0x1C
<CR> … ASCII 0x0D

3 MESSAGE STRUCTURE

3.1 HL7 message structure

The HL7 high level message structure is based on Version 2.4 of the Health Level Seven (HL7) Standard for electronic data exchange in all healthcare environments.

3.2 Patient measurement results to LIS

The Alere Afinion 2 Analyzer will transmit the following events for patient measurement results:

Message type	Event code	Description
ORU	R01	Unsolicited transfer of patient results

Message structure:

HL7 segment	Description
MSH	Message Header
PID	Patient Identification
PV1	Patient Visit
OBR	Observation Request
OBX	Observation Result

3.3 Acknowledgment

The Alere Afinion 2 Analyzer will receive the following acknowledgement:

Message type	Description
ACK	Acknowledge

Message structure:

HL7 segment	Description
MSH	Message Header
MSA	Acknowledgment

4 SEGMENTS

4.1 Legend

- Field name: according to Health Level Seven, version 2.4
- Interpretation: additional description
- Req.: F ... fix value
  C ... configured value via user interface
  A ... data comes from analyzer
  X ... calculated values (e.g. date/time)
  R ... required from LIS
  O ... optional from LIS
- HL7 Field: number of HL7 field
- Source of data: field of the Alere Afinion 2 Analyzer data record, where the data comes from.
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4.2 MSH

Field name	Interpretation	Req.	HL7 Field	Source of data
Field separator	Field separator byte	F	1	
Encoding characters	Other field separator characters	F	2	
Sending application	Model name Always " Alere Afinion 2 Analyzer " for Afinion2	F	3	
Receiving application	Name of the receiving application / dept. (configurable)	C	5	Configured value
Receiving facility	Receiving process / institution within the dept. (configurable)	C	6	Configured value
Date / time of message	Date and time of message creation	X	7	Current time stamp
Message type	Always "ORU"	F	9.1	
Event type	Always "R01"	F	9.2	
Message Control ID	Consecutive number starting with 1000	X	10	1000
Processing ID	P ... patient measurement results Q ... quality control results	A	11	
Version ID	HL7-version used	F	12	HL7: "2.4"
Accept Acknowledgement Type	Always "AL"	F	15	AL
Application Acknowledgement Type	Always "NE"	F	16	NE
Character Set	Always "8859/1"	F	18	8859/1

HL7-Example:
`MSH|^~\&|Alere Afinion 2 Analyzer||EPR|KH-1|20100610131643||ORU^R01|1048|P|2.4|||AL|NE||8859/1`

4.3 EVN

EVN is not supported for patient measurement result export to LIS.

4.4 MSA

Field name	Interpretation	Req.	HL7 Field	Source of data
Acknowledgement code	AA, CA will be accepted as acknowledgement from LIS	R	1	AA
Message Control ID	Verification of message control ID will not be performed.	O	2	
Text Message	Error text will not be analyzed.	O	3	
ErrorCondition	Error code. If Acknowledgement code is neither AA nor CA, Error condition will be saved into the log memory.	O	6	

HL7-Example: `MSA|AA|117715205|||F|`

4.5 PID

Field name	Interpretation	Req.	HL7 Field	Source of data
Set ID - Patient ID	PID segment number	F	1	
Patient Identifier List	(Local) patient ID	A	3	P- ID of header (configurable, to use PID or visitnumber)

HL7-Example: `PID|1||43|`

4.6 PV1

Field name	Interpretation	Req.	HL7 Field	Source of data
Set ID - Patient Visit	PV1 segment number	F	1	
Visit Number		A	19	

HL7-Example: `PV1|1|||||||||||||||||||43|`

4.7 OBR

Field name	Interpretation	Req.	HL7 Field	Source of data
Set ID - Observation Request	OBR segment number	F	1	
Filler Order Number		A	3	RUN# of header
Universal Service ID	Name of assay	A	4	Name of assay of header
Specimen action code	Constant value	F	11	N
Specimen Source	Alere Afinion 2 Analyzer HL7 description 0 ORH // other 1 BLDC // Blood capillary 2 BLDV // Blood venous	A	15	Assay variant of footer
Charge to practice	reagent lot	A	23.2	LOT# of header
Result Status	always "F" (final result)	F	25	

HL7-Example: `OBR|1||4|CRP|||||||N||||ORH|||||||^10183647||F|`

4.8 OBX

Field name	Interpretation	Req.	HL7 Field	Source of data
Set ID - Observational Simple	OBX segment number	F	1	
Value Type	ST: String representation of value	X	2	
Observation Identifier	Test Device ID	A	3	Test Name of sub record
Observation Value	measurement value	A	5	Result of sub record
Units	unit	A	6	Unit of sub record
Abnormal Flags	Flags are not generally standardized. The recommendation is: <: less than measurement lower limit >: higher than measurement upper limit L: less than normal range H: higher than normal range LL: less than extreme range HH: higher than extreme range !: result ambiguous	A	8	Only '<' and '>' will be supported by the Alere Afinion 2 Analyzer. The Observation Value shall not be presented if abnormal flag is present. See precaution below for ACR and Lipid Panel.
Observation result status	always "F" (final result)	F	11	
Responsible Observer	Operator ID of the user, which the measurement has done.	A	16	operator ID of footer
Equipment Instance Identifier	Serial number of Alere Afinion 2 Analyzer analyzer	A	18	instrument serial number
Date/Time of Analysis	measurement time	A	19	Date/Time of header

HL7-Example: `OBX|1|ST|CRP||16|mg/L|||||F|||||||AF0000030|20100608142352|`

Precaution for ACR and Lipid Panel:
The ACR observation value shall be interpreted as **not valid** if albumin and/or creatinine are below or above measurement limits.
The values for LDL, Non-HDL and Chol/HDL shall be interpreted as **not valid** if either of Chol, HDL or Trig are below or above measurement limits.

5 EXAMPLES

5.1 ORU-Message (HL7)

5.1.1 Example 1

```
MSH|^~\&|Alere Afinion 2 Analyzer||EPR|KH-1|20100610131643||ORU^R01|1048|P|2.4|||AL|NE||8859/1
PID|1|||
PV1|1|||||||||||||||||43|
OBR|1||3|CRP|||||||N||||ORH|||||||^10124809||F|
OBX|1|ST|CRP||16|mg/L|||||F|||||||AF0000030|20100608142352|
```

5.1.2 Example 2

```
MSH|^~\&|Alere Afinion 2 Analyzer||EPR||20100608185608||ORU^R01|1006|P|2.4|||AL|NE||8859/1
PID|1||55|
PV1|1|||||||||||||||||
OBR|1||1|ACR|||||||N||||ORH|||||||^10142193||F|
OBX|1|ST|ACR||0.5|mg/g|||||F|||||||AF0000030|20100608140517|
OBX|2|ST|Alb||8.0|mg/L|||||F|||||||AF0000030|20100608140517|
OBX|3|NM|Creat||17.4|mg/dL|||||F|||||||AF0000030|20100608140517|
```

5.1.3 Example 3

Invalid ACR value indicated with a “<” flag.

```
MSH|^~\&|Alere Afinion 2 Analyzer||EPR||20120412094138||ORU^R01|1011|P|2.4|||AL|NE||8859/1
PID|1||2|
PV1|1|||||||||||||||||
OBR|1||2|ACR|||||||N||||ORH|||||||^10142193||F|
OBX|1|ST|ACR||<5.6|mg/g||<|||F|||||||AF0000030|20100608140536|
OBX|2|ST|Alb||<5.0|mg/L||<|||F|||||||AF0000030|20100608140536|
OBX|3|ST|Creat||33.0|mg/dL|||||F|||||||AF0000030|20100608140536|
```

5.1.4 Example 4

Invalid ACR value indicated with “--- “ in the observation value field.

```
MSH|^~\&|Alere Afinion 2 Analyzer||EPR||20120412094138||ORU^R01|1016|P|2.4|||AL|NE||8859/1
PID|1||7|
PV1|1|||||||||||||||||
OBR|1||7|ACR|||||||N||||ORH|||||||^10142193||F|
OBX|1|ST|ACR||--- |mg/g|||||F|||||||AF0000030|20100608140626|
OBX|2|ST|Alb||<5.0|mg/L||<|||F|||||||AF0000030|20100608140626|
OBX|3|ST|Creat||<16.4|mg/dL||<|||F|||||||AF0000030|20100608140626|
```

5.1.5 Example 5

```
MSH|^~\&|Alere Afinion 2 Analyzer||EPR||20120412094252||ORU^R01|1056|P|2.4|||AL|NE||8859/1
PID|1||123|
PV1|1|||||||||||||||||
OBR|1||47|Lipid Panel|||||||N||||ORH|||||||^10162193||F|
OBX|1|ST|Chol||2.60|mmol/L|||||F|||||||AF0000030|20120222143007|
OBX|2|ST|LDL||1.39|mmol/L|||||F|||||||AF0000030|20120222143007|
OBX|3|ST|HDL||0.80|mmol/L|||||F|||||||AF0000030|20120222143007|
OBX|4|ST|Trig||0.90|mmol/L|||||F|||||||AF0000030|20120222143007|
OBX|5|ST|non-HDL||1.80|mmol/L|||||F|||||||AF0000030|20120222143007|
OBX|6|ST|Chol/HDL||3.3||||||F|||||||AF0000030|20120222143007|
```

5.1.6 Example 6

Invalid values indicated with “<” flag.

```
MSH|^~\&|Alere Afinion 2 Analyzer||EPR||20120412094308||ORU^R01|1063|P|2.4|||AL|NE||8859/1
PID|1||123|
PV1|1|||||||||||||||||||
OBR|1||54|Lipid Panel|||||||N||||ORH|||||||^10162193||F|
OBX|1|ST|Chol||<2.59|mmol/L||<|||F|||||||AF0000030|20120222143142|
OBX|2|ST|LDL||<0.16|mmol/L||<|||F|||||||AF0000030|20120222143142|
OBX|3|ST|HDL||0.79|mmol/L|||||F|||||||AF0000030|20120222143142|
OBX|4|ST|Trig||3.62|mmol/L|||||F|||||||AF0000030|20120222143142|
OBX|5|ST|non-HDL||<1.80|mmol/L||<|||F|||||||AF0000030|20120222143142|
OBX|6|ST|Chol/HDL||<3.3|||<|||F|||||||AF0000030|20120222143142|
```

5.1.7 Example 7

Invalid values indicated with “--- “.

```
MSH|^~\&|Alere Afinion 2 Analyzer||EPR||20120412094308||ORU^R01|1060|P|2.4|||AL|NE||8859/1
PID|1||123|
PV1|1|||||||||||||||||||
OBR|1||51|Lipid Panel|||||||N||||ORH|||||||^10162193||F|
OBX|1|ST|Chol||<2.59|mmol/L||<|||F|||||||AF0000030|20120222143059|
OBX|2|ST|LDL||--- |mmol/L|||||F|||||||AF0000030|20120222143059|
OBX|3|ST|HDL||<0.39|mmol/L||<|||F|||||||AF0000030|20120222143059|
OBX|4|ST|Trig||3.00|mmol/L|||||F|||||||AF0000030|20120222143059|
OBX|5|ST|non-HDL||--- |mmol/L|||||F|||||||AF0000030|20120222143059|
OBX|6|ST|Chol/HDL||--- ||||||F|||||||AF0000030|20
```