DATA SHEET

No Restriction

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1. INTRODUCTION

This document describes the Data Connectivity Protocol (patient and control records) for LIMS connectivity based on the ASTM 1381 – 95 ("Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems") - protocol in the ADCC (Afinion™ Data connectivity converter) for the Afinion™ AS100 Analyzer. It describes the protocol and the format of the records returned from the Analyzer. 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 Revision

Revision	Date	Author	Comments
1	28.01.2010	DZe/ TUh/ ESc	First version
2	10.06.2010	VEKJ	Ch.1.1 Changed header texts and removed unused table cells Ch.2.2 Corrected terminator record format Ch.3.1 Added explanation table of high level protocol Ch 4.2,4.4.,4.5 Changed example Ch 5.1 Changed and added example
3	30.06.2010	VEKJ	Ch 4.6,5.1.3 Updated with precaution and example for ACR out of range results. Ch 3.1 Updated standard reference
4	06.12.2010	IVFR	Ch. 2.2 Removed erroneous <CR> characters from table.

2 PHYSICAL TRANSMISSION OF MESSAGES

2.1 ASTM Socket transfer (High Level)

Each ASTM message will be transmitted without low level characters. The transmission of the data will be controlled by the TCP/IP socket layers. The ACK of the receiver is to mark, if the LIS could save the data successful.

Sender (PCC)	Direction	Receiver (LIS)
ASTM-result-message	-->	
	<--	<ACK>

wherein:
<ACK> … ASCII 0x06

2.2 ASTM Socket transfer (Low Level)

The serial interface is based on the ASTM 1381 – 95 "Standard Specification for
Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems".

Sender (PCC)	Direction	Receiver (LIS)	Description
<ENQ>	-->		Notifying receiver that there is information to send.
	<--	<ACK>	LIS sends back an ACK, if it is ready.
<STX>1H Message<ETX><CS><CR><LF>	-->		Header record
	<--	<ACK>	
<STX>2P Message<ETX><CS><CR><LF>	-->		Patient record
	<--	<ACK>	
<STX>3O Message<ETX><CS><CR><LF>	-->		Order record
	<--	<ACK>	
<STX>4R Message<ETX><CS><CR><LF>	-->		First result record
	<--	<ACK>	
<STX>5R Message<ETX><CS><CR><LF>	-->		Second result record
	<--	<ACK>	
.			
.			
.			
<STX>?L Message<ETX><CS><CR><LF>	-->		Terminator record
	<--	<ACK>	
<EOT>	-->		Message complete transmitted.

If one message will be answered by a <NAK>, this message will be repeated 3 times. After the third <NAK>, the transfer will be finished. Next try to transmit this measurement will start after 10 minutes.
If one message is longer than 240 characters, it is not broken into multiple messages, i.e. <ETB> is never used.

wherein:
<ENQ> … ASCII 0x05
<STX> … ASCII 0x02
<ETX> … ASCII 0x03
<EOT> … ASCII 0x04
<ACK> … ASCII 0x06
<NAK> … ASCII 0x15
<ETB> … ASCII 0x17

3 MESSAGE STRUCTURE

3.1 ASTM message structure

The ASTM high level message structure is based on the ASTM 1394-97 "Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems". An overview of the protocol is described in the table below.

Sender (PCC)	Direction	Receiver (LIS)	Description
H|Message<CR><LF> P|Message<CR><LF> O|Message<CR><LF> R|Message<CR><LF> R|Message<CR><LF> . . R Message<CR><LF> L|1|N<CR><LF>	-->		Record
	<--	<ACK>	

3.2 Patient measurement results to LIS

Message structure:

ASTM segment	Description
H	Message Header
P	Patient Identification
O	Observation Request
R	Observation Result

4 SEGMENTS

4.1 Legend

- Interpretation: additional description
- Req.: F ... fix value, C ... configured value via web interface, A ... data comes from analyzer, X ... calculated values (e.g. date/time), R ... required from LIS, O ... optional from LIS
- ASTM Field: Nr of ASTM field
- Source of data: Field of the Afinion data record, where the data comes from.

4.2 H - Record

Field name	Interpretation	Req.	ASTM Field	contents
Field separator	Field separator byte	F	H.2.1	
Encoding characters	Other field separator characters	F	H.2.1	
Sending application	Model name (always "Afinion AS100")	F	H.5.1	
Sending facility	DeviceID of measuring device.	A	H.5.3	Serial number of footer
Receiving application	Name of the receiving application / dept. (configurable)	C	H.10.1	Configured value
Processing ID	P ... patient measurement results Q ... quality control results	A	H.12.1	P for record,patient@ Q for record,control@
Version ID	ASTM-version used	F	H.13.1	ASTM: "1"
Date / time of message	date and time of message creation	X	H.14.1	current time stamp

ASTM-Example: `H|\^&|||Afinion AS100^^AS0007962||||EPR||P|1|20100608185448|`

4.3 Acknowledge-Message

ASTM-Example: `<ACK>`

4.4 P - Record

Field name	Interpretation	Req.	ASTM Field	contents
Set ID - Patient ID	PID segment number	F	P.2.1	
Patient Identifier List	(local) patient ID	A	P.4.1	P- ID of header

ASTM-Example: `P|1||43|||||U|`

4.5 O - Record

Field name	Interpretation	Req.	ASTM Field	contents
Set ID - Observation Request	OBR segment number	F	O.2.1	
Filler Order Number		A	O.4.1	RUN# of header
Universal Service ID	name of assay	A	O.5.4	Name of assay of header
Specimen action code	Constant value	F	O.12.1	N
Specimen Source	Afinion ASTM description 0 O // other 1 C // Blood capillary 2 V // Blood venous	A	O.16.2	Assay variant of footer
Charge to practice	reagent lot	A	O.24.2	LOT# of header
Result Status	always "F" (final result)	F	O.26.1	

ASTM-Example: `O|1||43|^^^CRP|||||||N||||^O|||||||||^10124809||F|`

4.6 R - Record

Field name	Interpretation	Req.	ASTM Field	contents
Set ID - Observational Simple	R – Segment number	F	R.2.1	
Observation Identifier	Test Device ID	A	R.3.4	Test Name of sub record
Observation Value	measurement value	A	R.4.1	Result of sub record
Units	unit	A	R.5.1	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	R.7.1	Only '<' and '>' will be supported by the Afinion analyzer. The Observation Value shall not be presented if abnormal flag is present. See precaution below for ACR.
Observation result status	always "F" (final result)	F	R.9.1	
Responsible Observer	Operator ID of the user, which the measurement has done.	A	R.11.1	operator ID of footer
Date/Time of Analysis	measurement time	A	R.13.1	Date/Time of header

ASTM-Example: `R|1|^^^CRP|16|mg/L||||F||||20100608142352|`

Precaution for ACR: The ACR observation value shall be interpreted as **not valid** if albumin and/or creatinine are below or above measurement limits, independent of the content in ACR abnormal flag field.See 5.1.3 for an example.

5 EXAMPLES

5.1 Result-Message (ASTM)

5.1.1 Example 1

```
H|\^&|||Afinion AS100^^AS0007962|||||EPR||P|1|20100608185448|
P|1||43|||||U|
O|1||43|^^^CRP|||||||N||||^O|||||||^10124809||F|
R|1|^^^CRP|16|mg/L||||F||||20100608142352|
L|1|N
```

5.1.2 Example 2

```
H|\^&|||Afinion AS100^^AS0007962|||||EPR||P|1|20100608185348|
P|1||ADCC PATIENT STX|||||U|
O|1||1|^^^ACR|||||||N||||^O|||||||^10142193||F|
R|1|^^^ACR|0.5|mg/g||||F||||20100608140517|
R|2|^^^Alb|8.0|mg/L||||F||||20100608140517|
R|3|^^^Creat|17.4|mg/dL||||F||||20100608140517|
L|1|N
```

5.1.3 Example 3

This example shows an ACR measurement where the ACR observation value must be interpreted as **not valid** even if abnormal flags are missing. This is caused by the albumin (Alb) observation value which is below measurement limit.

```
H|\^&|||Afinion AS100^^AS0007962|||||EPR||P|1|20100616123012|
P|1||2|||||U|
O|1||2|^^^ACR|||||||N||||^O|||||||^10142193||F|
R|1|^^^ACR|5.6|mg/g||||F||||20100608140536|
R|2|^^^Alb|4.1|mg/L||<||F||||20100608140536|
R|3|^^^Creat|33.0|mg/dL||||F||||20100608140536|
L|1|N
```