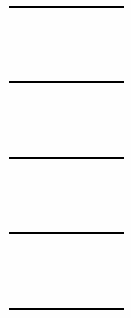
 **ABX Diagnostics** Montpellier

ABX Diagnostics
Output format for
Biochemistry Analyzers

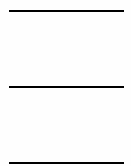
Pentra 400
RAA025AA





Chapter 1

Introduction

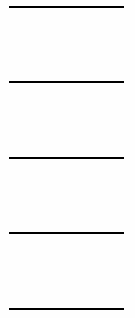




Introduction

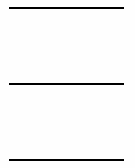
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Chapter 2

Physical Connection

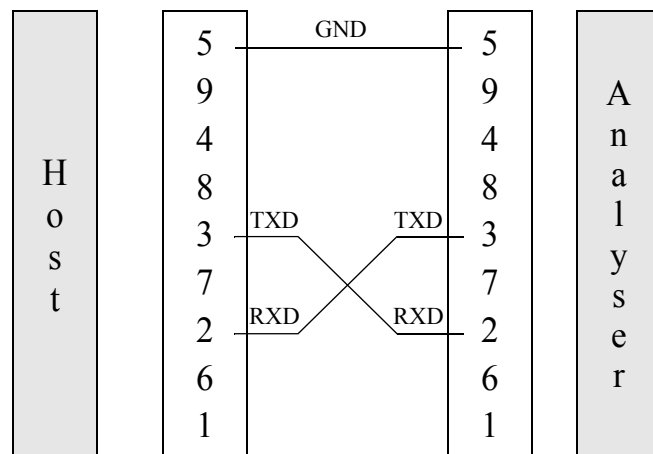


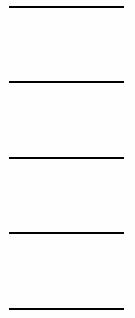


RS232 connection

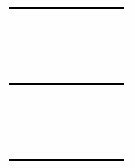
1. Instrument RS DB9

The Pentra 400 RS port connector is a standart DB-9 male connector





Chapter 3 ASTM Format





ASTM Format

ABX Diagnostics analyzers format responds to the ASTM specifications E-1381 & E-1394:

- E-1381: Standard specification for Low Level protocol to transfer messages between clinical or laboratory instruments and computer systems.
- E-1394: Standard specification for transferring Information between clinical or laboratory instruments and computer systems.

1. Connection specifications (ASTM E-1381)

1.1. Hardware and software characteristics

You can setup Baud rate, Parity, Stop bit,...

Hardware setting of the interface: Connect the Host and the instrument by the DB9 serial port.

1.2. Output data characteristics

Characters: ASCII
 Maximum message length: 247 characters.
 Analyzer manages Xon/Xoff protocol.

1.3. Communication protocol

Table 1: Standard control characters

Control String	Hexadecimal value
<ENQ>	\$05
<ACK>	\$06
<NAK>	\$15
<STX>	\$02
<ETX>	\$03
<CR>	\$0D
<LF>	\$0A
<EOT>	\$04

1.3.1. Instrument\Host connexion

Table 2: Typical discussion between Instrument and Host

Instrument	<>	Host
<ENQ>	>	
	<	<ACK>
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<STX>2...Data...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<EOT>	>	



Table 3: Typical discussion between Host and Instrument

Instrument	<>	Host
	<	<ENQ>
<ACK>	>	
	<	<STX>1...Data...<CR><ETX>xx<CR><LF>
<ACK>	>	
	<	<STX>2...Data...<CR><ETX>xx<CR><LF>
<ACK>	>	
	<	<EOT>

1.3.2. Discussion with conflict between Instrument and Host

Number of transmission if negative answer: 6
 Timeout: 15s
 Special timing: None
 Description of other specific treatments: None

In case of ENQENQ conflict analyzer waits for 2s and try emission again, in case of 6 successive tries, analyzer will wait 10s (default is 10s) before another downloading request.
 Analyzer is master in case of conflict.

Table 4: Discussion with conflict between Instrument and Host

Instrument	<>	Host
<ENQ>	>	
	<	<ENQ>
Wait 2 second...		
<ENQ>	>	

Table 4: Discussion with conflict between Instrument and Host

Instrument	<>	Host
	<	<ACK>
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<STX>2...Data...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<EOT>	>	

1.3.3. Defect packet during discussion between Instrument and Host

Table 5: Defect packet during discussion between Instrument and Host

Instrument	<>	Host
<ENQ>	>	
	<	<ACK>
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<NAK>
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<STX>2...Data...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<EOT>	>	



1.4. Flow control

Xon/Xoff protocol may be used on ABX instrument.

1.5. Interruptions

If the emission of results is started, the EOT interruption character will not be taking into consideration.

On the other hand, if the EOT interruption character is received during the frame preceding the results, the analyser will close its message by the terminal phase, then will wait for 20 s before to take the line again.

1.6. ASTM Data frame format

A sequential number located after the <STX> charcater is inserted into each Data frame. Frame number is set to 1 when transfer phase is initialized and is incremented by 1 for each frame up to 7 and then returns to 0.

Frame number is to permit receiver to distinguish between new and retransmitted frame, in case of retansmitted frame (after a <NAK> response from Host), frame number is not incremented: <STX>1...Data...<CR><ETX>xx<CR><LF>

Table 6: Frame format

ASTM field	Definition	Transmitted data	# of bytes	Comments
0	STX	\$02	1	
1	Frame number	1 to 7, 0, ...	1	Frame number is set to 1 and incremented by 1 for each frame up to 7 and then returns to 0
2	Data message		240 max.	Header, Patient, Order, Result & Comment messages

Table 6: Frame format

ASTM field	Definition	Transmitted data	# of bytes	Comments
3	End of data message ETB if data message contains 240 characters ETX if end frame		1	
4	Checksum		2	
5	CRLF	\$0D \$0A	2	

1.6.1. Frame cheksum

According to ASTM E-1381 frame checksum (<STX>1...Data...<CR><ETX>xx<CR><LF>) is defined as modulo 256 of ASCII values sum between <STX> not included and <ETX> included characters: 1...Data...<CR><ETX>

2. Records general format specifications (ASTM 1394)

2.1. Codes of characters

ABX analysers use Standard ASCII characters set with codes between 32 and 127 (Codes from 0 to 31 are reserved for protocol).

The Escape delimiter is not used in the datas sent by analysers.

Data frames encapsulate Records defined by ASTM E-1394 norm, Records themselves encapsulate ASTM fields.

The record is inside Data frame: <STX>1...Data...<CR><ETX>xx<CR><LF>



Table 7: ASTM Records

Record ID	ASTM Definition
H	Header
P	Patient
O	Order
R	Result
C	Comment
Q	Query (Request information order)
S	Scientific Record
M	Manufacturer informations
L	Terminator record

2.2. Structure of Records

2.2.1. Structure of records for Order transmission

- H (Header)
- ..P (Patient)
- ..C (Patient Comments) Optional
-O (Order)
-C (Order Comments) Optional
- L (Terminator)

The transmission of an Order without Patient record is not allowed, but Patient record can be empty. Example: <STX>2P|1<CR><ETX>BB<CR><LF>

2.2.2. Instrument Patient file modification by Host

- H (Header)
- ..P (Patient)
- ..C (Patient Comments) Optional
- L (Terminator)

2.2.3. Structure of records for Result transmission

- H (Header)
- ..P (Patient)
- ..C (Patient Comments) Optional
-O (Order)
-C (Order Comments) Optional
-C (Run Alarms) Optional
- R (Result)
- C (Flag Result) Optional
- R (Result)
- C (Flag Result) Optional
-
-
- R (Result)
- C (Flag Result) Optional
- L (Terminator)

2.3. Description of Records

- Only the fields described with their specified length, in further tables, are used by ABX instruments.
- Length of field can be less than maximum value but must not be more.
- Only «Sample ID», «Action Code», «Specimen descriptor» and «Test» fields from Order record must be informed, all other fields are optionals.
- Delimiter must be used even if field is free.



- Delimiters inside records are separate by «|» (ASCII \$7C).
- Delimiters inside fields are separate by «^» (ASCII \$5E).

2.3.1. Header record

R = Received by Pentra 400 from the Host
 S = Send by Pentra 400 to the Host

Table 8: Header record fields

ASTM field	Definition	Transmitted data	Used for		Fields length
			R	S	
7.1.1	Record Type	H	✓	✓	1
7.1.2	Delimiters definition	idem standard:	✓	✓	4
7.1.3	Message Control ID				
7.1.4	Access Password				
7.1.5	Sender Name	Text		✓	15
7.1.6	Sender Address				
7.1.7	Reserved				
7.1.8	Sender Telephone Nb				
7.1.9	Characteristics of Sender				
7.1.10	Receiver ID				
7.1.11	Comments or Special Instructions				
7.1.12	Processing ID	P		✓	1
7.1.13	Version Nb	E1394-97		✓	7
7.1.14	Date and Time of message	YYYYMMDDHHMMSS		✓	14

2.3.2. Patient record

Table 9: Patient record fields

ASTM field	Definition	Transmitted data	Used for		Fields length
			R	S	
8.1.1	Record Type	P	✓	✓	1
8.1.2	Sequence Nb	1, 2, 3...	✓	✓	1
8.1.3	Practice Assigned Patient ID				
8.1.4	Laboratory Assigned Patient ID	Patient Id (Advised for Workflow management)	✓	✓	25
8.1.5	Patient ID No 3				
8.1.6	Patient Name	LASTNAME^FIRSTNAME	✓	✓	20^20
8.1.7	Mother's Maiden Name				
8.1.8	Birthdate	YYYYMMDD	✓	✓	8
8.1.9	Patient Sex	M (male), F (female) or U (unspecified).	✓	✓	1
8.1.10	Patient Race-Ethnic Origin				
8.1.11	Patient Address				
8.1.12	Reserved				
8.1.13	Patient Telephone Nb				
8.1.14	Attending Physician ID	Text	✓		20
8.1.15	Special Field 1				
8.1.16	Special Field 2				
8.1.17	Patient Height				
8.1.18	Patient Weight				
8.1.19	Patient's Known or Suspected Diagnosis				
8.1.20	Patient Active Medication				

Table 9: Patient record fields

ASTM field	Definition	Transmitted data	Used for		Fields length
			R	S	
8.1.21	Patient's Diet				
8.1.22	Practice Field 1				
8.1.23	Practice Field 2				
8.1.24	Admission and Discharge Dates				
8.1.25	Admission Status				
8.1.26	Location	Text	✓		20
8.1.27	Nature of Alternative Diagnostic Code and Classifiers				
8.1.28	Nature of Alternative Diagnostic Code and Classifiers				
8.1.29	Patient Religion				
8.1.30	Martial status				
8.1.31	Isolation Status				
8.1.32	Language				
8.1.33	Hospital Service				
8.1.34	Hopital Institution				
8.1.35	Dosage Category				

The fields above are filled following the demographic level of information present on the analyser.

2.3.3. Order record

Table 10: Order record fields (control transmission are not available at this time of publication)

ASTM field	Definition	Transmitted data	Used for		Fields length
			R	S	
9.4.1	Record Type	O	✓	✓	1
9.4.2	Sequence Nb	1, 2, 3...	✓	✓	1
9.4.3	Specimen ID	Sample ID^rack^pos^repl- cate^Control Name^Lot N°	✓	✓	R:16 S:16+2+2+2+ 20+16
9.4.4	Instrument Specimen ID				
9.4.5	Universal Test ID	^^^Test code\^^^Test code... (from the Host) or empty from Pentra	✓		See Table 12, "Test codes", page 14
9.4.6	Priority	S (Stat) or R (Routine)	✓		1
9.4.7	Requested/Ordered Date and Time			✓	14
9.4.8	Specimen Collection Date and Time	YYYYMMDDHHMMSS	✓		14
9.4.9	Collection End Time				
9.4.10	Collection Volume				
9.4.11	Collector ID				
9.4.12	Action Code (See nota)	C: cancel request N: New request A: Add request Q: send a control	✓	✓	1 obligatory for reception (C/A/N)
9.4.13	Danger Code				
9.4.14	Relevant Clinical Informations				
9.4.15	Date/Time Specimen Received				

Table 10: Order record fields (control transmission are not available at this time of publication)

ASTM field	Definition	Transmitted data	Used for		Fields length
			R	S	
9.4.16	Specimen Descriptor	1: Serum / Plasma 2: Urine 3: Others (See Table 12, "Test codes", page 14)	✓	✓	1 (obligatory)
9.4.17	Ordering Physician		✓	✓	20
9.4.18	Physician Tel Nb				
9.4.19	User Field 1				
9.4.20	User Field 2				
9.4.21	Laboratory Field 1				
9.4.22	Laboratory Field 2				
9.4.23	Date and Time Results reported or last modified				
9.4.24	Instrument Charge to Computer System				
9.4.25	Instrument Section ID				
9.4.26	Report Types	F: final C: correction I: waiting for treatment Y: no test order for this sampling Z: no record for this patient Q: Answer to a Query		✓	1
9.4.27	Reserved				
9.4.28	Location or Ward of Specimen Collection				
9.4.29	Nosocomial Infection Flag				
9.4.30	Specimen Service		✓	✓	20
9.4.31	Specimen institution				



If the Action Code (field 9.4.12) is «A» for the first download, the order is created on the instrument.

2.3.4. Result record

Table 11: Result record fields

ASTM field	Definition	Transmitted data	Used for		Fields length
			R	S	
10.1.1	Record Type	R		✓	1
10.1.2	Sequence Nb	1, 2, 3...		✓	1
10.1.3	Universal Test ID* (See Test Codes table)	^^^Test number ^ Test Name		✓	7
10.1.4	Data or Measurement Value	Text xxx.xxx		✓	Max 11
10.1.5	Units	See Unities table		✓	2
10.1.6	Reference Range	Normal L to Normal H Panic L to Panic H			
10.1.7	Result Abnormal Flag	L,H,LL,HH,>,<,A		✓	2
10.1.8	Nature of Abnormality Testing				
10.1.9	Result Status	V: Operator Modified F: final result C: rerun result		✓	1
10.1.10	Date of Change in Normative Values or Units				
10.1.11	Operator Identification				
10.1.12	Date/Time Test Starting	YYYYMMDDHHMMSS		✓	14
10.1.13	Date/Time Test Completed				
10.1.14	Instrument Identification				

The transmitted numerical values correspond to the rounded values displayed on the analysers, therefore, they never exceed 6 characters.



The transmitted units are the ones parametrized by the method user.
 *:The Test codes Tables should be updatable on the Host according to the test definition, for the Open Channels, freely definable by the user. The test Codes available on Pentra 400 are between 000 and 999. The calculated parameters available on Pentra 400 are from 1000.

For example of calculated parameter: if Test Name «Ratio» = APO-A1/ APO-B (Test Code 1001), the LIS have to send only the test code 1001 in the Order record field «O» 9.4.5 to received results for Ratio with APO-A1 and APO-B parameters .

The relation between "Test Name" and "Specimen " should be respected according to the table below :
 (Only the orders created with the right relation will be accepted in the worklist)

Table 12: Test codes

Test Code	Test Name	Specimen	Test Code	Test Name	Specimen	Test Code	Test Name	Specimen
1	AcP-Tot	1	28			55	THb-WB	3
2	AcP-NP	1	29	Iron	1	56	THb-H	3
3	ALP	1	30	Lact	1	57	IgA	1
4	ALT	1	31	Magn	1	58	IgG	1
5	AST	1	32	Phos	1	59	IgM	1
6	Amy	1	33	Phos-U	2	60	Kappa	1
7	Amy-U	2	34	TP	1	61	Lambda	1
8	CK	1	35	TP-U	2	62		
9	CK-MB	1	36	Trigly	1	63	Myo	1
10	GGT	1	37	Uric	1	64	Oroso	1
11	LDH	1	38	Uric-U	2	65	Prealb	1
12	Lipase	1	39	Urea	1	66	RF	1
13	Alb	1	40	Urea-U	2	67	Transf	1

Table 12: Test codes

Test Code	Test Name	Specimen	Test Code	Test Name	Specimen	Test Code	Test Name	Specimen
14	Bili-T	1	41	AAT	1	68	UIBC	1
15	Bili-D	1	42	µALB	1	69	Carba	1
16	Calcium	1	43	µALB-U	2	70	Digo	1
17	Calc-U	2	44	Apo-A1	1	71	Phenob	1
18	Chol	1	45	Apo-B	1	72	Phenit	1
19	HDL	1	46	ASO	1	73	Theo	1
20	LDL	1	47	Cerulo	1	74	Valp	1
21	CO2	1	48	C3c	1	101	Na	1
22	Crea	1	49	C4c	1	102	K	1
23	Crea-U	2	50	CRP	1	103	Cl	1
24	Fructo	1	51	Ferri	1	104	Na -U	2
25	GluP	1	52	Hapto	1	105	K -U	2
26	GluP-U	2	53	A1c-WB	3	106	Cl -U	2
27	GluK	1	54	A1c-H	3			

2.3.5. Flags and alarms

2.3.5.1. Analytical alarms

All the results with an analytical flag are identified and transmitted by the following way:
 - «A» for Abnormal in the field 10.1.7 of the result.
 - The result record is following by a comment record. In this comment record are all the flags, separated by a delimiter (^).

Table 13: Flags

Flags	
SAMPLE_LIMIT	NOISE
LINEARITY_HIGH	NORM_RANGE_HIGH
LINEARITY_LOW	NORM_RANGE_LOW
ANTIGEN_EXCESS (not available)	CONF_RANGE_HIGH (not available) CONF_RANGE_LOW (not available)

2.3.5.2. Biological flags

All the results with a biological flag are identified and transmitted by the following way:
The field 10.1.7 of the record result is filled with one of those identifiers: «L / LL / H / HH / < / >».

2.3.6. Comment record

Table 14: Comments record fields

ASTM field	Definition	Transmitted data	Used for		Fields length
			R	S	
11.1.1	Record Type	C	✓	✓	1
11.1.2	Sequence Nb	1, 2,3...	✓	✓	1
11.1.3	Comment Source	I clinical instrument system		✓	1
11.1.4	Comment Text	Text	✓	✓	Comment Text dependent
11.1.5	Comment Type	G:Free text I: Instrument flag comment		✓	1

2.3.7. Units

Units are transmitted in the field 10.1.5 of the record result.

Table 15: Units

	Units		Units		Units
1	Ref	17	µg/dL	33	IU/dL
2	mol/L	18	ng/L	34	mIU/L
3	mol/dL	19	ng/dL	35	mIU/dL
4	mmol/L	20	mg/mL	36	mIU/mL
5	mmol/dL	21	µg/mL	37	mval/L
6	µmol/L	22	ng/mL	38	mEq/L
7	µmol/dL	23	pg/mL	39	%
8	nmol/L	24	µkat/L	40	s
9	nmol/dL	25	nkat/L	41	KU/L
10	pmol/L	26	U/L	42	kIU/L
11	pmol/dL	27	U/dL	43	g/mol
12	g/L	28	mU/L	44	mg/g
13	g/dL	29	mU/dL	45	Δ A
14	mg/L	30	U/mL	46	Δ A/min
15	mg/dL	31	mU/mL	47	Δ %
16	µg/L	32	IU/L	48	IU/mL

2.3.8. QUERY mode (Not available at this time)

The E1394 protocol imposes a specific treatment for the request to the LIS. The characteristics of this treatment are the followings:

2.3.8.1. Emission of a request to the LIS.

Table 16: Request information record fields

ASTM field	Definition	Transmitted data	Used for		Fields length
			R	S	
12.1.1	Record Type	Q	✓	✓	1
12.1.2	Sequence Nb	1	✓	✓	1
12.1.3	Starting Range ID Number	^SID1/^SID2^/.../SIDn	✓	✓	n* (16+1+1)
12.1.4	Ending Range ID Number				
12.1.5	Universal Test ID				
12.1.6	Nature of Request Time limits				
12.1.7	Beginning Request Result Date & Time				
12.1.8	Ending Request Result Date & Time				
12.1.9	Requesting Physician name				
12.1.10	Requesting Physician Tel N°				
12.1.11	User Field 1				
12.1.12	User Field 2				
12.1.13	Request information Status code	O: test informations and demographic request (no results) X: Request cancelled	✓	✓	

2.3.8.2. Test order on request reception

- Query messages are generated by P400 at each Barcode reading cycle following the «Start» action.

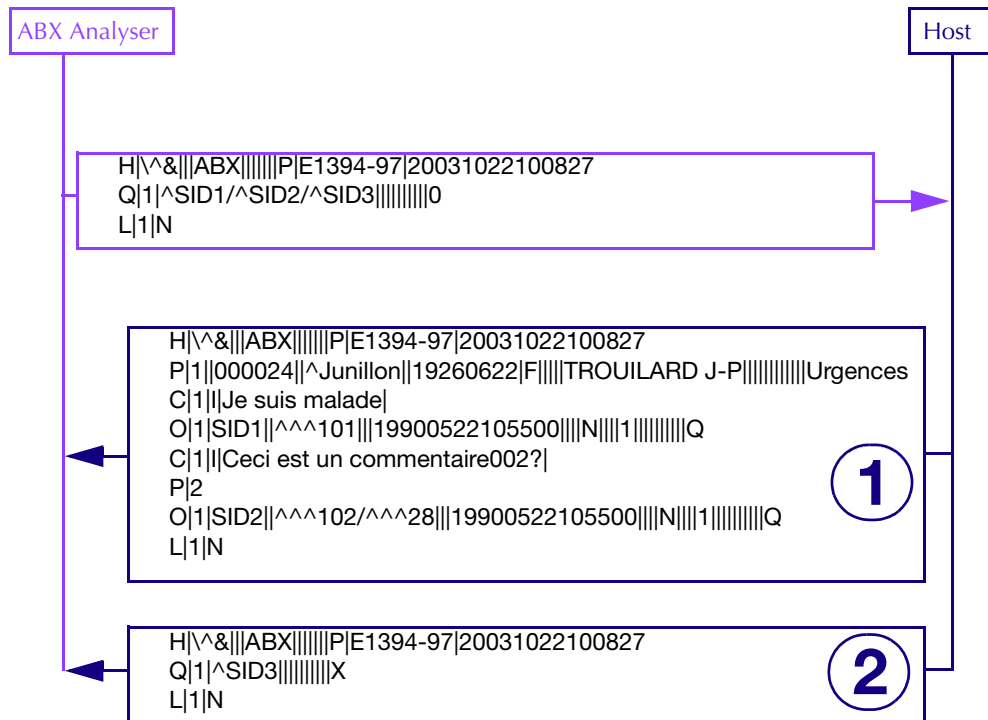
- A Query message is composed by the sequence H,Q,L. The Q record contains 1 or more SID.

- For each Query message, a response from the Host is expected. If the response is not received after a delay of 10 seconds, P400 will try to send 3 times the Query message.

- They are 2 cases of response returned by the Host (See Diag.1:“[Example](#)”, page 17):

- **1-** An order is matched for the SID: The response message is built by the following sequence of records H, P, O, L.

- **2-** There is no order matched for the SID: The response message is built by the sequence of records: H,Q, L with «x» for 12.1.13 field (Request information Status code).



Diag.1: Example

3. Management of errors

3.1. During Instrument transmission

During a single result transmission by the instrument, if the host lost the transmission (Time-Out or EOT) the full message will be transmitted again after a parametrable delay (10s by default).

In case of long files with several results the re-transmission will be done from the result lost to the end.

After 6 consecutive NAKs detected the sent file is deferred to later transmission.

3.2. During Host transmission

According to E-1381 protocol, error management of Time-out, Checksum and frame number, in case of none respect of these norms, will return NAK (or communication will be halted). In case of transmission of long files (Worklist upload for example), files previously transmitted before transmission error will be interpreted and managed by the instrument, others will not be used.

According to E-1394 protocol, all Orders without «Sample ID» or with «Sample ID» superiors to 16 characters, will not be interpreted by the instrument.

4. Example of data frame

4.1. Example of Order sent by Host

The color of the line defines the transmission way:

From HOST to PENTRA

From PENTRA to HOST

Table 17: Example of Order sent by Host

```

<ENQ>
<STX>1H|^&|||ABX|||||P|E1394-97|20031118154840<CR><ETX>59<CR><LF>
<ACK>
<STX>2P|1||PID12345||LASTNAME^FIRSTNAME||19641223|M||||Prescriptor|||||||Loca-
tion<CR><ETX>D6<CR><LF>
<ACK>
<STX>3C|1||Patient Comment|<CR><ETX>B8<CR><LF>
<ACK>
<STX>4O|1|2312015||^13v^^29|R||20031117||||N|||1<CR><ETX>25<CR><LF>
<ACK>
<STX>5C|1||Order Comment|<CR><ETX>E1<CR><LF>
<ACK>
<STX>6L|1|N<CR><ETX>09<CR><LF>
<ACK>
<EOT>
  
```



4.2. Example of Result sent by instrument

The color of the line defines the transmission way:

- From HOST to PENTRA
- From PENTRA to HOST

Table 18: Example of Result sent by instrument

<ENQ>
<ACK>
<STX>1H ^& 01 P E1394-97 20031118162410<CR><ETX>D7<CR><LF>
<ACK>
<STX>2P 1 PID12345 LASTNAME^FIRSTNAME 19641223 M<CR><ETX>C4<CR><LF>
<ACK>
<STX>3C 1 Patient Comment G<CR><ETX>FF<CR><LF>
<ACK>
<STX>4O 1 2312015 20031118154703 20031117000000 1 Prescriptor F Loca- tion<CR><ETX>EE<CR><LF>
<ACK>
<STX>5C 1 Order Comment G<CR><ETX>28<CR><LF>
<ACK>
<STX>6R 1 ^1002^RATIO 5.54 2 A F 18991230000000<CR><ETX>1D<CR><LF>
<ACK>
<STX>7C 1 Flag^NORM_RANGEL <CR><ETX>69<CR><LF>
<ACK>
<STX>0R 2 ^13^ALB 5.5494 6 H F 20031118162203<CR><ETX>7E<CR><LF>
<ACK>
<STX>1C 1 Flag^NORM_RANGEH <CR><ETX>5F<CR><LF>

Table 18: Example of Result sent by instrument

<ACK>
<STX>2R 3 ^29^IRON1 -0.01262 6 L F 20031118162215<CR><ETX>76<CR><LF>
<ACK>
<STX>3C 1 Flag^NORM_RANGEL <CR><ETX>65<CR><LF>
<ACK>
<STX>4L 1 N<CR><ETX>07<CR><LF>
<ACK>
<EOT>



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