PATHFAST

Host Interface Specifications

(Based on ASTM Specifications)

Final Version (Rev1.0)

05/December/2005

1. Index

2. Revision History

Revision History			
Revision	**Date**	**Modifications**	**Revised By**
0.0	3/3/2005	Newly Created	T. Inoue
0.1	3/10/2005	-. Changed expression of Japanese words. -. Added some description	T. Inoue
0.2	3/14/2005	-. Index was translated into Japanese and words in the body were changed accordingly -. Added explanation and appendices -. Made modifications of expression	T. Inoue
0.3	4/27/2005	-. Added supported fields of birth date and sex of patient	T. Inoue
1.0	7/31/2005 12/5/2005	-. Added limitations -. Other addition and revision -. The content of the Remarks is updated.	T. Inoue K.Kashiyama

3. Introduction

3.1 Purpose

This document is a guide to integrate a Laboratory Information Management system with PATHFAST instrument using the ASTM (American Society for Testing and Materials) specification to transfer information between clinical instruments and computer systems.

Communication between PATHFAST and Host computer consists of receiving test request from Host computer and sending test results to Host computer. Communication is performed through RS232C based on ASTM1394 (High Level) and ASTM1381 (Low Level) standards. ASTM1381 (Low Level) communication protocol is used for transferring or receiving messages in Host Interface of PATHFAST instrument.

ASTM1394-91 standard defines how to treat the transferred data as messages. The message consists of several records as described in the following. These messages are translated into one or more frames. Frames are transmitted based on ASTM1381 standard.

About frame configuration

Frame used by PATHFAST is based on the contents defined in ASTM1381-91.

[Frame Configuration (from ASTM 1381-91)]

<STX>[frame #][Text] (<ETB> / <ETX>) [Check Sum: upper byte][Check Sum: lower byte]<CR><LF>

[Text] consists of [Record] and <CR>=0x0d(hex).

When a [Text] exceeds 240 bytes, the rest is set in the next frame by setting control code of <ETB> =0x17(hex) for the first frame, called [Intermediate Frame]. When a [Text] is less than or equal to 240 bytes, control code of <ETX> =0x03 is set. Do not set <ETB> for a [Text] not more than 240 bytes.

Check sum is indispensable and can not be omitted.

The [Text] in a frame above consists of one single record of followings and <CR>=0x0d(hex) at the end.

Records are: Header (H), Terminator (L), Patient (P), Test Order (O), Test Result (R),and Comment (C)

PATHFAST does not support frames with more than one [Record] set inside.
Set only one [Text] in a single frame though the text length is less than or equal to 240 bytes.
When a [Text] exceeds 240 bytes, it is divided into more than two frames by setting <ETB> at the end of the divided frame.

Examples:
<STX>[frame #][H Record]<CR><ETX><C1><C2><CR><LF>
<STX>[frame #][P Record]<CR><ETX><C1><C2><CR><LF>
<STX>[frame #][O Record]<CR><ETX><C1><C2> <CR><LF>
<STX>[frame #][R Record]<CR><ETX><C1><C2><CR><LF>
<STX>[frame #][C Record]<CR><ETX><C1><C2><CR><LF>
<STX>[frame #][L Record]<CR><ETX><C1><C2><CR><LF>
Here: <C1> means upper byte of checksum and <C2> means lower byte of checksum.

Example for the [Text] exceeded 240 bytes (R Record exceeded 239 bytes)
[Intermediate Frame]
<STX>[frame #][R Record]<CR><ETB><C1><C2><CR><LF>
=>R Record contains first 239 bytes.
For last frame: R Record contains less than or equal to 239 bytes of data
<STX>[frame #][R Record]<CR><ETX><C1><C2><CR><LF>

About Check Sum
Check sum consists of two characters and set after <ETB> or <ETX>. Check sum is calculated by adding characters in binary code and then the least significant byte of the result is used as Check sum. Characters used for this calculation are frame number next to <STX> through <ETB> or <ETX>. <STX>, Check sum, <CR> and <LF> are not used for this calculation.
Check sum is an eight bit integer consisting of two nibbles. These nibbles are expressed in hexadecimal form ASCII characters. These two ASCII characters are set as check sum characters, in the order of upper and lower.
For example, if the Check sum is 122 in decimal, it is expressed 01111010 in binary and 7A in hexadecimal form.

4. General Description

4.1 Product Perspective

Communication sessions with host computer can be started by the operator request or the completion of the assay on PATHFAST instrument automatically.
The operator can request to start download session, and the host computer shall transmit test orders to PATHFAST instrument.

If the operator requires an upload session, PATHFAST instrument will transmit a subset of sample results (identified by the user) stored in the instrument patient database or QC database.

If the instrument is properly configured, automatic downloading or uploading sessions can be started by PATHFAST instrument.
Automatic downloading will occur at session start if host query is configured. In this condition PATHFAST instrument will request test orders for specific sample IDs recognized by using handheld barcode reader.

The second condition will occur, if automatic uploading has been requested, at session completion.

In case the communication session is not generated from PATHFAST instrument, any host computer message is ignored.

All information received by the host computer must be associated with a Sample ID which is the primary key of the database. In addition to programmed tests a certain amount of information can be associated with a Sample ID (patient data) and PATHFAST stores only information that PATHFAST uses.

The sample ID is the primary key to access information in the database.
If the checks fail, PATHFAST sends order reject information to the host computer.
The test orders that PATHFAST can receive are only those of samples PATHFAST queried by Sample IDs within the period of time (60 seconds) designated in low level standard. When timeout occurred or if PATHFAST received orders for different Sample ID, PATHFAST transmits reject information or error status in low level reported. Host computer shall not send such erroneous data.

PATHFAST can receive six (6) test orders for one batch assay at maximum. For example, when eight (8) test orders, PATHFAST sends reject information for those tests which could not be received. For those test, you need to start again with querying the host computer to get test orders. The host computer needs to send residual test orders and those retesting is needed. The ordered tests are set for lanes in the order of received test order records (“O” record).

The host computer must refer to the PATHFAST specific computer codes of the tests so that PATHFAST identifies tests ordered. Refer to “Appendix – PATHFAST Test Codes” of this document.

5. Specific Requirements

5.1 Protocol Specification

5.2 Low Level Interface

Low level interface conforms to ASTM specification E-1381-91. The following characteristics are supported and are configurable through Operator Interface in PATHFAST:

Baud Rate	2400, 4800, 9600
Stop Bit	1 or 2 bit
Character Length	7 or 8 bits
Parity	Odd, Even or None
Flow Control	None

5.3 Data Link and Logical Layer

For the Data Link and Logical Layer the ASTM specification E-1381-91 has been maintained as a reference. Protocol limits and constraints are those declared by the standard.
To mention some of them, the data part of the frames exchanged between the PATHFAST instrument and the host computer cannot exceed 240 bytes. As a consequence during transmission sessions specific routines provide the ability to divide large records into multiple frames and during a reception session they re-build partial frames in a single record. The application level has no evidence of this mechanism.

According to ASTM standard the following characters cannot be part of data records:
<SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3>, <DC4>.

Timeout and retry logic are those specified by ASTM standard; the Low Level Clinical Message State Diagram representing the automatic operation executed had been referenced.
In interrupt request status PATHFAST instrument accepts EOT from host computer. And message transmission is aborted. Refer to “Transmission Abort and Error Messages” for details.
PATHFAST sends [NAK] up to 6 times which request the host computer to retry transmission, when received message is invalid frame. When the repetition exceeds 6 or in case of error needed to be aborted, PATHFAST sends [EOT] of abort request to the host computer and wait for [EOT] to be sent.

5.4 Sessions

There are two types of sessions that PATHFAST instrument handles with the ASTM interface: the test orders download and the test results upload. These sessions can be initiated by the operator or automatically activated by the instrument.

When the user requests a download operation, PATHFAST instrument will send a request to the host computer for test orders requested for specific sample using Sample ID as a key, and the host will transmit test orders for that specific sample.

PATHFAST does not accept test orders initiated by the host computer.

Test results upload is initiated by the user or automatically by PATHFAST instrument.
At the end of a record, <CR> (0DH) is always added to show the end of record.

The maximum length of a record is defined as 1000 for PATHFAST instrument.
Delimiters used in a record are described in field description of Header Message Record section.
In general, delimiters for repetition and components can be omitted if they are not used but the delimiter which defines field component is not allowed to omit in any cases.

5.4.1 Common: Message Header and Message Terminator Records

According to ASTM specification, each type of transaction between the instrument (DTE) and the host computer (DCE) shall have two common records, the *Message Header* record and the *Message Terminator* record. These records are used to open or close data transmission between PATHFAST instruments and the host computer.

Refer to the following table for record configuration.

5.4.1.1 Message Header Record ("H" Record)

Refer to the following table for "H" Record configuration.
This record is not allowed to omit.

Message Header Record ("H" Record)

No.	Field Name	Description
1	Record Type ID	Always set 'H'. Identify message as header
2	Delimiter Definition	The 5 ASCII characters composing this field define the type of delimiters that will be used in the following records. PATHFAST supports only those defined in the following. | : Field delimiter between fields @ : Repetition delimiter for repetitious component in a field ^ : Component Delimiter for elements in a field \ : Escape delimiter for special character used ex) |@^| (Not allowed to omit)
3	Message Control ID	Not Supported
4	Access Password	Not Supported
5	Sender Name or ID	Consists of three components. When sending to host computer from PATHFAST, the following three components are set as instrument information. Component 1: instrument name PATHFAST01 Component 2: serial number (9 bytes) Component 3: software version (11 bytes) Ex) PATHFAST01^0502A0123^01.00.00.00
6	Sender Street Address	Not Supported
7	Reserved Fields	Not Supported
8	Sender Telephone Number	Not Supported
9	Characteristics of Sender	Not Supported

10	Receiver ID	Set instrument name PATHFAST01 as Receiver ID when sending from host to PATHFAST (Not allowed to omit). Instrument serial number is not supported.
11	Comment or special Instructions	Not Supported
12	Processing ID	Always set to 'P' meaning Production
13	Version No.	Set to the current ASTM standard version = '1'
14	Date and Time of Message	Format is YYYYMMDDHHMMSS System date of the data transmission.

Sample Record

From PATHFAST to the host computer
H|@^\|||PATHFAST01^1000000001^01-00-00-00|||||||P|1|20050228105347<CR>

From the host computer to PATHFAST
H|@^\|||||||| PATHFAST01||P|1|20050228105347<CR>

5.4.1.2 Message Terminator Record ("L" Record)

Refer to the following table for "L" Record configuration.

This record is not allowed to omit.

Message Terminator Record ("L" Record)

No.	Field Name	Description
1	Record Type ID	Always set 'L'. Identify message as terminator (Not allowed to omit)
2	Sequence Number	Always set '1' (Not allowed to omit)
3	Termination Code	Set 'N' for normal termination and 'E' for abnormal termination while transmitting to host; not considered for received data

Sample Record
L|1|N<CR>

5.5 Test Order Downloading

Test order downloading is used to request test orders available on the host computer and to have them on PATHFAST instrument.

When starting download session, the host computer shall be ready and it shall send the test orders stored for the specific sample designated by PATHFAST using Sample ID.
If PATHFAST is configured to communicate with the host computer, PATHFAST sends a query message created by reading Sample ID with handheld barcode reader to the host computer. And the host computer shall transmit test order information to PATHFAST within the designated time (60 seconds).

5.5.1 Receive Session from DMS

Host driven transmission of test orders are not supported.

5.5.2 Host Query

The host query is manually activated by PATHFAST instrument when the operator makes read of the Sample ID barcode. PATHFAST creates and sends Test Request Message for the specific Sample ID to host computer. The host computer shall create and send Test Order Message for that sample to PATHFAST.

The host computer sends all the requested tests need to be assayed by PATHFAST. The host computer shall send the test orders in separate messages, which means one Test Order Message shall contain null or only one test item. So there exist messages corresponding to the number of test items ordered by host computer. These Test Order Messages for one Sample ID shall be sent in one downloading session.

PATHFAST receives Test Order Messages and recognizes each needed field to store the data. The rest of the data which are not needed for PATHFAST shall be ignored.

Because PATHFAST is asking for information regarding a specific Sample ID, it will reject any type of information associated with different Sample IDs.

If the test order is not recognized as one of those supported by PATHFAST, it will be rejected. PATHFAST will inform the host computer by creating and sending Reject Message to the host computer
The details will be given in section 5.6.

5.5.3 Test Request Message (from PATHFAST to Host)

The *Test Request Message* is used by PATHFAST to request information for each specific sample that PATHFAST read its Sample ID barcode. It is composed from a ***Message Header Record***, a ***Request Information Record*** and a ***Message Terminator Record***.
The *Request Information* record requests information for one specific Sample ID at a time. (The ASTM protocol limits the number of Request Information records to one). As a consequence PATHFAST will wait for the host answer before sending a second Request Information record for a second sample.

5.5.3.1 Request Information Record ("Q" Record)

Based on the ASTM specification the fields composing the *Request Information* are described in the following.

This record is not allowed to omit.

Request Information Record:

No.	Field Type	Description
1	Record Type ID	Always set to 'Q', Identify record type as request.
2	Sequence Number	As defined by the standard set to '1' when query is sent
3	Starting Range ID Number	This field consists of two components. Component 1: Not used. Component 2: Sample ID to request sample information, 20 bytes at maximum. Ex.) ^12345678901234567890
4	Ending Range ID Number	Not Supported
5	Universal Test ID	Not Supported
6	Nature of Request Time Limit	Not Supported
7	Beginning request Results Date and Time	Not Supported
8	Ending request Results Date and Time	Not Supported
9	Requesting Physician Name	Not Supported
10	Requesting Physician Phone #	Not Supported
11	User Field #1	Not Supported
12	User Field #2	Not Supported
13	Request Information Status Code	Always set to 'O' (requesting test orders and patient information)

An example for the complete message (composed by header message record, request information record and message terminator record) is given by:

H|@^\|||PATHFAST01^1000000001^01.00.00.00|||||||P|1|20050228105347<CR>
Q|1|^00228411303|||||||||O<CR>
L|1|N<CR>

5.5.4 Test Order Message (from Host to PATHFAST)

As an answer to the PATHFAST *Test Request Message,* the host computer sends the *Test Order Message.* It contains the records specifying which tests are being requested for the queried Sample ID.
The host computer shall send this message within the designated time (60 seconds).

The message consists of Header Record, Patient Record, Order Record and Terminator Record.
If no requested assay found in the database, the host computer shall send only Header Record and Terminator Record.

PATHFAST process assays according to the information received from the host computer.
The maximum number of assays that PATHFAST can receive is 6.
The host computer shall not send assay item information which had been completed.

5.5.4.1 Patient Information Record ("P" Record)

Refer to the following table for record configuration.

This record is not allowed to omit, excepting no order exists.

Patient Information Record

No	Field	Description
1	Record Type ID	Always set "P", Identify record type as patient information. (Can not be omitted)
2	Sequence Number	As defined by the standard set to '1' when query is sent. (Can not be omitted)
3	Practice Assigned Patient ID	Not Supported
4	Laboratory Assigned Patient ID	Patient ID, 20 bytes at maximum.
5	Patient ID #3	Not Supported
6	Patient Name	This field consists of three components. Set patient name of the Patient Name. Component 1: Family Name Component 2: First Name Component 3: Middle Name or Initial 20 bytes maximum for these three components in total. Ex.) Smith^John^M Note: PATHFAST will show the name putting the three components together. If you need space in between, set spaces before after each component.
7	Mother's maiden Name	Not Supported
8	Birth date	Patient birth date is set in the format of YYYYMMDD
9	Patient Sex	Patient sex is expressed with following letters M or m for male, F or f for female, U or u for unknown sex. Any other letter shall be recognized as unknown.
10	Patient Race-Ethnic Origin	Not Supported
11	Patient Address	Not Supported

12	Reserved Field	Not Supported
13	Patient Telephone Number	Not Supported
14	Attending Physician ID	Not Supported
15	Special Field #1	Not Supported
16	Special Field #2	Not Supported
17	Patient Height	Not Supported
18	Patient Weight	Not Supported
19	Patient's Known or Suspected Diagnosis	Not Supported
20	Patient Active Medications	Not Supported
21	Patient's Diet	Not Supported
22	Practice Field #1	Not Supported
23	Practice Field #2	Not Supported
24	Admission and Discharged Dates	Not Supported
25	Admission Status	Not Supported
26	Location	Not Supported
27	Nature of Alternative Diagnostic Code and Classifiers	Not Supported
28	Alternative Diagnostic Code and Classifiers	Not Supported
29	Patient Religion	Not Supported
30	Marital Status	Not Supported
31	Isolation Status	Not Supported
32	Language	Not Supported
33	Hospital Service	Not Supported
34	Hospital Institution	Not Supported
35	Dosage Category	Not Supported

Sample record:
P|1||99999991||Smith^John^M||19980305|M|||||||||||||||||||||||<CR>

5.5.4.2 Test Order Record (“O” Record)

Refer to the following table for “O” Record configuration.

This record is not allowed to omit, excepting no order exists.

Test Order Record

No	Field	Description
1	Record Type ID	Always set “O”. Identify record type as test order. (Not allowed to omit.)
2	Sequence Number	1 through n. Sequential number starting from 1. (Not allowed to omit)
3	Specimen ID	Sample ID(received from PATHFAST) 20 bytes maximum. (Not allowed to omit)
4	Instrument Specimen ID	Not Supported
5	Universal Test ID	This field consists of four components, but first three components are not used. Only manufacturer’s test codes are supported. Component 4: Manufacturer’s test code Only one test code shall be set, repetition is not allowed. Ex.) ^^ Manufacturer’s test code When one sample has more than one test, individual Test Order Record shall be created for each test. (Not allowed to omit)
6	Priority	Not Supported
7	Requested/Ordered Date and Time	Not Supported
8	Specimen Collection Date and Time	Not Supported
9	Collection End Time	Not Supported
10	Collection Volume	Not Supported
11	Collector ID	Not Supported
12	Action Code	Not Supported
13	Danger Code	Not Supported
14	Relevant Clinical Information	Not Supported
15	Date and Time Specimen Received	Not Supported
16	Specimen Descriptor	Not Supported
17	Ordering Physician	Not Supported
18	Physician’s Telephone Number	Not Supported
19	User Field #1	Not Supported
20	User Field #2	Not Supported
21	Laboratory Field #1	Not Supported
22	Laboratory Field #2	Not Supported

23	Date/time Results Reported or Last Modified	Not Supported
24	Instrument Charge to Computer System	Not Supported
25	Instrument Section	Not Supported
26	Report Type	Always set “O” which means test order. (Not allowed to omit)
27	Reserved Field	Not Supported
28	Location of Ward of specimen Collection	Not Supported
29	Hospital Information Flag	Not Supported
30	Specimen Service	Not Supported
31	Specimen Institution	Not Supported

Sample Record:
O|1|00228411303||^^^11||||||||||||||||||||O|||||<CR>

The Test Order Message consists of Header Record, Patient Information Record, Test Order Record and Terminator Record.
Sample message is shown below.

H|@^\|||||||PATHFAST01||P|1|20050228105347<CR>
P|1||99999991||Smith^John^M|||||||||||||||||||||||||||<CR>
O|1|00228411303||^^^1|||||||||||||||||||O|||||<CR>
O|2|00228411303||^^^2|||||||||||||||||||O|||||<CR>
O|3|00228411303||^^^3|||||||||||||||||||O|||||<CR>
O|4|00228411303||^^^4|||||||||||||||||||O|||||<CR>
L|1|N<CR>

When the sample has no item to order, Test Order Message becomes as follows.

H|@^\|||||||PATHFAST01||P|1|20050228105347<CR>
L|1|N<CR>

5.6 Rejected Test Order Message Uploading

At completion of download operations, PATHFAST will transmit a message to inform the host computer about rejected test orders and samples.

5.6.1 Rejected Test Order Message

The *Rejected Test Order Message* consists of a *Message Header* record, one or more *Comment* records and the *Message Terminator Record*. A comment record will be transmitted for each rejected information.

When PATHFAST received illegal information from the host, it informs the host of the reason of rejection by using the above message.
If the download process has been completed normally, no Rejected Test Order Message shall be sent.

5.6.1.1 Comment Record ("C" Record)

Refer to the following table for "C" Record configuration.

Record Type ID	Always set 'C'. Identify record type as comment record.
Sequence Number	1 through n. Sequential number starting from 1. "1" is for the first comment record in a packet. "n" is for the last comment record before Terminator Record.
Comment Source	Always set to 'I'
Comment Text	This field indicates the reason of the test order rejection. It consists of three components. Component 1: Reason of Rejection. BAD_TEST: Invalid test code. QC_MA_ID: The ID is already used in QC database BAD_S_ID: Invalid Sample ID. WRONG_ID: SID sent by the host is already used PDB_FULL: Patient data base is full M_TEST_E: Too many tests received than supported UKNOWN_T: Unknown test requested NO_TESTS: No test ordered for patient record NO_PATIE: No patient information record received BAD_RECO: Incorrect record format Component 2: Sample ID Sample ID corresponding with the rejected test. Nothing is set depending on reason of rejection. Component 3: Assay Item Number Assay item number which is rejected. Nothing is set depending on reason of rejection. Ex.) when item number of 0001 is invalid, BAD_TEST^0305990001^0001
Comment Type	Always set to 'I'

The possible reasons for the rejection are summarized in the following table.

Component 1: Rejection Reason	Component 2: Sample ID	Component 3: Assay Item Number
QC_MA_ID	sample ID (causing the problem)	UNKNOWN
BAD_S_ID	sample ID (causing the problem)	UNKNOWN
PDB_FULL	sample ID (causing the problem)	Test ID
NO_TESTS	UNKNOWN	UNKNOWN
NO_PATIE	sample ID (causing the problem)	Test ID
INSTR_ID	UNKNOWN	UNKNOWN
M_TEST_E	sample ID	test ID (causing the problem)
UNKWOWN_T	sample ID	test ID (causing the problem)
BAD_TEST	sample ID	test ID (causing the problem)
BAD_RECO	Record No. (debug purpose)	Field No. (debug purpose)

Sample Record
C|1|I|BAT_TEST^00228310234^0011|I<CR>

Reject Message consists of Header Record, Comment Record and Terminator Record. Following is an example.

H|@^\|||PATHFAST01^1000000001^01.00.00.00|||||||P|1|20050228105347<CR>
C|1|I|BAT_TEST^00228310234^0011|I<CR>
C|2|I|BAT_SID^00228310234^|I<CR>
L|1|N<CR>

Note that all sample information is deleted because of the reject message. The valid test order for the sample is stored in PATHFAST, though some order for the sample is rejected.

5.7 Test Results Uploading

Test Result Uploading allows transmission of results of the tests performed on PATHFAST to the host computer. Results, related to patient, QC samples are transmitted on explicit user request or automatically at assay completion.
Beside the above, the operator can choose samples of which result data shall be transmitted to the host and manually start the uploading session.
The type of data to be transferred during an automatic upload session depends upon the instrument set-up (the automatic data transmission can be set to ON or OFF).

PATHFAST does not accept inquiries for test results.

5.7.1 Test Result Message (from PATHFAST to Host)

The *Test Result Message* is used by PATHFAST to transmit any available test results for a sample. The test results are automatically sent by item upon one assay batch has been completed or by the operator indication.

The message consists of a *Message Header* record, a *Patient Information* record, one or more pair *Test Order* records followed by one or more *Results* records (depending upon the number of available test results and the number of results for each specific test).

In the message, unit combined with the specific assay item is also sent to the host.
The *Message Terminator* record completes the transmission of data.
The Patient Information Record is set for each Test order record.

5.7.1.1 Patient Information Record (“P” Record)

This information is transmitted to the host only if available on the instrument.

This record is not allowed to omit.

Refer to the following table for “P” Record configuration.

Patient Information Record:

No	Field	Patient Sample	QC Sample
1	Record Type ID	Always set “P”. Identify this record as Patient Information Record.	
2	Sequence Number	1 through n. Sequential number starting from 1. “1” is for the first patient record in a packet. “n” is for the last patient record before Terminator Record.	
3	Practice Assigned Patient ID	Not Supported	
4	Laboratory Assigned Patient ID	Character string of up to 20 bytes.	Not Supported
5	Patient ID #3	Not Supported	
6	Patient Name	Single character string of up to 20 bytes. Component 1 through 3 of Patient name received from the host are combined in a single character string.	Not Supported
7	Mother’s maiden Name	Not Supported	
8	Birth date	Patient birth date is set in the format of YYYYMMDD	Not Supported

9	Patient Sex	Patient sex is expressed with following letters. M or m for male, F or f for female, U or u for unknown sex. Any other letter shall be recognized as unknown.	Not Supported
10	Patient Race-Ethnic Origin	Not Supported	
11	Patient Address	Not Supported	
12	Reserved Field	Not Supported	
13	Patient Telephone Number	Not Supported	
14	Attending Physician ID	Not Supported	
15	Special Field #1	Not Supported	
16	Special Field #2	Not Supported	
17	Patient Height	Not Supported	
18	Patient Weight	Not Supported	
19	Patient's Known or Suspected Diagnosis	Not Supported	
20	Patient Active Medications	Not Supported	
21	Patient's Diet	Not Supported	
22	Practice Field #1	Not Supported	
23	Practice Field #2	Not Supported	
24	Admission and Discharged Dates	Not Supported	
25	Admission Status	Not Supported	
26	Location	Not Supported	
27	Nature of Alternative Diagnostic Code and Classifiers	Not Supported	
28	Alternative Diagnostic Code and Classifiers	Not Supported	
29	Patient Religion	Not Supported	
30	Marital Status	Not Supported	
31	Isolation Status	Not Supported	
32	Language	Not Supported	
33	Hospital Service	Not Supported	
34	Hospital Institution	Not Supported	
35	Dosage Category	Not Supported	

Sample record:

P|1||99999991||SmithJohnM||||||||||||||||||||||||||||||<CR>

5.7.1.2 Test Order Record (“O” Record)

This record is not allowed to omit.

Refer to the following table for “O” Record configuration.

Test Order Record:

No	Field	Patient Sample	QC Sample
1	Record Type ID	Always set “O”. Identify this record as Test Order record.	
2	Sequence Number	1 through n. Sequential number starting from 1. “1” is for the first order record in a packet. “n” is for the last order record before Terminator Record.	
3	Sample ID	This field consists of three components. Component 1: Sample ID which equals to barcode ID of the sample or QC sample ID. Component 2: Lane Number Component 3: not used Ex.) Sample ID^Lane Number^	This field consists of three components. Component 1: QC ID Component 2: Lane Number Component 3: QC Level One of the followings QC1 QC2 QC3 Ex.) QC ID^Lane Number^QC Level-
4	Instrument Specimen ID	Not Supported	
5	Universal Test ID	This field consists of six components. The first three components are not supported. Component 4: Test Item Number Component 5: Test Name Component 6: Reagent Lot Number Ex.) ^^^01^cTnI^011010612 When one sample has plural tests, “O” Record is created for each test item.	
6	Priority	Not Supported	
7	Requested/Ordered Date and Time	Not Supported	
8	Specimen Collection Date and Time	Not Supported	
9	Collection End Time	Not Supported	
10	Collection Volume	Not Supported	
11	Collector ID	Not Supported	
12	Action Code	Not Supported	Always set “Q”.
13	Danger Code	Not Supported	
14	Relevant Clinical Information	Not Supported	
15	Date and Time Specimen Received	Not Supported	
16	Specimen Descriptor	Sample Type is set: “1” for whole blood and “2” for serum/plasma/urine	Not Supported
17	Ordering Physician	Not Supported	
18	Physician’s Telephone Number	Not Supported	

19	User Field #1	Not Supported
20	User Field #2	Not Supported
21	Laboratory Field #1	Not Supported
22	Laboratory Field #2	Not Supported
23	Date/time Results Reported or Last Modified	Not Supported
24	Instrument Charge to Computer System	Not Supported
25	Instrument Section	Not Supported
26	Report Type	Always set “F”
27	Reserved Field	Not Supported
28	Location of Ward of specimen Collection	Not Supported
29	Hospital Information Flag	Not Supported
30	Specimen Service	Not Supported
31	Specimen Institution	Not Supported

Sample Record:
O|1|00228411303^1^QC1||^^^2^Myo^00000000001||||||||||1|||||||||F|||||<CR>

5.7.1.3 Result Record (“R” Record)

A result record is sent to the host computer for each available test result. For double tests all available single values will be transmitted to the host computer (no mean values). Each result record will contain only one of available test results.

For quantitative assay, the test result is the quantitative value. So only one result record is created and sent to the host computer.
For qualitative assay, the test results are quantitative value and the judgment. So two result records are created and sent to the host computer.

This record is not allowed to omit.

Refer to the following table for “R” Record configuration.

Result Record:

No	Field	Patient Sample	QC Sample
1	Record Type ID	Always set “R”. Identify this record as Result.	
2	Sequence Number	1 through n. Sequential number starting from 1. “1” is for the first result record in a packet. “n” is for the last result record before Terminator Record.	
3	Universal Test ID	This field consists of six components. The first three components are not supported. Component 4: Test Item Number Component 5: Test Name Component 6: Reagent Lot Number Ex.) ^^^12^Myo^1234567890	
4	Data or Measurement Value	This field consists of two components. Component 1: test result (one of the quantitative value or judgment) Component 2: “F” for quantitative result or “I” for qualitative result “I” is on of the followings “-“, “+-“, “+”, “2+”, “3+”, “4+”, “5+” Ex.) 123.4^F	
5	Units	Unit is set in this field when the previous field (field #4 above) is filled with quantitative value. None is set for qualitative result.	
6	Reference range	Not Supported	

7	Result Abnormal Flag	This field contains one or combination of the following result abnormal flags. N: Normal A: Abnormal (Detailed remarks are set in comment record) >: Exceeded measurable upper limit <: Exceeded measurable lower limit L: Lower than normal range(Detailed remarks are set in comment record) H: Higher than normal range(Detailed remarks are set in comment record) Result abnormal flags are set at maximum of three of the above. @ is used as Repetition Delimiter. “L” or “H” is not added for qualitative assay result. Ex.) A@>@H
8	Nature of Abnormality Flag	Not Supported
9	Result Status	Always set “F”
10	Data of Change in Instrument Normative Values or Units	Not Supported
11	Operator Identification	Operator ID is set, 20 bytes maximum.-
12	Date/Time Test Started	Not Supported
13	Date/Time Test Completed	Assay date and time is set in the format of YYYYMMDDHHMMSS
14	Instrument Identification	Not Supported

Sample Record:
R|1|^^^2^Myo^00000000001|14.70^F|ng/dl||>@A||F||OperaterID||20050228105910|<CR>

5.7.1.4 Comment Record (“C” Record)

The Comment record allows integration of the transmitted test results with possible error messages.
One comment record always follows the result records.

This record is not allowed to omit.

Refer to the following table for “C” Record configuration.

Comment Record:

No	Field	Description
1	Record Type ID	Always set “C”. Identify this field as Comment Record.
2	Sequence Number	1 through n. Sequential number starting from 1. “1” is for the first comment record in a packet. “n” is for the last comment record before Terminator Record.
3	Comment Source	Always set “I”.
4	Comment Text	This field consists of five components. Component 1: Remark When “A” is set in “Abnormal Result Flag” field, remarks are set here. Five remarks can be set at maximum. @ is used as repetition delimiter. Component 2: Judge against reference range. When “L” is set in “Abnormal Result Flag” field, one of the following remarks is set here. “L”, “2L”, “3L”, “4L”, “5L” When “H” is set in “Abnormal Result Flag” field, one of the following remarks is set here. “H”, “2H”, “3H”, “4H”, “5H” Component 3: Information of mechanical error When mechanical error has been detected, errors are set here up to five at maximum. @ is used as repetition delimiter. Component 4: Hematocrit Value (%) When whole blood sample is assayed, HCT% is set here. None is set for samples other than whole blood. Component 5: Calibration date and time Date and time when calibration assay was performed for the test item corresponding to the assay result is set here. The format is YYYYMMDDHHMMSS Ex.) For remarks of “Ab”, “Cd” and “2H” and mechanical error of “ME_ERR_01” Ab@Cd^2H^48.5^ME_ERR_01^20050423104535 Refer to error codes for details.
5	Comment Type	Always set “I”.

Sample Record:
C|1|I|Ab@Cd^^ME_ERR_01^48.5^20050423104535|I<CR>

Test Result Message containing Header Record, Patient Information Record, Result Record, Comment Record and Terminator Record is shown below as an example.

H|@^\|||PATHFAST01^000000001^01.00.00.00|||||||P|1|20050228105347<CR>
P|1||99999991||SmithJohnM ||19980305|F|||||||||||||||||||||||||<CR>
O|1|00228411303^1^||^^^2^Myo^0000000001||||||||||1|||||||||F|||||<CR>

R|1|^^^2^Myo^0000000001|44.70^F|ng/dl||>@A||F||Administrator||20050228105910|

<CR>

R|2|^^^2^Myo^0000000001|+^I|||>@A||F||Administrator||20050228105910|<CR>
C|1|I|Ab@Cd^^ME_ERR_01^56.3^20050228080000|I<CR>
P|2||99999991||SmithJohnM ||19980305|F|||||||||||||||||||||||||<CR>
O|1|00228411303^1^||^^^1^cTn I^0000000002||||||||||1|||||||||F|||||<CR>
R|1|^^^1^cTn I^0000000002|128.5^F|ng/dl||H@A||F|| Administrator
||20050228121532|<CR>
C|1|I|SS@SA^3H^ME_ERR_01^64.1^20050228081512|I<CR>
L|1|N<CR>

5.7.1.5 Error Messages

Errors reported by PATHFAST are categorized in two types, Remark and Error Codes. Remarks are mostly assay related errors accompanied with assay results. Error Codes are mostly related to hardware and system malfunctions.

Remarks

Remarks are sent to the host computer in “C” record after the assay run completed. They show the reason of the blank data in result data field and they also indicate that the numeric result data sent shall be suspected as erroneous data.
In the table below, remarks are listed with their meanings, how the data is treated in PATHFAST.

Remark Code	Description	Data Handling	User Action
S	No Sample found	The Remark Code is added to the result. Asterisks are printed instead of data.	Re assay
NT	No Tip found	The Remark Code is added to the result. Asterisks are printed instead of data.	Re assay
NC	No valid calibration available on assay completion.	The Remark Code is added to the result. Asterisks are printed instead of data.	Re calibration
ED	Secondary count is lower than predefined value.	The Remark Code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative
H1	Temperature of Heat Block L is too high.	The Remark Code is added to the result.	Contact your PATHFAST representative
H2	Temperature of Heat Block S is too high.	The Remark Code is added to the result.	Contact your PATHFAST representative
H3	Temperature of Heat Block T is too high.	The Remark Code is added to the result.	Contact your PATHFAST representative

L1	Temperature of Heat Block L is too low.	The Remark Code is added to the result.	Contact your PATHFAST representative
L2	Temperature of Heat Block S is too low.	The Remark Code is added to the result.	Contact your PATHFAST representative
L3	Temperature of Heat Block T is too low.	The Remark Code is added to the result.	Contact your PATHFAST representative
UK	Error reported by sample recognition sensor	The Remark Code is added to the result. Asterisks are printed instead of data.	Contact your PATHFAST representative
ER	LED light signal of sample recognition sensor too low.	Assay run will be aborted.	Contact your PATHFAST representative
DF	Assay result was calculated with default Hct%.	Data will print with remark added.	None
OR	Measured QC is out of control range.	Data will print with remark added.	Re assay
RS	Remark added for recalculated data using new Hct% value when transmitted to the host computer.	None	None
AE	Abnormal luminescent count	The Remark Code is added to the result. Asterisks are printed instead of data	Re assay
HC	Hct% calculation error	The Remark Code is added to the result. Asterisks are printed instead of data	Contact your PATHFAST representative
CI	Calculation error other than HC above	The Remark Code is added to the result. Asterisks are printed instead of data	Contact your PATHFAST representative
BE	PMT position error	The Remark Code is added to the result. Asterisks are printed instead of data	Contact your PATHFAST representative

Error Codes

Error Codes are also sent to the host computer in “C” record after the assay run completed.

Only Error Codes reported during assay run are sent to host computer when the assay run completed and the results are reported. If the assay run is aborted by the operator or PATHFAST, no Error Codes are sent to host computer.

Kind	Message Code	Message	Note
Related with File Handling	F0050	%s file can not be opened	
	F0051	%s file can not be read	
	F0052	%s file can not be written into	
	F0053	%s file does not exist	
Related with PMT	P0200	Failed to open PMT Shutter	
	P0201	Failed to close PMT Shutter	
	P0202	No PMT count data	
	P0203	Detected PMT error	
Related with Temperatur e Controller	T0250	Error detected during setting temperature for Temperature Controller	Communication error
	T0251	Error detected during getting temperature from Temperature Controller	Communication error

6. Not Supported Records

The *Scientific* record and the *Manufacturer Information* record are not supported by PATHFAST protocol.

As a consequence the instrument ignores any type of information they contain.

7. Transmission Abort and Errors

The cases of transmission abort are described below.
The sender must initiate [EOT] to end the communication session.

-. Host computer is not responding
-. Host computer sent EOT
-. PATHFAST 's operator requested to stop communication
-. Number of retry in low level communication exceeded the designated number
-. Other:Invalid codes were received during waiting for ENQ or EOT

7. 1 Error Conditions and Actions

Each error condition is described in the following with actions that PATHFAST makes:

Condition	Action
Host computer is not responding	If PATHFAST is the sender, it initiates [EOT] to end the session and if it is the receiver, it initiates [EOT] to request for abortion to the host and wait for [EOT] from the host. No further messages are sent to the host. PATHFAST informs the operator by showing corresponding message.
Host computer sent EOT	If PATHFAST is the sender, it initiates [EOT] to end the session and if it is the receiver, it does nothing. No further messages are sent to the host. PATHFAST informs the operator by showing corresponding message.
PATHFAST 's operator requested to stop communication	If PATHFAST is the sender, it initiates [EOT] to end the session and if it is the receiver, it initiates [EOT] to request for abortion to the host and waits for [EOT] from the host. No further messages are sent to the host. PATHFAST informs the operator by showing corresponding message.
Number of retry in low level communication exceeded the designated number	If PATHFAST is the sender, it initiates [EOT] to end the session and if it is the receiver, it initiates [EOT] to request for abortion to the host and wait for [EOT] from the host. No further messages are sent to the host. PATHFAST informs the operator by showing corresponding message. Checks which need to be retried when failed: -. Check for starting [STX] -. Check for modular 8 -. Check for checksum -. Check for limited characters -. Check for text length -. Check for record sequence -. Check for number of fields -. Check for each field (specific for each field) -. Others
Frame error found in low level communication to abort	PATHFAST initiates [EOT] to request communication abort to the host and wait for [EOT] from the host. No further messages are sent to the host. PATHFAST informs the operator by showing corresponding message

	Checks which need abortion when failed: -. The number of frames in a message received exceeded 100. -. More than one record was found in a text -. Frame numbers inconsistent -. Other unexpected errors -. Total record length received exceeded 1000 -. Others
Other: Invalid codes were received during waiting for ENQ or EOT	PATHFAST sends nothing when it is waiting for [ENQ] from the host. PATHFAST informs the operator by showing corresponding message When it is waiting for [EOT], it initiates [EOT] to request for abortion to the host and waits for [EOT] from the host.

7. 2 List of Communication Errors

Errors occurred in low level are listed in the following table.

Errors	Description	Level/Action
None	Normal	None
STimeOut	Sender timeout (15 Seconds)	FATAL(Abort communication)
RTimeOut	Receiver timeout (30 Seconds)	FATAL(Abort communication)
OWTimeOut	Timeout for waiting order (60 seconds)	FATAL(Abort communication)
UsrCan	Canceled by User	FATAL(Abort communication)
SCntOver	Exceeded retry counts for sender (5 times)	FATAL(Abort communication)
RCntOver	Exceeded retry counts fro receiver (6 times)	FATAL(Abort communication)
HostCan	Requested by the host (Received [EOT])	FATAL(Abort communication)
FrmCntErr	Received frames exceeded 100	FATAL(Abort communication)
RecCntErr	More than two records found in a text	FATAL(Abort communication)
FrmPlgErr	Frame numbers inconsistent	FATAL(Abort communication)
FrmOtherErr	Other unexpected error	FATAL(Abort communication)
NotEnqErr	Received other than [ENQ] when waiting for [ENQ]	FATAL(Abort communication)
NotEotErr	Received other than [EOT] when waiting for [EOT]	FATAL(Abort communication)
PtherFatalErr	Other fatal error	FATAL(Abort communication)
RecLenErr	Combined record length exceeded 1000	FATAL(Abort communication)
NotStxErr	Error in first [STX] check	Warning(Retry)
Mod8Err	Error in Modular 8 check	Warning(Retry)
ChkSumErr	Checksum error	Warning(Retry)
DefCharErr	Error in limited character check	Warning(Retry)
TxtLenErr	Error in text length check	Warning(Retry)
RecSeqErr	Error in record sequence check	Warning(Retry)
FildCntErr	Error in number of fields check	Warning(Retry)
FildChkErr	Error in each field check (specific for each field)	Warning(Retry)
RealOtherErr	Other errors	Warning(Retry)
OtherWarningErr	Other warnings	Warning(Retry)
SContErr	Contention Error of the sender	Warning
SBusyRcvErr	Sender busy error	Warning

8. Appendix- PATHFAST Test Codes

PATHFAST Test codes are listed in the following table.

Test Code Number	Test Name
1	cTn I
2	Myo
3	CK-MB
5	D-Dimer

9. Appendix –Supported Characters by PATHFAST

9.1 Supported Characters for Sample ID

The ASCII set of characters considered is in the decimal range 32 to 126, because a Sample ID can be accepted only if it contains at least one character different from a space.

9.2 Supported Characters for Patient name

The ASCII set of characters considered is in the decimal range 32 to 255.

9.3 Supported Characters for Delimiters

Delimiters used in PATHFAST ASTM messages are defined in section 5.4.1. No other characters are supported.

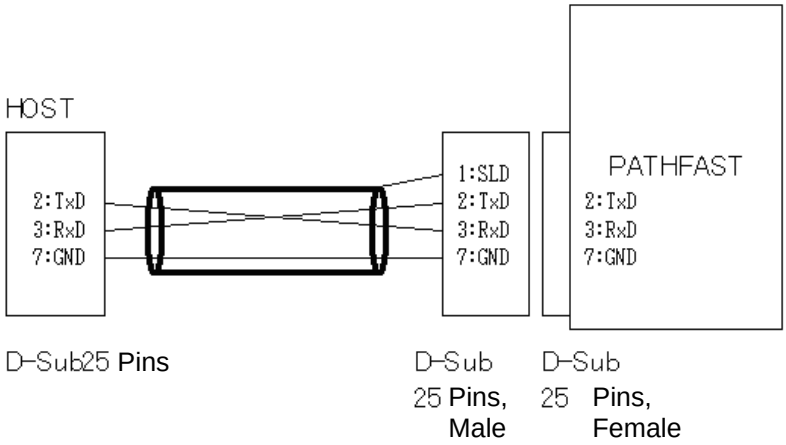
9.4 Connecting with Host Computer

To connect PATHFAST with the host computer, use RS232cC cross cable. The connector of PATHFAST is located on the back (refer to Operators Manual for details.) The connector prepared on PATHFAST is D-Sub type female connector with 25 pins.

In the drawings on the next page, “1:SLD” means shield line and it shall be connected on PATHFAST side, but it shall not be connected on PC side.

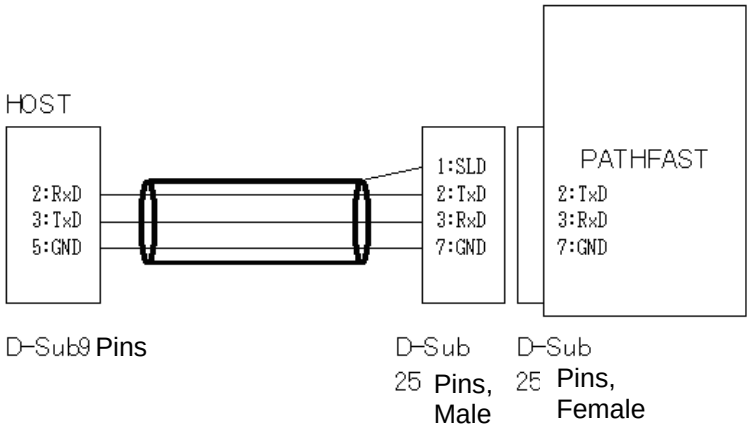
9.4.1 Using D-Sub Type Connector with 25 Pins

When you want to use D-sub type connector with 25 pins to hookup with the host computer, refer to the following drawing for cable wiring. Numeric value in front of each signal name is pin number of the connector.



9.4.2 Using D-Sub Type Connector with 9 Pins

When you want to use D-sub type connector with 9 pins to hookup with the host computer, refer to the following drawing for cable wiring. Numeric value in front of each signal name is pin number of the connector.



10. Limitations

PATHFAST communicates with host computer under the specifications based on ASTM specifications and its own limits (refer to the sentences with underlines in this document). Read this document and ASTM specifications get familiar with them before making interface program for PATHFAST instrument.