Chapter 12

ACL Elite/Elite Pro

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Host Communication Protocol

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December 07-2002	Added transmission examples Specified ASTM field numbers Add Notes for information Total number of pages Reviewed Test Codes
December 16-2002	Review some Notes
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1.0 Introduction

1.1 Purpose

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

ASTM specification E-1394-91 *Standard Specification for Transferring Information between Clinical instruments and Computer Systems* and E-1381-91 Standard Specification for the *Low Level Protocol to transfer Messages between Clinical Laboratory Instruments and Computer Systems* have been used as standard to develop ELITE/ELITE PRO Host Communication Protocol.

Specification E-1394 defines the logical layer of ASTM standard; all significant information for ELITE/ELITE PRO instruments application can be found in chapters Specific Requirements and following.

Specification E-1381 refers to low level protocol; significant information for ELITE/ELITE PRO family instruments application can be found later on in this document.

2.0 General Description

2.1 Product Perspective

Communication sessions with host computer can be started on ELITE/ELITE PRO family instruments by operator request or automatically at session completion.
If the operator requires a manual download session, the instrument will open communication with the host computer that will provide transmission of all test orders.
If the operator requires an upload session, the instrument will transmit a subset of sample results (identified by the user) stored in the instrument patient database or QC database or Analytical Reference database.

If the instrument is properly configured, automatic downloading or uploading sessions can be started by ELITE/ELITE PRO instrument.
Automatic downloading will occur at session start if host query is configured. In this condition the instrument will request test orders for specific sample IDs recognized on the sample tray.

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

In case the communication session is not generated from the 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 stored in ELITE/ELITE PRO database. This information is optional.

The sample ID is the primary key to access information in the database.
If the checks fail, any downloading operations will be aborted. See *Test Order Downloading* section.

At most 1000 samples can be stored in ELITE/ELITE PRO database; each sample can have a maximum of 30 tests associated (double tests are considered as 3 tests).
The system behavior when these limits are exceeded is explained in the paragraph *Test Order Downloading*.

If 1000 samples are present in the database, the FIFO (First In First Out) will not accept additional samples during a *Manual Downloading*.

The test ordering operation, to identify the type of ordered test, by host computer must refer to a computer code that is instrument specific. Refer to Test Order Downloading for further details and to the Appendix at the end of this document for the test codes table.

Note: for the downloading the Host should send to the ELITE/ELITE PRO string information in single frame (single line) during the transmission or up to 240 bytes maximum during the transmission.
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3.0 Specific Requirements

3.1 Protocol Specification

3.2 Low Level Interface

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

Baud Rate	2400, 4800, 9600, 19200, 38600
Character Length	8 bit
Parity	No parity
Stop Bits	1

3.3 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 instrument and the host computer should be done as single frame. 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 the standard; the Low Level Clinical Message State Diagram representing the implemented automatic is the reference.
In interrupt request status the instrument accept remote EOT.

3.4 Sessions

There are two types of sessions that the 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/operator requests a download operation (Receive Command), the instrument will send a request to the host for available test orders (all) or for test orders requested for specific samples, and the host will answer with the test orders available for the instrument.

Test results upload (Transmit Command) are initiated by the user or automatically by the instrument at the same way. The host is not allowed to transmit unsolicited messages, any type of inquiries or test orders not explicitly required by the instrument.

3.4.1 Message Header and Message Terminator Records

Following ASTM specification, each type of transaction between the instrument (DTE) and the host computer (DCE) has two common records that are the *Message Header* record and the *Message Terminator* record. These records open and close data transmission between ELITE/ELITE PRO instruments and host computer.
Their fields are described in the following:

Message Header Record:

Record Type ID	Always set to 'H'
Delimiter Definition	The 5 ASCII characters composing this field define the type of delimiters that will be used in the following records. See Appendix B for supported delimiters.
Message Control ID	Not provided
Access Password	Not provided
Sender Name or ID	Set to 'ACL9000' when transmitting to host or receiving. As an option, the ability to identify univocally the instrument by means of an extension to the instrument name is also supported: the name syntax becomes 'ACL9000-xx' where xx is a two digit code in the range 01-99. The extension to the instrument name is user configurable in the set-up environment. The instrument ID is always ACL9000 independently from the model; ELITE/ELITE PRO.
Sender Street Address	Not provided
Reserved Fields	Not provided
Sender Telephone Number	Not provided
Characteristics of Sender	Not provided
Receiver ID	Must be set to 'ACL9000' when receiving from host. Depending on the instrument set-up, the ability to identify univocally the instrument by means of the extension to the instrument name is also supported: the name syntax becomes 'ACL9000-xx' where xx is a two digit code in the range 01-99. If the ID is different from the expected one, the session is interrupted.
Comment or special Instructions	Not provided
Processing ID	Always set to 'P' meaning Production

Version No.	Set to the current ASTM standard version = '1'
Date and Time of Message	Format is YYYYMMDDHHMMSS

Example of message sent from the ELITE/ELITE PRO :

```
H|\^&|||ACL9000||||||P|1|20021205123956<CR>
```

Example of message sent from Host:

```
H|\^&|||||||ACL9000||P|1|20021205123956<CR>
```

Message Terminator Record:

Record Type ID	always set to 'L'
Sequence Number	always set to '1'
Termination Code	set to 'N' for normal termination and to 'E' for abnormal termination while transmitting to host; not considered for received data

Example of Terminator:

```
L|1|N<CR>
```

3.5 Test Order Downloading

Test order downloading is used to request test orders available on the host and to have them on the instrument. This operation can be obtained in two ways: manually opening a download session from the DMS environment or enabling on the instrument the host query function.

In the first case the host will have to transmit to the instruments all pending test requests; in the second case the instrument will automatically require specific information for the samples placed on the sample tray and without any test requests.

Details for both modalities are explained in *Receive Session from DMS* and *Host Query* paragraphs.

3.5.1 Receive Session from DMS

The operator manually initiates the test order download from the DMS environment. The host will provide to the instrument all available test requests. The host can send zero or more test orders in one or more messages, but all messages will be part of the same transmission session.
During a transmission session more test orders can be required for the same sample. The host sends usually all test orders for which it has not yet received results even if they have been previously transmitted.

ELITE/ELITE PRO instruments will process each received test order to validate fields supported; some information will be extracted from the received record while other information will be ignored.
Only test orders related to patient samples are considered, if the required sample ID does not exist in the patient database and the required sample ID is not used in the QC database, a new record is created. If the database is full, the transmission session will be aborted.

If the test orders are for a sample already existing in the sample data base, the new orders will be added to the existing tests but all tests already ordered or performed will remain unchanged.

If a test order with more than the maximum number of programmable tests is sent, the request is rejected. The limit is 30 single tests or 10 double tests.

If the test order is not recognized as one of those supported by ELITE/ELITE PRO family instruments, it is rejected. The instrument will inform the host computer using a record containing the list of rejected test orders.

During a downloading session the listed error conditions can be detected, the associated instrument behavior and actions are listed as well:

Error Condition	Action	User Message
Sample ID used in the QC data base	Abort communication	Sample ID already used in the QC data base
Bad Sample ID (long, unsupported characters)	Abort communication	Invalid Sample ID
Data Base full	Abort communication	Patient Data Base is full
Patient record has no associated test order record	Abort communication	Not identified sample ID for patient data
Test order has no associated patient record	Abort communication	No patient record for ordered tests
Instrument Identifier different from ACL9000 or extended name	Abort communication	Invalid instrument identifier
Too many test requests for the same sample ID	Reject test order	-
Unknown test request	Reject test order	-
Bad Test	Reject test orders	-
Illegal record format	Abort communication	Incorrect record format in host messages

All abort conditions imply that ELITE/ELITE PRO family instruments will send to the host computer a message with the reason for transmission interruption (see Reject Test Order) while a message is presented to the user on the instrument. When

transmission abort is not implied, at transmission completion one or more records will follow (see Reject Test Order) with an indication of rejected test orders.

Information rejected is typically unknown test requests or test requests exceeding the sample record size in ELITE/ELITE PRO Data Management System. It must be observed that if any of this information is rejected, it does not imply that all sample data have been rejected.
The set of legal test requests are normally stored while the illegal requests for the same sample ID will be rejected.

It also must be underscored that ELITE/ELITE PRO limits the size of handled records (independently from the record type supported by ASTM) to 1024 byte during downloading session.

Note: for the downloading the Host should send to the ELITE/ELITE PRO string information in single frame (single line) during the transmission or up to 240 bytes maximum during the transmission.

3.5.1.1 Test Request Message

The *Test Request Message* is used by ELITE/ELITE PRO to start the test order download session. It is composed from a *Message Header* record, a *Request Information* record and a *Message Terminator* record.
The *"Request Information record"* requests from the host ALL test orders available for the specific instrument.

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

Request Information Record:

Record Type ID	always set to 'Q'
Sequence Number	as defined by the standard set to '1' when query is sent
Starting Range ID Number	set to the string 'ALL'
Ending Range ID Number	not provided
Universal Test ID	not provided
Nature of Request Time Limit	not provided
Beginning request Results Date and Time	not provided
Requesting Physician Name	not provided
User Field #1	not provided
User Field #2	not provided
Request Information Status Code	always set to 'O' (requesting test orders and demographics only)

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

```
H|\^&|||ACL9000|||||||P|1|19960210103227<CR>
      Q|1|ALL|||||||O<CR>
L|1|N<CR>
```

3.5.1.2 Test Order Message

To answer the ELITE/ELITE PRO *Test Request Message*, the host computer sends the *Test Order Message.* It contains the records specifying which tests are being requested for each specified sample. The host computer may answer with one or more message; each one contains one or more test order specifications. The test order specification consists of a *Patient Information* record followed by one or more *Test Order* records. The host can send for the same sample ID a Patient Information record followed by many Test Order records or, for each test to be ordered, a pair composed by the Patient Information record followed the Test Order record.
Comment Record messages during downloading operations are ignored by ELITE/ELITE PRO.

3.5.1.2.1 Patient Information Record

The fields characterizing this record are specified in the following:

Patient Information Record:

Record Type ID	Must be 'P'
Sequence Number	Must begin with '1' and then must increment by one for each new Patient Information record
Practice Assigned Patient ID	Ignored
Laboratory Assigned Patient ID	Stored, if available, as a string in the Patient ID field of the sample record. No checks are performed for this field and the string will be truncated to 15 characters.
Patient ID #3	Ignored
Patient Name	Stored, if available, as a unique string in the 'name' field of sample record considering only the first two sub fields in this data field (second and first name). The string will be truncated to 30 characters. *If a character not supported is found (see Appendix for supported characters), the patient name and all the other strings in the same patient record will be ignored.* If the patient name is not available 4 separators must be transmitted: ^^^^.
Mother's maiden Name	Ignored
Birth date	Stored, if available. The data will be converted and displayed in the following in according to ELITE/ELITE PRO supported format. Expected format, conforming to ASTM

	standard, is YYYYMMDD
Patient Sex	Stored if available. Allowed characters are 'M', 'm', 'F', 'f', 'U', 'u'; any other character is interpreted as 'U'.
Patient Race-Ethnic Origin	Ignored
Patient Address	Ignored
Reserved Field	Ignored
Patient Telephone Number	Ignored
Attending Physician ID	Ignored
Special Field #1	Ignored
Special Field #2	Ignored
Patient Height	Ignored
Patient Weight	Ignored
Patient's Known or Suspected Diagnosis	Ignored
Patient Active Medications	Ignored
Patient's Diet	Ignored
Practice Field #1	Ignored
Practice Field #2	Ignored
Admission and Discharged Dates	Ignored
Admission Status	Ignored
Location	Stored if available as a free string in the 'department' field of sample record. The string will be truncated to 30 characters. See Appendix B for supported characters.
Nature of Alternative Diagnostic Code and Classifiers	Ignored
Alternative Diagnostic Code and Classifiers	Ignored
Patient Religion	Ignored
Marital Status	Ignored
Isolation Status	Ignored
Language	Ignored
Hospital Service	Ignored
Hospital Institution	Ignored
Dosage Category	Ignored

3.5.1.2.2 Test Order Record

The fields characterizing this record are specified in the following:

Test Order Record:

1. Record Type ID	Must be 'O' (letter)
2. Sequence Number	Must begin with '1' and then must increment by one for each new test order record for the same patient
3. Specimen ID	This is the ELITE/ELITE PRO sample ID; the field must be less than or equal to 15

	characters and must be consistent with rules on sample ID (ID already in use for QC database are not legal). Non conforming sample IDs will cause an abort of the download process. See Appendix B for ELITE/ELITE PRO supported characters.
4. Instrument Specimen ID	Ignored
5. Universal Test ID	The field is composed of 4 parts; only the Manufacturer's Code component is used as a 4 character code (user configurable on board); unknown test ID will be rejected.
6. Priority	If the field contains in any of the sub fields the S char the sample ID will be considered a priority sample; any additional flag will be ignored. If the field does not contain the S char or it is empty, the sample will be identified as a routine sample.
7. Requested/Ordered Date and Time	Ignored
8. Specimen Collection Date and Time	Ignored
9. Collection End Time	Ignored
10. Collection Volume	Ignored
11. Collector ID	Ignored
12. Action Code	Ignored
13. Danger Code	Ignored
14. Relevant Clinical Information	Ignored
15. Date/Time Specimen Received	Ignored
16. Specimen Descriptor	Ignored both fields
17. Ordering Physician	Stored if available as a free string in the 'physician' field of sample record. The string will be truncated to 30 characters. See Appendix for supported characters.
18. Physician's Telephone Number	Ignored
19. User Field No. 1	Ignored
20. User Field No. 2	Ignored
21. Laboratory Field No. 1	Ignored
22. Laboratory Field No. 2	Ignored
23. Date/Time Results Reported or Last Modified	Ignored
24. Instrument Charge to Computer System	Ignored
25. Instrument Section ID	Ignored
26. Report Types	Set to O (letter); other codes will cause records rejection
27. Reserved Field	Ignored
28. Location of Ward of Specimen Collection	Ignored
29. Hospital Information Flag	Ignored
30. Specimen Service	Ignored
31. Specimen Institution	Ignored

An example for a complete test ordering is given by:

```
H|\^&|||||||ACL9000||P|1|19982110134700<CR>
   P|1||PTNT1||ROSSI^MARIO^^^||19391127|M|||||||||||||||DEP
1|||||||||<CR>
       O|1|SMP01||^^^0001|S|||||||||^|DR. VERDI|||||||||O||||||<CR>

       O|5|SMP02||^^^0001||||||||||^||||||||||O||||||<CR>
   P|2||PTNT2||GIALLI^LUCA^^^||19551028|F|||||||||||||||||DEP
2|||||||||<CR>
       O|1|SMP10||^^^0001||||||||||^||||||||||O||||||<CR>
L|1|N<CR>
```

Example of download without patient name:

```
H|\^&|||||||ACL9000||P|1|20021205123956<CR>
   P|1||||^^^^|||||||||||||||||||||||||||||<CR>
      O|1|LAURA01||^^^0001||||||||||^||||||||||O||||||<CR>
L|1|N<CR>
```

Note: Separators are always expected from Host and are always transmitted independently from the information contained in the string.

3.5.2 Host Query

Host query is automatically activated by the instrument each time the system is properly configured. Beginning the pre-analysis phase of a single test or profile or test group, one or more samples have no type of test requests associated.

The instrument will send, using the requested information record, the sample IDs requiring test programming and will accept only test orders for those sample IDs. The instrument will accept for the queried samples any test orders independently by the type of test which will be executed in the starting session.

The mechanism supported by ASTM requires sending to the host a Request Information record for each sample ID or sending to the host a range of queried sample IDs. The mechanism supported by ELITE/ELITE PRO is the first option, so will be independent of the sorting system used by instrument or host computer on the samples.

As a consequence the instrument will send a query for the first sample, will wait for the host information and will send later a new query for the next samples (if any). All the host query sessions will be organized in this manner.

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

The host will provide to the instrument all available test requests. The host can send zero or more test orders in one or more messages, but all messages will be part of the same transmission session.
During a transmission session more test orders can be required for the same sample.

ELITE/ELITE PRO will process each received test order validating the fields that ELITE/ELITE PRO supports; some information will be extracted from the received record while other information will be ignored.

If the test order is not recognized as one of those supported by ELITE/ELITE PRO it will be rejected. The instrument will inform the host computer using a record containing the list of rejected test orders.

Host Query is only performed if the Sample ID is not located in the database for the ACL system.

During a download session the listed error conditions can be detected, the associated ELITE/ELITE PRO action is listed as well:

Error Condition	Action	User Message
Sample ID used in the QC data base	Abort communication	Sample ID already used in the QC data base
Bad Sample ID (long, unsupported characters)	Abort communication	Invalid Sample ID
Data Base full	Abort communication	Patient Data Base is full
Patient record has no associated test order record	Abort communication	Not identified sample ID for patient data
Test order has no associated patient record	Abort communication	No patient record for ordered tests
Instrument Identifier different from ACL9000 or extended name	Abort communication	Invalid instrument identifier
Too many test requests for the same sample ID	Reject test order	-
Unknown test request	Reject test order	-
Bad Test	Reject test orders	-
Illegal record format	Abort communication	Incorrect record format in host messages

All abort conditions imply that ELITE/ELITE PRO family instruments will send to the host computer a message with the reason of transmission interruption (see Reject Test Order) while a message is presented to the user on the instrument. When transmission abort is not implied, at transmission completion one or more records will follow (see Reject Test Order) with an indication of rejected test orders.
Information rejected is typically unknown test requests or test requests exceeding the sample record size in ELITE/ELITE PRO Data Management System. It must be observed that if any of this information is rejected, it does not imply that all the sample data have been rejected.
The set of legal test requests are normally stored while the illegal requests for the same sample ID will be rejected.

It also must be underscored that ELITE/ELITE PRO limits the size of handled records (independently from the record type supported by ASTM) to 1024 byte during downloading session.

Note: If the Sample ID is not present at the Host level during the Host Query, the Host will return only the Header and the terminator.

```
H|\^&|||||||ACL9000||P|1|20021205123956<CR>
L|1|N<CR>
```

Note: If the Host requests a test that is disabled on the ELITE/ELITE PRO, the test will not be programmed on the ELITE/ELITE PRO and a reject message of this type will be returned back to the Host.

```
C|1|I|UKNOWN_T|PatientID^0080|I<CR>
```

3.5.3 Test Request Message

The *Test Request Message* is used by ELITE/ELITE PRO to require information for each specific sample that has no test orders in the instrument database. It is composed from a *Message Header*, a *Request Information* and a *Message Terminator* record.

The *Request Information* record requests in this case information for one specific ID at time. The ASTM protocol limits the number of Request Information records to one. As a consequence the instrument will wait for the host answer before sending a second Request Information record for a second sample.

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

Request Information Record:

Record Type ID	always set to 'Q'
Sequence Number	as defined by the standard set to '1' when query is sent
Starting Range ID Number	set to the specific sample ID to require information on; the meaningful component is the second one
Ending Range ID Number	not provided
Universal Test ID	not provided
Nature of Request Time Limit	not provided
Beginning request Results Date and Time	not provided
Requesting Physician Name	not provided
User Field #1	not provided
User Field #2	not provided
Request Information Status Code	always set to 'O' (requesting test orders and demographics only)

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

```
H|\^&|||ACL9000|||||||P|1|19960210103227<CR>
      Q|1|^S001^|||||||O<CR>
L|1|N<CR>
```

Answer from Host:

```
H|\^&|||||||ACL9000||P|1|19960210103256<CR>
    P|1||||ROSSI^MARIO^^^||19391127|M|||||||||||||||DEP
1|||||||||<CR>
       O|1|S001||^^^0001|||||||||||^| DR. VERDI |||||||||O||||||<CR>
       O|5|S001||^^^0002|||||||||||^|||||||||||O||||||<CR>
L|1|N<CR>
```

3.5.4 Test Order Message

As an answer to the ELITE/ELITE PRO *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.

See Test Order Message for details.

3.6 Rejected Test Order

At completion of download operations, or at completion of the download operation for a single sample in the host query mechanism, ELITE/ELITE PRO can transmit a message to inform host computer about rejected test orders and samples or about the reasons for transmission interrupt.

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

It must be observed that if no legal information has been received, the download process is interrupted and the rejected test order message will signal the reason for the interruption.
If the download process has been completed normally, the possible following rejected test order message will report no legal test orders.

Comment Record structure is described in the following table:

Record Type ID	Always set to 'C'
Sequence Number	Must begin with '1' and then it will increment by one for each new comment record
Comment Source	Always set to 'I' (as ASTM: clinical instrument system)
Comment Text	This field indicates the reason of the test order rejection. It is a string with two components, each one can assume the reported values: Rejection Reason: BAD_TEST: the transmitted test code is invalid QC_MA_ID: the specified ID is already used as a material in the QC data base BAD_S_ID: the specified ID is invalid WRONG_ID: the host is sending information for a sample ID different from the expected one PDB_FULL: patient data base is full M_TEST_E: more tests than expected UKNOWN_T: unknown test requested INSTR_ID: invalid instrument identifier NO_TESTS: no test ordered for patient record

	NO_PATIE: no patient record for ordered test BAD_RECO: incorrect record format
	Identification: This string contains the identification of the sample causing the problem; if a test order caused the problem the sample ID and test ID are transmitted sequentially. The character used to separate the rejection reason, and the two strings used for the identification field is '|'. Lacking information will be signaled as "UNKNOWN". If BAD_RECO is the reason of the rejection the field will contain the record number and the field number caused the failure.
Comment Type	Always set to 'I' (as ASTM: instrument flag comment)

To summarize the possible values for the rejection reason and identification fields are reported in the following table:

Rejection Reason	Transmission Interrupted	Identification: first sub_field	Identification: second sub_field
QC_MA_ID	yes	sample ID (causing the problem)	UNKNOWN
BAD_S_ID	yes	sample ID (causing the problem)	UNKNOWN
PDB_FULL	yes	sample ID (causing the problem)	test_ID
NO_TESTS	yes	UNKNOWN	UNKNOWN
NO_PATIE	yes	sample ID (causing the problem)	test_ID
INSTR_ID	yes	UNKNOWN	UNKNOWN
M_TEST_E	no	sample ID	test ID (causing the problem)
UNKWOWN_T	no	sample ID	test ID (causing the problem)
BAD_TEST	no	sample ID	test ID (causing the problem)
BAD_RECO	yes	Record No. (debug purpose)	Field No. (debug purpose)

An example for a complete rejection phase is given by:

```
H|\^&|||ACL9000||||||P|1|19982110103227<CR>
      C|1|I|M_TEST_E|SMP01       ^010|I<CR>
      C|2|I|BAD_TEST|SMP01       ^000|I<CR>
L|1|N<CR>
```

3.7 Download Session Volumes

Approximate data volumes for download sessions is provided as a guide for estimating the time required completing typical sessions. System latencies (both in ELITE/ELITE PRO and host computer) are not considered.

The minimal session would occur if the host has no test orders available for ELITE/ELITE PRO. In this condition ELITE/ELITE PRO sends the test request

message, the host would respond with a message containing no test orders (only message header and message terminator record).
In conditions in which the host has test orders for the instrument, the estimated data volume is:

Test Request Message = Message Header (41) +17 + Message Terminator Record (6) = 64

Test Order Message = Message Header (41) +
Number of patient records (82 + 55 *number of ordered test)
+ Message Terminator Record (6)

Test Order Rejected = Message Header (41) +
+ 41 * number of rejected records
+ Message Terminator Record (6)

So considering the following situation: the host has 50 sample IDs to be download, each one with 4 tests, consider 10 rejected records the data volume can be estimated in:

Test Request Message = 64
Test Order Message = 41+ 50 (82 + 55 *4) + 6 = 15147
Test Order Rejected = 41 + (41 * 10) + 6 = 457
Total = 15668 characters

At 9600 “baud rate” and with no system overhead it would take approximately 17 seconds and considering a system efficiency of 60% it becomes about 27 seconds.

All estimations have been done using the maximum expected length for string fields.

4.0 Test Results Uploading

Test Result Uploading allows transmission of results of the tests performed on ELITE/ELITE PRO to the host computer. Results, related to patient, QC samples and Analytical Reference materials, are transmitted on explicit user request or automatically at session completion.
In the first case the user must require the transmission command in the DMS or in the QC or in the AR environment, select the patient samples or QC samples or AR set of data to be transmitted (in according with one of the supported selection criteria) and start operation.
In the second case the transmission will happen automatically at session completion and the instrument will provide to upload patient and/or QC samples data and/or AR data.
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 “patient samples only” or “QC and patient samples” or “QC and AR patient samples”).

If upload is manually requested, all data are transmitted independently from the transmission flag.

If transmission is performed automatically at session completion, the instrument will upload for patient samples all the data available for the sample IDs just analyzed and will upload, for QC data, the results just obtained.

From a general point of view the automatic data transmission of the patient samples is equivalent to the manual data transmission, requested in DMS, of patient samples belonging to a specific load-list. While the automatic data transmission of the QC data or AR data is equivalent to the manual data transmission, requested in QC database or AR database, or the data in a specified interval for the QC material present in the load-list.

Considering that ELITE/ELITE PRO fills the strings used for Sample ID, department and patient name with space characters (to align data), the host computer must ignore space characters on the right of these fields.

If uploading is completed successfully for patient, QC samples and AR data, the transmission flag associated to the single record will be updated from 'L' to 'T' (transmitted).

It must also to be underscored that on ELITE/ELITE PRO, modifications to sample data already transmitted (such as adding of a new test result or modifications of sample data) cause the transmission flag to change from 'T' to 'L'.
It does not apply to QC or AR data because the only modification the user can request on these data is to omit or to clear statistic. The effect of omit operation is to exclude the data from the statistic but the data is not modified.
Modifications in the set-up values and note field do not modify the transmission status of QC data and AR data.

While transmission is in progress the user will be updated on the number of the sample being transmitted.

ELITE/ELITE PRO does not accept inquiries for test results.

4.1 Test Result Message

The *Test Result Message* is used by ELITE/ELITE PRO to transmit any available test results for a sample. All available test results will be transmitted for patient samples even if data have been already transmitted partially.
The message consist 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).
The *Result* record can be completed with a *Comment* record containing flags associated to the executed test.
Tests are uploaded using the same sorting used on board. The complete set of available test results is globally uploaded to the host computer independently by the set of results defined as to show in the sample list.
In some conditions, depending by the instrument status (i.e. calibrated, not calibrated, AR used, etc.) only a subset of the results supported by the test will be transmitted to the host computer.

The *Message Terminator* record completes the transmitted data.

The same structure is used also to upload QC and AR data. In the following paragraphs any differences in the way to treat patient, QC and AR data will be underlined.

4.1.1 Patient Information Record

This information is transmitted to the host only if available on the instrument. The Patient Information structure is:

Patient Information Record:

File Type	Patient Sample	QC Sample or AR
Record Type ID	Must be 'P'	must be 'P'
Sequence Number	Must begin with '1' and then must increment by one for each new Patient Information record	must begin with '1' and then must increment by one for each new Patient Information record
Practice Assigned Patient ID	Not provided	not provided
Laboratory Assigned Patient ID	Provided if defined as a string containing up to 15 characters.	not provided
Patient ID #3	Not provided	not provided
Patient Name	Provided if known as a single string containing up to 30 characters	not provided
Mother's Maiden Name	Not provided	not provided
Birth date	Provided if known as a single string without any checks	not provided
Patient Sex	Provided if known as a single character	not provided
Patient Race-Ethnic Origin	Not provided	not provided
Patient Address	Not provided	not provided
Reserved Field	Not provided	not provided
Patient Telephone Number	Not provided	not provided
Attending Physician ID	Not provided	not provided
Special Field #1	Not provided	not provided
Special Field #2	Not provided	not provided
Patient Height	Not provided	not provided
Patient Weight	Not provided	not provided
Patient's Known or Suspected Diagnosis	Not provided	not provided
Patient Active Medications	Not provided	not provided
Patient's Diet	Not provided	not provided
Practice Field #1	Not provided	not provided
Practice Field #2	Not provided	not provided
Admission and Discharged	Not provided	not provided

Dates		
Admission Status	Not provided	not provided
Location	Provided if known as a 30 characters free string	not provided
Nature of Alternative Diagnostic Code and Classifiers	Not provided	not provided
Alternative Diagnostic Code and Classifiers	Not provided	not provided
Patient Religion	Not provided	not provided
Marital Status	Not provided	not provided
Isolation Status	Not provided	not provided
Language	Not provided	not provided
Hospital Service	Not provided	not provided
Hospital Institution	Not provided	not provided
Dosage Category	Not provided	not provided

4.1.2 Test Order Record

The fields characterizing this record are specified in the following:

Test Order Record:

File Type	**Patient Sample**	**QC Sample or AR data**
Record Type ID	Must be 'O'	Must be 'O'
Sequence Number	Must begin with '1' and then must increment by one for each new test order record for the same patient	Must begin with '1' and then must increment by one for each new test order record for the same patient
Specimen ID	Provided, is the ELITE/ELITE PRO sample ID. See Appendix for ELITE/ELITE PRO supported characters.	Provided, is the ELITE/ELITE PRO QC material ID for QC data; or is the 'AR' keyword for AR data. See Appendix for ELITE/ELITE PRO supported characters.
Instrument Specimen ID	Not provided	Not provided
Universal Test ID	The field is composed of 4 parts, only the Manufacturer's Code component is used as a 4 character code (host codes are user configurable on board).	The field is composed of 4 parts; only the Manufacturer's Code component is used as a 4 character code (host codes are user configurable on board).
Priority	Provided if set as a 'S' char for priority samples.	Not provided
Requested/Ordered	Not provided	Not provided

Date/Time		
Specimen Collection Date and Time	Not provided	Not provided
Collection End Time	Not provided	Not provided
Collection Volume	Not provided	Not provided
Collector ID	Not provided	Not provided
Action Code	Not provided	Set to 'Q'
Danger Code	Not provided	Not provided
Relevant Clinical Information	Not provided	Not provided
Date and Time Specimen Received	Not provided	Not provided
Specimen Descriptor	Not provided both fields	Not provided both fields
Ordering Physician	Provided, if available, as a string containing up to 30 chars	Not provided
Physician's Telephone Number	Not provided	Not provided
User Field #1	Not provided	Not provided
User Field #2	Not provided	Not provided
Laboratory Field #1	Not provided	Not provided
Laboratory Field #2	Not provided	Not provided
Date/time Results Reported or Last Modified	Not provided	Not provided
Instrument Charge to Computer System	Not provided	Not provided
Instrument Section	Not provided	Not provided
Report Type	Set to F	Set to F
Reserved Field	Not provided	Not provided
Location of Ward of specimen Collection	Not provided	Not provided
Hospital Information Flag	Not provided	Not provided
Specimen Service	Not provided	Not provided
Specimen Institution	Not provided	Not provided

4.1.3 Result Record

The fields characterizing this record are specified in the following table.
A result record is send 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 one of available test results.

Result Record:

File Type	**Patient Sample**	**QC Sample or AR data**
Record Type ID	Set to 'R'	Set to 'R'
Sequence Number	Must begin with '1' and	Must begin with '1' and

	then must increment by one for each result record for the same patient test record for the same patient record	then must increment by one for each result record for the same patient test record for the same patient record
Universal Test ID	The field is composed of 4 parts, only the Manufacturer's Code component is used as a 4 character code (host codes are user configurable on board).	The field is composed of 4 parts, only the Manufacturer's Code component is used as a 4 character code (host codes are user configurable on board).
Data or Measurement Value	The field contains the obtained numeric value or qualitative message (Error xx). All numerical results are sent. *	The field contains the obtained numeric value or qualitative message (Error xx). All numerical results are sent. *
Units	Provided if the previous field is a numeric value; is a free string (see Appendix C for standard units) maximum number of characters is 8).	Provided if the previous field is a numeric value; is a free string (see Appendix C for standard units) maximum number of characters is 8).
Reference range	Not provided	Not provided
Result Abnormal Flag	Not provided	Not provided
Nature of Abnormality Flag	Not provided	Not provided
Result Status	Set to 'F'	Set to 'F'
Data of Change in Instrument Normative Values or Units	Not provided	Not provided
Operator Identification	Not provided	Not provided
Date/Time Test Started	Not provided	Not provided
Date/Time Test Completed	Execution time, string of the type YYYYMMDDHHMMSS	Execution time, string of the type YYYYMMDDHHMMSS
Instrument Identification	Not provided	Not provided

* Specific ranges must be set at the Host level.

4.1.4 Comment Record

The Comment record allows integration of the transmitted test results with possible error messages.
One or more comment records can follow the result records. Fields characterizing this record are specified in the following.

Comment Record:

Record Type ID	set to 'C'
Sequence Number	must begin with '1' and then must increment by one

	for each comment record
Comment Source	set to ‘I’
Comment Text	this field specifies the instrument errors (see table) as a numeric code (2 characters) plus the associated message
Comment Type	set to ‘I’

4.1.5 Error Codes

TEMPERATURE WARNING

```
ROTOR STACK TEMPERATURE Out of Range                    =  41,
SLIDER TEMPERATURE Out of Range                         =  43,
REAGENT TEMPERATURE Out of Range                        =  45,
INCUBATION TEMPERATURE Out of Range                     =  49,
```

MECHANICAL WARNING

```
AUTOSAMPLER WARNING                                     =  50,
ROTOR MOTOR WARNING                                     =  51,
HORIZONTAL MOTOR WARNING                                =  52,
VERTICAL MOTOR WARNING                                  =  53,
REAGENT DILUTOR WARNING                                 =  54,
SAMPLE DILUTOR WARNING                                  =  55,
PHOTOMETRIC COVER WARNING                               =  56,
STIRRER1_FAIL                                           =  57,
STIRRER2_FAIL                                           =  58,
STIRRER3_FAIL                                           =  59,
STIRRER4_FAIL                                           =  60,
```

LIQUID WARNING

```
LIQUID_SENSOR OFF (SAMPLE)                              =  73,
LIQUID_SENSOR OFF (REAGENT)                             =  74,
LIQUID_SENSOR_FAIL (SAMPLE)                             =  75,
LIQUID_SENSOR_FAIL (REAGENT)                            =  76,
MATERIAL_SHORT                                          =  77,
MANDATORY_MATERIAL_SHORT                                =  78,
FLUSH_PRE_WARNING                                       =  79,
FLUSH WARNING                                           =  80,
CLEANING_NOT_PERFORMED                                  =  83,
```

MISCELLANEOUS WARNING

```
COVER_OPEN_DURING_LOADING_OR_INCUBATION                 =  86,
TIMEOUT_EXPIRED_DURING_LOADING                          =  87,
```

ERRORS ON RESPONSE

```
OUTSIDE SCALE RANGE LOW                                 = 98
OUTSIDE SCALE RANGE HIGH                                = 99
SATURATION_ERROR                                        = 205,
FIRST_THRESHOLD_ERROR                                   = 206,
SECOND_THRESHOLD_ERROR                                  = 207,
DELTA_ERROR                                             = 208,
INITIAL_SLOPE_ERROR                                     = 209,
FINAL_SLOPE_ERROR                                       = 210,
FINAL_REACTION CURVE ERROR                              = 211,
FIRST_DERIVATIVE_ERROR                                  = 212,
SECOND_DERIVATIVE_ERROR                                 = 213,
FIRST_PART_REACTION CURVE ERROR                         = 214,
```

ERRORS ON CALIBRATION CURVES

```
INSUFFICIENT_STANDARD POINTS IN ONE_SEGMENT                = 215,
INVALID CURVE INSUFFICIENT DATA                            = 216,
NUMBER OF_STANDARD OUT OF RANGE                            = 217,
INVALID_TRANSLATION_OR_MANDATORY_STANDARD                  = 219,
INVALID_STD_INSUFFICIENT_REPLICATES                        = 220,
INSUFFICIENT_REPLICATES                                    = 221,
INVALID_REPLICATES                                         = 222,
CV_OUT_OF_RANGE                                            = 223,
SLOPE OUT OF RANGE: INVALID CALIBRATION CURVE              = 225,
R2_OUT_OF_RANGE                                            = 226,
NOT MONOTONIC CURVE                                        = 228,
```

ERRORS ON ANALYTICAL REFERENCE, QC, RATIO AND NORMALIZED RATIO

```
AR_INVALID                                                 = 229,
AR_OUT_OF_RANGE                                            = 230,
AR_NOT_CHECKED                                             = 233,
DUPLICATE OUT OF RANGE                                     = 239,
QC_INVALID                                                 = 240,
QC_OUT_OF_RANGE                                            = 242,
RATIO_CALCULATION_ERROR                                    = 249,
RATIO_CALCULATION_ERROR: S/Sa out of range                 = 250,
NORMALIZED RATIO ERROR: AR/Ara out of range                = 251,
NORMALIZED RATIO: CALCULATION ERROR                        = 252,
STD_NOT_FOUND                                              = 253,
AR_NOT_FOUND                                               = 254,
ACTIVATE SAMPLE NOT_FOUND                                  = 255,
ARa_NOT_FOUND                                              = 256,
RATIO_NOT_FOUND                                            = 257,
AR_OUT_OF_RANGE                                            = 258,
AR_NULL                                                    = 259,
STD_NULL                                                   = 260,
SAMPLE_NULL                                                = 262,
REF_NULL                                                   = 263,
AR_RATIO_ NULL_                                            = 264,
ACTIVATED_AR NULL_                                         = 265,
NULL_DIFFERENCE                                            = 266,
```

Out of range indications referring to normal or test ranges are not transmitted to the host computer. The * symbol (outside Normal Range) is presented only on the Cumulative and Sample Reports.

An example for a complete test uploading sequence is given by:

Sample

```
H|\^&|||||||ACL9000||P|1|19982110134700<CR>
   P|1||PTNT1||BLU^^^^||19391127|M|||||||||||||||DEP
1|||||||||<CR>
       O|1|SMP01||^^^0001|S|||||||||^|DR. VERDI|||||||||O||||||<CR>
          R|1|^^^0001|12.8|||||F||||19960119114215|<CR>
               C|1|I|31^Invalid for QC |I<CR>
   P|2||PTNT1||Gialli^^^^||19391127|M|||||||||||||||DEP
1|||||||||<CR>
       O|1|SMP10||^^^0001|S|||||||||^|DR. VERDI|||||||||O||||||<CR>
          R|1|^^^0001|14.5|s||||F||||19960119114215|<CR>
               C|1|I|31^Invalid for QC |I<CR>
L|1|N<CR>
```

QC

```
H|\^&|||ACL9000|||||||P|1|20021205123956<CR>
P|1|||||||||||||||||||||||||||||||<CR>
O|1|Normal  C.||^^^0001|||||||Q||||^||||||||||F||||||<CR>
L|1|N<CR>
```

AR

```
H|\^&|||ACL9000|||||||P|1|20021205123956<CR>
P|1|||||||||||||||||||||||||||||||<CR>
O|1|AR||^^^0001|||||||Q||||^||||||||||F||||||<CR>
L|1|N<CR>
```

4.2 Upload Session Volumes

Approximate data volumes for upload sessions is provided as a guide for estimating the time required to complete typical sessions. Obviously, system latencies (both in ELITE/ELITE PRO and host computer) are not considered.
The minimal session would occur if ELITE/ELITE PRO has no test results to be transmitted; no data is sent and the data volume is zero.
In conditions in which the ELITE/ELITE PRO has results to be transmitted, the data volume can be estimated on the Test Order and Test Result record size base.

Test Order Message = Message Header (41) +
Number of patient records (82 + Results) + Message Terminator Record (6)

Results = number of ordered test (55 + 60*number of test result + 56* number of error messages)

Consider the following situation: ELITE/ELITE PRO has 50 sample IDs to be uploaded each with 4 tests, each test with 3 results and each test with 2 flags, the data volume can be estimated in:

Test Result Message = 41+ 50 (82 + 4(55 + 60*3 + 56*2)) + 6

Total = 69547 characters

At 9600 "baud rate" and with no system overhead it would take approximately 73 seconds and considering a system efficiency of 60% it becomes about 116 seconds.

5.0 Not Supported Records

The *Scientific* record and the *Manufacturer Information* record are not supported by ELITE/ELITE PRO protocol.

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

6.0 Transmission Abort

The download or upload transmission session can be interrupted for an explicit user request detected on the instrument, because the host computer is not responding or because the host computer required interruption of the transmission process.

Further, as reported above, the download process can be interrupted because an illegal sample Identifier has been received. Instrument behavior in this particular condition was defined in and Reject Test Orders.

ELITE/ELITE PRO family instruments behavior in each of the listed conditions is described in the following:

Condition	Action
ELITE/ELITE PRO's operator requested stop download process	ELITE/ELITE PRO will signal the end of transmission to the host and will discard any following messages. The host must consider the interrupt request. It must be emphasized that ELITE/ELITE PRO will signal the transmission interruption with a message that is a rejected test order message if any information has been rejected or with a message header plus a message terminator record if no information has been rejected.
ELITE/ELITE PRO 's operator requested stop upload process	ELITE/ELITE PRO will complete the message in progress with the message terminator and will not transmit any further test results.
Host computer is not responding	During download and upload transmission sessions, operation by ELITE/ELITE PRO is stopped. If download was in progress, no rejected test messages will be transmitted. A message will inform the user that the transmission has been interrupted: "Host Computer not responding"
Host computer required EOT	Both during download and upload sessions, operation by ELITE/ELITE PRO is stopped. If download was in progress, no

	rejected test messages will be transmitted. It must be emphasized that the host computer must request the transmission interruption with a message composed by a message header plus a message terminator record. A message will inform the user that the transmission has been interrupted: “Host Computer required interrupt transmission”
Incorrect record format	Transmission/reception is aborted and the user is informed: “Incorrect format in host messages”

7.0 Appendix- ELITE/ELITE PRO Test Codes

Test codes are user definable. Codes from 1 to 500 are assigned to IL pre-defined tests. Codes greater than 500 are assigned to the user definable tests. IL Library proposes the default test codes reported in the following table.

Test Code	Test Code for host	Test ID (8 char. max)	Extended Test Name (15 char. max)
001	0001	PT	PT
002	0002	PT e	PT Extended
003	0003	PT d	PT Double
004	0004	PT ed	PT Ext. Db.
005	0005	PT HS	PT HS
006	0006	PT HS e	PT HS Extended
007	0007	PT HS d	PT HS Double
008	0008	PT HS ed	PT HS Ext. Db.
009	0009	PT HS +	PT PLUS
010	0010	PT HS + e	PTPLUS Extended
011	0011	PT HS + d	PT PLUS Double
012	0012	PT HS + ed	PT PLUS Ext. Db.
013	0013	R-PT	Recombipl-PT
014	0014	R-PTe	Recombipl-PTex
015	0015	PT R	PT Rec.
016	0016	PT R e	PT Rec Extended
017	0017	PT R d	PT Rec. Double
018	0018	PT R ed	PT Rec Ext. Db.
023	0023	R-PT d	Rec-PT Double
024	0024	R-PT ed	Rec-PT Ext Db
030	0030	FIB_	FIB (PT)
031	0031	FIB	FIB (PT)
032	0032	FIB e_	FIB (PT e)
033	0033	FIB e	FIB (PT e)
034	0034	FIB d_	FIB (PT d)
035	0035	FIB d	FIB (PT d)
036	0036	FIB ed_	FIB (PT ed)
037	0037	FIB ed	FIB (PT ed)
038	0038	FIB HS_	FIB (PT HS)
039	0039	FIB HS	FIB (PT HS)
040	0040	FIB HSe_	FIB (PT HS e)
041	0041	FIB HSe	FIB (PT HS e)
042	0042	FIB HSd_	FIB (PT HS d)
043	0043	FIB HS d	FIB (PT HS d)
044	0044	FIBHSed_	FIB (PT HS ed)
045	0045	FIB HSed	FIB (PT HS ed)
046	0046	FIB HS+_	FIB (PT PLUS)
047	0047	FIB HS+	FIB (PT PLUS)
048	0048	FIB HS+e_	FIB (PLUS e)
049	0049	FIB HS+e	FIB (PLUS e)

Test Code	Test Code for host	Test ID (8 char. max)	Extended Test Name (15 char. max)
050	0050	FIB HS+d_	FIB (PLUS db)
051	0051	FIB HS+d	FIB (PLUS db)
052	0052	FIB+ed_	FIB (PLUS ed)
053	0053	FIB+ed	FIB (PLUS ed)
054	0054	R-FIB_	Recombipl-FIB
055	0055	R-FIB	Recombipl-FIB
056	0056	R-FIBe_	Recombipl-FIBex
057	0057	R-FIBe	Recombipl-FIBex
058	0058	FIB R_	FIB (Rec)
059	0059	FIB R	FIB (Rec)
060	0060	FIB Re_	FIB (Rec e)
061	0061	FIB Re	FIB (Rec e)
062	0062	FIB Rd_	FIB (Rec d)
063	0063	FIB Rd	FIB (Rec d)
064	0064	FIB Red_	FIB (Rec ed)
065	0065	FIB Red	FIB (Rec ed)
074	0074	R-Fibd_	Recombipl-FIBd
075	0075	R-Fibd	Recombipl-FIBd
076	0076	R-Fibed_	Recombipl-FIBed
077	0077	R-Fibed	Recombipl-FIBed
080	0080	APTT Ly	APTT Ly
081	0081	APTT Lye	APTT Ly Ext.
082	0082	APTT Lyd	APTT Ly Db.
083	0083	APTTLyed	APTT Ly Ext.Db.
084	0084	APTT-SP	APTT-SP
085	0085	APTT-SPe	APTT-SP Ext.
086	0086	APTT-SPd	APTT-SP Db.
087	0087	APTTSPed	APTT-SP Ext.Db.
088	0088	APTT-C	APTT-C
089	0089	APTT-C e	APTT-C Ext.
090	0090	APTT-C d	APTT-C Db.
091	0091	APTT-Ced	APTT C-Ext.Db.
092	0092	APTTSYS	APTT SynthASil
093	0093	APTTSYSe	APTT SynthASile
094	0094	APTTSYSd	APTT SynthASild
095	0095	APTTSSed	APTTSynthASiled
096	0096	APTTSYF	APTT SynthAFax
097	0097	APTTSYFe	APTT SynthAFaxe
098	0098	APTTSYFd	APTT SynthAFaxd
099	0099	APTTSFed	APTT SynthAFaxed
102	0102	FVIII SF	FVIII SynthAFax
107	0107	FIX SF	FIX SynthAFax
112	0112	FXI SF	FXI SynthAFax
117	0117	FXII SF	FXII SynthAFax
120	0120	TT-5	TT - 5
121	0121	TT e-5	TT Ext. 5
122	0122	TT d-5	TT Dbl. 5
123	0123	TT ed-5	TT Ext. Dbl. 5
124	0124	TT-8	TT - 8
125	0125	TT e-8	TT Ext. 8
126	0126	TT d-8	TT Dbl. 8
127	0127	TT ed-8	TT Ext. Dbl. 8
128	0128	TT-2	TT - 2
129	0129	TT e-2	TT Ext. 2
130	0130	TT d-2	TT Dbl. 2
131	0131	TT ed-2	TT Ext. Dbl. 2
150	0150	PCX	Pro-IL-Complex
151	0151	HPX	Hepatocomplex
152	0152	P-ClotLy	Pro-Clot Ly
153	0153	P-ClotSP	Pro-Clot SP

Test Code	Test Code for host	Test ID (8 char. max)	Extended Test Name (15 char. max)
154	0154	P-ClotC	Pro-Clot C
159	0159	PS	Protein S
160	0160	Free PS	Free Protein S
161	0161	Pro S	Protein S
199	0199	AT*	Antithr. Liquid
200	0200	AT	Antithr. In cup
201	0201	FIB-C_	Fib. Clauss
202	0202	FIB-C	Fib. Clauss
203	0203	FIB-C l_	Fib. Clauss low
204	0204	FIB-C l	Fib. Clauss low
205	0205	FIB-C h_	Fib Clauss high
206	0206	FIB-C h	Fib. Clauss high
225	0225	APCR-V	APCR V
208	0208	HEP LMW	Heparin LMW
210	0210	HEP UHF	Heparin UHF
212	0212	PLG	Plasminogen
213	0213	PL-IN	Plasmin Inhib.
214	0214	P-C	Protein C
220	0220	F8 Chr H	F8Chr High
221	0221	F8 Chr L	F8Chr Low
225	0225	APCR V	APCR V
250	0250	D-Dimer	D-Dimer
251	0251	D-Dh	D-Dimer high
275	0275	F8SP-P	FVIII SP Par
276	0276	F9SP-P	FIX SP Par
300	0300	FVIII Ly	F VIII - Ly
302	0302	FVIII SP	F VIII - SP
304	0304	FVIII C	F VIII – C
305	0305	FVIII SS	FVIII SynthASil
310	0310	FIX Lyo	F IX - Ly
312	0312	FIX SP	F IX - SP
314	0314	FIX C	F IX - C
315	0315	FIX	FIX SynthASil
320	0320	FXI Lyo	F XI - Ly
322	0322	FXI SP	F XI - SP
324	0324	FXI C	F XI - C
325	0325	FXI SS	FXI SynthASil
330	0330	FXII Lyo	F XII - Ly
332	0332	FXII SP	F XII - SP
334	0334	FXII C	F XII - C
335	0335	FXII SS	FXII SynthASil
336	0336	FVII PT	F VII - PT
338	0338	FVII HS	F VII - HS
340	0340	FVII HSP	F VII - HS Plus
342	0342	FVII R	F VII - R
343	0343	R FVII	FVII RecombPT
350	0350	FX PT	F X - PT
352	0352	FX HS	F X - HS
354	0354	FX HSP	F X - HS Plus
356	0356	FX R	F X - R
357	0357	R FX	FX RecombPT
360	0360	FV PT	F V - PT
362	0362	FV HS	F V - HS
364	0364	FV HSP	F V - HS Plus
366	0366	FV R	F V - R

Test Code	Test Code for host	Test ID (8 char. max)	Extended Test Name (15 char. max)
367	0367	R FV	FV RecombPT
370	0370	FII PT	F II - PT
372	0372	FII HS	F II – HS
374	0374	FII HSP	F II - HS Plus
376	0376	FII R	F II – R
377	0377	R FII	FII RecombPT
155	155	SCT-S	SCT Screen
156	156	SCT-C	SCT Confirm
400	0400	VWF:Ag	vWF Antigen
401	0401	vWF:AgH	vWF Antigen Hig
410	0410	LAC_S	LAC_S
411	0411	LAC_C	LAC Confirm

Note: This table represents the situation for the IL Library 7.

8.0 Appendix – ELITE/ELITE PRO Supported Characters

8.1 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.

8.2 Supported Characters for Patient name, Department and Units

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

8.3 Supported Characters for delimiters

!	“	#	$	%
&	‘	(	)	*
+	/	:	;	=
@	[	\	]	^
_	{	|	}	~

ASCII character 127 is not allowed as delimiter.

Note: Separators are always expected from Host and are always transmitted independently from the information contained in the string.

9.0 Appendix - ELITE/ELITE PRO Supported Units

Unit	Abbreviation
Time	s
Activity	%
Ratio	R
International Normalized Ratio	INR
	NR
Concentration	mg/dL
	g/L
	ng/mL
	U/mL
	µg/L
	µmol/L
	IU/mL
	mg/L
	ug/mL
Delta Optical Absorbance	Δ Abs
Delta	Δ (Δ ASCII code is 7F)
Activated Sample S_a	S_a (Hex code EC)
Curve behavior	offset
	min
	max
	Final
User defined	free string containing up to 8 chars

Notes: For duplicate (d) and extended duplicate (ed) tests only the individual replicate results are sent to the host system. The mean value is not sent from the ACL8/9/10000 system. This applies to all sample types including patient, QC and Analytical reference.

Chapter 12
Appendix B

ACL Elite / ElitePro

Bar Code Label Specification

(REV 0.0)

Index

1.0 Introduction

In the following sections the characteristics of the bar code labels that can be read with the Welch Allyn SCANTEAM 3700 scanner installed on ACL 9000 family instruments are described.

1.1 Purpose

Purpose of this document is to give indication of the scanner characteristics in terms of readable codes, identify the requirements the barcode labels have to satisfy and define constraints in terms of label positioning within ACL 9000 instrument.

1.2 Definitions, Acronyms and Abbreviations

WA Walch Allyn SCANTEAM 3700

Near Distance is the nearest distance that a scanner can accurately digitize a given bar code.

Far Distance is the farthtest distance that a scanner can accurately digitize a given bar code.

Scan Width is the length of the widest bar code that can be successfully interpreted by the scanner.

Quiet Zone is the blank area located just before and just after the bar space pattern.

1.3 References

Ref. 1 SCANTEAM 3700 - Technical Manual - Walch Allyn

2.0 General Description

The WA is a fixed mount CCD bar code scanner with integrated decoder for easy integration into host equipment (ACL 9000 family instruments in our case).

The 3700 features Walch Allyn's time-proven decoding algorithms in a micro-processor-controlled bar code scanner/decoder and offers configurable operating parameters.

The following mean features are available with every WA:

- High scan rate per second (100 is the standard)
- Flexible scan trigger configurations
- Decoder configurable for high security
- Scan voting to ensure bar code data integrity
- Ease of configuration through RS-322 interface

2.1 Supported Codes and Checksum type

Code Type	**Checksum Type**	**Data Digits**
Code 128	No checksum	up to 15
Code 39	Modulus 43	up to 15
	No Checksum	up to 15
Interleaved 2 of 5	USS - Modulus 10	up to 15
	OPCC - Modulus 10	up to 15
	No checksum	up to 15
Codabar	AIM - Modulus 16 with start/stop digits	up to 15
	NW7 - Modulus 11	up to 15
	NW7 - Modulus 16 with start/stop digits	up to 15
	No Checksum	up to 15

2.2 Bar Code Symbol Specifications

All bar code symbols have to satisfy the appropriate AIM Uniform Symbology Specification. In particular the following characteristics have to considered:

- Background substrate

The barcode symbol should be printed on a material type that is reflective and has a matte (not glossy) finish. A background diffuse reflectance of at least 70% to 80% is suggested for optimum contrast.

- Ink color and type

The ink type has to be compatible with 660 nm LEDs used in the scanner. The barcode symbols inked bars should not exceed 10% reflectance at 660 nm that is being used for reading, whether printed with black ink or colored ink.

- Voids and Specks

The code has to be printed clearly, free of voids, specks, blemishes and lines which could “fool” the scanner.

- Definition

The bars in the barcode symbols should be well defined. Their edges should not be rough or fuzzy, so that bar and spaces have the proper widths intended for the used barcode symbology used. Definition should be sharp and consistent.

- Tolerance

The ratio of the widths and spaces in a barcode symbol must conform to the appropriate AIM barcode specifications and can cause problems if not correct throughout the barcode. Problems can occur if bar edges are smeared or rough, or when they exhibit voids.

2.3 Barcode Parameters

Parameters have to be considered in that context are:

- Density (bar code): refers to the number of cheracters in a linear inch of bar code.
- Ratio: refers to the ratio of the nominal wide element width to the nominal narrow element width.

In order to ensure a good bar code reading (in addition to what indicated in the 2.2 section) the parameters above mentioned should be as follows:

- Density: not less 10 Mils
- Ratio: not less 2.5

These values are valid for all the above mentioned bar code types.

The relationship between reading distances, scan width and bar code density are displayed in the following:

Near Distance	**Far Distance**	**Scan Width (near distance)**	**Scan Width (far distance)**	**Density (bar code)**
63.5 mm (161.29'')	114.5 mm (290.83'')	101.6 mm (258.064'')	152.4 mm (387.096'')	7.5 MIL
34.3 mm (87.122'')	130.3 mm (330.962'')	82.3 mm (209.042'')	178.3 mm (452.882'')	13 MIL

In *Appendix Decoder Zone Map* the attached drawing defines the "decoder zone map" for the data above displayed. The displayed graph has been experimentally obtained from Welch Allyn Laboratories because the WA equipped for the IL requirement has not a standard optics.

2.4 Barcode Label Positioning

In *Appendix Barcode Label Dimension* the attached drawing defines the barcode labels dimensions and identifies constraints in positioning labels on vacutainers. The 13x75 vacutainers have been considered. The proposed barcode labels dimension and positioning apply to all sample tray models. The following measurements are reported:

Barcode label feature	**Dimension**
Maximum label length (global label size)	52.6 mm (2.071”)
Maximum barcode length (printed area)	39.6 mm (1.559”)
Quite zone (white area before and after the printed area)	6.35 mm (0.256”)
Label position (it is identified as the label edge measured starting from the vacutainer lower part)	58 mm (2.283”)

2.5 Barcode Label Dimensions