Roche Diagnostics

AMPLILINK 3.0.1

Host Interface Manual

Version 1.0

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VERSION HISTORY

Version	Date	Modifications
1.0	January 2004	Function of AMPLILINK 3.0.1 implemented in this Manual. Author C. Felder

Table of contents

1 Purpose

This document describes the behavior of the AMPLILINK data interchange interface when interacting with a *Laboratory Information System (LIS)* also called host system.

The Roche ASTM+ standard serves as protocol for the data interchange between AMPLILINK and the host system. To understand this document the reader must be familiar with the Roche ASTM+ standard. This document only describes features and implementation details of the AMPLILINK LIS interface which are not a part of the ASTM+ standard. The document does not describe the low level transmission of the ASTM+ protocol.

1.1 Audience

This document is written for technicians which must configure the AMPLILINK LIS Interface in the environment of a lab. Depending on the type of the host system and on the work flows in the laboratory the AMPLILINK LIS interface offers a set of configurable features.

1.2 References

Referenced documents:

[1] Roche Diagnostics ASTM 2.0 Interface Specification

[2] E 1394-91 Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems, American Society for Testing and Materials (ASTM)

1.3 Used Syntax and Abbreviations

Reserved word and delimiters

The ASTM-standard defines the following delimiters:

Field delimiter	= vertical bar	|
Repeat delimiter	= backslash	\
Component delimiter	= caret	^
Escape delimiter	= ampersand	&

The Roche ASTM+ and the AMPLILINK host interface support the reserved word “ALL” (case-insensitive) as value of an ASTM-field in certain work-flows.

Used Syntax

<SpecimenID>	Meaning any string (not containing delimiters), representing a value of the ASTM field “SpecimenID”. The usage of bold fonts shows, that this is a required field in the ASTM stream.
<OrderID>	Meaning as described above, but this is an optional field.
char	Single character. Content specified by standard.
text	String. Variable length.
pos_int	Positive integer (0 to 65535)
d_t	Date and time format as specified by ASTM 6.6.2 (YYYYMMDDHHMMSS)
date	Date format as specified by ASTM 6.6.2 (YYYYMMDD)

Terms

AL	AMPLILINK
ASTM	American Society for Testing and Materials
LIS	Laboratory Information System
Processed on instrument: Required	The instrument needs this information.
Processed on instrument: Conditional	The instrument might needs this information under certain conditions.
Processed on instrument: Optional	The instrument accepts and stores this information but it is not compulsory

1.4 Further Help

In case of questions or difficulties please contact your Roche Diagnostics Service Department or alternatively the Global Systems Support at:

Roche Instrument Center AG
T-SLI
Forrenstrasse
CH-6343 Rotkreuz

E-Mail Address: rotkreuz.GSSLABIN@roche.com

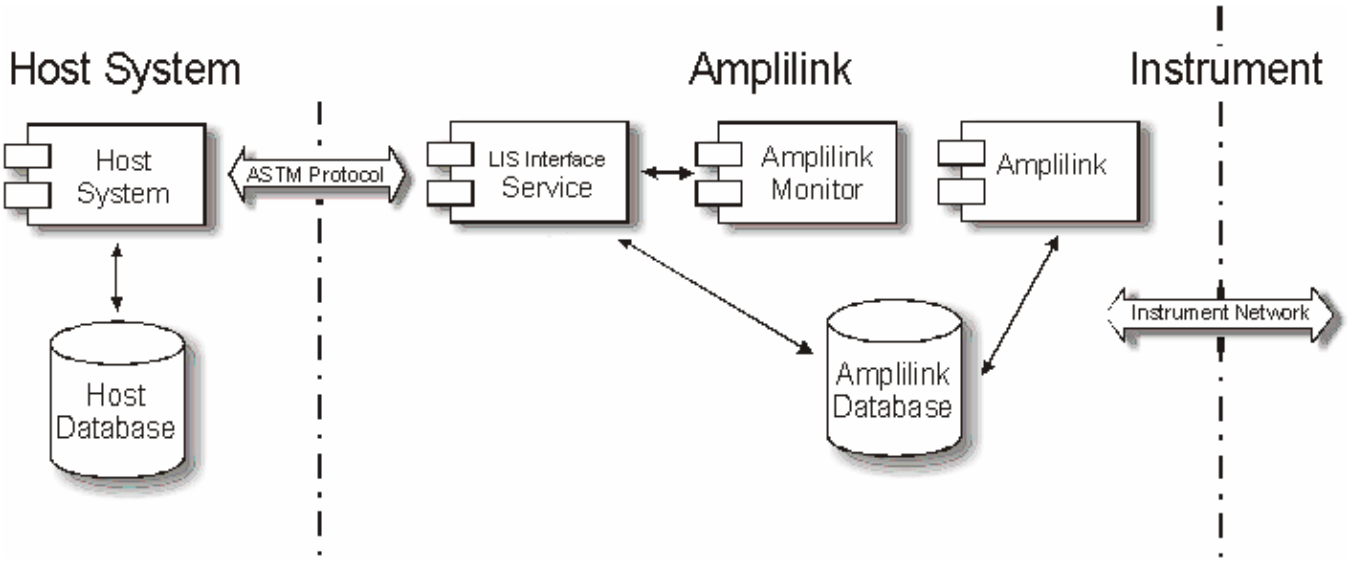
Clarify Queue: GSSLABIN

2 Introduction

To understand all the details of the AMPLILINK LIS interface it is important to know the context of the LIS interface between the AMPLILINK system and the host, e.g. a Laboratory Information System.

2.1 System overview

AMPLILINK interacts with the instruments over the Instrument Network, commonly an Ethernet LAN. Separated of this Instrument Network the LIS interface communicates with the host system over another network (e.g. the hospital network) or over a serial communication (RS232 interface).



The LIS interface consists of the two parts LIS Service and LIS Configuration in AMPLILINK. The LIS Service has a direct access to the AMPLILINK database. The whole interaction and data exchange between AMPLILINK and the LIS Service runs over the AMPLILINK database.

The AMPLILINK Monitor visualizes the states of the AMPLILINK services: Database Maintenance Service and LIS Service.

2.2 LIS Interface service

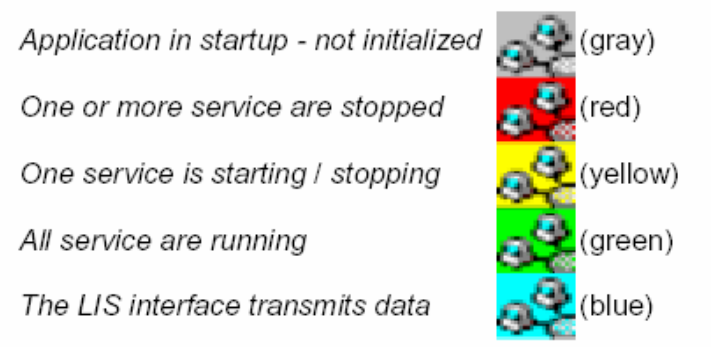
The LIS Service is implemented as a Windows NT Service. A NT Service is a kernel process, which is depending on the LIS interface configuration auto started and can only be stopped and restarted by a service user using the LIS Configuration or the service manager.

The LIS Service communicates with the operator over two different channels. The AMPLILINK Monitor and the LIS interface trace log.

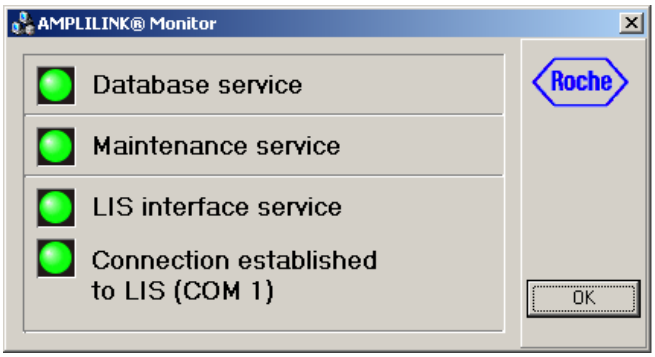
2.3 AMPLILINK Monitor

The AMPLILINK Monitor is implemented as tray icon application. During runtime you only see a small icon of the LIS Monitor in the windows system task bar on the right bottom edge of the screen.

The following figure shows all visualized service process states which the AMPLILINK Monitor displays in the windows task bar.



A mouse click on the monitor tray icon opens the monitor window.



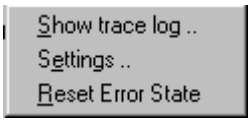
The two top lines show the windows service state of the database and the Maintenance Service. The next line shows the state of the LIS Service. The bottom line shows the current connection state to the LIS host.
In the example above a connection to an LIS client using the port COM 1 was established.

The green led stands for a running state.
The red led stands for a stopped state.
The yellow led informs about current state changes

2.4 LIS Interface trace log

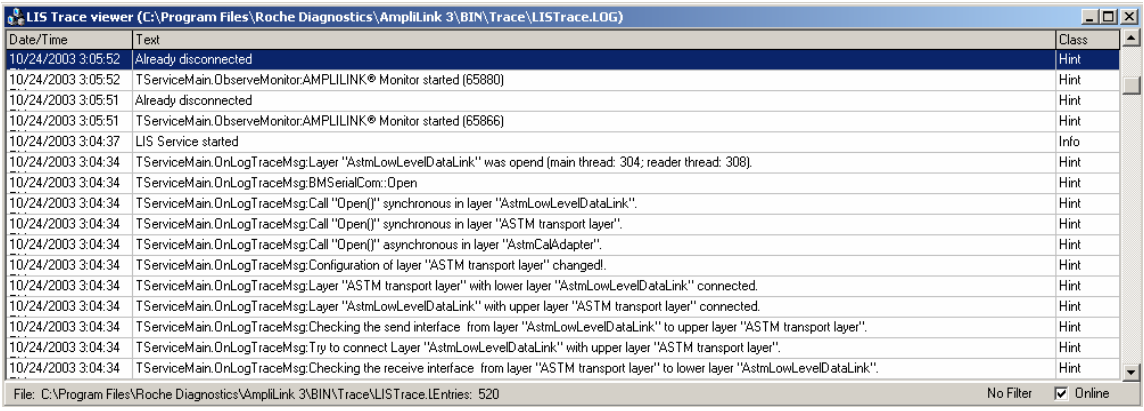
To track the process for debugging purposes the LIS Service writes all its activities in a log book.

To open the trace log, click the right mouse button in the AMPLILINK Monitor over the LIS Service interface area.
The following popup menu appears:



Show Trace Log

The trace log viewer of the LIS monitor shows the last activities of the LIS service.



There are different classifications for the log entries:

Hint:	Informs about a successful run of a sub process step in the LIS Service process.
Info:	Informs about a successful run of a process step in the LIS Service.
Warn:	Warning about a failed process step in the LIS Service. The failure was expected and doesn't have an influence to the next process steps.
Error:	A process has failed and the concerning order download or result upload was properly aborted.

Settings
Starts the LIS configuration popup.

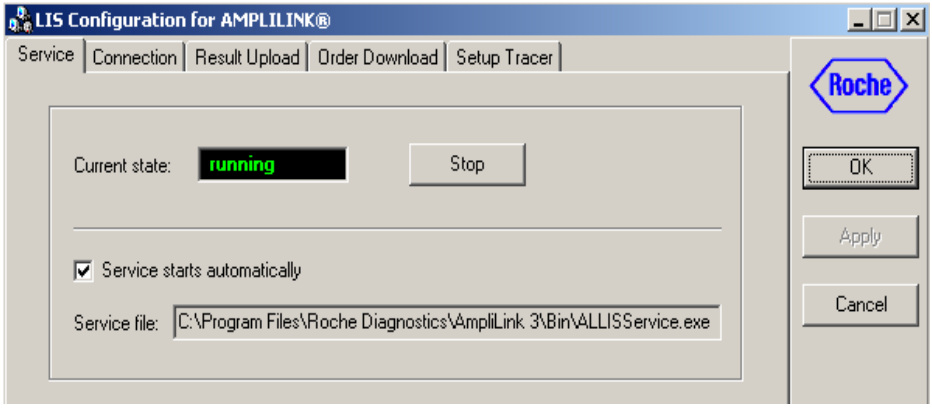
Reset Error State
Resets the error state information in the LIS Interface status display.

2.5 LIS Interface configuration

The LIS interface works with a set of operator configurable settings. For this purpose a configuration dialog allows the operator to change all this settings in order to adapt the LIS interface to the requirements of the host system and to the real laboratory work flow.

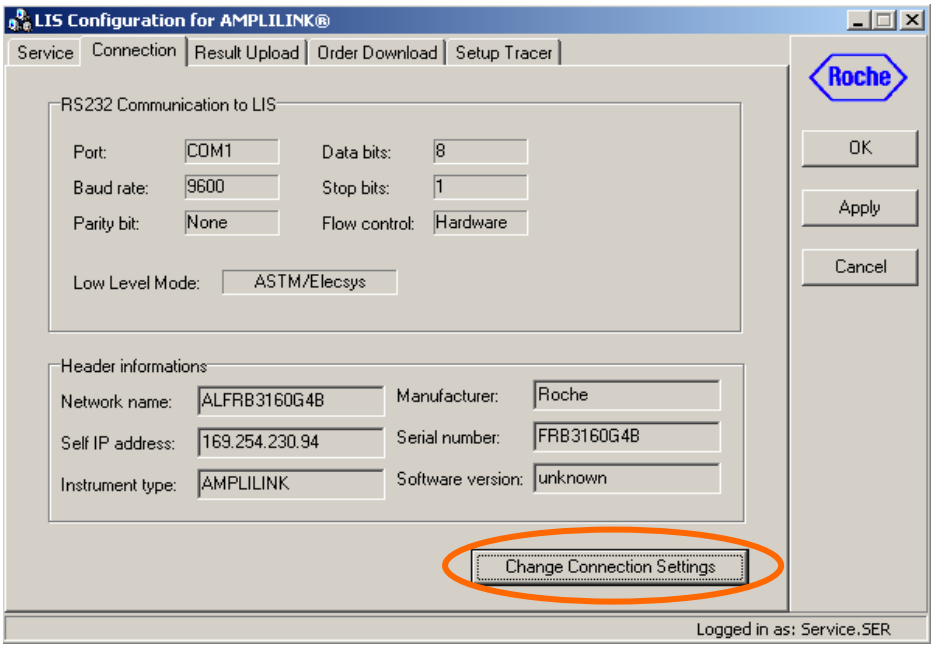
At the first tab sheet on the LIS Configuration screen, you see the current state of the AL LIS service. From here you can start or stop the service.
There is a checkbox to activate the automatic start of the service after rebooting the compter.

Note: This checkbox **must** be activated!
(Changes only possible when logged in as Service User)

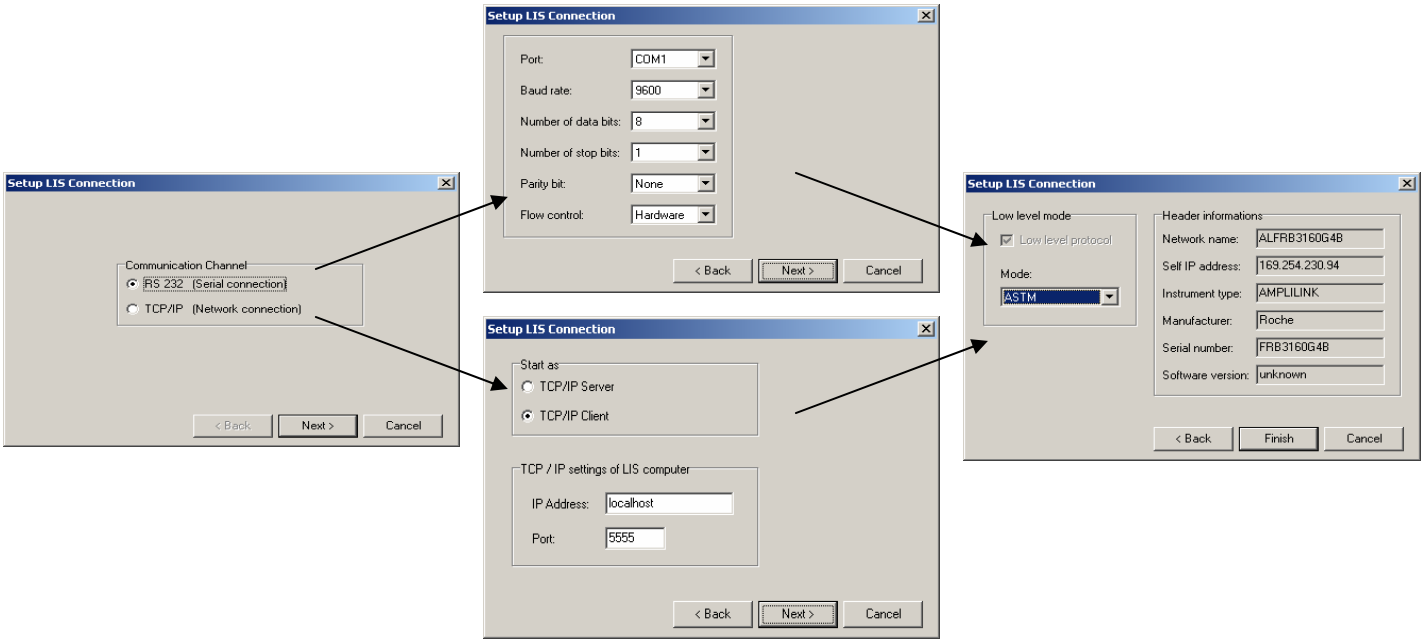


2.5.1 Connection settings

In the tab sheet Connection the actual configured communication settings are displayed.



By pressing the button Change Connection Settings you start a wizard, which in a first step asks, if a serial or a network communication should be installed. Depending on this, the wizard asks in the second step for settings concerning the different communication channels.



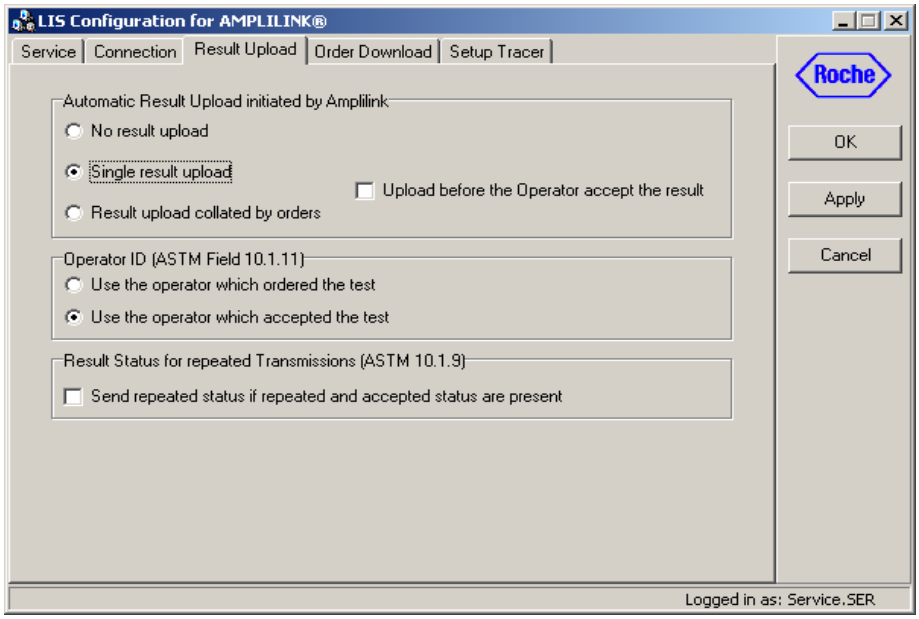
When using a network connetion, select **start as TCP/IP Client**. In this case AMPLILINK tries to connect to the computer specified by the "IP-Address".
A Port-Number higher than 1024 is recommended (no conflict with well-known services).

If start as a TCP/IP-server is selelcted the host is responsible for reconnecting.
This can cause problems when the connection is lost and the interface should be restarted.

Low-Level-Mode
When RS232 is selected “Use Low-Level” is active. It is not possible to deselect.
RS232 requires a low-level-protocol, chose between ASTM or ASTM/Elecsys.
TCP/IP uses a self-implemented data-link-layer. Therefore using a low-level-protocol is optional.

2.5.2 Result Upload settings

The tab sheet Result Upload allows the configuration of the work flows 2 and 3.



2.5.2.1 Automatic Result Upload Mode initiated by Amplilink

There are the tree options to configure the Result Upload Mode of the work flow 3.

- No result upload: Disables the automatic result upload. But it is possible to manual upload the results by pressing send in the AL resultscreen.
- Single result upload: The test-result is transmitted to the host as soon as the result is accepted by an operator.
- Collated result upload: The test-results are transmitted to the host as soon as all test-results of a certain sample-order are available.

The checkbox “Upload before the Operator accepts the result“ allows sending the results immediately without any manual acceptance of the operator.

2.5.2.2 Operator Id (ASTM field 10.1.11)

The LIS interface offers two different sources of information for this field:

- Use the operator which ordered the test.
- Use the operator which accepted the test.

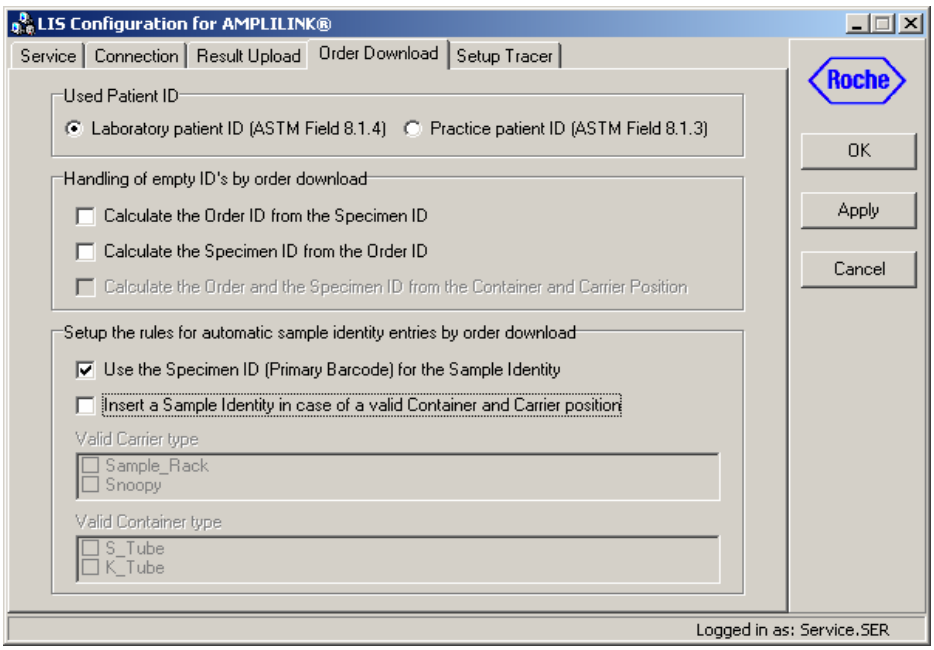
Note that in work flow 2 results, which are not accepted by an operator, will also be transmitted. In this case the operator is empty.

2.5.2.3 Result Status for repeated transmissions (ASTM field 10.1.9)

If the checkbox “Send repeated status“ is ticked, the LIS Interface sends the value “Repeated Transmitted“ for results which are Operator Accepted and allready transmitted once.

If the checkbox is not ticked, the state Operator Accepted will be transmitted for the same state.

2.5.3 Order download settings



2.5.3.1 Used Patient Id

In accordance with the Roche ASTM+-specification the key for patient-data is configurable. You can either choose ASTM-field 8.1.4 "Laboratory Patient ID" (the default-setting) or ASTM-field 8.1.3 "Practice Assigned patient ID".

2.5.3.2 Handling of empty ID's by order download

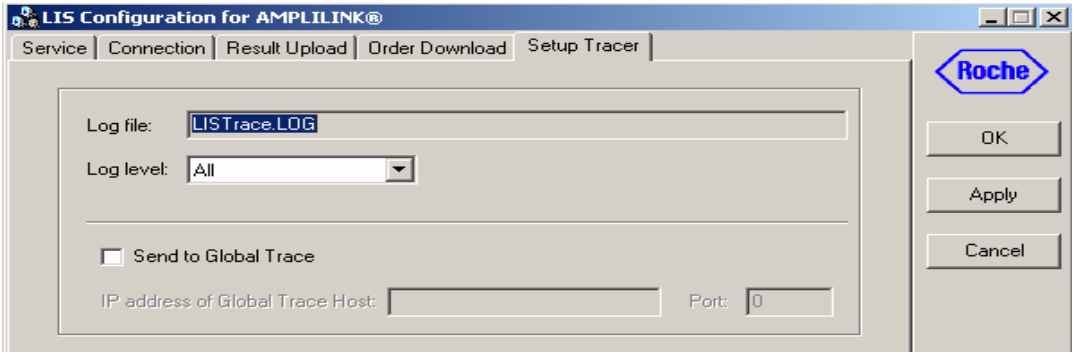
With the three checkboxes:
"Calculate the Order ID from the Specimen ID"
"Calculate the Specimen ID from the Order ID"
"Calculate the Order and the Specimen ID from the Container and Carrier Position"
it is possible to switch on and off these special rules. For futher information see chapter 2.7.1.2.

2.5.3.3 Setup the rules for automatic sample identity entries by order download

Not supported in this Amplilink Version.

2.5.4 Setup Tracer

In this tab sheet you find information about the LIS log file. It is possible to send the trace file to a Global Trace Host by entering the IP address and a Port number.



2.6 Supported Work Flows

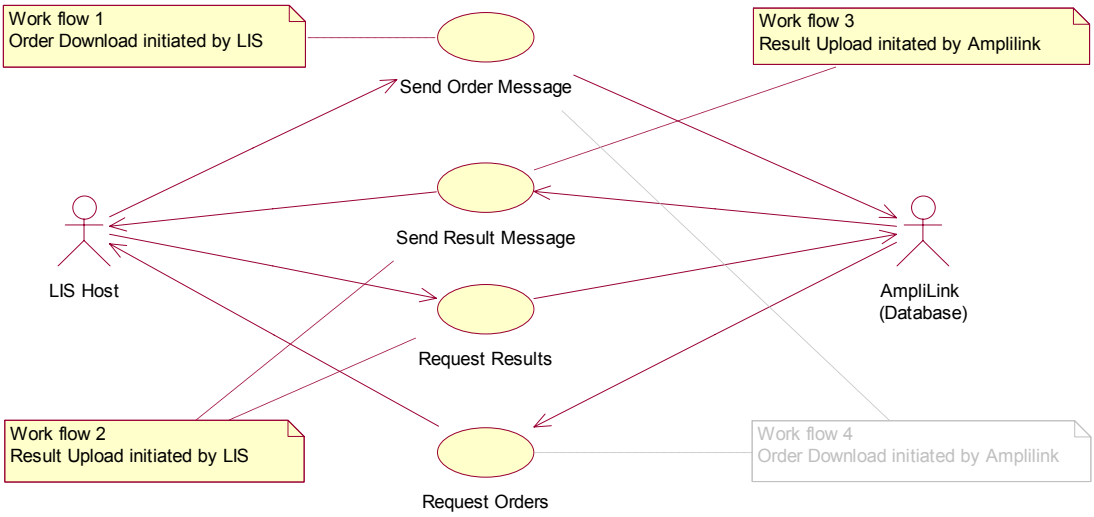
The LIS interface interacts between the host (LIS) and the instrument (AMPLILINK) in the following different ways:

- The host initiates the communication to the instrument (AMPLILINK).
- The instrument (AMPLILINK) initiates the communication to the host.

For both interactions the following two tasks can be identified:

- Order Download: The host sends new orders to the instrument
- Result Upload: The instrument sends results to the host

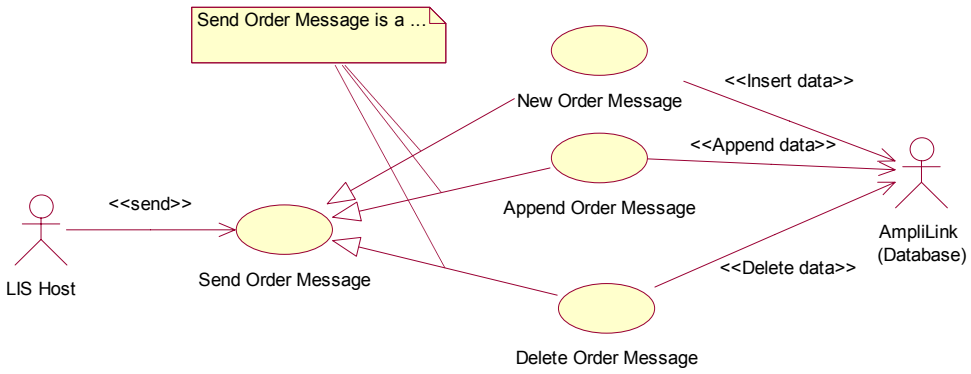
The following diagram shows all four work flows. The work flow 4 Order Download initiated by AMPLILINK1 is not implemented in the AMPLILINK LIS Interface.



[1] Workflow 4: Query of orders from *AMPLILINK* (instrument) to host.

2.7 Work flow (1) Order Download initiated by LIS Host

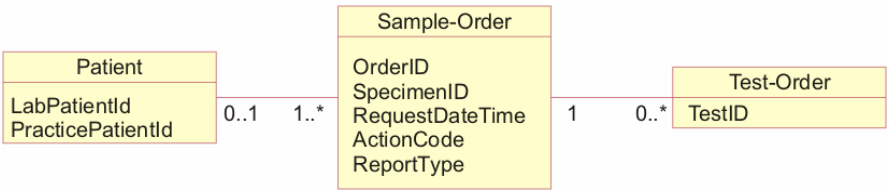
Orders can either be entered into the AMPLILINK database directly within the AMPLILINK software or "remotely" by the LIS host. The diagram below shows the different use cases for the Order Download.



The three functions New, Add and Delete of orders are implemented according to the specification of ASTM+[2].

2.7.1 Data structure of an Order

To understand the details of the three functions it is necessary to know the notation and the data structure behind an order.



One or more test-order data belong to the same sample-order and one or more sample-order data belong to one patient data. But the same test can only be ordered once from the same sample-order.

[2] See document [1], ASTM+ Interface Specification

2.7.1.1 Patient Data

In the AMPLILINK userinterface the main patient information is displayed. Further patient information is stored in the database. If the host has no patient data for an order the patient data can be empty.

2.7.1.2 Sample-Order Data

The **unique identification** of a sample-order data in the AMPLILINK database is achieved by the triple: **OrderId** (ASTM Field 9.4.4), **SpecimenId** (ASTM Field 9.4.3) and the date part of the field **RequestedDateTime** (ASTM Field 9.4.7).

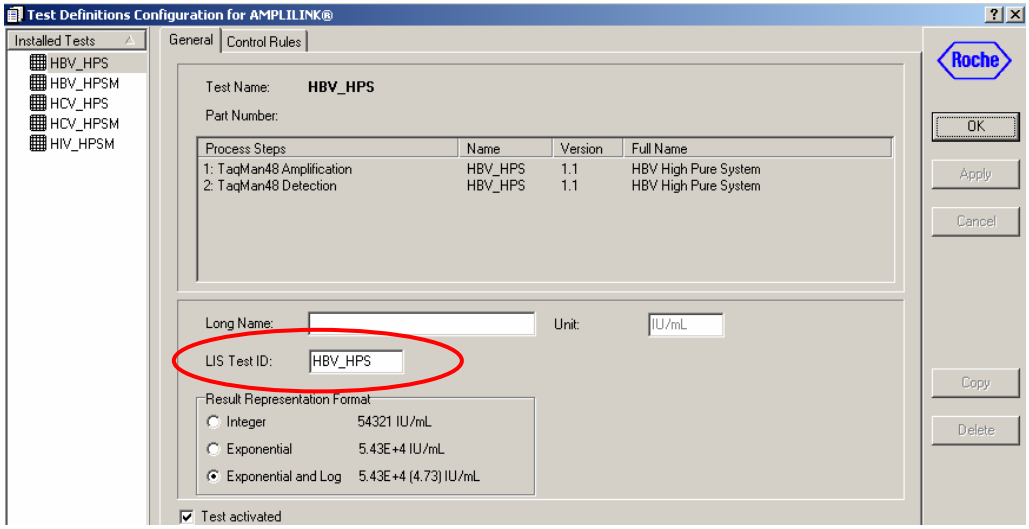
Usually all three fields must contain a valid value, but AMPLILNK uses the following rules and configurations for the handling of empty key fields:

1. If the RequestedDateTime is empty the LIS Interfaces always takes the current date and time of the order download.
2. If the Host can handle empty OrderIds the LIS Interface offers with the configuration Calculate Order Id a possibility to fetch an artificial identifier derived from the valid SpecimenId.
3. If empty SpecimenIds must be handled the LIS Interface offers with a second configuration Calculate Specimen Id a possibility to fetch an artificial identifier derived from the valid OrderId.
4. With a third configuration it is possible to calculate SpecimenID and OrderID from the valid RackCarrierId and PositionOnRackCarrier.

2.7.1.3 Test-Order Data

The TestID (ASTM Field 9.4.5) must be a known unique test-code in the AMPLILINK database.

The TestID is translated to the AMPLILINK's test-codes by a user configurable translation table (see in the configuration of AMPLILINK, Test Definitions Configurations for AMPLILINK).



In this window you can also select the appereance of the result value in the AMPLILINK userinterface. Neverless what is selected in the Result Representation Format, the Result format transmitted to the LIS will always be sent as Integer.

2.7.1.4 Abstract message format

According to the specification of ASTM+ the host can send messages of the following EBNF[3]:

Message = (Patient (Sample-Order (Test-Order)*)*)*

The figure below shows this structure in linear form.

```
Patient 1
       Sample-Order 1.1
              Test-Order 1.1.1
              Test-Order 1.1.2
              ..
              Test-Order 1.1.A1
       Sample-Order 1.2
              Test-Order 1.2.1
              Test-Order 1.2.2
              ..
              Test-Order 1.2.A2
       Sample-Order 1.3
       ..
       Sample-Order 1.B
Patient 2
       Sample-Order 2.1
       ..
       Sample-Order 2.B
..
Patient C
```

The operation mode New, Add or Delete is only valid for the level of the sample-order data

Patient data can only be inserted or updated and not deleted by the host. The AMPLILINK internal database maintenance function deletes unused patient data from time to time.

2.7.2 New Order

In the ASTM+ specification, in the field ActionCode (ASTM Field 9.4.12) of the data sample-order, the character 'N' defines the function for creating a new sample-order with tests.

If an identical sample-order with the same unique identification already exists, the function New deletes first all tests which were ordered to this sample-order before. If any of these earlier tests are already being processed or even have a measured result, the function terminates with an error and returns this New Order Message to the host. All fields of a new sample-order will be overwritten if the sample-order already exists before.

[3] In the EBNF (Enhanced Backus Nauer Form) an asterisk stands for iteration.

2.7.3 Add Order

In the ASTM+ specification the character 'A' in the ActionCode (ASTM Field 9.4.12) defines the function for appending a new test to a sample-order.

If the sample-order does not already exist in the AMPLILINK database before, the LIS Interface creates this order in the same manner as the new function. Otherwise, if the sample-order and also the patient data already exist, all fields of both data will be updated by the newer version of the Add Order Message.

Remember that the same test can only be ordered once to the same sample-order. If the same test will be ordered at twice nothing happens except that the test is already in process or has a valid result. In this case the Add Order Message will be returned to the host and the function terminates with an error.

2.7.4 Delete Order

In the ASTM+ specification the character 'C' in the ActionCode (ASTM Field 9.4.12) defines the function for deleting an existing sample-order and test-orders.

The deleting function has more aspects than the function new and append of orders. Besides deleting one or more distinct test-order of a sample-order, the deletion of several test-orders is supported. For the deleting of the whole set of test-orders, concerning a given sample-order, the reserved word ALL can be used as TestID (ASTM Field 9.4.5).

Before each single test-order can be deleted several conditions (instrument rules) must be true.

1. The test must not be in process.
2. The test must not contain a final measured result regardless whether the result is accepted by an operator or the test was already sent to the host.
3. The test must be ordered previously by LIS (and not manually by an operator in AMPLILINK)

There is no function to delete old tests and their sample-orders from the host side if they are already processed and have a final result which is transmitted to the host. The AMPLILINK database maintenance function can remove old tests and its results from time to time. The host must take care that sample-orders and their results, which were transmitted more than once from the instrument to host by workflow 3/4, are unique in the host database.

At the end of the deletion of test-orders the LIS interface tests if there are still test-orders linked to the given sample-order. In case of an empty test-order list the sample-order will be subsequently deleted.
The patient data however is not deleted. This is the duty of the AMPLILINK database maintenance service.

Furthermore the LIS interface supports the deletion of a set of sample-orders with the same OrderId and the same requested date but with different SpecimenId. For this purpose the reserved word ALL can be used in the field SpecimenId.

Both these functions for deleting sets of test-orders are a powerful operation, but they will only work, if the instrument rules allow the deletion of every single test-order.

2.7.5 Error handling of Order Download

According to the ASTM+ specification the LIS interface returns the received message in cases of errors during the order download task to the host. With that the host system is informed, that certain orders could not be entered into or removed from the AMPLILINK database.

The field ReportType (ASTM Field 9.4.26) of a returned message is set to RT_FAILED (character X).

For detailed analysis in cases of error only the log file of the LIS interface contains enough information to understand the error cause.

The following table shows all error causes during the order download process with their relevant behavior of the LIS interface:

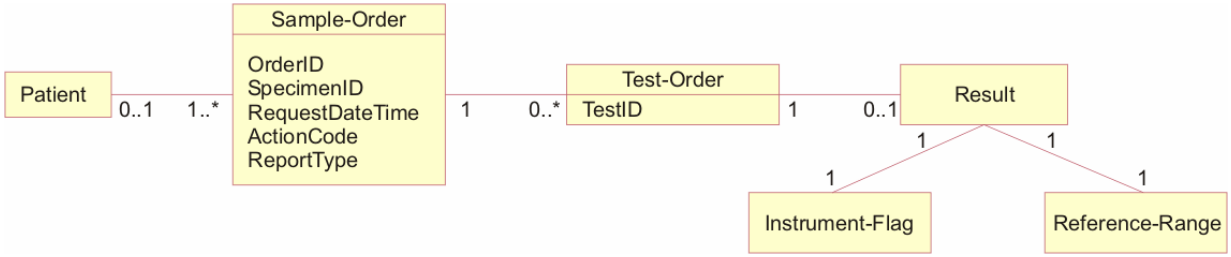
Operation	Error cause	Exception handling
All Operation (New , Append or Delete)	A patient with the same ID already exists in the AMPLILINK database	The patient data will be overwritten by the newer patient data of the order download message
	Ordering of a patient in the AMPLILINK database failed	The other parts (sample and test orders) of the message will be processed
	Empty Specimen or Order ID (without usage of ID calculation)	The order download message will be returned The message will not be processed
	Receive unexpected Report Type (ASTM Field 9.4.26)	The order download message will be returned Ignore the received message
	Internal software error	Ignore the received message
New or Append Operation	The sample order already exists and the accessory test orders are not erasable (because the test orders are being processed)	The order download message will be returned to the host The ordering of the accessory tests will be ignored
	The test code of a test order is undefined in the AMPLINK database	The order download message will be returned to the host with the failed accessory test orders only The ordering of the remaining test order will be processed
	The test order of an existing sample order is already being processed	
New sample order	The insertion of a new sample in the AMPLILINK database failed	The order download message will be returned to the host The ordering of the accessory tests will be ignored
	The sample order identification logic is enabled and failed (because the sample-order is already reserved)	The order download message will be returned to the host The ordering of the accessory test orders will be ignored
Append sample order	The update of an already existing sample in the AMPLILINK database failed	The order download message will not be returned The other parts (test orders) of the message will be processed
	The sample order does not exist and the sample order identification logic is enabled and failed (because it is already reserved)	The order download message will be returned to the host The ordering of the accessory tests will be ignored
Delete one sample order	The sample order to be deleted does not exist	The deleting operation will be ignored
	Deletion of a sample order in the AMPLILINK database failed	The order download message will not be returned The deleting of the test orders will be processed
	Deletion of a test order in the AMPLILINK database failed (because the test has already been processed)	The order download message will be returned with the failed test orders only The other test orders of the same sample order will be processed
Delete all sample orders of one order	The order of the samples for deleting does not exist	The deleting operation will be ignored
	Deleting of an order in the AMPLILINK database failed	The order download message will not be returned The deleting of the test orders will be processed
	Deleting of one test order in the AMPLILINK database failed (because this test has already been processed)	The order download message will be returned

2.8 Work Flow (2 and 3) Result Upload

Within the work flow 2 and 3 the LIS interface sends results from the instrument to the host.

2.8.1 Data structure of a Result

To understand the details of the result upload work flow it is necessary to know the notation and the data structure behind the results.



Notation and data structure of the LIS host (ASTM specification) and the dependencies between patient, sample-order, test-order and result with instrument-flag and reference-range. Notice that in this diagram only the key fields are displayed.

2.8.1.1 AMPLILINK Result Status

AMPLILINK handles for every test-result a result status which can be one of the following states:

NotDef:	The test result is not yet available.
Fail:	An error occurred during the processing of the test and the result is not available.
Preliminary:	The test has not finished yet but there is a first result available.
FinalResult:	The instrument has completed the measurement and the result is available.

For Final Results the AMPLILINK's operator must manually accept the results. Then the state will be changed from Final Results to Operator Accepted.

Operator Accepted: An operator has accepted the final result in the AMPLILINK (Result view).

2.8.1.2 LIS Interface Transmission Status

The LIS Interface manages a LIS transmission state for every distinct result with the following values:

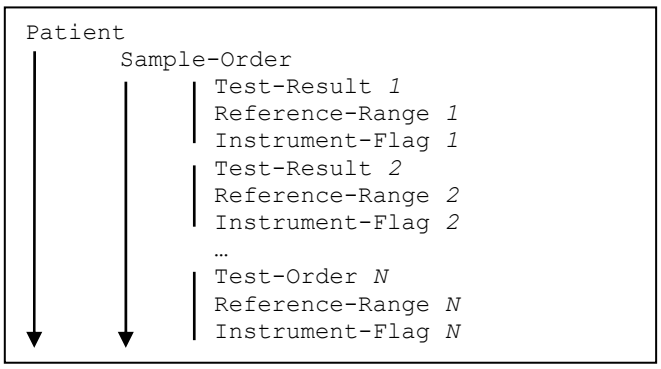
- None: The result is not yet transmitted to host.
- SendRequest: The result should be transmitted (only used by workflow 3: manual result upload)
- Sent: The result is transmitted once.
- ResendRequest: The result should be retransmitted (only used by workflow 3: manual result upload)
- Resent: The result is transmitted more than once.

2.8.2 Result upload Message

The instrument sends messages according to the specification of ASTM+ of the following EBNF:

Message = (Patient (Sample-Order (Test-Result, Reference-Range, Instrument-Flag)*)*)*

The LIS interface does not apply both the outer iteration over the patient and over the sample-order. In order not to get not too large messages the LIS interface sends for every sample-order and its patient a single message with a set of results, references and instrument data. The figure below shows the structure of one message in a linear form:



2.8.3 Work flow (2) Result Upload initiated by LIS Host

The host can request a subset of results with the message Result Query.

Filters for Result Upload

The LIS interface supports the following list of filters:

- PatientID
- OrderID
- SpecimenID
- TestID
- RackCarrierID
- PositionOnRackCarrier
- RackCarrierType
- TubeContainerPos

All these fields are connected by the LIS interface with a logical AND.

The logic of these filters allows the request of a single result of a specified test, which belongs to a specified OrderId, SpecimenId and PatientId.
Or if all filters are empty or contain the reserved word ALL, the host requests the whole result set, which is stored in the AMPLILINK database at the current time.

2.8.3.1 Message "No Results"

When the result subset is empty for the given requested filter; the LIS interface sends a special message "No Result for Upload" to the host.

```
Patient (Empty)
       Sample-Order (Empty)
              Result (Empty)
```

In this message all fields of the patient, sample-order and result data are empty except the identifier of the filter (PatientId, OrderId, SpecimenId, RackCarrierID, PositionOnRackCarrier, RackCarrierType, TubeContainerPos and TestId), which contain the filter values from the Requested Information Data.
Additional the ReportType (ASTM field 9.4.26) contains the value "Z" which stands for the condition RT_NO_PATIENT.

2.8.4 Work flow (3) Result Upload initiated by AMPLILINK

The LIS interface offers the following three different ways to upload results initiated by AMPLILINK:

- No result upload
- Single result upload
- Result upload collected by orders

2.8.4.1 Function "No Result Upload"

This function transmits a result only after an operator instruction.
In the AL results screen select first the result(s) you like to send, then go to Tools and press send.

The LIS interface sends the result immediately to the host and sets back the LIS transmission state to Sent or to Resent. As precondition for a manual upload the AMPLILINK program offers this function only for results which were previously accepted by an operator.

2.8.4.2 Automatic Result Upload Modes

As default, after the installation, the automatic result upload of the LIS interface is disabled.
Only one of the modes "Single Result Upload" or "Result upload collated by orders" can be activated at the same time.
But the automatic result upload and the manual result upload work simultaneously.

Usually the LIS interface does not upload a result before the operator has accepted it.
But the LIS interface can also be configured to upload the results without the acceptance of the operator (see chapter 2.5.2).

3 ASTM connection

This chapter describes the restriction of the ASTM+ standard for the LIS interface.

Supported fields

The tables in the following chapter specify which fields are supported by the LIS interface and which restriction is demanded.

The ASTM+ standard distinguishes between required, conditional (required only in some work flows) and optional fields of the data interchange between the host system and the instrument (see also the document [1], ASTM+ Interface Specification).
Furthermore the ASTM+ standard also defines some fields of the ASTM standard which are not supported in ASTM+ at all.
This unsupported ASTM fields are not even listed in this document.
A grayed background shows optional or conditional ASTM+ fields
In cases of data receiving the fields are marked **bold**, if the AMPLILINK requires a valid (non empty) value.

3.1 Message Header Record

The message header record defined by the Roche ASTM+ standard is intended for transporting some general static data. The following table shows which fields of the message header record are supported by the LIS interface.

Message Header Record		
ASTM	Field Name	Remark
7.1.1	**Record Type Id**	"H" (Header): Filled up by CAL Server
7.1.2	**Field delimiter**	"|" : Filled up by CAL Server
	Repeat delimiter	"\" : Filled up by CAL Server
	Component delimiter	"^" : Filled up by CAL Server
	Escape delimiter	"&" : Filled up by CAL Server
7.1.5	SenderName	Computer name in network, Windows configuration
	Manufacturer	Fixed text "Roche"
	InstrumentType	Fixed text AMPLILINK
	SoftwareVersion	Version of LIS interface
	ProtocolVersion	Version of COM CAL Server
	SerialNumber	Serial number of AMPLILINK LIS interface
	SenderNetworkAddress	Self IP address
7.1.10	ReceiverName	Default: empty string, configurable by registry entry
	ReceiverNetworkAddress	Default: empty string, configurable by registry entry
7.1.12	ProcessingID	Default: PT_UNDEFINED, configurable by registry entry
7.1.13	Version No	ASTM-Version level, filled up by CAL Server
7.1.14	Date and Time of Message	Filled up by CAL Server with the current date and time

3.2 Patient Record

The patient information record is used for the ordering, for the negative acknowledge during the ordering and for the result upload initiated by the AMPLILINK and also by the host.

In cases of empty patient information the key value should be empty. This key value (unique identification) can either be the LabPatientId or the PracticePatientId depending of the LIS configuration (see chapter 2.5.3.1).

Patient Record			
ASTM	Field Name	Remark for receive record	Remark for send record
8.1.1	**Record Type Id**	"P" (Patient), filled up by CAL Server	
8.1.2	**Sequence Number**	Defined by ASTM 6.6.7, filled up by CAL Server	
8.1.3	PracticePatientID	Which item will be used is depending of the LIS configuration. An empty ID stands for an empty patient record, Only ASCII characters are supported, Maximal field length: 20 characters	
8.1.4	LabPatientID		
8.1.6	Name.LastName	Only ASCII characters are supported, Maximal field length: 30 characters	
	Name.FirstName	Only ASCII characters are supported , Maximal field length: 30 characters	
	Name.MiddleName, Name.Suffix, Name.Title	not supported	always empty
8.1.7	MothersMaidenName	Only ASCII characters are supported, Maximal field length: 20 characters	
8.1.8	BirthDate	ASTM date time format. See [1]	
8.1.9	Sex	M,F,X	
8.1.10	Race	Supported values are: NotDef, white, black , asian_pacific_islander, native_american_alascan, hispanic	
8.1.11	Address.Street, Address.City, Address.ZIPorPostalCode, Address.CountryCode	All comma trimmed in the address fields, Only ASCII characters are supported, Maximal field length: 69 characters	
8.1.13	PatientPhoneNumber	Only ASCII characters are supported, Maximal field length: 20 characters	
8.1.17	Height.Scalar	Fix unit cm	
8.1.18	Weight.Scalar	Fix unit kg	
8.1.19	PatientDiagnosis	Only ASCII characters are supported, Maximal field length: 40 characters	
8.1.20	PatientMedication	Only ASCII characters are supported, Maximal field length: 40 characters	
8.1.21	PatientDiet	Only ASCII characters are supported, Maximal field length: 40 characters	
8.1.24	AdmissionDate DischargeDate	ASTM date time format. See [1]	
8.1.25	AdmissionStatus	Only ASCII characters are supported, Maximal field length: 4 characters	
8.1.26	Location	Only ASCII characters are supported, Maximal field length: 40 characters	
8.1.27	NatureOfDiagnosticCode	not supported	always empty
8.1.28	AlternativeDiagnosticCode	not supported	always empty
8.1.29	Religion	Only ASCII characters are supported, Maximal field length: 20 characters	
8.1.30	MaritalStatus	not supported	always empty
8.1.31	IsolationStatus	Only ASCII characters are supported, Maximal field length: 20 characters	
8.1.32	Language	Only ASCII characters are supported, Maximal field length: 20 characters	
8.1.33	HospitalService	not supported	always empty
8.1.34	HospitalInstitution	not supported	always empty
8.1.35	DosageCategory	Only ASCII characters are supported, Maximal field length: 40 characters	

3.3 Test-Order Record

The definition of the ASTM standard unites the sample-order data and its test-order data in the following way to test-order records:

test-order-record = sample-order (test-order)*

The test-order-record is used for ordering, for negative acknowledge during the order process and for the result upload initiated by the AMPLILINK and also by the host.

Test-Order Record		
ASTM	Field Name	Remark for receive record
9.4.1	**Record Type Id**	"O" (Order): Filled up by CAL Server
9.4.2	**Sequence Number**	Filled up by CAL Server
9.4.3	**SpecimenID**	Depending on LIS Configuration can be empty. Only ASCII characters are supported, Maximal field length: 40 characters
9.4.4	**OrderID**	Depending on LIS Configuration can be empty. Only ASCII characters are supported, Maximal field length: 20 characters
	^RackCarrierID	Only ASCII numbers 0..9 are supported
	^PositionOnRackCarrier	Only ASCII numbers 0..9 are supported
	^TrayOrLocationID	not supported
	^RackCarrierType	not supported
	^TubeContainerType	not supported
9.4.5	**TestID** **^^^TestID**	Case insensitive, The TestID must be a valid Test-Code. The mapping of Test-Codes to Testnames are done by the AMPLILINK database (AMPLILINK configuration) Only ASCII characters are supported, Maximal field length: 8 characters
	Treatment type	not supported
	Pre-Treatment type	not supported
	Result Evaluation type	not supported
9.4.6	Priority	0 .. 3
9.4.7	RequestedDateTime	if RequestedDateTime is empty, then the current date and time is filled in
9.4.8	CollectionDateTime	ASTM date time format. See [1]
9.4.9	CollectionEndDateTime	not supported
9.4.10	CollectionVolume	fix unit ml
9.4.12	**ActionCode**	Supported action codes are: N= NEW A= ADD C= CANCEL_REQUEST (Delete Order and TestOrders)
9.4.13	DangerCode	not supported
9.4.14	ClinicalInformation	not supported
9.4.15	ReceivedDateTime	ASTM date time format. See [1]
9.4.16	SampleData.SpecimenType	0 .. 32
	SpecimenSource	Only ASCII characters are supported, Maximal field length: 20 characters
9.4.21	LabField	Only ASCII characters are supported, Maximal field length: 1000 characters
9.4.23	ResultsReportedDateTime	not supported
9.4.26	**ReportType**	O: Ordering X: neg. acknowledge during ordering F: Final result upload to host Z No reult available (Answer to query):

3.4 Result Record

The result record is used for result uploading to the host. In cases of outstanding results (pending or processing test-orders) no result data will be sent, because the LIS interface only supports requests for final results.

Result Record		
ASTM	Field Name	Remark
10.1.1	Record Type Id	"R" (Result), Filled up by CAL Server
10.1.2	Sequence Number	Filled up by CAL Server
10.1.3	TestID ^^^TestID	Case insensitive, The TestID must be a valid Test-Code. The mapping of Test-Codes to Testnames are done by the AMPLILINK database (AMPLILINK configuration) Only ASCII characters are supported, Maximal field length: 8 characters
Result		
10.1.4	DataMeasurementResult.Scalar	Send the interpretation (Text) if available, otherwise send the result value
	DataMeasurementResult.ValType	not supported
	DataCutOffIndex	not supported
10.1.5	DataMeasurementResult.ValUnit	Send the unit only if in 10.1.4 the result value was sent (otherwise empty string)
Reference Range		
10.1.6	Lower Limit	
	Upper Limit	
	Limit Name	empty text because AMPLILINK handles only one kind of limits
10.1.7	ResultAbnormalFlag	See ASTM 10.1.7 for values
10.1.8	NatureOfAbnormability	not supported
10.1.9	ResultStatus	See description in chapter 2.8.11
10.1.11	Operator	Depending of LIS configuration name of the operator which ordered the test or name of the operator which accepted the test. See chapter 2.5.2.2 for details.
10.1.12	DateTimeTestStarted	
10.1.13	DateTimeTestCompleted	
10.1.14	InstrumentIdentification	Name of the instrument which performed the test.

3.4.1 COBAS TaqMan48 Instrument Flag Codes

The Instrument Flag Codes are a special part of the result record

Flag Code	Flag Comment	Description
‘TM00’	'TEMPRNG'	Cycler Temperature Out of Range
‘TM01’	'LAMPINST'	Lamp Instability (low light intensity)
‘TM02’	'DARKRNG'	Sample dark value out of range (>0, < 1000000)
‘TM03’	'BRIGHTRNG'	Sample bright value out of range (>dark value, < 128000000)
‘TM04’	'TEMPCOVER'	TCCover under limit
‘TM05’	'DARKDRIFT'	Dark drift greater than MaxDarkDrift (4000)
‘TM06’	'SYS_CALC'	Calculation error (Div by 0)
‘TM07’	'SYS_ABORT'	Result processing broken down
‘TM08’	'REFRNG'	Reference Channel dark out of range (<150;>2000)
‘TM09’	'REFRNG'	Reference Channel bright out of range (<10000)
‘TM10’ - ‘TM49’		Reserved
‘TM50‘	'EVAL_ERROR'	DB-Error while getting data
‘TM51‘	'NO_DATA'	Too few datapoints
‘TM52‘	'STEP_CORR'	Pre-checks QS: BL step correction
‘TM53‘	'SPK_DETECT'	Pre-checks QS: Spike(s) detected
‘TM54‘	'SPK_CORR'	Pre-checks QS: Spike(s) corrected
‘TM55‘	'SPKREMOVED'	Pre-checks QS: Spike(s) removed
‘TM56‘	'SPK_INFL'	Pre-checks QS: Spike influence
‘TM57‘	'DRIFT_HIGH'	Pre-checks QS: Drift of BL too high
‘TM58‘	'CURVENOISE'	Pre-checks QS: BL Curvenoise > MaxBLnoise
‘TM59‘	'BLTOOLOW'	Pre-checks QS: BL range check too low
‘TM60‘	'BLTOOHIGH'	Pre-checks QS: BL range check too high

Flag Code	Flag Comment	Description
‘TM61‘	'RFITOOLOW'	Pre-checks QS: RFI (Rel. Fluor. reading) < RFImin
‘TM62‘	'STEP_CORR'	Pre-checks target: BL step correction
‘TM63‘	'SPK_DETECT'	Pre-checks target: Spike(s) detected
‘TM64‘	'SPK_CORR'	Pre-checks target: Spike(s) corrected
‘TM65‘	'SPKREMOVED'	Pre-checks target: Spike(s) removed
‘TM66‘	'SPK_INFL'	Pre-checks target: Spike influence
‘TM67‘	'DRIFT_HIGH'	Pre-checks target: Drift of BL too high
‘TM68‘	'CURVENOISE'	Pre-checks target: BL Curvenoise > MaxBLnoise
‘TM69‘	'BLTOOLOW'	Pre-checks target: BL range check too low
‘TM70‘	'BLTOOHIGH'	Pre-checks target: BL range check too high
‘TM71‘	'RFITOOLOW'	Pre-checks target: RFI (Rel. Fluor. reading) < RFImin
‘TM72‘	MATH_ERROR'	Plausib. checks QS: General calculation error
‘TM73‘		Reserved
‘TM74‘	'QS_INVALID'	Plausib. Checks QS: Plausibility QS failed
‘TM75‘	'MATH_ERROR'	Plausib. Checks target: General calculation error
‘TM76‘		Reserved
‘TM77‘		Reserved
‘TM78‘	'MATH_ERROR'	General error post quantification (Target/Control)
‘TM79‘		Reserved
‘TM80‘		Reserved
‘TM81‘	'NC_INVALID'	
‘TM82‘	'LPCINVALID'	
‘TM83‘	'MPCINVALID'	
‘TM84‘	'HPCINVALID'	

3.5 Comment Record

Comment Record		
ASTM	**Field Name**	**Remark**
11.1.1	**Record Type Id**	"C" Comment Record
11.1.2	**Sequence Number**	Defined by ASTM 6.6.7.
11.1.4	**Comment Text**	Only ASCII characters are supported, Maximal field length: 1000 characters Patient comment Test Order comment Result comment (Instrument test comment or instrument flag comment)

3.6 Message Terminator Record

Message Terminator Record		
ASTM	**Field Name**	**Remark**
13.1.1	**Record Type Id**	"L" (Message Terminator)
13.1.2	**Sequence Number**	Defined by ASTM 6.6.7. Always 1
13.1.3	**Termination Code**	N: Normal termination

3.7 Request Information Record (Query Record)

In the workflow 2 the request-information record is received by the AMPLILINK LIS interface from the host to determine the result subset.
If the filters are empty or filled with “ALL” (case insensitive), the host requests all available results.

Result Upload initiated by LIS Host (Query)

Request-Information Record		
ASTM	Field Name	Remark
12.1.1	**Record Type Id**	"Q" (Query)
12.1.2	**Sequence Number**	
12.1.3		
	^RackCarrierId	
	^PositionOnRackCarrier	
		not supported
	^RackCarrierType	
	^TubeContainerType	Filters for sample-order record
12.1.5	Test Id	Filter for test-order record
12.1.13	**Request Information Status**	Only request for final results are supported (must be set to "F")

4 Changes from AL 2.41 to AL 3.0.1

Transmission of Orders
- It is possible to send more than one patient order per message.
- The sample-order data in the AMPLILINK database is achieved by the triple: OrderId, SpecimenId and RequestedDateTime.

Transmission of Results
- Results (Field 10.1.4) are transmitted as:
  for Qualitative Tests: POS, NEG, GZ (**without the OD values**)
  for Quantitative Tests: as integer value
- Accepted results can be transmitted to the LIS as often as required.

5 Restrictions

- Quality Control orders are not received by AMPLILINK 3.0.1
- Quality Control results are not sent to LIS by AMPLILINK 3.0.1

6 Installation

The AMPLILINK LIS interface will be installed within the AMPLILINK setup.