AMPLILINK 3.2 Software Series

Host Interface Manual

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1. Preface

Document information

Revision History

Version	Revision Date	Revision info
1.0	October 2007	First officially released version
1.1	September 2008	- Added information on Use Specimen ID (Primary Barcode) as Sample Identity - Added information about Action Codes - Result value transmission details added - Added information in chapters *5.1.4.4 Result Record* and *5.2.1 Mapping of AMPLILINK Flags and LIS Abnormal Flag* - Chapter links corrected - New example *8.7.4 Manual Sample and Control result upload (two results)* - Chapter links corrected
1.2	October 2008	- Added information in chapter *4.2.7 Result format* including new chapters *4.2.7.1 Raw numeric format (float or integer value)*, *4.2.7.2 Formatted numeric format (identical to AMPLILINK result view)* and *4.2.7.3 Examples and exceptions* - Exceptional result value "-1" documented in chapter *4.2.7.3 Examples and exceptions*
1.3	December 2008	- Modified information in chapter *5.1.2.2 Test-Order Record*
1.4	February 2009	- Missing characters ">" and "<" added in table chapter *4.2.7.3 Examples and exceptions (Formatted numeric format, Result 10.1.4)*

Every effort has been made to ensure that all the information contained in the AMPLILINK 3.2 Software series Host Interface Manual is correct at the time of printing.
However, Roche Diagnostic Systems reserves the right to make any changes necessary without notice as part of ongoing product development and product life cycle.

Edition notice

The Data Station AMPLILINK runs the Microsoft Windows XP Professional operating system and AMPLILINK Software to control the operation of the connected COBAS instruments and analyzers.

The AMPLILINK software supports an interface (LIS Interface) to an external host or Laboratory Information System (LIS) for downloading orders and uploading test results.

This manual describes the behavior of date exchange between the AMPLILINK software version 3.2 series with a Laboratory Information System (LIS).

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

Some of the tests identified for use with the AMPLILINK software version 3.2 series may not be approved for use in all countries. Contact a Roche representative for tests that are commercially available in your country.

Intended use

This manual is for use with the AMPLILINK software version 3.2 series Laboratory Information System (LIS) in conjunction with the AMPLILINK Software Version 3.2 Series Application Manual and the instrument manuals for the COBAS® AmpliPrep Instrument, the COBAS® TaqMan® Analyzer, the COBAS® TaqMan® 48 Analyzer, and the COBAS® AMPLICOR Analyzer.

References

Referenced documents:

[1] Roche Diagnostics ASTM 2.0 Interface Specification (also called 'Roche ASTM+ standard')

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

[3] E 1381 – 95 Standard Specification for Low-Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems

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Instrument approvals

COBAS® TaqMan® Analyzer, COBAS® TaqMan® 48 Analyzer, and COBAS® AMPLICOR Analyzer meet the requirements laid down in IVD Directive 98/79/EC and the European Standard EN 591.

Furthermore, COBAS® TaqMan® Analyzer, COBAS® TaqMan® 48 Analyzer, and COBAS® AMPLICOR Analyzer are manufactured and tested according to the international standard IEC 61010-1 (EN 61010-1), IEC 61010-2-101 (EN 61010-2-101).

Compliance is demonstrated by the following marks:

CE Complies with the IVD directive 98/79/EC.

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Contact addresses

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How to use this manual

This manual is for use with the AMPLILINK software version 3.2 series Laboratory Information System (LIS) in conjunction with the AMPLILINK Software Version 3.2 Series Application Manual and the instrument manuals for the COBAS® AmpliPrep Instrument, the COBAS® TaqMan® Analyzer, the COBAS® TaqMan® 48 Analyzer, and the COBAS® AMPLICOR Analyzer

To help you to find information quickly, there is a table of contents at the beginning. In addition, a complete a glossary of terms can be found at the end.

This manual is organized to reflect the major functions supported by the AMPLILINK software and Data Station AMPLILINK in conjunction with a Laboratory Information System (LIS). It contains the following chapters.

Conventions used in this manual

Text conventions

To convey information readily and consistently, certain text conventions are used throughout this manual. These text conventions are as follows:

Text convention	**Used for**
Numbered lists	Procedures that should be implemented in order during an operation.
Italics	Designating another section of this manual or another manual that should be consulted
Bold	Designating that this is a required date or field

Symbols

Certain symbols are used throughout this manual to provide a ready visual reference. These symbols are as follows:

Symbol	Used for
	Note. Designates a note that provides additional information concerning the current topic or procedure.
	Caution. Indicates a possible hazardous situation that, if not avoided, may result in personal injury and/or in damage to the system.
	Warning. Indicates a possible hazardous situation that, if not avoided, may result in death or serious injury.
	Warning Potential Biohazard Material. Indicates possible biohazard material. Universal safety precautions should be taken when handling and processing samples.

Graphics

All graphics including screens and printouts are for illustration purposes only and may deviate from your system.

Units

The following measurement abbreviations are used:

Unit	Explanation
cm	Centimeters
C/mL	Copies per milliliter
Hz	Hertz
in	Inches
IU	International Units
kg	Kilogram
lb	Pounds (weight)
mL	milliliters (10^-3 liters)

Safety

This chapter provides general safety information. Specific safety information are provided in the manual where required. For specific safety information see also the AMPLILINK Software and Instrument Manuals as well as the assay-specific package inserts and Method Manuals.

Software virus warning

Data loss or unavailability of the system due to software viruses which may put patients at risk

The data station for AMPLILINK software does not contain anti-virus protection software. Therefore, it is essential to follow these recommendations:

- Check all diskettes, CDs, or DVDs with an anti-virus program (on another PC) to ensure that they are virus free, before using them on the data station for AMPLILINK software.
- Do not load and execute any other software on the system.
- Keep all diskettes in a secure place so that they can only be accessed by authorized personnel.
- Use the remote services modem for contacting Roche Service or for authorized usage only.
- Make sure other computers on the AMPLILINK software network (e.g. the LIS) are properly secured and protected from viruses.
- Use of cobas IT firewall strongly recommended.

Windows display settings warning

Improper viewing of AMPLILINK software screen
The Roche field service engineer loads the AMPLILINK software and enters default configuration settings during system installation.

Do not change the Windows display setting. “Windows Classic style” and “Auto-hide the taskbar” must be selected for proper viewing of AMPLILINK software screens

2. Key Features and changes

This chapter lists the main differences between the different AMPLILINK Software LIS Interfaces. More details can be found in the following chapters.

2.1 General

What	AMPLILINK Software, Version		
	2.41 2.42	3.1 series	3.2 series
Default settings in the Trace Viewer shows all the detailed information needed for an investigation by GSS (see also chapter *7.2.6 Setup Tracer*)	-	-	X
Communication to LIS: Timeout after send failure for reconnection (only if Low Level protocol is used. Mandatory for RS232, not needed for LAN)	250ms	>1000ms	250ms
Every Test Definition File (LIS Test ID) has to be configured (entered) to match the ID used on the LIS. For more details see also *7.2.5.6 Configuring the Test Definitions*	-	X	X
The AMPLILINK Software has to be started in order to have a communication with the LIS	X	-	-
The AMPLILINK Monitor has to be started in order to have a communication with the LIS (AMPLILINK Monitor starts automatically with the Operating System but can be shut down by the operator)		X	X

2.2 Order Download

What	AMPLILINK Software, Version		
	2.41 2.42	3.1 series	3.2 series
More than one patient order can be sent per message	-	X	X
Mandatory Order data needed by the AMPLILINK Software (see below, AMPLILINK 3 Software configurable to calculate OrderID from SpecimenID and vice versa)	OrderID - RequestedDateTime TestID	OrderID SpecimenID RequestedDateTime TestID	OrderID SpecimenID RequestedDateTime TestID
AMPLILINK Software calculates OrderID from SpecimenID if RequestedDateTime empty	X	-	-
AMPLILINK Software configurable to calculate OrderID and/or SpecimenID. *See 7.2.4.1 Handling of empty ID's by order download*	-	X	X
Automatic Rack Assignment *(7.2.4.3 Automatic Rack Assignment)*	-	-	X
Automatic Control Ordering (when using Automatic Rack Assignment feature) *(7.2.4.4 Automatic Control Ordering)*		-	X
More than one Test including Internal Controls for one A-Ring Position (e.g. CT/NG)	X	-	Not directly possible! *See7.2.4.3 Automatic Rack Assignment*
The same TestID can only be ordered once for the same OrderID/SpecimenID as long as long as the OrderID/SpecimenID exists in the AMPLILINK Database	-	X	X

2.3 Result Upload

What	AMPLILINK Software, Version		
	2.41 2.42	3.1 series	3.2 series
Quality Control results can be sent	-	X	X
AMPLILINK Software configurable to send result with status 'failed'		X	X
Accepted results can be (re-)transmitted to the LIS as often as required	X	X	X
AMPLILINK Software configurable to send results value as displayed in the AMPLILINK Software or as float/integer value to the LIS. (Exception results from COBAS AMPLICOR and text results (i.e. "Invalid", "Failed"), see also below. See *4.2.7 Result format* and *7.2.3.7 Result Format (Format of Result value)* for more details. See also Application Manual, AMPLILINK Software, Version 3.2 Series (Result calculation)	-	-	X
Results Transmission for COBAS AMPLICOR qualitative Results with no titer: "POS^", "NEG^"	X	-	-
Results Transmission for COBAS AMPLICOR qualitative Results with no titer: "POS^*.***", "NEG^*.***"	-	-	X
Results Transmission for COBAS AMPLICOR quantitative Results with no titer (display in AL "*.**E*") : (empty field)	X	-	-
Results Transmission for COBAS AMPLICOR quantitative Results with no titer: "*.**E*"	-	-	X
Results Transmission for COBAS TaqMan and TaqMan 48 Results with no target detected: "TARGET NOT DETECTED"	-	X	X
Results Transmission for COBAS TaqMan and TaqMan 48 Results with no titer calculated: "Invalid" or "INVALID"	-	X	-
Results Transmission for COBAS TaqMan and TaqMan 48 Results with no titer calculated: "Invalid"	-	-	X
Results Transmission for COBAS AmpliPrep Results with processing failure: "Failed"	-	X	X

For more information on result cases with the COBAS AmpliPrep Instrument, COBAS AMPLICOR, TaqMan or TaqMan 48 Analyzer please see *Application Manual for AMPLILINK 3.2 Software series (Result calculation)*.

2.4 Restrictions

This chapter lists important configuration restrictions

- Control Orders can not be downloaded from the LIS.

Result Flags displayed in AMPLILINK can not be transmitted to the LIS (all the Detail Flags are transmitted but not the collected Flag) .The ASTM 'Abnormal Flag as well as the Instrument Flag (if any available) indicates the validity of a result and must be captured by the LIS for result interpretation.

- Flagged Results:
  Be aware that flagged results can have a numeric (titer) value.

Valid results can have flags. Some flags indicate that a result has to be repeated. See package insert and/or method manual for the specific test and/or Application Manual for AMPLILINK 3.2 Software series.

For possible result cases with the COBAS AmpliPrep Instrument, COBAS AMPLICOR, TaqMan or TaqMan 48 Analyzer please see Application Manual for AMPLILINK 3.2 Software series (Result calculation).

- When the Automatic Rack Assignment is used, the Control rule setting in TDF is not checked. Set the assignment of controls in the Automatic Rack Assignment.

- When using the Automatic Rack Assignment feature for a test, this test can no longer be ordered without Rack and Position information

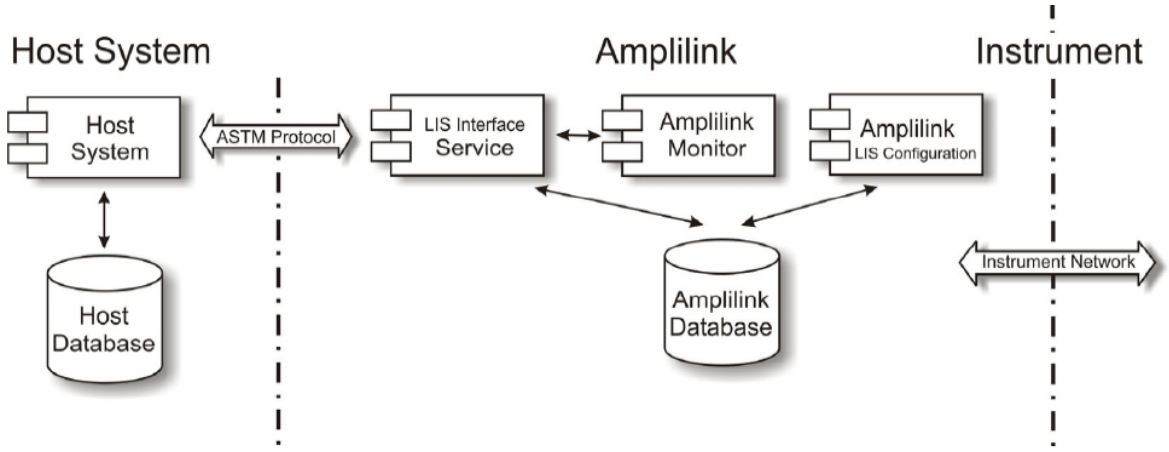
To learn more about rules and restrictions with the Automatic Rack Assignment, please have a look to the chapter *4.1.4 Automatic Rack Assignment.*

3. System overview

To understand the details of the AMPLILINK LIS interface it is important to know the functionality of the LIS interface service between the AMPLILINK system and the Laboratory Information System.

AMPLILINK interacts with the instruments over the Instrument Network (Instrument LAN), commonly an Ethernet LAN. Separated from the Instrument Network the LIS Interface service communicates with the host system via a serial communication (RS232 interface) or the Laboratory Network (Laboratory LAN)

The Data Station AMPLILINK is equipped with two Network Cards.
Use the Laboratory LAN for the LIS connection. It is disabled by default. If a LIS connection via LAN has to be configured, enable the Laboratory LAN and change the Properties settings according to your needs. See also chapter 7 Configuration.



This is a System overview with the laboratory instrument on the right side, the AMPLILINK System with the LIS interface components in the middle and, on the left side, a host system connected by a communication based on the ASTM+ protocol.

The LIS interface consists of the two components LIS Interface service and LIS Configuration in the AMPLILINK Software. The LIS Interface service has direct access to the AMPLILINK database. The interaction and data exchange between AMPLILINK and the LIS Interface service run via the AMPLILINK database.

The AMPLILINK Monitor visualizes the states of the three AMPLILINK Services: Database Service, Maintenance Service and LIS Interface service. See chapter *3.2 AMPLILINK Monitor* for more details.

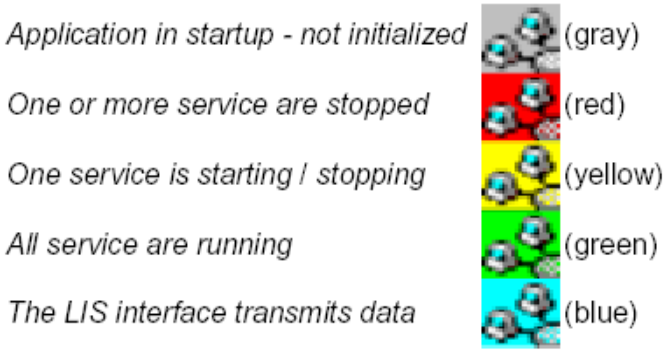
3.1 LIS Interface configuration

The LIS Interface service works according to operator configurable settings. In the AMPLILINK software in tab Configuration / Lab Definitions there is the function LIS Interface, which allows the operator to change the settings in order to adapt the LIS Interface service to the requirements of the host system and also of the laboratory workflows.
See chapter *7.2 Configuration of the LIS Interface in the AMPLILINK Software* for further information about the LIS configuration.

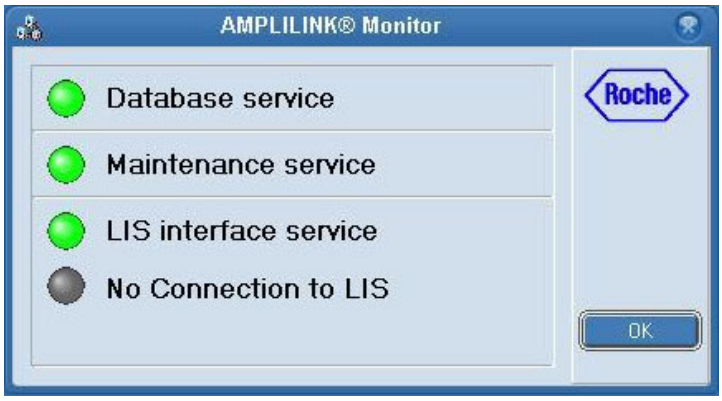
3.2 AMPLILINK Monitor

The AMPLILINK Monitor is implemented as tray icon application. The AMPLILINK Monitor can be found as a small icon in the windows system task bar on the right bottom edge of the screen.
(If the Monitor has been closed by right click, Exit, it is recommended to restart the Monitor by a restart of the Data Station AMPLILINK and not via the Start, Program selection.)

The following figure shows all possible service process states:



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

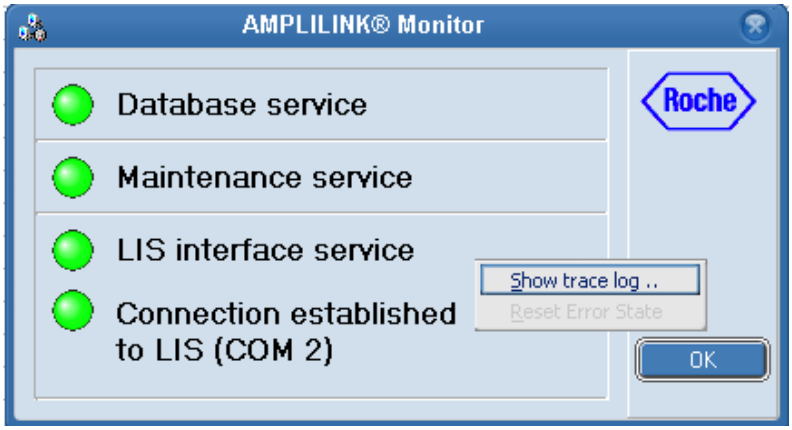


The two top lines show the windows service state of the Database and the Maintenance Service. The third line shows the state of the LIS Interface Service. The bottom line shows the current connection state to the LIS and error states.

3.3 LIS Interface service trace log

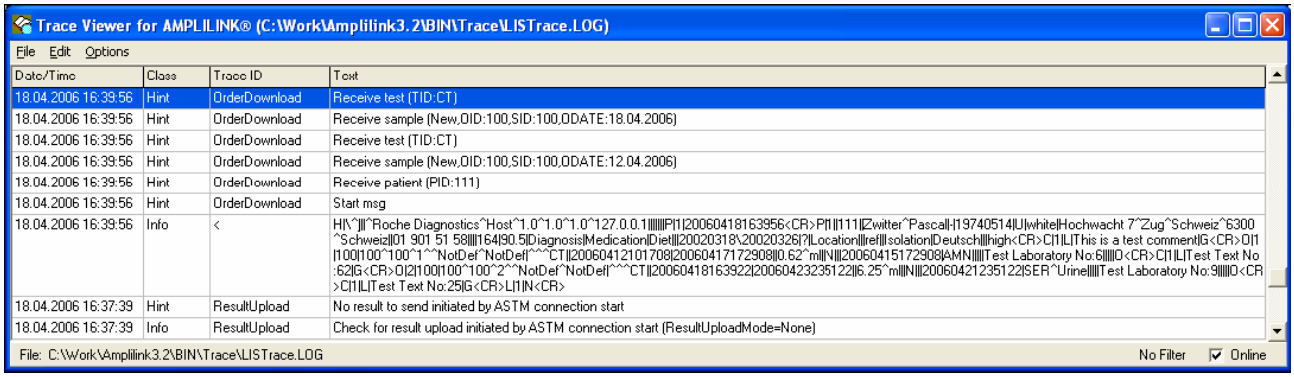
To track the interface process the LIS Interface Service writes all its activities in a log file.

Depending on the LIS configuration for the Setup Tracer, there will be more or less detailed activity messages written in the LISTrace.log file (see also chapter *7.2.6 Setup Tracer)*
In the AMPLILINK Monitor do a right mouse click on the LIS Service interface area to get a popup menu which allows the displaying of the LIS trace log window.



3.3.1 Trace Log

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



There are different classifications in the log entries:

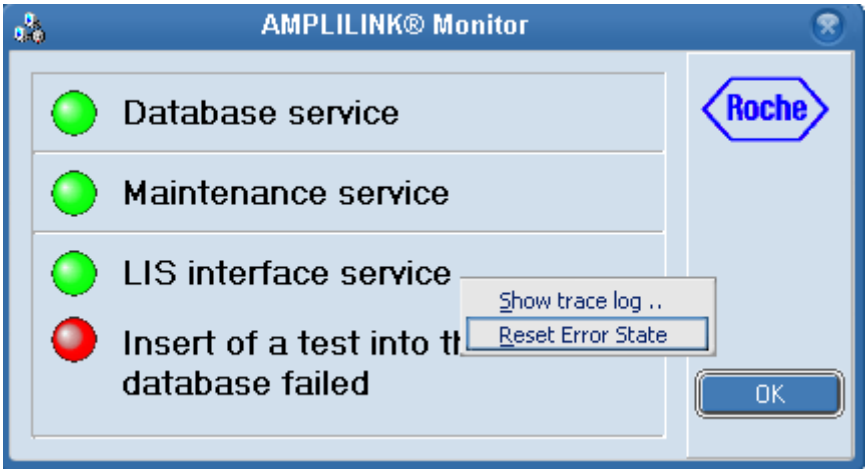
Hint:	Informs about a successful run of a sub process step in the LIS Service process.
Info:	Informs about a successful run of a process step in the LIS Service.
Warn:	Warning about a failed process step in the LIS Service. The failure was expected and doesn't have an influence to the next process steps.
Error:	A process has failed and the concerning order download or result upload was properly aborted. (It is recommended to restart the Data Station AMPLILINK)
FATAL:	There was a fatal exception occurred. A restart of the LIS Service process is recommended. (It is recommended to restart the Data Station AMPLILINK)

For better understanding of the trace view, the log entries have additional information in the trace viewer column Trace ID. These Trace IDs are grouped into the following sources:

- > (OutMsg): Transmitted message to *LIS.*
- < (InMsg): Received message from *LIS.*
- NTService: LIS Service handling, start and stop of the service
- OrderDownload: Information about the Order Download process
- ResultUpload: Information about the Result Upload process
- ResultQuery: Information about the Result Query process
- AL Monitor: Information about the communication between LIS Service and AMPLILINK
- ASTM Connection: Information about the establishing of a connection to the Host
- ASTM CAL: Internal information from the ASTM communication component CAL
- EXCEPTION: Information about not expected exception

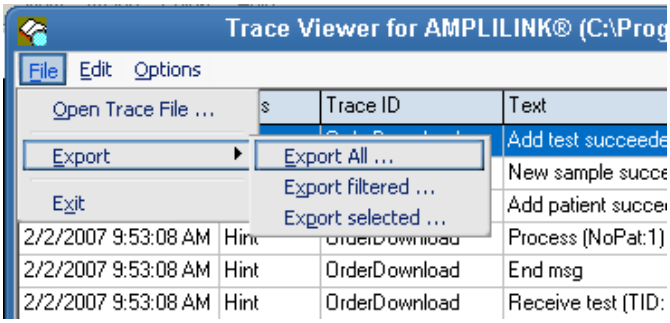
3.3.2 Reset Error State

The function Reset Error State resets the error state information in the LIS Interface service status display.



3.3.3 Export the Trace Log file

The following screen shows how the Trace Log file can be exported.



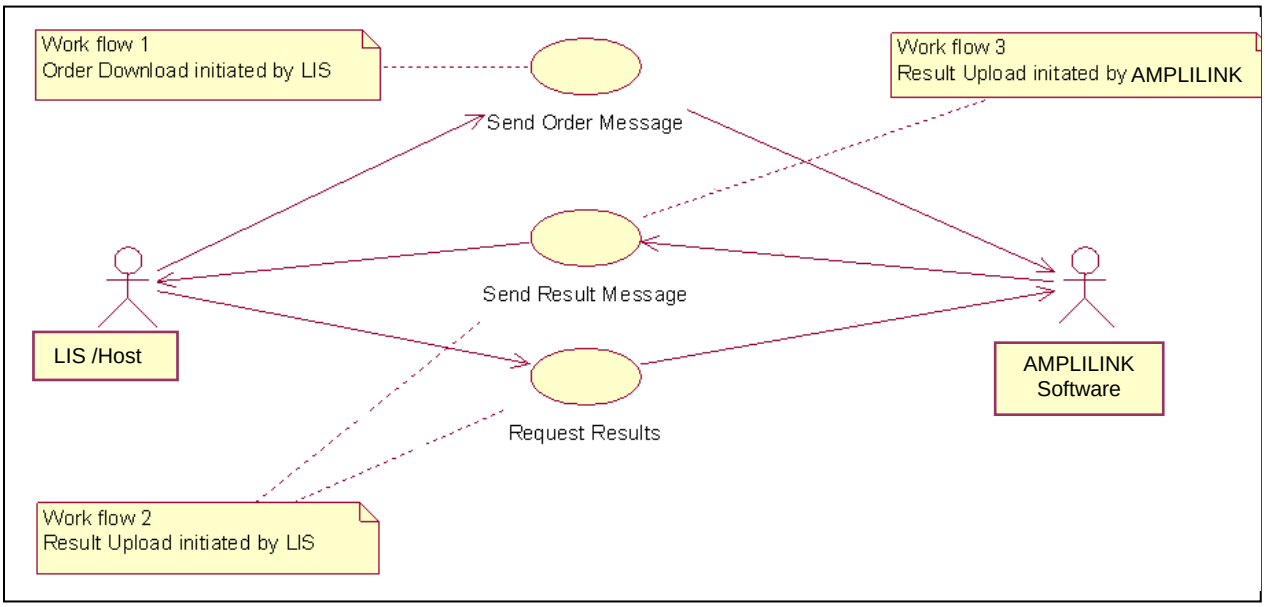
The Trace Log is part of the Problem Report.

4. Supported Work Flows

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

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

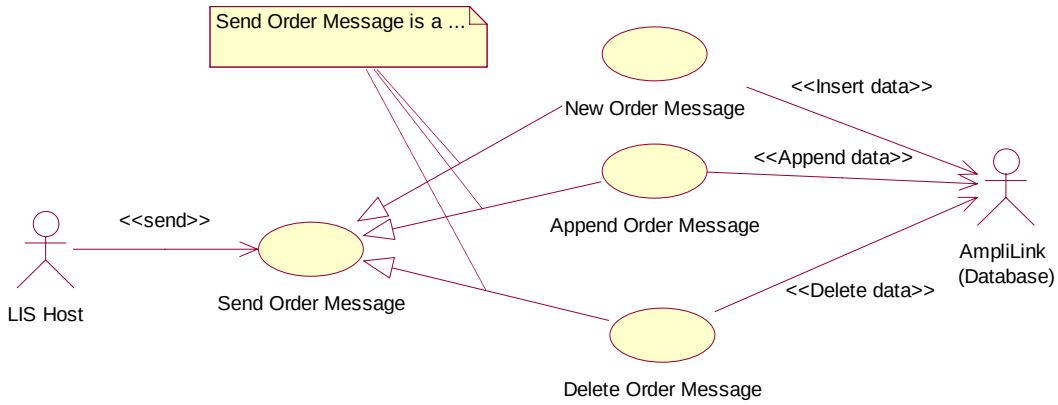
The following diagram shows all possible workflows (workflow 1, 2 and 3)



4.1 Workflow 1: Order Download initiated by the LIS (Host)

Orders can either be entered manually in the AMPLILINK Software or be sent by the LIS (Host).

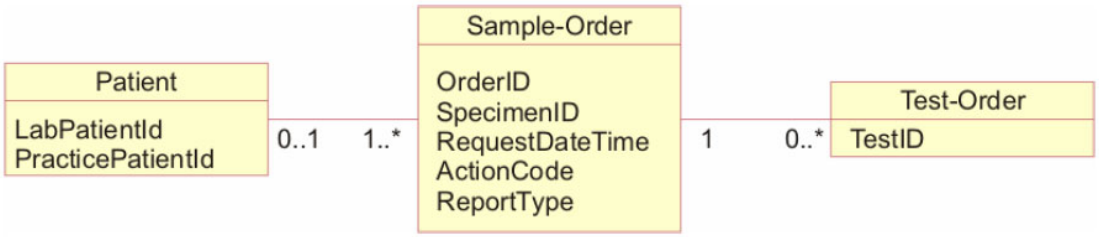
The three functions New, Add (Append) and Delete of orders are implemented according to the specification of ASTM+[1].



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

4.1.1 Data structure of an Order

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



Notation and data structure of the LIS host (ASTM specification) and the dependencies between patient data, order data, sample-order data and test order data. Notice that in this diagram only the key fields are displayed. For more information about all fields see chapter *4.1.1.1 Patient Data.*

Means:

- One or more Sample-Order data can link to one or none patient data
- One or more test-order data can link to one Sample-Order
  ⇨ But the same test can only be ordered once for one Sample-Order data

An automatic ordering of Quality Control samples is only supported indirectly (means AMPLILINK can automatically assign Quality Controls to a Sample Rack/ K-carrier or A-ring order see chapters *4.1.5.1 Automatic Control Ordering and 4.1.4 Automatic Rack Assignment)*

4.1.1.1. Patient Data

If the host has no patient data for an order, the patient data, respectively its key value, can be empty. The key value (unique identification) of the patient data is configurable either as the LabPatientId (ASTM Field 8.1.4) or as the PracticePatientId (ASTM Field 8.1.3) *(*see chapter *7.2.5.1 Patient ID for Patient Data)* .For more details about the patient data see chapter *4.1.1.1 Patient Data.*

4.1.1.2. 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: Instrument Specimen ID: Order ID), **SpecimenID** (ASTM Field 9.4.3) and the **date part** of the field **RequestedDateTime** (ASTM Field 9.4.7: Requested Date and Time).
Therefore only one sample-order can exist with the same OrderID and SpecimenID at once with the requested date.
If the RequestedDateTime is empty, the LIS Interfaces always takes the current date and time of the order download.
If any of this information is not sent by the LIS, consider the feature *'Handling of empty ID's by order download in the LIS Interface Settings 7.2.4.1:*

In chapter *5.1.2.2 Test-Order Record* you find the details of the Sample-Order Download Record.

4.1.1.3. Test-Order Data

The TestID (ASTM Field 9.4.5: Universal Test ID: Test ID) must be available so that it is practicable on the corresponding system. Therefore the TestID ordered from the LIS must be a known 'test-code' in the AMPLILINK database. These settings are done in the fields shown in *7.2.5.6 Configuring the Test Definitions.*
For details concerning the Test-Order Record see chapter *5.1.2.2 Test-Order Record*.

Abstract message format
According to the specification of ASTM+ the host can send messages of the following EBNF[2]:

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
```

See chapter *8.1 Order Formats* for an example.

The operation mode New, Add or Delete can be applied for each sample-order data.
Patient data can only be inserted or updated but not deleted by the host.
The AMPLILINK database maintenance service deletes unused patient data after a configurable amount of days. See Service Manual of AMPLILINK 3.2 Software series for default settings and ranges.

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

4.1.2 Action Codes

Overview on the Action Codes:

An Action Code has to be sent with each Sample Order. The possible codes are N for new orders, A for appending an Order or C to delete an Order.

	N = New	A = Append	C = Delete
Creates a new order if order does not yet exist	X	X	
Overwrite existing incomplete orders	X		
Appends orders to an existing order		X	
Deletes an parts of an order or whole orders in status incomplete			X
Automatic Rack Assignment: create a new rack	X		
Automatic Rack Assignment: add order to rack		X	
Automatic Rack Assignment: Delete orders that were created using the Automatic Rack Assignment feature			X

4.1.2.1. 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 previously ordered for this sample order.

All fields of an incomplete sample-order will be overwritten if the sample-order exists.
See chapter *8.2.1 Overwriting existing incomplete orders* for an example.

If any of these earlier orders are not marked with the status  incomplete, the function terminates with an error and returns this New Order Message to the host.
The ReportType (ASTM Field 9.4.26) will then show 'X' for neg. acknowledge during ordering.
See chapter *8.2.2 Refuse to overwrite an existing order which is not in the status incomplete* for an example.

Order status

Patient sample orders, in the Sample tab, and control orders, in the Quality Control tab are preceded by an icon to indicate their status.

Icon	Definition	Description
	Incomplete	The order is incomplete or has not yet been assigned to a rack or a batch.
no icon	Ready	The order is complete.
	Started	The order is in process.
	Running	The order is running on a COBAS® instrument.
	Prepared	The sample has been successfully prepared on the COBAS® AmpliPrep instrument.
	Blocked	The order is blocked at a COBAS® instrument.
	Failed	The order failed processing.
	Done	The order is finished.

Table A-52 Order status

Source: *Application Manual for AMPLILINK 3.2 Software series*.

4.1.2.2. Add an 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 service creates this order in the same manner as with the ActionCode N, New... 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 for the same sample-order. If the same test is ordered twice, nothing happens unless 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. The ReportType (ASTM Field 9.4.26) will then show 'X' for neg. acknowledge during ordering.
See chapter *8.3 Order Record: Action Code Append* for an example.

4.1.2.3. Delete an 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 deletion 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 must be true.

1. The test order must not be in process.
2. The test order was never assigned to a sample rack.
3. The test order 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.
4. The test order must be previously ordered 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 test orders and its results according to customizable settings see *Application Manual for AMPLILINK 3.2 Software series*.

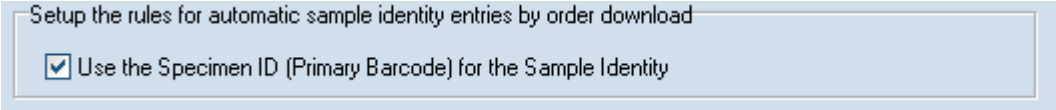
At the end of the deletion of test-orders the LIS interface service checks, if there are still test-orders linked to the given sample-order. In case of an empty test-order list the sample-order will be subsequently deleted. The patient data will not be deleted by the LIS Interface service but by the Database Maintenance service.

Furthermore the LIS interface service 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 all conditions mentioned above allow the deletion of every single test-order.

4.1.3 Sample-Order Identification

AMPLILINK has an own reservation system for the usage of primary barcodes, the position of a container (e.g. a tube) in a carrier (e.g. a rack). Normally the entries in this reservation system are done automatically by ordering in the AMPLILINK Software.
With the default settings in AMPLILINK LIS Service 'Use the Specimen ID (Primary Barcode) as the Sample Identity' unticked, the rules that exist for ordering in the AMPLILINK Software are not checked.
This means that the hierarchy of the Identification of a Sample (Order Number and Sample ID) is not checked. This means that without the setting a Sample ID can be linked to different Order Numbers and vice versa.



If the 'Use the Specimen ID (Primary Barcode) for the Sample Identity is checked, a Sample ID (Primary Barcode) can only be linked to one Order Number (linked to a day and time). This means that the linking of Sample ID and Order Number is treated, as if ordering in AMPLILINK Software. See also chapter *7.2.4.2 Rules for linking of the Sample ID.*

4.1.4 Automatic Rack Assignment

In the LIS Interface Settings of AMPLILINK version 3.2 a new optional feature was introduced which allows for certain workflows the creation of racks and the assignment of Sample-Orders to a rack during the order download. For this purpose the RackCarrierID (ASTM Field 9.4.4) and the PositionOnRackCarrier will be used.
Because the LIS Interface service of AMPLILINK version 3.2 does not support the downloading of lot specific calibration parameters (Coefficient A, B and C) this function is only for test types available which do not need these calibration parameters by manual entering.
Because the ASTM Standard supports only Sample-Order oriented ordering but not batch (rack) oriented the LIS Interface Service has to check by receiving of each Sample-Order if the rack exists already or if the rack shall be created. Afterwards the downloaded Sample-Order will be linked (assigned) to this rack.
Depending on the workflow there can be a need for more than one rack assignment for preparation, amplification and detection steps. But the LIS Interface service handles only one rack assignment. This is the rack assignment of the first (input) step. Further steps in the workflow involve an operator interaction with AMPLILINK for a second rack assignment. The following list shows all workflows which support the 'Automatic Rack Assignment' function. Additionally for each workflow the expected RackCarrierType und ContainerTubeType (ASTM Field 9.4.4) of the input rack are listed.

The naming of the Input Rack Type and the Tube Type have to fit with the settings in AMPLILINK, **Configuration Tab, Laboratory, Rack / Tube definitions**.

Description	Input Rack Type	Tube Type
CAP - COBAS TaqMan48 TNAI ASR Test	SampleRack	STube
CAP - COBAS TaqMan48 TNAI Utility Channel Test	SampleRack	STube
CAP - COBAS TaqMan48 TNAI IVD	SampleRack	STube
CAP - COBAS TaqMan48 TNAI ASR Test	SampleRack	STube
CAP - COBAS TaqMan48 Utility Channel Test	SampleRack	STube
CAP - COBAS TaqMan96 undocked IVD	SampleRack	STube
CAP - COBAS TaqMan96 docked IVD	SampleRack	STube
CAP - COBAS TaqMan96 Utility Channel Test	SampleRack	STube
CAP - COBAS AMPLICOR Quantitative	SampleRack	STube
CAP - offline TNAI Test	SampleRack	STube
Manual Prep. - COBAS TaqMan48 Utility Channel Test	KCarrier	KTube
Manual Prep. - COBAS TaqMan96 Utility Channel Test	SampleRack	KTube
Manual Prep. - COBAS AMPLICOR Quantitative	ARing	ATube

CAP – COBAS AmpliPrep Instrument

Note: During **manual ordering** of the workflows COBAS AmpliPrep – COBAS TaqMan docked and undocked the AMPLILINK **checks configurable control rules** which ensure that controls must be always ordered (Configurable under Test definition Icon, Control Rules). **By ordering whole Racks with LIS Interface service these control rules will not be tested**. The operator can either add controls manually on a LIS created rack or use fixed rack positions for control levels and have them automatically assigned using the Automatic Control Ordering in the Automatic Rack Assignment Feature, see chapter *7.2.4.4 Automatic Control Ordering*.

Additionally to the restriction of the test type the following conditions must be fulfilled for automatic rack creation and assignment:

- The automatic rack assignment (and creation) function must be enabled in general and for the ordered test individually (see chapter *7.2.4.3 Automatic Rack Assignment*)
- **A new rack will be created only by achievement of the New Order function (ActionCode 'N')** and in case the rack with the requested RackCarrierID and the requested RackCarrierType does not exists before
- •By achievement of the Add Order function (ActionCode 'A') received Sample-Orders will only be assigned to an existing rack. The rack assignment will be done regardless if the rack was created by LIS or by an operator in the AMPLILINK order view
- The LIS Interfaces checks the validity of the RackCarrierType and ContainerTubeType (ASTM Field 9.4.4). For this purpose see the columns input rack type and tube type in the table on the last page. Wrong or empty type strings causes in case of enabled automatic rack assignment a rejection of the Sample-Order.
- •Beside the check of the rack and tube type also the range of the PositionOnRackCarrier and the RackCarrierID (ASTM Field 9.4.4) will be tested. For Sample racks a value between 1 and 24 will be expected in PositionOnRackCarrier. For K-Carrier racks this range is 1 to 24 and for A-Ring racks this range is 1 to 12. For Sample and K-Carrier racks the range of RackCarrierID is 1 to 999. For A-Ring racks this range is 1 to 999999.
- Of course each position on a rack can be assigned only to one Sample-Order. Every Sample-Order, which should be assigned to an already used position, will be rejected
- The **same Sample ID can be assigned to only one rack**. That is why in AMPLILINK 3.2 Software series it is not possible to order more than one test on different racks for the same Sample-Order AMPLILINK's database structure does not allow the reusing of the same SpecimenID (SampleID) on one distinct order. In such case for AMPLILINK the LIS has to split the primary Sample-Order in several artificial Sample-Orders
- For Sample and K-Carrier racks the LIS Interface service checks that only one Test-Order can be assigned to a Sample-Order. A second Test-Order will be rejected.
- For COBAS AMPLICOR workflow which bases on A-Rings, up to six Test-Orders can be assigned to the same A-Ring Position. For tests which are declared as internal control (e.g. CNC) these Test-Orders can be ordered not as first Test-Order but only as second or subsequent Test-Order of a Sample-Order.

An order can not be assigned to a Sample Rack that is loaded on the COBAS AmpliPrep Instrument and not to a Sample Rack that contains processed samples.

Note: If an order message is rejected due to an issue in the Rack Assignment information, the whole sample is rejected and not only the assignment to the rack.

Examples for Automatic Rack Assignment can be found in chapter *8.6 Automatic Rack Assignment*

4.1.5 Automatic rack deletion

After deleting the last Sample-Order of a rack by LIS (using a message with ActionCode 'C') the rack will be deleted if the rack was created by the LIS Interface service during automatic rack creation.

4.1.5.1. Automatic Control Ordering

If the option 'Automatic Rack Assignment' is used an optional automatic control ordering is available with AMPLILINK version 3.2. for certain workflows. This function concerns a subset of workflows which supports the 'Automatic Rack Creation and Assignment' and which does not need manual entering of control parameters. Control parameters are the control range low and high, the lot ID and expiration date of a lot.
If the Automatic Control Ordering in the Automatic Rack Assignment feature is configured in the AMPLILINK Software, the predefined set of controls will be assigned to the rack, when a rack order is sent by the LIS. The following control types are supported: Low Positive Control (LPC), High Positive Control (HPC) and Negative Control (NC). Each predefined Control-Order will be placed on the configured positions in the rack. For this purpose in the LIS Configuration for automatic control ordering for each test a different set of controls can be configured (see chapter *7.2.4.4 Automatic Control Ordering)*.
The following list shows all workflows which support the automatic control ordering after rack creation:

Description	Control types
Ampliprep - TM48 IVD	NC, LPC, HPC
Ampliprep - TM96 docked IVD	NC, LPC, HPC
Ampliprep - TM96 undocked IVD	NC, LPC, HPC

Additionally to the restriction in the automatic rack creation the following conditions must be fulfilled for automatic control ordering:

- The automatic control ordering function must be configured for the ordered test (see chapter *7.2.4.4 Automatic Control Ordering)*
- The position of the Control-Orders can not be used by Sample-Orders at the same time. A Control-Order which should be assigned to an already used position will be rejected.

4.1.5.2. Deletion of controls

Control Orders created by the feature 'Automatic Control Ordering' will be deleted automatically by the LIS Interface Service when the last Sample-Order of the rack was deleted by the corresponding message from the LIS with ActionCode 'C'.
By manual deletion of the last Sample-Order inside the AMPLILINK's order view the automatic created Control-Orders will not be deleted automatically.

4.1.6 Error handling of Order Download (negative acknowledge)

According to the ASTM+ specification the LIS Interface Service returns the received message in cases of errors during the order download task to AMPLILINK. Herewith the LIS is informed that a certain order 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 FAILED (character X).

If an order string is not well defined (the field ActionCode (ASTM Field 9.4.12) does not contain a valid code) the LIS Interface service returns an empty message (blank error message) with the termination code "E" to the LIS.

The ASTM+ standard does not offer to append a detailed error message to the returned message to the LIS. For detailed analysis, in cases of error, the log file (the LIS Trace Log) of the LIS Interface service contains information to understand the error cause.
In the LIS Trace Log of the AMPLILINK Monitor the history of positive and negative (error) conditions of the LIS Interface service can be seen (LIS Trace Log see chapter *3.3.1 Trace Log*)

The following table shows error causes during the order download process with the corresponding behavior of the LIS Interface service:

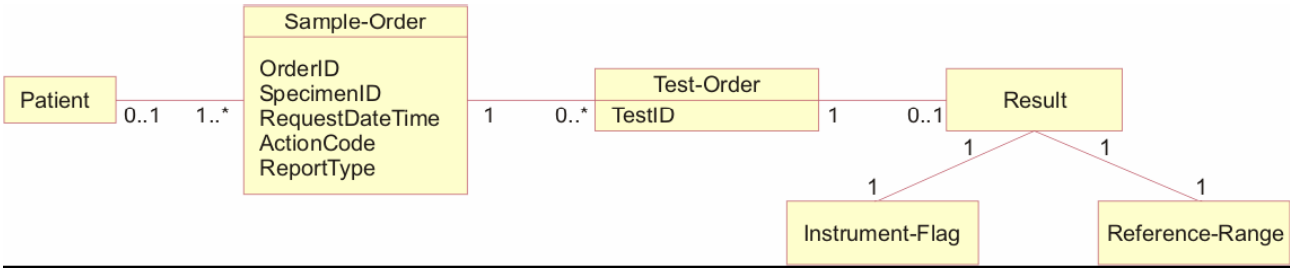
Operation	Error cause	Exception handling
All Operation (New , Append or Delete)	A patient with the same ID already exists in the AMPLILINK database	• The patient data will be overwritten by the newer patient data of the order download message
	Ordering of a patient in the AMPLILINK database failed	• 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)	• Return a blank error message to the host • Ignore the received message
	Internal software error	• Ignore the received message
New or Append Operation	The sample order previously 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 AMPLILINK database	• The order download message will be returned to the host with the failed accessory test orders only • The ordering of the remaining test orders 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 previously 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 for clearing does not exist	• The clearing operation will be ignored
	Clearing of a sample order in the AMPLILINK database failed	• The order download message will not be returned • The clearing of the test orders will be processed
	Clearing 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 clearing does not exist	• The clearing operation will be ignored
	Clearing of an order in the AMPLILINK database failed	• The order download message will not be returned • The clearing of the test orders will be processed
	Clearing of one test order in the AMPLILINK database failed (because this test has already been processed)	• The order download message will be returned

4.2 Workflows: Result Upload

Within the workflow 2 and 3 the LIS interface service sends results from the instrument to the host.

4.2.1 Data structure of a Result

To understand the details of the result upload workflow 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. For more information about all fields see chapter *4.2.8 Workflow 2: Result Upload initiated by LIS Host.*

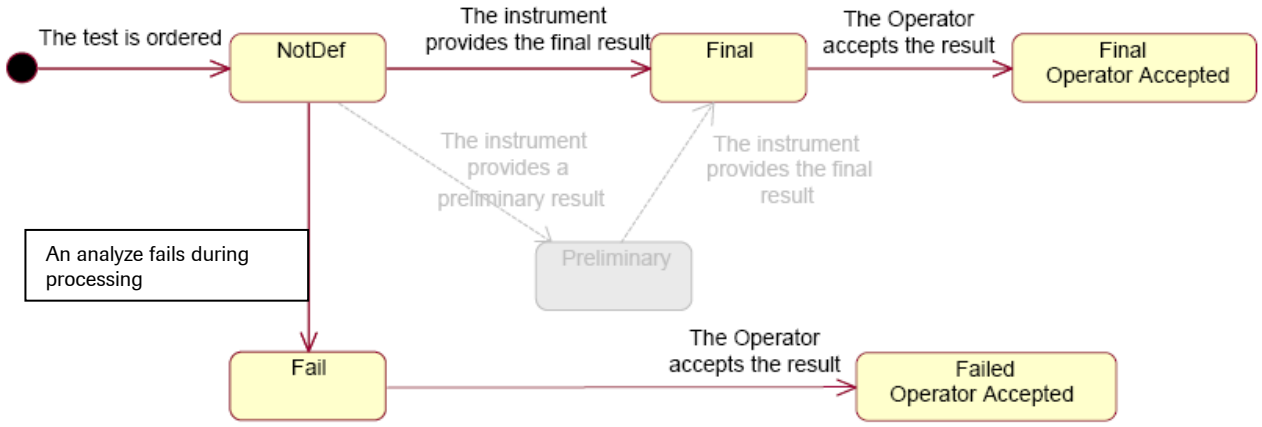
Every distinct test-order gets a linked result data when an analysis has finished.
In opposite to the order download, where the same Test can be linked only once to the same sample-order, for the result upload the same Test can be linked more than once to one sample-order. This is a consequence because the AMPLILINK Software allows to manually ordering the same test multiple to one sample-order.

4.2.2 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. This state is for future use and not yet implemented.)
- FinalResult: The instrument has completed the measurement and the result is available.
- Operator Accepted: Final Result that has been accepted by an operator

The figure on the next page shows the AMPLILINK result states and the transition between them.



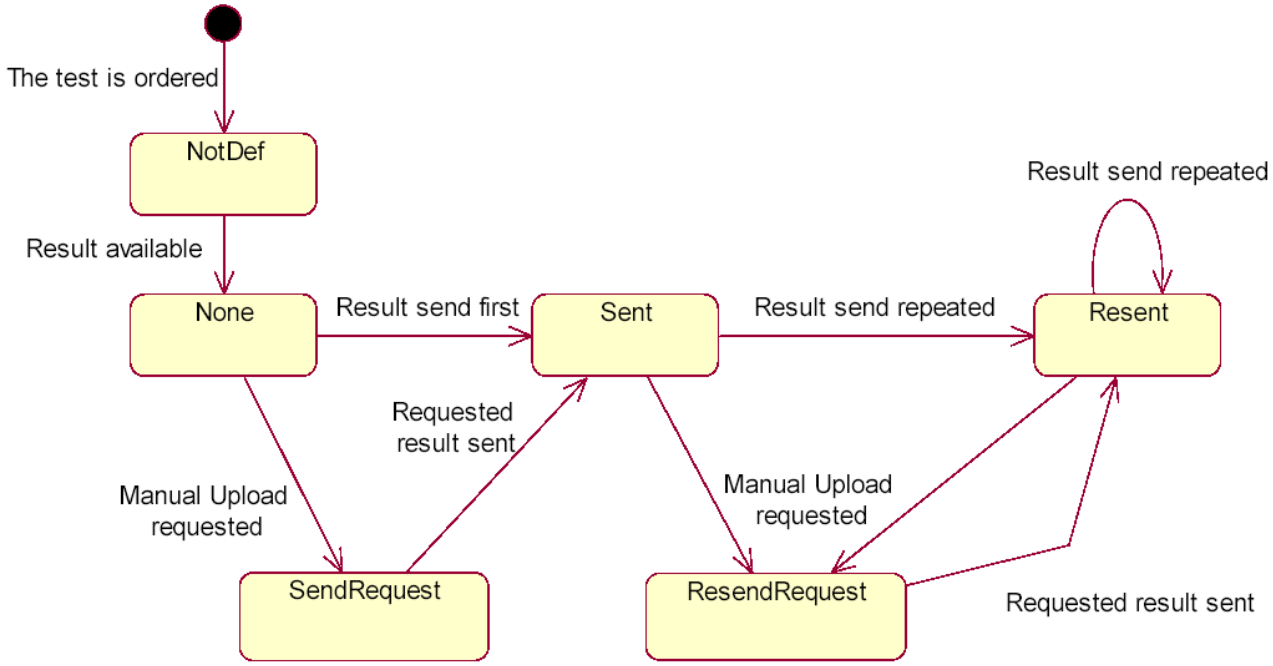
The State/Event diagram of the AMPLILINK Result State

4.2.3 LIS Interface Service Transmission Status

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

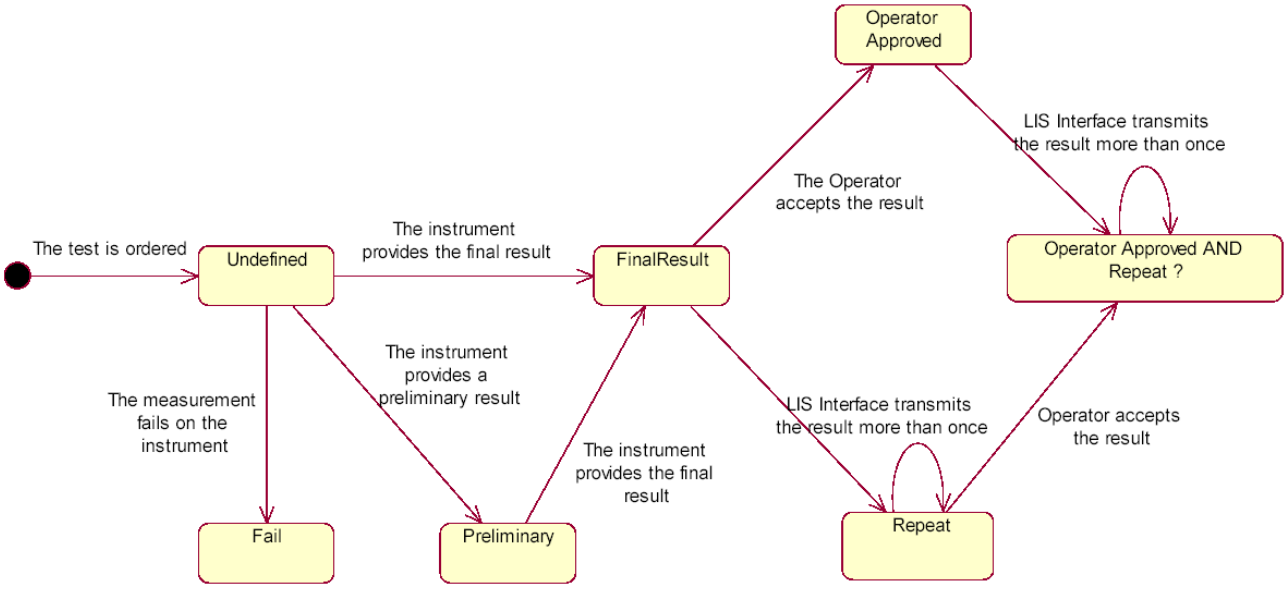
- None*:* The result is not yet transmitted to host.
- SendRequest*:* The result should be transmitted by workflow 3
- Sent: The result is transmitted once.
- ResendRequest*:* The result should be transmitted by workflow 3 for an additional time.
- Resent: The result is transmitted more than once.

The following figure shows the LIS transmission states and the transmission between them.



4.2.4 Result Status of the ASTM +Standard

The ASTM+ Standard does not distinguish between the two kinds of status (LIS Transmission status and AMPLILINK result status) and collects both states together to its result state (ASTM Field 10.1.9).
The following figures show the collected result state which the LIS Interface service internally prepares according to the LIS Interface settings.



The AMPLILINK result status is the important information for a result than the LIS transmission state. Therefore for invalid or failed results the state **Fail will be transmitted independent if the operator has approved the result or if the result was sent more than once**.

The ASTM+ Standard does not support the final state Operator Accepted and Repeat at the same time. That's why the **customer has to decide** if such a state will be signalized only as **Operator Accepted or only as Repeat.** The LIS configuration in the AMPLILINK Software offers both ways (see chapter *7.2.3.6 Result Status for repeated transmissions*).

For automatic result upload initiated by AMPLILINK the state **FinalResult** will be transmitted only if the option **'Upload before the Operator accepts the result'** is enabled. Otherwise the state **OperatorAccepted** will be transmitted (see chapter *7.2.3.4 Function "Upload before the Operator accepts the result"*).

The LIS must be able to handle or reject results that are transmitted more than once from the AMPLILINK Software.

4.2.5 Quality Control Results

The LIS interface Settings can be configured to support the result upload of Quality Control results. The Quality Control results are distinguishable from normal results by a different sample-order record.

When Quality Controls are entered in AMPLILINK four controls of each level are created at the same time. The entered Quality Control Lot is used as Order ID. If no specific Control Sample ID is entered one Lot of control can be entered more than once. The following control types are supported in AMPLILINK:

- High Positive Control (HPC)
- Medium Positive Control (MPC)
- Low Positive Control (LPC)
- Negative Control (NC)

For details about the transmission of Quality Control Results refer to chapter *5.1.4.3 Test-Order Record for Quality Control Result Upload*

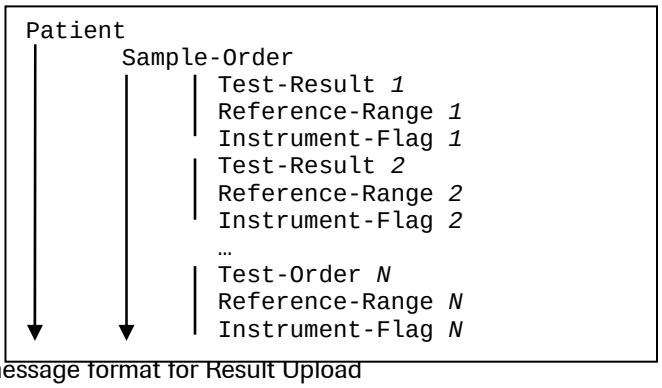
See chapter *8.7.1 Automatic result upload QC results* for an example.

4.2.6 Result upload Message

4.2.6.1. Abstract message format

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 to get not too large messages the LIS interface Service 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:



Structure of the message format for Result Upload

See chapters *8.7.2 Automatic Sample result upload 1* and *8.7.3 Automatic Sample result upload 2.*

4.2.7 Result format

In the record Test-Result the result value of each test will be transmitted in the ASTM field 10.1.4 depending on the peculiarity of the result. The following result categories are in AMPLILINK distinguished:

- Numerical results (raw or formatted)
- Textual results (e.g. "Invalid", "Target Not Detected", "POS", "GZ")
- Two results: combination of numerical and text result (e.g. "POS^1.900", "NEG^*.***")

Result Flags displayed in AMPLILINK can not be transmitted to the LIS (all the Detail Flags are transmitted but not the collected Flag) .The ASTM 'Abnormal Flag as well as the Instrument Flag (if any available) indicates the validity of a result and must be captured by the LIS for result interpretation.

For more details about the Abnormal Flag: see chapter *5.2 Instrument Detail Flag Codes*.

For more details about the Instrument Flags: see chapter *5.1.1.2 Comment Record*.

For more details about other values sent in the result record (such as Lower and Upper limit) see chapter *5.1.4.4 Result Record*. In case the Raw numeric format is configured on the AMPLILINK side but the limits given in the TDF are needed on the LIS side those limits might be needed as well.

Since AMPLILINK version 3.2 the LIS Interface supports two formats for result upload *(*see chapter *7.2.3.7 Result Format (Format of Result value)).*

1. Raw numeric format (float or integer value)
2. Formatted numeric format (identical to AMPLILINK result view)

	Textual results	**Two results**	**Numerical result**
Raw numeric format	YES	YES	- Precision: max. 15 digits - Max. 20 char - Values are raw values (not formatted)
Formatted numeric format	YES	YES	- Precision: max. 15 digits - Max. 20 char - Values are formatted depending on TDF settings (see also chapter *7.2.5.6 Configuring the Test Definitions*

The following table show possible values for "Textual results" and "Two results" which are independent on the chosen LIS Result format settings.

Position Examples	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Textual results	T	a	r	g	e	t		N	o	t		D	e	t	e	c	t	e	d	
Textual results	I	n	v	a	l	i	d													
Textual results	F	a	i	l	e	d														
Textual results	P	O	S																	
Textual results	N	E	G																	

For AMPLICOR qualitative tests one or two results can be transmitted (a combination of text and numerical values). The text will be transmitted in DataMeasurementResult.Scalar and the numerical values in the field DataCutOffIndex, divided by a "^", neither depending on the chosen LIS Result format settings (see chapter *7.2.3.7 Result Format)* nor the TDF settings (see chapter *7.2.5.6 Configuring the Test Definitions).*

Position Examples	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Two results	N	E	G	^	*	.	*	*	*											
Two results	P	O	S	^	0	.	0	0	6											
Two results	P	O	S	^	*	.	*	*	*											
One result		^	0	.	0	0	8													

4.2.7.1. Raw numeric format (float or integer value)

The following table show possible values for "Numerical results" which are dependent on the chosen LIS Result format settings (see chapter *7.2.3.7 Result Format (Format of Result value)).*

Position Examples	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
*Integer min.	-	1																		
Integer	1																			
Integer	1	2	3	4	5	6														
Integer	2	5	8	7	5	7	8													
Integer max.	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9					

* See details for this exceptional value in chapter *4.2.7.3 Examples* and exceptions

Position Examples	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Float. Point	1	E	-	2	0															
Float. Point	1	.	2	3	4	5	6	7	8	9	0	1	2	3	4	5	E	-	5	
Float. Point	0	.	0	0	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
Float. Point	0	.	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5			
Float. Point	1	.	2	3	4	5	6	7	8	9	0	1	2	3	4	5				
Float. Point	1	2	3	4	5	.	6	7	8	9	0	1	2	3	4	5				
Float. Point	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5					
Float. Point	1	.	2	3	4	5	6	7	8	9	0	1	2	3	4	5	E	+	1	5
Float. Point	9	.	9	9	9	9	9	9	9	9	9	9	9	9	9	9	E	+	2	0

4.2.7.2. Formatted numeric format (identical to AMPLILINK result view)

The following table show possible values for "Numerical results" which are dependent on the chosen LIS Result format settings (see chapter *7.2.3.7 Result Format (Format of Result value))* as well as the TDF settings (see chapter *7.2.5.6 Configuring the Test Definitions).*

TDF setting: Integer																				
Position Examples	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Integer min.	1																			
Integer	1	2	3	4	5	6														
Integer	2	5	8	7	5	7	8													
Integer max.	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9					

TDF setting: Exponential																				
Position Examples	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Float. Point	1	.	2	0	E	+	1													
Float. Point	8	.	6	7	E	+	2													
Float. Point	4	.	5	3	E	+	5													
Float. Point	1	.	1	0	E	+	8													

TDF setting: Exponential and Log																				
Position Examples	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Float. Point	1	.	2	0	E	+	1		(	1	.	0	8	)						
Float. Point	8	.	6	7	E	+	2		(	2	.	9	4	)						
Float. Point	4	.	5	3	E	+	5		(	5	.	6	6	)						
Float. Point	1	.	1	0	E	+	8		(	8	.	0	4	)						

4.2.7.3. Examples and exceptions

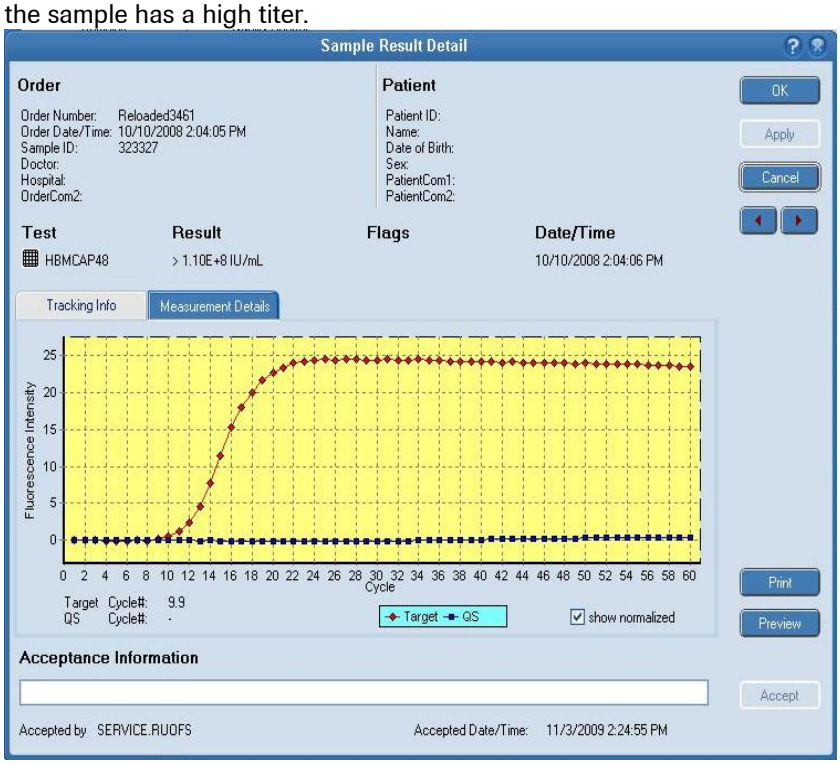
The following table shows examples of possible result values
-: Empty field

AMPLILINK Software displayed	Transmitted to LIS by AMLILINK Software					
	Raw numeric format			Formatted numeric format		
Result (Value + Unit)	Result 10.1.4	Unit 10.1.5	A-Flag 10.1.7	Result 10.1.4	Unit 10.1.5	A-Flag 10.1.7
Target Not Detected	Target Not Detected	-	N	Target Not Detected	-	N
> 1.10E+8 IU/mL	110000000.01008	IU/mL	>	> 1.10E+8	IU/mL	>
> 1.10E+8 IU/mL	127545666.7623	IU/mL	>	> 1.10E+8	IU/mL	>
> 1.10E+8 IU/mL	-1	IU/mL	>	> 1.10E+8	IU/mL	>
1.58E+6 IU/mL	1581980.625	IU/mL	N	1.58E+6	IU/mL	N
6.44E+1 (1.81) IU/mL	64.421615605859	IU/mL	N	6.44E+1 (1.81)	IU/mL	N
< 1.20E+1 IU/mL	0.354105174541473	IU/mL	<	< 1.20E+1	IU/mL	<
POS	POS^*.***	-	N	POS^*.***	-	N
POS	POS^1.243	-	N	POS^1.243	-	N
POS (*.***)	POS^*.***	-	N	POS^*.***	-	N
POS (1.243)	POS^1.243	-	N	POS^1.243	-	N
NEG	NEG^0.000	-	N	NEG^0.000	-	N
NEG (0.000)	NEG^0.000	-	N	NEG^0.000	-	N
(3.526 OD)	^3.526	OD	N	^3.526	OD	N
Invalid	Invalid	-	-	Invalid	-	A

A-Flag: For more details about the Abnormal Flag: see chapter *5.2 Instrument Detail Flag Codes*.
-: Empty field

Exceptional result value "-1"

1. In the beginning of the result calculation within the AMPLILINK Software the result value is initialized to -1
2. If the target elbow is smaller than the "Target elbow min. (in the example shown below = 10)" , the titer-calculation will be bypassed, that means that no titer-calculation will be done
3. In the example shown below the target elbow was 9.9 and the QS was negative. That means that the sample has a high titer.



4. The view in the AMPLILINK Software shows "> 1.1E+08 IU/mL"(TiterMax = 1.1E+08 IU/mL) but the result value (raw value) in the AMPLILINK Database remains "-1" and is transmitted via LIS.

4.2.8 Workflow 2: Result Upload initiated by LIS Host

The host can request a subset of results with the message Result Query. As parameter of this message within the Requested Information Data a list of filters specify the result subset for the transmission.

4.2.8.1. Filters for Result Upload

The following filters are supported by the LIS Interface:

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

All these fields are connected by the LIS interface with a logical AND.
The result serves as a query statement for referencing the requested data. All of these eight fields can contain empty strings or the reserved word ALL, which also stands for an empty filter. With an empty filter the result subset is not further restricted by this filter.

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. If all filters are empty, the host can request the whole result set, which is stored in the AMPLILINK database.

Note: The filter RackCarrierID, PositionOnRackCarrier, RackCarrierType and TubeContainerPos are only operable for Sample-Orders which are ordered by LIS Interface. Manual ordered Sample-Orders does not support these fields.

See chapter *8.7.5 Result request* for an example.

4.2.8.2. 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)
```

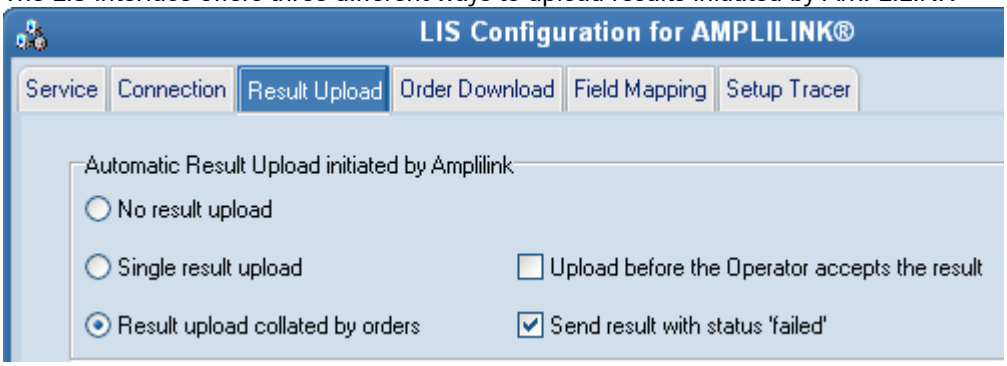
Structure of the message “No Result for Upload”

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.

See chapter *8.7.6 Result request with ‘No Results’* for an example.

4.2.9 Workflow 3: Automatic Result Upload initiated by AMPLILINK

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



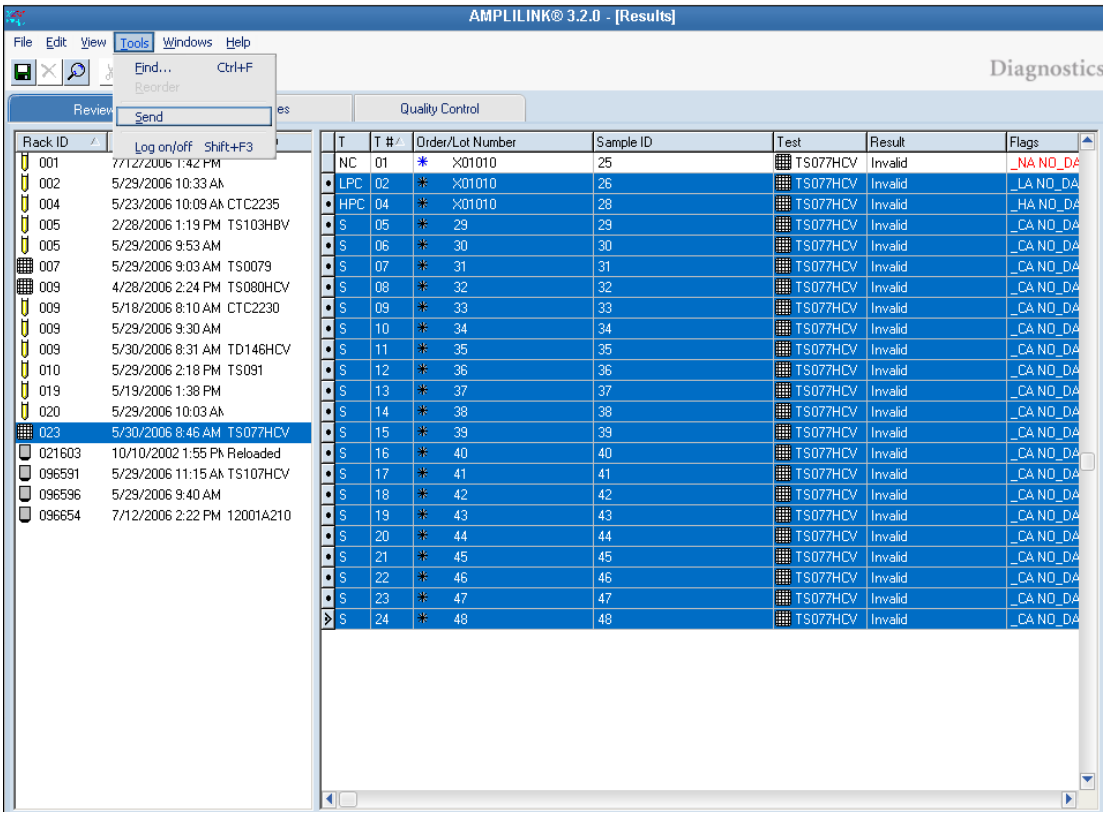
- No result upload: no automatic result upload initiated by AMPLILINK
- Automatic Single result upload
- Automatic Result upload collated by orders

More details can be found in chapter *7.2.3 Result Upload settings: Workflow 2 and 3*.

4.2.9.1. Function: Manual Result Upload

This function transmits a result from the instrument to the host after an operator instruction. For this purpose the AMPLILINK program offers in the result view the functionality to mark every distinct result for transmission to the host. Subsequently the LIS transmission state of the result will be set to SendRequest or to ResendRequest depending if the result was transmitted to the host before

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



4.2.9.2. Automatic Result Upload Modes

The automatic result upload is completely configurable by the LIS Interface Settings (see chapter *7.2.3.1 Result Upload Mode: Workflow 3*). 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 *7.2.3.1 Result Upload Mode: Workflow 3*).
The automatic result upload does upload result usually independent of its result state. But the LIS Interface offers the possibility to upload only valid results and suppress the upload for results with a status failed (see chapter *7.2.3.1 Result Upload Mode: Workflow 3)*.

4.2.9.3. Mode: Single Result Upload

In the mode Single Result Upload the LIS Interface service permanently sends all new operators accepted results to the host. After the transmission the LIS Interface Service sets the LIS transmission state of every result to Sent.

4.2.9.4. Mode: Result Upload collated by orders

The mode Result Upload Collated by orders collates all results of a Sample-Order and transmits them together. The LIS Interface does not transmit the result subset of a Sample-Order before the last result was accepted by an operator. If any distinct results were transmitted before (within workflow 2) these results will not be transmitted within workflow 3 anymore.

4.2.9.5. Transmission Status display in the AMPLILINK Software

In the Results Screen of the AMPLILINK Software the following Transmission Status of a result can be displayed (once a result has been accepted -> black asterisk).

	T	T #	Order/Lot Number	Sample ID	Test	Result
▶	NC	01	* X01010	25	TS077HCV	Invalid
	LPC	02	* X01010	26	TS077HCV	Invalid
	HPC	04	* X01010	28	TS077HCV	Invalid
	S	05	* 29	29	TS077HCV	Invalid
	S	06	* 30	30	TS077HCV	Invalid
	S	07	* 31	31	TS077HCV	Invalid
	S	08	* 32	32	TS077HCV	Invalid

- a black asterisk: indicates (an accepted) not sent result
- a blue asterisk: indicates a send request
- a green asterisk: indicates a result that is sent

.

See chapter *7.2.3 Result Upload settings: Workflow 2 and 3* for additional information.

5. ASTM connection

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

5.1 Supported fields

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

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

5.1.1 General used Records

This chapter describes records which are used in the same manner in all workflows.

5.1.1.1. 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	IP address of LIS network adapter in AMPLILINK PC
7.1.10	ReceiverName	Empty (configurable by database entry)
	ReceiverNetworkAddress	Empty (configurable by database entry)
7.1.12	ProcessingID	UNDEFINED: empty (configurable by database entry)
7.1.13	Version No	ASTM-Version level, filled up by CAL Server
7.1.14	Date and Time of Message	Current time stamp, ASTM date and time format. See [1]

5.1.1.2. Comment Record

Comment Record		
ASTM	**Field Name**	**Remark**
11.1.1	**Record Type Id**	"C" Comment Record
11.1.2	**Sequence Number**	Filled up by CAL Server
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 code)

5.1.1.3. Message Terminator Record

Message Terminator Record		
ASTM	**Field Name**	**Remark**
13.1.1	**Record Type Id**	"L" (Message Terminator)
13.1.2	**Sequence Number**	Filled up by CAL Server. Always 1
13.1.3	**Termination Code**	N: Normal termination E: Error/abort (Whole Message will be ignored)

5.1.2 Workflow 1, Order Download

5.1.2.1. Patient Information 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 on the LIS configuration (see chapter *7.2.5.1 Patient ID for Patient Data).*

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	
8.1.3	PracticePatientID	Which item will be used depends on the LIS configuration, see chapter *7.2.5.1 Patient ID for Patient Data* An empty ID stands for an empty patient record, Only ASCII characters are supported[3], Maximal field length: 20 characters[4]	
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. YYYYMMDD	
8.1.9	Sex	Supported values are: “M” male “F” female “U” unknown	
8.1.10	Race	Supported values are: 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 Value	Integer value or empty, Only ASCII characters "0". . "9" are supported	
	Height Unit	Unit "cm" if value is not empty, otherwise empty	
8.1.18	Weight Value	Float value or empty, Only ASCII characters "0.."9" and "." for decimal point are supported	
	Weight Unit	Unit "kg" if value is not empty, otherwise	
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. YYYYMMDD	
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	
11.1.4	Comment Text	Only ASCII characters are supported , Maximal field length: 1000 characters	
	Comment.Source	Not interpreted	UNDEFINED: empty

[3] ASCII characters are characters from 32 to 127 (decimal notation).
In this range the following ASCII characters (with their decimal notation) are not allowed in the Roche ASTM+ Protocol: “ (34) & (38) \ (92) ^ (94) ¦ (124)
[4] Strings longer than maximal size will be truncated to the maximal size

5.1.2.2. Test-Order Record

The following test-order-record is used for ordering or for negative acknowledge during the order process. The record will be received and transmitted by the LIS Interface.

Test-Order Record			
ASTM	Field Name	Remark for receive record	Remark for send record
9.4.1	**Record Type Id**	"O" (Order)	
9.4.2	**Sequence Number**	Defined by ASTM 6.6.7	
9.4.3	**SpecimenID**	Depending on LIS Configuration can be empty. See chapter *7.2.4.1 Handling of empty ID's by order download* Only ASCII characters are supported, Maximal field length: 40 characters	
9.4.4	**OrderID**	Depending on LIS Configuration can be empty. See chapter *7.2.4.1 Handling of empty ID's by order download* 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	Supported values are: “SampleRack", "KCarrier", "KTubePlate", "KTray", "ARing" (Depending on the AMPLILINK configuration Laboratory/Rack and Tube Definitions)	
	^TubeContainerType	Supported values are: "KTube", "STube", "ATube" (Depending on the AMPLILINK configuration Laboratory/Rack and Tube Definitions)	
9.4.5	^ ^ ^**TestID**	Case insensitive, the TestID must be a valid Test-Code. The mapping of Test-Codes to Test-Names is done by the AMPLILINK database (AMPLILINK Test Definition configuration screen). Only ASCII characters are supported, Maximal field length: 8 characters	
	^Treatment type	not supported	
	^Pre-Treatment type	not supported	
9.4.6	Priority	Supported values are: UNDEFINED “” STAT .”S” ROUTINE “R”	
9.4.7	RequestedDateTime	If the LIS Interface receives an empty RequestedDateTime the current date/time will be used	
9.4.8	CollectionDateTime	ASTM date time format. See [1]	
9.4.9	CollectionEndDateTime	not supported	
9.4.10	CollectionVolume.Value	Float value or empty, Only ASCII characters "0".."9" and "." for decimal point are supported	
	^CollectionVolume.Unit	Unit "ml" if value is not empty, otherwise empty	
9.4.11	CollectorID	not supported	
9.4.12	**ActionCode**	Supported action codes are: NEW “N” ADD “A” (Append) CANCEL_REQUEST “C” (Delete)	
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	SpecimenType	Supported types are: UNDEFINED: "" SERUM: "SER" AMNIOTIC_FLUID: "AMN" CEREBRAL_SPINAL_FLUID: "CSF" CORD_BLOOD: "CBLD" PLASMA: "PLAS" SUPERNATANT: "SUP" GENITAL_VAGINAL: "GENV" WHOLE_BLOOD: "BLD"	
	^SpecimenSource	Only ASCII characters are supported, Maximal field length: 20 characters	
9.4.17	OrderingPhysician	not supported	
9.4.18	Physician’sPhone	not supported	
9.4.19	UserFieldNo.1	not supported	
9.4.20	UserFieldNo.2	not supported	
9.4.21	LabFieldNo.1	Only ASCII characters are supported, Maximal field length: 1000 characters	
9.4.22	LabFieldNo..2	not supported	
9.4.23	ResultsReportedDateTime	not supported	
9.4.24	InstrumentCharge	not supported	
9.4.25	Instr.SectionID	not supported	
9.4.26	**ReportType**	Order from LIS: “O” Negative acknowledge from AMPLILINK: “X”	

5.1.3 Workflow 2: Result Upload initiated by LIS Host (Query)

5.1.3.1. Request Information Record

In the workflow 2 the request-information record is received by the AMPLILINK LIS Interface from the host to determine the result subset.

Request-Information Record			
ASTM	Field Name	Remark	
12.1.1	**Record Type Id**	"Q" (Query)	
12.1.2	**Sequence Number**	Defined by ASTM 6.6.7	
12.1.3	PatientID	Filter for patient record	ASCII max 20 characters
	SpecimenId	Filters for sample-order record	ASCII max 40 characters
	OrderID		ASCII max 20 characters
	RackCarrierId		Number
	PositionOnRackCarrier		Number
	TrayOrLocationID	not supported	
	RackCarrierType	Filter for sample-order record	Number
	TubeContainerType	Filter for sample-order record	Number
12.1.5	Test Id	Filter for test-order record (Test ID or 'ALL')	ASCII max 8 characters
12.1.13	Request Information Status	Only request for final results are supported (must be set to "F")	

5.1.4 Workflow 2 and 3: Result Upload

5.1.4.1. Patient Record

This record is defined in the same way for upload and download (See chapter *5.1.2.1 Patient Information Record*).

5.1.4.2. Test-Order Record: Upload

The test-order-record is transmitted by the AMPLILINK LIS Interface to the host to identify the subsequent result record.

Test-Order Record		
ASTM	Field Name	Remark for receive record Remark for send record
9.4.1	Record Type Id	"O" (Order)
9.4.2	Sequence Number	Defined by ASTM 6.6.7
Sample-Order		
9.4.3	**SpecimenID**	ASCII characters, maximal field length: 40 characters
9.4.4	**OrderID**	ASCII characters, maximal field length: 40 characters
	^RackCarrierID	Number [5]
	^PositionOnRackCarrier	Number [6]
	^TrayOrLocationID	not supported, always empty
	^RackCarrierType	ASCII characters, Text depending on the *AMPLILINK* configuration[7]
	^TubeContainerType	ASCII characters, Text depending on the *AMPLILINK* configuration[8]
9.4.6	Priority	Supported values are: UNDEFINED “” STAT ……..”S” ROUTINE “R”
9.4.7	RequestedDateTime	ASTM date time format. YYYYMMDD / YYYYMMDDHHNNSS
9.4.8	CollectionDateTime	ASTM date time format. YYYYMMDD / YYYYMMDDHHNNSS
9.4.9	CollectionEndDateTime	not supported, always empty
9.4.10	CollectionVolume	Float Number, fix unit ml
9.4.12	ActionCode	ADD character “A” (Append)
9.4.13	DangerCode	not supported, always empty
9.4.14	ClinicalInformation	not supported, always empty
9.4.15	ReceivedDateTime	ASTM date time format. YYYYMMDD / YYYYMMDDHHNNSS
9.4.16	SpecimenType	Supported types are: UNDEFINED : "" SERUM: "SER" AMNIOTIC_FLUID: "AMN" CEREBRAL_SPINAL_FLUID : "CSF" CORD_BLOOD: "CBLD" PLASMA: "PLAS" SUPERNATANT: "SUP" GENITAL_VAGINAL: "GENV" WHOLE_BLOOD: "BLD"
9.4.13	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, always empty
9.4.26	**ReportType**	ReportType is set to RT_FINAL_RESULT or in case of no Results RT_NO_PATIENT
11.1.4	Comment Text	Only ASCII characters are supported , Maximal field length: 1000 characters
	Comment.Source	UNDEFINED: empty character
Test-Order		
9.4.5	**TestID**	ASCII characters, maximal field length: 8 characters
	Treatment type	not supported, always empty
	Pre-Treatment type	not supported, always empty
	Result Evaluation type	not supported, always empty

[5] For the fields RackCarrierID, PositionOnRackCarrier RackCarrierType and TubeContainerPos are only valid for Sample-Orders which are ordered by LIS Interface. Manual ordered Sample-Orders does not support these fields.

5.1.4.3. Test-Order Record for Quality Control Result Upload

The following table shows only the fields in the test-order record which are different for Quality Control results in opposite to normal results.

Test-Order Record		
ASTM	**Field Name**	**Remark**
9.4.12	ActionCode	Actioncode is set to ADD_QUALITY: character
9.4.16	SpecimenType	Coded the type of the Quality Control: HPC, MPC, LPC or NC ASCII characters with predefined texts
	SpecimenSource	Contains Lotnumber,[6] maximal field length: 20 characters

Note: The transmission of the Quality Control information in the ASTM field 9.4.16 is not based on the Roche ASTM+ standard. That's a convention of AMPLILINK LIS interface.

5.1.4.4. 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 TestName are done by the AMPLILINK database (AL Test Definition configuration screen) Only ASCII characters are supported, Maximal field length: 8 characters
Test-Order		
10.1.3	TestID	max 8 ASCII characters (see configurations of the Test Definitions "LIS Test ID")
Result		
10.1.4	DataMeasurementResult.Scalar	Send the interpretation (Text) if available (ASCII max 20 characters), otherwise send the result value- For additional information see *4.2.7 Result format*
	DataMeasurementResult.ValType	not supported, always empty
	DataCutOffIndex	Additional numerical value (for AMPLICOR Standard Results only)
10.1.5	DataMeasurementResult.ValUnit	Send the unit only if in 10.1.4 the result value was sent (otherwise empty string) ASCII max 8 characters
Reference Range		
10.1.6	Lower Limit	Float Number
	Upper Limit	Float Number
	Limit Name	empty text because AMPLILINK handles only one kind of limits
10.1.7	ResultAbnormalFlag See also chapter *5.2.1 Mapping of AMPLILINK Flags and LIS Abnormal Flag*	Supported values are: NORMAL: character "N" ABNORMAL: character "A" ABOVE_NORMAL: character ">" BELOW_NORMAL: character "<" [1)] ABOVE_ABSOLUTE_SCALE: character ">" [1)] BELOW_ABSOLUTE_SCALE: character "<" [1)] ABOVE_NORMAL: character "H" [1)] BELOW_NORMAL: character "L" [1)] ABOVE_EXTREME: character "HH
10.1.8	NatureOfAbnormability	not supported
10.1.9	ResultStatus	X: Result failed or invalid F: Final result (only if the checkbox Upload before the Operator accept the result is ticked) V: Operator approved R: resend or repeated
10.1.11	Operator	Depending of the LIS configuration name of the operator which ordered the test or name of the operator which accepted the test. ASCII max 25 characters
10.1.12	DateTimeTestStarted	ASTM date time format. YYYYMMDDHHNNSS
10.1.13	DateTimeTestCompleted	ASTM date time format. YYYYMMDDHHNNSS
10.1.14	InstrumentIdentification	Name of the instrument which performed the test. ASCII max 20 characters
11.1.4	Comment.Text	ASCII max 1000 characters
11.1.5	Comment.Source	UNDEFINED: empty character
Instrument Flag		
11.1.4	Comment.Tex	Flag code, Flag comment.ASCII max 65 characte
11.1.5	Comment.Source	INSTRUMENT: character "I"

[1)] Concerns quantitative result of COBAS AMPLICOR only.

5.2 Instrument Detail Flag Codes

The Instrument Flag Codes are a special part of the result record (see chapter *5.1.4.4 Result Record)*. This chapter describes the details of these codes.

5.2.1 Mapping of AMPLILINK Flags and LIS Abnormal Flag

All the Details Flags available in the AMPLILINK Software (**excluding** the COBAS AmpliPrep instrument flags; APxxx) are mapped to the 'Instrument Flag' (11.1.4). and sent as separately if available

If more than one Detail Flag is present for one result in the AMPLILINK Software all the flags will be transmitted.
If no Details Flags and not Result comment are available for a result the Instrument Flag (11.1.4 and 11.1.5) will **NOT** be sent at all.
If both Detail Flags and Result comment are available for a result first the Result comment and in the next message strings the Detail Flags are sent.

Valid results can also have flags. Some flags indicate that a result has to be repeated. See package insert and/or method manual for the specific test and/or Application Manual for AMPLILINK 3.2 Software series.

AMPLILINK Software			AMPLILINK LIS Interface			
			'Abnormal Flag'		'Instrument Flag'	
Result Case	**Flag**	**Detail Flag**	**Value (10.1.7)**	**Priority**	**Comment Text (11.1.4)**	**Comment Source (11.1.5)**
process failure or invalid result	-	-	A	highest	-	-
process failure or invalid result	-	D1	A	highest	D1	I
process failure or invalid result	C1	D1	A	highest	D1	I
a high copy sample: result value > assay titer range	-	-	>	..	-	-
a high copy sample: result value > assay titer range	-	D2	>	..	D2	I
a high copy sample: result value > assay titer range	C2	D2	>	..	D2	I
a low copy sample: result value < assay titer range	-	-	<	..	-	-
a low copy sample: result value < assay titer range	-	D3	<	..	D3	I
a low copy sample: result value < assay titer range	C3	D3	<	..	D3	I
[1] Above normal	-	-	H	..	-	-
[1] Above normal	-	D1	H	..	D1	I
[1] Above normal	C1	D1	H	..	D1	I
[1] Below normal	-	-	L	..	-	-
[1] Below normal	-	D1	L	..	D1	I
[1] Below normal	C1	D1	L	..	D1	I
[1] Above extreme	-	-	HH	..	-	-
[1] Above extreme	-	D1	HH	..	D1	I
[1] Above extreme	C1	D1	HH	..	D1	I
within assay range or no titer	-	-	N	lowest	-	-
within assay range or no titer	-	D4	N	lowest	D4	I
within assay range or no titer	C4	D4	N	lowest	D4	I

[1)] Concerns quantitative result of COBAS AMPLICOR only.

C1..C4 : (Collected) Flags in AMPLILINK Result overview
D1..D4 : Detail Flags in AMPLILINK Result Details
- : Empty (no value) for the AMPLILINK Software, field not sent by the AMPLILINK LIS Interface

6. Installation

The AMPLILINK LIS interface Service will be installed automatically during the AMPLILINK Software installation. However, both the Data Station AMPLILINK and the AMPLILINK Software have to be configured for an establishment of an LIS Connection. See *7 Configuration*

7. Configuration

7.1 Configuration of the Data Station AMPLILINK

The Data Station AMPLILINK in combination with a LIS provides two connection possibilities

- LAN Connection, TCP/IP (Laboratory LAN)
- Serial connection (RS232)

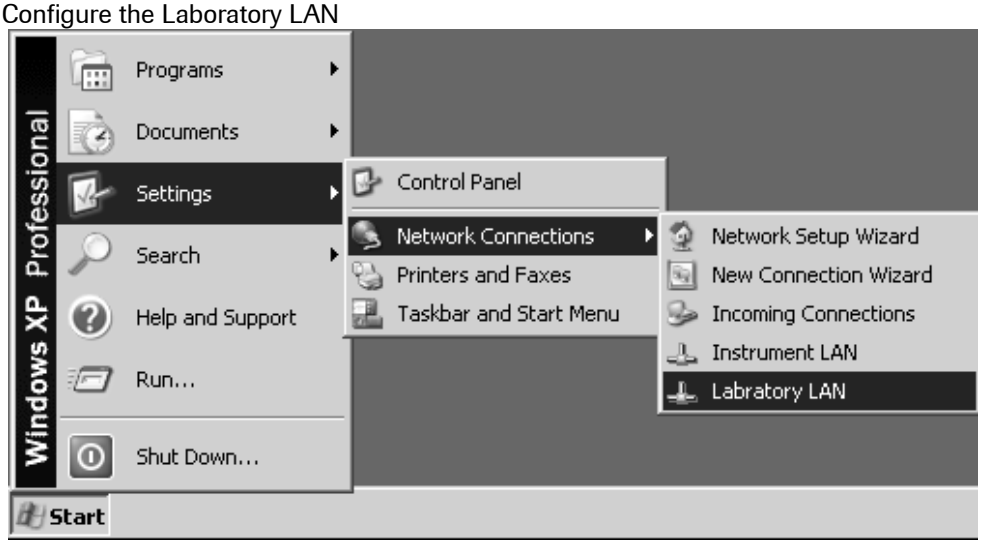
The necessary configurations for the Data Station AMPLILINK can only be done by Roche personnel

Please see the AMPLILINK 3.2 Software series Service Manual for more detail

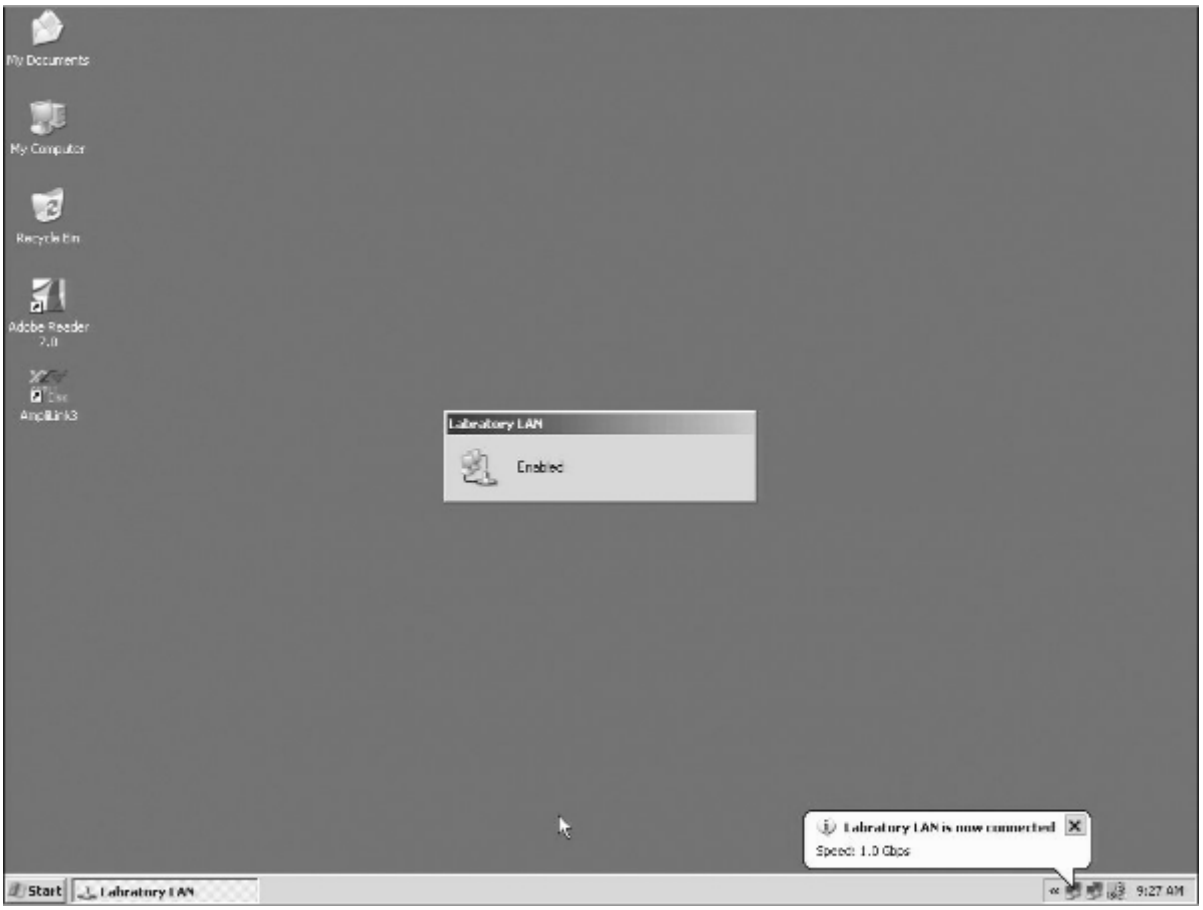
7.1.1 LAN Connection, TCP/IP (Laboratory LAN)

The LIS connection to a LIS is done via the reserved Roche Laboratory LAN. This LAN has to be protected. See also chapter 6 Installation

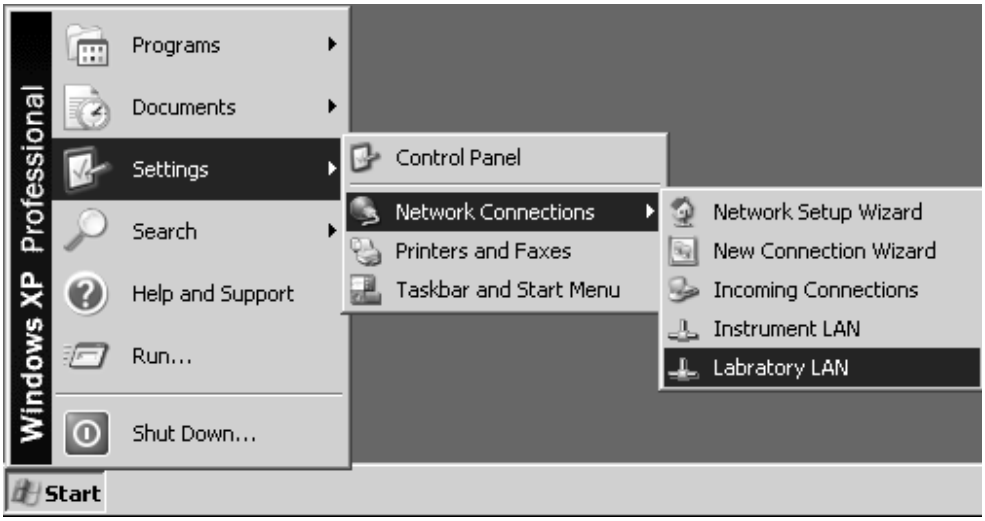
Configure the Laboratory LAN



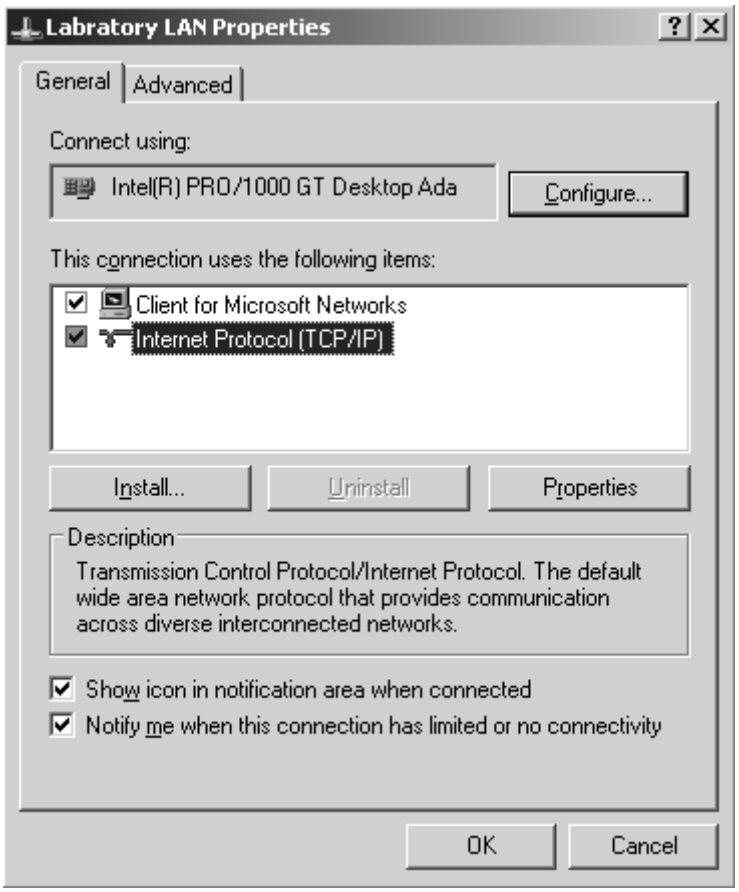
1. Select Start / Settings / Network Connections / Laboratory LAN



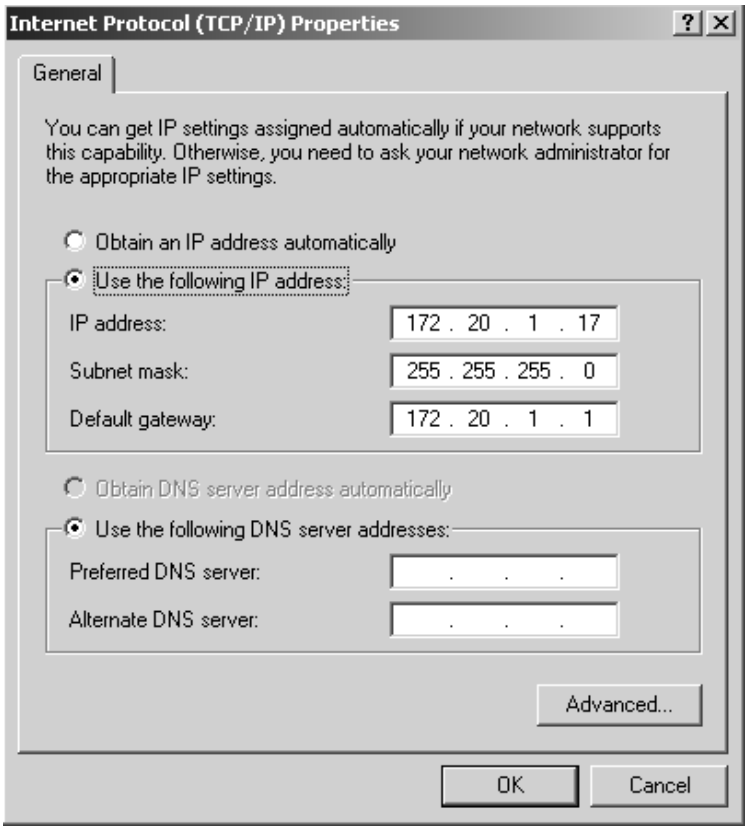
The Laboratory LAN will be enabled



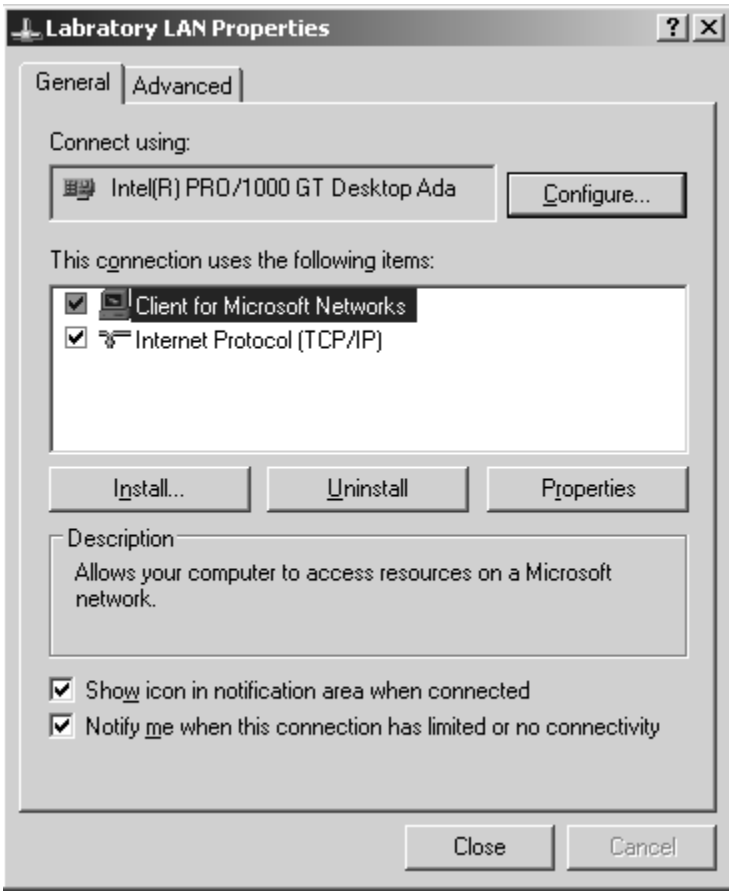
2. Select **Start / Settings / Network Connections / Laboratory LAN**



3. Select **Internet Protocol (TCP/IP)**, Click on **Properties**



4. Adjust the IP Settings depending on the FTP Server settings (screenshot is only an example)
5. Click **OK**



6. Click **Close**

7.1.2 Serial connection (RS232)

If the installation is for use with COBAS AMPLICORs, make sure that the Data Station AMPLILINK offers enough COM Ports.
If you need to install additional COM Ports, you can order the Digi-Board as a Spare Part.
All the details are available in the iSDoc of Data Station AMPLILINK.

Serial cable specifications
Null modem - crossover cable DB9 to DB9.

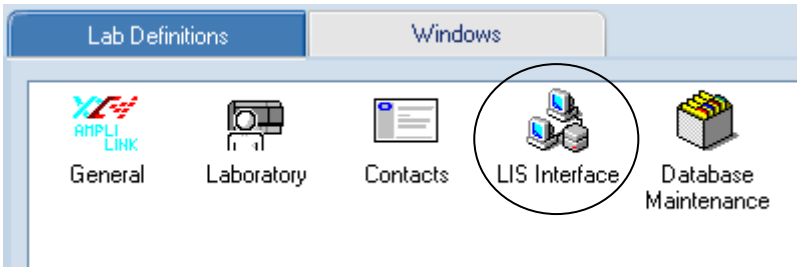
Plug 9 pin female		Plug 9 pin female
1	———	7
2	———	3
3	———	2
4	———	6/8
5	———	5
6/8	———	4
7	———	1
9	———	9

Cable length max 15 m!

7.2 Configuration of the LIS Interface in the AMPLILINK Software

This chapter describes the details of the LIS Interface Settings in the AMPLILINK Software.

1. Click the Configuration tab. 
2. Select the Lab Definitions tab.
3. Double-click the LIS Interface icon to display the LIS Configuration dialog box.

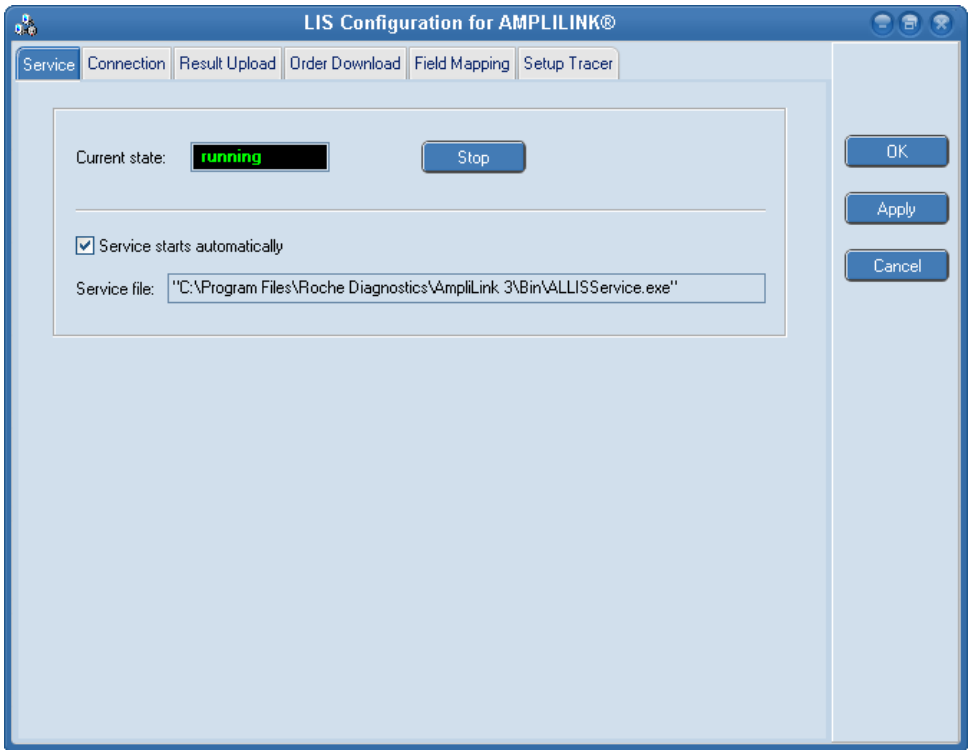


7.2.1 Starting and stopping LIS service

Use the Service tab to start and stop the LIS service manually or automatically.

Roche personnel only has the access rights to start and stop the LIS service

In this folder a Roche Employee can set the LIS Interface Service to start automatically with a start of the Data Station AMPLILINK., The current state is displayed in the black field and can be manually changed.



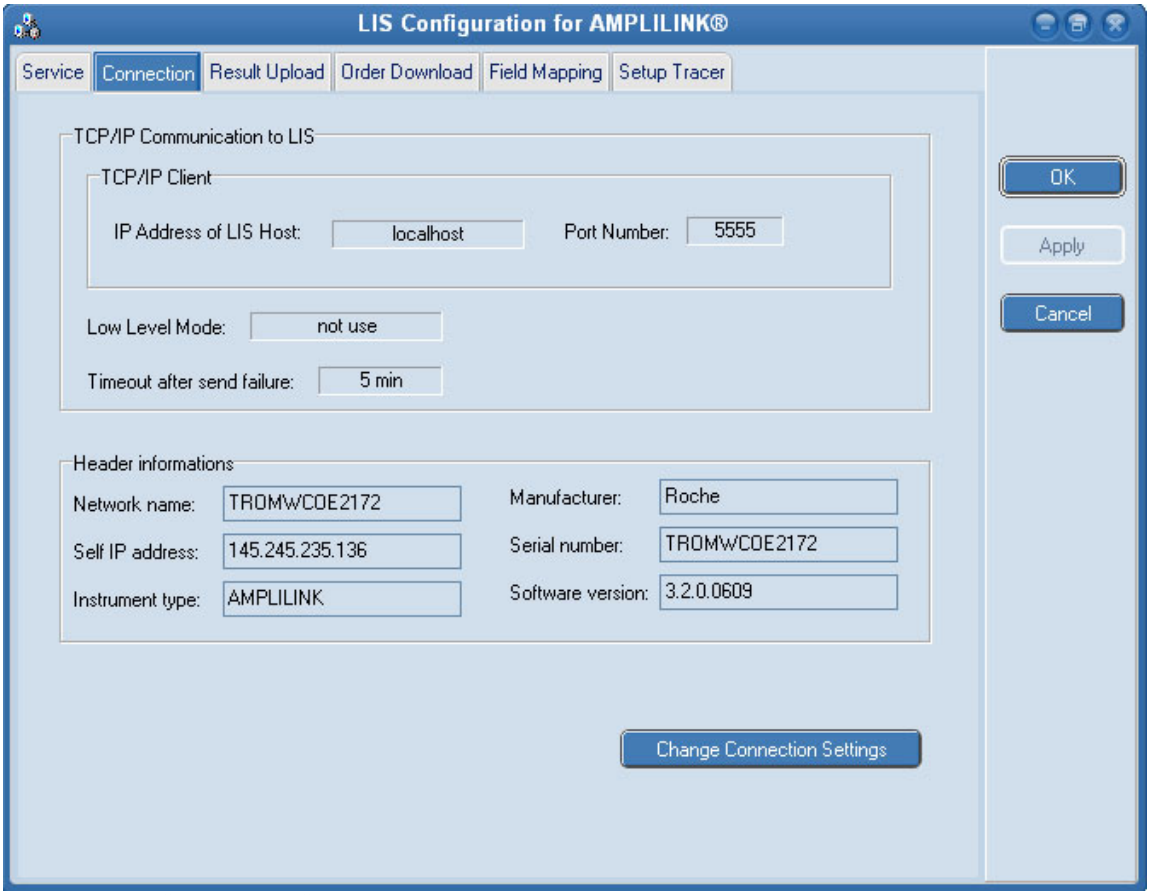
The upper part of the tab sheet shows the current running state of the LIS Service. Depending on this state the button on the right side offers to stop or start the service. During changing of the state the button is disabled and the color of the current state is yellow.

The lower part allows changing the startup mode of the service. If Service starts automatically is ticked the startup mode is set to automatic and the service starts after boot up of the system before any user logged in. Otherwise the startup mode is set to manual and the operator has to start the service manually in this tab sheet. Normally if the LIS Interface will be used this checkbox must be ticked on.

If any changes were made, click on Apply so that they take affect.

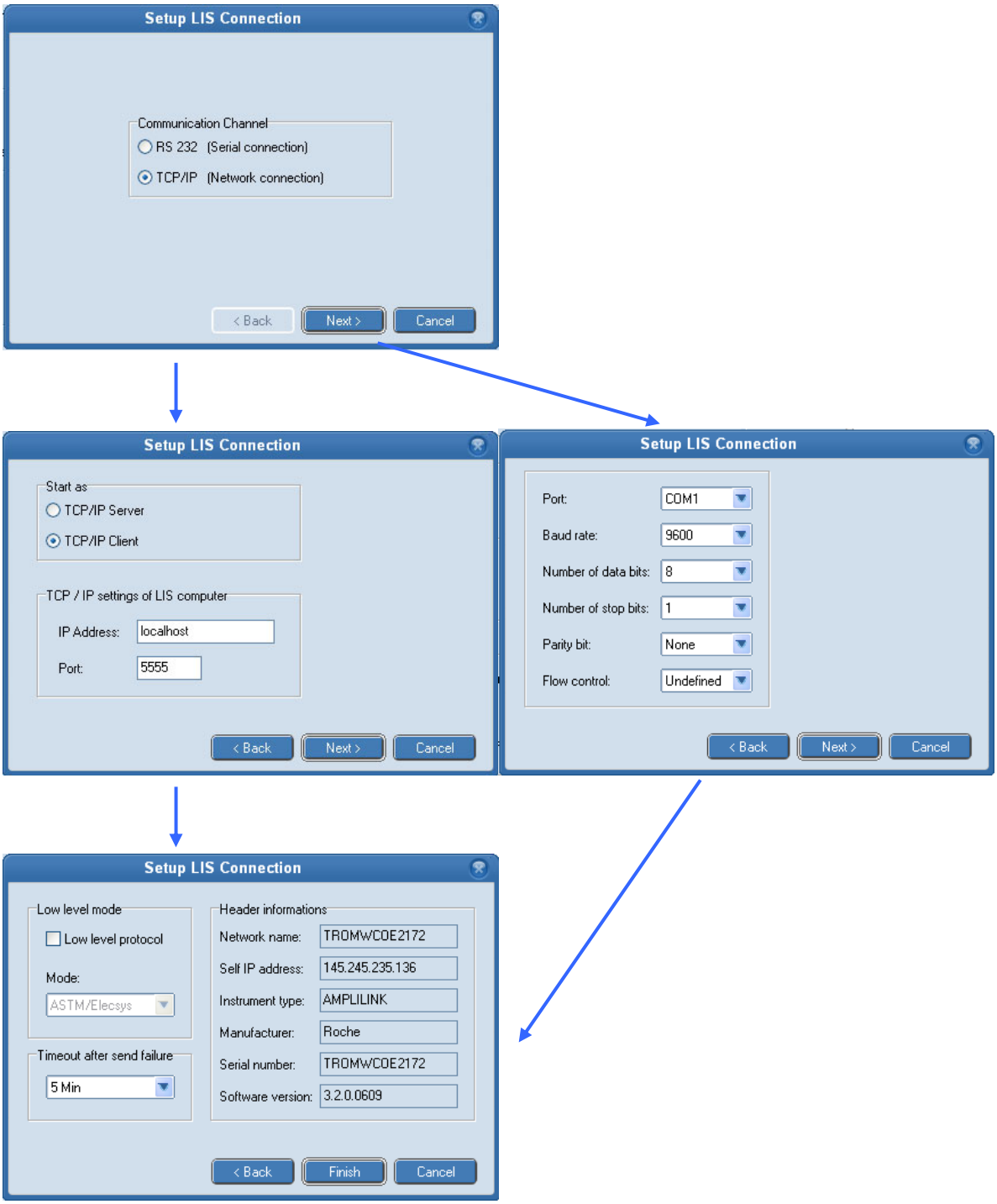
7.2.2 Connection settings

The tab sheet Connection allows the setup of the communication between the LIS Interface and the host system.



The tab sheet "Connection" shows in this example the settings of a TCP/IP Server configuration.

By the button Change Connection Settings you can start a wizard, which in a first step asks, if a serial or a network communication should be installed. Depending of this first question the wizard asks in the second step for settings concerning the different communication channels. The setting Timeout after send failure allows to save processor time in case of broken connection.



This figure shows the "LIS Connection" wizard (with default values), which helps to setup the connection settings.

An example for a connection with RS 232 and TCP/IP can be found in the *AMPLILINK 3.2 Software series* ***Service Manual***

7.2.2.1. Low-Level-Mode

When RS232 is selected “Use Low-Level” is activated. It is not possible to deselect it, as RS232 requires a low-level-protocol.

ASTM = each frame contains a maximum of 247 characters (including frame overhead). Messages longer than 240 characters are divided between two or more frames. Intermediate frames terminate with the characters <ETB>, checksum, <CR> and <LF>. End frames terminate with the characters <ETX>, checksum, <CR> and <LF>.

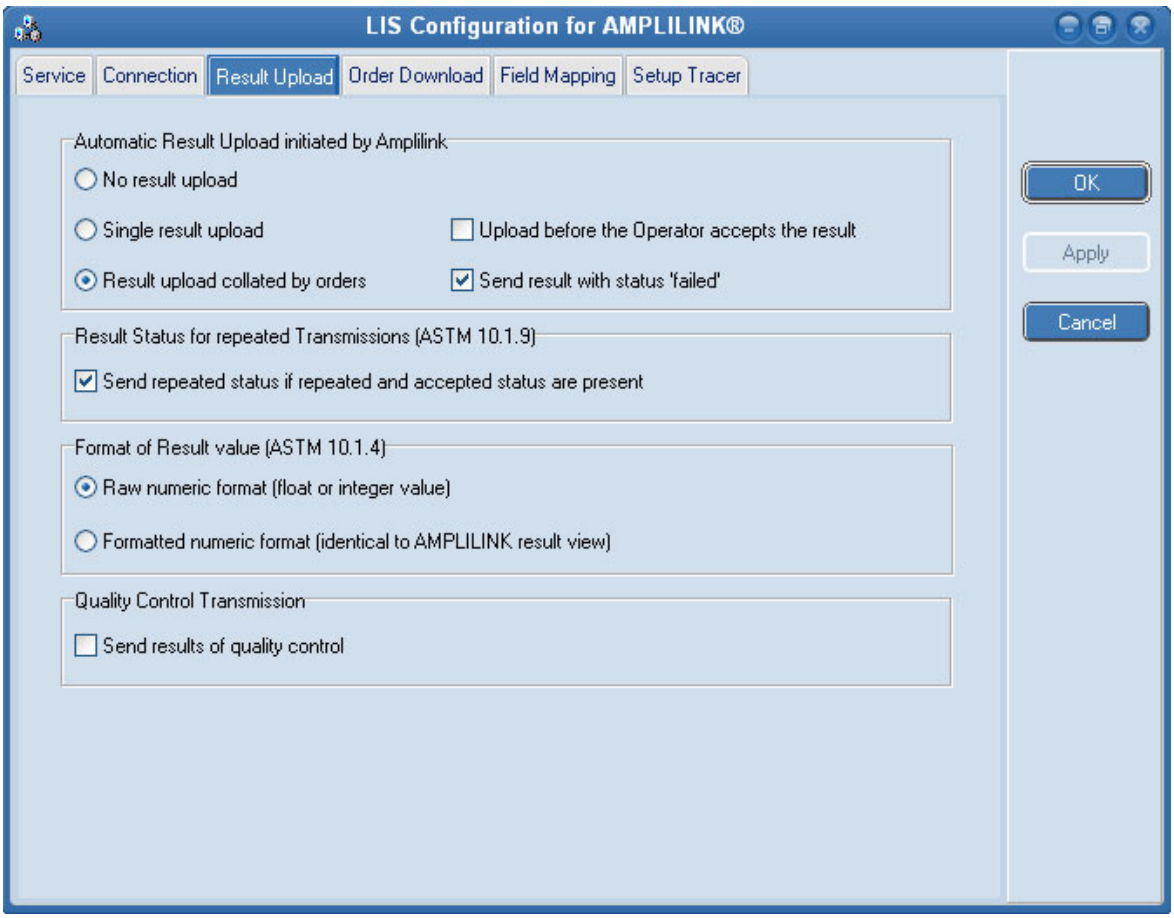
ASTM/Elecsys = each record terminates with the characters <ETX>, checksum, <CR> and <LF>.

Using the low level mode with AMPLILINK 3.2 Software series a timeout of approximately 250ms is needed between the sending of messages.
If a timeout is too short the AMPLILINK LIS Interface service will send a <NAK>..
If a <NAK> is sent the Sender has to wait for 15 seconds according the ASTM low level specification before retransmission. This behavior can slow down the communication markedly.

	Low level mode		
	Low level protocol (Data Link Layer)	**Mode**	**Comments**
RS232 (Serial connection)	Always activated	ASTM	RS232 needs Low level protocol (Data Link layer) independent of the Mode ASTM or ASTM/Elecsys
RS232 (Serial connection)	Always activated	ASTM/Elecsys	
TCP/IP (Network connection)	Deselected	N/A	TCP/IP has already a Data Link Layer and therefore the Low level Protocol should be deselected in order to avoid transmission delays

7.2.3 Result Upload settings: Workflow 2 and 3

The tab sheet Result Upload allows the configuration of the workflows 2 and 3. In addition there is a single setting (Patient Id) of the next tab sheet Order Download, which also has an influence on the result upload workflow.



Tab sheet for settings concerning the result upload workflows (2/3)

7.2.3.1. Result Upload Mode: Workflow 3

There are the following options to configure the Result Upload Mode of the workflow 3.

- No result upload initiated by AMPLILINK: Disables the automatic result upload.
- Single result upload initiated by AMPLILINK: See chapter *4.2.9.3 Mode: Single Result Upload* for details about this mode
- Collated result upload initiated by AMPLILINK: See chapter *4.2.9.4 Mode: Result Upload collated by orders* for details about this mode

Only one of the modes "Single Result Upload" or "Result upload collated by orders" mode can be activated at the same time. If automatic result upload of results is checked, results can be uploaded also manually. Automatic and manual result uploads work simultaneously

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

The checkbox 'Send result with status 'failed'' allows enabling or disabling the transmission of failed results during the automatic result upload.

7.2.3.2. Function “Single Result Upload”

In this mode the LIS interface Service permanently sends all new operator accepted results to the host. After the transmission the LIS interface Service sets the LIS transmission state of every result to Sent.

7.2.3.3. Function “Result upload collated by orders”

This mode collates all results of a sample-order and transmits them at the same time. The LIS interface Service does not transmit the result subset of a sample-order before the last result was accepted by an operator. If a distinct results was transmitted before (within workflow 2) these results will not be transmitted within workflow 3 again.

7.2.3.4. Function “Upload before the Operator accepts the result”

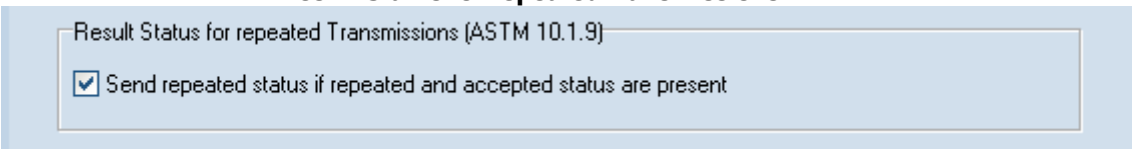
Usually the LIS interface does not upload a result before the operator has accepted it.
But using this function, the LIS interface Service can also be configured to upload the results **without** the acceptance of the operator. That way the result is transmitted to the host as soon as it is available.

This checkbox can only be activated if an automatic result upload is selected.

7.2.3.5. Function “Send result with status failed”

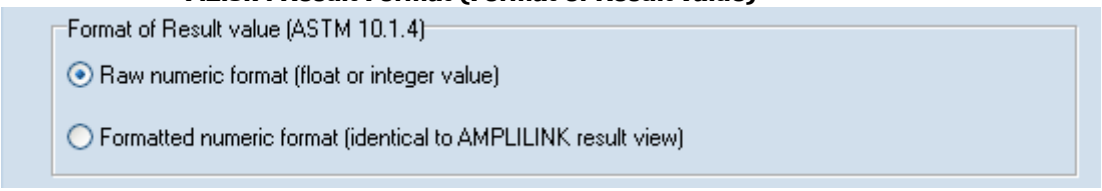
The LIS interface Settings offer to disable the ‘sending of results with status failed’ so that an automatic upload of results does not include results with status failed. Nevertheless, if this field is unchecked, results with status failed can be uploaded manually.

7.2.3.6. Result Status for repeated transmissions



Chapter *4.2.4 Result Status of the ASTM +Standard* describes the treatment of the ASTM result status (ASTM Field 10.1.9). If the checkbox ‘Send repeated status’ is ticked the LIS Interface Service sends the value’ Repeated Transmitted’, if the result state is set to ‘Operator Accepted’ and ‘Repeated Transmitted’. **If the checkbox is not ticked, the state ‘Operator Accepted’ will be transmitted for the same state**.

7.2.3.7. Result Format (Format of Result value)

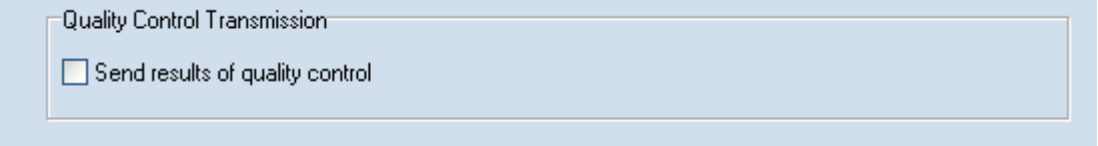


As described in chapter *4.2.7 Result format* the LIS Interfaces supports for numerical result two formats:

- Raw numeric format: integer or fix comma floating point value. This option was in the AMPLILINK 3.1 Software series the only transmission option
- • AMPLILINK formatted numeric format: Inside the test definitions the result format is defined test specific. The placeholder for the unit is ignored because the unit text will be transmitted separated (see also *Setup LIS Test ID in 7.2.5.6 Configuring the Test Definitions)*

Textual results are not affected by this setting, as they are always transmitted as text.

7.2.3.8. Quality Control transmissions

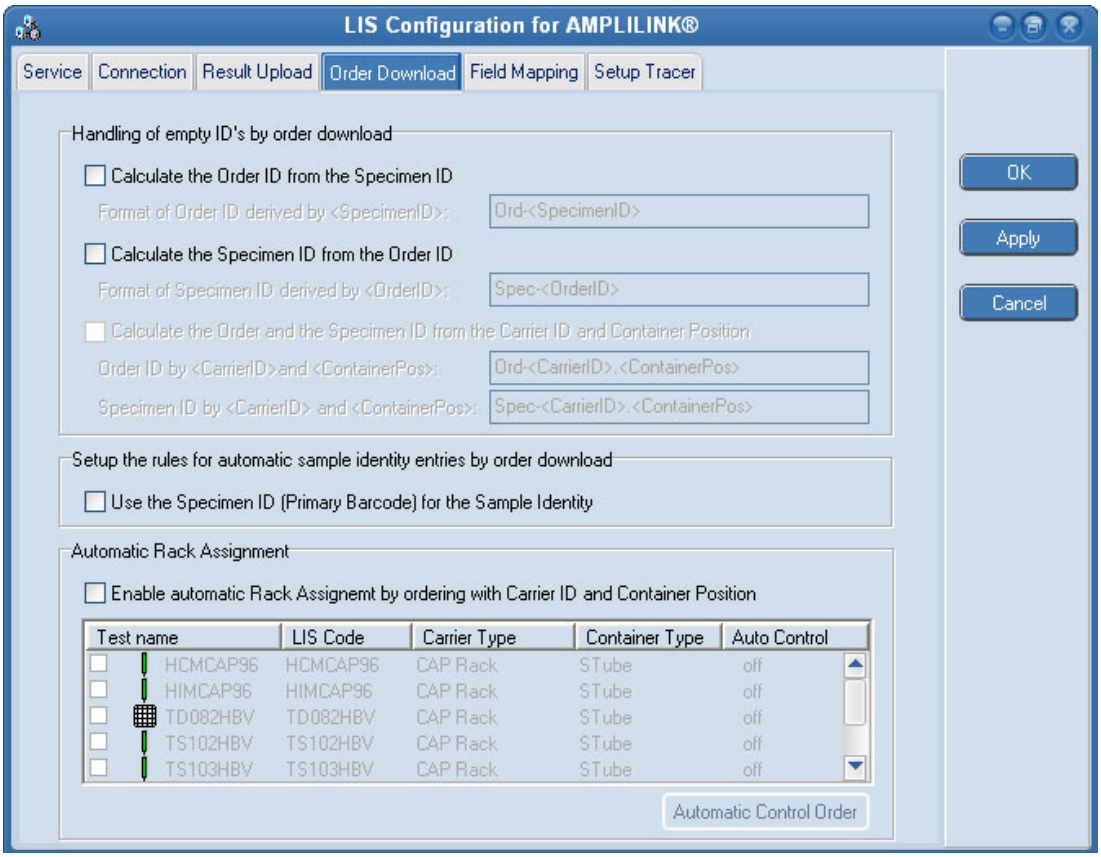


This checkbox allows enabling or disabling of the result upload transmission of Quality Control results by the Workflow 2/3. For details about the transmission of Quality Control results see chapter *4.2.5 Quality Control Results*.

Note: In opposite to the result upload workflow, the order download workflow does not support Quality Control data

7.2.4 Order download settings

The tab sheet Order Download allows the configuration of the workflow 1.

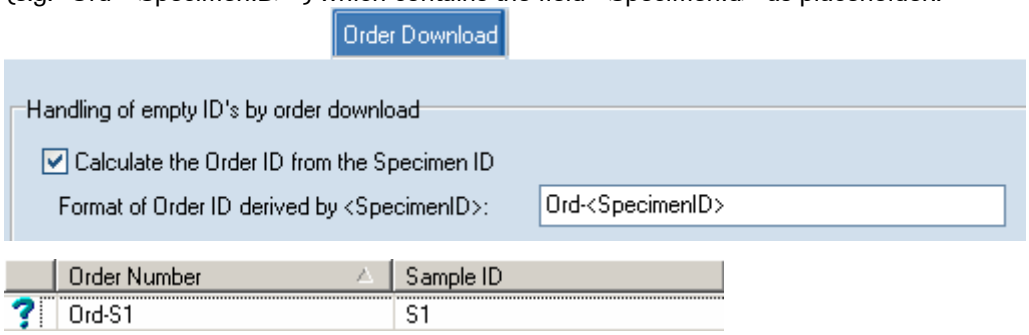


Tab sheet for settings concerning the order download workflow 1

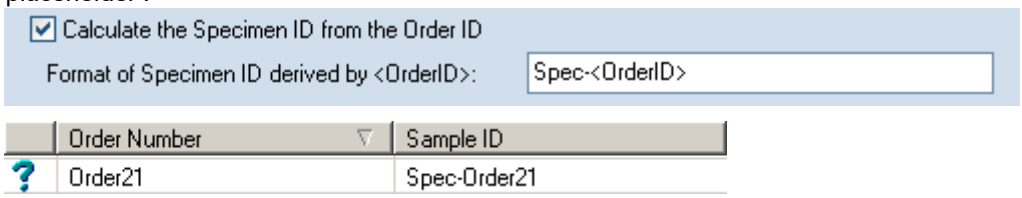
7.2.4.1. Handling of empty ID's by order download

This chapter describes in details the handling of empty identifiers. With the three checkboxes Calculate the Order ID, Calculate the Specimen ID and Calculate both ID's it is possible to switch on and off these special rules. The format fields contain the rules for building the artificial identifiers. For this purpose you can write any text before and afterwards of the placeholder. As placeholder the derived IDs in brackets (< >) are expected.

If the Host does not provide an Order ID to AMPLILINK (empty OrderID) the AMPLILINK Software offers with the configuration 'Calculate Order Id' a possibility to fetch an artificial identifier derived from the valid SpecimenID. The calculated OrderID results of a **configurable text** (e.g. "Ord-<SpecimenID>") which contains the field <SpecimenId> as placeholder..



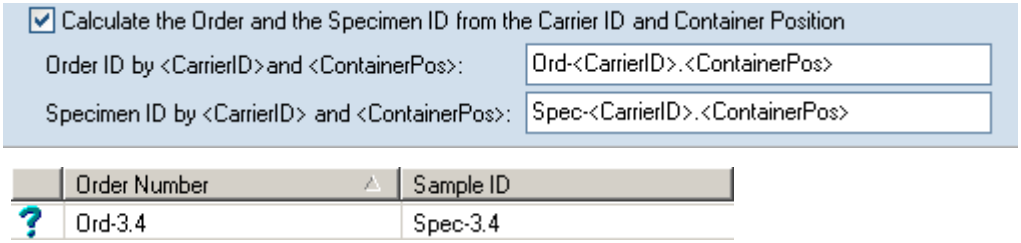
If the Host does not provide an SpecimenID to AMPLILINK (empty SpecimenID) the AMPLILINK Software offers with a second Configuration, 'Calculate Specimen Id', a possibility to fetch an artificial identifier derived from the valid OrderID. The calculated SpecimenId results of a **configurable text** (e.g. "Spec-<OrderID>") which contains the field <OrderID> as placeholder .



If the Host does not provide the OrderID and the SpecimenID, the AMPLILINK Software can create OrderID and SpecimenID out of valid RackCarrierID and PositionOnRackCarrier (ASTM Field 9.4.4: Instrument Specimen ID: Carrier ID and Position on Rack). Therefore 'Calculate both Ids' is a possibility to fetch two artificial identifiers derived from the valid RackCarrierID and PositionOnRackCarrier. The calculated OrderID and SpecimenId will be built by two **configurable text** which contains both placeholder fields <RackCarrierID> and <PositionOnRackCarrier> (For more details see chapter *7.2.4.1 Handling of empty ID's by order download).*

E.g. The OrderID and SpecimenId will be build by the following rules:

<OrdId> ::= "Ord-" <RackCarrierId> "." <PositionOnRackCarrier>
<SpecId> ::= "Spec-" <RackCarrierId> "." <PositionOnRackCarrier>)



In case that all functions are ticked and that either the order ID or Specimen ID is sent by the host, the AMPLILINK software will behave as if the 'Calculate the Order and the Specimen ID from the Container and Carrier Position' are not ticked.

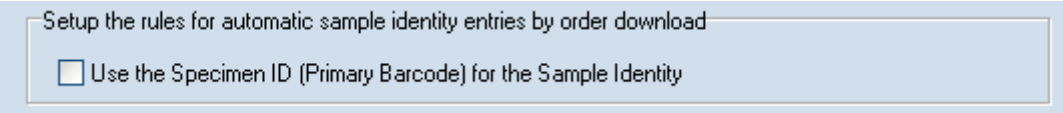
The database of the AMPLILINK software supports only numbers for the RackCarrierType and the TubeContainerType (ASTM Fields 9.4.4: Instrument Specimen ID: Rack/Carrier type and Tube/Cont. type). But both fields are defined in the Roche ASTM+ standard as string fields. Therefore a conversation between the strings and their corresponding numbers is needed. This conversation is completely configurable under the LIS configuration Icon (See chapter *7.2.5.5 Setup data types for carrier and container types*).

Examples can be found in chapter:

8.4.3 Order download with SpecimenID and OrderID
8.4.4 Calculated Order ID
8.4.5 Calculate Specimen ID
8.4.6 Calculate OrderID and SpecimenID from the Container and Carrier Position

7.2.4.2. Rules for linking of the Sample ID

The chapter *4.1.3 Sample-Order Identification* describes the possibilities for linking the sample ID. The checkbox 'Use the SpecimenID for the Sample Identity' enables the restrictions for the linking of the Sample ID, so that an Sample ID can only be linked to one Order Number.

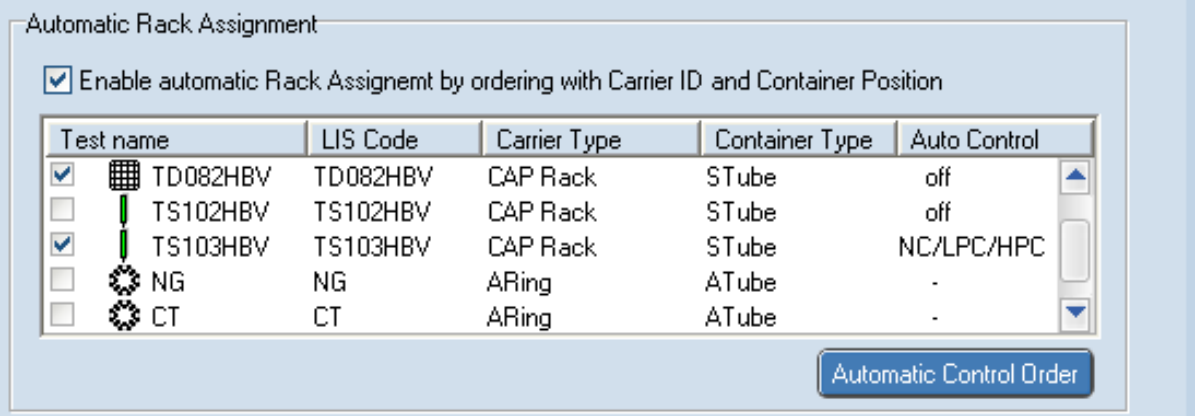


If this setting is not checked (default setting), it is possible to use one Sample ID (Primary Barcode) linked to different Order Numbers.

For more information on what is possible and what not, when this setting is checked see example in chapter *8.5 Use the Specimen ID (Primary Barcode) as the Sample Identity.*

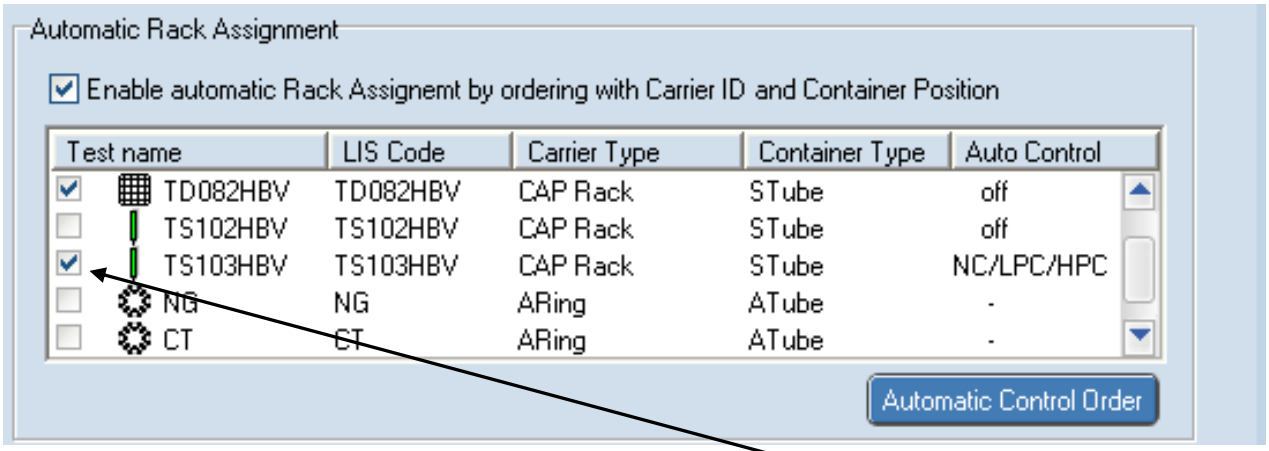
7.2.4.3. Automatic Rack Assignment

The chapter *4.1.4 Automatic Rack Creation and Assignmen*t describes this function in details. The checkbox Enable automatic Rack Assignment by ordering with Carrier ID and Container Position allows enabling/disabling of the function in general.

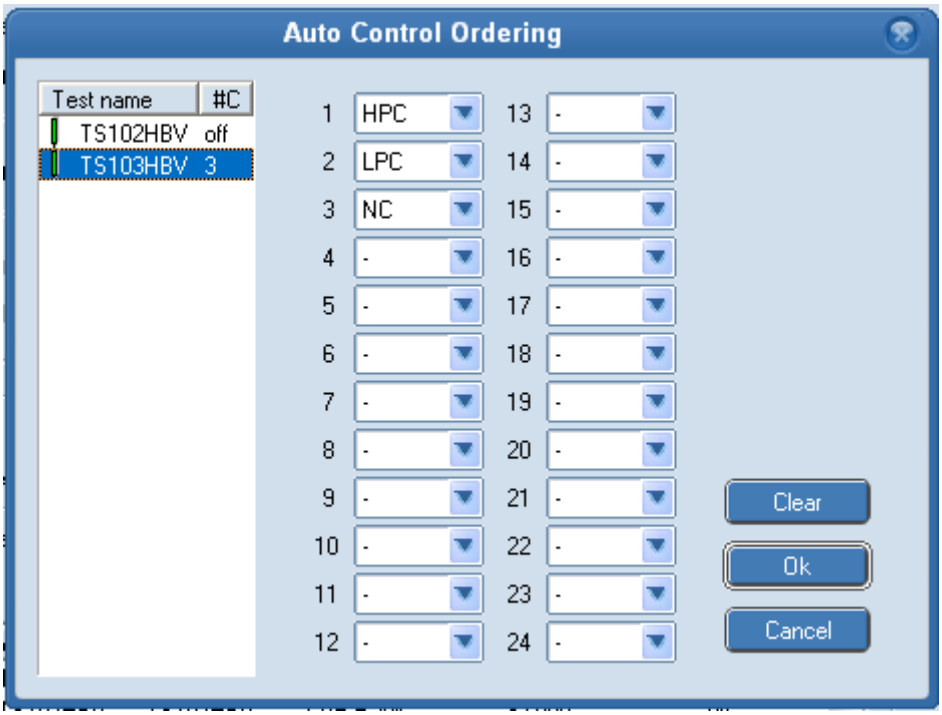


The list box shows **all in the current AMPLILINK installation** installed tests which base on workflows that support automatic rack assignment. With the checkbox on the left side on each line you can decide for every single test if the automatic rack creation and assignment function shall be enabled or not.
The first column describes the test name in AMPLILINK. The next column contains the Test ID which is used for communication with the LIS. The columns carrier and container (tube) type inform about the expected strings in these ASTM fields 9.4.4. The last column shows, for workflows which support the automatic control ordering, if there is a set of controls defined, **Auto Control NC/LPC/HPC**, or **Auto Control off**. For all workflows which do not support automatic control assignment **Auto Control** - is displayed.

7.2.4.4. Automatic Control Ordering



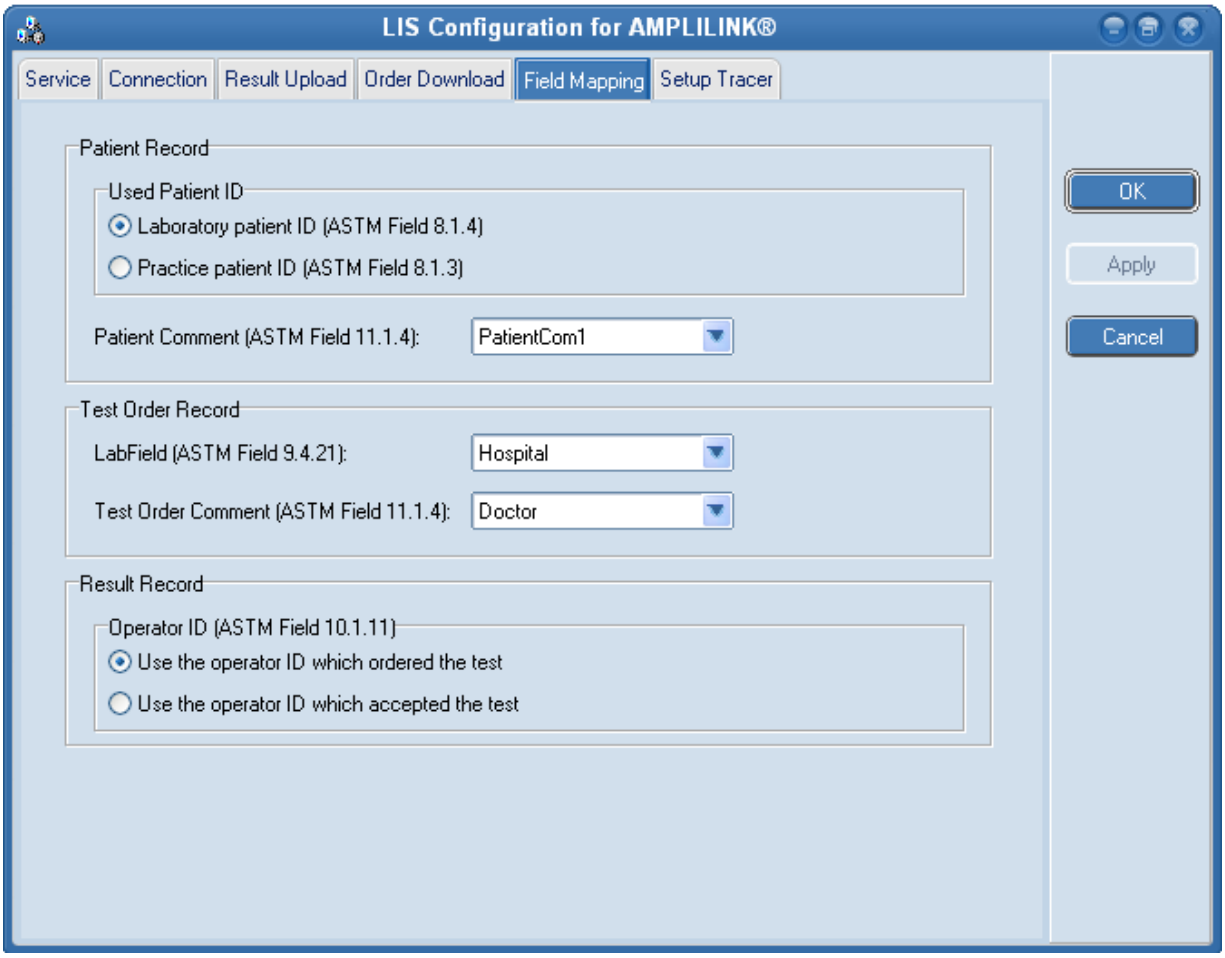
The button 'Automatic Control Order' is only active, if there are tests **enabled,** which base on a workflow that supports automatic control ordering. By pressing this button the following dialog appears:



Dialog for edit profiles for automatic control ordering

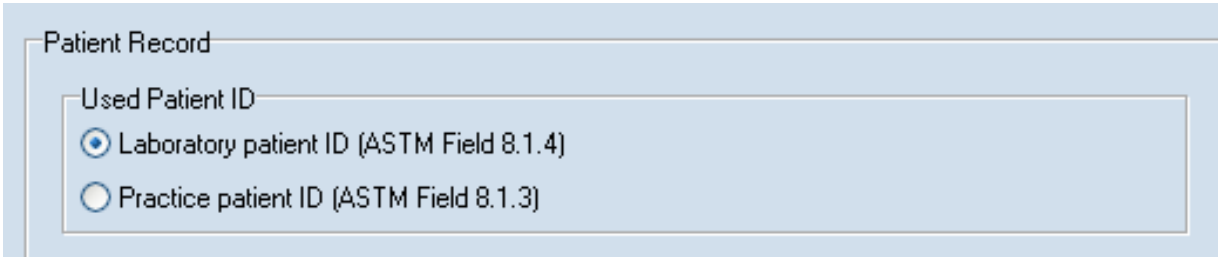
The list on the left side shows all tests that are enabled in the window before. The second column #C informs about the number of controls which are defined. On the right side the profile of the control ordering for the selected test on the left side is shown. On each rack position, 1 to 24 on the Sample rack, you can order a Low Positive Control (LPC), High Positive Control (HPC) or Negative Control (NC). Usually a set of these three controls will be placed on the rack.

7.2.5 Field Mapping



Tab sheet for settings for ASTM field mapping

7.2.5.1. Patient ID for Patient Data

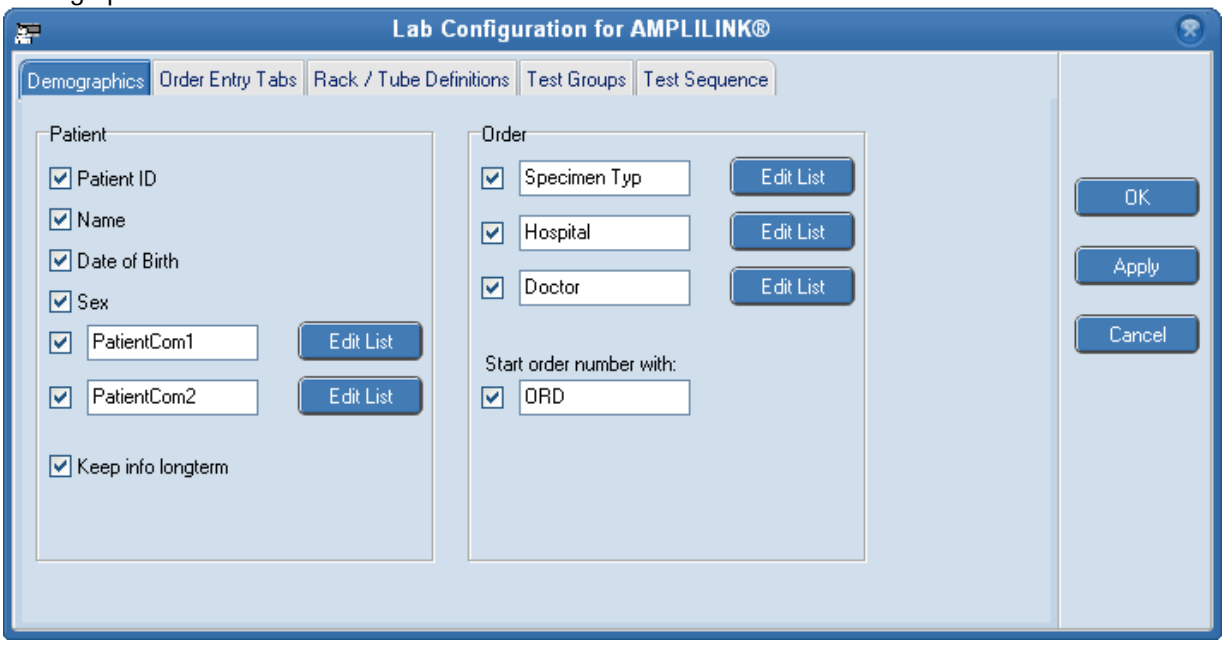


The AMPLILINK database does not support two distinct patients identifier in contrast to the Roche ASTM+ standard.

7.2.5.2. Patient Comment

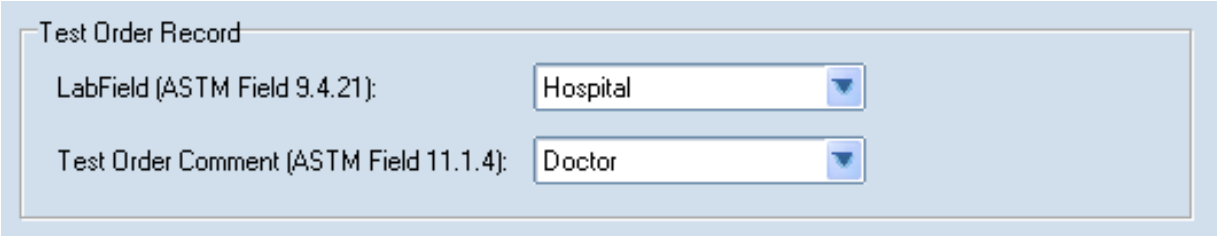
The comment of the patient record will be assigned either to the first or to the second patient comment field in AMPLILINK.

The name of the Comment Fields can be manually changed in AMPLILINK Configuration Tab, Laboratory, Demographics



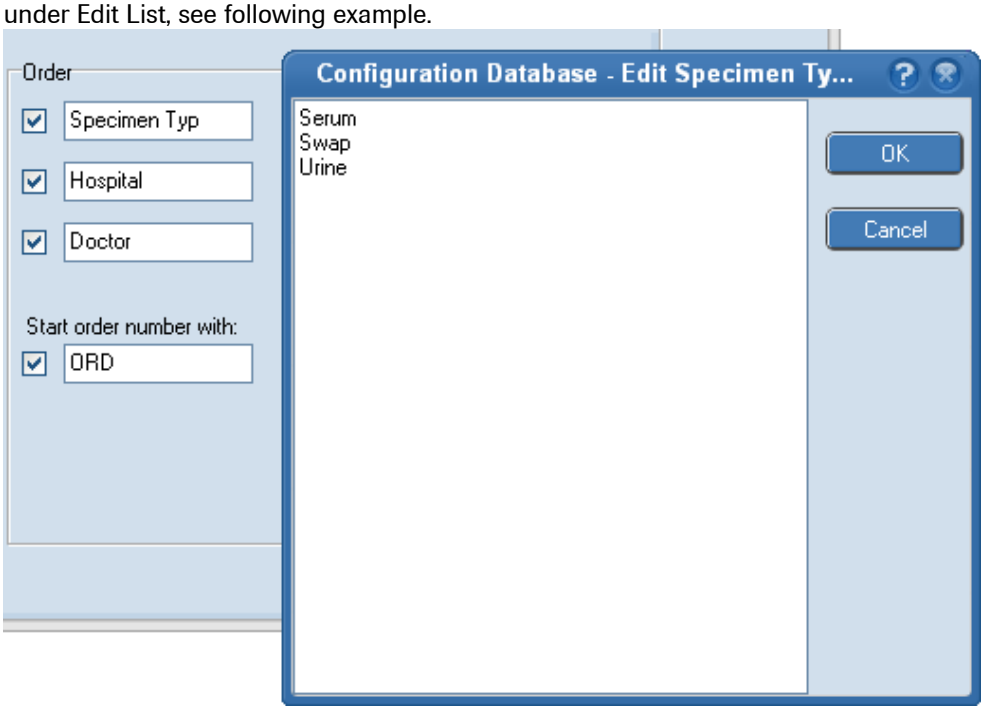
Field naming of comment fields in AMPLILINK

7.2.5.3. Lab Field Comment and Test Order Comment

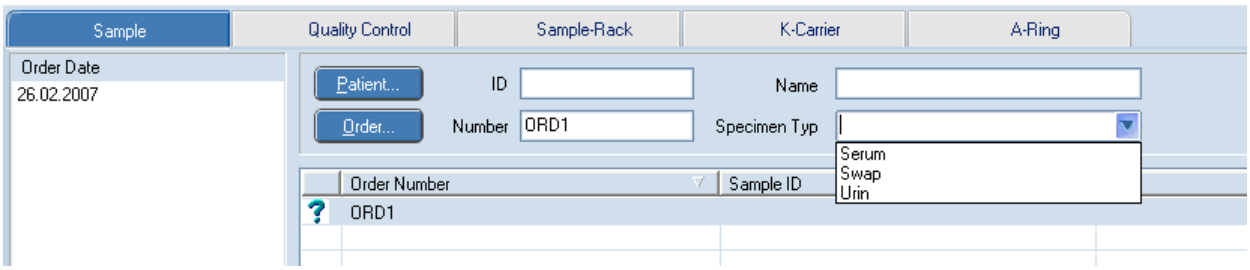


The Lab Field (ASTM Field 9.4.21) and the Test Order Comment (ASTM Field 11.1.4) will each be mapped to one field of the three comment field of the AMPLILINK order record, see Figure above. The default naming Specimen Typ, Hospital, Doctor can be changed by overwriting. The in Figure defined fields can then be selected in the Lab Field Comment and Test Order Comment.

For the default or self named Order fields (Figure above) you can enter a choice of selectable text/number under Edit List, see following example.

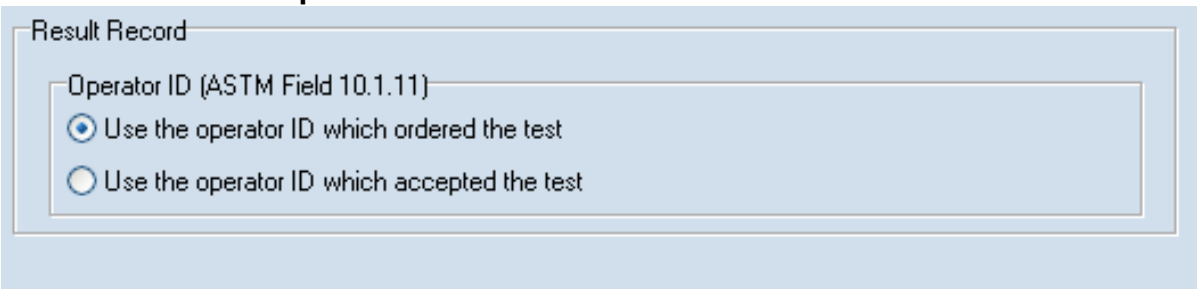


The entered list is then available in the Order Tab, Sample



Note: AMPLILINK prevents that the test order comment and the lab field comment can be mapped to the same comment field of the AMPLILINK order record.

7.2.5.4. Operator Id for test data

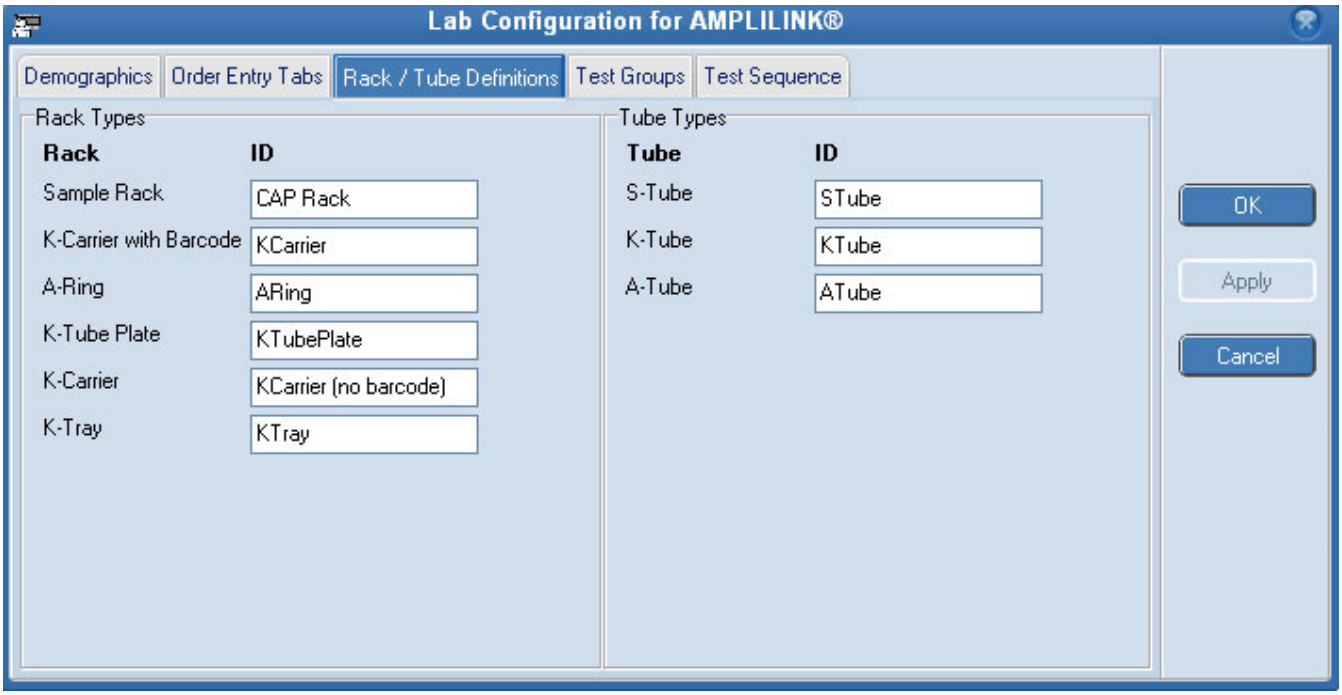


The Roche ASTM+ standard does not define exactly the meaning of the operator field used in ASTM 10.1.11. The LIS Interface offers two different sources of information for this field:

- Use the operator which ordered the test. (In case the test was ordered by the LIS, the text 'LIS' will be used)
- Use the operator which accepted the test. Note that in workflow 2 results, which are not accepted by an operator, will also be transmitted. In this case the field Operator ID is empty.

7.2.5.5. Setup data types for carrier and container types

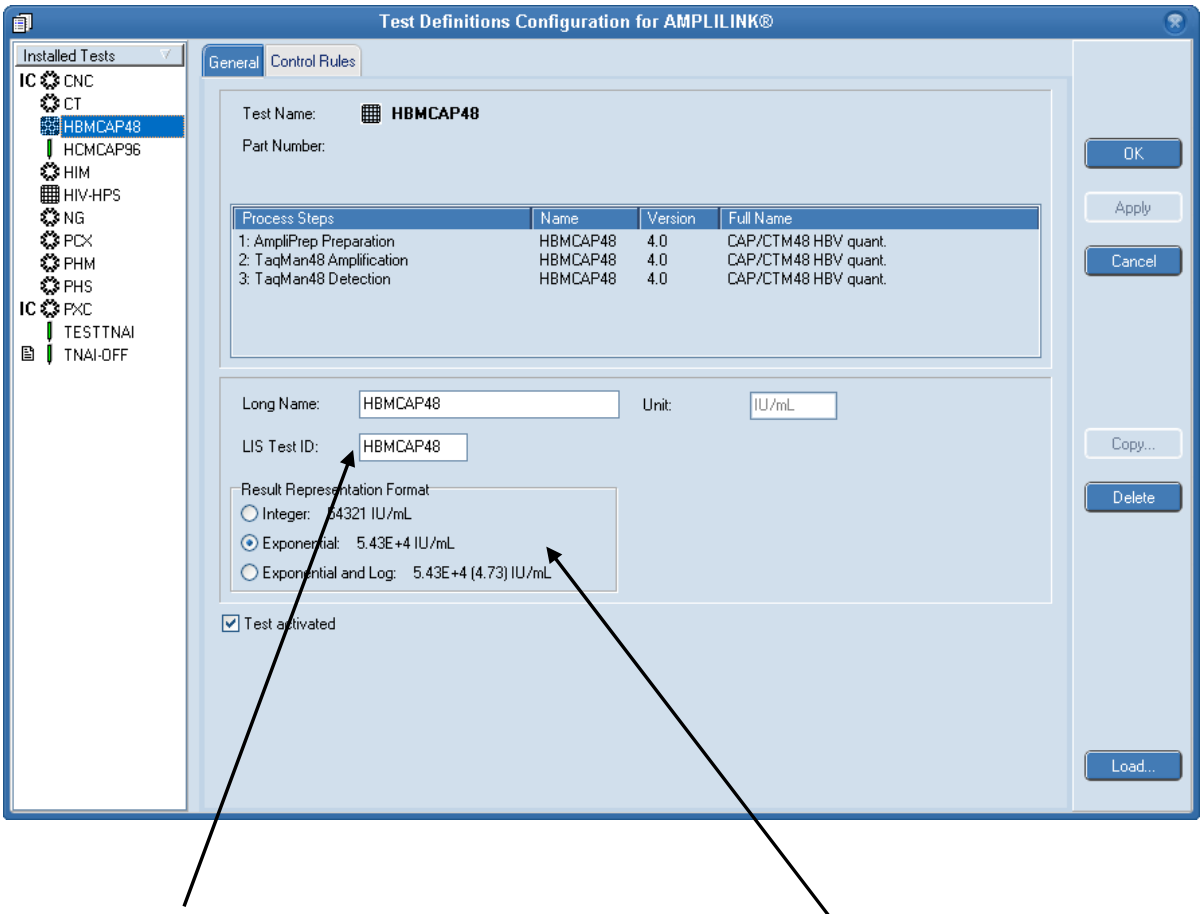
As described in chapter *4.1.1.2 Sample-Order Data* the translation of the CarrierType and the ContainerType (ASTM Field 9.4.4: Instrument Specimen ID: Rack/Carrier type and Tube/Cont. type) from text (string) to number requires a predefined correspondence list with carrier and container types. These settings can be done in the Lab Configuration for AMPLILINK in the tab Rack / Tube Definitions.



Tab sheet Rack / Tube Definitions in the settings Lab Configuration In the column Mapped the checkbox allows to disable the usage of a specific container or carrier type.

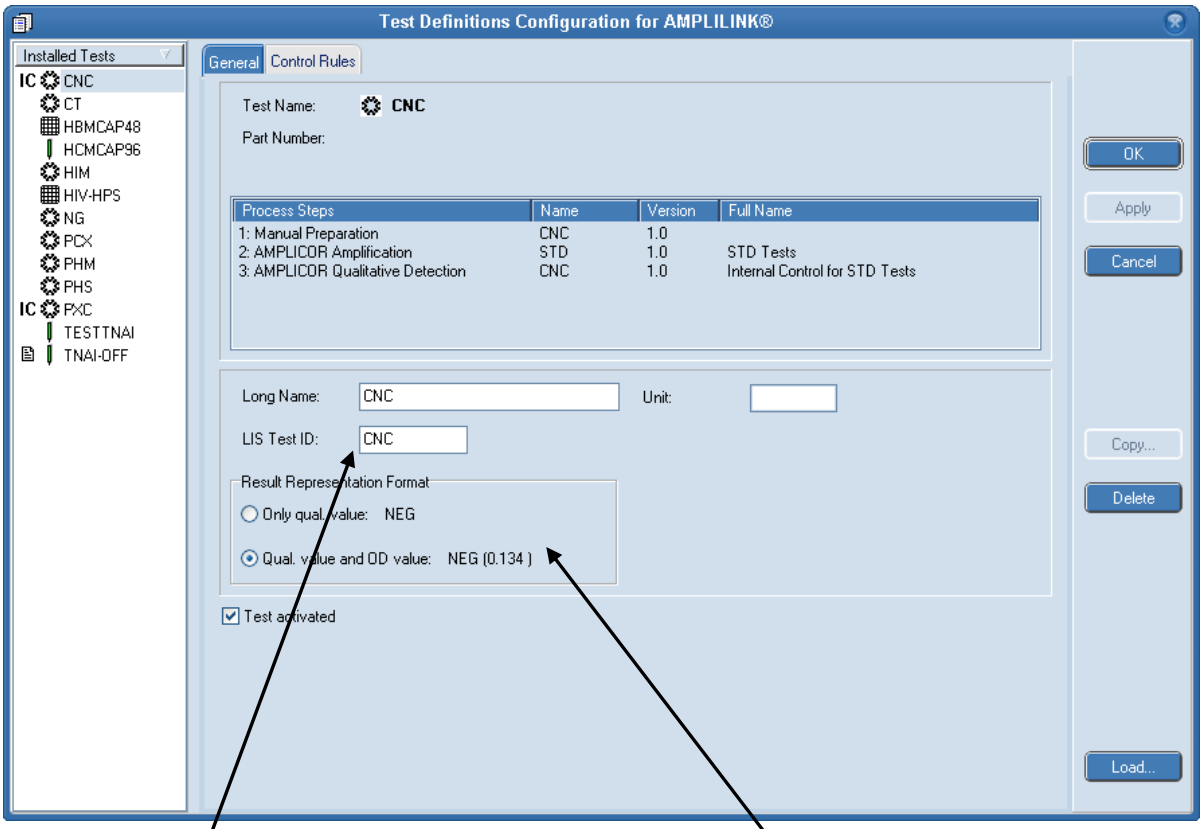
7.2.5.6. Configuring the Test Definitions

With this setting a translation between AMPLILINK Test Name and the Test ID sent by LIS (ASTM Field 9.4.5) is possible. In the Test Definitions field LIS Test ID the 'Test Code' that is used for this test from the LIS has to be entered. The Test is then displayed in the AMPLILINK Software as defined in Test Name.



Setup LIS Test ID in AMPLILINK's Test Definitions. This is an example showing the name CA CT used by LIS. By default the LIS Test ID is either empty or the same as the Test Name.

The Setting of the Result Representation Format can be applied to the format of the result transmitted to the LIS

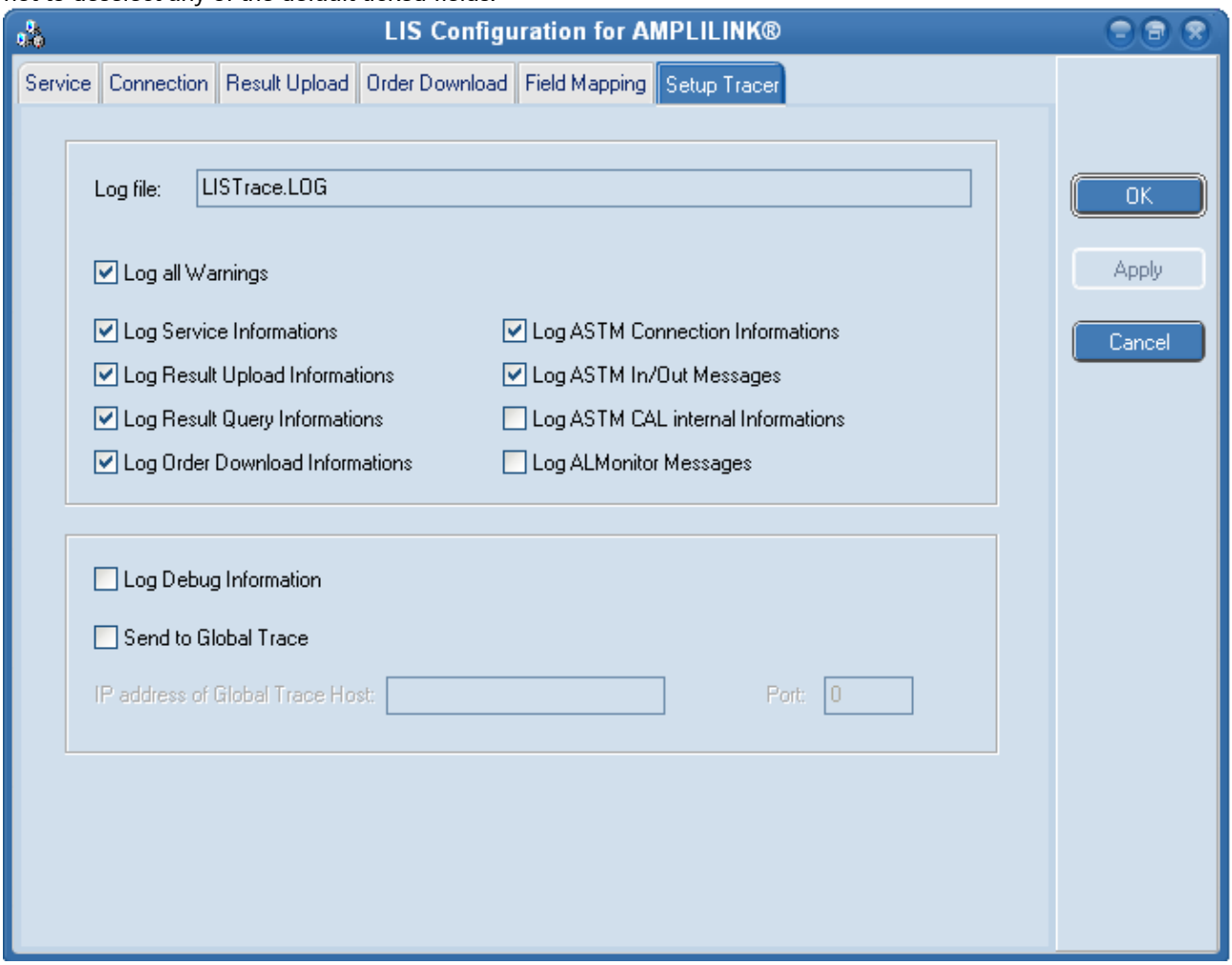


Setup LIS Test ID in AMPLILINK's Test Definitions. This is an example showing the name CA CT used by LIS. By default the LIS Test ID is either empty or the same as the Test Name.

The Setting of the Result Representation Format can be applied to the format of the result transmitted to the LIS

7.2.6 Setup Tracer

The tab sheet Setup Tracer allows the configuration of the LIS Interface trace log. We strongly recommend not to deselect any of the default ticked fields.



Tab sheet for settings concerning the LIS Interface trace function

Log entries of the class Fatal and Error will always be traced. With the checkbox' Log all Warnings' you can enable or disable the logging of all entries of the class Warn. Log entries of the class Hint, Info and Warn (in case the checkbox 'Log all Warnings' is not checked) will be logged only if the concerning log group is enabled. The lower section of the tab sheet Setup trace will be displayed only for operator with highest access level.
The checkbox 'Log Debug Information' will be used for Research & Development purpose only. The Option 'Send to global trace' allows sending the trace information to a TraceViewer which is running on another Data Station. If this option should be used an IP address and the listening port of the global trace host (TraceViewer) must be configured.

8. Examples

The trace examples relate to a communication including Low-Level protocol.

8.1 Order Formats

There are to possibilities in the Test Order to order more than one test for a sample:

8.1.1 Order Record, one test in one test order line

Order Record

```
H|\^&||||||||||P|1|
P|1||1001||Mueller^Sabrina||19750101|F||
O|1|900706220001|220001|^^^CT|||||||A|||||||||||||O
O|2|900706220001|220001|^^^NG|||||||A|||||||||||||O
O|3|900706220001|220001|^^^CNC|||||||A|||||||||||||O
L|1|N
```

Trace of ASTM Host Simulator Tool

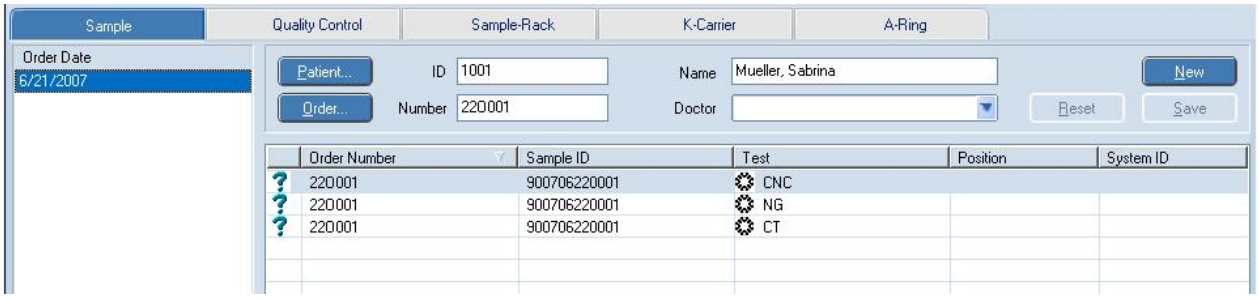
```
HOST   14:36:37,499 [ENQ]
AL3    14:36:37,589 [ACK]
HOST   14:36:37,629 [STX]1H|\^&|||||||||P|1|[CR][ETX]36[CR][LF]
AL3    14:36:37,709 [ACK]
HOST   14:36:37,769 [STX]2P|1||1001||Mueller^Sabrina||19750101|F||[
           CR][ETX]2F[CR][LF]
AL3    14:36:37,849 [ACK]
HOST   14:36:37,919 [STX]3O|1|900706220001|220001|^ ^ ^CT|||||||A||||
           |||||||||O[CR][ETX]A0[CR][LF]
AL3    14:36:38,010 [ACK]
HOST   14:36:38,080 [STX]4O|2|900706220001|220001|^ ^ ^NG|||||||A||||
           |||||||||O[CR][ETX]A0[CR][LF]
AL3    14:36:38,160 [ACK]
HOST   14:36:38,240 [STX]5O|3|900706220001|220001|^ ^ ^CNC|||||||A|||
           ||||||||||O[CR][ETX]E1[CR][LF]
AL3    14:36:38,320 [ACK]
HOST   14:36:38,350 [STX]6L|1|N[CR][ETX]09[CR][LF]
AL3    14:36:38,430 [ACK]
HOST   14:36:38,440 [EOT]
```

Trace Log of the LIS Interface Service

	22.06.2007			22.06.2007	
419	14:25	-	450	14:25	

Info	<	<ENQ>
Info	>	<ACK>
Info	<	<STX>1H|\^&||||||||P|1|<CR><ETX>36<CR><LF>
Info	>	<ACK>
Info	<	<STX>2P|1||1001||Mueller^Sabrina||19750101|F||<CR><ETX>2F<CR><LF>
Info	>	<ACK>
Info	<	<STX>3O|1|900706220001|220001|^^^CT||||||A|||||||||||O<CR><ETX>A0<CR><LF>
Info	>	<ACK>
Info	<	<STX>4O|2|900706220001|220001|^^^NG||||||A|||||||||||O<CR><ETX>A0<CR><LF>
Info	>	<ACK>
Info	<	<STX>5O|3|900706220001|220001|^^^CNC||||||A|||||||||||O<CR><ETX>E1<CR><LF>
Info	>	<ACK>
Info	<	<STX>6L|1|N<CR><ETX>09<CR><LF>
Info	>	<ACK>
Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:1001)
Hint	OrderDownload	Receive sample (Add,OID:220001,SID:900706220001,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:CT)
Hint	OrderDownload	Receive sample (Add,OID:220001,SID:900706220001,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:NG)
Hint	OrderDownload	Receive sample (Add,OID:220001,SID:900706220001,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:CNC)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:1001)
Info	OrderDownload	New sample succeeded (OID:220001,SID:900706220001,ODATE:6/22/2007 2:25:43 PM)
Info	OrderDownload	Add test succeeded (TID:CT)
Info	OrderDownload	Append sample succeeded (OID:220001,SID:900706220001,ODATE:6/22/2007 2:25:43 PM)
Info	<	<EOT>
Info	OrderDownload	Add test succeeded (TID:NG)
Info	OrderDownload	Append sample succeeded (OID:220001,SID:900706220001,ODATE:6/22/2007 2:25:43 PM)
Info	OrderDownload	Add test succeeded (TID:CNC)

AMPLILINK Software: Order Tab



8.1.2 Order Record, more than one test in one test order line

Order Record

```
H|\^&|
P|1|7258969|7258969||Muster^Hans||19691014
O|1|1237651|116335|^^^HBMCAP96\^^^HCMCAP48|||||||A|||||||||||||O
L|1|N
```

Trace of ASTM Host Simulator Tool

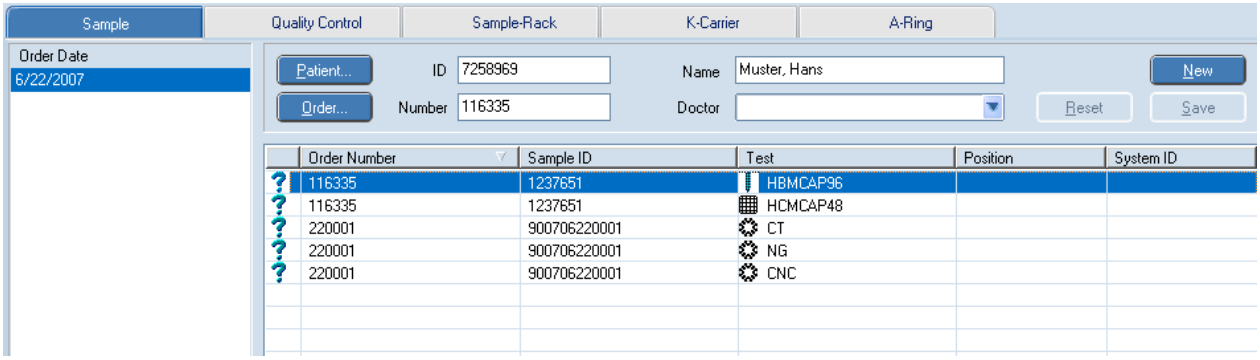
HOST 15:02:37,131 [ENQ]
AL3 15:02:37,222 [ACK]
HOST 15:02:37,242 [STX]1H|\^&|[CR][ETX]61[CR][LF]
AL3 15:02:37,322 [ACK]
HOST 15:02:37,372 [STX]2P|1|7258969|7258969||Muster^Hans||1969101
4[CR][ETX]2A[CR][LF]
AL3 15:02:37,462 [ACK]
HOST 15:02:37,552 [STX]3O|1|1237651|116335|^ ^ ^HBMCAP96\^ ^ ^HCMCAP4
8|||||||A|||||||||||||O[CR][ETX]CD[CR][LF]
AL3 15:02:37,632 [ACK]
HOST 15:02:37,662 [STX]4L|1|N[CR][ETX]07[CR][LF]
AL3 15:02:37,742 [ACK]
HOST 15:02:37,752 [EOT]

Trace Log of the LIS Interface Service

533 22.06.2007 15:02 - 554 22.06.2007 15:02

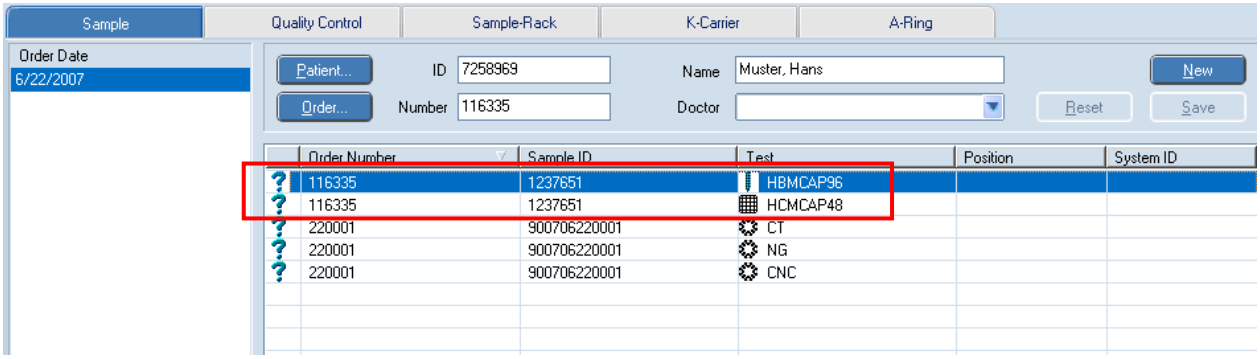
Info	<	<EOT>
Info	<	<ENQ>
Info	>	<ACK>
Info	<	<STX>1H|\^&|<CR><ETX>61<CR><LF>
Info	>	<ACK>
Info	<	<STX>2P|1|7258969|7258969||Muster^Hans||19691014<CR><ETX>2A<CR><LF>
Info	>	<ACK>
Info	<	<STX>3O|1|1237651|116335|^^^HBMCAP96\^^^HCMCAP48|||||||A|||||||||||O<CR><ETX>CD<CR><LF>
Info	>	<ACK>
Info	<	<STX>4L|1|N<CR><ETX>07<CR><LF>
Info	>	<ACK>
Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:7258969)
Hint	OrderDownload	Receive sample (Add,OID:116335,SID:1237651,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:HBMCAP96)
Hint	OrderDownload	Receive test (TID:HCMCAP48)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:7258969)
Info	OrderDownload	New sample succeeded (OID:116335,SID:1237651,ODATE:6/22/2007 2:51:42 PM)
Info	<	<EOT>
Info	OrderDownload	Add test succeeded (TID:HBMCAP96)
Info	OrderDownload	Add test succeeded (TID:HCMCAP48)

AMPLILINK Software: Order Tab

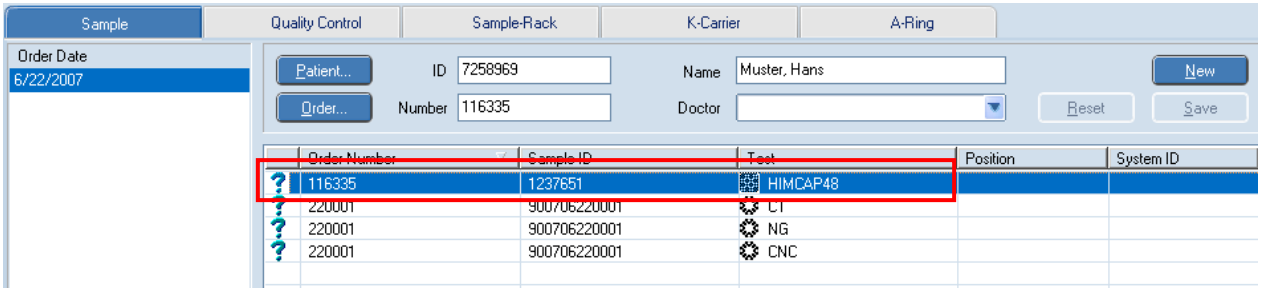


8.2 Order Record: Action Code New

8.2.1 Overwriting existing incomplete orders



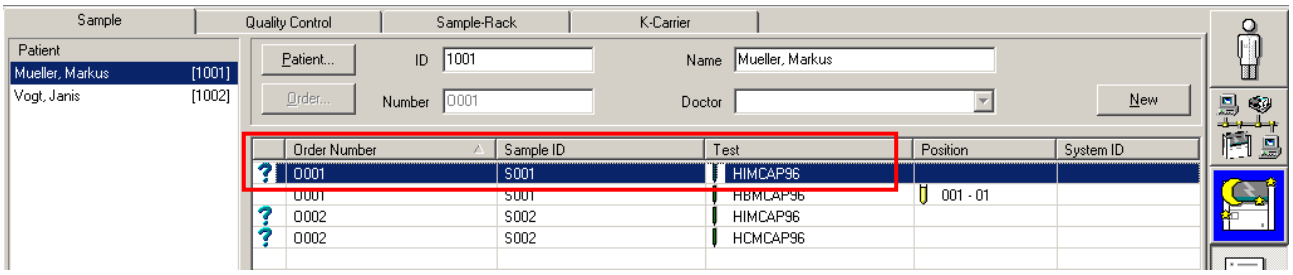

```
H|\^&|
P|1|7258969|7258969||Muster^Hans||19691014
O|1|1237651|116335|^^^HIMCAP48|||||||N|||||||||||||O
L|1|N
```



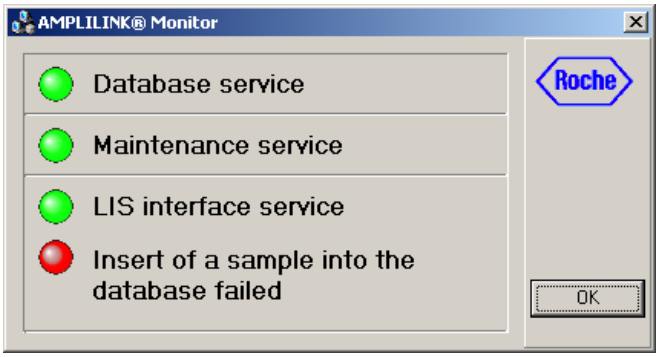
Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:7258969)
Hint	OrderDownload	Receive sample (New,OID:116335,SID:1237651,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:HIMCAP48)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:7258969)
Info	OrderDownload	Append sample succeeded (OID:116335,SID:1237651,ODATE:6/22/2007 2:52:45 PM)
Info	OrderDownload	Add test succeeded (TID:HIMCAP48)

8.2.2 Refuse to overwrite an existing order which is not in the status incomplete

(In this example there are the print screens and traces of AMPLILINK 3.1 Software series. There are no changes to AMPLILINK 3.2 Software series)

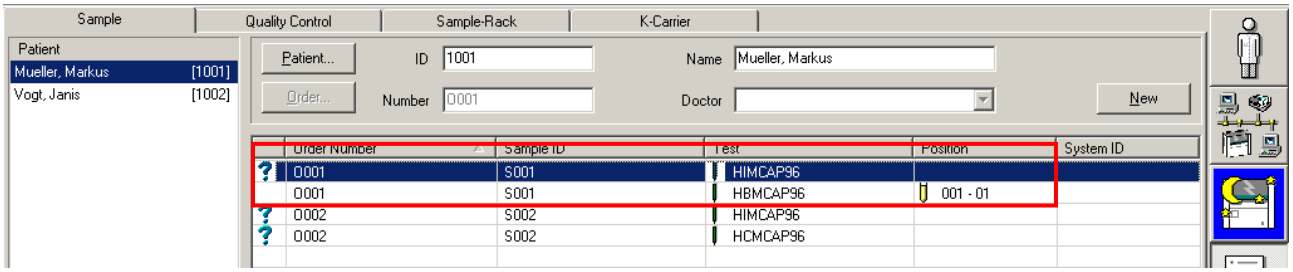



```
AMPLI 10:54:11,12 [ENQ]
HOST  10:54:11,12 [ACK]
AMPLI 10:54:11,25 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^169.254.159.61|||||||1|2
                  0051221105411[CR][ETX]0B[CR][LF]
HOST  10:54:11,29 [ACK]
AMPLI 10:54:11,39 [STX]2P|1||1001||Mueller^Markus||19780408|M|whi
                  te[CR][ETX]9B[CR][LF]
HOST  10:54:11,42 [ACK]
AMPLI 10:54:11,53 [STX]3O|1|S001|O001|^^^HCMCAP96||20040608170912
                  |||||N|||||||||||||X[CR][ETX]46[CR][LF]
HOST  10:54:11,56 [ACK]
AMPLI 10:54:11,64 [STX]4L|1|N[CR][ETX]07[CR][LF]
HOST  10:54:11,65 [ACK]
AMPLI 10:54:11,73 [EOT]
```



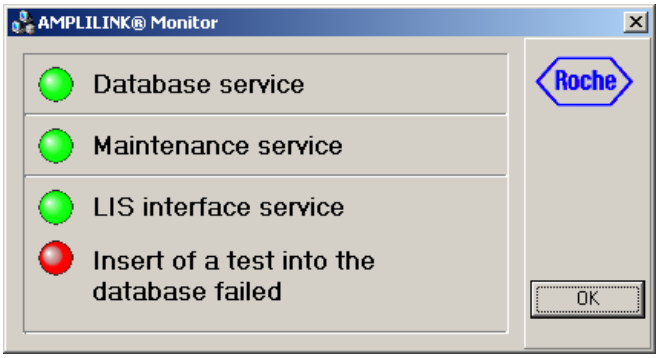
8.2.3 Refuse to add existing order which is already processed

(In this example there are the print screens and traces of AMPLILINK 3.1 Software series. There are no changes to AMPLILINK 3.2 Software series)



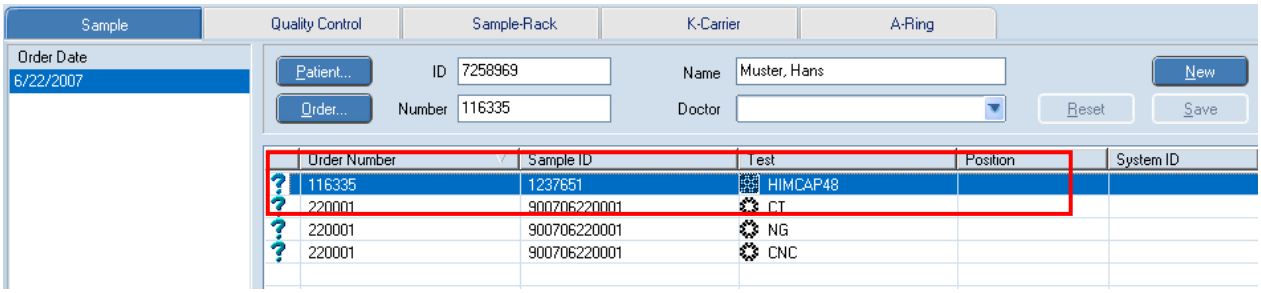

```
HOST  11:07:29,76 [ENQ]
AMPLI 11:07:29,84 [ACK]
HOST  11:07:29,87 [STX]1H|\^&|||^Roche^Host|||||||P|1|20040804133
                  658[CR][ETX]4D[CR][LF]
AMPLI 11:07:29,95 [ACK]
HOST  11:07:29,98 [STX]2P|1||1001||Mueller^Markus||19780408|M|whi
                  te|[CR][ETX]17[CR][LF]
AMPLI 11:07:30,06 [ACK]
HOST  11:07:30,09 [STX]3O|1|S001|O001|^^^HBMCAP96||20040608170912
                  |||||A||||||||||||||O[CR][ETX]2F[CR][LF]
AMPLI 11:07:30,18 [ACK]
HOST  11:07:30,20 [STX]4L|1|N[CR][ETX]07[CR][LF]
AMPLI 11:07:30,28 [ACK]
HOST  11:07:30,28 [EOT]

AMPLI 11:07:30,45 [ENQ]
HOST  11:07:30,46 [ACK]
AMPLI 11:07:30,59 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^169.254.159.61|||||||1|2
                  0051221110730[CR][ETX]0B[CR][LF]
HOST  11:07:30,67 [ACK]
AMPLI 11:07:30,76 [STX]2P|1||1001||Mueller^Markus||19780408|M|whi
                  te[CR][ETX]9B[CR][LF]
HOST  11:07:30,79 [ACK]
AMPLI 11:07:30,90 [STX]3O|1|S001|O001|^^^HBMCAP96||20040608170912
                  |||||A|||||||||||||X[CR][ETX]38[CR][LF]
HOST  11:07:30,93 [ACK]
AMPLI 11:07:31,01 [STX]4L|1|N[CR][ETX]07[CR][LF]
HOST  11:07:31,03 [ACK]
AMPLI 11:07:31,10 [EOT]
```

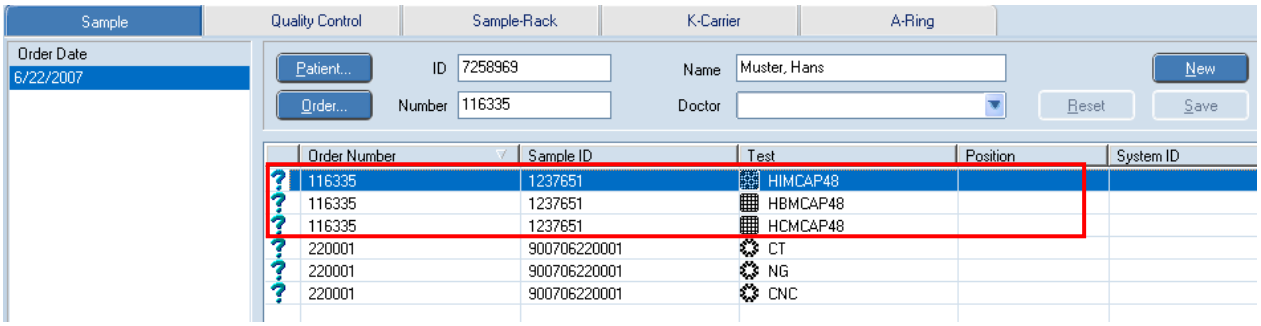


8.3 Order Record: Action Code Append

8.3.1 Append a Test to an existing order



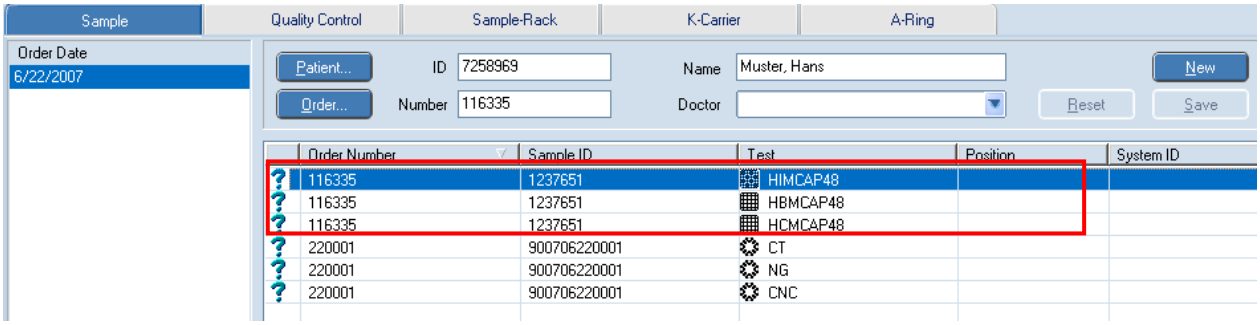

```
H|\^&|
P|1|7258969|7258969||Muster^Hans||19691014
O|1|1237651|116335|^^^HBMCAP48\^^^HCMCAP48|||||||A|||||||||||||O
L|1|N
```



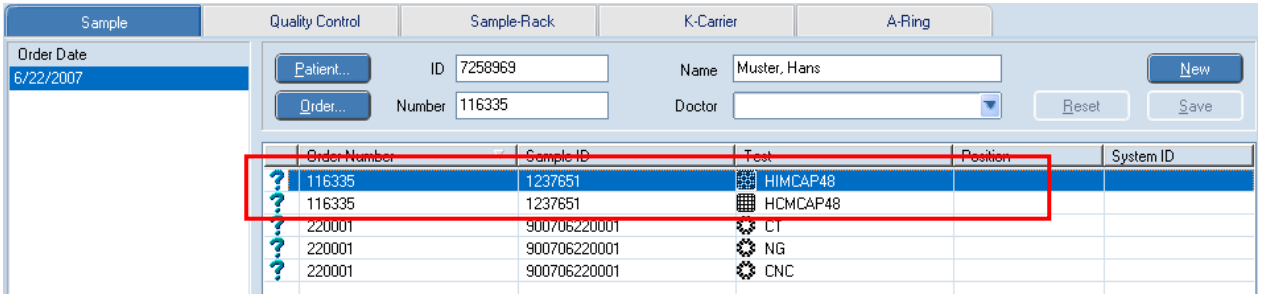
Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:7258969)
Hint	OrderDownload	Receive sample (Add,OID:116335,SID:1237651,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:HBMCAP48)
Hint	OrderDownload	Receive test (TID:HCMCAP48)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:7258969)
Info	OrderDownload	Append sample succeeded (OID:116335,SID:1237651,ODATE:6/22/2007 2:53:37 PM)
Info	<	<EOT>
Info	OrderDownload	Add test succeeded (TID:HBMCAP48)
Info	OrderDownload	Add test succeeded (TID:HCMCAP48)

8.4 Order Record: Action Code Cancel

8.4.1 Cancel a single order

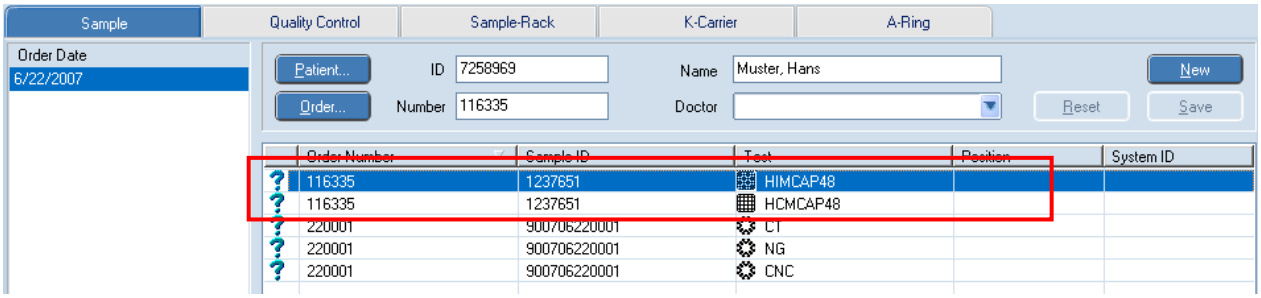



```
H|\^&|
P|1|7258969|7258969||Muster^Hans||19691014
O|1|1237651|116335|^^^HBMCAP48|||||||C|||||||||||||O
L|1|N
```

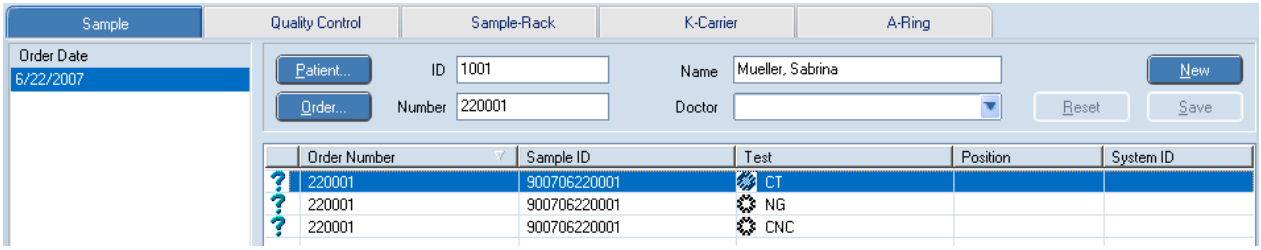


Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:7258969)
Hint	OrderDownload	Receive sample (Del,OID:116335,SID:1237651,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:HBMCAP48)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:7258969)
Info	OrderDownload	Del test succeeded (TID:HBMCAP48)

8.4.2 Cancel multiple orders




```
H|\^&|
P|1|7258969|7258969||Muster^Hans||19691014
O|1|1237651|116335|^^^all|||||||C|||||||||||||O
L|1|N
```



Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:7258969)
Hint	OrderDownload	Receive sample (Del,OID:116335,SID:1237651,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:all)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:7258969)
Info	OrderDownload	Del all tests succeeded
Info	OrderDownload	Del sample succeeded (OID:116335,SID:1237651)

8.4.3 Order download with SpecimenID and OrderID

The LIS sends one patient record with patientID and patient demographics. The orderrecord include a Specimen ID (ASTM field 9.4.3) and an OrderID (ASTM field 9.4.4).

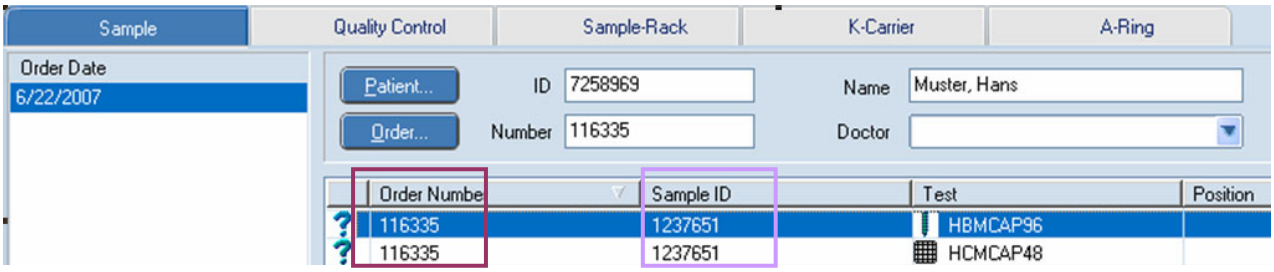
Order Record

```
H|\^&|
P|1|7258969|7258969||Muster^Hans||19691014
O|1|1237651|116335|^^^HBMCAP96\^^^HCMCAP48||||||A||||||||||||O
L|1|N
```

Trace Log of the LIS Interface Service

Info	<	<EOT>
Info	<	<ENQ>
Info	>	<ACK>
Info	<	<STX>1H|\^&|<CR><ETX>61<CR><LF>
Info	>	<ACK>
Info	<	<STX>2P|1|7258969|7258969||Muster^Hans||19691014<CR><ETX>2A<CR><LF>
Info	>	<ACK>
Info	<	<STX>3O|1|1237651|116335|^^^HBMCAP96\^^^HCMCAP48||||||A||||||||||O<CR><ETX>CD<CR><LF>
Info	>	<ACK>
Info	<	<STX>4L|1|N<CR><ETX>07<CR><LF>
Info	>	<ACK>
Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:7258969)
Hint	OrderDownload	Receive sample (Add,OID:116335,SID:1237651,ODATE:6/22/2007)
Hint	OrderDownload	Receive test (TID:HBMCAP96)
Hint	OrderDownload	Receive test (TID:HCMCAP48)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:7258969)
Info	OrderDownload	New sample succeeded (OID:116335,SID:1237651,ODATE:6/22/2007 2:51:42 PM)
Info	<	<EOT>
Info	OrderDownload	Add test succeeded (TID:HBMCAP96)
Info	OrderDownload	Add test succeeded (TID:HCMCAP48)

AMPLILINK Software: Order Tab



8.4.4 Calculated Order ID

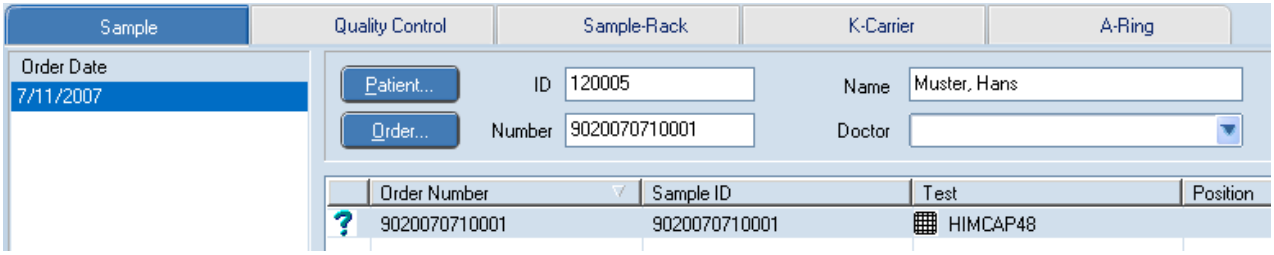
The LIS sends a patient record with patientID *(ASTM field 8.1.4)*, patient name and date of birth. With the order record only the SpecimenID *(ASTM field 9.4.3)* is sent. The OrderID is empty.
The OrderID is limited to 20 characters. With the setting displayed below you can use the **maximum length of 20 characters for SampleID/OrderID**. SampleID and OrderID will then be identical with that setting.
In LIS Configuration / Order Download select "Calculate Order ID from Specimen ID.
If the RequestedDateTime field is empty the LIS Interface always takes the current date and time

Example of an Order:

```
H|\^&|
P|1|120005|||Muster^Hans||19531014
O|1|9020070710001||^^^HIMCAP48|||||||A|||||||||||||O
L|1|N
```

LIS Trace Log

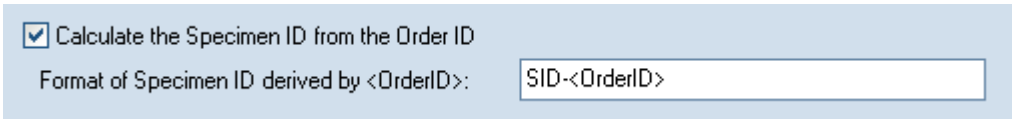
Info	<	<ENQ>
Info	>	<ACK>
Info	<	<STX>1H|\^&|<CR><ETX>61<CR><LF>
Info	>	<ACK>
Info	<	<STX>2P|1|120005|||Muster^Hans||19531014<CR><ETX>4F<CR><LF>
Info	>	<ACK>
Info	<	<STX>3O|1|9020070710001||^^^HIMCAP48|||||||A||||||||||||O<CR><ETX>32<CR><LF>
Info	>	<ACK>
Info	<	<STX>4L|1|N<CR><ETX>07<CR><LF>
Info	>	<ACK>
Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:)
Hint	OrderDownload	Receive sample (Add,OID:,SID:9020070710001,ODATE:7/10/2007)
Hint	OrderDownload	Receive test (TID:HIMCAP48)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	No patient to add (PID:<NULL>)
Info	OrderDownload	New sample succeeded (OID:9020070710001,SID:9020070710001,ODATE:7/10/2007 10:40:31 AM)
Info	OrderDownload	Add test succeeded (TID:HIMCAP48)



8.4.5 Calculate Specimen ID

The LIS sends one patient record with patientID *(ASTM field 8.1.4)* and patient name.
With the order record only the OrderID *(ASTM field 9.4.4)* is sent. The SpecimenID is empty.
In LIS Configuration / Order Download select “Calculate Specimen ID from OrderID.
If the RequestedDateTime field is empty the LIS Interface always takes the current date and time

AMPLILINK LIS Configuration Setting



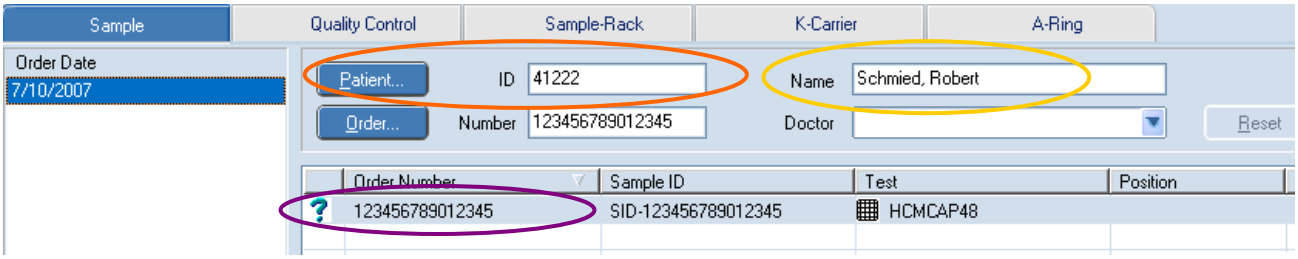
Example of an Order:

```
H|\^&|
P|1||41222||Schmied^Robert||19870117
O|1||12345678901234567890|^^^HCMCAP48|||||||A|||||||||||||O
L|1|N
```

LIS Trace Log

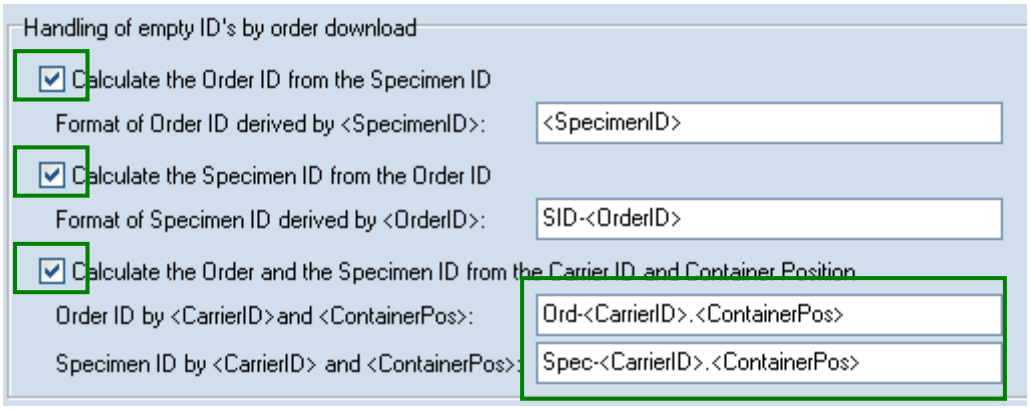
Info	>	<ACK>
Info	<	<STX>1H|\^&|<CR><ETX>61<CR><LF>
Info	>	<ACK>
Info	<	<STX>2P|1||41222||Schmied^Robert||19870117<CR><ETX>4D<CR><LF>
Info	>	<ACK>
Info	<	<STX>3O|1||123456789012345|^^^HCMCAP48|||||||A|||||||||||O<CR><ETX>AD<CR><LF>
Info	>	<ACK>
Info	<	<STX>4L|1|N<CR><ETX>07<CR><LF>
Info	>	<ACK>
Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:41222)
Hint	OrderDownload	Receive sample (Add,OID:123456789012345,SID:,ODATE:7/10/2007)
Hint	OrderDownload	Receive test (TID:HCMCAP48)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:41222)
Info	OrderDownload	New sample succeeded (OID:123456789012345,SID:SID-123456789012345,ODATE:7/10/2007 1:15:27 PM)
Info	OrderDownload	Add test succeeded (TID:HCMCAP48)

AMPLILINK Order Tab



8.4.6 Calculate OrderID and SpecimenID from the Container and Carrier Position

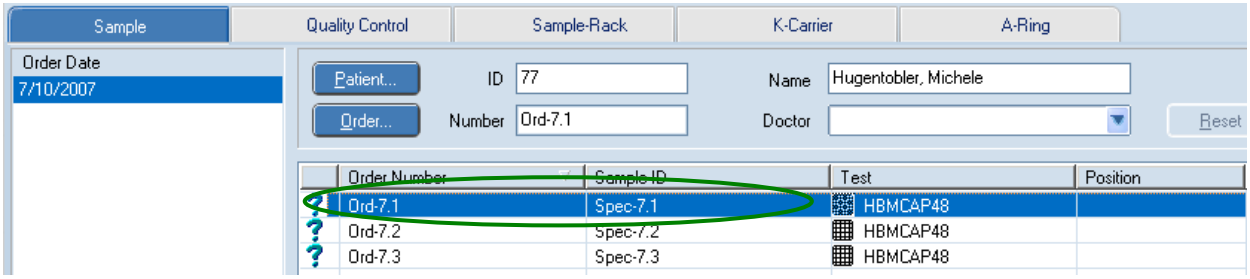
The LIS Interface calculates the OrderID and the SpecimenID from the **Container and Carrier Position**. Configuration if a host sends orders that do not contain an OrderID and a SpecimenID.



Example of an Order:

```
H|\^&||||||||||P|1|
P|1||77||Hugentobler^Michele||19810509|F||
O|1||^7^1|^^^HBMCAP48|||||||N|||||||||||||O
L|1|N
```

Info	>	<ACK>
Info	<	<STX>1H|\^&||||||||P|1|<CR><ETX>36<CR><LF>
Info	>	<ACK>
Info	<	<STX>2P|1||77||Hugentobler^Michele||19810509|F||<CR><ETX>84<CR><LF>
Info	>	<ACK>
Info	<	<STX>3O|1||^7^1|^^^HBMCAP48|||||||N||||||||||||O<CR><ETX>D1<CR><LF>
Info	>	<ACK>
Info	<	<STX>4L|1|N<CR><ETX>07<CR><LF>
Info	>	<ACK>
Hint	OrderDownload	Start msg
Hint	OrderDownload	Receive patient (PID:77)
Hint	OrderDownload	Receive sample (New,OID:,SID:,ODATE:7/10/2007)
Hint	OrderDownload	Receive test (TID:HBMCAP48)
Hint	OrderDownload	End msg
Hint	OrderDownload	Process (NoPat:1)
Info	OrderDownload	Add patient succeeded (PID:77)
Info	OrderDownload	New sample succeeded (OID:Ord-7.1,SID:Spec-7.1,ODATE:7/10/2007 2:03:34 PM)
Info	OrderDownload	Add test succeeded (TID:HBMCAP48)
Info	<	<EOT>



Order Download

No patient information (low level mode ASTM/Elecsys)

```
HOST  16:57:56,02 [ENQ]
AMPLI 16:57:56,02 [ACK]
HOST  16:57:56,04 [STX]1H|\^&|||·LIS-Simu^Roche^LIS-Simu^CAL·1.00
                  ^Roche·ASTM+^0.00|||||Instrument^localhost[CR][
                  ETX]50[CR][LF]
AMPLI 16:57:56,04 [ACK]
HOST  16:57:56,05 [STX]2P|1[CR][ETX]3F[CR][LF]
AMPLI 16:57:56,05 [ACK]
HOST  16:57:56,07 [STX]3O|1|30|30|^^^HCV\^^^HIV\^^^HBV|||||||A|||
                  ||||||||||O[CR][ETX]E3[CR][LF]
AMPLI 16:57:56,07 [ACK]
HOST  16:57:56,08 [STX]4O|2|31|31|^^^HCV\^^^HIV\^^^HBV|||||||A|||
                  ||||||||||O[CR][ETX]E6[CR][LF]
AMPLI 16:57:56,08 [ACK]
HOST  16:57:56,13 [STX]5O|3|32|32|^^^HCV\^^^HIV\^^^HBV|||||||A|||
                  ||||||||||O[CR][ETX]E7[CR][LF]
AMPLI 16:57:56,13 [ACK]
HOST  16:57:56,15 [STX]6L|1|N[CR][ETX]09[CR][LF]
AMPLI 16:57:56,15 [ACK]
HOST  16:57:56,15 [EOT]
```

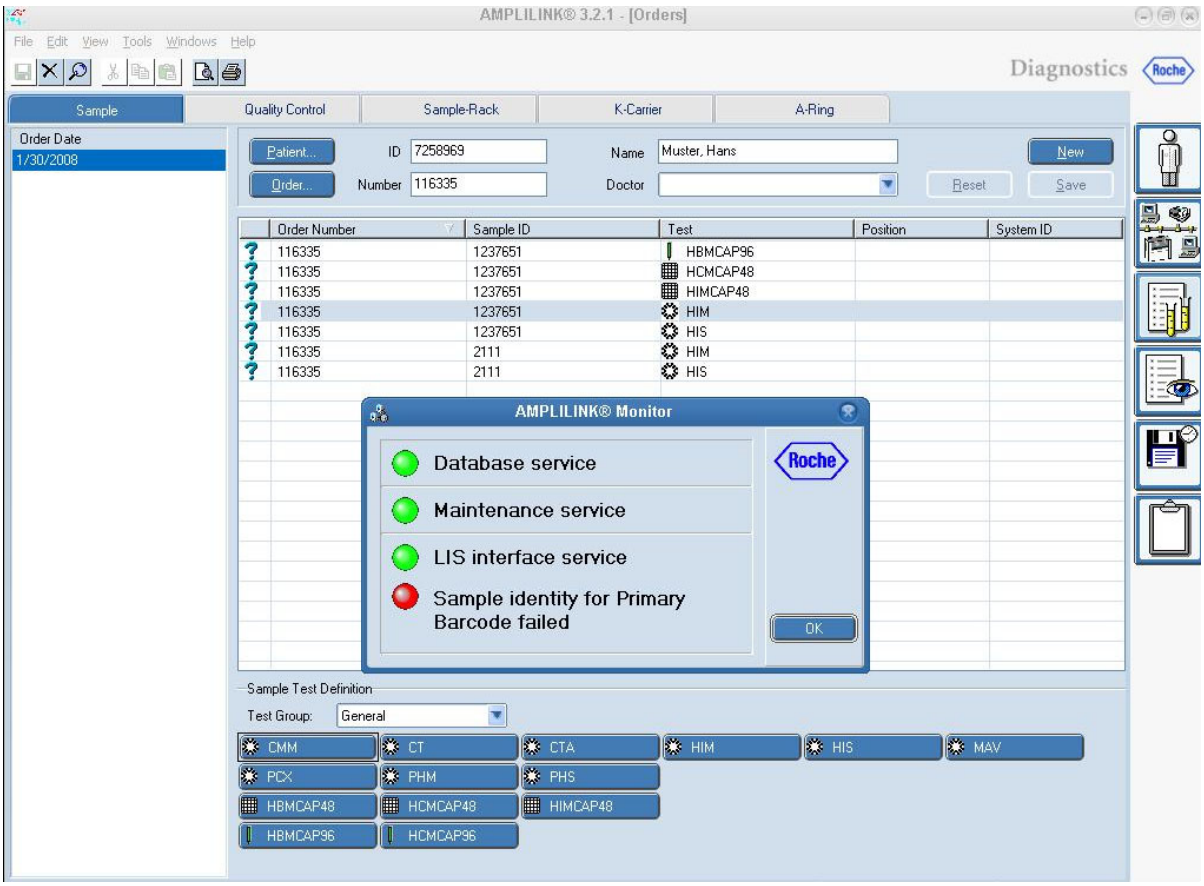
With patient demographics (without low level)

```
H|\^&|||^Roche^Host^1.0^1.0^1.0^127.0.0.1|||||||P|1|20040804133658<CR>
P|1||1001||Potter^Harry||19870408|M|white|||||||165|52|||||||||||||||<CR
>
O|1|15153|15153|^^^HIV||20040608170912|||||A||||||||||||O<CR>
L|1|N<CR>
```

8.5 Use the Specimen ID (Primary Barcode) as the Sample Identity

The following example has been made using the 'Use the Specimen ID (Primary Barcode) as the Sample Identity' Feature. (Setting is ticked).

It is possible to have the Order Number linked with several Sample ID:
Order Number 116335, with Sample ID 1237651 and Sample ID 211.



The Error Message 'Sample identity for Primary Barcode failed' occurs as an Order was sent to AMPLILINK for Order Number 11 and Sample ID 211. As the picture above shows Sample ID 211 is already linked to the Order Number 116335 in AMPLILINK. Therefore the Order with Order Number 11 and Sample ID 2111 is rejected (see also following trace log)

430	30.01.2008 12:44	Info	>	<ACK>
431	30.01.2008 12:44	Info	<	<STX>1H|\^&|<CR><ETX>61<CR><LF>
432	30.01.2008 12:44	Info	>	<ACK>
433	30.01.2008 12:44	Info	<	<STX>2P|1|7258969|7258969||Muster^Hans||19691014<CR><ETX>2A<CR><LF>
434	30.01.2008 12:44	Info	>	<ACK>
435	30.01.2008 12:44	Info	<	<STX>3O|1|2111|11|^^^CT\^^^CNC||||||A||||||||||||O<CR><ETX>91<CR><LF>
436	30.01.2008 12:44	Info	>	<ACK>
437	30.01.2008 12:44	Info	<	<STX>4L|1|N<CR><ETX>07<CR><LF>
438	30.01.2008 12:44	Info	>	<ACK>
439	30.01.2008 12:44	Hint	OrderDownload	Start msg
440	30.01.2008 12:44	Hint	OrderDownload	Receive patient (PID:7258969)
441	30.01.2008 12:44	Hint	OrderDownload	Receive sample (Add,OID:11,SID:2111,ODATE:1/30/2008)
442	30.01.2008 12:44	Hint	OrderDownload	Receive test (TID:CT)
443	30.01.2008 12:44	Hint	OrderDownload	Receive test (TID:CNC)
444	30.01.2008 12:44	Hint	OrderDownload	End msg
445	30.01.2008 12:44	Hint	OrderDownload	Process (NoPat:1)
446	30.01.2008 12:44	Info	OrderDownload	Add patient succeeded (PID:7258969)
447	30.01.2008 12:44	Info	OrderDownload	New sample succeeded (OID:11,SID:2111,ODATE:1/30/2008 12:44:00 PM)
448	30.01.2008 12:44	ERROR	OrderDownload	Add sample identity failed (PrimaryBarcode,SID:2111)
449	30.01.2008 12:44	Info	OrderDownload	Reject (PID:7258969,OID:11,SID:2111,TID:CT,TID:CNC)
450	30.01.2008 12:44	Info	<	<EOT>

8.6 Automatic Rack Assignment

Action Code N

The action code N (new) is needed in the first order message for an Automatic Rack Assignment.
Only then this first order message can create a new Sample Rack, K-Carrier or A-Ring ID.
The following orders that are assigned to an A-Ring that already exists in the AMPLILINK Database can have an N or an A (append) as Action Code.

LIS Trace Log:

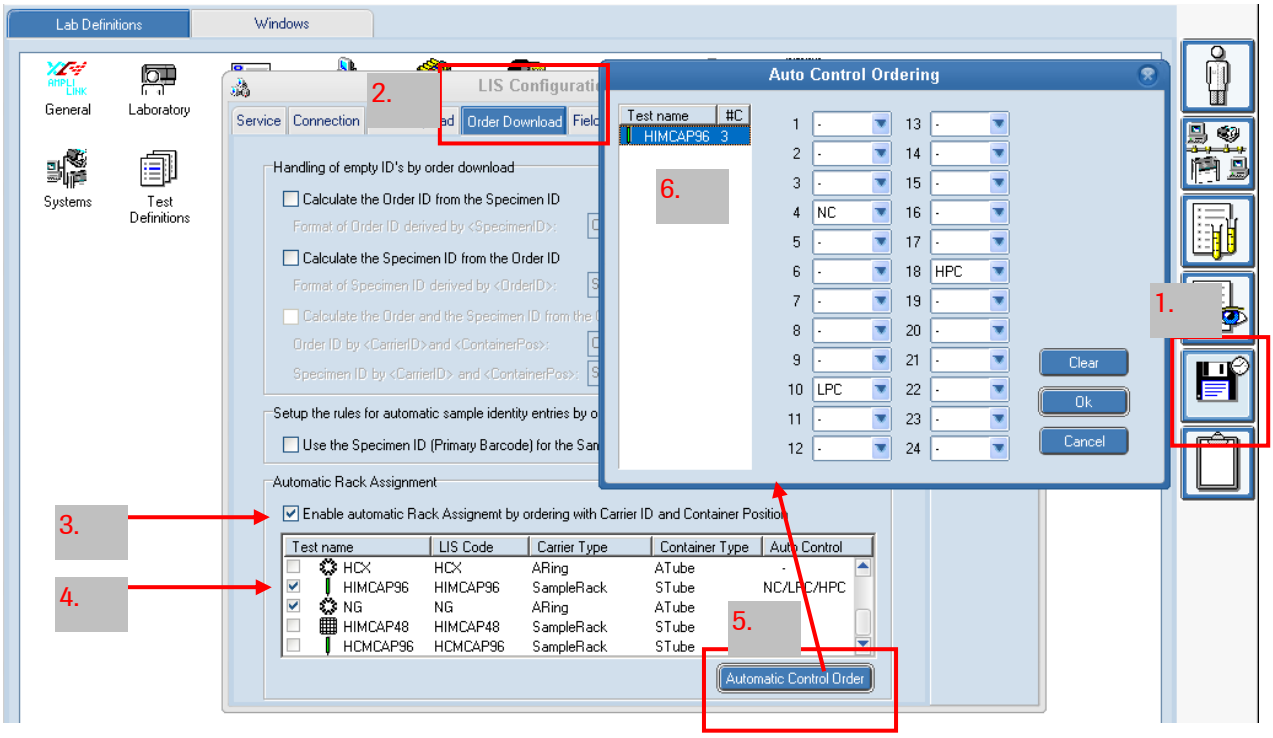
The first Sample that has to be assigned to an A-Ring contains the Action Code N for the creation of the A-Ring Rack:

Info	OrderDownload	Add patient succeeded (PID:150)
Info	OrderDownload	New sample succeeded (OID:112007020700001,SID:112007020700001,ODATE:7/2/2007 4:17:46 PM)
Info	OrderDownload	Add test succeeded (TID:CT)
Info	OrderDownload	Create ARing-Rack : (RID:105)
Info	OrderDownload	Add and bind sample identity for ARing: (RID:105,COP:1,TIN:1)

The following Samples can contain an N or an A as Action Code and are then added to the existing A-Ring Rack:

Info	OrderDownload	Add patient succeeded (PID:23007)
Info	OrderDownload	New sample succeeded (OID:112007020700003,SID:112007020700003,ODATE:7/12/2007 4:18:07 PM)
Info	OrderDownload	Add test succeeded (TID:CT)
Hint	OrderDownload	ARing-Rack found:105
Info	OrderDownload	Add and bind sample identity for ARing: (RID:105,COP:3,TIN:1)
Info	OrderDownload	Add test succeeded (TID:NG)

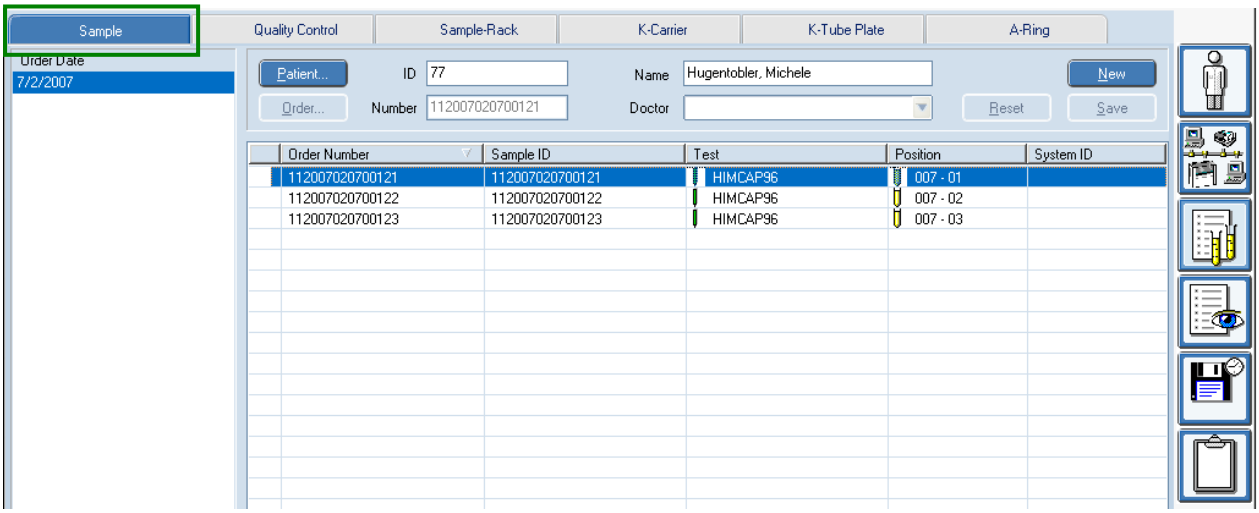
8.6.1 Automatic Rack Assignment for COBAS AmpliPrep Workflow:

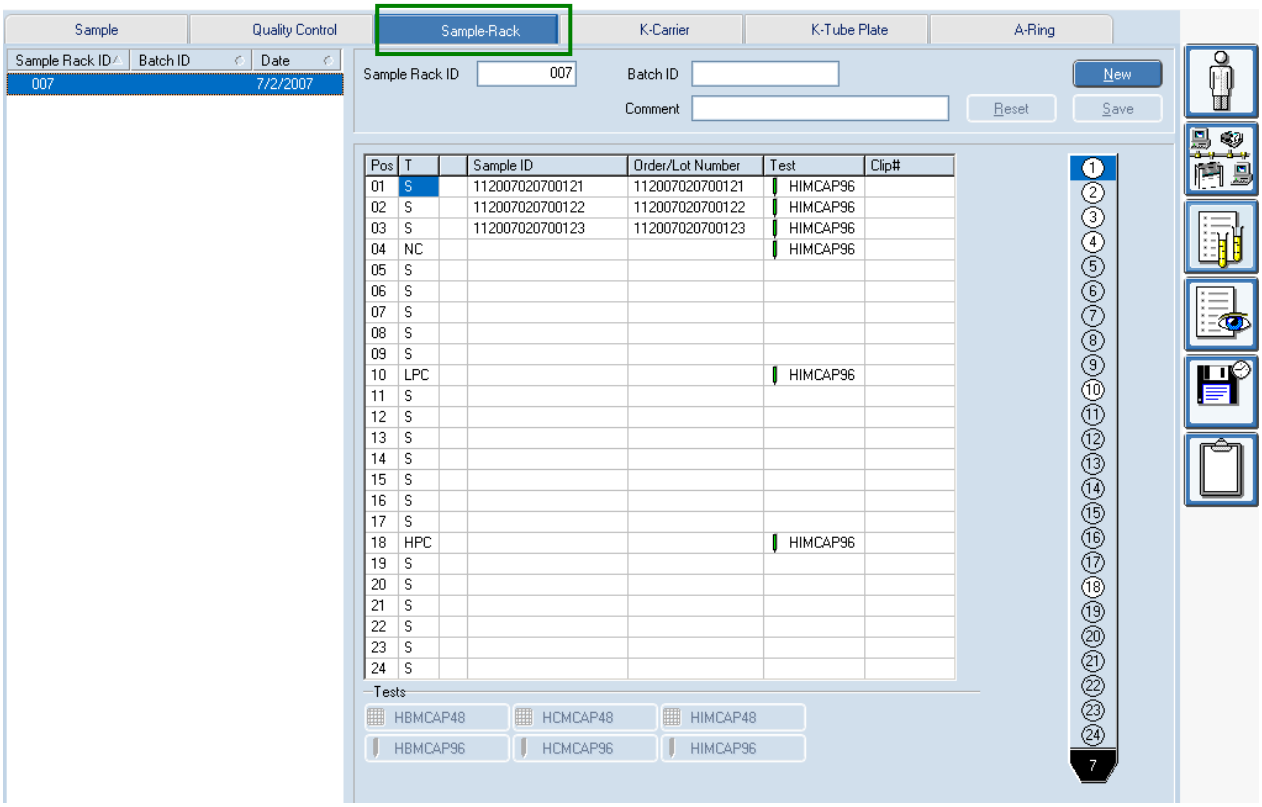


H|\^&|||||||||P|1|
P|1||77||Hugentobler^Michele||19810509|F||
O|1|112007020700121|112007020700121^7^1^^SampleRack^STube|^^^HIMCAP96|||||**N**|||||||||||O
L|1|N

H|\^&|||||||||P|1|
P|1||98||Meier^Martin||19780707|M||
O|1|112007020700122|112007020700122^7^2^^SampleRack^STube|^^^HIMCAP96|||||A|||||||||||O
L|1|N

H|\^&|||||||||P|1|
P|1||8854||Frei^Daniela||19880511|F||
O|1|112007020700123|112007020700123^7^3^^SampleRack^STube|^^^HIMCAP96|||||A|||||||||||O
L|1|N





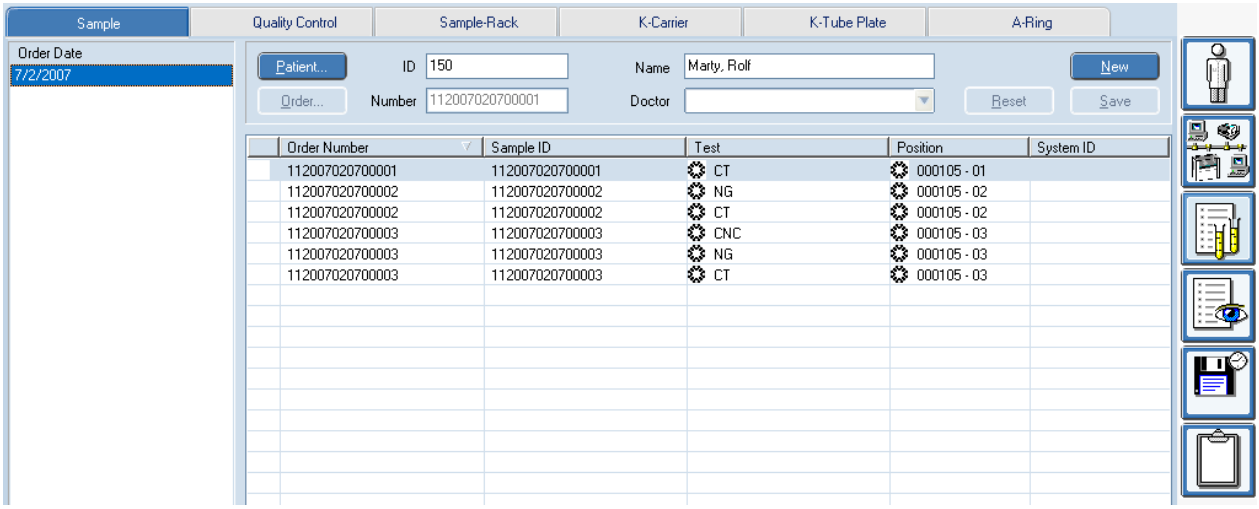
Controls are set automatically according to the settings in the Auto Control Ordering.

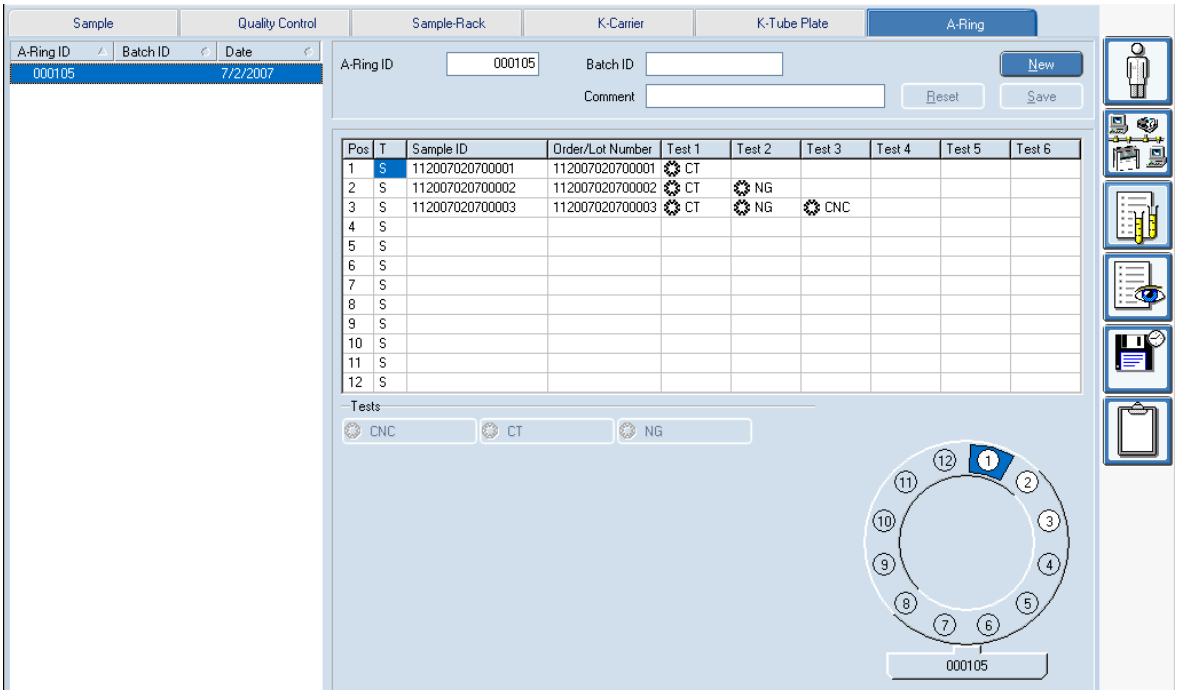
8.6.2 Automatic Rack Assignment for COBAS AMPLICOR Workflow:

H|\^&|||||||||P|1|
P|1|150|150||Marty^Rolf||19751005|M||
O|1|112007020700001|112007020700001^105^1^^ARing^ATube|^^^CT|||||||N|||||||||||||O
L|1|N

H|\^&|||||||||P|1|
P|1|85|85||Muster^Hans||19651703|M||
O|1|112007020700002|112007020700002^105^2^^ARing^ATube|^^^CT\^^^NG|||||||N|||||||||||||O
L|1|N

H|\^&|||||||||P|1|
P|1|23007|23007||Frei^Ulrich||19852101|M||
O|1|112007020700003|112007020700003^105^3^^ARing^ATube|^^^CT\^^^NG\^^^CNC|||||||N|||||||||||
||O
L|1|N





8.7 Result upload

In AMPLILINK 3.2 Software series the result format can be changed, *see 7.2.3.7 Result Format (Format of Result value))*Result Format

8.7.1 Automatic result upload QC results

(In this example there are the print screens and traces of AMPLILINK 3.1 Software series. There are no changes to AMPLILINK 3.2 Software series)

```
AMPLI 08:51:22,21 [ENQ]
HOST  08:51:22,21 [ACK]
AMPLI 08:51:22,31 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222085122[CR][ETX]CF[CR][LF]
HOST  08:51:22,32 [ACK]
AMPLI 08:51:22,40 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  08:51:22,40 [ACK]
AMPLI 08:51:22,51 [STX]3O|1||G0193400000|^^^ALL||20051118092128||
                  |^ml||Q\A||||HPC^G0193400000[CR][ETX]90[CR][LF]
HOST  08:51:22,51 [ACK]
AMPLI 08:51:22,60 [STX]4R|1|^^^HIMCAP96|455631.25|cp/mL|40^100000
                  00|N||V||JAMES|20051118102459|20051118132842
                  |391232[CR][ETX]B4[CR][LF]
HOST  08:51:22,62 [ACK]
AMPLI 08:51:22,70 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  08:51:22,70 [ACK]
AMPLI 08:51:22,79 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  08:51:22,79 [ACK]
AMPLI 08:51:22,87 [STX]7L|1|N[CR][ETX]0A[CR][LF]
HOST  08:51:22,87 [ACK]
AMPLI 08:51:22,95 [EOT]

AMPLI 08:51:23,06 [ENQ]
HOST  08:51:23,07 [ACK]
AMPLI 08:51:23,17 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222085123[CR][ETX]D0[CR][LF]
HOST  08:51:23,18 [ACK]
AMPLI 08:51:23,26 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  08:51:23,26 [ACK]
AMPLI 08:51:23,39 [STX]3O|1||G0193400000|^^^ALL||20051118092128||
                  |^ml||Q\A||||LPC^G0193400000[CR][ETX]94[CR][LF]
HOST  08:51:23,39 [ACK]
AMPLI 08:51:23,50 [STX]4R|1|^^^HIMCAP96|947.079895019531|cp/mL|40
                  ^10000000|N||V||JAMES|20051118102459|2005111
                  8132842|391232[CR][ETX]32[CR][LF]
HOST  08:51:23,50 [ACK]
AMPLI 08:51:23,57 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  08:51:23,57 [ACK]
AMPLI 08:51:23,65 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  08:51:23,65 [ACK]
AMPLI 08:51:23,73 [STX]7L|1|N[CR][ETX]0A[CR][LF]
HOST  08:51:23,73 [ACK]
```

```
AMPLI 08:51:23,81 [EOT]

AMPLI 08:51:23,92 [ENQ]
HOST  08:51:23,93 [ACK]
AMPLI 08:51:24,03 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222085123[CR][ETX]D0[CR][LF]
HOST  08:51:24,04 [ACK]
AMPLI 08:51:24,15 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  08:51:24,17 [ACK]
AMPLI 08:51:24,26 [STX]3O|1||G0193400000|^^^ALL||20051118092128||
                  |^ml||Q\A||||NC^G0193400000[CR][ETX]46[CR][LF]
HOST  08:51:24,26 [ACK]
AMPLI 08:51:24,35 [STX]4R|1|^^^HIMCAP96|Target·Not·Detected||40^1
                  0000000|N||V||JAMES|20051118102459|200511181
                  32842|391232[CR][ETX]26[CR][LF]
HOST  08:51:24,37 [ACK]
AMPLI 08:51:24,45 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  08:51:24,45 [ACK]
AMPLI 08:51:24,53 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  08:51:24,53 [ACK]
AMPLI 08:51:24,60 [STX]7C|3|I|TM71^·_S_RFITOOLOW|I[CR][ETX]9C[CR]
                  [LF]
HOST  08:51:24,60 [ACK]
AMPLI 08:51:24,68 [STX]0L|1|N[CR][ETX]03[CR][LF]
HOST  08:51:24,68 [ACK]
AMPLI 08:51:24,76 [EOT]
```

8.7.2 Automatic Sample result upload 1

(In this example there are the print screens and traces of AMPLILINK 3.1 Software series. There are no changes to AMPLILINK 3.2 Software series)

T	T #	Order/Lot Number	Test	Result
S	01	ORDER0001	HBMCAP96	1060758592 IU/mL
S	02	ORDER0001	HBMCAP96	1060758592 IU/mL
S	03	ORDER0001	HBMCAP96	1060758592 IU/mL
S	04	ORDER0002	HBMCAP96	TARGET NOT DETECT
S	05	ORDER0002	HBMCAP96	TARGET NOT DETECT
S	06	ORDER0002	HBMCAP96	TARGET NOT DETECT

```
AMPLI 08:35:34,18 [ENQ]
HOST  08:35:34,18 [ACK]
AMPLI 08:35:34,32 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^169.254.159.61|||||||1|2
                  0051221083533[CR][ETX]15[CR][LF]
HOST  08:35:34,32 [ACK]
AMPLI 08:35:34,42 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  08:35:34,43 [ACK]
AMPLI 08:35:34,54 [STX]3O|1|SA1|ORDER0001|^^^ALL||20051221083300|
                  ||^ml||A[CR][ETX]51[CR][LF]
HOST  08:35:34,54 [ACK]
AMPLI 08:35:34,67 [STX]4R|1|^^^HBMCAP96|1060758592|IU/mL|86823910
                  4^1299799040|N||V||SIMULATOR|20051221083518|200
                  51221093518|391278[CR][ETX]50[CR][LF]
HOST  08:35:34,68 [ACK]
AMPLI 08:35:34,82 [STX]5R|2|^^^HBMCAP96|1060758592|IU/mL|86823910
                  4^1299799040|N||V||SIMULATOR|20051221083518|200
                  51221093518|391278[CR][ETX]CF[CR][LF]
HOST  08:35:34,82 [ACK]
AMPLI 08:35:34,95 [STX]6R|3|^^^HBMCAP96|1060758592|IU/mL|86823910
                  4^1299799040|N||V||SIMULATOR|20051221083518|200
   51221093518|391278[CR][ETX]72[CR][LF]
HOST  08:35:34,96 [ACK]
AMPLI 08:35:35,07 [STX]7C|1||Test·comment·for·test·HBMCAP96·on·in
                  strument·TaqMan|G[CR][ETX]FE[CR][LF]
HOST  08:35:35,07 [ACK]
AMPLI 08:35:35,17 [STX]0L|1|N[CR][ETX]03[CR][LF]
HOST  08:35:35,17 [ACK]
AMPLI 08:35:35,26 [EOT]

AMPLI 08:35:35,48 [ENQ]
HOST  08:35:35,48 [ACK]
AMPLI 08:35:35,64 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^169.254.159.61|||||||1|2
                  0051221083535[CR][ETX]17[CR][LF]
HOST  08:35:35,64 [ACK]
AMPLI 08:35:35,75 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  08:35:35,78 [ACK]
AMPLI 08:35:35,89 [STX]3O|1|SA2|ORDER0002|^^^ALL||20051221083300|
                  ||^ml||A[CR][ETX]53[CR][LF]
HOST  08:35:35,89 [ACK]
AMPLI 08:35:36,01 [STX]4R|1|^^^HBMCAP96|TARGET·NOT·DETECTED||0^0|
                  N||V||SIMULATOR|20051221083518|20051221093518|3
                  91278[CR][ETX]6E[CR][LF]
```

```
HOST  08:35:36,03 [ACK]
AMPLI 08:35:36,17 [STX]5R|2|^^^HBMCAP96|85313496|IU/mL|483043040^
                  566864192|L||V||SIMULATOR|20051221083518|200512
                  21093518|391278[CR][ETX]AA[CR][LF]
HOST  08:35:36,17 [ACK]
AMPLI 08:35:36,28 [STX]6C|1||Test·comment·for·test·HBMCAP96·on·in
                  strument·TaqMan|G[CR][ETX]FD[CR][LF]
HOST  08:35:36,29 [ACK]
AMPLI 08:35:36,42 [STX]7R|3|^^^HBMCAP96|TARGET·NOT·DETECTED||0^0|
                  N||V||SIMULATOR|20051221083519|20051221093519|3
                  91278[CR][ETX]75[CR][LF]
HOST  08:35:36,43 [ACK]
AMPLI 08:35:36,53 [STX]0L|1|N[CR][ETX]03[CR][LF]
HOST  08:35:36,53 [ACK]
AMPLI 08:35:36,60 [EOT]
```

8.7.3 Automatic Sample result upload 2

(In this example there are the print screens and traces of AMPLILINK 3.1 Software series. There are no changes to AMPLILINK 3.2 Software series)

T #	Order/Lot Number	Test	Result
01	G0193400000	HIMCAP96	4.10E+5 cp/mL
02	G0193400000	HIMCAP96	7.45E+2 cp/mL
03	G0193400000	HIMCAP96	Target Not Detected
04	01	HIMCAP96	1.72E+2 cp/mL
05	02	HIMCAP96	8.33E+1 cp/mL
06	03	HIMCAP96	< 4.00E+1 cp/mL
07	04	HIMCAP96	Target Not Detected

```
AMPLI 09:04:41,57 [ENQ]
HOST  09:04:41,57 [ACK]
AMPLI 09:04:41,67 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222090441[CR][ETX]CF[CR][LF]
HOST  09:04:41,68 [ACK]
AMPLI 09:04:41,76 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  09:04:41,76 [ACK]
AMPLI 09:04:41,85 [STX]3O|1|S1|O1|^^^ALL||2
                  0051118073840|||0^ml||A[CR][ETX]D8[CR][LF]
HOST  09:04:41,85 [ACK]
AMPLI 09:04:41,95 [STX]4R|1|^^^HIMCAP96|171.801971435547|cp/mL|40
                  ^10000000|N||V||JAMES|20051118085515|2005111
                  8120555|391232[CR][ETX]25[CR][LF]
HOST  09:04:41,96 [ACK]
AMPLI 09:04:42,04 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  09:04:42,04 [ACK]
AMPLI 09:04:42,12 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  09:04:42,12 [ACK]
AMPLI 09:04:42,20 [STX]7L|1|N[CR][ETX]0A[CR][LF]
HOST  09:04:42,20 [ACK]
AMPLI 09:04:42,28 [EOT]

AMPLI 09:04:42,37 [ENQ]
HOST  09:04:42,37 [ACK]
AMPLI 09:04:42,46 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
```

```
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222090442[CR][ETX]D0[CR][LF]
HOST  09:04:42,48 [ACK]
AMPLI 09:04:42,57 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  09:04:42,57 [ACK]
AMPLI 09:04:42,67 [STX]3O|1|S2|O2|^^^ALL||2
                  0051118073844|||0^ml||A[CR][ETX]CB[CR][LF]
HOST  09:04:42,67 [ACK]
AMPLI 09:04:42,76 [STX]4R|1|^^^HIMCAP96|83.302604675293|cp/mL|40^
                  10000000|N||V||JAMES|20051118085515|20051118
                  120555|391232[CR][ETX]F0[CR][LF]
HOST  09:04:42,78 [ACK]
AMPLI 09:04:42,85 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  09:04:42,85 [ACK]
AMPLI 09:04:42,95 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  09:04:42,95 [ACK]
AMPLI 09:04:43,03 [STX]7L|1|N[CR][ETX]0A[CR][LF]
HOST  09:04:43,03 [ACK]
AMPLI 09:04:43,10 [EOT]

AMPLI 09:04:43,21 [ENQ]
HOST  09:04:43,21 [ACK]
AMPLI 09:04:43,31 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222090443[CR][ETX]D1[CR][LF]
HOST  09:04:43,32 [ACK]
AMPLI 09:04:43,40 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  09:04:43,40 [ACK]
AMPLI 09:04:43,53 [STX]3O|1|S3|O3|^^^ALL||2
                  0051118073848|||0^ml||A[CR][ETX]CC[CR][LF]
HOST  09:04:43,53 [ACK]
AMPLI 09:04:43,65 [STX]4R|1|^^^HIMCAP96|28.1697330474854|cp/mL|40
                  ^10000000|<||V||JAMES|20051118085515|2005111
                  8120555|391232[CR][ETX]1B[CR][LF]
HOST  09:04:43,65 [ACK]
AMPLI 09:04:43,73 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  09:04:43,73 [ACK]
AMPLI 09:04:43,81 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  09:04:43,81 [ACK]
AMPLI 09:04:43,89 [STX]7L|1|N[CR][ETX]0A[CR][LF]
HOST  09:04:43,89 [ACK]
AMPLI 09:04:43,96 [EOT]

AMPLI 09:04:44,04 [ENQ]
HOST  09:04:44,04 [ACK]
AMPLI 09:04:44,14 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222090443[CR][ETX]D1[CR][LF]
HOST  09:04:44,15 [ACK]
AMPLI 09:04:44,23 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  09:04:44,23 [ACK]
AMPLI 09:04:44,34 [STX]3O|1|S4|O4|^^^ALL||2
                  0051118073852|||0^ml||A[CR][ETX]D0[CR][LF]
HOST  09:04:44,35 [ACK]
AMPLI 09:04:44,45 [STX]4R|1|^^^HIMCAP96|Target·Not·Detected||40^1
```

```
                  0000000|N||V||JAMES|20051118085515|200511181
                  20555|391232[CR][ETX]27[CR][LF]
HOST  09:04:44,46 [ACK]
AMPLI 09:04:44,54 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  09:04:44,54 [ACK]
AMPLI 09:04:44,62 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  09:04:44,62 [ACK]
AMPLI 09:04:44,70 [STX]7C|3|I|TM71^·_S_RFITOOLOW|I[CR][ETX]9C[CR]
                  [LF]
HOST  09:04:44,70 [ACK]
AMPLI 09:04:44,78 [STX]0L|1|N[CR][ETX]03[CR][LF]
HOST  09:04:44,78 [ACK]
AMPLI 09:04:44,85 [EOT]

AMPLI 09:04:44,93 [ENQ]
HOST  09:04:44,93 [ACK]
AMPLI 09:04:45,04 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222090444[CR][ETX]D2[CR][LF]
HOST  09:04:45,04 [ACK]
AMPLI 09:04:45,14 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  09:04:45,14 [ACK]
AMPLI 09:04:45,25 [STX]3O|1||G0193400000|^^^ALL||20051118074658||
                  |^ml||Q\A||||HPC^G0193400000[CR][ETX]98[CR][LF]
HOST  09:04:45,25 [ACK]
AMPLI 09:04:45,34 [STX]4R|1|^^^HIMCAP96|410342.75|cp/mL|40^100000
                  00|N||V||JAMES|20051118085515|20051118120555
                  |391232[CR][ETX]B0[CR][LF]
HOST  09:04:45,35 [ACK]
AMPLI 09:04:45,43 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  09:04:45,43 [ACK]
AMPLI 09:04:45,53 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  09:04:45,53 [ACK]
AMPLI 09:04:45,60 [STX]7L|1|N[CR][ETX]0A[CR][LF]
HOST  09:04:45,60 [ACK]
AMPLI 09:04:45,68 [EOT]

AMPLI 09:04:45,75 [ENQ]
HOST  09:04:45,76 [ACK]
AMPLI 09:04:45,85 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11|||||||1|20
                  051222090445[CR][ETX]D3[CR][LF]
HOST  09:04:45,87 [ACK]
AMPLI 09:04:45,95 [STX]2P|1|||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  09:04:45,96 [ACK]
AMPLI 09:04:46,06 [STX]3O|1||G0193400000|^^^ALL||20051118074658||
                  |^ml||Q\A||||LPC^G0193400000[CR][ETX]9C[CR][LF]
HOST  09:04:46,06 [ACK]
AMPLI 09:04:46,15 [STX]4R|1|^^^HIMCAP96|744.925415039063|cp/mL|40
                  ^10000000|N||V||JAMES|20051118085515|2005111
                  8120555|391232[CR][ETX]24[CR][LF]
HOST  09:04:46,17 [ACK]
AMPLI 09:04:46,25 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  09:04:46,25 [ACK]
AMPLI 09:04:46,32 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
```

```
                  [LF]
HOST  09:04:46,32 [ACK]
AMPLI 09:04:46,40 [STX]7L|1|N[CR][ETX]0A[CR][LF]
HOST  09:04:46,40 [ACK]
AMPLI 09:04:46,48 [EOT]

AMPLI 09:04:46,54 [ENQ]
HOST  09:04:46,56 [ACK]
AMPLI 09:04:46,65 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^196.254.10.11||||||||1|20
                  051222090446[CR][ETX]D4[CR][LF]
HOST  09:04:46,67 [ACK]
AMPLI 09:04:46,75 [STX]2P|1||||||||NotDef|||||||^cm|^kg[CR][ETX]9
                  D[CR][LF]
HOST  09:04:46,75 [ACK]
AMPLI 09:04:46,87 [STX]3O|1||G0193400000|^^^ALL||20051118074658||
                  |^ml||Q\A||||NC^G0193400000[CR][ETX]4E[CR][LF]
HOST  09:04:46,87 [ACK]
AMPLI 09:04:46,96 [STX]4R|1|^^^HIMCAP96|Target·Not·Detected||40^1
                  0000000|N||V||JAMES|20051118085515|200511181
                  20555|391232[CR][ETX]27[CR][LF]
HOST  09:04:47,00 [ACK]
AMPLI 09:04:47,07 [STX]5C|1|I|TM52^·_Q_STEP_CORR|I[CR][ETX]A1[CR]
                  [LF]
HOST  09:04:47,07 [ACK]
AMPLI 09:04:47,15 [STX]6C|2|I|TM62^·_S_STEP_CORR|I[CR][ETX]A6[CR]
                  [LF]
HOST  09:04:47,15 [ACK]
AMPLI 09:04:47,23 [STX]7C|3|I|TM71^·_S_RFITOOLOW|I[CR][ETX]9C[CR]
                  [LF]
HOST  09:04:47,23 [ACK]
AMPLI 09:04:47,31 [STX]0L|1|N[CR][ETX]03[CR][LF]
HOST  09:04:47,31 [ACK]
AMPLI 09:04:47,39 [EOT]
```

8.7.4 Manual Sample and Control result upload (two results)

In this example there are the print screens of AMPLILINK 3.2 Software series and traces from the ASTM Host Simulator. There are two results being sent. See also chapter *4.2.7 Result format* for more details.

	T	T #	Order/Lot Number	Sample ID	Test	Result
▶	NC	01	J13565	CT-NG+	CT	(0.008 OD)
	PC	01	J13565	CT-NG+	NG	(3.812 OD)
	PC	02	J13565	NG-CT+	CT	(3.511 OD)
	NC	02	J13565	NG-CT+	NG	(0.006 OD)
	S	03	08027439	08027439	CT	NEG (0.007 OD)
	S	03	08027439	08027439	NG	NEG (0.007 OD)
	S	03	08027439	08027439	CNC	POS (3.812 OD)
	S	04	08027440	08027440	CT	NEG (0.006 OD)
	S	04	08027440	08027440	NG	NEG (0.006 OD)
	S	04	08027440	08027440	CNC	POS (*.*** OD)

Trace of ASTM Host Simulator Tool

```
*       15:20:26,187 Amplilink 3.x - ASTM Host Simulator [V 6.7]
*                    Trace File    : ASTM_AL3.TRC
*                    Date and Time: 09/04/2008 03:20 PM
*                    Interface     : TCP/IP - SERVER
*                                    Local:127.0.0.1
*                                    Remote:127.0.0.1
*                    Operator      :
*                    Spaces        : · (Code: 183)


AL3     15:28:38,316 H|\^&|||TROMWCOE5239^Roche^AMPLILINK^3.2.0.0609
                     ^Roche·ASTM+^TROMWCOE5239^10.130.247.62|||||||
                     1|20080904152837[CR]
AL3     15:28:38,363 P|1||19470210RMHR15||RMH0800322^R||194702100000
                     00|F|||||||0^cm|0^kg[CR]
AL3     15:28:38,425 O|1|08027440|08027440|^^^ALL|R|20080812154800||
                     |0^ml||A[CR]
AL3     15:28:38,456 R|1|^^^CT|NEG^0.006|OD||N||V|||200808
                     14202628|20080814202628|396451[CR]
AL3     15:28:39,519 R|2|^^^NG|NEG^0.006|OD||N||V||LIS|2008081420551
                     1|20080814205511|396451[CR]
AL3     15:28:39,550 R|3|^^^CNC|POS^*.***|OD||N||V|||20080
                     814211910|20080814211910|396451[CR]
AL3     15:28:39,566 L|1|N[CR]

AL3     15:28:39,988 H|\^&|||TROMWCOE5239^Roche^AMPLILINK^3.2.0.0609
                     ^Roche·ASTM+^TROMWCOE5239^10.130.247.62|||||||
                     1|20080904152838[CR]
AL3     15:28:40,003 P|1||19671208RMHR05||RMH0800321^R||196712080000
                     00|M|||||||0^cm|0^kg[CR]
AL3     15:28:40,034 O|1|08027439|08027439|^^^ALL|R|20080812154600||
                     |0^ml||A[CR]
AL3     15:28:40,081 R|1|^^^CNC|POS^3.812|OD||N||V|||20080
                     814211758|20080814211758|396451[CR]
AL3     15:28:40,097 L|1|N[CR]

AL3     15:28:40,456 H|\^&|||TROMWCOE5239^Roche^AMPLILINK^3.2.0.0609
                     ^Roche·ASTM+^TROMWCOE5239^10.130.247.62|||||||
```

```
                    1|20080904152838[CR]
AL3     15:28:40,488 P|1||19671208RMHR05||RMH0800321^R||196712080000
                    00|M|||||||0^cm|0^kg[CR]
AL3     15:28:40,519 O|1|08027439|08027439|^^^ALL|R|20080812154600||
                    |0^ml||A[CR]
AL3     15:28:40,831 R|1|^^^CT|NEG^0.007|OD||N||V|||200808
                    14202516|20080814202516|396451[CR]
AL3     15:28:40,863 R|2|^^^NG|NEG^0.007|OD||N||V||LIS|2008081420535
                    9|20080814205359|396451[CR]
AL3     15:28:40,878 L|1|N[CR]

AL3     15:28:40,925 H|\^&|||TROMWCOE5239^Roche^AMPLILINK^3.2.0.0609
                    ^Roche·ASTM+^TROMWCOE5239^10.130.247.62|||||||
                    1|20080904152838[CR]
AL3     15:28:40,941 P|1[CR]
AL3     15:28:40,988 O|1|CT-NG+|J13565|^^^ALL||20080710092340|||||Q\
                    A||||NC^J13565[CR]
AL3     15:28:41,003 R|1|^^^CT|·^0.008|OD||N||V||BOS10|2008081420225
                    2|20080814202252|396451[CR]
AL3     15:28:41,034 R|2|^^^NG|·^3.812|OD||N||V|||20080814
                    205138|20080814205138|396451[CR]
AL3     15:28:41,050 L|1|N[CR]

AL3     15:28:41,113 H|\^&|||TROMWCOE5239^Roche^AMPLILINK^3.2.0.0609
                    ^Roche·ASTM+^TROMWCOE5239^10.130.247.62|||||||
                    1|20080904152839[CR]
AL3     15:28:41,128 P|1[CR]
AL3     15:28:41,159 O|1|NG-CT+|J13565|^^^ALL||20080710092340|||||Q\
                    A||||PC^J13565[CR]
AL3     15:28:41,175 R|1|^^^CT|·^3.511|OD||N||V|||20080814
                    202404|20080814202404|396451[CR]
AL3     15:28:41,206 R|2|^^^NG|·^0.006|OD||N||V||BOS10|2008081420524
                    7|20080814205247|396451[CR]
AL3     15:28:41,222 L|1|N[CR]
```

8.7.5 Result request

```
Result request for all HIMCAP96 tests:

HOST  11:29:13,95 [ENQ]
AMPLI 11:29:14,03 [ACK]
HOST  11:29:14,06 [STX]1H|\^&|||LIS-Simulator^Roche^LIS-Simulator
                  ^CAL·1.00^Roche·ASTM+^0.00||||||P|1.00|2003091
                  6100257[CR][ETX]D7[CR][LF]
AMPLI 11:29:14,14 [ACK]
HOST  11:29:14,15 [STX]2Q|1|||HIMCAP96|||||||F[CR][ETX]FB[CR][LF
                  ]
AMPLI 11:29:14,23 [ACK]
HOST  11:29:14,25 [STX]3L|1|N[CR][ETX]06[CR][LF]
AMPLI 11:29:14,32 [ACK]
HOST  11:29:14,32 [EOT]
```

8.7.6 Result request with 'No Results'

(In this example there are the print screens and traces of AMPLILINK 3.1 Software series. There are no changes to AMPLILINK 3.2 Software series)

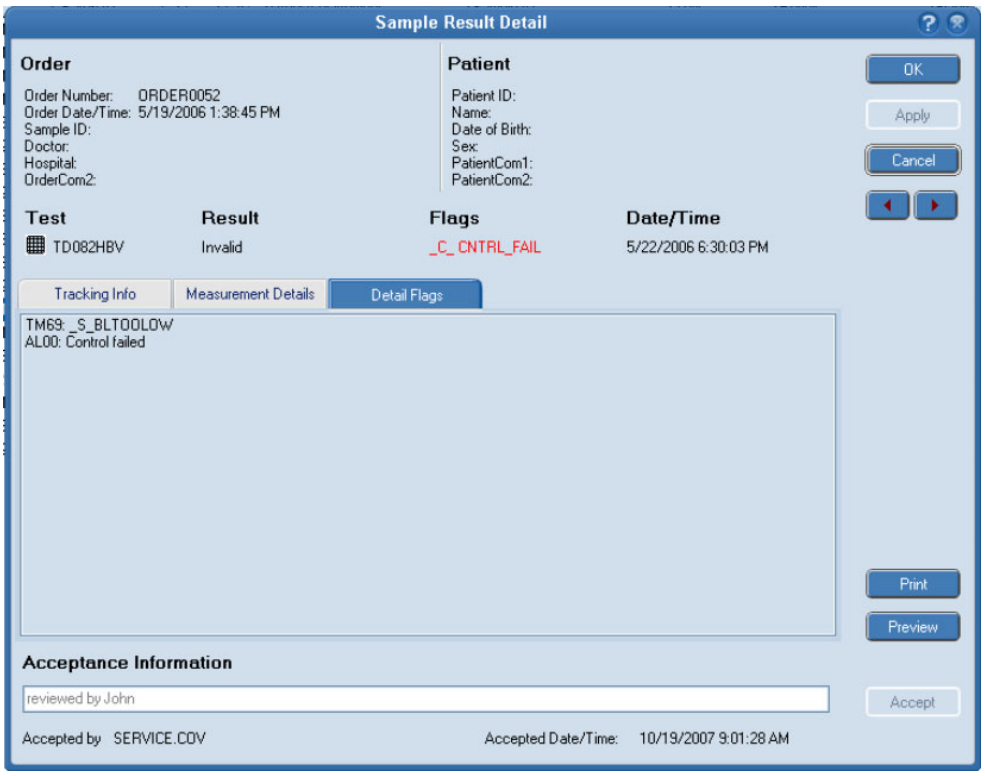
```
HOST  09:43:57,37 [ENQ]
AMPLI 09:43:57,45 [ACK]
HOST  09:43:57,51 [STX]1H|\^&|||LIS-Simulator^Roche^LIS-Simulator
                  ^CAL·1.00^Roche·ASTM+^0.00|||||||P|1.00|2003091
                  6100257[CR][ETX]D7[CR][LF]
AMPLI 09:43:57,59 [ACK]
HOST  09:43:57,62 [STX]2Q|1|^^ORDER0005||||||||||F[CR][ETX]D7[CR]
                  [LF]
AMPLI 09:43:57,70 [ACK]
HOST  09:43:57,71 [STX]3L|1|N[CR][ETX]06[CR][LF]
AMPLI 09:43:57,79 [ACK]
HOST  09:43:57,79 [EOT]

AMPLI 09:43:58,35 [ENQ]
HOST  09:43:58,37 [ACK]
AMPLI 09:43:58,51 [STX]1H|\^&|||ALFR9999^Roche^AMPLILINK^3.1.1.05
                  01^Roche·ASTM+^FR9999^169.254.159.61||||||||1|2
                  0051221094358[CR][ETX]1C[CR][LF]
HOST  09:43:58,51 [ACK]
AMPLI 09:43:58,59 [STX]2P|1[CR][ETX]3F[CR][LF]
HOST  09:43:58,60 [ACK]
AMPLI 09:43:58,71 [STX]3O|1||ORDER0005|||||||A|||||||||||||Z[CR
                  ][ETX]BB[CR][LF]
HOST  09:43:58,71 [ACK]
AMPLI 09:43:58,79 [STX]4L|1|N[CR][ETX]07[CR][LF]
HOST  09:43:58,81 [ACK]
```

Query for Order0005 which does not exist in the AMPLILINK Database

Empty reply by AMPLILINK

8.7.7 Result upload: Mapping of AMPLILINK Flags and LIS Abnormal Flag



Trace ASTM Host Simulator

```
AMPLI 09:11:55,41 [ENQ]
HOST  09:11:55,41 [ACK]
AMPLI 09:11:55,44 [STX]1H|\^&|||ALFRB3270K6S^Roche^AMPLILINK^3.2.
                  0.0609^Roche·ASTM+^FRB3270K6S^172.25.1.17||||||
                  ||1|20071019090135[CR][ETX]76[CR][LF]
HOST  09:11:55,45 [ACK]
AMPLI 09:11:55,51 [STX]2P|1[CR][ETX]3F[CR][LF]
HOST  09:11:55,52 [ACK]
AMPLI 09:11:55,59 [STX]3O|1||ORDER0052|^^^ALL||20060519133845||||
                  |A[CR][ETX]5D[CR][LF]
HOST  09:11:55,60 [ACK]
AMPLI 09:11:55,61 [STX]4R|1|^^^TD082HBV|Invalid||0^999999995904|A
                  ||X||1|20060522161354|20060522183003|1345[CR][E
                  TX]4A[CR][LF]
HOST  09:11:55,63 [ACK]
AMPLI 09:11:55,64 [STX]5C|1||reviewed·by·John|G[CR][ETX]F5[CR][LF
                  ]
HOST  09:11:55,65 [ACK]
AMPLI 09:11:55,66 [STX]6C|2|I|TM69^·_S_BLTOOLOW|I[CR][ETX]4E[CR][
                  LF]
HOST  09:11:55,67 [ACK]
AMPLI 09:11:55,68 [STX]7C|3|I|AL00^·Control·failed|I[CR][ETX]10[C
                  R][LF]
HOST  09:11:55,69 [ACK]
AMPLI 09:11:55,70 [STX]0L|1|N[CR][ETX]03[CR][LF]
HOST  09:11:55,71 [ACK]
AMPLI 09:11:55,72 [EOT]
```

9. Glossary

The terminology that is used with the AMPLILINK software is generally the same as that used in clinical laboratories. Certain specific terms, however, are used for description of an operation or a component. A summary of these terms and their definitions is provided below.

Term	Definition
AL	AMPLILINK Software
AMPLILINK Software	Custom software running under the Microsoft Windows XP Professional operating system.. AMPLILINK software allows operation and data management of various COBAS® instruments.
ASTM	American Society for Testing and Materials. The protocol used for data exchange between AMPLILINK software and the LIS.
Instrument LAN	Reserved Roche LAN to connect **only** COBAS instruments and analyzers supported by the AMPLILINK Software via Hub or Switch
Laboratory LAN	Reserved Roche LAN to connect i.e. different Data Stations AMPLILINK or a printer via Hub or Switch. This LAN has to be protected by e.g. the cobas IT firewall if connected to a customer network. See also chapter *Safety*
LAN	Local Area Network. The data station for AMPLILINK software has to network card, called the Instrument LAN and Laboratory LAN.
LIS	Laboratory Information System. A computerized system for entering, managing and reporting laboratory information. Information includes but is not limited to patient demographics, test orders, and test results..