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## **Updated URGENT FIELD SAFETY NOTICE**

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Product Name: AMPLILINK (AL) software v. 3.2  
FSCA Identifier: PAN\_RMD\_2012\_01

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Type of Action: Field Safety Corrective Action

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Date: xx-Apr-2012

Attention: Laboratory Director  
PCR Laboratory

### **Detail on Affected Device:**

Product Name	Material Number	Lot Number	Expiration
AMPLILINK (AL) software v. 3.2	05666678001	N/A	N/A

### **Description of the Problem:**

As may have been previously informed, when using a Laboratory Information System (LIS) with automated systems utilizing AMPLILINK software v3.2 series (AL v3.2), there is a potential for wrong results to be assigned to an order due to an intermixed message packet from AMPLILINK. Blood screening systems, **cobas**<sup>®</sup> AmpliScreen and **cobas**<sup>®</sup>s 201 are not affected. The issue has been corrected in AL software v. 3.3 series.

As an interim measure, until your lab has been upgraded to AMPLILINK Software v. 3.3.5, the following two procedures should be followed to prevent wrong results from being assigned to an order due to this issue.

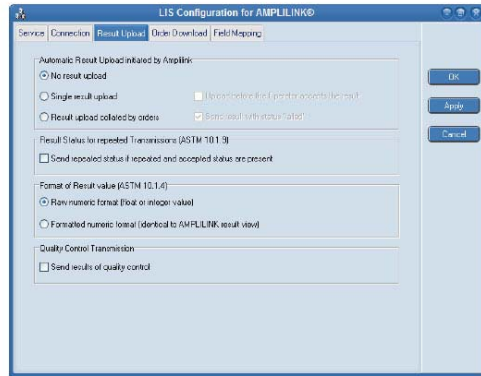
#### **1. Disable the automatic result upload and manually schedule the upload of results to the LIS**

The intermixed message will only occur when a rejected order message is sent at the same time that a result is uploaded. By manually scheduling the uploading of results (i.e. the user controls when results are transmitted from AMPLILINK to LIS), users can limit uploading results to the LIS at the same time that orders are downloaded from the LIS to AMPLILINK.

The procedure to disable the automatic result upload is described in the AMPLILINK SW 3.2 Application Manual V 1.1 - Revision V 2.0, chapter 'Defining result upload', page B-159/B-160:

► **To upload results to the LIS**

- 1 Click the Configuration button.
- 2 Select the Lab Definitions tab.
- 3 Double-click the LIS Interface icon to display the LIS Configuration dialog box (Figure B-69).
- 4 Click the Result Upload tab.



- 5 Select a collate option.

Option	Description
No result upload	Disables automatic results transmission.
Single result upload	Single test results are transmitted to the host.
Result upload collated by orders	Results are held until all tests for one order are complete.

**Table B-23** Collate options

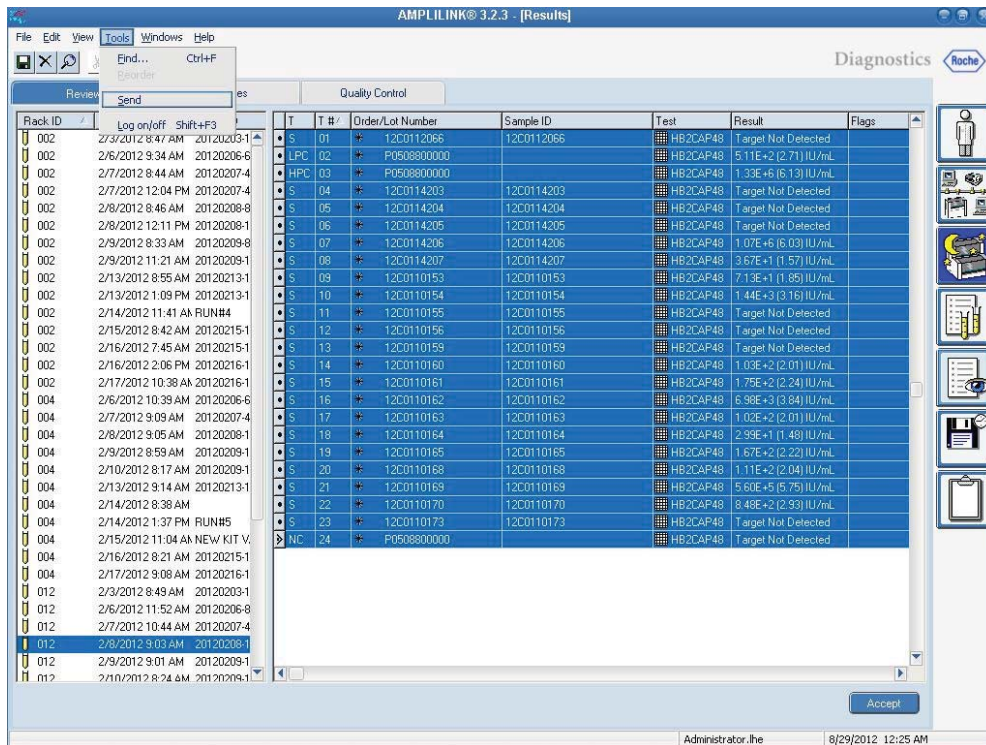
- 6 Check Upload before the Operator accepts the results to transmit results as soon as the selected collate option is met.  
If this box is not checked, results are held by AMPLILINK software until they are reviewed and accepted. Not available if the No result upload collate option is selected.
- 7 Check Send result with status 'failed' to transmit results with the result value "Invalid" or "Failed".  
If this box is not checked, only results with reported qualitative or quantitative result values are included in the automatic transmission to the LIS. Not available if the No result upload collate option is selected.
- 8 Place a check in Send repeated status... to always set the Result Status field, ASTM Result Record field 10.1.9, to "R" for previously transmitted results. If this option is not checked, "V" is transmitted in the Result Status field for all accepted results.
- 9 Select a result format for numerical results. Text results (for example "Target Not Detected") are not affected.

Option	Description
Raw numeric format	Float or integer value
Formatted numeric format	Identical to AMPLILINK result view (see <i>Format options</i> on page B-184)

**Table B-24** Result format options

- 10 Place a check in Send results of quality control to transmit control data along with patient sample results.  
Downloading of control orders from the LIS is not currently supported.
- 11 Click OK to save the selections.

With the automatic result upload disabled, the user needs to manually schedule the upload of results to the LIS: To manually schedule the upload of results, select the results or batch and click on menu Tools > Send.



## 2. Monitor the AMPLILINK Monitor during result upload

In the rare case that an upload does occur simultaneously with the rejection of an order, checking the AMPLILINK monitor flag before and after a result upload will detect occurrence. Users MUST monitor the AMPLILINK monitor when sending results. Even if a LIS is not sending an order to AMPLILINK, a reject order could occur and the user MUST check the status of the LIS Interface before and after manually scheduling the results upload.

If the AMPLILINK monitor is not visible on the AMPLILINK workstation, call Roche Technical Support immediately.

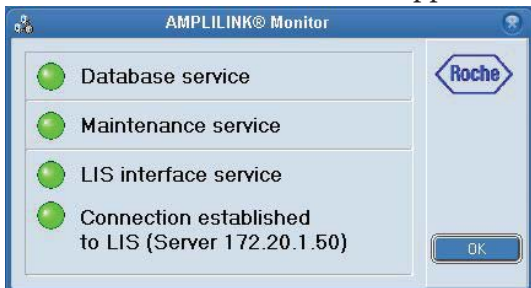
The AMPLILINK monitor will alarm the user in case there was an issue with the order download that may cause the message to be intermixed.

### 1. Open the AMPLILINK monitor:

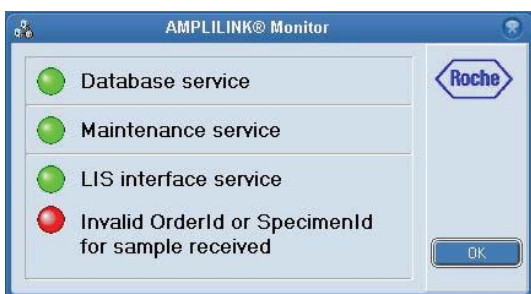
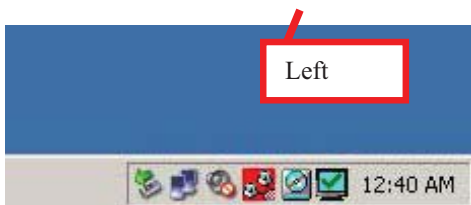
Click (left) on the AMPLILINK monitor icon on the task bar (right bottom):



The AMPLILINK Monitor will appear:



If an error occurs during order download, the connection icon will turn red. Additionally, text is shown providing more information about the root cause of the failed order download.



If the LIS Interface Service turns RED, contact Roche Technical Support immediately and provide an AMPLILINK Problem Report for investigation.

➤ **Actions to be Taken by the User:**

- As an interim measure, until your lab has been upgraded to AMPLILINK Software v. 3.3.5, the above procedures should be implemented to ensure that wrong results are not assigned to an order.
- These are interim procedures and your lab should be upgraded to AMPLILINK software v.3.3.5 as soon as possible.

**Contact Details:** <TO BE COMPLETED LOCALLY>

*Name*

*Title*

*Company Name*

*Address*

*Phone*

*Email*

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