

intelliPATH™ LIS Activation Guide

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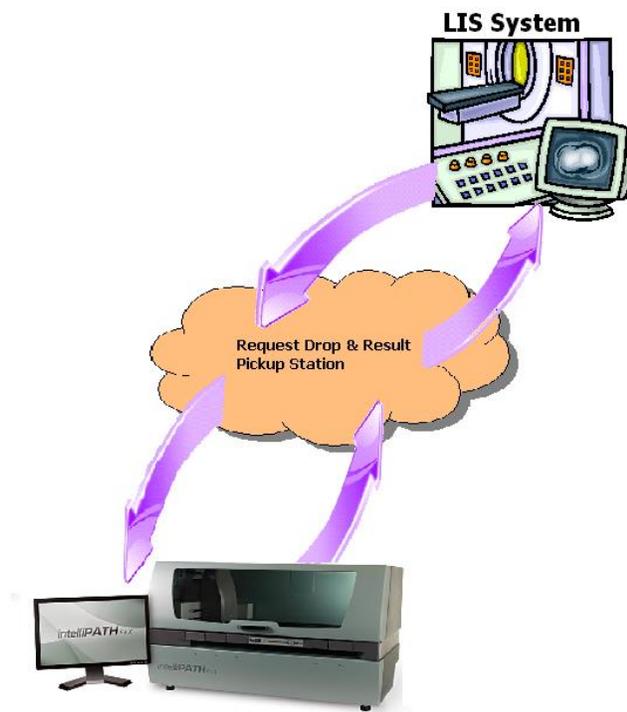
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Section 1: Activation

1.1 Overview

This document describes the interface between the LIS System and the IntelliPATH using a XML file-drop mechanism. In this method, The LIS System creates a file (XML) for each request, and stores the file(s) in the pre-defined folder. The IntelliPATH System Software reads this file and constructs the Staining Order to process on the IntelliPATH instrument. After the requested Staining Order is processed on the IntelliPATH instrument, a Result File is uploaded to a pre-defined folder. The LIS System may read this file and update the status of the request, if needed. As the communication between the IntelliPATH and the LIS System happens both ways, but not in real-time, this method is considered to be bi-directional and indirect.

Here is an illustration of this interface:



To enable the IntelliPATH to interface with an LIS System with this method and to process requests, the following steps are required:

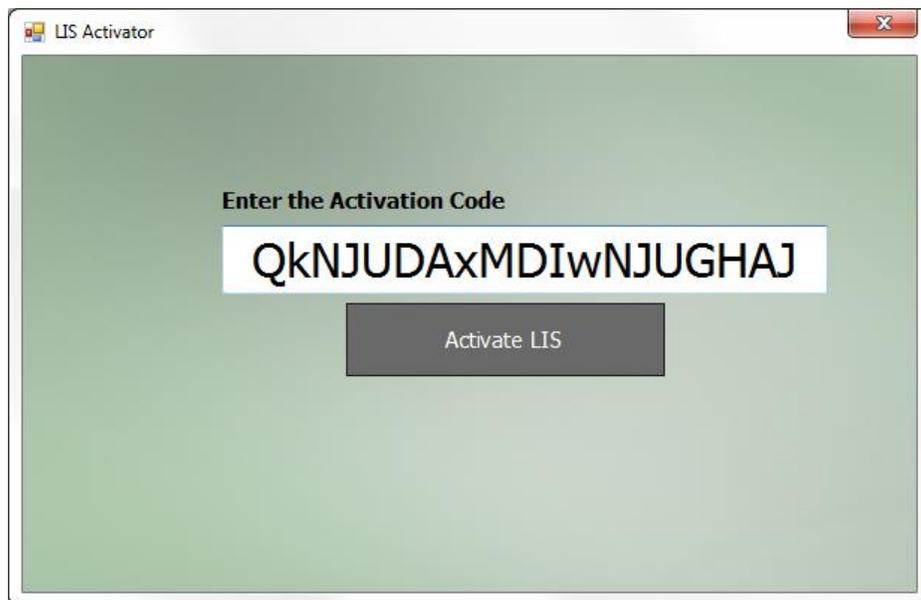
1. Activate LIS in IntelliPATH System Software
2. Setup LIS Folders
3. Import Slides from LIS

1.2 intelliPATH™ LIS Activation Instructions

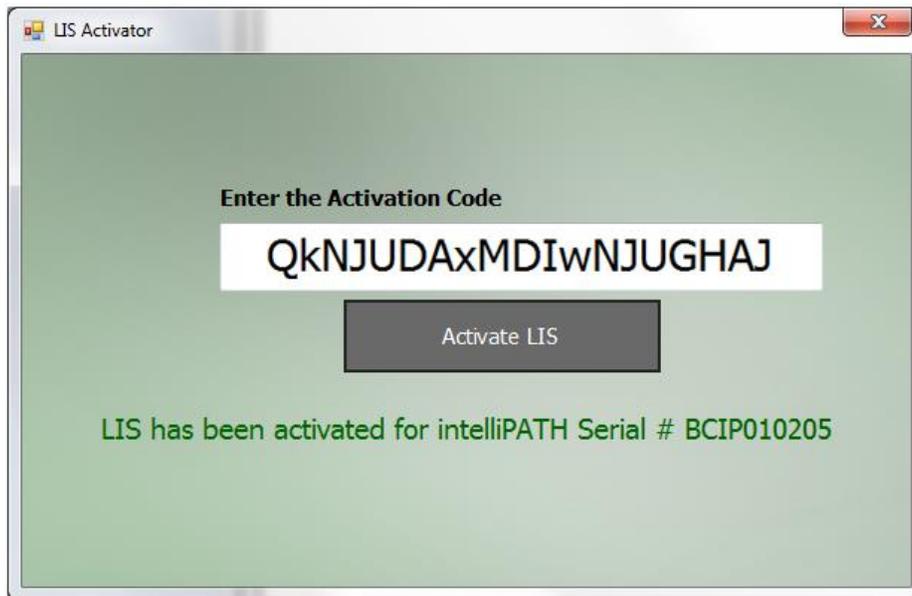
The LIS Activator performs the changes required to operate the intelliPATH System Software in the LIS mode. A pre-requisite for the LIS Activator software is the installation of intelliPATH software version 3.0.0.14 or later. Activation of the LIS mode in the intelliPATH System Software is only required once and is specific to the intelliPATH instrument connected.

The LIS Activator uses an encrypted activation code to enable the intelliPATH System Software in LIS mode. Upon entering the activation code, the LIS Activator decrypts it and if the code is compatible for the current instrument, then the LIS mode is enabled on that instrument. To activate the LIS mode:

1. Open LIS Activator Software (LISActivator.exe).
2. Contact Biocare Medical's Technical Support via email at Techsupport@biocare.net or by phone at 1-800-799-9499, OPTION 3, to receive the activation code. You will need to request the intelliPATH LIS Activation Code and provide the intelliPATH instrument serial number.
3. Enter the activation code (example below).



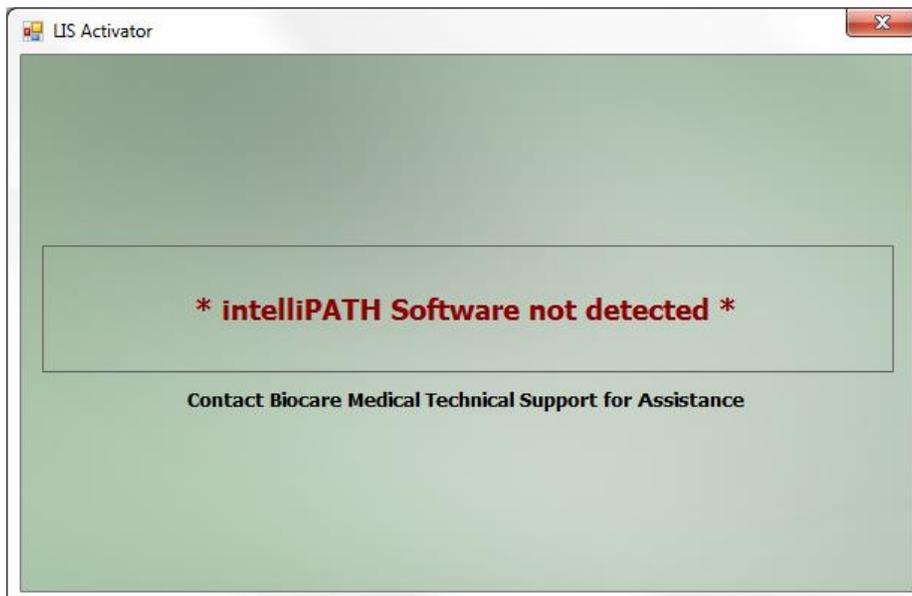
4. Click on the "Activate LIS" button.
 - a. If the decryption is successful and the code matches the intelliPATH unit, the required configuration changes are performed in the intelliPATH Software and the following message is displayed.



1.3 Possible Activation Error Conditions

If Activation Error Conditions 1, 2, or 3 are detected, please contact Biocare Medical Technical Support.

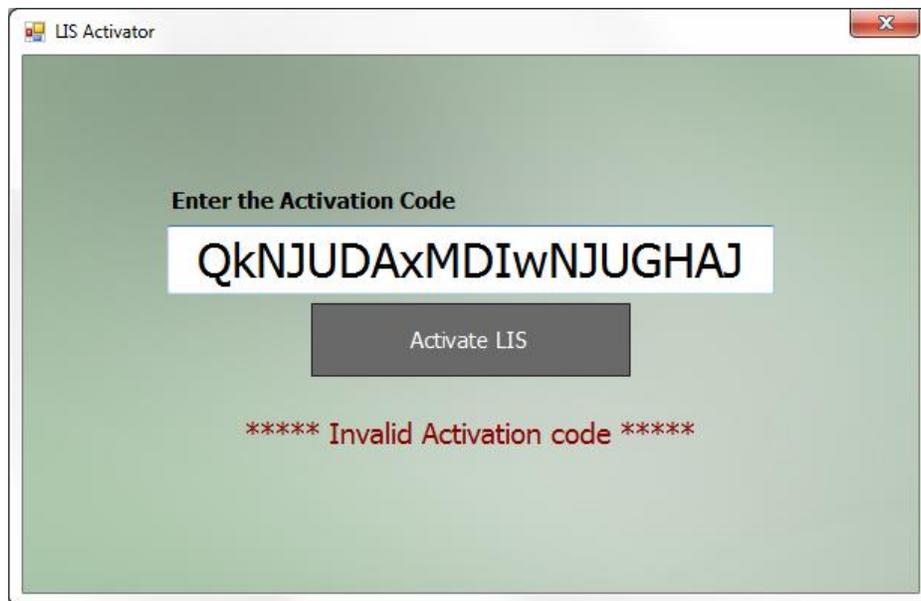
1. If an installation of intelliPATH System Software is not detected, the following message is displayed.



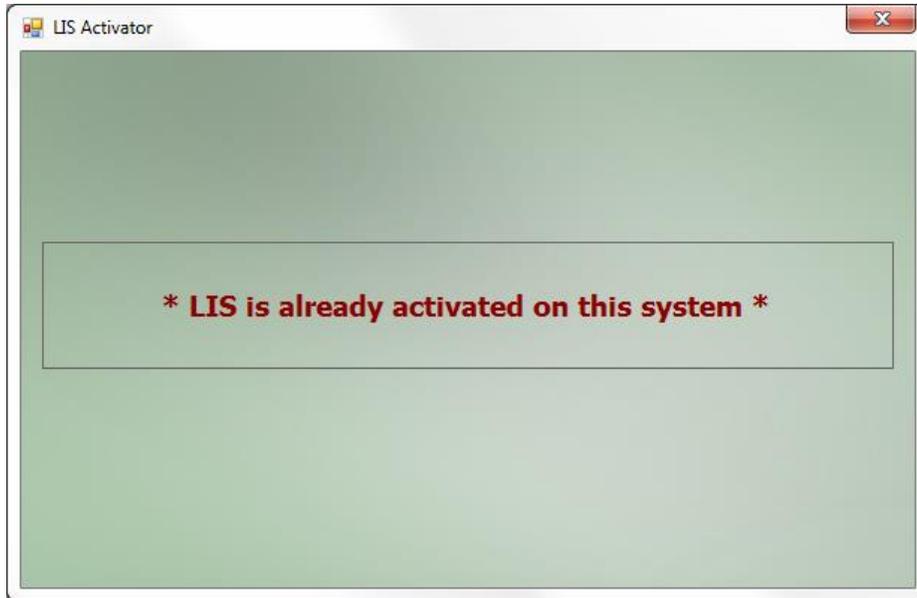
2. If an invalid version of IntelliPATH System Software is detected, the following message is displayed.



3. If decryption is successful and the activation code does not match the IntelliPATH instrument serial number, the following message is displayed.



4. If a valid IntelliPATH System Software is detected and LIS is already enabled on the computer, the following message is displayed.



Section 2: Configuration

There is no need to exclude any folders/sub-folders from virus scanning. It is recommended to schedule any virus scanning after hours, during a time when the instrument is not running.

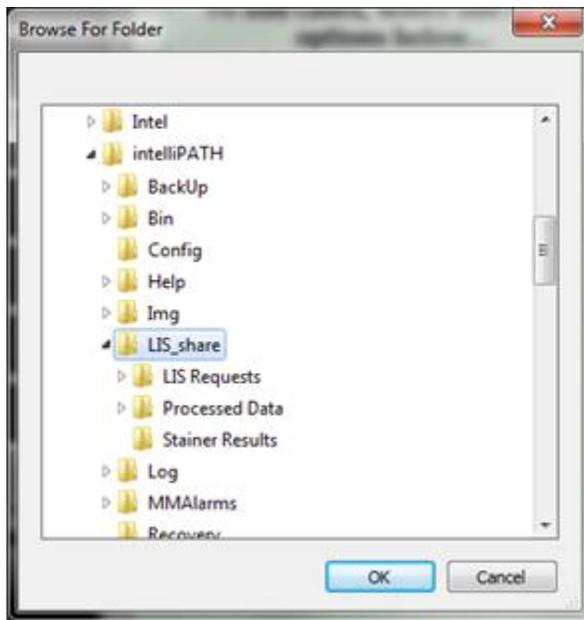
2.1 Enabling the LIS Interface

2.1.1 Setting up LIS Folders

- a. Start IntelliPATH FLX software and select '**Stainer Application**' from the module list.
- b. Select '**Set LIS Folder**' from the **LIS** menu.



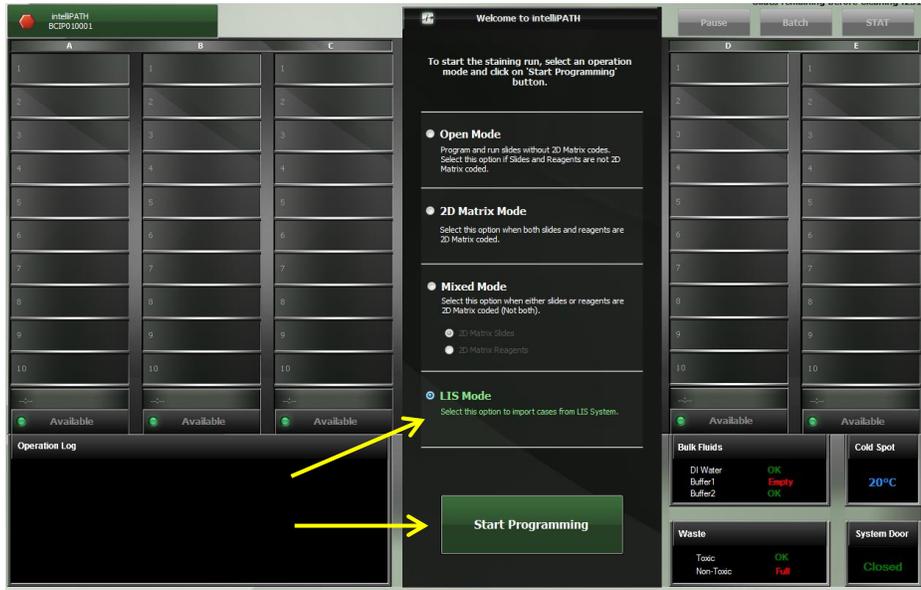
- c. Set the folder to **C:\intelliPATH\LIS_Share** in the folder selection form. Click the **OK** button to save the selection.



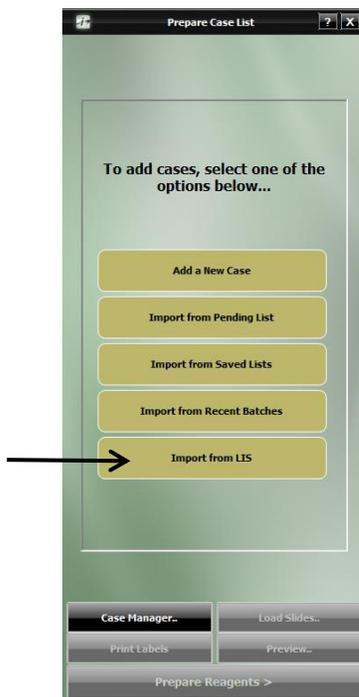
Note: The LIS folder may be placed on the network. However, it must have the same folder structure as the local folder: C:\intelliPATH\LIS_share.

2.1.2 Importing Slides from the LIS

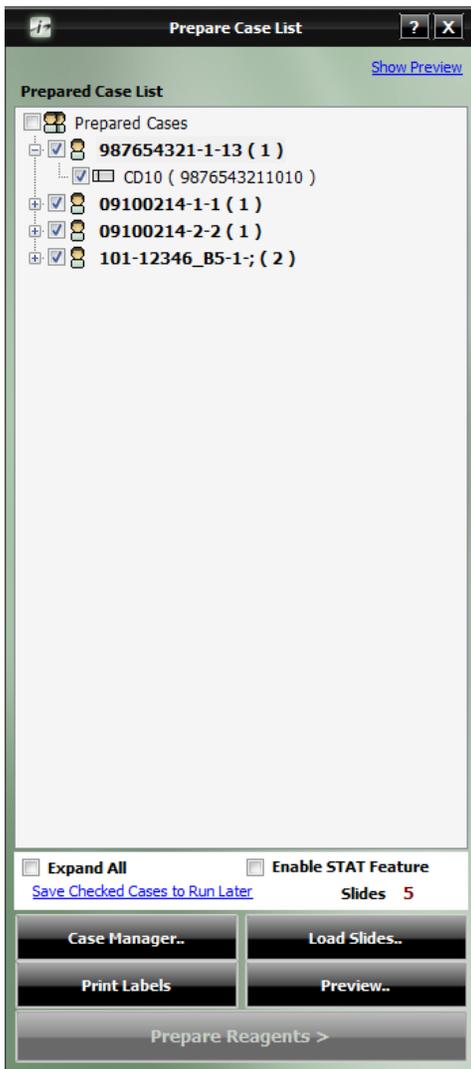
- a. Select '**LIS Mode**' for operation mode and click '**Start Programming**'



- b. In the '**Prepare Case List**' form, click on '**Import from LIS**'



- c. If there are new request files in the LIS folder (LIS_Share/LIS Requests), they are processed and added to the consolidated request file. Each original file is moved to either 'Processed Requests' (LIS_Share/LIS Requests/Processed Requests) for a successfully parsed request OR 'Error Requests' (LIS_Share/LIS Requests/Error Requests) if the request couldn't be imported.
- d. The Case List is prepared by parsing the consolidated requests file and displayed for selection or scanning as below.



2.2 LIS Request File Name Format

LIS Request File names must follow the following convention to be successfully processed by the IntelliPATH staining application.

XXXXX-YYYYMMDD-hhmmssmmm.xml

Where:

XXXXX	= Serial Number or Lab identifier (e.g., BCIP01001)
YYYY	= Year
MM	= Month
DD	= Date
Hh	= Hour (0-23)
Mm	= Minutes (0-59)
Ss	= Seconds (0-59)
Mmm	= Milliseconds (0-999)

Below are some examples for request file names:

BCIP01LIS-20121116-100717292.xml
intellipath-20130531-130710014.xml
Test-20150413-090710014.xml

2.2.1 Example Sample Request File

It is possible to group multiple slides in a single request file. But it is recommended to send a separate request (file) for each slide as it is easier to troubleshoot when there is an issue.

Here is an example of a request file. This file contains request for one slide. More fields can be added in the request file if additional information is required.

```
<?xml version="1.0" encoding="utf-8"?>
<slides>
  <slide>
    <Mode>Add</Mode>
    <CaseNr>200555666</CaseNr>
    <Staining>AQ_NO_RBAB</Staining>
    <SlideNr>1</SlideNr>
    <LISId>200555666_131739A0600</LISId>
    <Stainer>Any</Stainer>
  </slide>
</slides>
```

Note: If the Sample Request File is picked up but is then put into the Error Requests Folder, one of the following conditions may need to be corrected.

- 1) Some additional characters may be preventing the XML parser to fail. See above Example Sample Request File.

- 2) The Protocol specified in the request does not exist on the intelliPATH. Create a protocol with the matching name on the intelliPATH.
- 3) LISID fields must be unique to each request.

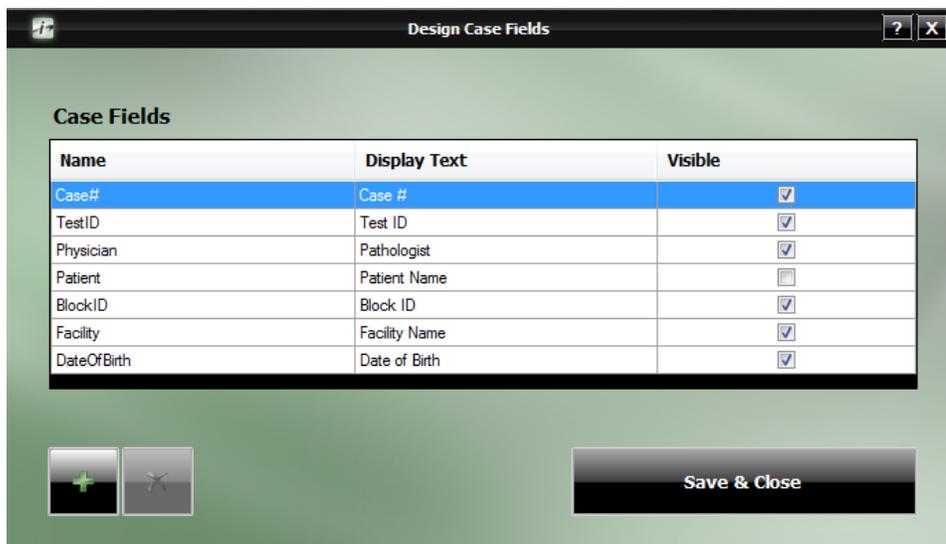
2.3 Brief Description of Fields and Possible Values

Mode	The purpose of the request. Possible values are Add & Delete
CaseNr	Case Number
Staining	Name of the staining protocol (e.g., CD3). Protocol name in the request must match the instrument protocol exactly.
SlideNr	If multiple slides are included in the same request file, this value must be unique for each slide in the file. For a single slide request, its value must be 1.
LISID	Unique identifier. Each request generated from the LIS for the instrument must have a unique value for this field. This value is used for the barcode. When barcode label is printed on the LIS system, this value must be used in the barcode.
Stainer	Serial number of the instrument where the slide must be processed. If it is not required to process on a specific instrument, its value must be 'Any'.

2.4 Configuring LIS Fields

It is possible to add more fields in the LIS request file. In order for intelliPATH to parse and correctly associate with the slide data, following steps must be performed on the intelliPATH.

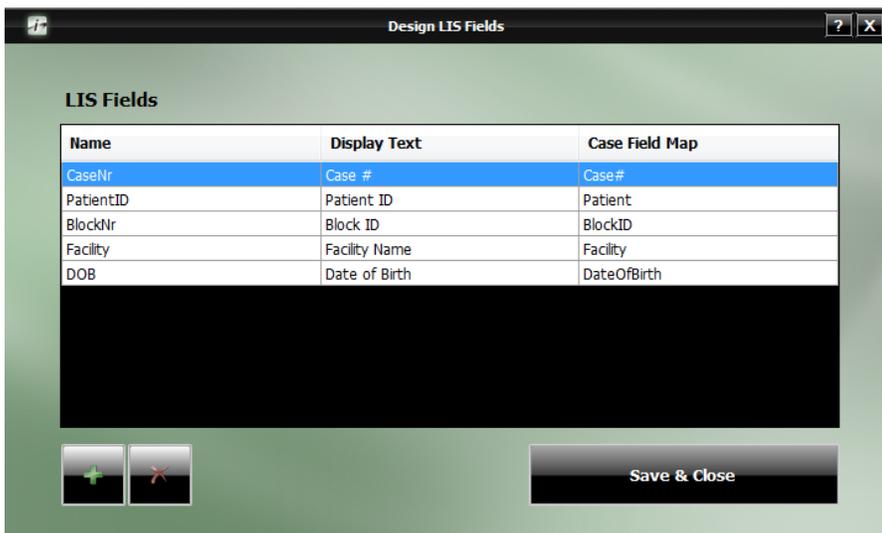
- a. Create more 'Case Fields' to store the additional information. Here is a sample of the case field manager with additional information. In this example, PatientName, Facility & DateOfBirth are the new fields.



- b. Create a map (or association) between each new case field and the LIS field. Start this by selecting **'Setup LIS Fields'** from the **'LIS'** menu as shown below.



- c. Sample map for the additional data is shown below.



Here is an example of a request file with additional information.

```
<?xml version="1.0" encoding="utf-8"?>
<slides>
<slide>
<Mode>Add</Mode>
<CaseNr>200555670</CaseNr>
<BlockNr>B1</BlockNr>
<Staining>AFP</Staining>
<PatientID>DANGERZONE, ARCHER</PatientID>
<SlideNr>1</SlideNr>
<LISId>200555670_131739A0600</LISId>
<Stainer>Any</Stainer>
<Facility>Biocare2</Facility>
<DOB>April13</DOB>
</slide>
</slides>
```

2.6 Exporting Results

After the successful completion of an LIS slide, a result file is created and stored in the Stainer Results folder (LIS_Share\Stainer Results). A separate file is created for each slide (successfully processed). LIS system may periodically check this folder for any new information and update the status of its requests accordingly.