BIOCARE

M E D I C A L

intelliPATH™ Research Software Manual
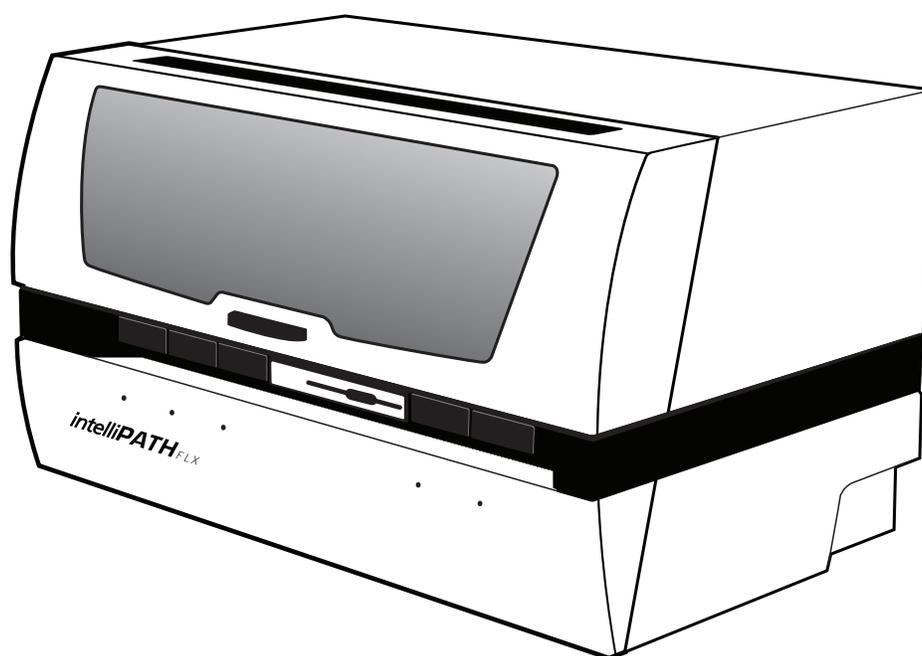
*intelli**PATH**_{FLX}*

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Introduction

Intended Use

This manual is intended for research laboratory personnel who utilize the intelliPATH automated slide stainer to perform immunohistochemistry (IHC) staining. The manual describes how to operate the instrument using the intelliPATH software version 3.0 or later. This guide assumes that you are trained in basic IHC procedures.

About the intelliPATH

The intelliPATH is Biocare's automated slide stainer designed to perform reliable and consistent IHC staining in such a manner that closely mimics the manual staining methods. This enables easy transfer of established manual staining methods to an automated platform with minimal protocol optimization.

Instrument Specifications

Slide capacity	50
Independent trays	5 trays, 10 slides per tray
Reagent vial capacity	48 (20 ml vials)
Cold spot capacity	2 (6 ml vials)
Cold spot temperature range	2-8°C / 35-46°F
Mixing vial capacity	18 (6 ml vials)
Reagent dispensing range	Delivers 100 µl to 600 µl
Multi-dispensing range	4.5 ml
Buffer inlets	3
Waste separation	Separated hazardous and non-hazardous
LIS	Compatible with XML and HL-7 messaging standards
Electrical requirements	900W; 115V/230V; 50/60 Hz
Instrument Dimensions (W x H x D)	40" X 24" X 25" / 102 cm X 61 cm X 64 cm
Instrument Weight	145 lbs / 66 kg

⚠ Not for use with flammable solvents or gases

Warranty

The intelliPATH warranty is for one year from receipt of purchase and covers all parts and labor when performed solely by Biocare Medical. Warranty is invalidated if equipment is abused, damaged, or improperly maintained by customer. Warranty is not transferable to any other party should the equipment be resold or transferred by the customer to another party. To the extent permitted by law, Biocare Medical disclaims any liability for any incidental or consequential damages related to this equipment or for any warranty related services it performs.

Instrument Components

System Door

Mixing Vials

Wash Station

Cold Spot

Reagent Vials

Z-Head

Carboy Tubing Connections

intelli**PATH**_{FLX}

Slide Racks

LED Indicators

Power Switch

Z-head Components

2D Matrix Scanner

Reagent Probe

Liquid Level Sensor

Wash Nozzle

Air Nozzle

Carboy Tubing Connections

USB   Fluid Level Sensors   Buffer 2   Buffer 1

Overflow   Waste   Hazardous Waste   Deionized Water

Carboy

Tubing Connector

Fluid Level Sensor Connector

Carboy Level Sensor Hub

Carboy Connections
- 🟨 DI Water (yellow)
- ⬛ Hazardous Waste (black)
- 🟦 Buffer 1 (blue)
- ⬜ Buffer 2 (white)
- 🟩 Waste (green)

Description of Parts

Parts	Description
Slide racks	The intelliPATH automated slide stainer includes five removable slide racks, each with a 10 slide capacity. They secure the slides firmly in a horizontal position at all times during the staining run. The slide racks can be removed from the instrument for loading slides, and then reinserted. There is a sensor which engages when the slide racks are properly inserted. The LED indicator light is green when the slide rack is correctly inserted. The LED indicator light is red when the slide rack is removed or incorrectly inserted.
System door	The intelliPATH system door operates with a hydraulic lift system which allows access to the work surface. The system door locks in the beginning of a run. It must be closed during the operation of the instrument. The system door status can be viewed in the Stainer Application Module.
Cold Spot	The intelliPATH Cold Spot is capable of holding two vials of heat labile reagents at 4°C during the staining process.
Mixing vials	The intelliPATH has 18 mixing vial positions. The mixing vials have a 6 ml reagent capacity. The instrument will mix designated reagents before use. The software calculates a 300 μl dead volume for all mixing vial reagents.
Reagent racks and reagent vials	The instrument has one reagent rack that holds 48 reagent vials. The reagent vials have a 20 ml capacity with a screw cap. Vials can be filled with the volume specified by the selected program or with excess volume in preparation for use of the same reagent in a subsequent run. All reagent vials have a 300 μl dead volume.
Z-head	The Z-head is mounted on the Y-arm that moves along the horizontal X-axis inside the main frame of the instrument. The following are components of the Z-head: Reagent Probe: The instrument uses a Teflon coated stainless steel probe. The probe is washed inside and out before each new reagent is applied. There is no need for disposable pipette tips. Liquid Level Sensor: The ultrasonic level sensor detects the reagent volume level and sends a signal to the software without contacting the reagent. The system will provide visual and audible alarms if there is insufficient reagent to complete the run. The run will not start if reagent volumes are insufficient for the programmed protocols. Air Nozzle / Wash Nozzle: The wash nozzle applies buffer or DI water to the slides at each rinse step and also at preset intervals to keep slides moist during the holding time before the start of a run. The air nozzle applies an air nozzle step used to remove excess liquid from a slide before applying reagents. 2-D Matrix scanner: An electrical device used for reading 2-D matrix codes on slide and reagent labels. Consists of a laser beam light source that integrates the unique 2-D matrix code into the intelliPATH software.
Buffer and distilled/ deionized water storage	The buffer and water carboy assemblies have liquid level sensors. If there is insufficient buffer or water in the carboy assemblies the instrument will not start the staining process. The intelliPATH uses 20 liter storage containers (carboys) to hold the buffer and 10 liter carboy for distilled or deionized water. Check the buffer and water levels before each run, and replenish and reset if indicated by the software during the staining process. The required volumes for each run are calculated by the software and displayed during the programming process. Buffer is also required for the idle rinse application before the actual start of a delayed run. Water or buffer is used as determined by the last step in the protocol template.
Waste Storage	A separate 20 liter carboy is provided for non-hazardous waste, and a 10 liter carboy is provided for hazardous waste. The actual amount of waste volume will depend on the number of reagents used, the number of wash cycles and the number of washes per cycle.

Storage and Handling

Reagents

Always follow the manufacturer's instructions for storage and handling. To prevent contamination, follow good laboratory practices of sterile technique when opening, diluting, and decanting all solutions. Store Biocare reagents at 2-8°C as specified in the data sheets to maintain reagent stability.

Instrument

Storage temperature: 10-40°C (50-104°F)
Transportation temperature: 0-50°C

Waste Disposal

Some of the reagents used on the intelliPATH automated slide stainer may be hazardous, and must be disposed of properly in accordance with your local regulations. You can determine from the SDS sheet for a given reagent if a reagent is hazardous. The intelliPATH automated slide stainer can be programmed to separate waste streams for the chromogen or other hazardous materials if used. The carboy used for this waste stream is marked "Hazardous Waste." This carboy must only be used for hazardous waste in order to avoid increasing the volume of any hazardous waste unnecessarily. If a reagent known to be hazardous is used in other steps of the protocol, the hazardous waste carboy must be selected during programming; otherwise the non-hazardous waste carboy will become contaminated and considered hazardous waste, whether or not it is marked as such, and must be disposed of according to local regulations.

Instrument Disposal

If the intelliPATH is to be removed from service and disposed of, the instrument must be disinfected using a 10% bleach solution through the fluid delivery and waste systems and all exposed surfaces disinfected using Lysol brand industrial cleaner before it is disposed of in accordance with local, State and Federal regulations.

Installation Site Requirements

Performance checks are conducted by the manufacturer prior to shipping. Biocare Medical field service personnel will unpack, or supervise the unpacking of the intelliPATH. Biocare field service personnel will verify the system performance to determine any deficiencies in operation as a result of shipping. They will rectify any problems with regard to performance or components. Biocare personnel will also provide basic operating instructions.

> Note: The intelliPATH automated slide stainer must be handled by the side chassis bottom by at least two people capable of lifting 75 pounds each. Do not lift the automated slide stainer from the front access cover.

The intelliPATH automated slide stainer must be placed on a solid, vibration-free laboratory bench with a flat area, capable of safely supporting the weight of the instrument. Additional consideration must be made for a minimum clearance of 5.0 cm (2 in.) on all sides for ventilation and room for the computer and monitor next to the instrument. The label and report printers for the automated slide stainer may be located anywhere that allows them to be connected to the automated slide stainer's dedicated PC. Surge protection is required. The backup power supply (UPS), if used, should be placed on a surface capable of safely supporting its weight, away from liquids and within 1 meter of the instrument power cord and within 1 meter of a properly grounded power outlet. The use of a dedicated circuit is recommended for the instrument. Avoid connecting the instrument on the same circuit as refrigeration equipment.

Environmental Conditions

Placement	Indoor
Operating temperature range	15-30°C (59-86°F). Recommended temperature for optimal staining is 68-75°F
Min. to Max. Temperature range	10-40°C (50-104°F)
Maximum relative humidity	80%, Non-condensing

Ventilation

Do not block the vent openings on the instrument. Leave a minimum of 5 cm (2 in.) of space between the automated slide stainer and the wall, cabinets or other obstructions.

Venting (exhaust)

The instrument does not need special exhaust ventilation, unless required by safety regulations when using certain reagents.

Humidity

Avoid humidity extremes. Low humidity can cause electrostatic problems that may affect the computer. High humidity may create condensation.

Temperature

The intelliPATH automated slide stainer must be placed in a location away from direct sunlight and extreme heat or cold.

Support

To contact Biocare Medical Technical Support by telephone, please call 1-800-799-9499, Option 3.
You may also email Technical Support at techsupport@biocare.net or submit a message online at www.biocare.net

Safety Precautions

The intelliPATH is designed for use with formalin-fixed tissue samples or non-infectious cell smears. Fresh (unfixed) tissue or cell smears may contain infectious organisms. Use only tissue sections or cell smears that have been fixed in a biocidal/virocidal/fungicidal fixative. Infectious sample use is limited to tissues/specimens that are specified on Biocare's product datasheets. Handle control slides and test formalin-fixed paraffin-embedded (FFPE) slides as if capable of transmitting infectious agents, and dispose with proper precautions. It is recommended that the specimens are handled using established good laboratory working practices.

Reagents and Chemicals

Some of the reagents and chemicals recommended by Biocare for use on the intelliPATH are hazardous. They must always be used according to the manufacturer's instructions and good laboratory practices. Always wear gloves, eye protection and a protective lab coat when handling any chemical solution used on the automated slide stainer, and when cleaning the equipment or emptying waste carboys. Obtain a Safety Data Sheet (SDS) from the manufacturer for each chemical constituent. Do not use any flammable chemicals on the intelliPATH automated slide stainer. Danger from hazardous fumes, fire or explosion may result with the possibility of injury to the operator or damage to the instrument. Maintenance and cleaning procedures may recommend the use of flammable chemicals. These procedures specify solutions with concentrations below the flash point of the chemicals and are to be used only when the instrument has been disconnected from the power source.

Instrument

Use only the authorized software program that is supplied with the instrument, or authorized updates.

Do not install any other software applications onto the intelliPATH dedicated computer system. This may cause unexpected operation of the stainer or corrupt the operating software and will void the instrument warranty.

Do not switch off power to the computer until the intelliPATH program is properly closed.

Do not turn off power to the automated slide stainer until all motion has stopped and the robotic arm is in the home position.

The front door of the instrument must be closed before operation will begin.

Keep carboy assemblies below the level of the stainer.

Proper cleaning is important for the reliable operation of the instrument. Follow the recommended cleaning procedures in the System Cleaning chapter (page 74).

The robotic arm must be stopped before the instrument door can be opened. The system door status can be observed from the intelliPATH software screen.

Programming Cautions

Errors in programming staining protocols will likely cause false positive or false negative results. If such errors occur, check the programming first. The intelliPATH provides the option to enter patient information for each slide. Make sure to enter the correct information for patient, physician, etc., for each slide to prevent misidentified and incorrectly reported results.

Warning Symbols

The following symbols may appear on the instrument label:

☣	Warning. Biohazardous materials may be present. Personal Protection is required
CE	CE marking
⚒	Manufacturer
SN	Serial number
📖i	Consult instructions for use (consult operating instruction)
⏚	Electrical Earth Ground
⏻	Main Power (ON/OFF)

Software Features & Functions

This chapter is intended to familiarize you with key software features, providing details of all operation Modules available to Administrative and Regular Users.

User access

There are two levels of access for users of the intelliPATH™ software: regular user and administrator. Users with Administrator privileges have access to all the screens available to regular users, but have some additional privileges. Screens used by both kinds of user are described in this chapter. The software only allows one administrative account.

Login

To log in, double-click on the intelliPATH icon on the desktop, enter your username and password in the dialog box, and press **Login** to continue.

> Note: Default User ID is **Admin**, default password is **ipflx**.

Module Selection Screens

Administrator User Module Selection
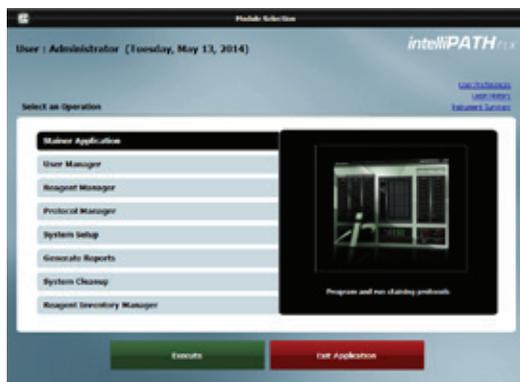
Regular User Module Selection
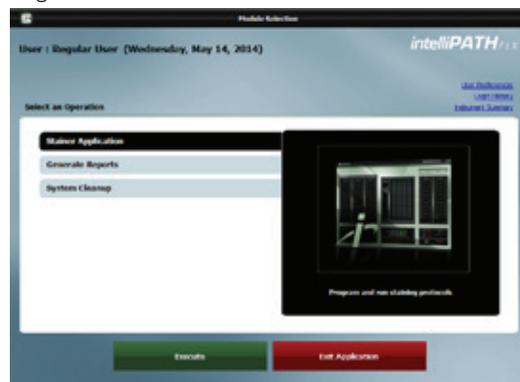
User Preferences

On the **Module Selection Screen**, click the **User Preferences** link in the upper right. **Change My Information** window will open. Currently logged in user can change their user preferences.

Login History

On the **Module Selection Screen**, click the **Login History** link in the upper right. **View User Login History** window will open. A list of the dates and times that a user has logged into the intelliPATH software will appear. Administrator can view all login details. Regular User can only view their login details.
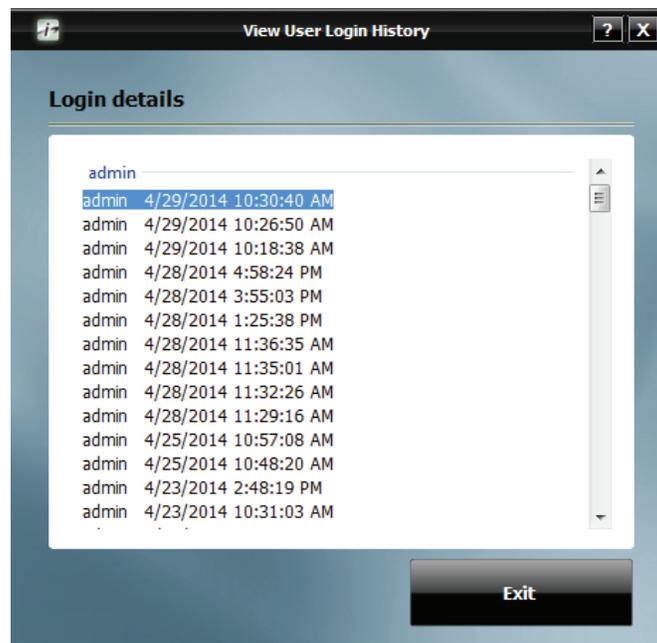
Instrument Summary

If the number of slides is less than 250, then the Status is 'OK'. If it is 250 or more, then the Status is 'Needs Cleaning'. If the instrument needs cleaning, click on **Clean Now** button.
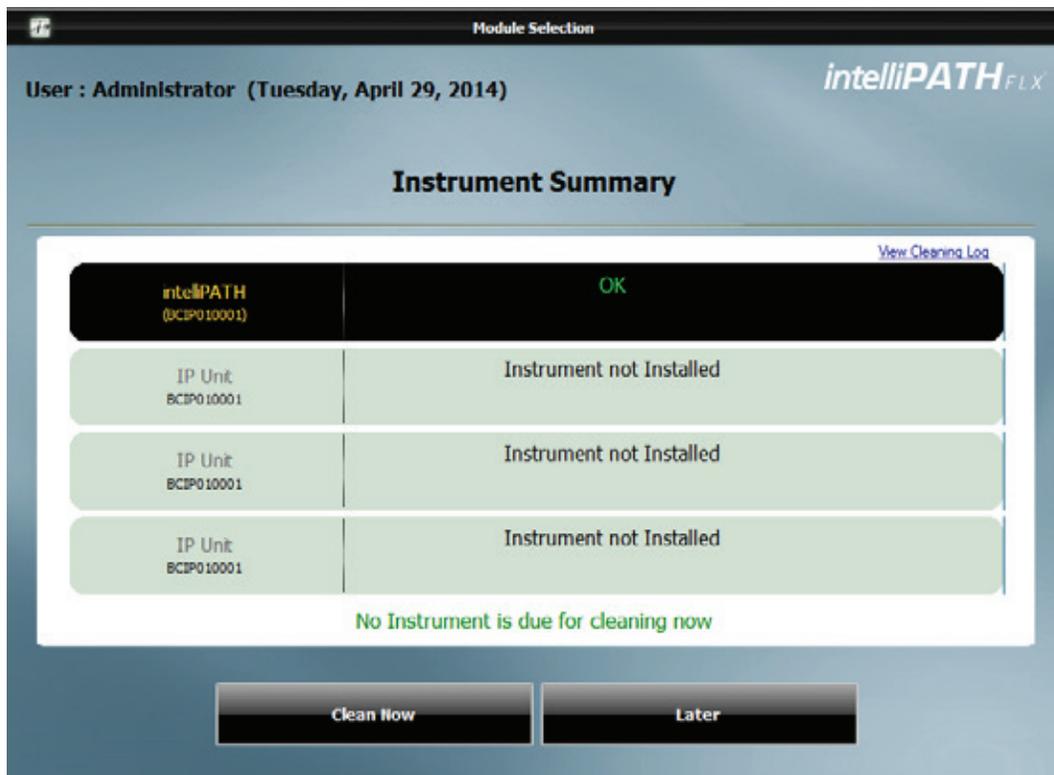
Module Descriptions

Module	Description	User	Admin
Stainer Application	Program and run staining protocols. Manage slides, slide staining protocols, and slide stainer operations.	⊕	⊕
User Manager	Create new user accounts and modify existing accounts.	*	⊕
Reagent Manager	Create new/modify existing reagents/steps. Print Reagent Labels.	*	⊕
Protocol Manager	Save, design, and manage protocols. Access Group Manager.	*	⊕
System Setup	Set preferences and defaults for dispensing properties, institution parameters and system parameters.	⊖	⊕
Generate Reports	Used to generate and print reports.	⊕	⊕
System Cleanup	Enables manual and automatic cleaning of instrument parts.	⊕	⊕
Reagent Inventory Manager	Track reagent lot numbers, expiration dates and reagent volume.	⊖	⊕

*The Reagent Manager, Protocol Manager and User Manager are available to regular users to view only (not to modify) from the Stainer Application screen.

Stainer Application Module

Use the Stainer Application Module to program, run, and manage slide staining operations. The main screen for the Stainer Application Module is a diagram of the slide areas as described below.
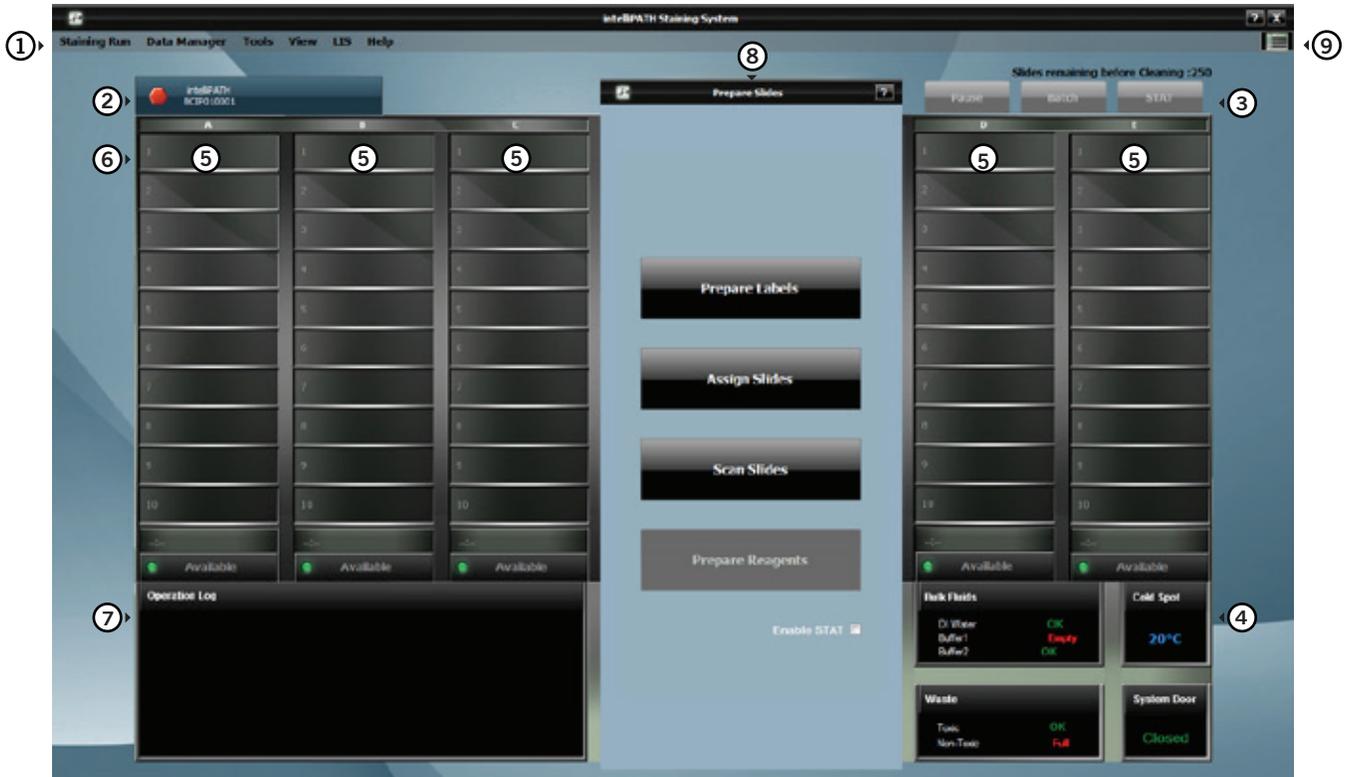
1. Menu bar, 2. Stainer tab, 3. Run designation buttons, 4. System status, 5. Slide tray positions, 6. Slide Position, 7. Operation log, 8. Slide Preparation, 9. Instrument View.

① Menu Bar
The menu bar in the upper left corner of the Stainer Application's main screen provides access to a number of other functions:

Staining Run Menu
The Staining Run menu allows the user to Start a New Staining Run, Recover a Staining Run, Clear the Completed Trays, Stop an Active Instrument, or Exit the Stainer Application module.
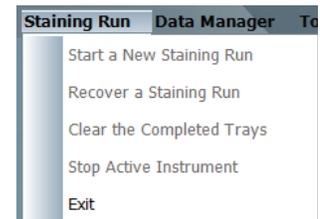
Recover a Staining Run
The **Crash Recovery System** screen is displayed whenever there is an interruption of the staining run. This can occur if the user accidentally STOPS a run, during power outages/surges that exceed the power buffering of the UPS or by Windows Operating System errors.

After an incident, when the user logs back in to the intelliPATH and executes the **Staining Application**, this screen is displayed. It is also possible to access this screen by choosing **Recover a Staining Run** from the **Staining Run** drop down menu of the **Staining Main Screen.**

This screen lists all of the slides that were used in the previous run with the following information:
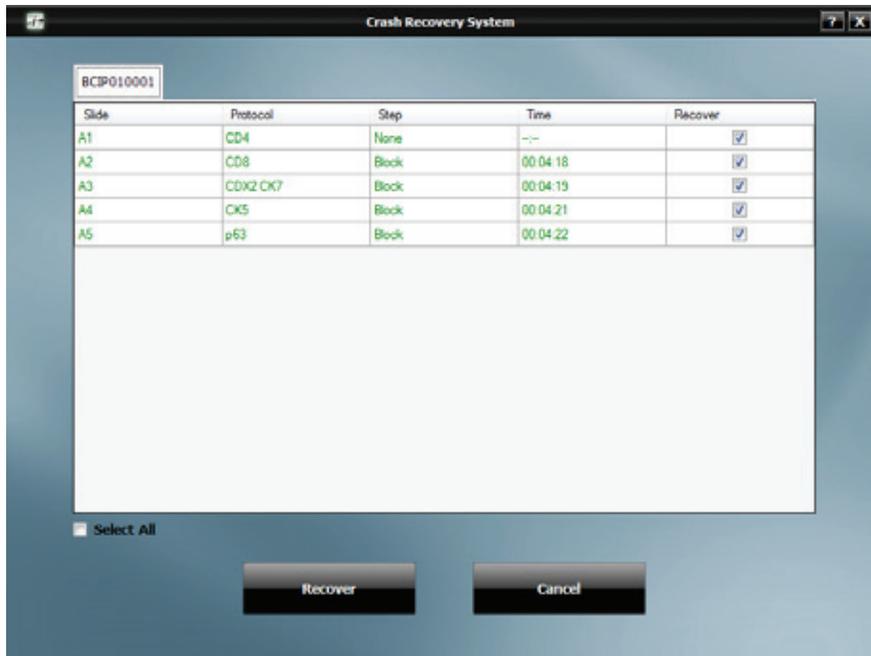
Check all of the slides to be recovered and click on the **Recover** button. The checked slides are loaded and staining run begins where the interrupted run left off taking into account incubation that has occurred during the delay.

Clear the Completed Trays

When a tray of slides is complete, user can select **Clear the Completed Trays** from the **Staining Run** drop down menu of the **Staining Main Screen**. This will remove the slides from completed trays so that the user can remove the slides and program a new batch with those trays. This is an optional feature as the system will prompt you to clear up used trays when the run completes.

Data Manager Menu

The Data Manager menu allows the user to access the Reagent Manager, Protocol Manager, User Manager, Reagent Inventory Manager or Group Manager.

Tools Menu

The Tools menu allows the user to access the Stainer Options, Print Slide Layout Report, Print Reagent Layout Report, Print Run Log Report, Print Reports, Clear Used up Reagents, Turn ON Cold Spot, Reset Carboys, Drain Waste & Prime Buffers, Prime Probe, Dilution Calculator, System Cleaning, Label Designer, Setup Slide Fields, Slide Display Fields and Print Reagent Worksheet.
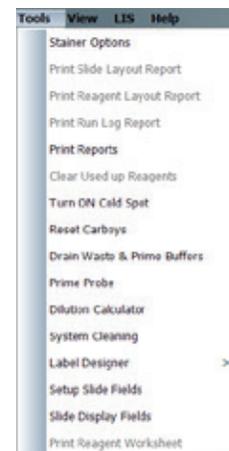
Clear Used Up Reagents

If the user needs to remove reagent vials from the reagent rack or from the cold station, select **Clear Used up Reagents** from the **Tools** drop down menu of the **Staining Main Screen**.This clears the vials from the system that are no longer needed to complete the run. Their slots become free so that the reagents can be replaced with new ones. This is an optional feature as the system will prompt you to clear up used reagents when the run completes.

Turn ON Cold Spot

The Cold Spot is in the central part of the work area, next to the Reagent Rack. It is an area kept refrigerated below room temperature and is used for reagents needed in a staining run that are unstable at room temperature.

The current temperature of the Cold Spot is displayed on the **Status Box** in the lower right corner of the **Staining Main Screen.**

You can turn the Cold Spot on and off from the **Tools** menu on the **Staining Main Screen.**

Reset Carboys

If the instrument's sensors detect that a buffer carboy is full or a waste carboy is empty, select **Reset Carboys** from the **Tools** drop down menu of the **Staining Main Screen.**
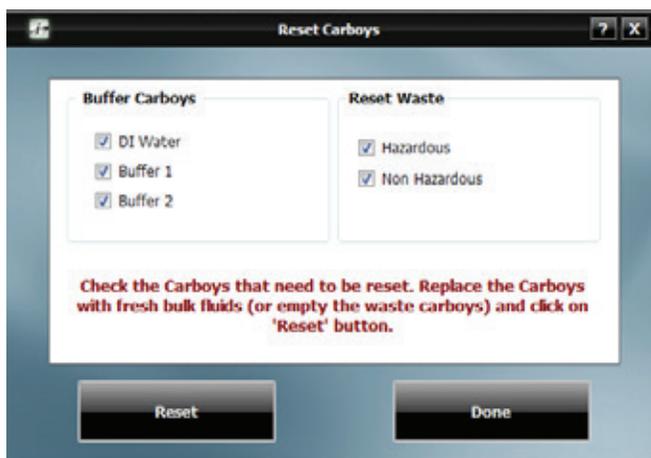
After you have remedied the problem with the carboy, check the carboy that needs to be reset and click **Reset.** This will tell the intelliPATH software that you have filled the input carboys and/or emptied the waste carboys.

Click **Done** when finished.

Drain Waste & Prime Buffers
This screen can be reached from the **Tools** drop down menu of the **Staining Main Screen.**

There are 2 radio buttons: one for Drain Waste and one for Prime Buffers.

When Drain Waste radio button is selected, the following radio buttons are enabled:

    Non – Hazardous
    Hazardous

To drain Non – Hazardous waste, select Non – Hazardous radio button and click on 'Start' button and the Start button changes to 'Done'. After draining is done, click on 'Done' button.

To drain Hazardous waste, select Hazardous radio button and click on 'Start' button and the Start button changes to 'Done'. After draining is done, click on 'Done' button.
When Prime Buffers radio button is selected, the following radio buttons are enabled:

DI Water
Buffer1
Buffer2

To prime DI Water, select DI Water radio button and click on 'Start' button and the Start button changes to 'Done'. After priming is done, click on 'Done' button.

To prime Buffer1, select Buffer1 radio button and click on 'Start' button and the Start button changes to 'Done'. After priming is done, click on 'Done' button.

To prime Buffer2, select Buffer2 radio button and click on 'Start' button and the Start button changes to 'Done'. After priming is done, click on 'Done' button.

Dilution Calculator

The **Dilution Calculator** is a useful tool which allows you to calculate how to dilute a stock solution of known concentration. You can locate the **Dilution Calculator** in the **Tools** menu of the **Staining Main Screen.**
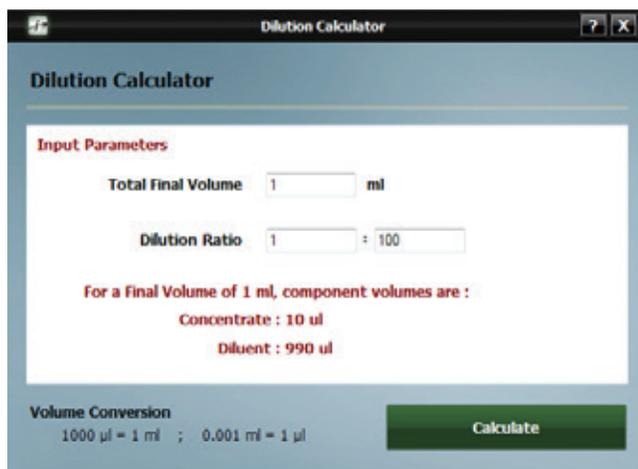
Ⓐ View Menu
The View menu allows access to Display Error List, Run Time Estimates, and System View.
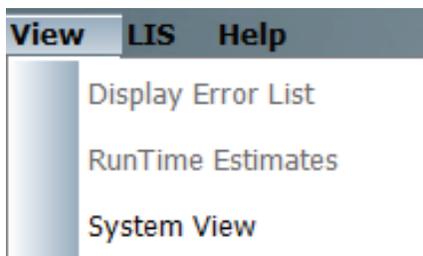
Display Error List
If a problem occurs during the run, the intelliPATH software will notify you so you can correct it.

When an Attention message is displayed on the **Staining Main Screen**, perform the action requested or click on the **View Details** button. You can also see a list of them and address them by selecting **Display Error** List in the **Tools** drop down menu of the **Staining Main Screen** or by clicking on the **View Details** button.

If an available **View Details** button is clicked, the **Notification Details** window will appear with a description of the action required and the slide(s) that are affected.

Click **Clear this Notification** to be prompted as to what steps must occur to clear the notification.

This appears for conditions such as the system door being opened, the waste carboy becoming full or manual reagent application.

RunTime Estimates

When a staining run is started or when a new Batch/STAT is started, the Run Time is estimated for each slide, tray and the complete run. These estimates can be viewed from the **RunTime Estimates** option of the **View** drop down menu in the **Staining Main Screen**. This menu item is enabled only when the instrument is running and is disabled otherwise (when the run is not started, completed, canceled or when a Batch/STAT is initiated and programming is in process).

The following are the 2 different views of the Run Time Estimates:

1. Map View

The instrument that is connected will appear in the Select Instrument field.

Similar to the **Staining Main Screen** interface, the slides in process are green with the estimated time and the ones that are complete are gray.

2. Snapshot View

A Snapshot View of the instrument connected is shown below. If an instrument is not connected, it will show as Instrument not Installed.
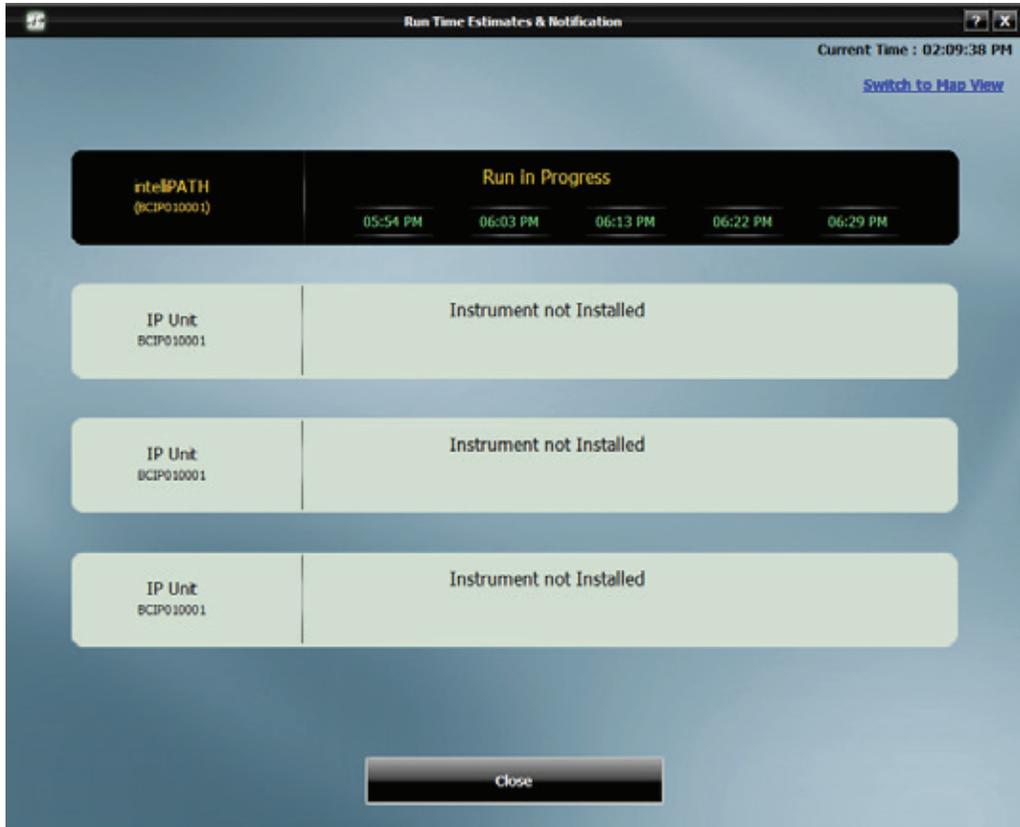
B LIS Menu (contact Biocare Medical For LIS Feature availability.)

The LIS menu allows access to Setup LIS Fields and Set LIS Folder.
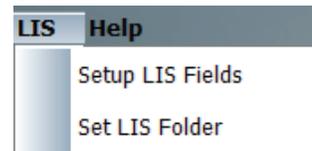
C Help Menu

The Help menu allows the user to view the product name, build and software version.
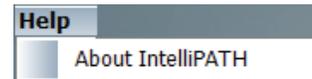
② Stainer Tab

The stainer tab indicates the name and the serial number of the instrument. The red hexagon indicates the stainer is idle. (Figure A), the green arrows (Figure B) designate a stainer in process, and the green arrows indicate the stainer is in process (Figure C) indicates a completed staining run. The yellow triangle (Figure D) indicates that a problem has occurred. The information icon (Figure E) notifies the user that a user-involved action is required later during the run. The pause (Figure F) indicates that the run has been paused.

③ Run Designation Buttons

The **Pause** button allows the user to interrupt the run while it is in process. The instrument will process the request and pause the instrument when it has completed its current operation. To confirm the pause request, click **Yes.** To resume the run, click **Resume**.

> **Note:** The instrument will initiate a count down with a notification message that slides may over-incubate if the pause is prolonged.

The **Batch** button allows the user to start a non-STAT run while another run is in process. A dialog box then appears for verification to start a new staining run. If the user selects **Yes,** then the **Prepare Slides** dialog box will appear and the user will follow the sequence of steps to start a new staining run.

The **STAT** button allows the user to designate a run as STAT. Slide rack E must be available to start a STAT run. The software will prioritize slide rack E to process first. If the user clicks the STAT button, a message will appear asking for verification to start a STAT run. If the user selects **Yes,** then the **Prepare Slides** dialog box will appear and the user will follow the sequence to start a new staining run designated as STAT.

④ System Status

The System Status area indicates if there is sufficient DI Water, Buffer1 and Buffer2 available in the **Bulk Fluids** carboys, if the **Waste** carboys have space for additional waste, the **Cold Spot's** actual temperature and the **System Door** status.

⑤ Slide Tray Positions

The software depicts the slide trays and the slide positions graphically on the user interface. The trays are designated A-E. Tray status indicates whether the tray is **In Process**, **Available**, **No Rack** or **Unload**.

⑥ Slide Position

The software depicts the location of each slide on the slide tray.

Right clicking on a scanned slide allows the user to **View/Edit, Copy Slide** or **Unload Slide**. When **View/Edit** is selected, the **Slide Edit** window will open. If **Copy Slide** is selected, the user can then right click on an open **Slide Position** and choose **Paste Slide**. Selecting **Unload Slide** will unload the slide from the slide layout. If case information is associated with the slide, it will be moved to the **Prepared Slides** List in **Slide Manager**.

⑦ Operation Log

The Operation Log documents the date/time, instrument name, serial number, software version and run name/number. The Operation Log also displays all the operations performed by the instrument. As an operation is performed, the log is updated.

⑧ Slide Preparation

The **Prepare Slides** window is the starting point to begin a staining run. The following is displayed:

Prepare Labels

Slide Labels are generated and printed within the **Prepare Labels** section. User can enter Slide Details (case#, Block ID, Pathologist, Patient Name, etc), order protocols, and print slide labels. **Slide Details** are optional.

Assign Slides

Protocols can be mapped with or without a slide label or from an LIS import in the **Assign Slides** section. **Slide Details** are optional.

Scan Slides

Labels that have been printed with 2D Matrix codes can be scanned in the **Scan Slides** section.

Prepare Reagents

Once slides have been loaded in the system, reagents can be mapped or scanned in the **Prepare Reagents** section.

Enable STAT

The STAT feature can be reserved by clicking the **Enable STAT** checkbox. This disables Rack E and reserves it for future use as a STAT rack.

⑨ Instrument View

This button allows the user to view the instrument's status.

User Manager Module

This module is used to create new user accounts and to modify (edit or delete) existing accounts.

Use the buttons at the bottom left side of the screen to add, delete, or edit users.

User ID

This must be unique. The system does not require a specific naming convention. The naming convention is at the discretion of the end user.

Password

Admin users can assign temporary passwords to new Regular users or users who have forgotten passwords. Regular user may change their password through the User Preferences link.

Full Name

Enter user first and last names. The Full Name may be duplicated, but the User ID must remain unique.

Title

List end-user title. This is a free form text field.

Access Level

Access level is defined. Click on Details to view the available modules.

Language

Select from the available languages displayed.

Reagent Manager Module

The Reagent Manager module is used to create new or to modify existing reagents.
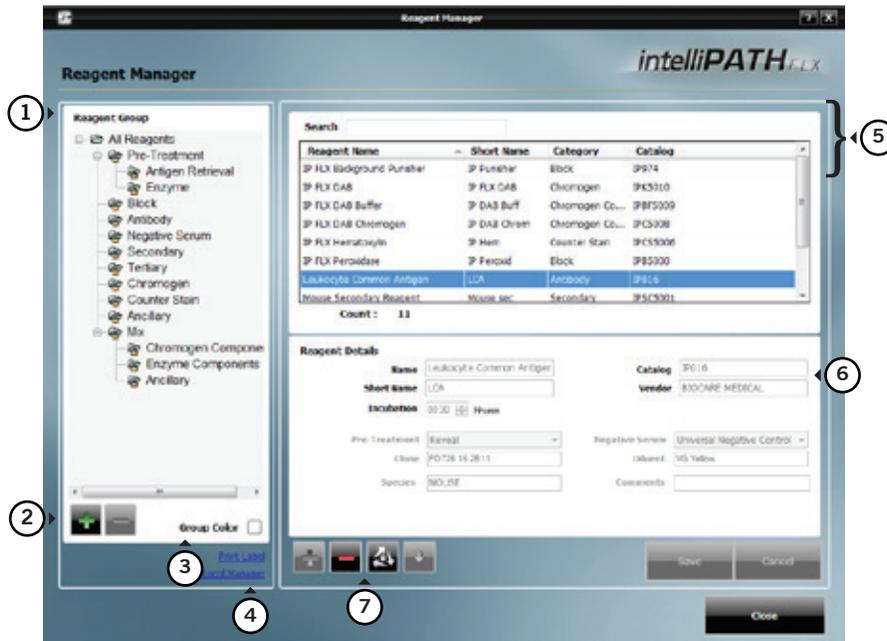
① **Reagent Groups**, listed on the left side of the screen, are standard headings for IHC staining protocols. The following Reagent Groups are available in the intelliPATH software: Pre-Treatment, Block, Antibody, Negative Serum, Secondary, Tertiary, Chromogen, Counter Stain, Ancillary, and Mix. Click to highlight the reagent field of choice.

② Use these buttons to 'Add New Reagent Group' (plus sign +) or to 'Delete Reagent Group' (minus sign -). When 'Add New Reagent Group' (plus sign +) is clicked, **Create New Step** window will open. Create a **Step Name** and click **OK**.

③ The software has assigned default colors to the Reagent Groups.

④ The **Print Label** and **Protocol Manager** links are available on the bottom side of the screen.

⑤ Highlighting a group in the Reagent Group list will display a list of reagent group members in the upper right of the Reagent Manager screen.

⑥ Highlighting a reagent in the Reagent list will display information about the reagent in the **Reagent Details** box in the lower right side of the Reagent Manager screen.

⑦ Use the buttons at the bottom of the screen to add (plus sign), delete (minus sign), edit (3 white arrows surrounding an unlocked padlock), or import (down arrow) reagents. To change the information about a particular reagent, make the changes in the **Reagent Details** section.

Please Note:

1.The import button will display the **Non IP Reagent Master** window where a list of all non-IP reagents for the selected reagent group is displayed. To import the reagents from the **Non IP Reagent Master**, check the reagents to be imported and click on **Add Selected Reagents** button.

2. When creating a new Reagent in the Reagent Manager and thereafter saving it, the Pre-treatment and Negative Control values from a previous selection are displayed in, "Pre-treatment" and "Negative Serum" fields, the user should visually inspect the values and modify the values accordingly.

3. Deleting all reagents within a group will cause an "Unhandled Exception" pop-up, please close the pop up to continue operating the software normally.

21
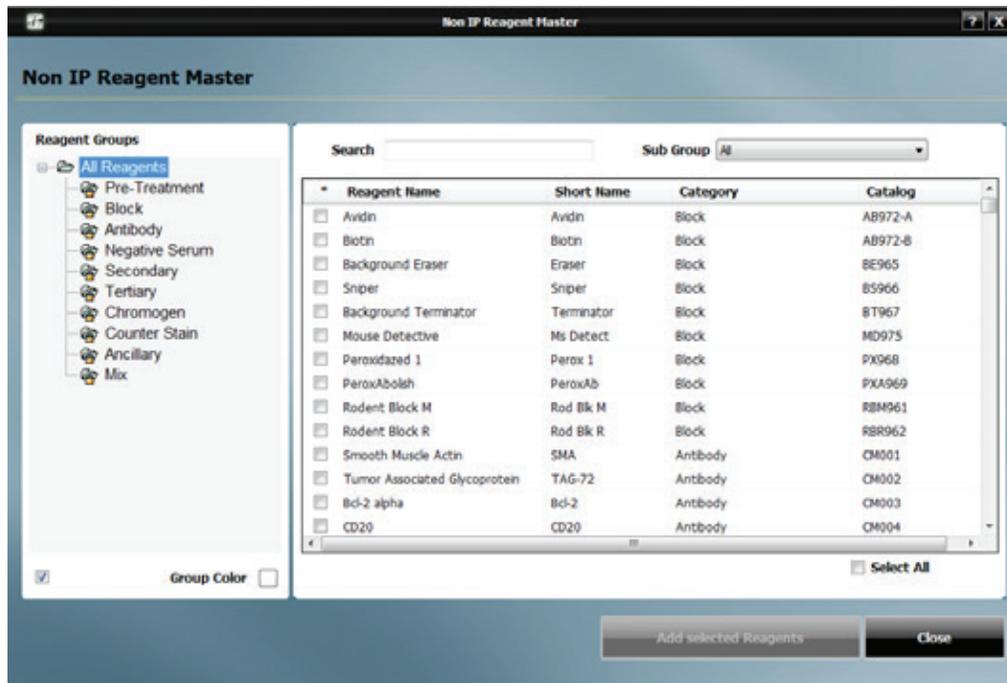
To exit the screen, click **Close**.

Reagent Groups

Pre-Treatment Group

The Pre-Treatment reagent group includes Antigen Retrieval solutions and Enzymes. This screen will allow the addition, modification, and deletion of pretreatment reagents.

To add, delete, or modify a Pre-Treatment group, a **Sub Group** (Antigen Retrieval or Enzyme) must first be selected.

At the bottom of the **Reagent Details** box, the option to perform offline pre-treatment is displayed.

Block Group

The Block reagent group is used to enter solutions designed to block non-specific enzyme activity or protein binding. This screen will allow the addition of new blocking reagents, editing of existing blocking reagents and deletion of blocking reagents.

Antibody Group

The Antibody reagent group should be utilized to enter new primary antibodies. This screen will allow the addition, modification, and deletion of antibodies.

At the bottom of the **Reagent Details** box:

Designate the appropriate **Pre-Treatment** and **Negative Serum** fields that are linked to the primary antibody of interest. For your own references, you have the option to indicate the **Clone**, **Species**, **Diluent** and **Comments** associated with the antibody of interest.

Negative Serum Group

The Negative Serum reagent group is utilized to assign negative controls associated with antibodies. This screen will allow the addition, modification, and deletion of negative control reagents.

When a negative control is ordered for a particular antibody, a duplicate protocol will be assigned to the case utilizing the negative serum linked to the antibody.

Secondary Group

The Secondary reagent group is used to add, modify, and delete secondary reagents.

Tertiary Group

The Tertiary reagent group is used to add, modify, and delete tertiary reagents.

Chromogen Group

The Chromogen reagent group is utilized to enter new chromogens. This screen will allow the addition, modification, and deletion of chromogens. The Chromogen reagent group includes elements not found on most groups' screens. At the bottom of the Reagent Details box the following information is displayed:

Type

If chromogen mixing properties are not desired, select **Regular**. If chromogen has multiple components that require mixing, select **Mix**.

Waste Disposal Properties

Specifies whether the used reagent is considered hazardous.
Note: The designation of Hazardous or Non Hazardous is dependent upon local and national government regulations.

Stability

A reagent is Unstable if it must be mixed immediately prior to use. Reagents that can be mixed when convenient and then applied at any point during the run after mixing are considered Stable.
Note: The designation of Stability is specified in the manufacturer's recommendations on the product insert.

Counter Stain Group

The Counterstain reagent group includes all counterstains. This screen will allow the addition, modification, and deletion of counterstains. At the bottom of the **Reagent Details** box the following information is displayed:

Waste Disposal Properties: Specifies whether the used reagent is considered hazardous.

Note: The designation of Hazardous or Non Hazardous is dependent upon local and national government regulations.

Ancillary Group

The Ancillary reagent group includes all ancillary reagents not included in any other Reagent Group options. This screen will allow the addition, modification, and deletion of ancillary reagents. The option for mixing ancillary reagents is available in this group.

Mix Group

The Mix group is used to designate components of chromogens, enzymes, and ancillary reagents which will be used by the intelliPATH to perform on-board mixing of these reagents.

1. To add a mixing component reagent, click the desired sub group category. (Chromogen Components, Enzyme Components, Ancillary).

2. Click on the 'Add new Reagent' (+) button below the Reagent Details box.

3. Enter the Name, Catalog number, Short Name, Vendor, and Incubation time.

4. Select **Stability** (Stable or Unstable) to designate whether the reagent needs to be refrigerated while being loaded. Stable reagents are loaded in a 20ml Reagent Vial and do not need to be refrigerated during loading. Unstable reagents are loaded in a 6ml Mixing Vial that require refrigeration in the Cold Spot during loading.

Mixing Properties

Available in Enzyme, Chromogen and Ancillary Reagent Groups. Specifies whether the mixing is performed **Online** (by the instrument during a run) or **Offline** (manually).

Once **Type** is set to **Mix**, the **Mixing Components** link will be available in the top right corner of the **Reagent Details** box.

Example: Chromogen. Use the **Mixing Components** screen to designate the volume (in μl) of chromogen buffer and the volume (in μl) of chromogen substrate. The available components are listed on the left; the components to be mixed are listed on the right. Total volume of mixing components cannot exceed 6ml. To add a new component, go to the **Mix Group**.

1. From the **Chromogen Components** list on the left, highlight the catalog number for chromogen buffer and click the **Add** button to add to the list on the right.

2. Click on the Volume field drop-down menu to select the desired volume (in μL) of buffer.

3. Add Chromogen (concentrate) to the mix in the same way. The minimum volume which may be selected is 100 μl.

4. To delete a component from the list on the right of the screen, highlight it in either list and click the Subtract button.

5. Click Save, then click Close to exit.

AP Labeled Detection System Requirements

Important Note:
intelliPrep Solution is an additional reagent that is required for the use of alkaline phosphatase (AP) labeled detection systems and compatible chromogens. To ensure intelliPrep Solution is included as a required reagent, one of the following Chromogen Kit component part numbers must be used in the **Mixing Components** of the **Chromogen Reagent**: IPBF5016, IPBF5023 or IPBF5026. One of the following detection catalog numbers *must be used* in the step <u>immediately preceding</u> the **Chromogen Incubation Step(s)**: IPSC5004, MRAP536, MRCT525, MM624, GAP628, RALP525, AP605, MRT623, MAP532, MALP521, RAP533, RMR625, RTAP631 or RDS513.

If another catalog number is desired for use, then please contact Biocare Medical Technical Support for assistance.

Protocol Manager Module

Protocol Manager can be reached from the **Data Manager** drop down menu on the **Staining Main Screen** or from a link in the **Reagent Manager**. Administrator users can also open it directly from the **Module Selection Screen**. Use the Protocol Manger module to save, design, and manage protocols and detection templates.
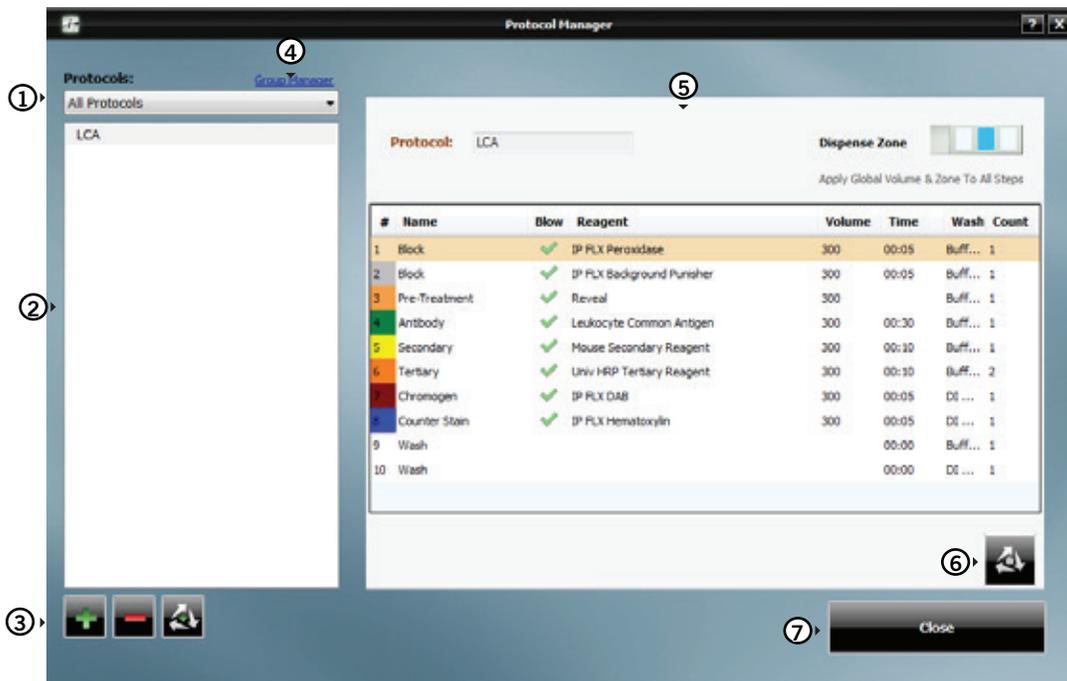
① You can filter the list of protocols by choosing **All Protocols** or by choosing a Custom Group in the **Protocols:** drop down menu.

② A filtered list of protocols will appear below the **Protocols:** drop down menu based on the drop down choice.

③ Use the buttons at the bottom left of the window to 'Create New Protocol'(+), 'Delete Selected Protocol'(-), or 'Create New from Selected Protocol' (3 white arrows surrounding a green plus sign).

④ The **Group Manager** link is available above the **Protocols:** drop down menu in the top left of the window.

⑤ The information about the selected protocol will appear in the **Protocol** section on the right half of the window.

- The name of the protocol appears in a window which can be edited if the edit button is clicked.
- The **Dispense Zone** can be viewed in the **Protocol** section.
- In the Dispense Zone diagram, the slide is divided into top, ▨▨▨ middle, ▨▨▨ and bottom ▨▨▨ sections. Blue color in a section indicates reagent dispense zone. Dispense volume for each zone is determined by dividing the total dispense volume by the number of dispense zones.
- All steps of the protocol are viewable including all details associated with those steps.

⑥ The **Edit** button allows a user to change the following items in a protocol:
- Modify existing protocol name
- Modify dispense zone for the entire slide
- Click **Apply Global Volume & Zone To All Steps** to assign the global settings from **Stainer Options** or choose a new setting (**Select Volume & Zone** will open)
- Modify existing reagent, blow, volume, time, wash type and wash count for any step in a protocol
- Use buttons to add, insert, delete or move steps in the protocol

⑦ To exit, click the **Close** button.

System Setup Module (Stainer Options)

This module allows the Administrative user to set preference and default parameters. The system software settings will either be entered manually or be accessible from drop down menus. The menu items are categorized ⊞≡, but they may also be alphabetized in ascending ⒜↓ order. The menu item components may be expanded or collapsed by clicking the + or - box to the left of the menu item.
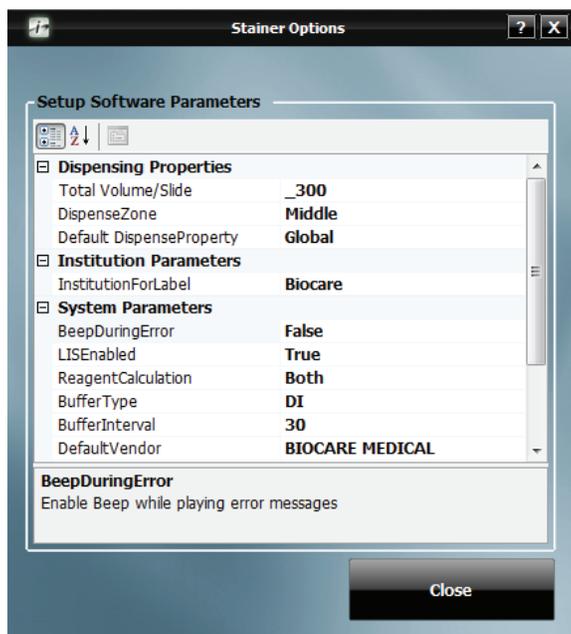
Dispense Properties

This is the global default value, but it can be changed for individual protocol steps in the **Slide Manager** screen (which you reach from the Prepare Labels button of the Prepare Slides window), **Protocol Manager** and **Slide Edit.**

Total Volume/Slide

Set the default dispense volume in µl. The dispense volume is divided by the number of dispense zones. The minimum dispense volume is 100 µl for one zone, 150 µl for two zones , and 200 µl for three zones.

Dispense Zone

Set the default dispense zone for the slides. Dispense zone options are Bottom [ ], Middle [ ], Top [ ], Bottom Middle [ ], Top Bottom [ ], Top Middle [ ], Full Slide [ ].

Default Dispense Property

Users can choose either Global or Protocol. Global will pull from here. Protocol will pull from **Protocol Manager.**

Institution Parameters

Institution For Label

Free text field to enter institution name. This information may appear on slide labels.

System Parameters

Beep During Error

Select True or False. If **True** is selected, system beeps while displaying error messages. If **False** is selected, system does not beep while displaying error messages.

LIS Enabled (to be set by authorized Biocare Personnel Only)

Select False or True. If **False** is selected, LIS is not enabled. If True is selected, LIS is enabled.

Reagent Calculation

Set option for software to calculate reagent volumes in **Load Reagents** window for **Loaded Slides**, **Checked Slides** or **Both**.

Buffer Type

Designates which **Buffer** or **DI Water** solution will be applied if **Buffer Slides After Completion** is set to **True**.

Buffer Interval

Time in minutes between buffering of slides after run completion. Valid range is between 30 and 60 minutes.

Default Vendor

Default Vendor name can be specified. Default Vendor is displayed when creating a new reagent in **Reagent Manager**.

Buffer Slides After Completion

Select True or False. If **True** is selected, buffer will be applied to slides after the run completes at the designated interval. If **False** is selected, slides will air dry after the run completes.

Default Delay

The staining run can be delayed from the **PreStart CheckList**. The default delay drop down has options from 2- 12 hrs. The default delay can be specified here.

System View Displayed

Select False or True. If False is selected, Map View will be displayed in Staining Main Screen. If True is selected, System View will be displayed in Staining Main Screen.

Use Touch Screen Keyboard

Use **Touch Screen Keyboard** to select True or False. Touch Screen Monitor must be installed prior to selecting True.

Generate Reports Module

The Generate Reports module is available from the **Module Selection Screen** and also from the **Tools** drop down menu in the **Staining Main Screen** under **Print Reports**.

To print a report, highlight it in the list on the left side of the Generate Reports screen. In most cases, you will also have to set parameters for the report from drop down menus on the right. Then click **Generate Report**.
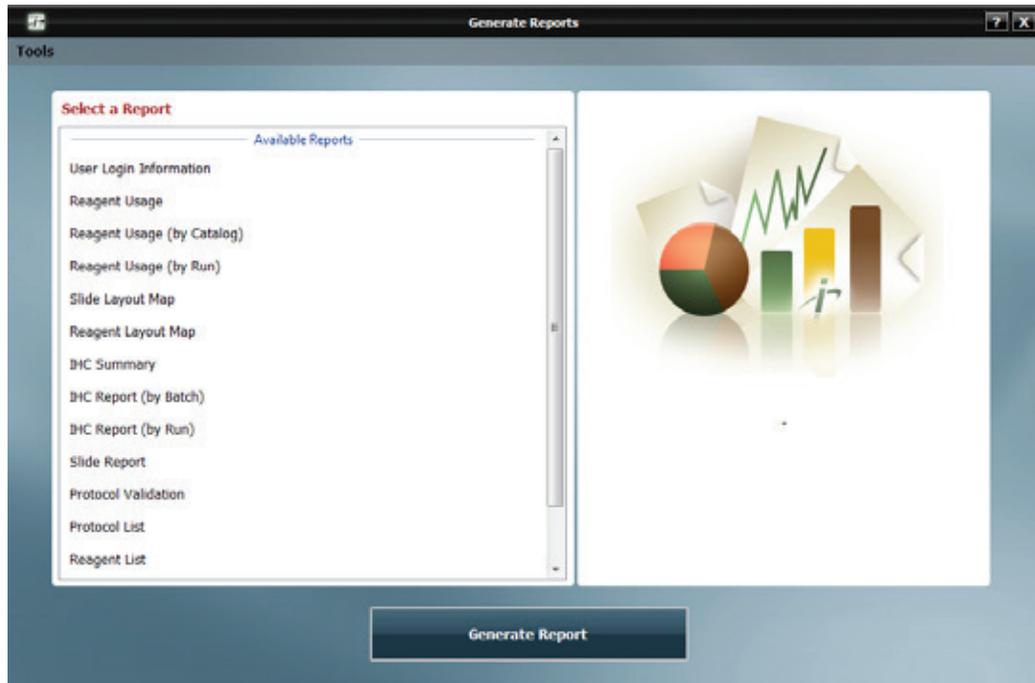
| Report Types	Description
User Login Information	States the user activities, including user ID and Login Date/Time
Reagent Usage	Provides the total volume of all the reagents used for the various runs.
Reagent Usage (by Catalog)	Lists the total volume of reagent usage by catalog number for all runs.
Reagent Usage (by Run)	Collates all the information for reagent usage for a specific run.
Slide Layout Map	A diagram of the slides used in a run and their positions in the slide racks.
Reagent Layout Map	A diagram of the reagents used in a run and their positions in the reagent rack.
IHC Summary	Provides a combination of Reagent Details similar to Reagent Usage (by Run) as well as Slide Details including Slide Position, Case, Block, and Protocol name.
IHC Report (by Batch)	Provides detailed information of every slide in a Batch such as slide position as well as all protocol steps.
IHC Report (by Run)	Provides detailed information of every slide in a Run such as slide position, batch number as well as all protocol steps.
Slide Report	Provides details of the slide that was stained (by Slide ID)
Protocol Validation	Provides a report for a protocol indicating all the steps performed, a comment section, and sign off section for the pathologist.
Protocols List	Generates a list of all protocols.
Reagents List	Generates a list of all reagents grouped by vendor.
Slide Volume (by Protocol)	Provides a report of the number of slides performed for each protocol for a specific date range.
Slide Volume (for a Date Range)	Provides a graphic for number of slides processed for a specific date range (grouped by month) as well as a list of the same.

The user may also **Print Slide Layout Report, Print Reagent Layout Report** or **Print Run Log Report** from the **Tools** drop down menu of the **Staining Main Screen.**

System Cleanup Module

The System Cleaning module provides instructions for performing the instrument cleaning protocol. It is recommended that the instrument be cleaned after every 250 stained slides once a week. During the cleaning protocol, do not allow the Buffer and Water intake filters to touch unclean surfaces. The System Cleanup module is available from the **Module Selection Screen** and also from the **Tools** drop down menu in the **Staining Main Screen** under **System Cleaning**.

1. Perform each of the **Pre-Requisites for Cleaning** listed on the screen below, in the specified order, and check the boxes as you complete the tasks.

   - Mix 5 ml hydrochloric acid with 95 ml of ethanol. Pour the mixture into the waste sink. Wait for 30 minutes.
   - Fill 4 liters of deionized (DI) water into the DI Water carboy.
   - Fill 4 liters of buffer into the Buffer 1 carboy.
   - Mix 0.5 ml of DAB Away Reagent 1, 0.5 ml DAB Away Reagent 2, and 4 ml of DI water in a reagent vial. Place the vial in position **A1.**
   - Load 5 ml of DAB Decolorizer in a reagent vial. Place the vial in position **A2.**
   - Empty the Hazardous Waste carboy.
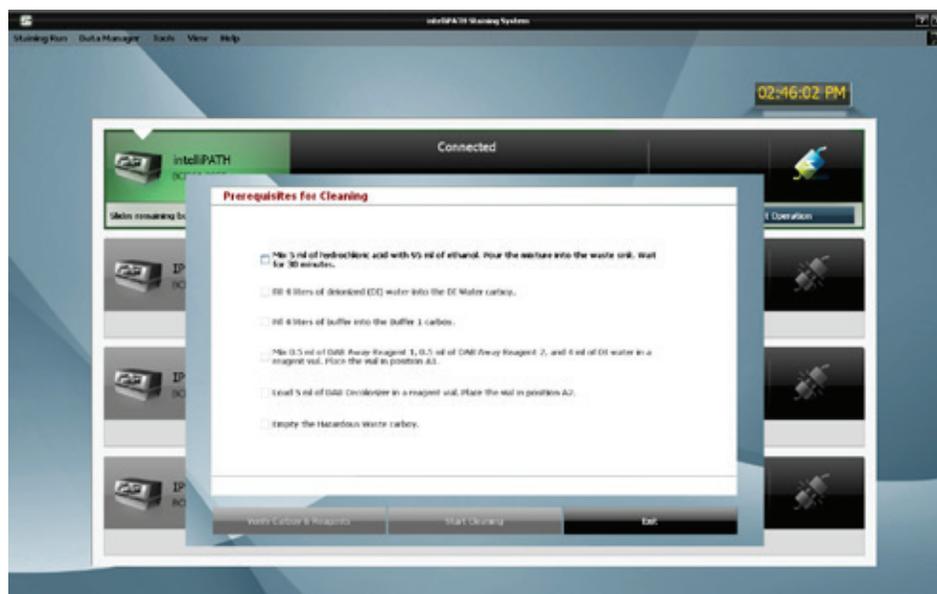
Caution: Do not allow cleaning reagents to come into contact with bleach (if used).

2. Click **Verify Carboys & Reagents.**
3. Click **Start Cleaning.**
4. To exit the **System Cleaning** Module, click **Done with Cleaning**.
5. The **Cleaning Log** can be reached by clicking the **View Cleaning Log** link in the **System Cleaning** screen.
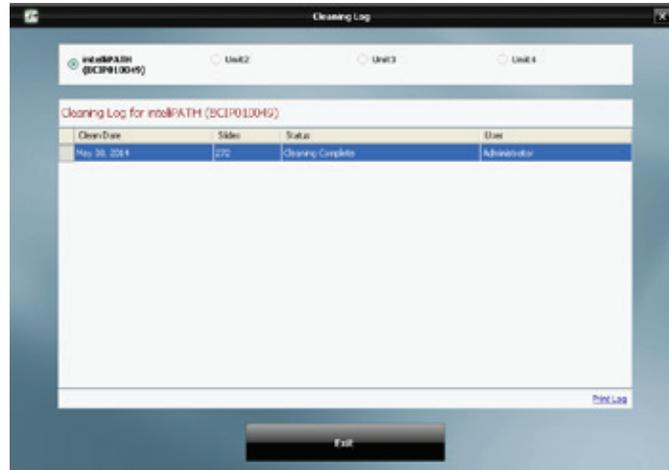
- The name of the instrument is the name of the radio button. If an instrument is not connected, a placeholder name of Unit# is listed.
- The user can choose the instrument by clicking on desired instrument radio button.
- The following information is displayed:
  - o Clean Date - Date of the cleaning
  - o Slides - Number of slides that were run before cleaning
  - o Status - Completed or Canceled
  - o User - Logged in User
- To print the cleaning log, click the **Print Log** link.

6. If "Slides remaining before Cleaning" has reached zero or less than zero, the **Cleaning Required** message will appear upon executing the **Stainer Application Module**.
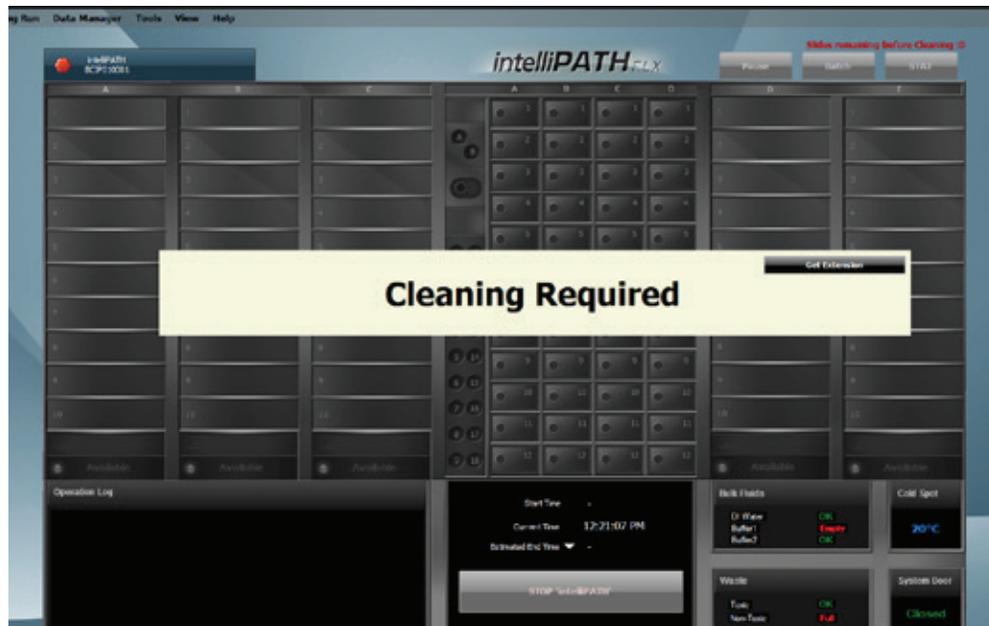
- Go to the **Tools** drop down menu and choose **System Cleaning** at this time.
- In the event that it is not possible to clean the instrument when the cleaning is required, the user may click the **Get Extension** button. The following window will appear.
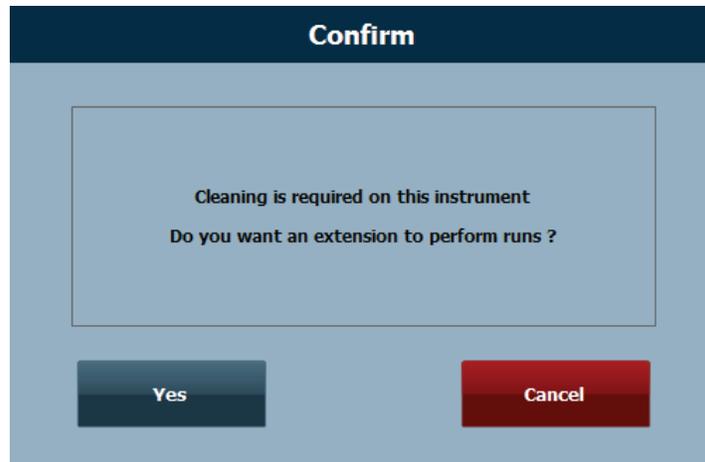
- A one time extension may be performed. This extension will allow the user to perform runs for that day only.

Reagent Inventory Manager Module

The reagent Inventory Manager allows the user to enter and track reagent lot, expiration, starting volume, current volume, and serial number to be used on the instrument.
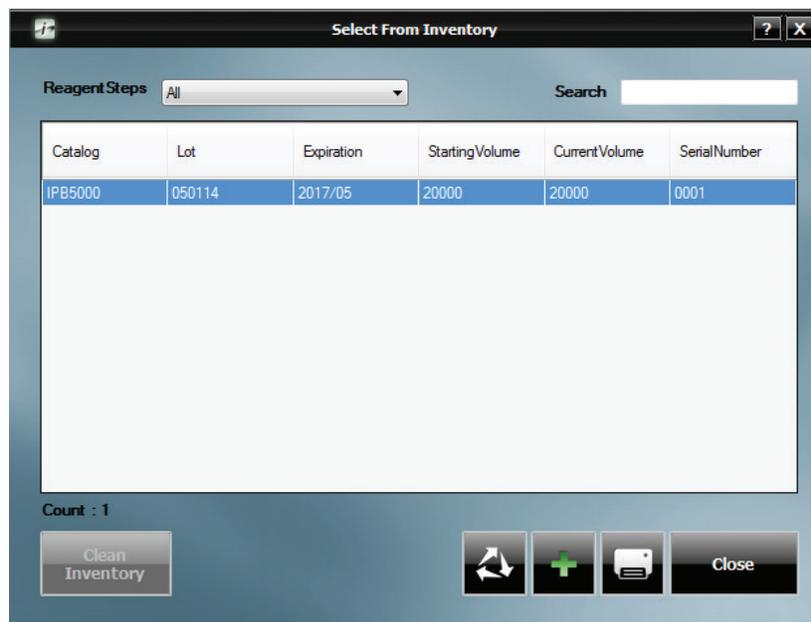
Reagent Inventory Manager can be reached from the **Module Selection** Screen as well as the **Data Manager** drop down menu in the **Staining Main Screen**. When **Reagent Inventory Manager** is chosen, the **Select From Inventory** window is displayed. The list of reagents can be sorted by any field by clicking on the header.

Note: When **Reagent Inventory Manager** is opened from the **Data Manager** drop down menu in the **Staining Main Screen**, the **Register Reagents** button is not displayed as it is not available after initialization.

Clicking **Clean Inventory** will remove any reagents that have no more usable volume or that are expired.

To register Biocare reagents via the **2D Matrix Scanner** and add them to the **Reagent Inventory Manager**, click the **Register Reagents**

button. Note that this can only be done from the **Module Selection** screen. The **Scan Reagent Inventory** window is displayed.

     • To scan the reagents, click on **Scan** button. The instrument will scan for all of the reagents that are loaded in the **Reagent Rack** and lists them in this screen.

     • To save these listed reagents to the inventory, click the **Save** button. The Reagents with valid lot number and expiration dates are saved to the inventory and this window is closed.

     • To Cancel scanning further, click the **Cancel** button.

This list of reagents in **Reagent Inventory Manager** is also populated by right clicking on a reagent in the **Reagent Rack** during the **Load Reagents** process and choosing **Reagent Register**.

     • Upon doing so, the **Reagent Register** window will appear.

     •   Lot Number, Expiration and Serial ID can be entered (each registered reagent requires a unique 4-digit Serial ID). Enter the information requested and click **OK**.

     •   Reagent Registration information will be permanently stored in **Reagent Inventory Manager** for future use.

Click the **Add** button to manually enter reagents to the inventory. The **Add Reagent Inventory** window will be displayed.

     •   Enter the information in the input fields. All inventoried (registered) reagents require a 4 digit serial number. Use the Browse feature to find an existing Catalog Number. The **Reagent Lookup** window will be displayed.

Catalog	Reagent Name
IPAS018	intelliPrep Solution
IPB5000	IP FLX Peroxidase
IPBF5009	IP FLX DAB Buffer
IPC5008	IP FLX DAB Chromogen
IPCS5006	IP FLX Hematoxylin
IPK5010	IP FLX DAB
IPSC5001	Mouse Secondary Reagent
IPT5002	Univ HRP Tertiary Reagent
IP016	Leukocyte Common Antigen
RV1000	Reveal
IP498	Universal Negative Control
IP974	IP FLX Background Punisher
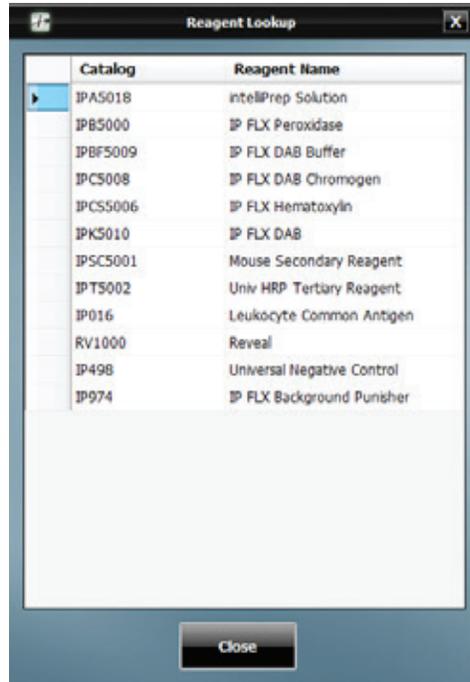
- If the browse feature is utilized, select the desired reagent and click **Close**.
- Once all information has been entered, click **Save** and the **Select From Inventory** window of **Reagent Inventory Manager** will appear again.

The **Current Volume** is calculated by the intelliPATH software as the reagent is used up during staining runs.

Use the **Print Label** button to print the label for the reagent directly from the **Select From Inventory** screen in order to capture lot and expiration information within the label needed for use.

Administrative Program Preparation & Setup

Administrative users can follow the detailed steps in this chapter to incorporate or change users, passwords, reagents, and protocols on the instrument.

Assign or Modify Users

Only Administrative users can assign or modify user accounts. Regular Users can modify their own passwords.

1. From the **Module Selection** menu select the **User Manager** Module. Press **Execute** to proceed.
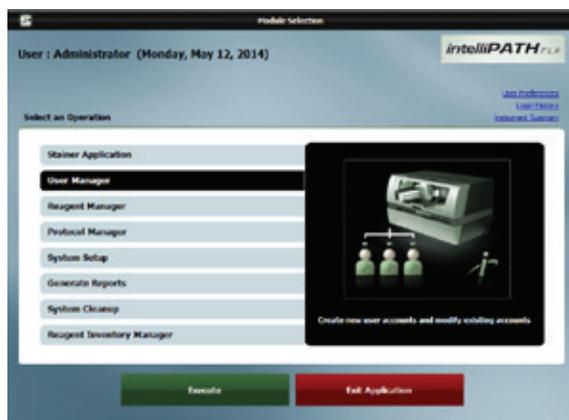
Assign a user account

2. To add a new user, press the **Add** button at the bottom left side of the screen.

3. Enter the appropriate user information and press **Save**.

Modify a user account

4. To modify an account or password, select the appropriate account and press **Delete** or **Edit** button at the bottom left side of the screen.
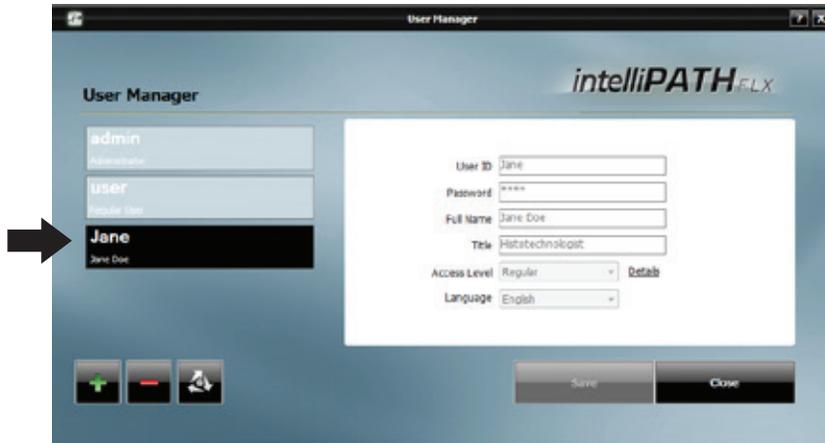
Modify Passwords

Users may change their password through the User Preference link.

1. From the top right side of the **Module Selection** menu select the **User Preferences** Module. From the **Change My Information** window, update the password information and click **OK** to proceed.
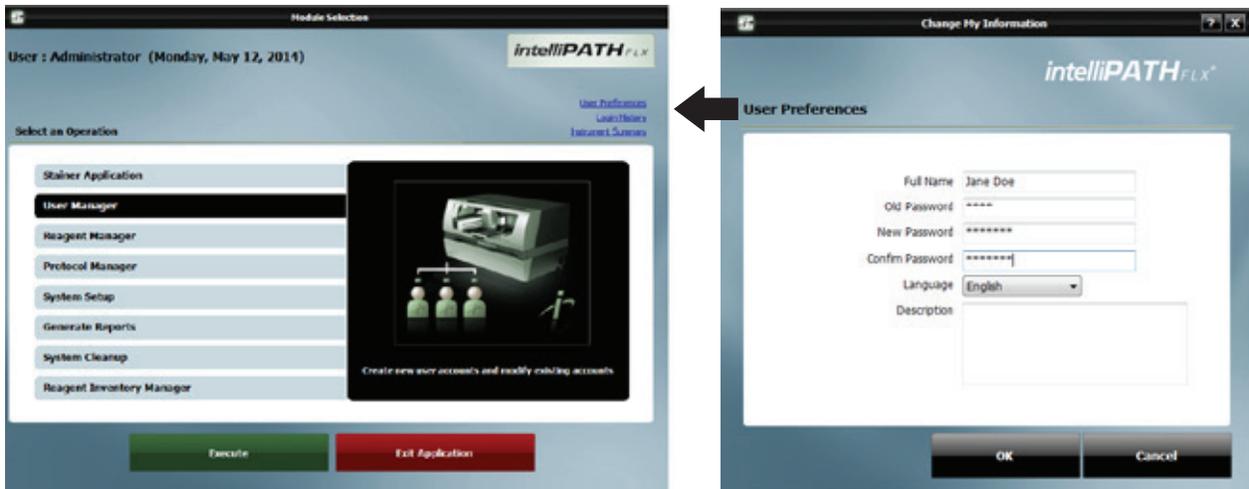
Assign or Modify Reagents
Only Administrative users can assign or modify Reagents in the Reagents Manager.

> **Example Setup**
>
> To better illustrate how to setup and perform a run, an example scenario is provided. You may use this tool as a quick-start procedure to familiarize yourself with the workflow process. See product datasheet for protocol details.
>
> - **Pre-Treatment:** Reveal
> - **Block:** Peroxidazed 1 (Cat. No. PX968) for 5 min
> - **Antibody:** Ki-67 (M) (Cat. No. IP375) for 30 min
> - **Detection:** MACH 3 Mouse AP Polymer Detection (Cat. No. M3M532)
>   - **Secondary:** MACH 3 Mouse Probe (MP530) for 10 min
>   - **Tertiary:** MACH 3 Mouse AP-Polymer (MAP532) for 10 min
> - **Chromogen:** iP Warp Red (Cat. No. IPK5024) for 7 min
> - **CounterStain:** iP FLX Hematoxylin (Cat. No. IPCS5006) for 5 min

1. From the **Module Selection** menu select **Reagent Manager** Module. Press **Execute** to proceed. **Reagent Manager** can also be reached from the **Data Manager** drop down menu on the **Staining Main Screen**.

2. Go through each **Reagent Group** and confirm that the desired reagent exists or set up the appropriate reagents and conditions.

    2a. Pre-Treatment Group

- Select **Pre-Treatment** from Reagent Group at the left side of the screen.
- **Note: Reveal** exist as a Pre-Treatment reagent.
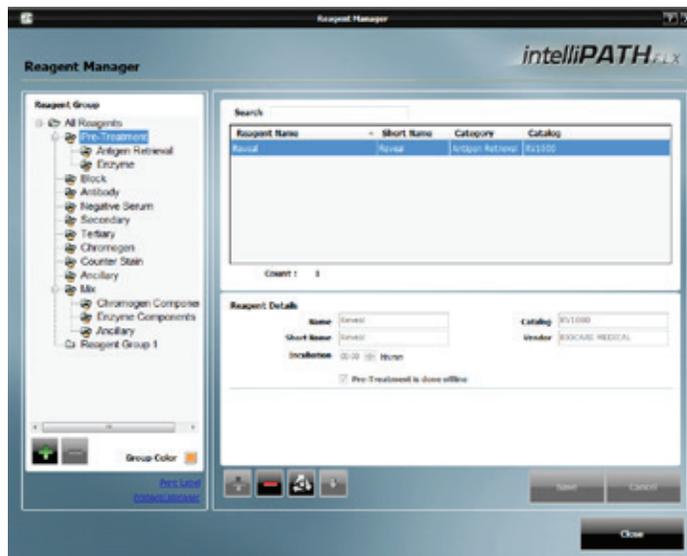
- **Note:** If you would like to add a new pretreatment reagent which is not in the list, select the desired subgroup (**Antigen Retrieval** or **Enzyme**) under **Pre-Treatment** in the **Reagent Group** list. Then click the 'Add new Reagent' (+) button in the lower center of the window. Enter the appropriate Name, Catalog Number, Short Name and Vendor information in the **Reagent Details** section. Enter Incubation for Enzyme or check the box **Pre-Treatment is done offline** for Antigen Retrieval. Click **Save**.

Within Enzyme Sub Group, if **Type** is set to **Mix**, the **Mixing Components** link will be available in the top right corner of the Reagent Details box. Use the Mixing Components screen to designate the volume (in µl) of each component. The available components are listed on the left; the components to be mixed are listed on the right. Total volume of mixing components cannot exceed 6ml.

2b. Block Group

- Select **Block** from the **Reagent Group** at the left side of the screen.
- Note that **Peroxidazed 1** does not exist.
- To add **Peroxidazed 1**, click the 'Add new Reagent' (+) button. Enter the appropriate Name, Catalog Number, Short Name, Vendor and Incubation information in the **Reagent Details** section. Click **Save**.
- Alternatively, click **Import Reagent From Master List** button and import desired reagent.
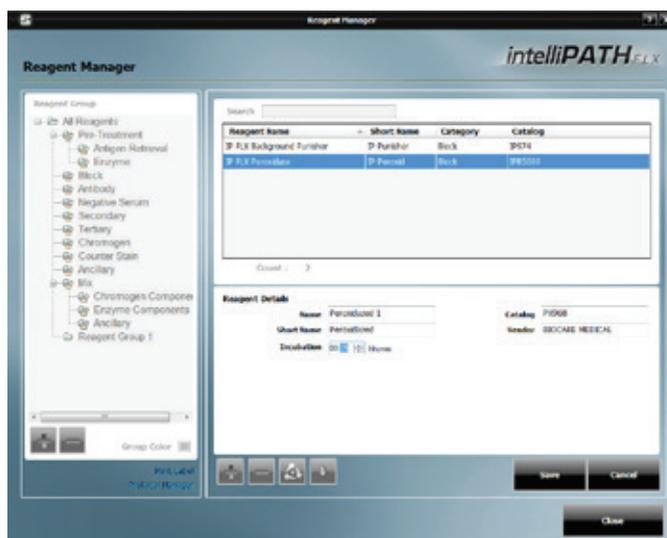
2c. Antibody Group

- Select **Antibody** from Reagent Group at the left side of the screen.
- Note that **Ki-67** does not exist.
- To add a new antibody, click the 'Add new Reagent' (+) button. Enter the appropriate Name, Catalog Number, Short Name, Vendor, Incubation, Pre-Treatment and Negative Serum in the **Reagent Details** section. Clone, Diluent, Species and Comments may also be entered. These four fields are optional. Click **Save**.

- **Note:** Choosing a pretreatment to associate with a specific antibody in the **Antibody Reagent Group** of **Reagent Manager** will allow it to automatically populate that pretreatment when selecting that antibody in a Protocol.
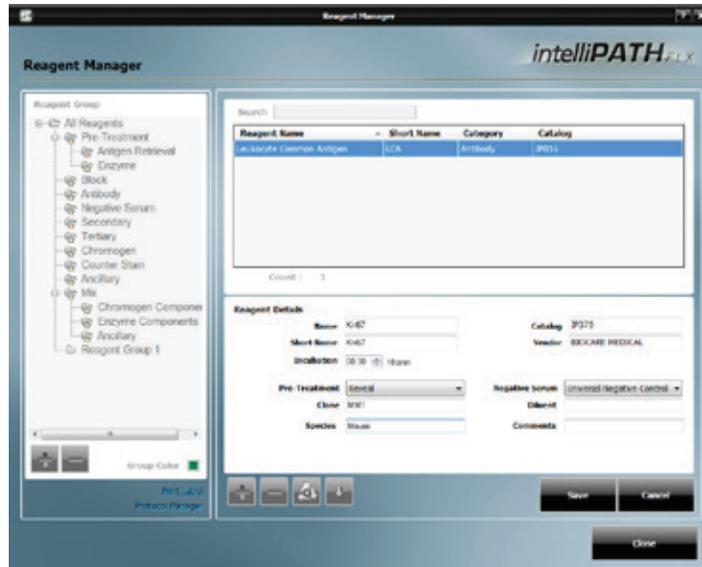
2d. Secondary Group

- Select **Secondary** from the **Reagent Group** at the left side of the screen.
- Note that **MACH 3 Mouse Probe** does not exist.
- To add **MACH 3 Mouse Probe**, click the 'Add new Reagent' (+) button. Enter the appropriate Name, Catalog Number, Short Name, Vendor and Incubation information in the **Reagent Details** section. Click **Save.**
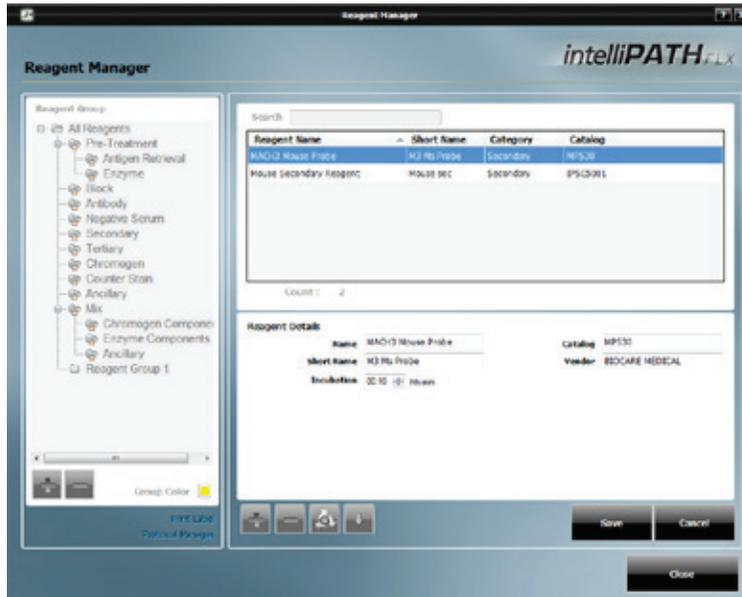
2e. Tertiary Group

- Select **Tertiary** from the **Reagent Group** at the left side of the screen.
- Note that **MACH 3 Mouse AP Polymer** does not exist.
- To add **MACH 3 Mouse AP Polymer**, click the 'Add new Reagent' (+) button. Enter the appropriate Name, Catalog Number, Short Name, Vendor and Incubation information in the **Reagent Details** section. Click **Save**.
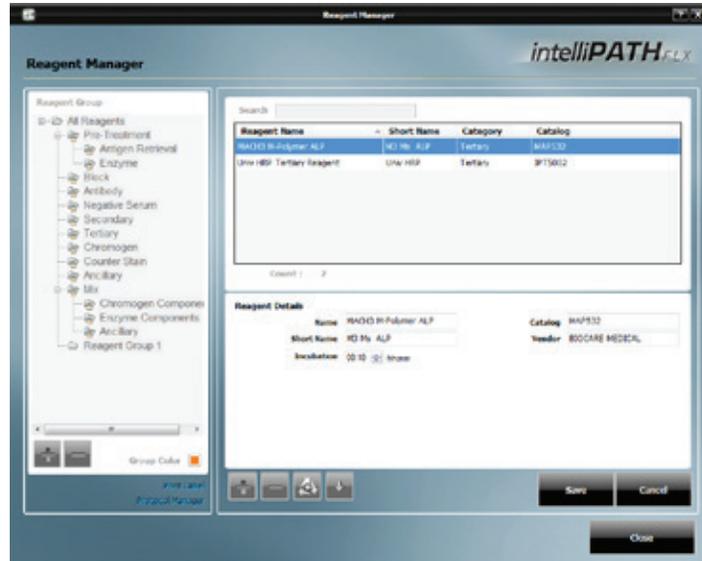
2f. Chromogen Group

- Select **Chromogen** from the **Reagent Group** at the left side of the screen.
- Note that **IP Warp Red** does not exist.
- To add a new chromogen, click the 'Add new Reagent' (+) button.
  - o Enter the appropriate Name, Catalog Number, Short Name, Vendor and Incubation information in the **Reagent Details** section.
  - o Choose Regular (if mixed offline) or Mix (if mixed online) from the drop down menu.
  - o Select desired properties for Waste Disposal, Mixing (Online to have the instrument mix the chromogen or Offline to have the user mix the chromogen), and Stability (Stable if the mixed chromogen can be applied anytime during the course of the run or Unstable if the mixed chromogen must be applied immediately after mixing).
  - o Click the **Mixing Components** link, choose a component from the left window, click the **Plus (+) Sign** to add the component, set the minimum mixing volume. Repeat until all components have been added in the order desired. The total mixing volume cannot exceed 6 ml.
  - o Click **Save** to close the **Mixing Components** window. Click **Save**.
- For more information, refer to the **Reagent Manager Module** section of **Module Descriptions.**

2g. Counter Stain Group

- Select **Counter Stain** from the **Reagent Group** at the left side of the screen.
- Locate **IP FLX Hematoxylin** from the reagent list.
- To add a new Counterstain, click the 'Add new Reagent' (+) button. Enter the appropriate Name, Catalog Number, Short Name, Vendor and Incubation information in the **Reagent Details** section. Choose **Waste Disposal Properties** and click **Save.**
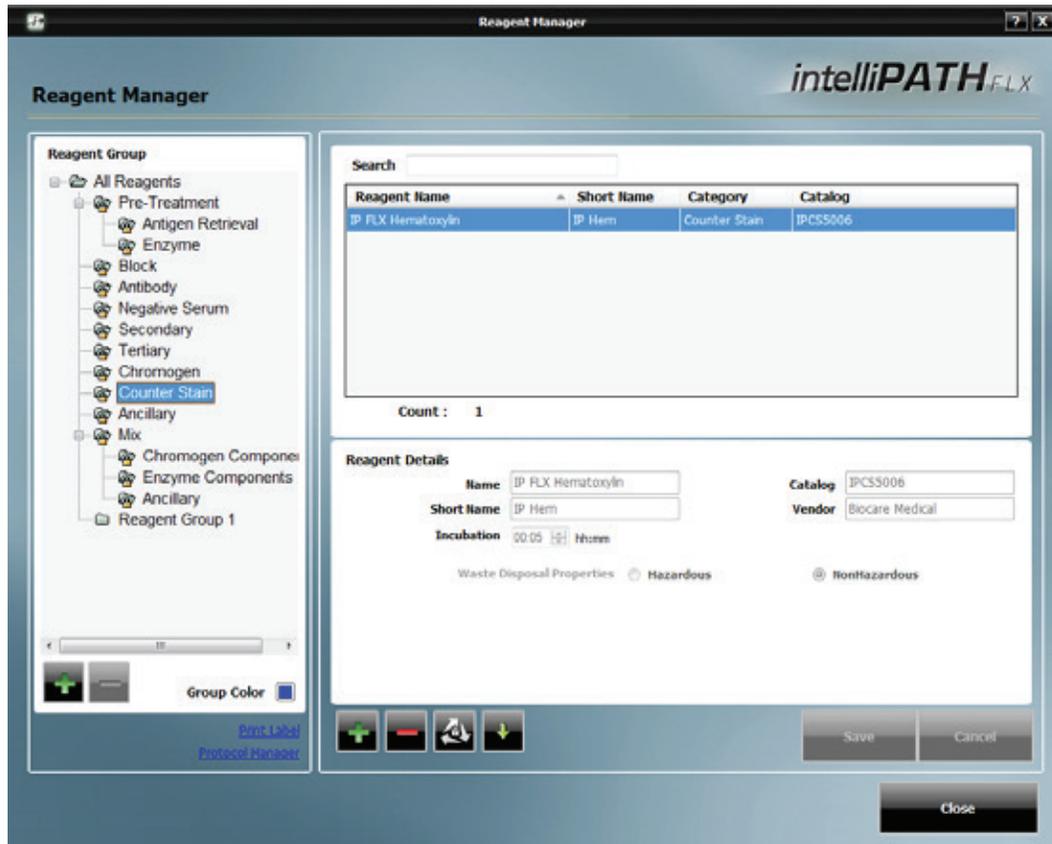
2h. Negative Serum Group

- If a desired Negative Serum was not available in the Negative Serum drop down menu when creating an antibody, then select the **Negative Serum Reagent Group** at the left side of the screen.
- Click the 'Add new Reagent' (+) button. Enter the appropriate Name, Catalog Number, Short Name, Vendor and Incubation in the **Reagent Details** section. Species and Comments may also be entered. These two fields are optional. Click **Save**.

3. Select **Protocol Manager Link** to continue**.**

Assign or Modify Protocols

Only Administrative users can assign or modify Protocols in Protocol Manager.


Example Setup

To better illustrate how to setup and perform a run, an example scenario is provided. You may use this tool as a quick-start procedure to familiarize yourself with the workflow process. See product datasheet for protocol details.

- **Pre-Treatment:** Reveal
- **Block:** Peroxidazed 1 (Cat. No. PX968) for 5 min
- **Antibody:** Ki-67 (M) (Cat. No. IP375) for 30 min
- **Detection:** MACH 3 Mouse AP Polymer Detection (Cat. No. M3M532)
    - **Secondary:** MACH 3 Mouse Probe (MP530) for 10 min
    - **Tertiary:** MACH 3 Mouse AP-Polymer (MAP532) for 10 min
- **Chromogen:** iP Warp Red (Cat. No. IPK5024) for 7 min
- **CounterStain:** iP FLX Hematoxylin (Cat. No. IPCS5006) for 5 min

---

1. Select **Protocol Manager** link from the bottom left of the **Reagent Manager** window, from the **Module Selection** window or from the **Data Manager** drop down menu.

2. Create a New Protocol

    2a. Create a new protocol <u>not</u> based on an existing protocol
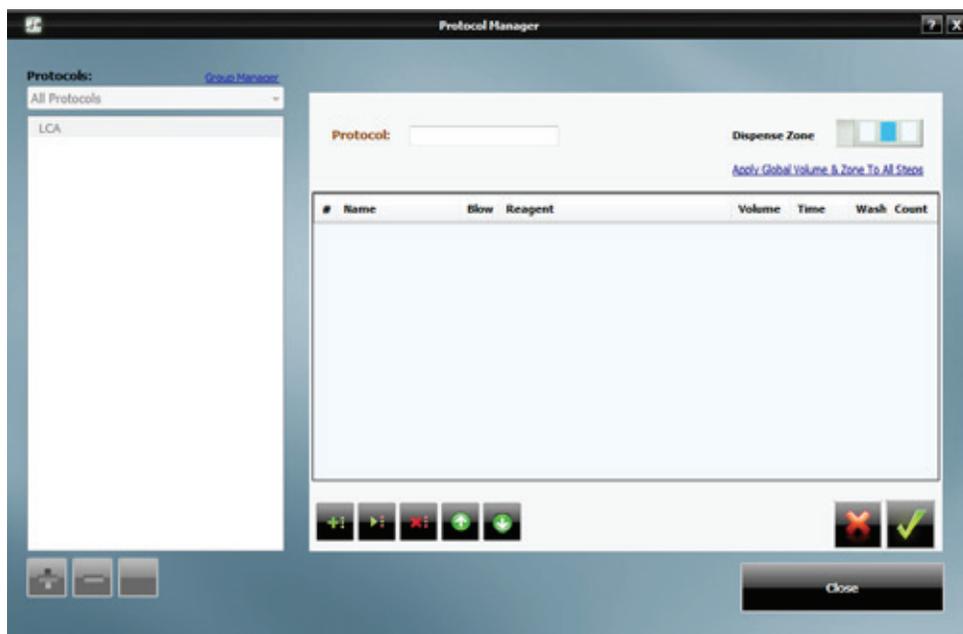
- Click **Plus (+) Sign** to create a new protocol.
- Enter the new protocol name, **Ki67 AP**, in the **Protocol**: field.
- Select desired Dispense Zone. (Note that this will only be activated if **System Setup Stainer Options** section is set to **Protocol** for **Default DispenseProperty.**)
- Click **Plus (+) Sign** to add a step. In the **Name** column, choose **Block** from the drop down menu of **Reagent Group** names.
    - o To create a new **Reagent Group**, type the name of the new group (new reagent group will automatically be added to **Reagent Manager**).
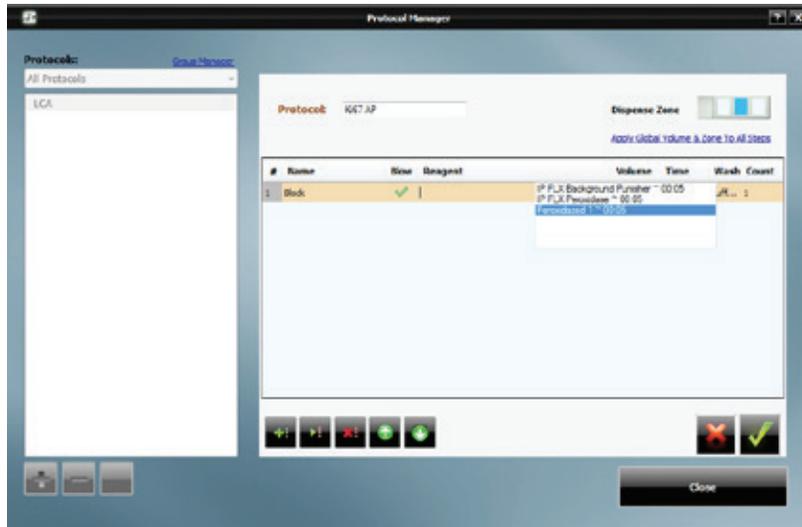
• In the **Reagent** column, choose **Peroxidazed 1** from the drop down menu of **Reagent** names. The Volume will automatically populate from **Stainer Options** and may be changed. Incubations of existing reagents will automatically populate from **Reagent Manager** and may be changed.

   o To create a new **Reagent Name**, type in the name of a new reagent (new reagent will automatically be added to **Reagent Manager**). New reagents are assigned a 10 minute incubation which may be changed to the desired incubation.
   o The **Blow** may also be turned off or left on. Turning off the **Blow** will leave any fluid from the previous step on the slide (including Pre-Rinse). Modifying the **Blow** status was designed for double application of reagent.
   o The type of **Wash** may also be changed to **DI Water** or **Buffer 2** or may remain **Buffer 1**.
   o The **Wash Count** may be increased or decreased or may remain a count of 1. Setting the **Count** to 0 will leave the current reagent on the slide without washing it off before performing the next step. Setting the **Count** to 0 and then turning off the **Blow** to the next step will allow for double application of a reagent if both steps apply the same reagent.

• Click **Plus (+) Sign** to add a new step and repeat the above process until all steps have been programmed.

   o The **> (right triangle)** allows the user to insert a step above the currently selected step.
   o The **X** allows the user to delete a step.
   o The **Up Arrow (↑)** will move the currently selected step up in the protocol.
   o The **Down Arrow (↓)** will move the currently selected step down in the protocol.

• Click **Green Check Mark** to save the protocol.

2b. Create a new protocol based on an **existing protocol**

   • Choose protocol from which to base new protocol from the list of protocols
   • Click **Create New from Selected Protocol** button
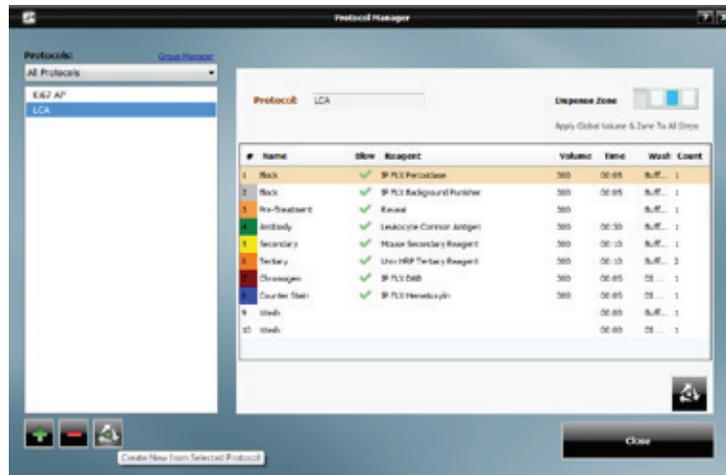
• Protocol name will automatically update to xxx copy (1). User may change if desired.
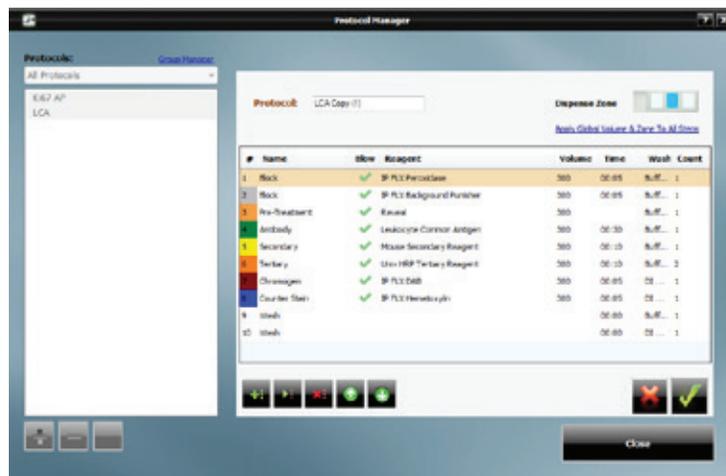
• Make changes to existing selections as needed.
• Utilize any of the available options:
    o The **Plus (+) Sign** allows the user to add a new step.
    o The **X** allows the user to delete a step.
    o The **> (right triangle)** allows the user to insert a step above the currently selected step.
    o The **Up Arrow (↑)** will move the currently selected step up in the protocol.
    o The **Down Arrow (↓)** will move the currently selected step down in the protocol.
• Click **Green Check Mark** to save the protocol.

2c. Additional Wash, Blow or Pause steps

• A separate additional Wash or Blow Step as well as a Pause Step may be inserted into a Protocol.
• If a Pause Step exists within a Protocol, when the system reaches the Pause step, the slide display will blink. Right clicking on the paused slide will offer the following options: Cancel Slide or Resume Operation.
    o Choosing Cancel Slide will cancel the slide.
    o Choosing Resume Operation will resume the slide process.

Additional Program Preparation & Setup

Creating Custom Groups

The creation of Custom Groups allows the laboratory to create groups of Protocols utilized by the laboratory rather than having to scroll through the list of All Protocols.

1. Select **Group Manager** link from the top left of the **Protocol Manager** window or from the **Data Manager** Drop Down Menu on the **Staining Main Screen**.

2. Click **Plus (+) Sign** to add a new **Group** in the **Group Manager** window.
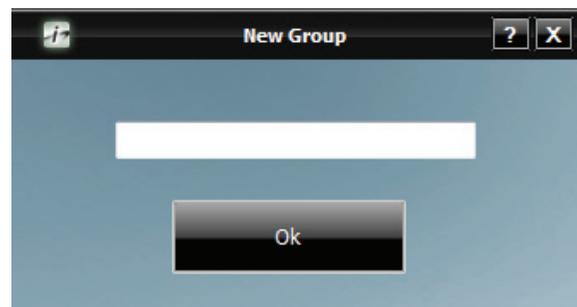
3. Enter the desired **Group** name in the **New Group** window and click **OK**.
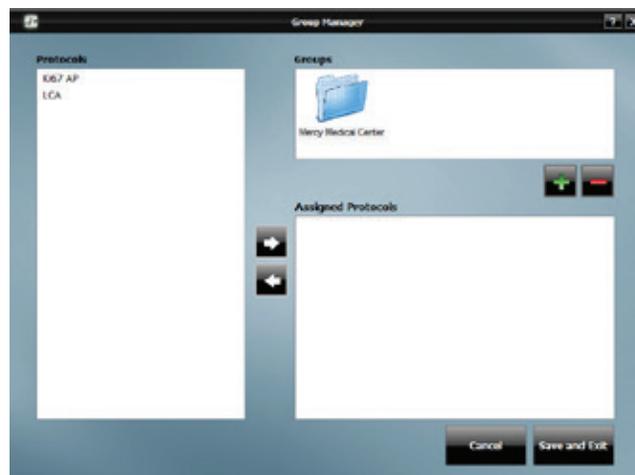
4. Use the **Right Arrow (→)** to add **Protocols** to the selected **Group.** Use the **Left Arrow (←)** to remove Protocols from the Group. When finished, click **Save and Exit.**
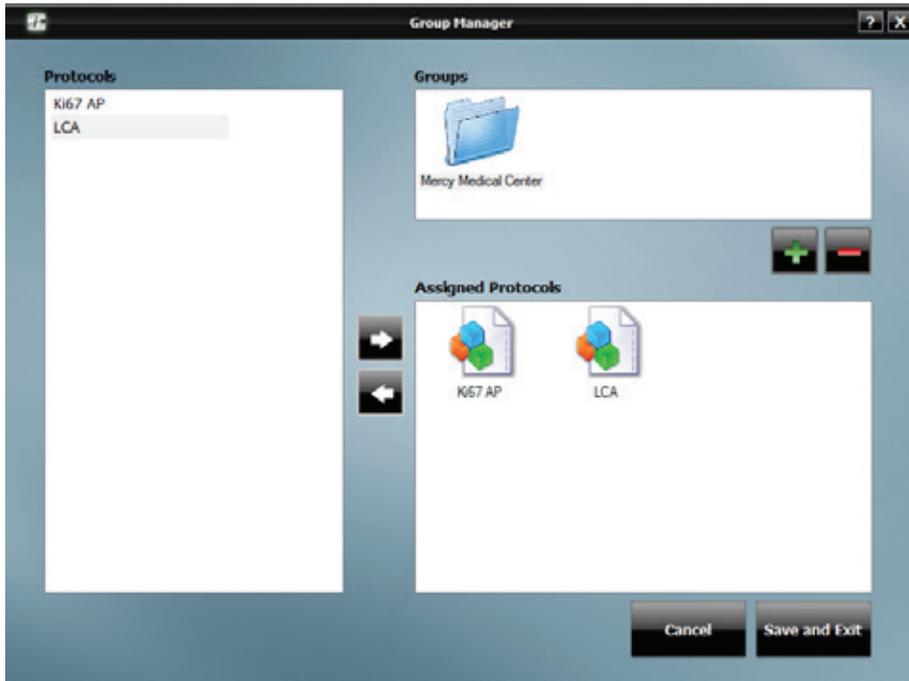
Setting Up Slide Fields

1. From the **Tools** drop down menu of the **Staining Main Screen**, choose **Setup Slide Fields**. The **Design Slide Fields** window will open.
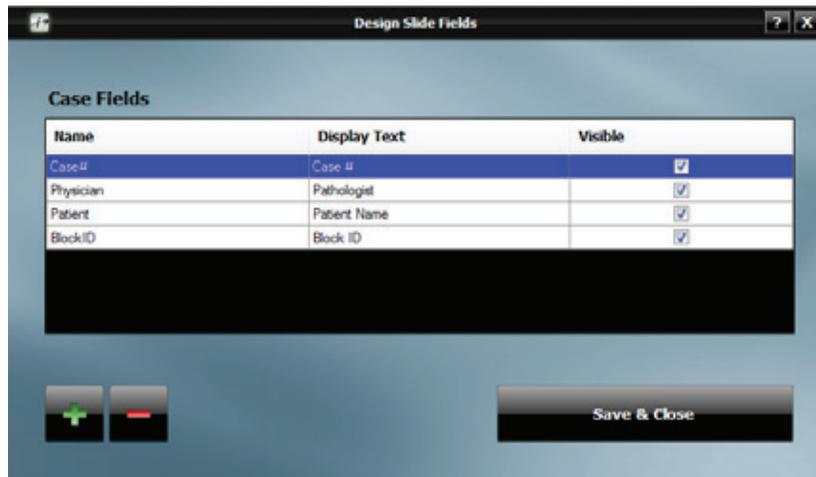
2. Use the **Add** and **Delete** buttons to make changes to the list of fields.

3. Each Case Field has the following properties:
- **Name:** The name of the field that can be referenced by other parts of the program.
- **Display Text:** The text that appears in the **Slide Details** section of **Add Slides, Slide Manager** and **Assign Slides** to identify the field.
- **Visible:** Whether the field appears in the **Slide Details** section at all.

Designing the Slide Label

1. The **Slide Label Designer** is located under **Label Designer** in the **Tools** menu of the **Staining Main Screen**. Upon selection, the **Design Slide Label** window will open.
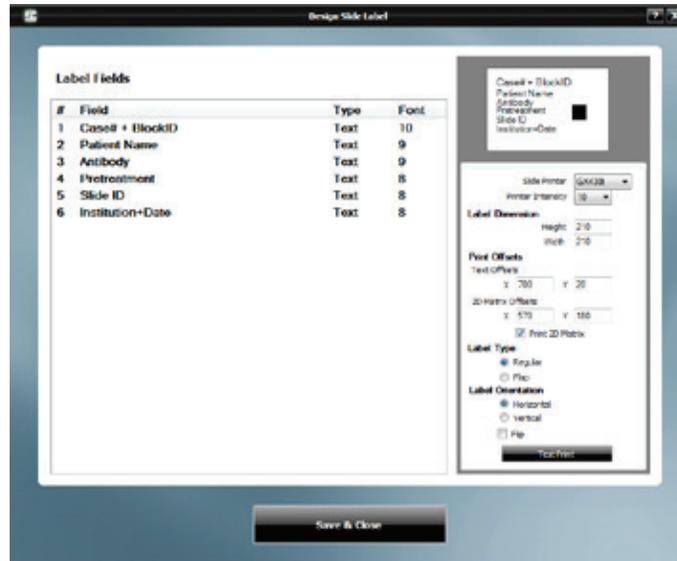
2. There are 4 columns in the Label Fields section.

- The first column is the Line # on the label.
- The second column is the field displayed in that line. There are 6 Label Field lines which are configurable by the user. The available options in the drop down menu are: Slide ID (unique identifier), Patient Name, Pathologist, Protocol Name, Pretreatment, Antibody, Case #, Block ID, Case# + BlockID, Institution, and Institution+Date. Additional options may be created by the user in Design Slide Fields. Institution Name can be set in Stainer Options.
- The Type of field (ie: Text) is displayed in the third column.
- The fourth column is the Font size. This ranges from 8 (smallest) to 12 (largest). If not all Fields are printing on a Slide Label, then the Font may be too large. Decreasing the Font size should resolve this.

3. A preview of the label is available in the upper right.

4. A number of settings are visible in the lower right. These are set up by Biocare Personnel.

- Slide Printer: TLP3842 or GX430t (model of label printer)
- Printer Intensity: 5 (light) to 30 (dark)
- Label Dimension:
    - o Height: 190 to 210
    - o Width: 210
- Print Offsets:
    - o Text Offsets:
        - X: 500 to 780
        - Y: 10 to 220
    - o 2D Matrix Offsets:
        - X: 500 to 680
        - Y: 40 to 180
- Print 2D Matrix (check the box to print 2D Matrix)
- Label Type: Regular (default) or Flap
- Label Orientation:
    - o Horizontal (default) or Vertical

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o Flip (check the box to flip the label orientation)

5. To activate the 2D Matrix on the slide label so that the 2D Matrix Scanner may be utilized when loading slides, check the box **Print 2D Matrix**.

6. Click **Test Print** to test and confirm desired settings have been achieved.

7. Click **Save & Close** to save changes.

Designing the Reagent Label

1. The **Reagent Label Designer** is located under **Label Designer** in the **Tools** menu of the **Staining Main Screen.**
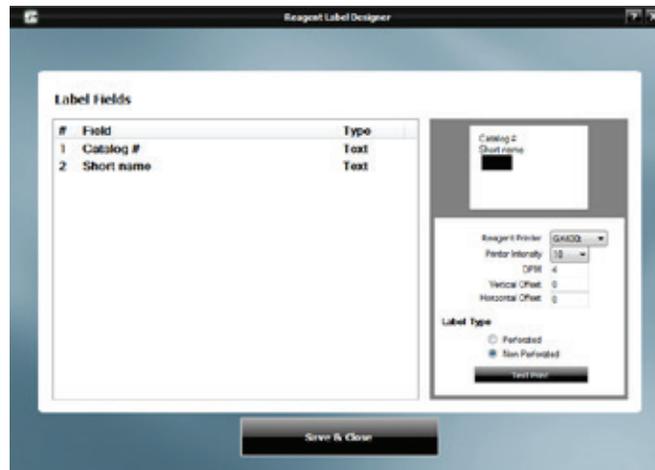

2. There are 3 columns in the Label Fields section.

3. The first column is the Line # on the label.

4. The second column is the field displayed in that line. There are 2 Label Field lines which are configurable by the user. The available options in the drop down menu are: Reagent Name, Short Name, Catalog #, Lot #, Exp Date, Incubation Time, Date.

5. 2D Matrix is always active on reagent labels so that the 2D Matrix Scanner may be utilized when loading reagents.

6. Upon choosing a Label Field option from the Field drop down menu, the Type (ie Text) will be displayed in the third column: Text.

7. A preview of the label is available in the upper right.

8. A number of settings are visible in the lower right. These are set up by Biocare Personnel.

- Reagent Printer: TLP3842 or GX430t (model of label printer)
- Printer Intensity: 5 (light) to 30 (dark)
- DPM: 4 (disabled field)
- Vertical Offset: -100 to 100
- Horizontal Offset: -100 to 100
- Label Type: Perforated or Non-Perforated (default)

9. Click **Test Print** to test and confirm desired settings have been achieved.

10. Click **Save & Close** to save changes.

Setting the Slide Display Information

1. **Slide Display Fields** is located in the **Tools** menu of the **Staining Main Screen.** Upon selection, the **Set Slide Display Information** window will open.

2. There are 2 configurable fields:

    a. **Top Line**
    b. **Bottom Line**

3. These fields refer to the text that is displayed in the two lines of the Slide Image of a mapped slide on the **Staining Main Screen.**

4. In each of the 2 fields, choose from the following options in the drop down menu: CASE#, Protocol Name, Primary Antibody, Physician, Patient, or BlockID.

5. Click **OK** when finished.

Setting Up Report Fields

1. Choose **Print Reports** in **Tools** drop down menu of the **Staining Main Screen** and the **Generate Reports** window will open. Choose **Configure Report Fields** from the **Tools** drop down menu of the **Generate Reports** window and the **Setup Report Fields** window will open.

2. Select a Report to configure from the **Select a Report** drop down menu.
    a. Slide Layout Map
    b. Reagent Layout Map
    c. IHC Summary

If **Slide Layout Map** is chosen, the following options will appear in the window:
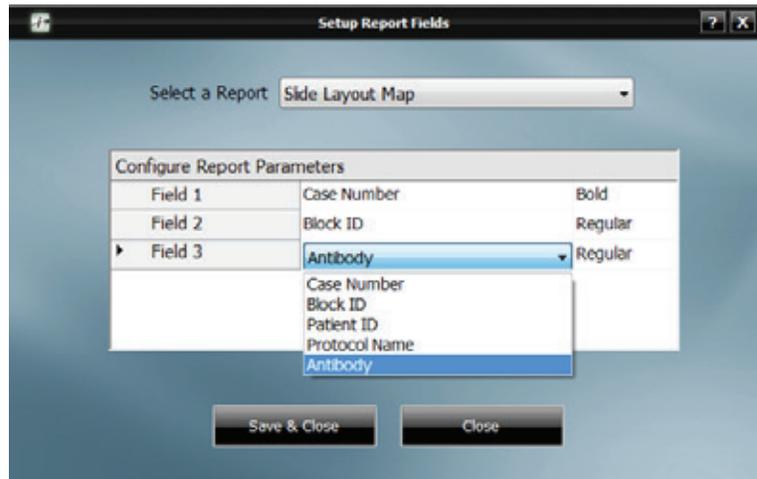
There are 3 configurable fields which can be set to Case Number, Block ID, Patient ID, Protocol Name or Antibody. Each of these fields can be set to either Regular font or Bold font.

When finished, click **Save & Close**.

If **Reagent Layout** Map is chosen, the following options will appear in the window:
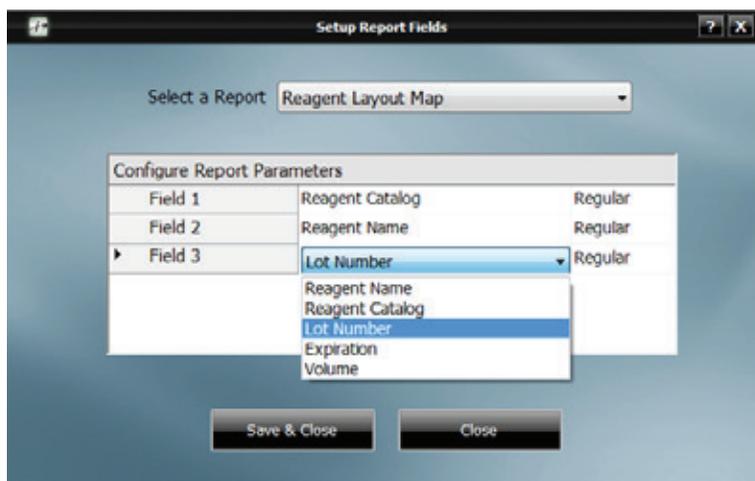
There are 3 configurable fields which can be set to Reagent Name, Reagent Catalog, Lot Number, Expiration or Bolume. Each of these fields can be set to either Regular font or Bold font.

When finished, click **Save & Close**.

If **IHC Summary** is chosen, the following options will appear in the window:
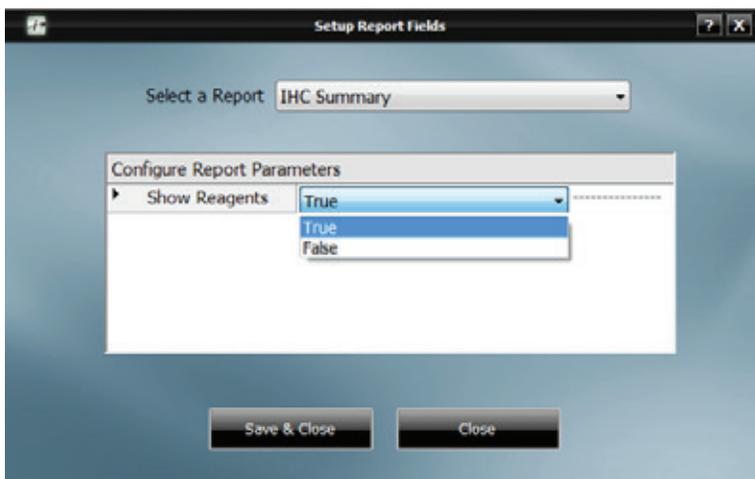
There is 1 configurable field, **Show Reagents**, which can be set to True or False.
When finished, click **Save & Close**.

Setting Up LIS

1. When intelliPATH software is installed, the following folders are created by default below LIS_Share folder:

   - LIS Requests folder: contains all of the individual requests from the LIS system and from the consolidated list for IP stainer processing. As soon as an individual request file is processed, the consolidated list is updated and the request file is moved into the 'Processed Requests' sub folder. An 'In-Process' file is created and the imported slides are added to this file. When the run is completed, the 'In-Process' file is removed. Errors are moved to the 'Error Requests' sub folder.
   - Processed Data folder: contains all the cases/slides that were stained by the IP system. After every 30 days, these cases are archived and the processed list starts over again. Individual result files that are created for the purpose of the LIS system are backed up in 'Result Uploads' sub folder purely for the archival and QC purpose.
   - Stainer Results folder: contains all of the result files that are generated by the IP software after processing LIS slides. The LIS system can scan this folder periodically to read the results and update the database. Once read, The LIS system can delete these files.

2. To set the LIS folder, click on the **Set LIS Folder** link and choose the folder hosting the LIS Requests. The xml files are imported and set as cases with information specified in the xml files.

3. To access and modify the LIS Fields, select **Setup LIS Fields** from the **LIS** drop down menu in the **Staining Main Screen.** The **Design LIS Fields** window will open.

4. The intelliPATH software provides several default LIS fields. However, the user can change the list if the institution keeps its records differently. In the **Design LIS Fields** window, use the **Add** or **Delete** button to make changes to the list of fields.

5. You may edit and/or add to the following LIS areas:

   - **Name:** The name of the field that can be referenced by other parts of the program
   - **Display Text:** The text that appears in the **Import from LIS** screen to identify the field
   - **Case Field Map:** Available case fields that can be mapped

6. After making the appropriate changes, click on **Save & Close** button.

7. LIS Slides can be viewed by selecting **LIS Slides** from the **Assign Slides** window.

Before Starting a Run

This chapter contains general guidelines for preparing samples and the intelliPATH prior to starting your run.

Reagent Preparation

Buffer 1
Add 9.5L of deionized water to 500mL of Automation Wash Buffer, 20X (Cat. No. TWB945 M)

DI Water
Add 9.5L of deionized water to 500mL of Automation Tween, 20X (Cat. No. TWA20 M)

Tissue and Slide Preparation

1. Deparaffinize tissue sections and wash in DI water.
2. If applicable, ensure that the slides have been through the appropriate retrieval process.
3. Hydrate in DI water and solvate in buffer prior to loading on the intelliPATH.
4. To ensure accurate and reliable staining, quality control is recommended by any or all of the following:

   Positive Tissue Control
   Include a known positive tissue, preferably with variable levels of reactivity. Test result should indicate positive.

   Positive Antibody Control
   Absorb primary antibody with its antigen before staining and apply to known positive tissue. Test result should indicate positive.

   Negative Process Control
   Replace primary antibody with negative control serum. Test result should indicate negative with no background.

   Negative Tissue Control
   Include a known negative tissue and apply primary antibody. Test result should indicate negative with no background.

   Positive Process Control:
   Include more than one antibody and its control: If one is positive, the process worked.

Instrument Preparation

1. Make sure both waste carboys are empty and properly connected to the instrument.
2. Make sure Buffer and DI Water carboys are prepared and filled with appropriate water or reagent and properly connected to the instrument.
3. Make sure there are no obstructions to the movement of the robotic arm.
4. Rinse the slide racks with DI water, and carefully brush away any residual deposits of dried buffer that may be present. This will prevent contamination from previous runs.
5. Load the reagent rack with filled reagent vials in the correct orientation; the label "FRONT" must be positioned toward the front of the intelliPATH.
6. Confirm that the slides are leveled. If the slides are not leveled, the instrument must be leveled.
7. If you will print labels, make sure the label printer is attached to the computer.
8. If you want to use the 2-D Matrix programming feature, affix the 2-D matrix labels to the slides and reagent vials.
9. Turn the instrument on using the main power switch located above the power cord on the right side of the stainer.
10. Turn on the computer and open the intelliPATH application.

    Important: Be sure to turn on the instrument before logging into the intelliPATH software.
    Otherwise, software will automatically be opened as a demo mode and the run will not start.

Prepare and Start a Run

Assuming that all the necessary reagents and protocols have already been entered in the instrument software by the Administrative user, Regular users can use chapter as guide to setup and begin their staining run.

Important: Before starting this chapter, be sure to follow the instrument preparation section. Specifically, ensure to turn on the instrument before logging into the intelliPATH software, otherwise, software will automatically open in demo mode, not allowing an actual run to start.

Process Overview (Option 1)

Summary of the run setup process using slide. Details of each are provided throughout this chapter.

```
[Login] ▶ [Select Stainer Application] ▶ [Prepare Labels] ▶ [Print Labels]

[Scan Slides] ▶ [Prepare Reagents] ▶ [Load Reagents] ▶ [Complete Prestart Checklist]

[Start Staining]
```
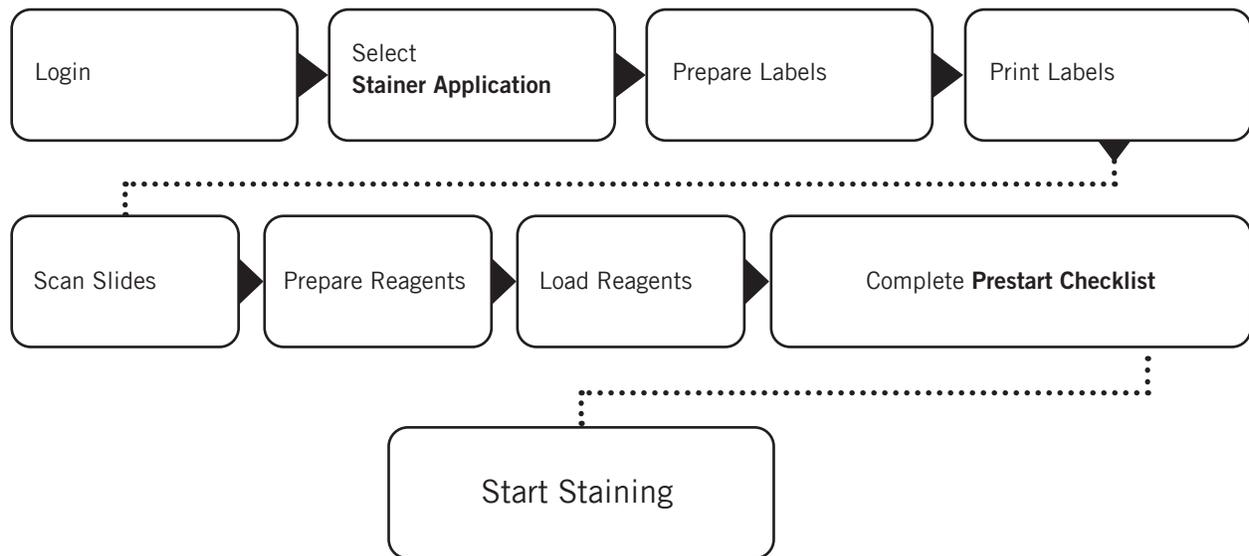
Process Overview (Option 2)

Summary of the run setup process without slide labels. Details of each are provided throughout this chapter.

```
[Login] ▶ [Select Stainer Application] ▶ [Assign Slides] ▶ [Prepare Reagents]

[Load Reagents] ▶ [Complete PreStart Checklist] ▶ [Start Staining]
```
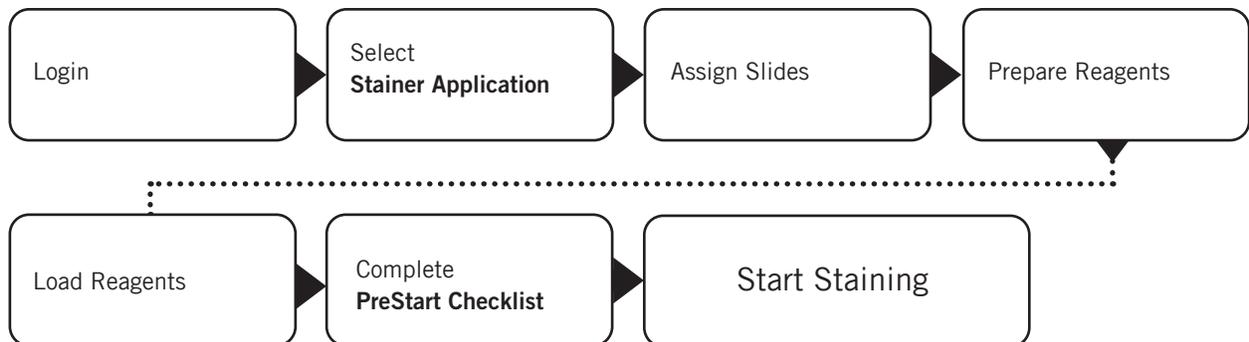
Login to intelliPATH Software

1. Login to intelliPATH software. Enter your username and password in the dialog box.

Select Stainer Application Module

2. From the **Module Selection Menu**, select the **Stainer Application** Module. Press **Execute** to proceed.

Select Slide Preparation

3. The Prepare Slides window is the starting point to begin a staining run. From **Prepare Slides**, select an option:

Prepare Labels
Slide Labels are generated and printed within the **Prepare Labels** section. User can enter Slide Details (Case#, Pathologist, Patient Name, Block ID etc), order protocols, and print slide labels. **Slide Details** are optional.

Assign Slides
Protocols can be mapped with or without a slide label or from an LIS import in the **Assign Slides** section. **Slide Details** are optional.

Scan Slides
Labels that have been printed with 2D Matrix codes (either from **Slide Manager** or from an LIS System) can be scanned in the **Scan Slides** section.

Prepare Reagents
Once slides have been loaded in the system, reagents can be mapped or scanned in the **Prepare Reagents** section.

Enable STAT
The STAT feature can be reserved by clicking the **Enable STAT** checkbox. This disables Rack E and reserves it for future use as a STAT rack.
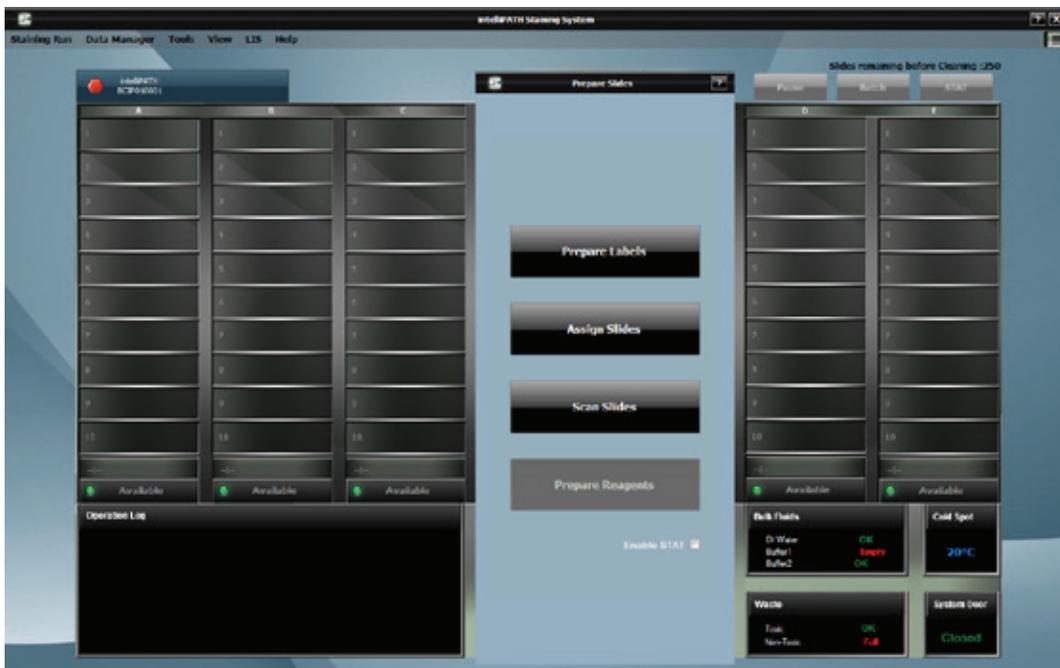
Prepare Slides

4. Press **Prepare Labels** to continue.

Prepare Labels

5. Prepare Labels in the **Add Slides** window
  - Optional: enter **Slide Details** such as Case #, Pathologist, Patient Name.
  - Choose **Group** of protocols to view from **Available Protocols** drop down menu (all protocols or a custom group created by the user).
  - Select the desired protocol from the list of **Available Protocols** (hold the CTRL button down to select more than one protocol).
  - If Global Volume and Zone is desired, check the box **Apply Global Volume and Zone to Added Slides.** This will assign the global settings from **Stainer Options**. Otherwise, settings will be assigned from the programmed volume and zone preference of the specific protocol in **Protocol Manager.**
  - Click the **Right Arrow (→) to order that protocol.**
  - If positive and/or negative controls are desired, check the box under the **Plus (+) Sign** to order a positive control and check the box under the **Minus (-) Sign** to order a negative control.
  - Click **OK.**
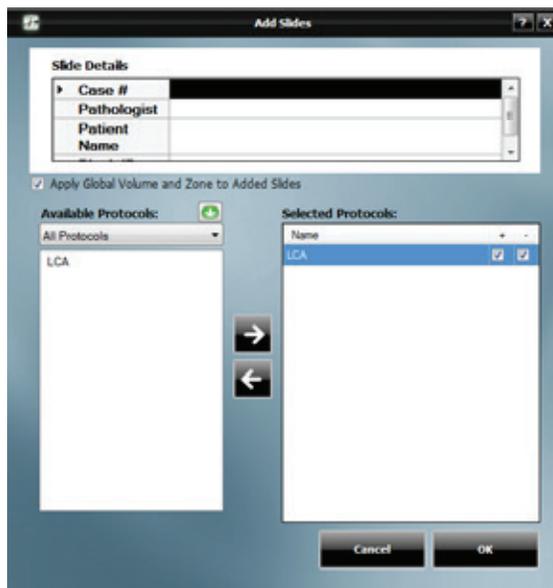
Print Labels

6. **Slide Manager** window will open to allow for additional features including printing labels.
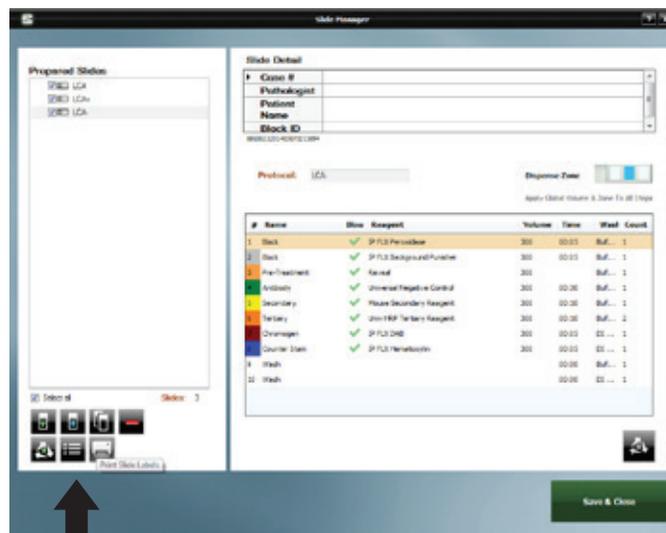
- **Slide Detail** and **Protocol** information can be modified by clicking the **Edit** button in the bottom right corner
  - o **Slide Detail** such as Case #, Pathologist, Patient Name or Block ID can be entered or modified (these fields can be changed in **Design Slide Fields**).
  - o **Protocol** information such as Protocol Name, Dispense properties and reagent steps and their properties can be deleted, added, inserted or moved.
  - o Click the **Check (✓)** to **Save Protocol Changes.**

- Additional slides can be added by clicking the **Plus (+) Sign Slide Image.** This will bring the user back to the **Add Slides** window.
- Processed Slides, Recent Slides and Saved Slides can be imported by clicking the **Import Slides Arrow.**
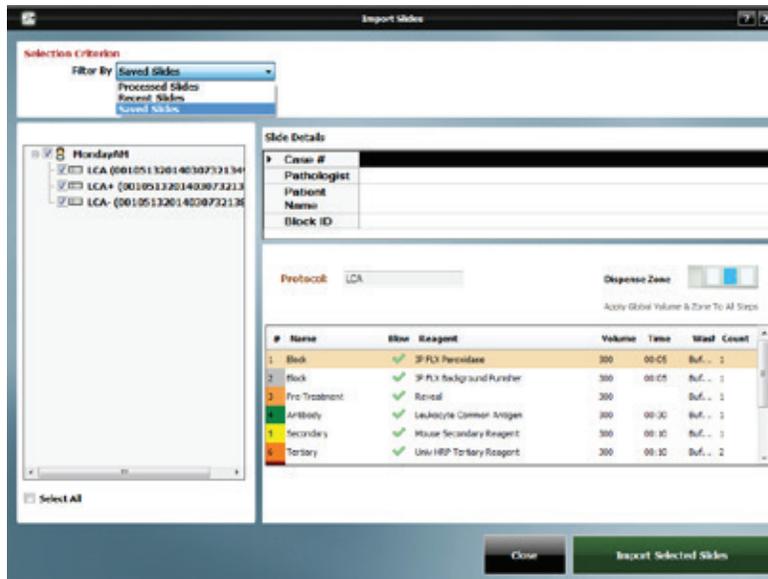
- A user can make copies of a Prepared Slide by clicking the **Multiple Slide Image** and entering the number of copies (maximum copies is 25 at a time).
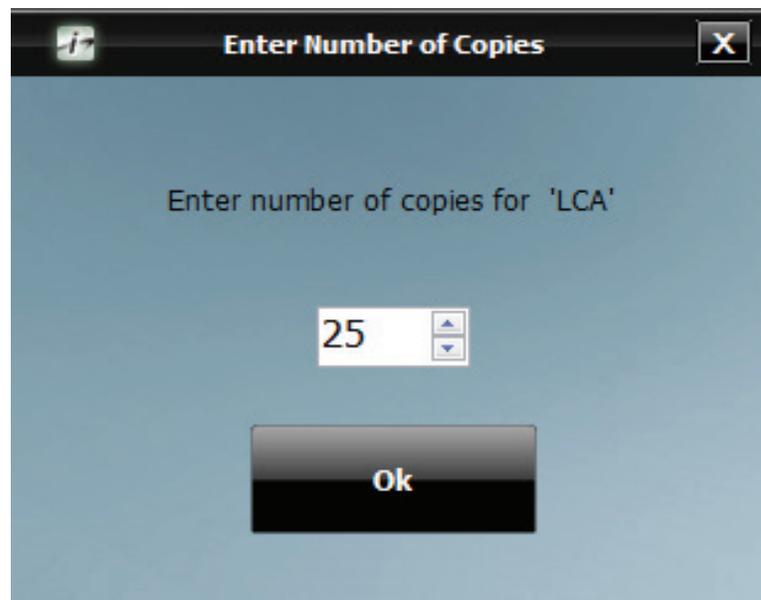
- A Prepared Slide can be deleted by checking the box next to the slide to be deleted and clicking the **Red (-) Sign.**
- To save slides to run later, click the **Save Slides** button (three white arrows surrounding a green down arrow). The **Save Slides To Run Later** window will open.
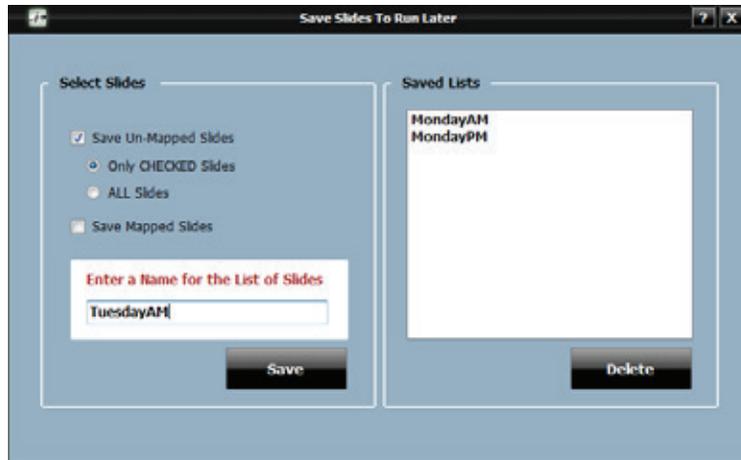
    o To save only unmapped slides (slides that are still in the **Prepared Slides** list), check the box next to **Save Un-Mapped Slides.**

   ■ To save only the checked slides within unmapped slides, select **Only CHECKED Slides.**

        ■ To save both checked and unchecked slides within unmapped slides, select **ALL Slides.**

    o To save only mapped slides, check the box next to **Save Mapped Slides.**

    o Enter a name for the list of slides in the box.

    o Click **Save**.

    o A representation for each existing list appears on the right. To delete an existing list, select and click **Delete.**

    o To map a saved list, go to **Assign Slides**. To scan saved slides, utilize Scan Slides feature in **Prepare Slides** window.

• **Reagent Worksheet** can be viewed and printed by clicking the **Bulleted List** button. The **Reagent Worksheet** window will open.

    o Choose from the drop down: **Prepared Slides** or **Mapped Slides**.

    o All slides from the chosen drop down menu are listed on the left.

    o All reagents required to run these slides are listed on the right.

    o Selecting specific slides from the **Slides List** will show only the reagents needed for those slides in the **Reagent List** on the right.

    o To print the **Reagent List**, click **Print Reagent Worksheet**.

    o To print labels, check the boxes next to the reagents needing labels and click **Print Labels. Select All** checkbox is available if desired.

    o **Reagent Worksheet** may also be printed from the **Tools** drop down menu of the **Staining Main Screen**.

• To print labels, check the boxes of the Prepared Slides or utilize the **Select All** checkbox and click **Print Labels.**

• Click **Save & Close** when finished.

Scan Slides

7. Click **Scan Slides** to open the **Select Slide Tray To Scan** window
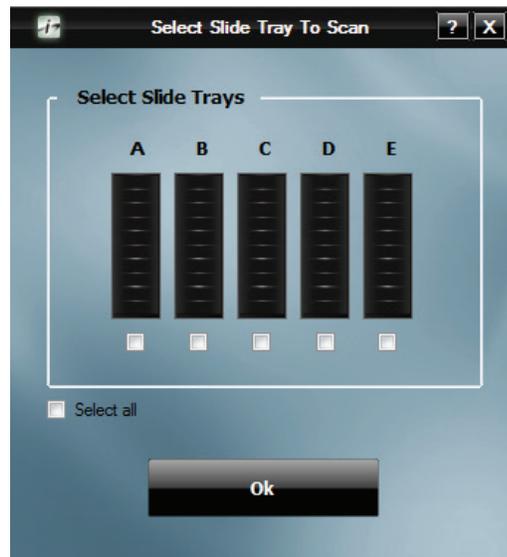
- Place labels on the slides and physically load the slides onto the instrument after slides have been deparaffinized and retrieved if necessary. Alternatively, slides may be labeled prior to deparaffinization and retrieval.
- Check the box for each tray that contains slides (the **Select all** checkbox may be utilized if all 5 trays contain slides)
- Click **OK** to begin slide scanning. The **Scanning Labels…intelliPATH** window will appear displaying the actions of the 2D Matrix Scanner and allowing for **Cancel** button

- Once all **Printed Slides** have been located, scanning will cease

8. Scanned Slides can be viewed, edited or unloaded

• Hover the mouse over a scanned slide for the **Slide Information** window to appear
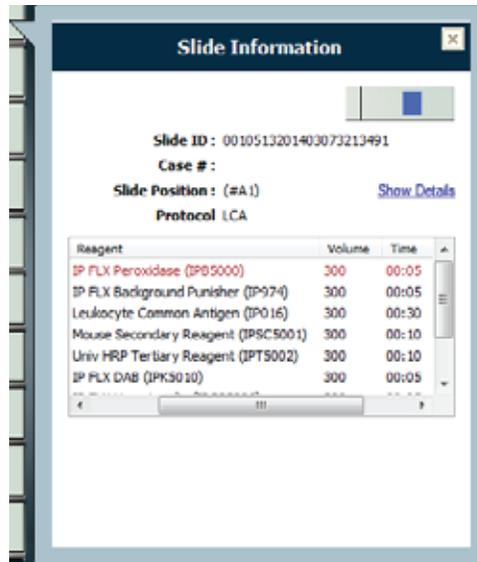
 o **Slide Details** and **Protocol** information can be viewed.
 o Additional **Slide Details** can be viewed by clicking the **Show Details** link.
 o Additional **Slide Details** can then be hidden by clicking the **Hide Details** link.

• Right clicking on a scanned slide allows the user to **View/Edit, Copy Slide or Unload Slide**
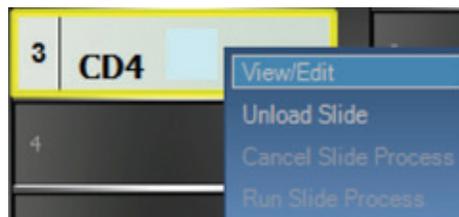
• When **View/Edit** is selected, the **Slide Edit** window will open.
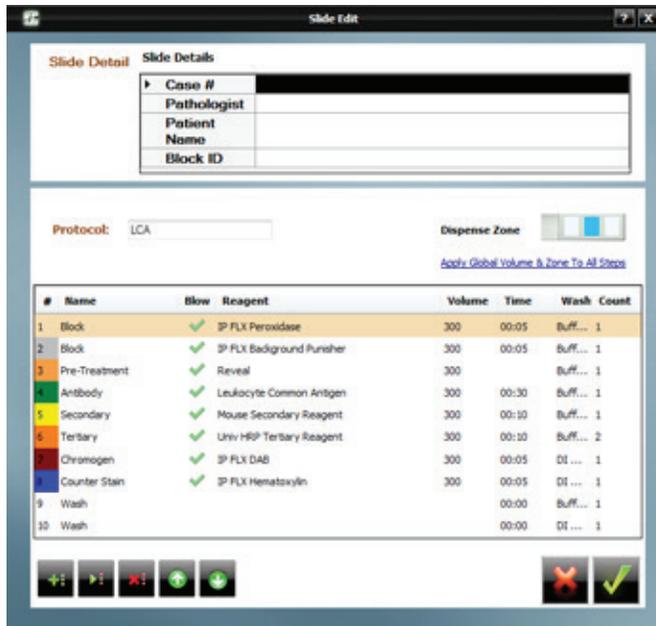
o The **Left Green Arrow** and the **Right Green Arrow** allow the user to navigate between loaded slides.

o **Slide Details** such as Case # can be edited by clicking **Edit.**

o All **Protocol** information including name, dispense properties, protocol steps and reagents can be edited by clicking **Edit.**

• If **Copy Slide** is selected, the user can then right click on an open **Slide Position** and choose **Paste Slide.**

• Selecting **Unload Slide** will unload the slide from the slide layout. If case information is associated with the slide, it will be moved to the **Prepared Slides** List in **Slide Manager.**

Assign Slides

9. Alternatively, user can **Assign Slides** instead of Scanning Slides.

• Click **Assign Slides** and the **Assign Slides** window will appear.
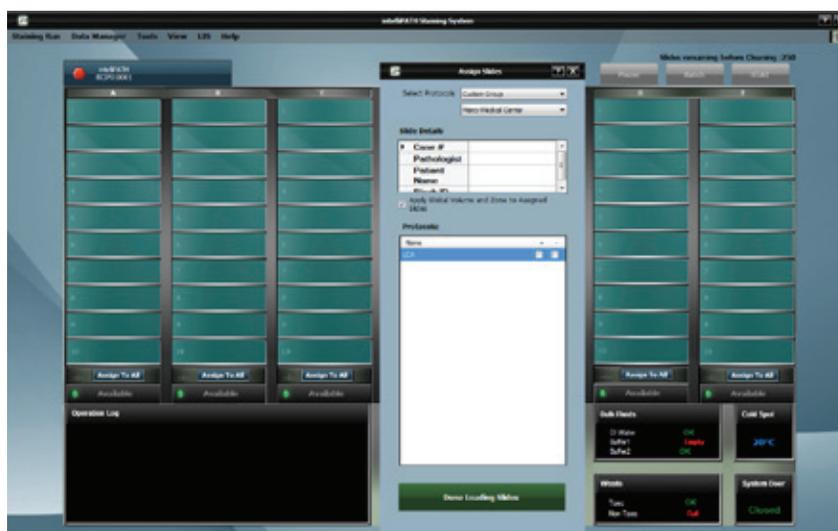
• Multiple view options are available from the **Select Protocols** drop down menus.

o **All Protocols** lists every protocol in the system.

o **Custom Group** only shows the **Protocols** from a particular **Custom Group.**

■ An additional drop down exists to filter by specific **Custom Group**

o **Prepared Slides** only shows the **Protocols** from the **Prepared Slides** section of the **Slide Manager** Window.

■ An additional drop down exists where the user can choose to view **All Prepared Slides** or **Printed Slides** (both prepared slides and printed slides come from the **Prepared Slides** section of the **Slide Manager** window; printed slides have an asterisk (*) next to the protocol name).
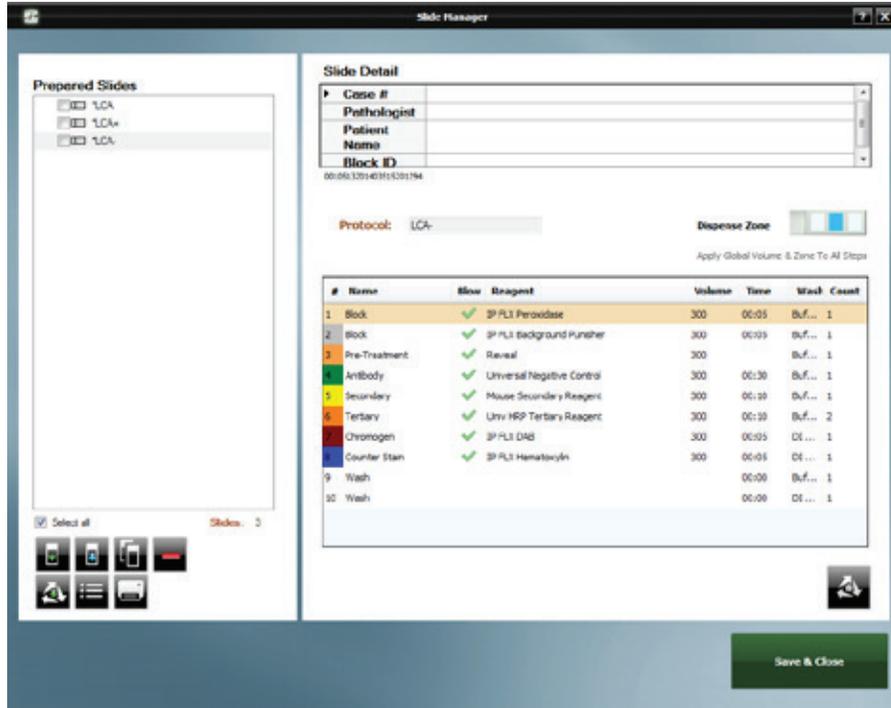

o **LIS Slides** lists all LIS imported slides

o **Saved Slides** only shows the Protocols from a paricular **Saved List.**

■ An additional drop down exist to filter by specific **Saved List.**

• From the **Protocols** list, choose the protocol to assign and then click on the **Slide Position** where the user would like to load the slide and the **Protocol** will be assigned to that **Slide Position.**

o To assign the same **Protocol** to an entire tray, choose the **Protocol** and click **Assign To All** is not available for **Printed Slides, LIS Slides or Saved Slides).**

o To automatically assign the protocols to the slide positions in the order listed, click the **Auto Map** button (**Auto Map** is not available for **All Protocols** or **Custom Group**).

o If positive and/or negative controls are desired, check the box under the **Plus (+) Sign** to order a positive control and check the box under the **Minus (-) Sign** to order a negative control. (Ordering controls is not available in **Prepared Slides, LIS Slides** or **Saved Slides** as controls are ordered when these lists of protocols are generated).

o If Global Volume and Zone is desired, check the box **Apply Global Volume and Zone to Assigned Slides** This will assign the global settings from **Stainer Options.** Otherwise, settings will be assigned from the programmed volume and zone preference of the specific protocol **in Protocol Manager.**

• Click **Done Loading Slides** when finished.

Prepare Reagents

10. Once desired slides have been loaded and scanned, click **Prepare Reagents** to open the **Load Reagents** window
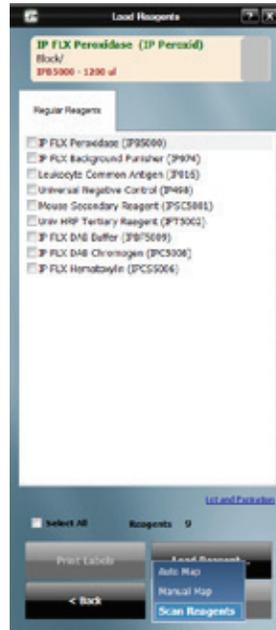

- A list of all reagents required for the run will be displayed.
- A **Lot and Expiration** link is available to view and edit Lot Numbers and Expiration Dates for the reagents listed. This information will only be tracked for this run. If a permanent entry is needed, go to **Reagent Inventory Manager** Module.

| Catalog	Reagent Name	Lot Number	Expiration (YYYY/MM)
IPB5000	IP FLX Peroxidase	050114	2017/05
IP974	IP FLX Background Punisher		
IP016	Leukocyte Common Antigen		
IPSC5001	Mouse Secondary Reagent		
IPT5002	Univ HRP Tertiary Reagent		
IPBF5009	IP FLX DAB Buffer		
IPC5008	IP FLX DAB Chromogen		
IPCS5006	IP FLX Hematoxylin		
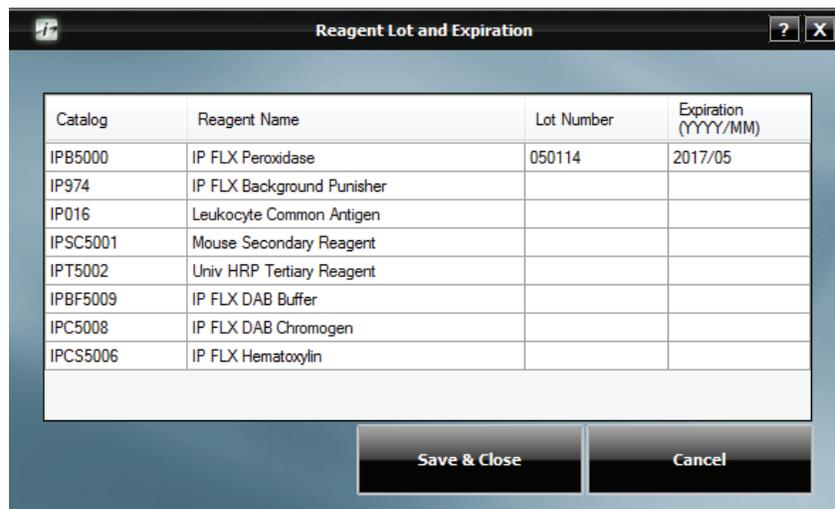
- If reagent labels are needed, check the box for each reagent that a label is needed or utilize the **Select All** checkbox and click **Print Labels**.
- Label reagent vials and load all reagents listed in the **Reagent Rack** in any order.
- Be sure to load all required **Mixing Vials** as well as depicted by a gray circle in the **Mixing Vial Rack** with a number in the center.
- Click **Load Reagents** and choose from three options: **Auto Map, Manual Map, Scan Reagents.**

o **Auto Map** will load reagents in the **Reagent Rack** in the order listed in the **Load Reagents** screen (reagents will load in the rack in the following order: A1-A12, B1-B12, C1-C12, D1-D12). It is the user's responsibility to physically load the reagent vials in the auto mapped locations.

o **Manual Map** allows the user to choose a reagent from the **Load Reagents** list and then choose the position in the **Reagent Rack** to which the user desires it to be loaded. Repeat until all reagents in the **Load Reagents** list have been mapped. It is the user's responsibility to physically load the reagent vials in the manually mapped locations.

o **Scan Reagents** will cause the 2D Matrix Scanner to scan the **Reagent Rack** until all required reagents have been located. **The Scanning Labels...intelliPATH** window will appear.

o Click **Start Scan**. The **Scanning Labels...intelliPATH** window will display the actions of the 2D Matrix Scanner and allow for **Cancel** button.
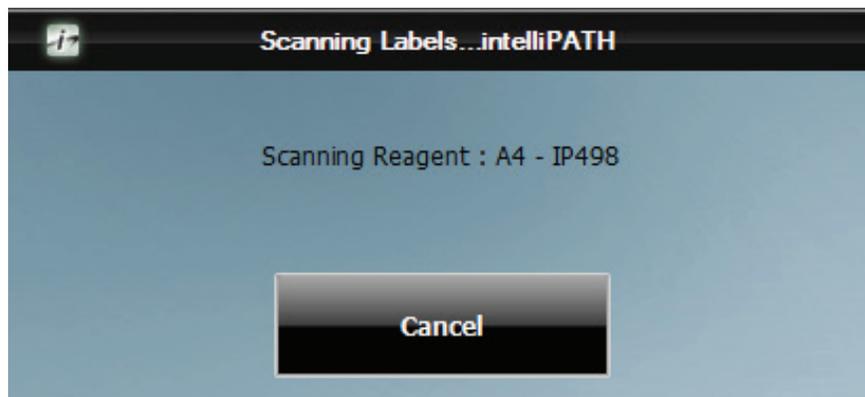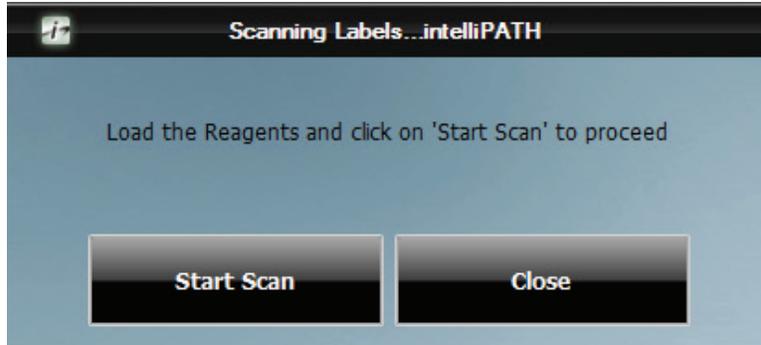
• When using the **Auto Map** or the **Manual Map** feature, if a reagent exists in inventory, the **Select from Inventory** window will appear.
    o Choose from the list and click **Use Selected Vial** if the inventoried vial will be used.
    o Choose **Use New** if a non-inventoried vial will be used.
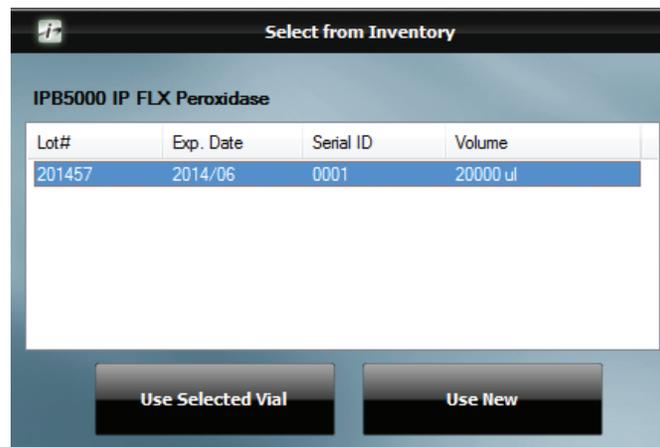
• Right clicking on a loaded reagent will offer two options: **Register Reagent** or **Unload Reagent.**
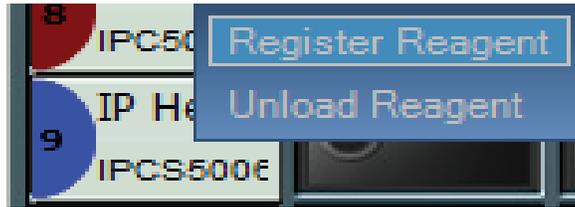
o Choosing **Register Reagent** will cause the **Reagent Register** window to appear.
- ■ Lot Number, Expiration and Serial ID can be entered.
- ■ Each registered reagent requires a unique 4-digit Serial ID.
- ■ Reagent Registration information will be permanently stored in **Reagent Inventory Manager** for future use.

o Choosing **Unload Reagent** will move that reagent back to the **Load Reagents** list.
o Hover the mouse over a scanned reagent for the **Reagent Information** window to appear.

11. After all of the required reagents have been loaded, click **Next** to proceed. The **Verify Reagent Levels…intelliPATH** window will appear.
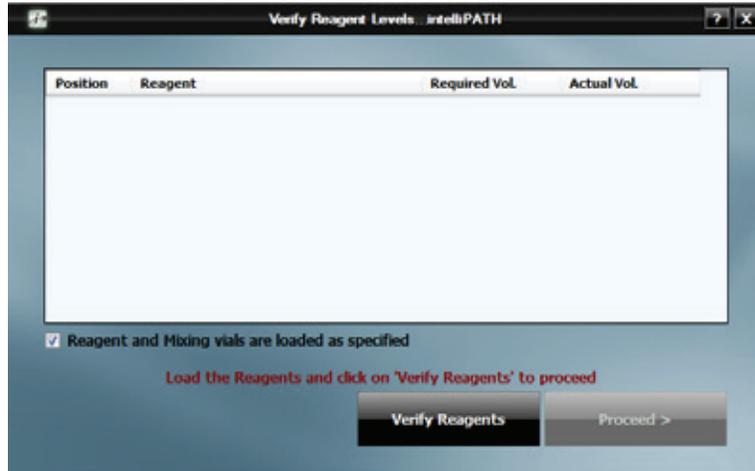
• Make sure that all reagents and mixing vials have been loaded as shown on the screen and then check the box **Reagent and Mixing vials are loaded as specified.**

• Click **Verify Reagents** and the instrument will check the reagent volumes to verify that there is enough reagent to complete the run. Accepted reagents will appear in green. Reagents with insufficient volume will appear in red.

    o If a **Mixing Vial** is loaded upside down or an old **Mixing Vial** with residual volume still exists in a position requiring a new vial, it will appear in red.
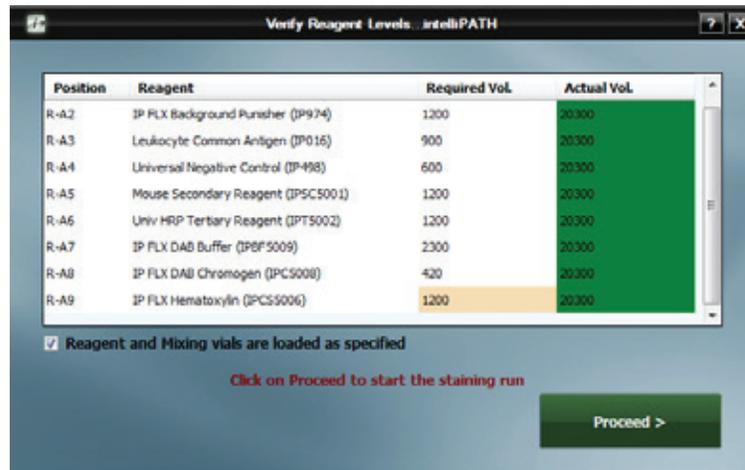
• Once all reagents and mixing vials have been accepted, click **Proceed.**

Note: If the Delayed Run box was selected in the PreStart CheckList screen, after clicking **Start Staining** the **Run Starts** countdown clock will appear at the bottom of the **Stainer Application** screen. The run automatically begins after the countdown is completed. Alternatively, user may select **Start Now** or **Cancel Run**.

PreStart CheckList

1. Use the **PreStart CheckList** to verify that the required buffer carboys have been filled, hazardous and non-hazardous carboys have been emptied. Check all the carboy status categories in the **Waste Carboy Status** upon confirmation.

2. The **Delayed Run** checkbox on the top right side of the **PreStart CheckList** window allows the user to set a delayed start time for the run.

> **2a.** Select the **Delayed Run** box.
> **2b.** Set the **Start Time.**
> **2c**. The user also has the option to **Rinse Slides,** with DI Water, Buffer 1, or Buffer 2 and set the **Rinse Buffer Interval** of 30 minutes, 1 hour, or 2 hours.

3. Click **Prime Buffers**, located at the bottom right side of the screen, for first run of the day.

4. The Pre-Start Checklist includes buttons to Estimate Run Time, Home Arm, Drain Waste, Prime Probe, and Print Layout Maps (for slides and reagents).

5. It is recommended that the user selects the **Rinse Slides before the Run** checkbox to ensure that the slides will be solvated to allow the reagents to adequately spread across the slide.

Start the Run

1. Start the run by clicking on **Start Staining**.

> Note: If the Delayed Run box was selected in the Pre-Start Checklist screen, after clicking **Start Staining** the **Run Starts** countdown clock will appear at the bottom of the **Stainer Application** screen. The run automatically begins after the countdown is completed. Alternatively, user may select **Start Now** or **Cancel Run**.

2. While a run is in progress you may start a new Batch staining run or start a STAT staining run if slide tray E is available.

Batch

The Batch button allows the user to start a non-STAT run while the current run is in process.

1. Click on the **Batch** button on the top right corner of the **intelliPATH Staining System** window.

2. A dialog box appears, asking whether you want to **"Do you want to Add more Slides?"** Select **Yes** to proceed.

3. The **Prepare Case List** dialog box will appear and the user will follow the prompts.

4. After the slides are scanned and **Prepare Reagents** has been selected, the system door will open, allowing the user to load reagents. System door will lock when **Scan Reagents** is clicked. User should have reagents ready to load to prevent slides in process from over-incubating.

STAT

This button allows the user to designate a run as STAT. Slide rack E must be available to start a STAT run. The software will prioritize slide rack E to process first.

1. Click on the **STAT** button on the top right corner of the **intelliPATH Staining System** window.

2. A dialog box appears, asking whether you want to "**Add STAT Slides**". Select **Yes** to proceed.

3. The **Prepare Case List** dialog box will appear and the user will follow the prompts.

4. After the slides are scanned and **Prepare Reagents** has been selected, the System door will open, allowing the user to load reagents. System Door will lock when **Scan Reagents** is clicked. User should have reagents ready to load to prevent slides in process from over-incubating.

Manual Application of Reagent

Any reagent can be set to be applied manually by the user. This can be done permanently in **Protocol Manager** or as needed when ordering slides within the **Prepare Slides** window.
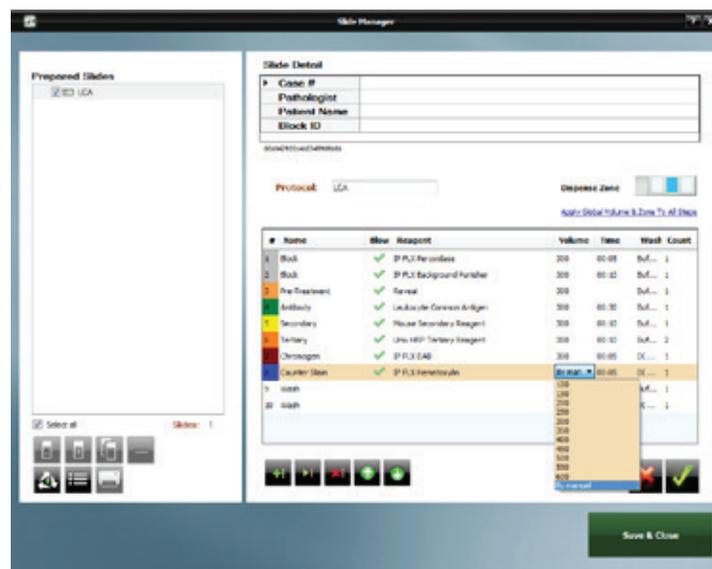
Select the **Volume** drop down menu for the **Reagent** that the user wishes to manually pipette onto the slide themselves and choose **By manual**. Save changes.

During the Staining Run, the instrument will prompt the user to manually apply the reagent. If the user would like to preview the time at which this will be necessary, in the **Map View** of the **Staining Main Screen**, select the drop down menu adjacent to the **Estimated End Time** and the option to view **Next Manual Operation** is available. This will display the time that the next manual application of reagent will be ready for dispensing by the user.

In the **System View**, the same drop down is available for viewing.
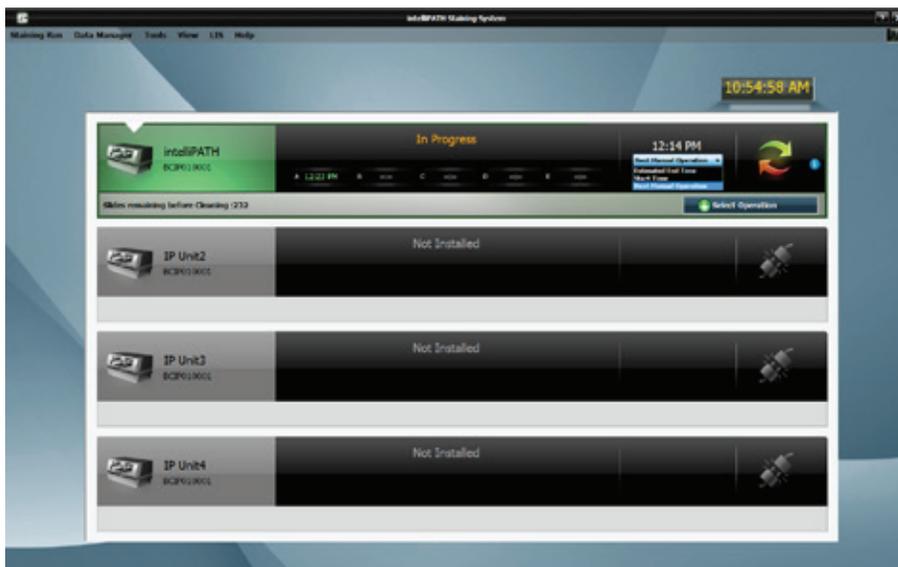
An **Information** icon is also available in the **System View** which gives further detail notifying the user which reagent will be ready for application.
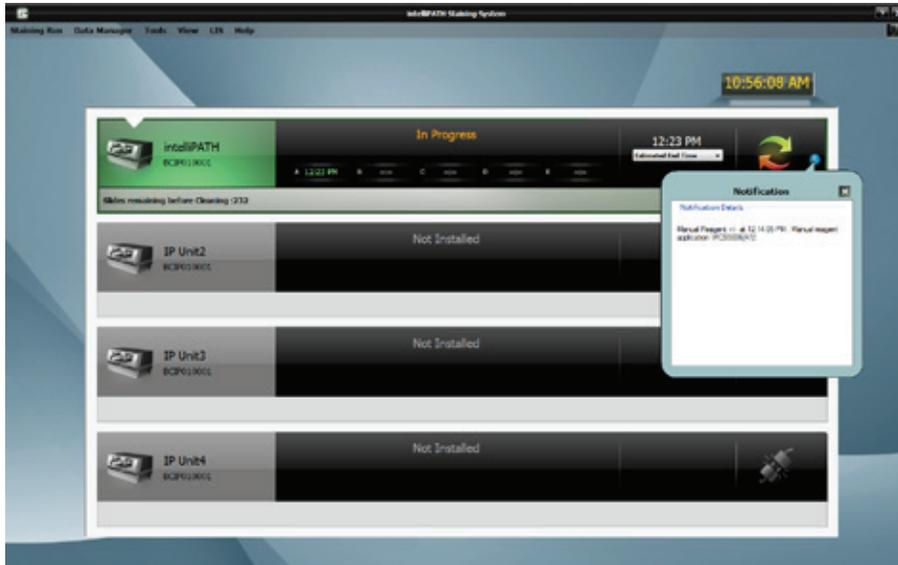
When the system is ready for the user to manually apply the reagent, an **Attention** message will appear on the screen.

Click on the **View Details** button. The **Notification Details** window will appear with a description of the action required and the slide that is affected.
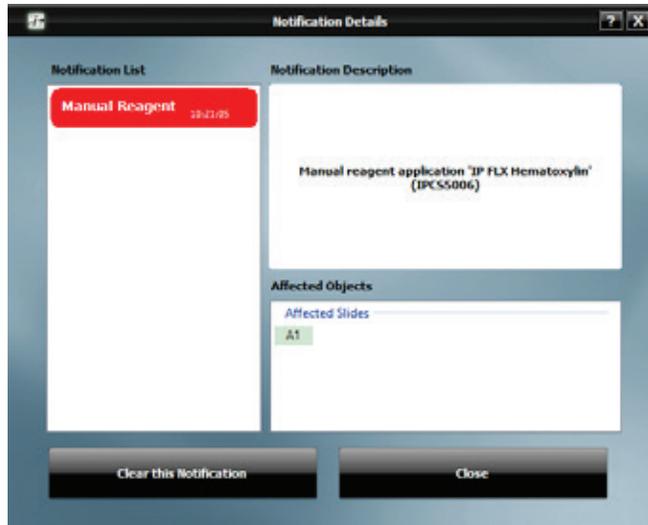
Click **Clear this Notification** to be prompted as to what steps must occur to clear the notification
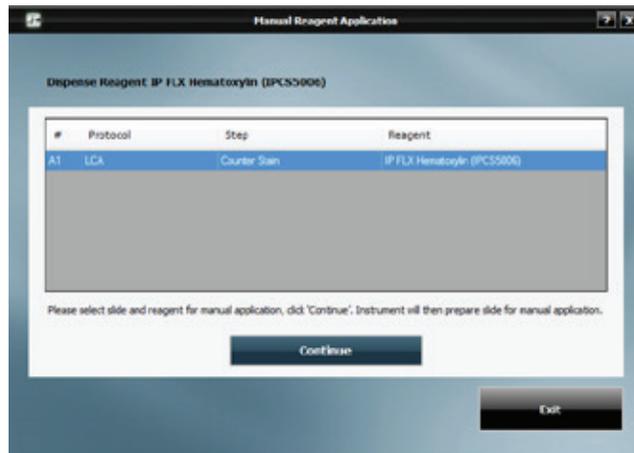
Manual Reagent Application window will appear prompting the user to select the desired action that they would like to perform first. Select the slide and reagent and click **Continue.** The instrument will then prepare the slide for manual application by Blowing the Wash Buffer off of the slide. Once the slide is ready for the user to manually pipette the reagent onto the slide, the window message will change reflecting this.
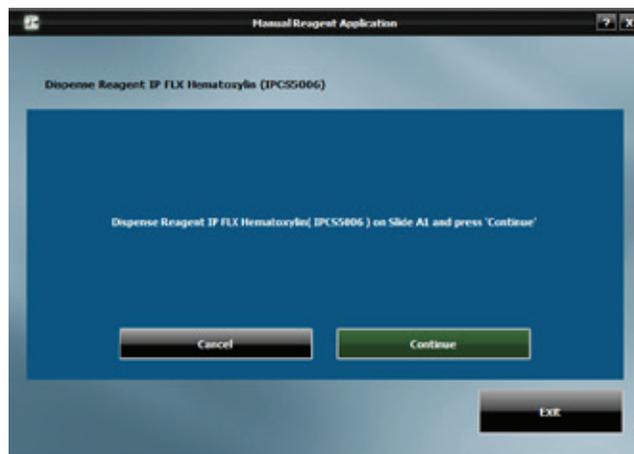
The user must then immediately dispense the reagent to prevent tissue dry out. Once completed, click **Continue**. If additional applications are pending, the screen will designate so. Otherwise the instrument will continue to process all slides until the run is complete.
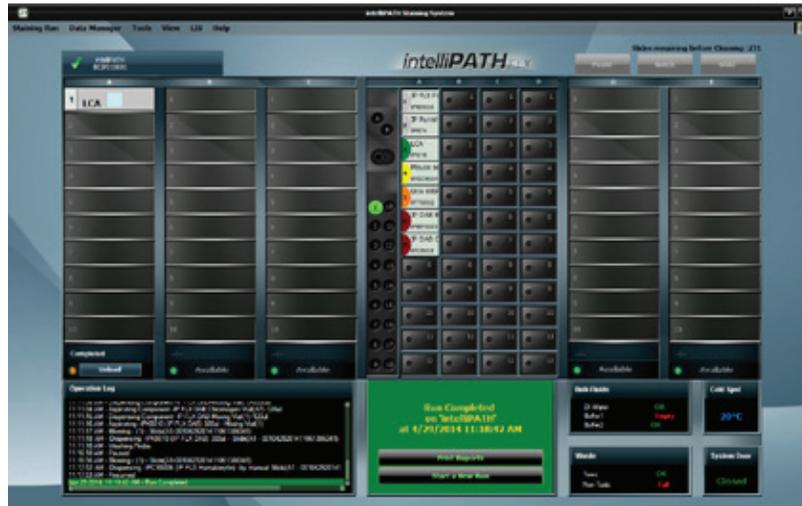
Once the run completes, the user can **Print Reports** or **Start a New Run**. If **Print Reports** is chosen, the **Generate Reports** module will open. If **Start a New Run** is chosen, the system will prompt the user to **Clear Trays** and **Clear Reagents**.
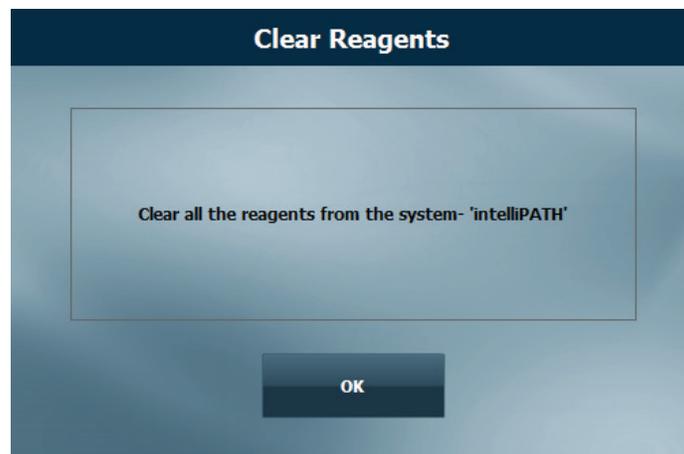
System Cleaning

When the intelliPATH software notifies operator that cleaning is necessary, follow on-screen instructions. This cleaning cycle should be performed at a minimum of once per week if the user has not reached the maximum slide count allowed.

Daily

- Rinse the used racks in tap water after every run.
- Using a DI squirt bottle, simply rinse the built-up buffer off the gap between the rear frame of the instrument and the slide tray rails (where the rails meet the back of the instrument).
- Add a DI Water wash at the end of every protocol. Probably the most effective way to keep your instrument clean.
- Always use DI water with Tween 20 and Proclin such as Biocare's Automation Tween 20 (TWA 20).

Weekly

Note: This procedure cleans only the reagent 'probe' (pipettor) and waste-reservoir drain.

- Weekly or every 250 slides, perform the DAB Away cleaning as required or, at least, once a week to clean the reagent Probe and Waste Reservoir Drain.
- Using a soft brush and a non-abrasive, non-corrosive cleaning agent, gently clean each rack (especially clips), then rinse thoroughly in tap water. Do not bend clips in process.
- Use a Kimwipe dampened with DI water to wipe the Liquid Level Sensor, the Barcode Reader and the outside of the probe.

Monthly

- Disinfect carboys and internal supply lines using a 10% Lysol solution.
  - o Fill Buffer 1, DI and Buffer 2 carboy (if used) with at least 2L of a 10% Lysol solution.
  - o Shake the carboys so the walls of the carboys are well washed.
  - o Log in to the IntelliPATH system.
  - o Execute the Stainer Application
  - o Within the tools menu, click prime probe and prime the probe for 30 seconds.
  - o Within the tools menu, click on Drain Waste and Prime Buffers.
  - o Click the "Prime Buffer" radio button; sequentially prime all the Lysol solution out of each carboy. Use the "Drain Waste" function to drain the waste into non-hazardous carboy as needed.
- After all the solution has been primed through the instrument lines, dump out the remaining solution, and rinse the carboys 2-3 times with DI water.
- Fill each carboy with at least twice as much DI water (4-5L) as Lysol solution and repeat the above steps. Be certain to prime the probe for at least 2 minutes. This will ensure your instrument is well rinsed.
- Soak removable components in a 10% Lysol solution.
- Remove the slide racks and soak in solution. Scrub if necessary, paying particular attention to the slide clips.
- Remove the splash guard dividers and soak in solution
- Remove the slide rails by unscrewing the thumb screws – soak in solution. Scrub if necessary, paying particular attention to the rail guide area.
- With all components removed, clean the interior of the stainer.
- White stains are typically Buffer buildup and can be rinsed with DI water.
- Brown stains are DAB stain. DAB stain can be removed with DAB Away.

Troubleshooting

Occasionally, you may encounter problems while obtaining stain results or performing associated procedures. This chapter describes the most commonly reported problems, and identifies the possible causes and solutions. If a problem persists, contact Technical Support immediately at 1-800-799-9499 Option 3. Provide details, such as the number of occurrences and associated conditions, and the condition and appearance of the slides. Be prepared to fax copies of the protocol and program used.

Staining Performance

Optimal staining results depend on the quality of tissue and the way in which it is processed prior to staining.

Problem	Possible Causes & Solutions
No staining, weak or inconsistent staining, false negatives	**Cause:** Programming errors. **Solution:** Review programming and correct errors. **Cause:** For AEC stains, Tween-20 content in buffer may cause weak staining. **Resolution:** Reduce Tween-20 concentration to 0.05% and increase incubation time for the AEC, or divide the AEC incubation into two protocol steps of the same, total incubation time. Use blow step between AEC steps. Non-standard background appearance. **Cause:** Buffer and deionized water, in their respective carboys, are not at proper capacity. **Resolution:** Fill carboys. **Cause:** Slides positioned incorrectly in slide racks. Instrument and slides must be horizontal, verified by level gauge. **Resolution:** Reposition slides. **Cause:** Protocol did not include rinse step between reagent steps. **Resolution:** Add rinse steps to protocol using the Protocol Manager.
Slides dry out	**Cause:** Buffer and deionized water are not at proper capacity. **Resolution:** Fill carboys. **Cause:** Slides positioned incorrectly in the intelliPATH. **Resolution:** Position slides correctly. Position must be verified by level gauge. Inspect slides positioned at back of instrument. **Cause:** Prolonged incubation requires dispensing increased volume of reagent on each slide. **Resolution:** For incubation time exceeding one hour, divide protocol step into two, consecutive steps with the same reagent. Apply an intermittent blow step to avoid an exceedingly long total run time.

Fluid Handling

Problem	Possible Causes & Solutions
Drops form on probe	Multiple causes, call Technical Support with details on where drops appear on probe: When probe is moved from wash station to reagent vials? When moved from wash station to slide for rinse step? When moved from reagent vial to slides? When moved from slide to slide?
Buffer not operating at optimal flow	**Cause:** Buffer container is not at proper capacity. **Resolution:** Fill the container and prime the pump. **Cause:** Tubing between pump and Z head is obstructed or bent. **Resolution:** Inspect tubing and clear obstruction.
Reagent dropped on slides spreads in H-shaped pattern	**Cause:** Buffer container is not at proper capacity. **Resolution**: Fill the container and prime the pump. **Cause:** Slides' surfaces are hydrophilic. **Resolution:** Immerse slides in buffer for 15 minutes (minimum) before placing them in the intelliPATH. **Cause:** Buffer has incorrect concentration of Tween-20. **Resolution:** Remix buffer to contain Tween-20 in prescribed concentration of 0.1%. **Cause:** De-paraffinizing procedure not followed properly. **Resolution:** Review procedure and results for possible errors. **Cause:** Slide level is inaccurate. **Resolution:** Verify by level gauge. If unable to level instrument, contact technical support. **Cause:** Buffer nozzle is obstructed. **Resolution:** Remove obstruction and confirm flow. **Cause:** Air blow outlet is obstructed. **Resolution:** Rinse nozzle and use small brush to clear passage. **Cause:** Compressor is not operating. Machine emits no sound during operation. **Resolution:** Contact technical support.
Buffer or deionized/ distilled water not flowing from buffer head	**Cause:** Carboys are empty. **Resolution:** Fill carboys. **Cause:** Tubing between containers and instrument is obstructed, bent, or damaged. **Resolution:** Re-route tubing and clear obstructions. **Cause:** Standard priming procedures for buffer and deionized water pump not followed properly. **Resolution:** Repeat priming procedures. If problem not solved contact technical support.

Fluid Handling (continued)

Problem	Possible Causes & Solutions
Reagent dosage uneven across slides	**Cause:** Buffer does not have the proper concentration of Tween-20. **Resolution:** Adjust the buffer formula and prime the buffer pump. Repeat run. **Cause:** Air bubbles in the clear plastic tubing from reagent probe. **Resolution:** Call Technical Support for instructions on how to remove bubbles. **Cause:** Leaks in syringe. **Resolution:** Call Technical Support for instructions.
Waste backs up in the sink	**Cause:** Overflow tubing kinked or obstructed, waste pump filter obstructed, waste pump failed, waste level sensor failed. **Resolution:** Check overflow tubing for obstructions or kinks. **Resolution:** Check waste pump operation. If pump is operational but no waste is pumped from the stainer, contact Technical Support. Check waste level sensor by manually activating sensor and observing waste pump operation.

Electrical

Problem	Possible Causes & Solutions
The Power On LED (green light) is off, indicating no power to instrument	Cause: Instrument is unplugged. **Resolution:** Plug cord into working outlet via the surge control unit and confirm circuit breakers between power outlet and instrument are switched on. Cause: Short in fuse. **Resolution:** Fuses can be checked and replaced by a Biocare Service Engineer or a qualified Electrical Engineer only. The fuse access is located in the power entry module. The stainer must be unplugged in order to access the fuse holder. Check and if required replace the fuse only with the same size and type of fuse specified in this manual. **Warning** Use of any other fuse other than those specified can cause personal injury, damage the stainer and void the warranty. If the fuse fails a second time, contact Technical Support. Do not continue to operate the stainer.

Mechanical

Problem	Possible Causes & Solutions
Bent pipette	**Cause:** Caps on vials were not removed. Z-head encountered an obstruction. Software will not proceed with caps on vials. Reads the volumes as zero. **Resolution:** Replace probe. **Cause:** Stainer out of calibration **Resolution:** Contact technical support
Toxic and non-toxic waste pumped to single, external waste container	**Cause:** Waste diverter valve malfunctioned. **Resolution:** Call Technical Support to have valve changed. Note: that despite the inconvenience of mixed waste streams, the instrument continues to function and remains safe to operate.
Waste is flowing out of overflow tube (large diameter, clear tube)	**Cause:** Waste pump has malfunctioned or level of waste generated during the staining process reaches level of over flow tubing. **Resolution:** Call Technical Support to confirm malfunction and to change pumps.
Probe or wash-blow head misaligned	**Cause:** Stainer is out of calibration. **Resolution:** Call Technical Support to calibrate the instrument.