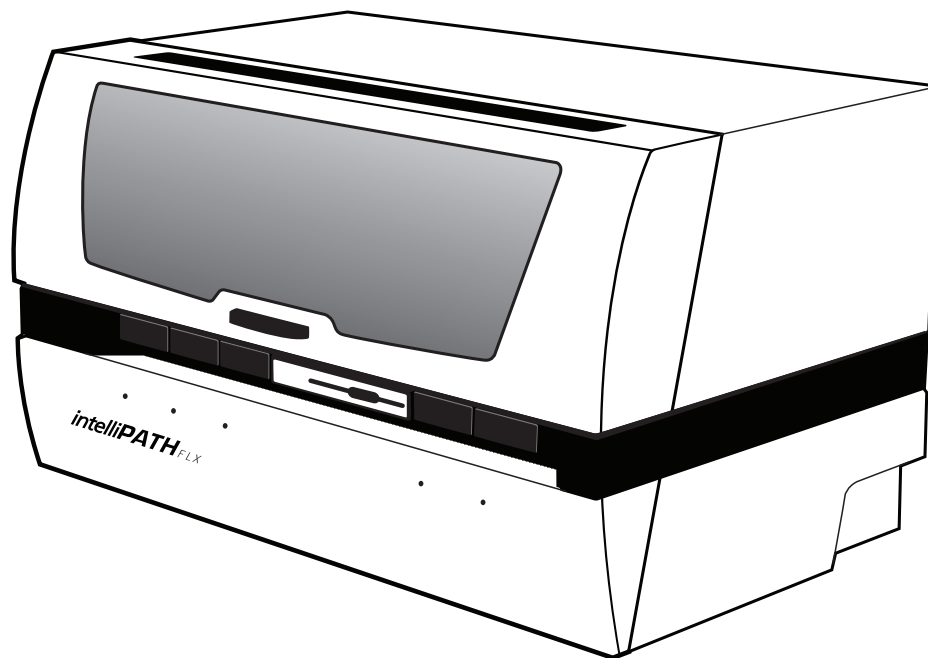# BIOCARE
M E D I C A L

intelliPATH™ Manual
Automated Slide Stainer

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Introduction

Intended Use

This manual is intended for 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

intelliPATH_{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, State and Federal 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.

Water Quality

The intelliPATH requires CLSI Type II water or equivalent (referred to as deionized water).

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 Precations

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 49).

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 could 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.
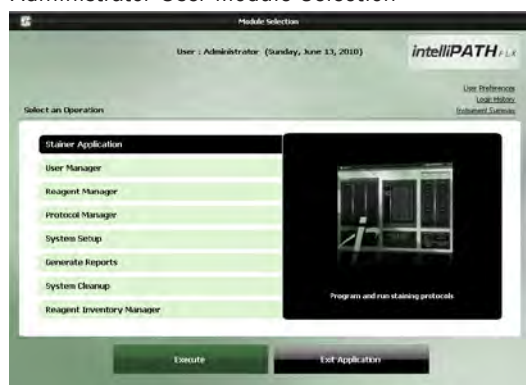
Login

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.

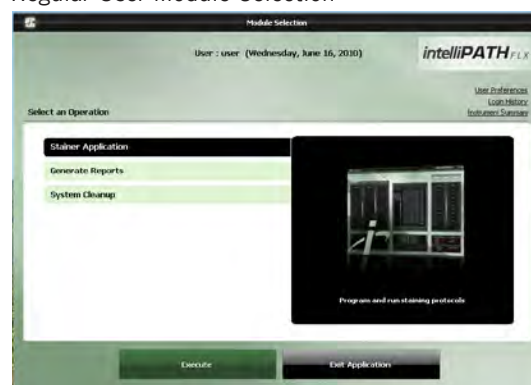Note: Default User ID is **Admin**, default password is **ipflx**.

Module Selection

Administrator User Module Selection

Regular User Module Selection

Module Descriptions

Module	Description	User	Admin
Stainer Application	Program and run staining protocols. Manage cases, slide staining protocols, and slide stainer operations. Access Reagent Manager, Protocol Manager, Reagent Inventory, and User Manager.	⊕	⊕
User Manager	Create new user accounts and modify existing accounts.	*	⊕
Reagent Manager	Create new/modify existing reagents/steps.	*	⊕
Protocol Manager	Save, design, and manage protocols and detection templates.	*	⊕
System Setup	Set preferences and defaults; save system software operating parameters for labels and onboard mixing.	⊖	⊕
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 only view (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.
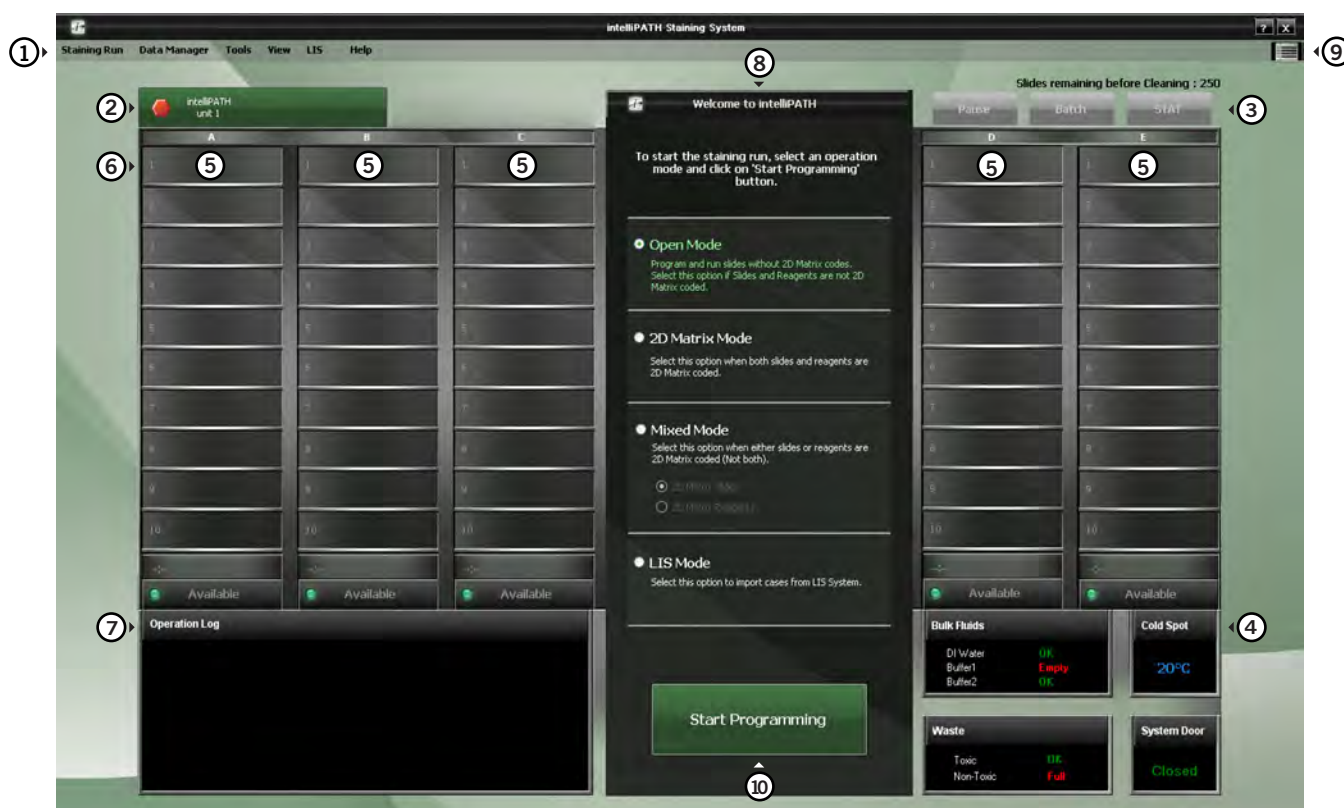

1. Menu bar, 2. Stainer tab, 3. Run designation buttons, 4. System status, 5. Slide tray positions, 6. Slide Position, 7. Operation log, 8. Welcome menu, 9. Instrument View, 10. Start Programming.

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.
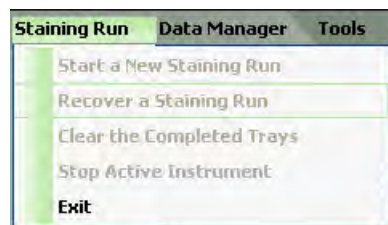
Data Manager Menu

The Data Manager menu allows the user to access the Reagent Manager, Protocol Manager, User Manager, or Reagent Inventory 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 the Cold Spot, Reset Carboys, Drain Waste and Prime Buffers, Prime Probe, Dilution Calculator, System Cleaning and Label Designer.
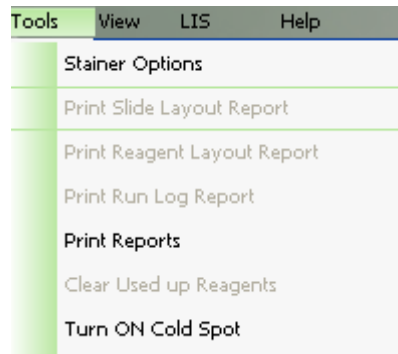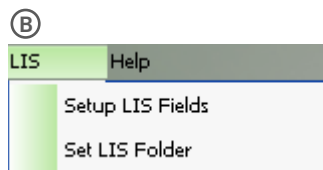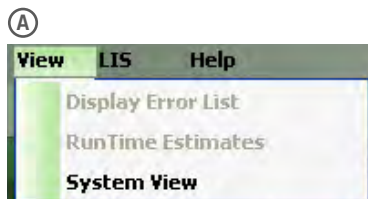
Ⓐ View Menu

The View menu allows access to Display Error List, Run Time Estimates, and System View.

Ⓑ LIS Menu (Contact Biocare Medical for LIS feature availability)

The LIS menu includes Setup LIS Fields and Set LIS Folder.

Ⓒ Help Menu

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

Ⓐ

Ⓑ

Ⓒ

② Stainer Tab

The stainer tab displays the name and serial number of the instrument. The red hexagon indicates the stainer is idle (Figure A), the green arrows designate the stainer is in process (Figure B) designate a stainer in process, and the green check (Figure C) indicates a completed staining run. The yellow triangle (Figure D) indicates that a problem has occurred.

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 Case List** 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 Case List** 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 view 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.
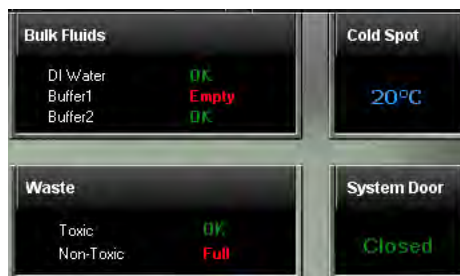

⑤ Slide Tray Positions

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 Racks** or **Unload**.

⑥ Slide Position

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

⑦ Operation Log

The Operation Log documents the instrument name, serial number, software version, run name/number and operation mode. The Operation Log also displays all the operations performed by the instrument. As an operation is performed, the log is updated.
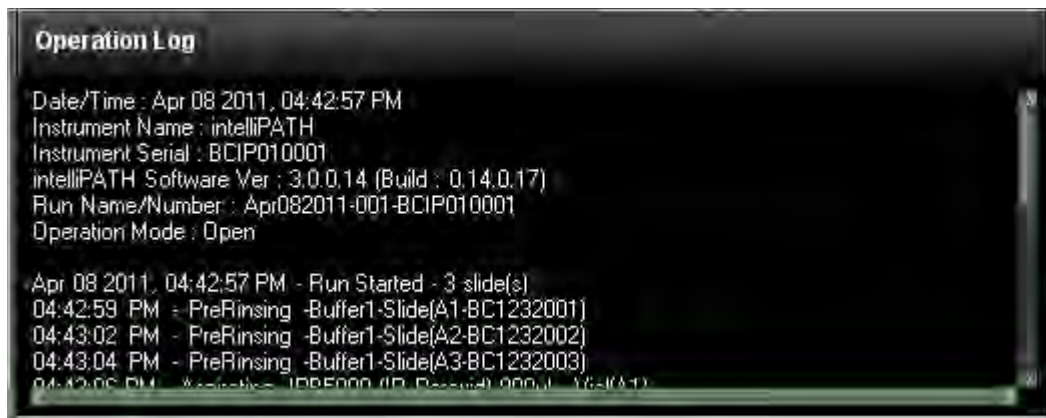
⑧ Welcome Menu

The Welcome menu displays the selected mode of operation:

Open Mode

Programming involves staining slides without labeling the slides or reagents. The software generates a Slide Layout Map, and a Reagent Layout Map for the user to follow. Alternatively, user can select the manual map option for reagents and slides.

2-D Matrix Mode

Programming involves labeling the slides and reagents; the software scans the slides and reagents. User may load the slides or reagents in any order.

Mixed Mode

Programming involves selecting either labeled slides or labeled reagents. For the option not labeled the software will generate a layout map for the user to follow. Alternatively, user can select the manual map option for unlabeled reagents or slides.

LIS Mode

Requires a software patch for uni- or bi-directional communication between the intelliPATH instruments and the user's Information Technology System. The system is XML and HL-7 compatible.

⑨ Instrument View

This button allows the user to view the status of the instrument.

⑩ Start Programming

The Start Programming button is used to initiate a staining run. Clicking on the **Start Programming** button will display the Prepare Case List dialog box that will indicate Start Time and Estimated End Time after a run has started.

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.
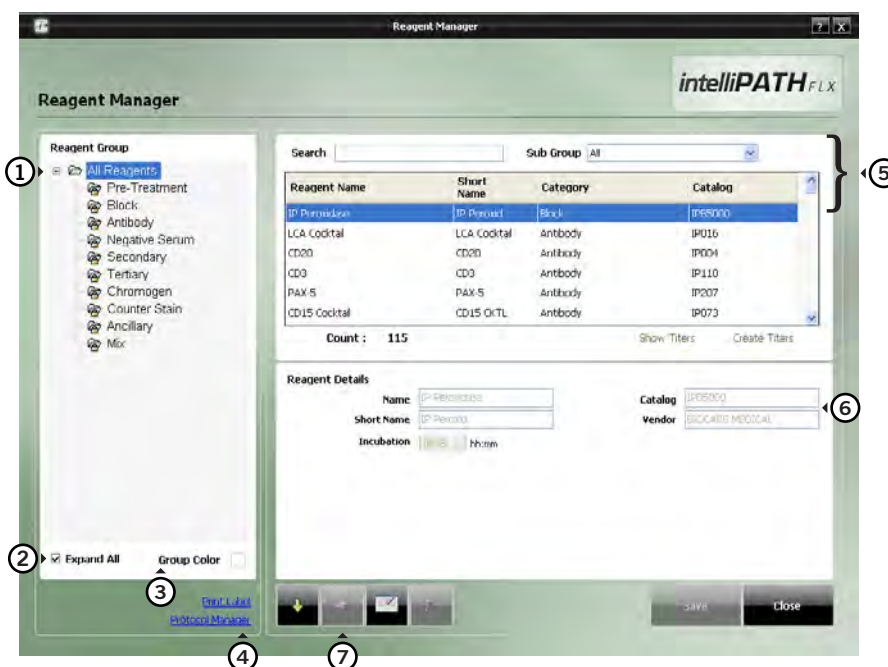
Access Level

    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. Reagents set by Biocare Medical cannot be edited or modified by the end user.

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 You can expand or collapse the Reagent Manager Menu items by checking the **Expand All** box on the bottom left side of the screen.

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

④ The **Protocol Manager** and **Print Label** 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. Use **Search** or **Sub Group** field to narrow the reagent list results.

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.
Note: The intelliPATH automatically generates a Short Name for reagents. To change the Short Name, highlight the Short Name field, click Delete on the keyboard, and then enter the desired Short Name.

⑦ Use the buttons at the bottom of the screen to import (down arrow) , add (plus sign), edit (pencil and tablet), or delete (X mark) reagents. To change the information about a particular reagent, make the changes in the **Reagent Details** section.
Note: 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 exit the screen, click **Close**.

Reagent Groups

Pre-Treatment Group

The Pre-Treatment reagent group includes enzymes and heat-induced epitope retrieval (HIER) solutions. 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**, and **Diluent** associate with the antibody of interest.

Below the reagents table, the **Show Titers** and **Create Titers** links are available. One of them will be accessible, depending on whether the highlighted reagent includes associated titers.

Antibody Titer

Use the Create Titers/View Titers screen to view or change the titer ratios for a particular reagent.

1. From the Reagent Manager Module's **Antibody** Reagent Group, click on the available Titers link.

2. To create an antibody titer, click on the **Add** button. Enter the numerical value of the titer
    (for example, for a 1:200 titration, enter 200).

3. Click **Save**.

4. To enter additional titrations click on the **Add** button and enter the numerical value of the next
    titration, then click **Save**. The software will automatically generate an antibody titration name with
    the following convention: Name of Antibody-T (numerical value of titer). A unique catalog number
    for each new titration will also be generated.

5. To delete a titration, click on gray area on the left side of the unwanted row, then click **Delete.**

6. Click **Save** to save changes or **Close** to exit.

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:

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.

Reconstituted 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 Reconstituted Stability is specified in the manufacturer's recommendations on the product insert.

Type

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

Mixing Properties

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.

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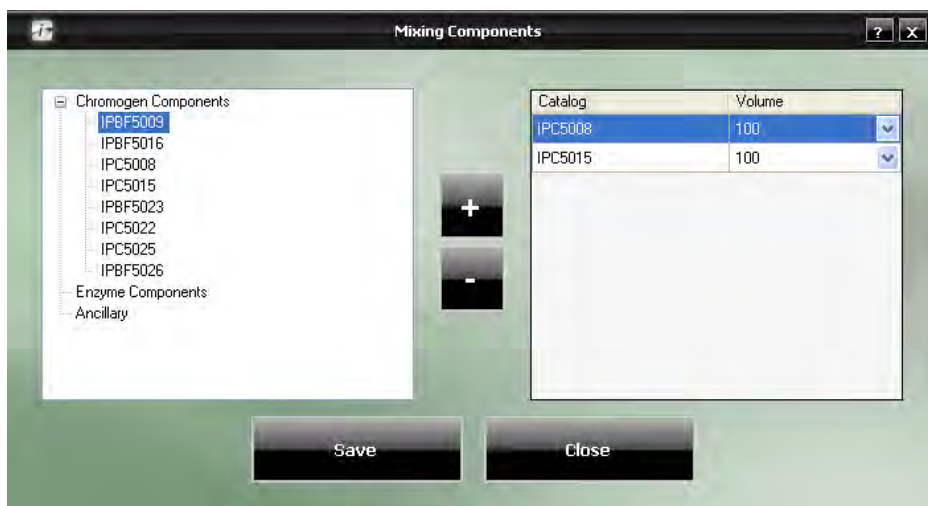
1. From the **Chromogen Components** list on the left, highlight the catalog number for chromogen buffer and click the **Add** button to add to the list on the right.

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

3. Add **Enzyme Components** to the list 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.

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 **Sub Group** drop-down menu, on the top right of the screen, and select the desired sub group category.

2. Click on the Add button.

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.

Protocol Manager Module

Use the Protocol Manger module to save, design, and manage protocols and detection templates.
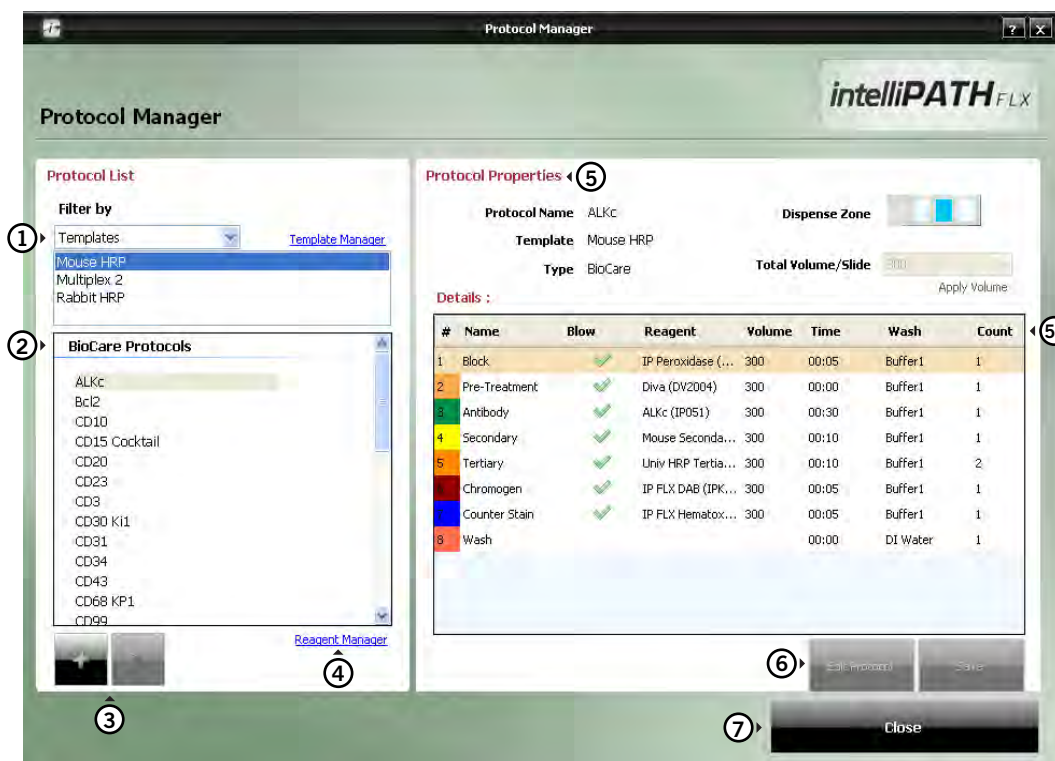
① You can filter the list of protocols by Templates or Custom Groups. The filter will determine the subsequent links available on the screen:

- Filtering by Templates allows access to the **Template Manager** link.
- Filtering by Group gives access to the **Group Manager** link.

② A list of **Biocare Protocols** will appear below the selected **Filter By** drop-down menu on the left side of the Protocol Manager screen.

③ Use the buttons at the bottom left of the window to add or delete protocols.

④ The **Reagent Manager** link is available on the bottom left side of the Protocol Manager screen.

⑤ The information about the selected protocol will appear in the **Protocol Properties** and **Details** sections on the right side of the screen.

⑤ₐ The **Protocol Properties** section allows you to view the Reagent Volume per Slide and the Dispense Zone. In the Dispense Zone diagram, the slide is divided into top , middle , and bottom sections. Blue color in a section indicates reagents dispense zone. Dispense volume for each zone is determined by dividing the total dispense volume by the number of dispense zones.

⑤♭ The **Details** section allows changes to the Reagent Name, Dispense Volume, air nozzle on/off option, Incubation Time, Wash solution options, and the wash Count values from drop menus.

⑥ To edit an existing Protocol click **Edit Protocol.** Select fields to edit then click **Save.**

⑦ To exit click **Close.**

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System Setup Module

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

Dispense Properties

Dispense Zone

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

Total Volume/Slide

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

Default Dispense Property

Users can choose either Global or Protocol.

Institution Parameters

Institution For Label

Free text field to enter institution name. This information will appear on all slides.

System Parameters

    Reagent Calculation

        Set option to for software to calculate reagent volumes for loaded slides or checked slides.
        System View Displayed: Select False or True.

    Buffer Type

        Buffer or DI water selected for application at the end of the run.

    Buffer Interval

        Time in minutes between application of designated buffer or DI water at the end of a run. Minimum of a 30 minute interval.

    Default Vendor

        User to enter vendor information.

    Buffer Slides After Completion

        Set option to buffer slides or to end run dry to True or False.
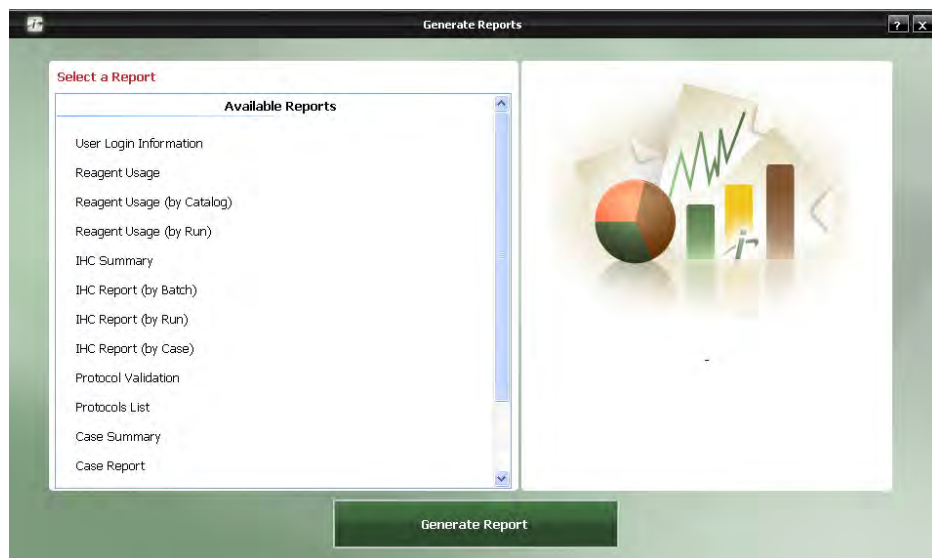
    Default Delay

        User can choose the number of hours to delay their run.

Use Touch Screen Keyboard

    Select True or False.

Generate Reports Module

To generate a report highlight the desired report, then click on **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.
IHC Summary	Provides a summary of all the slides in a run with the protocol for each slide.
IHC Report (by Batch)	Provides a summary of all the slides in a batch with the protocol for each slide.
IHC Report (by Run)	Provides a summary of all the slides in a run with the protocol for each slide.
IHC Report (by Case)	Provides a summary of all the slides in a case with the protocol for each slide.
Protocol Validation	Provides a report for a protocol indicating all the steps performed, a comment section, and sign off section for the pathologist.
Protocol List	Generates a list of all protocols.
Case Summary	Provides a summary of all the tests performed for a particular case.
Case Report	This report provides a summary of all the tests performed for a particular case along with protocol details.
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.
Slide Volume (for a Date Range)	This report generates a list of the number of slides performed for each protocol by date range.

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.

1. View the Cleaning Summary and dentify the instrument that requires cleaning and click on the **Clean Now** button.
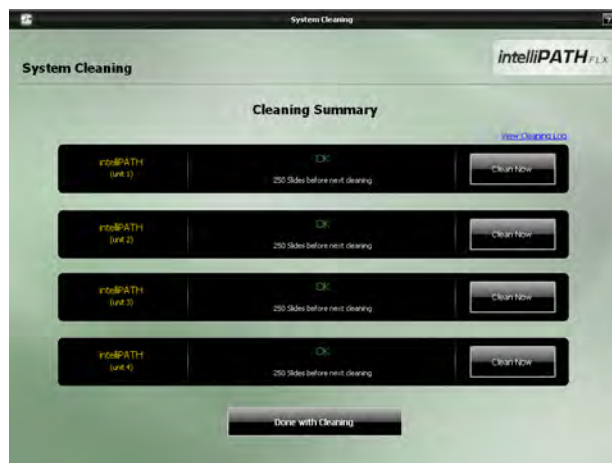
2. Perform each of the **Pre-Requisites for Cleaning** listed on the screen below, in the specified order, and check the boxes as you complete the tasks.

- 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 (mix right before use). Place the vial in position **A2**.
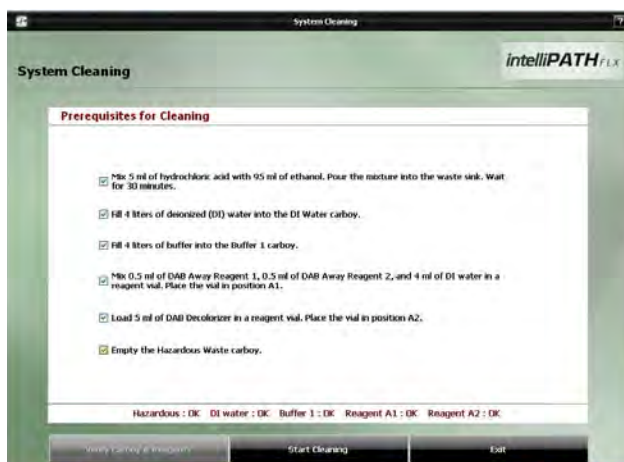
Caution: Do not allow cleaning reagents to come into contact with bleach (if used).

3. Click **Verify Carboys & Reagents.**

4. Click **Start Cleaning.**

5. To exit the **System Cleaning** Module, click **Done with Cleaning**.

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.

1. From top of the window, select the reagent category of choice from **Reagent** drop- down menu.

2. At the bottom of the window, click on **Add** to enter the reagent catalog number, lot, expiration, staining volume (starting volume of reagent in vial), and serial number. The serial number is a unique identifier for each vial of a reagent. Biocare reagents will be pre-coded with a lot, expiration date, and serial number. The intelliPATH software will track the Current Volume based on the reagent usage. Note: The serial number must be a unique identifier for each reagent. The user can not add duplicate items to the Reagent Inventory. The software will generate a warning message: Cannot add duplicate Reagent Inventory, Please change your input value.

3. Press **Save** to return to the **Reagent Inventory Manager** window.

4. Click on **Print Label** to print reagent label with lot and expiration date information.

5. Click **Close** to exit.

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.
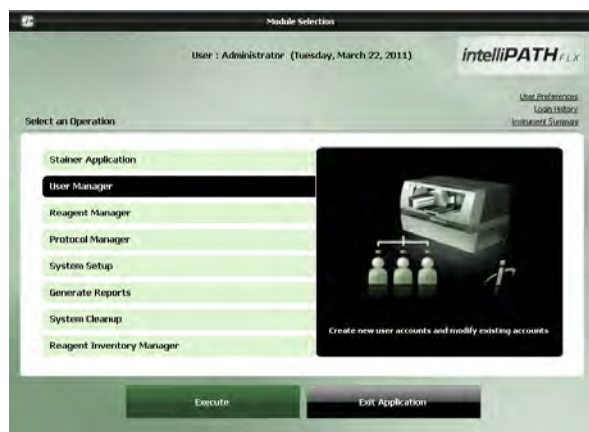
Assign a user account

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.
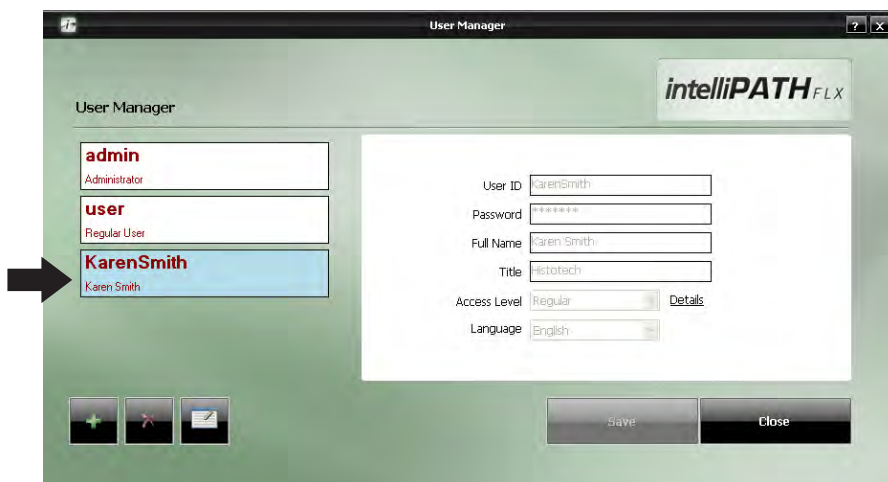
Modify passwords

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.
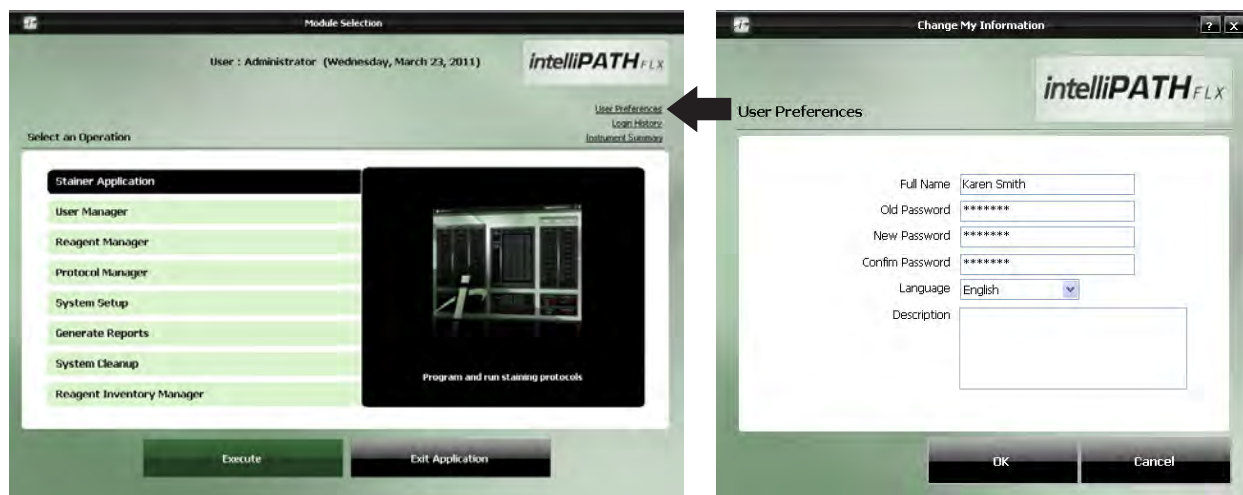
Assign or modify reagents

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)
- **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

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1. From the **Module Selection** menu select **Reagent Manager** Module. Press **Execute** to proceed.

**2.** Go through each **Reagent Group** and set up the appropriate reagents and conditions.

   2a. Pre-Treatment Group

- Select **Pre-Treatment** from Reagent Group at the left side of the screen.
- Select **Reveal** as your pre-treatment reagent.

   Note: If you would like to add a new pre-treatment reagent not in the list, first select a **Sub Group** (Antigen Retrieval or Enzyme), then select the **Add** button.
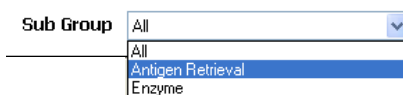
2b. Block Group

- Select **Block** from Reagent Group at the left side of the screen.
- Select **Peroxidazed 1** as your blocking reagent.
- To add Peroxidazed 1, click the **Add** button. Enter the appropriate information in the Reagent Details section. Press **Save**.
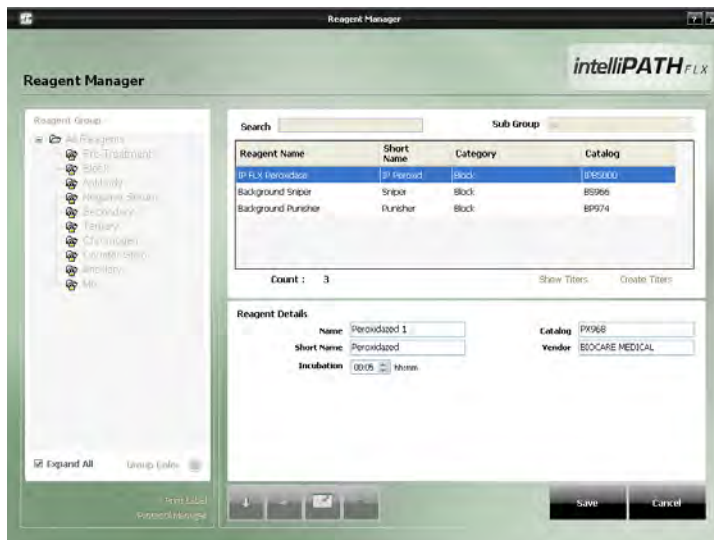
2c. Antibody Group

- Select **Antibody** from Reagent Group at the left side of the screen.
- Locate **Ki-67** from the reagent list by viewing the entire reagent list or using the Search box to type "ki-67".
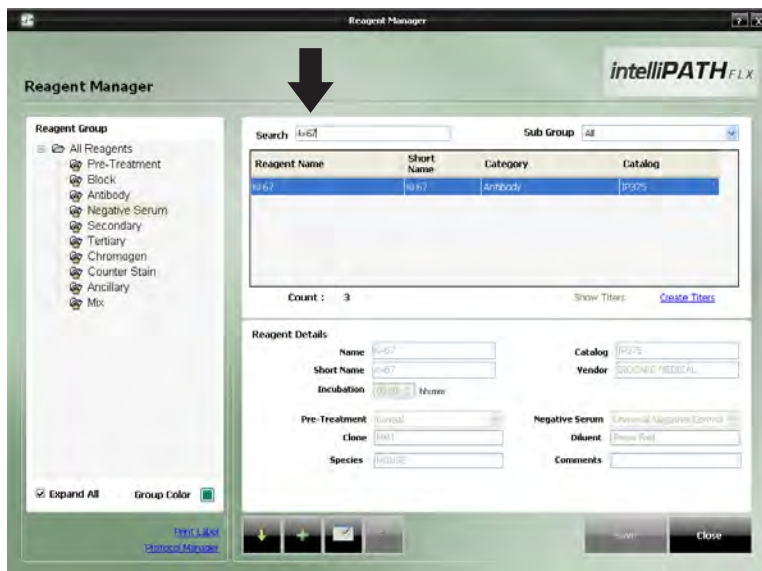
To add a new antibody, click the **Add** button. Enter the appropriate information in the Reagent Details section. Press **Save**.

2d. Negative Serum Group

- Select **Negative Serum** from Reagent Group at the left side of the screen.
- Select the appropriate negative serum reagent.
- To add a new negative serum, click the **Add** button. Enter the appropriate information in the Reagent Details section. Press **Save**.

2e. Secondary Group

- Select **Secondary** from Reagent Group at the left side of the screen.
- Select **MACH 3 Mouse Probe AP** as your secondary reagent.
- To add **MACH 3 Mouse Probe AP**, click the **Add** button. Enter the appropriate information in the Reagent Details section. Press **Save**.

2f. Tertiary Group

- Select **Tertiary** from Reagent Group at the left side of the screen.
- Select **MACH 3 Mouse AP Polymer** as your tertiary reagent.
- To add **MACH 3 Mouse AP Polymer**, click the **Add** button. Enter the appropriate information in the Reagent Details section. Press **Save**.

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2g. Chromogen Group

- Select **Chromogen** from Reagent Group at the left side of the screen.
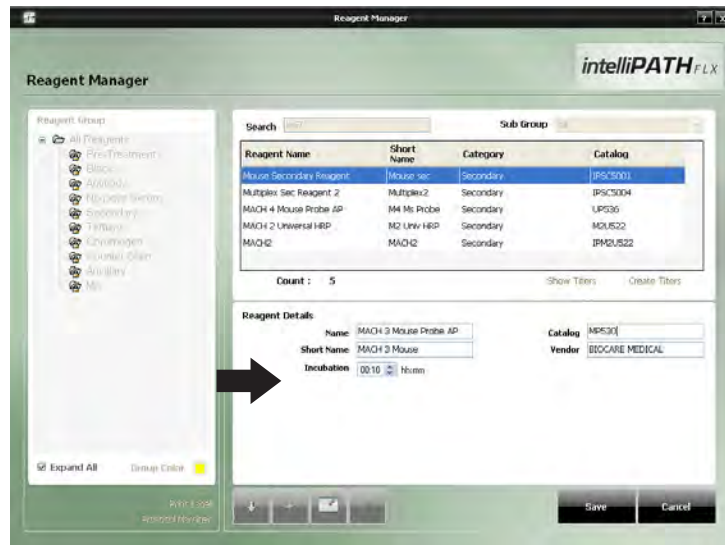- Select **iP Warp Red** as your chromogen.
- To add a new chromogen, click the **Add** button.
- Enter the appropriate information in the Reagent Details section. Press **Save**.

2h. Counter Stain Group

- Select **Counter Stain** from Reagent Group at the left side of the screen.
- Select **iP FLX Hematoxylin** as your counter stain reagent.
- To add a new chromogen, click the **Add** button.
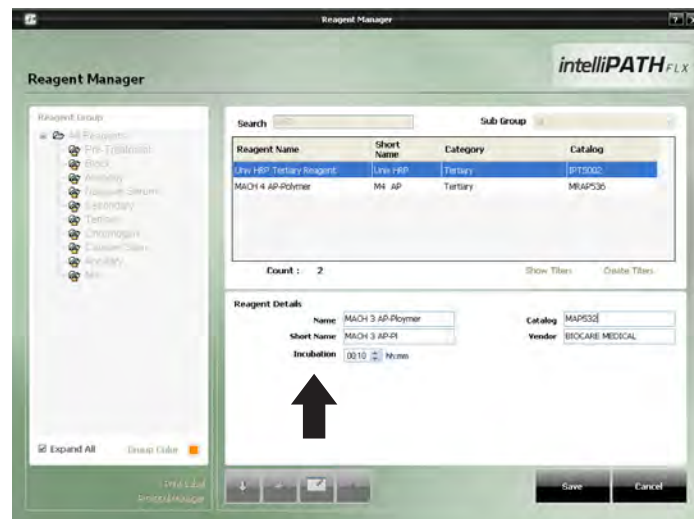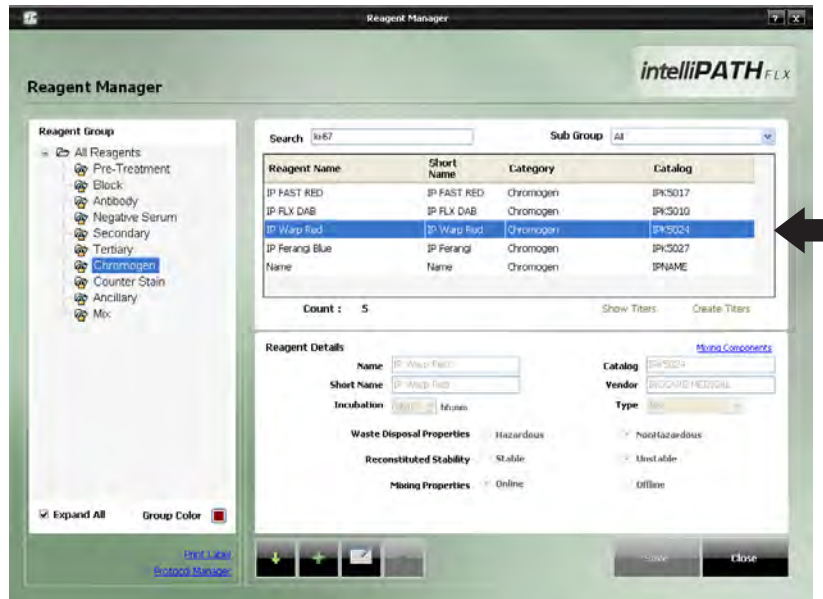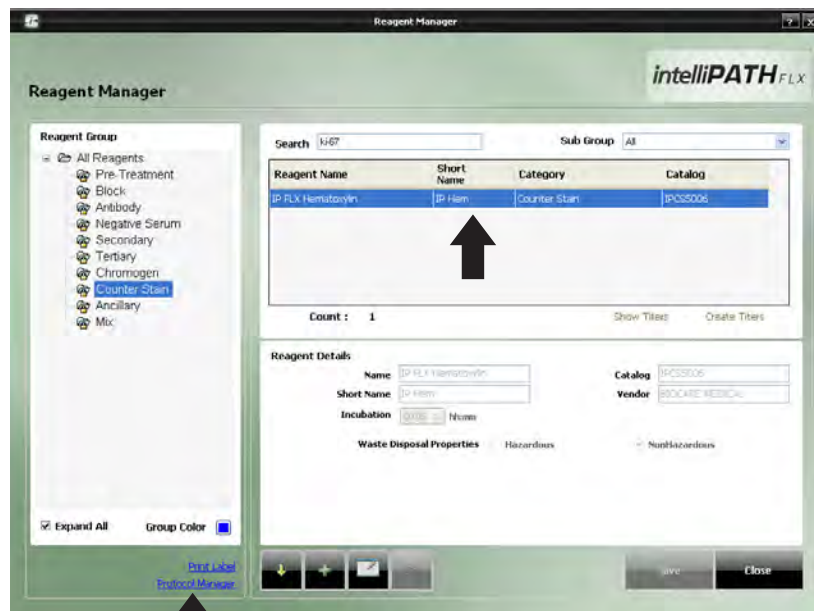- Enter the appropriate information in the Reagent Details section. Press **Save**.

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

Assign or modify protocol
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)
- **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

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1. From the **Module Selection** menu select **Protocol Manager** Module. Press **Execute** to proceed. Alternatively, select Protocol Manager from the bottom right side of the Reagent Manager screen.

2. Design a New Template

    2a. Select the **Template Manager** link.
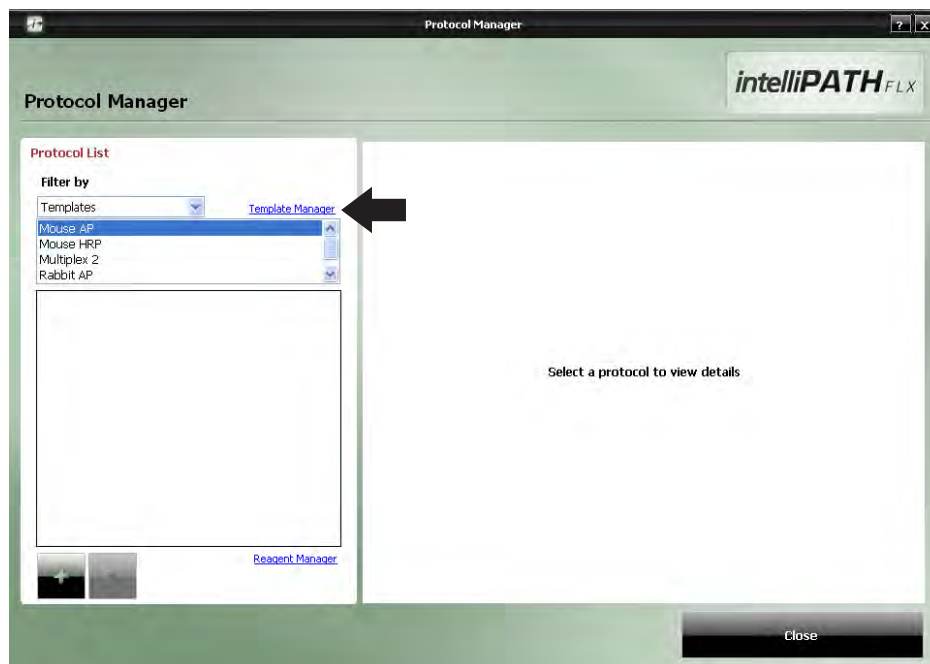
2b. From the **Template Manager** screen, add a new template by clicking the **Add** button.

2c. In the **Create a New Template** screen, enter your template name. Select **From Existing Template** (alternatively, you may create a blank template). Click **Create** to continue.

2d. In the **Details** section of the **Template Manager** screen below, the user can edit details such as Blow, Volume, Incubation time, Wash type, and Count by clicking on the desired area. Name and Reagent fields cannot be altered at this stage.

Note: Click on the Insert Step button to enter step in the list above the highlighted step. Add Step button to enter step at the end of the list. Click on the Delete Step button to remove step from list.
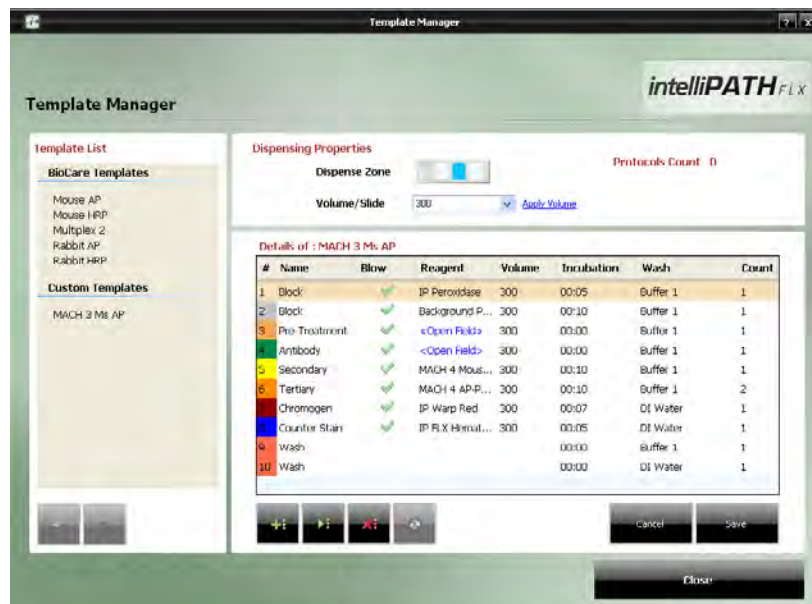
2e. Click **Save** to save the template.

2f. Click **Close** to exit the screen.

Adding the New Protocol to a Template

1. To link the new protocol to a template, select the template of choice from **Templates** in the **Filter by** drop-down menu, then click the **Add** button.
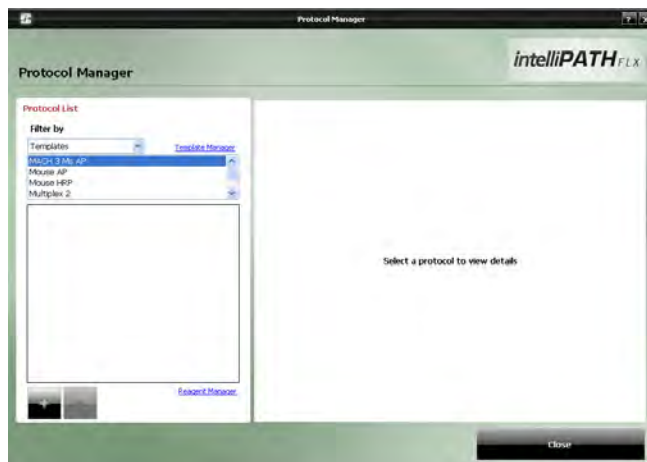
2. Enter the Protocol Name and click **Create**.
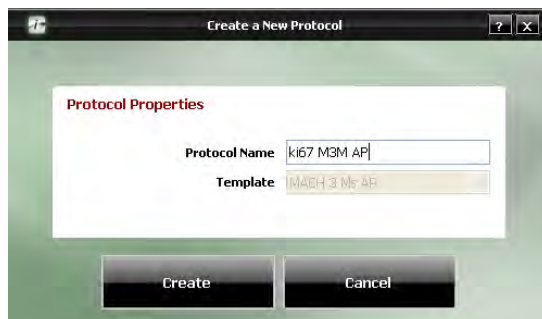
3. From the Antibody field drop down menu in the **Details** table, select the Antibody of choice. The Antibody and Pre-Treatment fields are linked. Thus, selection of the primary antibody, then clicking outside of the field will update the Pre-Treament reagent.
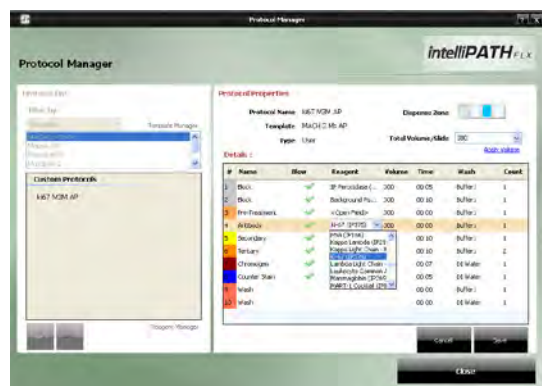
4. Click **Save** to save the protocol.

> Note: If a template is deleted, all protocols associated with the template become invalid.

5. Click **Close** to exit the screen.

Creating Custom Groups

Filtering the Protocol List by Custom Groups provides access to the Group Manager link. 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 **Custom Groups** in the **Filter by** drop-down menu. Select the **Group Manager** link.
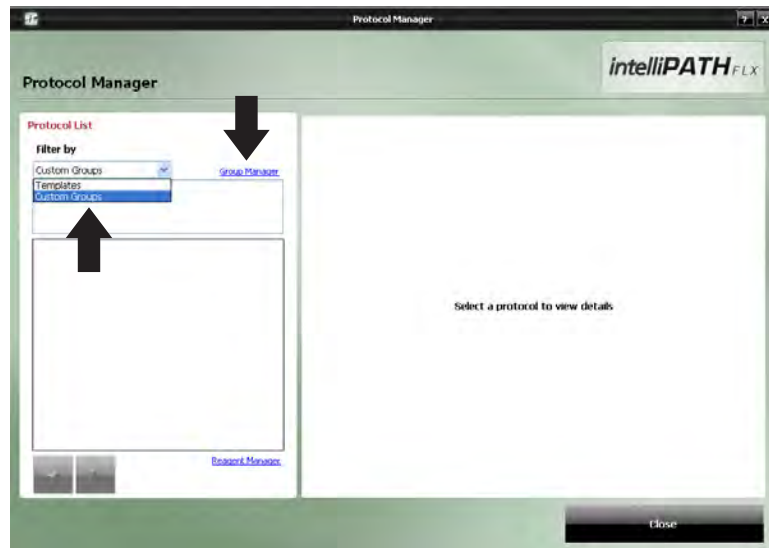
2. To add a new Group from the **Manage Protocol Groups** window, click the **Add** button.

3. In the **New Protocol Group** screen, enter the Custom Name and click **Create Group**.
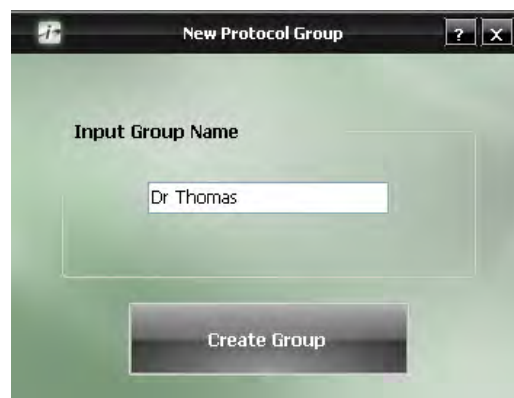
4. To add protocols to a custom group, select the Group name on the left side of the **Manage Protocol Groups** screen. Click on the **Add Protocols** link.
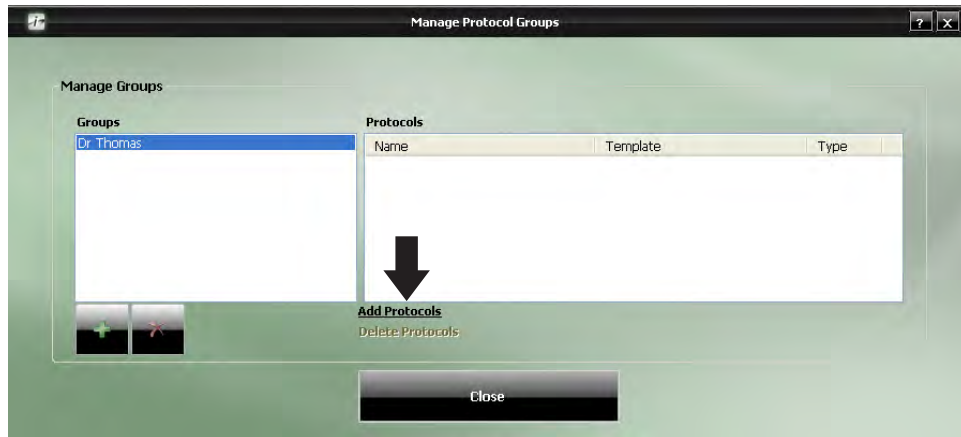
5. The **Filter By** drop down menu, in the **Select Protocol** screen, allows selection of Protocols by **Custom Groups** or **All Protocols**. Highlight the desired Protocols to include in the Custom Group. To select concurrent protocols, highlight the first protocol then hold down the Shift key on your keyboard before selecting the last protocol. To select multiple protocols, highlight protocols while holding down the Ctrl (Control) key. Click **Select**.

6. To delete Protocols click **Delete Protocols**, to add additional Protocols click **Add Protocols**.

7. Click **Close**.

Before Starting a Run

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

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:

   Note: For optimal staining, use of HP-Barrier slide labels or a Super Pap Pen (PEN1111) is recommended.

   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. Result should indicate positive.

   Negative Process Control
   Replace primary antibody with buffer or nonsense antibody. 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. To use the closed run 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 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.
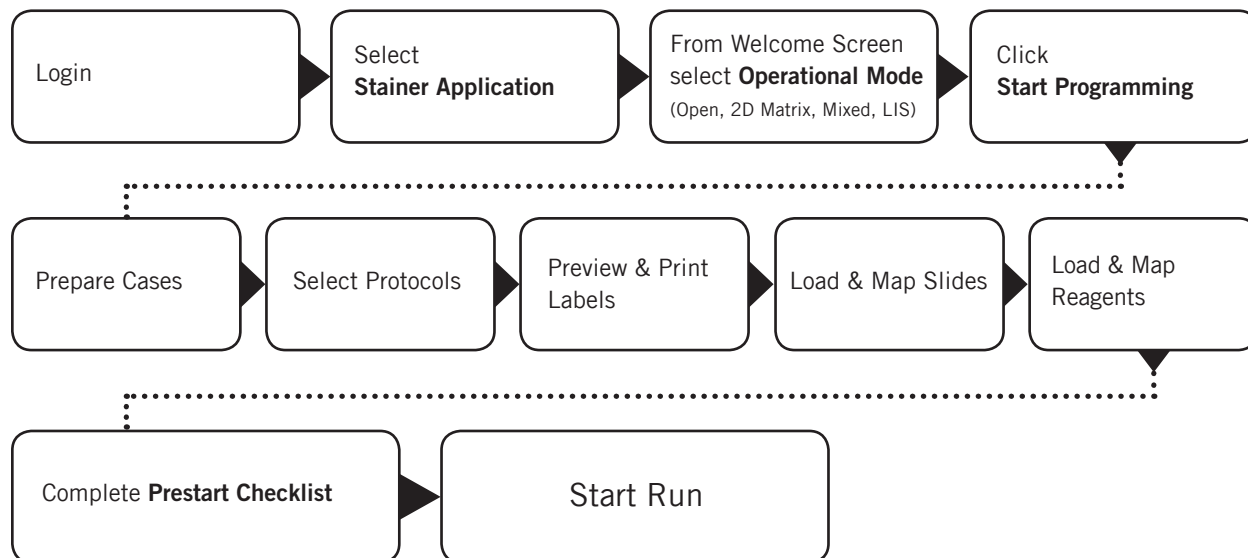
Prepare and Start a Run

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 in Chapter 5. 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

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

```
┌──────────┐    ┌──────────────┐    ┌──────────────────┐    ┌──────────────────┐
│          │    │ Select       │    │ From Welcome Screen│   │ Click            │
│ Login    │───▶│ Stainer      │───▶│ select Operational Mode│▶│ Start Programming│
│          │    │ Application  │    │ (Open, 2D Matrix, Mixed, LIS)│ │           │
└──────────┘    └──────────────┘    └──────────────────┘    └──────────────────┘
                                                                       │
       ┌───────────────────────────────────────────────────────────────┘
       ▼
┌──────────────┐    ┌──────────────┐    ┌──────────────┐    ┌──────────────┐    ┌──────────────┐
│              │    │              │    │ Preview & Print│  │              │    │ Load & Map   │
│ Prepare Cases│───▶│ Select Protocols│▶│ Labels       │──▶│ Load & Map Slides│▶│ Reagents    │
│              │    │              │    │              │    │              │    │              │
└──────────────┘    └──────────────┘    └──────────────┘    └──────────────┘    └──────────────┘
       ▲                                                                                  │
       └──────────────────────────────────────────────────────────────────────────────────┘
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       ▼
┌──────────────────────────┐    ┌──────────────┐
│                          │    │              │
│ Complete Prestart Checklist│─▶│ Start Run   │
│                          │    │              │
└──────────────────────────┘    └──────────────┘
```
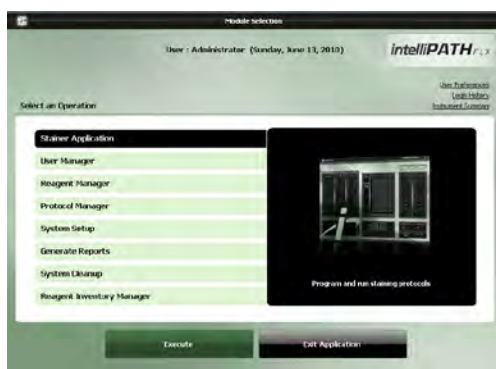
Login to intelliPATH Software

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 an Operation Mode

3. From **Welcome to intelliPATH**, select an Operation Mode (Open, 2D Matrix, Mixed, LIS).

Open Mode
Programming involves staining slides without labeling the slides or reagents. The software generates a Slide Layout Map, and a Reagent Layout Map for the user to follow. Alternatively, user can select the manual map option for reagents and slides.

2-D Matrix Mode
Programming involves labeling the slides and reagents; the software scans for the slides and reagents. User may place the slides or reagents in any order.

Mixed Mode
Programming involves selecting either labeled slides or labeled reagents. For the option not labeled the software will generate a layout map for the user to follow. Alternatively, user can select the manual map option for unlabeled reagents or slides.

LIS Mode
Requires a software patch for uni- or bi-directional communication between the intelliPATH and the user's Information Technology System. The system is XML and HL-7 compatible.
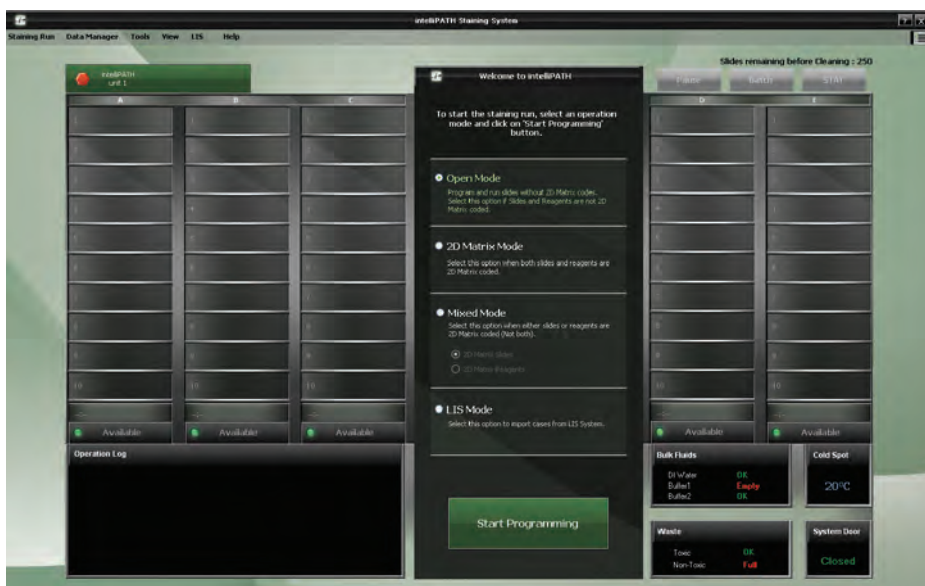
Start Programming

4. Press **Start Programming** to continue.

Prepare Cases

5. Prepare Case List (where **Welcome to IntelliPATH** was previously located) by selecting either of the links (Add a New Case, Import from Pending List, Import from Saved Lists, or Import from Recent Batches).
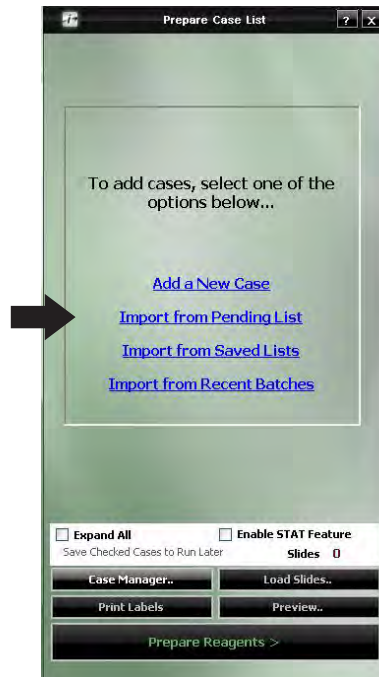
6. To add a new case, enter the patient case number in the **Case Details** section (right side of the screen). The software automatically assigns a Test ID. The other fields on the right side of the **Create a New Case** screen are optional.
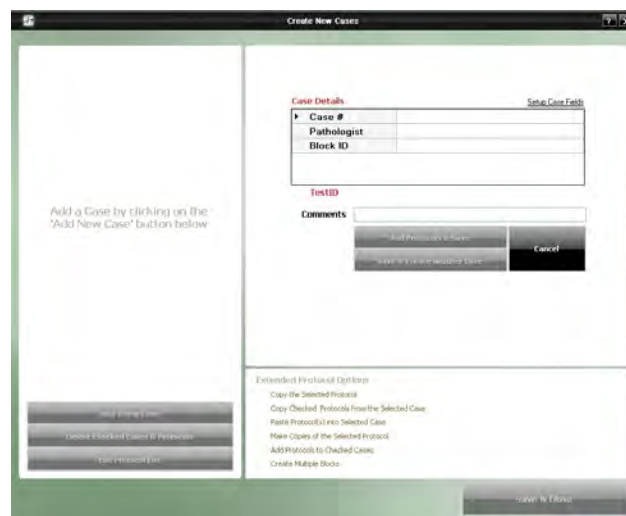
7. Click on the **Add Protocols & Save** button to proceed.

Select Protocols

8. On the upper left side of the **Select Protocols** window, select protocol filter from **Filter By** drop-down menu. Filter protocols by **Custom Groups** or **All Protocols.**
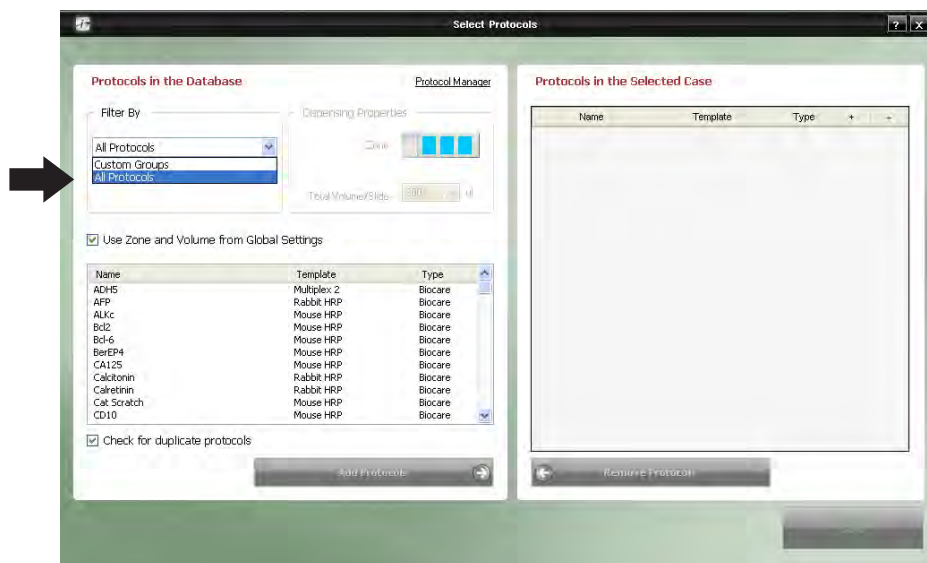
9. Highlight the protocol(s) on the left side of the screen. Click on the **Add Protocols** on the screen's lower left side. The selected protocols will then be displayed on the right. To select multiple protocols, highlight protocols while holding down the Ctrl (Control) key. To remove selected protocols from the case, highlight the list on the right, and then click **Remove Protocols**.

10. For each selected protocol, user has the option to select positive and negative control.
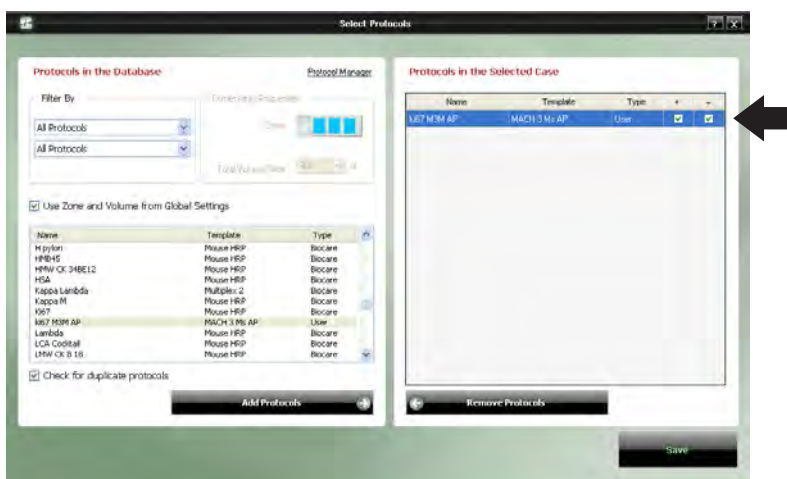
11. Click **Save** to proceed.

12. In the window below, you have the option to **Add a New Case** (see button on lower left side of the screen). Otherwise, press **Save & Close** to proceed.

Preview & Print Labels

13. From the bottom of the **Prepare Case List** window, preview the slide labels by first pressing the **Preview** button, followed by selecting **Slide Labels** at the bottom of the screen.

14. Preview the slide labels on the right side of the screen. To print the slide labels, click on **Print Labels** at the bottom right side of the screen.

15. Click on **Close** to proceed.

Load & Map Slides

15. 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.

16. Click on **Load Slides**.

16a. For **Open Mode** or **Mixed Mode** (2-D Matrix Reagents), select **Auto Map** or **Manual Map**.

Auto Map: The instrument will suggest the slide positions.
Manual Map: The user specifies the slide positions.

16b. For **2-D Matrix** or **Mixed Mode** (2-D Matrix Slides) select **Scan Slides**. The **Select Slide Tray** dialog box will appear. Select loaded trays. Click **Ok**. Next, click on **Start Scan** to proceed.
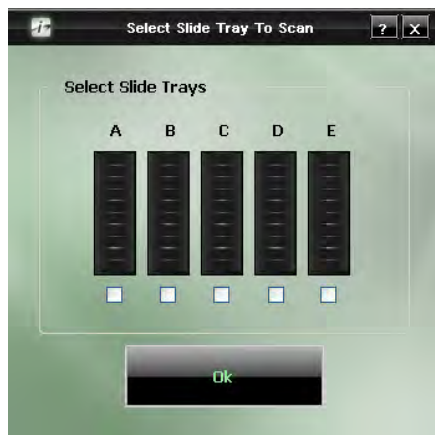
Load & Map Reagents

17. From the bottom of the **Prepare Case List** window, click on **Prepare Reagents**.
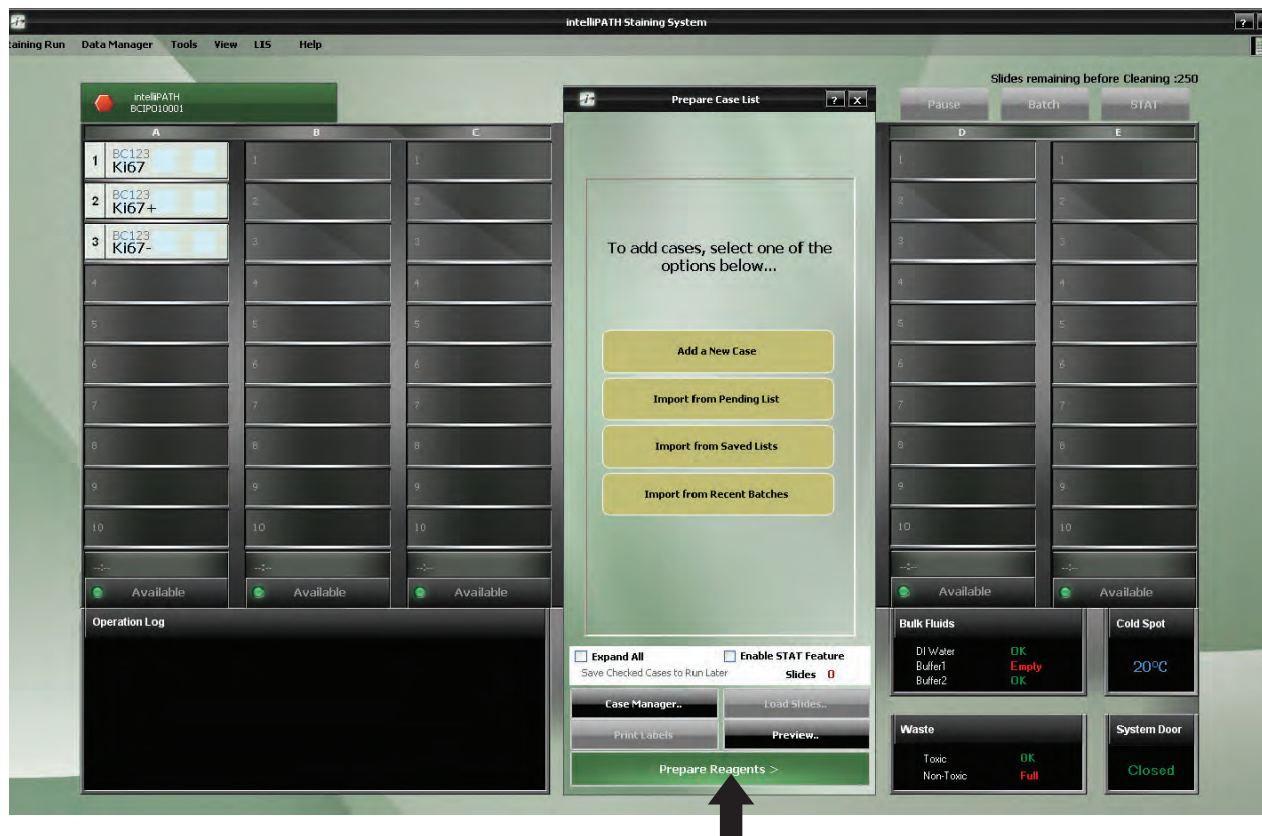
18. Select the appropriate reagents or check the **Select All** to select all reagents to print reagent labels if needed. Click on **Load Reagents** in the bottom right side of the screen to load reagents.

18a. For **Open Mode** or **Mixed Mode** (2-D Matrix Slides), select **Auto Map** or **Manual Map**.

18b. For **2-D Matrix** or **Mixed Mode** (2-D Matrix Reagents) select **Scan Reagents**. Click on **Start Scan** to proceed.
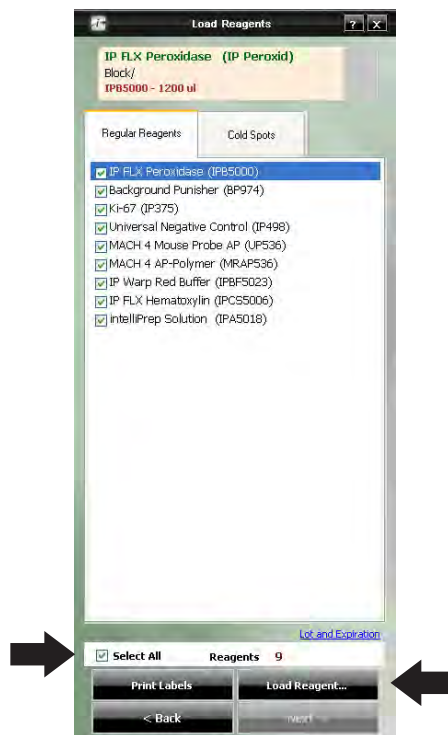
19. Click **Next**.

20. Verify Reagent levels by first checking the **Reagent and Mixing vials are loaded as specified** checkbox. Click on **Verify Reagents**. Upon reagent volume verification, press **Proceed**.
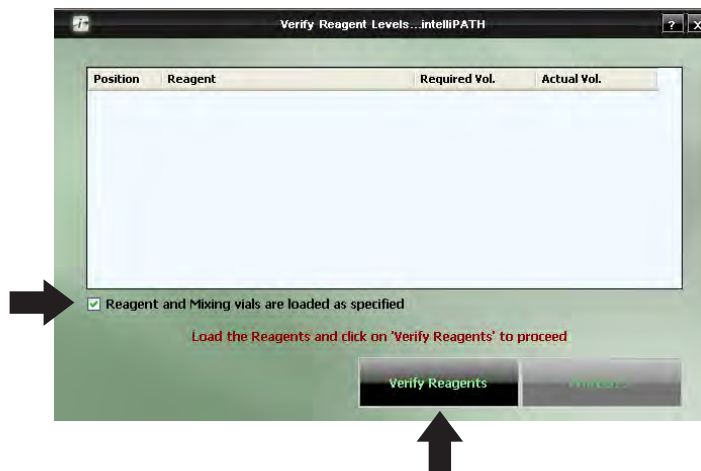
Pre-Start Checklist

21. Use the **Pre-Start 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.

22. 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.

    22a. Select the **Delayed Run** box.
    22b. Set the **Start Time.**
    22c. 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.

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

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

25. 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

26. 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**.

27. 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.

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.
    - Fill Buffer 1, DI and Buffer 2 carboy (if used) with at least 2L of a 10% Lysol solution.
    - Shake the carboys so the walls of the carboys are well washed.
    - Log in to the IntelliPATH system.
    - Execute the Stainer Application.
    - Within the tools menu, click prime probe and prime the probe for 30 seconds.
    - Within the tools menu, click on Drain Waste and Prime Buffers.
    - 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 malfunctioned. **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:** Fuse is blown. **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. **Note:** If the fuse blows 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 Service 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.