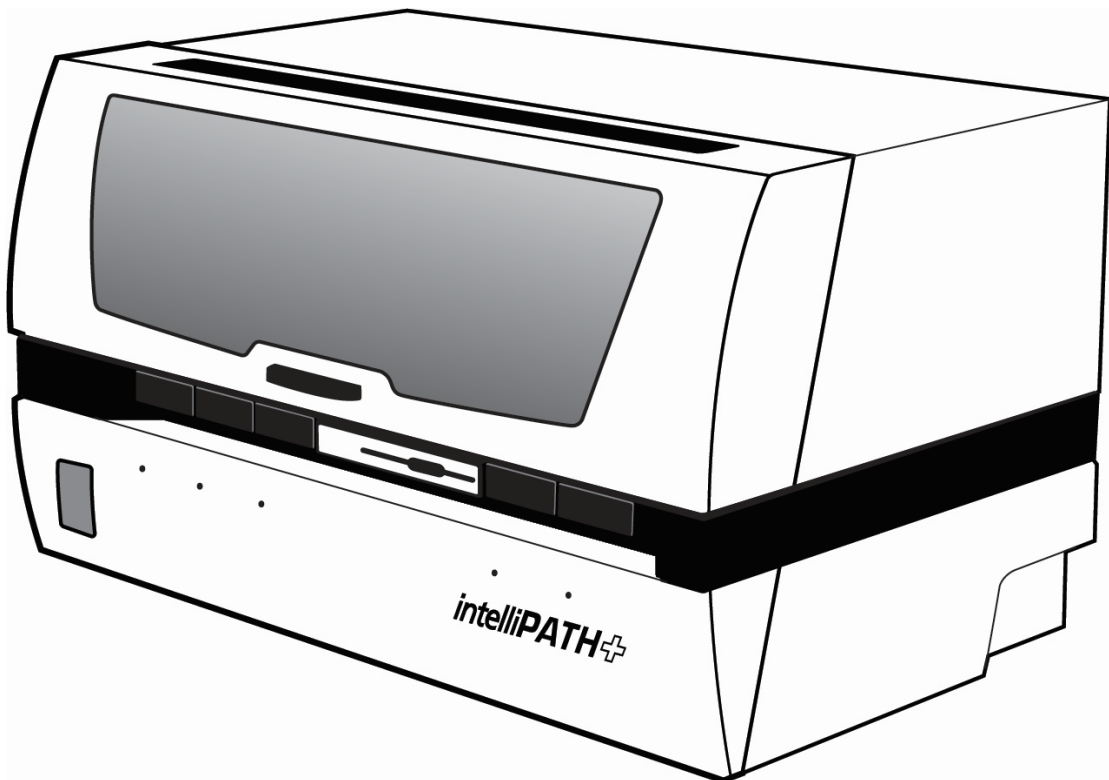


intelliPATH™ PLUS and intelliPATH™ MAX User Manual



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# Introduction

## Intended Use

For In Vitro Diagnostic Use:

The IntelliPATH Plus and IntelliPATH MAX are an automated instrument used by professional laboratory personnel for performing immunohistochemistry (IHC) tests to stain formalin-fixed, paraffin-embedded (FFPE) tissue samples mounted on glass microscope slides.

*Note: The IntelliPATH MAX is a configuration of the IntelliPATH PLUS capable of running double wide slides.*

Intended Purpose:

The IntelliPATH PLUS is intended for professional laboratory use in automated clinical protocols for immunostaining of formalin-fixed paraffin embedded (FFPE) tissue mounted on microscope slides. The microscope slides subsequently undergo interpretation by a qualified healthcare professional to aid diagnosis. The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

## About the IntelliPATH PLUS and IntelliPATH MAX

The IntelliPATH PLUS and IntelliPATH MAX are Biocare Medical's latest automated slide stainers for processing patient slides in anatomical pathology and histology laboratories. The IntelliPATH PLUS and IntelliPATH MAX are designed to perform reliable and consistent IHC staining in such a manner that closely mimics manual staining methods. This enables easy transfer of established manual staining methods to an automated platform with minimal protocol optimization. The IntelliPATH PLUS has the capacity to process 50 slides per run for standard size tissues. For larger tissues, the IntelliPATH MAX has the capability to process double wide slides at a maximum capacity of 25 slides (5 slides per slide tray) per run. The IntelliPATH PLUS and IntelliPATH MAX are open platforms intended for both Clinical and Research Markets.

## Instrument Specifications

Slide capacity	IntelliPATH PLUS (standard size slides): 50 IntelliPATH MAX (double wide slides): 25
Independent slide trays	IntelliPATH PLUS (standard size slides): 5 slide trays, 10 slide positions per tray IntelliPATH MAX (double wide slides): 5 slide trays, 5 slide positions per tray
Slide specifications	IntelliPATH Plus Standard microscope slides: Width: 24.2 – 25.6 mm Length: 76.5 mm (maximum) Thickness: 1.3 mm (maximum)  IntelliPATH MAX Double wide microscope slides: Width: 49.5 – 51.0 mm Length: 76.5 mm (maximum) Thickness: 1.3 mm (maximum)
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 on the IntelliPATH PLUS Delivers 200 µL to 1200 µL on the IntelliPATH MAX
Multi-dispensing range	20 mL
Buffer inlets	3
Waste separation	Separated hazardous and non-hazardous
LIS	Compatible with LIS2-A2 (ASTM) and HL7 messaging standards

Electrical requirements	900W; 115V/230V; 50/60 Hz
Instrument Dimensions (W x H x D)	40" X 24" X 27" / 102 cm X 61 cm X 69 cm (excludes optional computer arm)
Computer arm	Optional, attaches to the left or right side of the instrument (P/N: IPP10108)
Instrument Weight	145 lbs / 66 kg (excl. optional computer arm)



Not for use with flammable solvents or gases

## Warranty

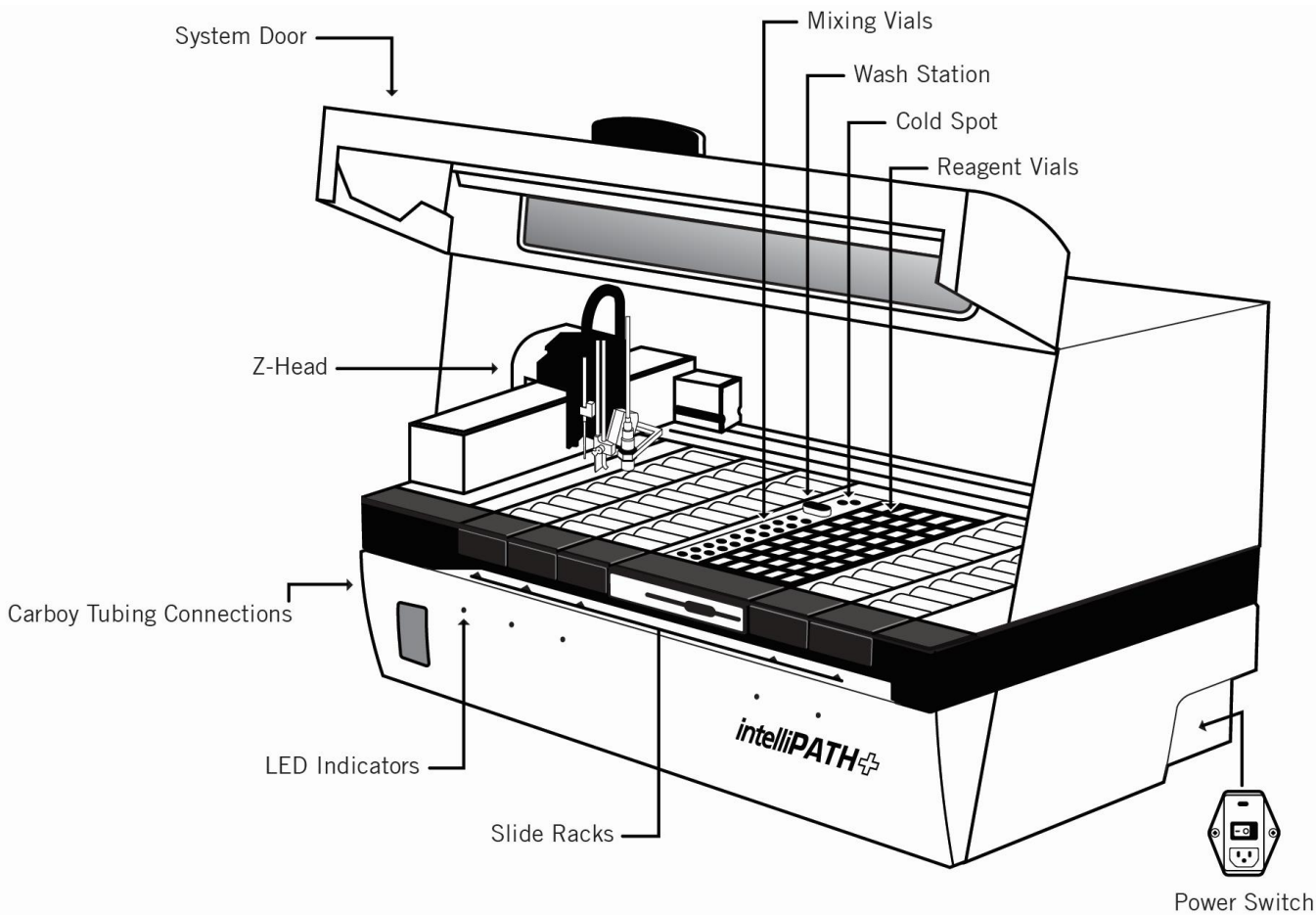
The IntelliPATH PLUS and IntelliPATH MAX warranties are valid for one year from receipt of purchase and covers all parts and labor when performed solely by Biocare Medical. Warranty is invalidated if equipment is abused, damaged, or improperly maintained by customer. Warranty is not transferable to any 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.

## Serious Incident Reporting

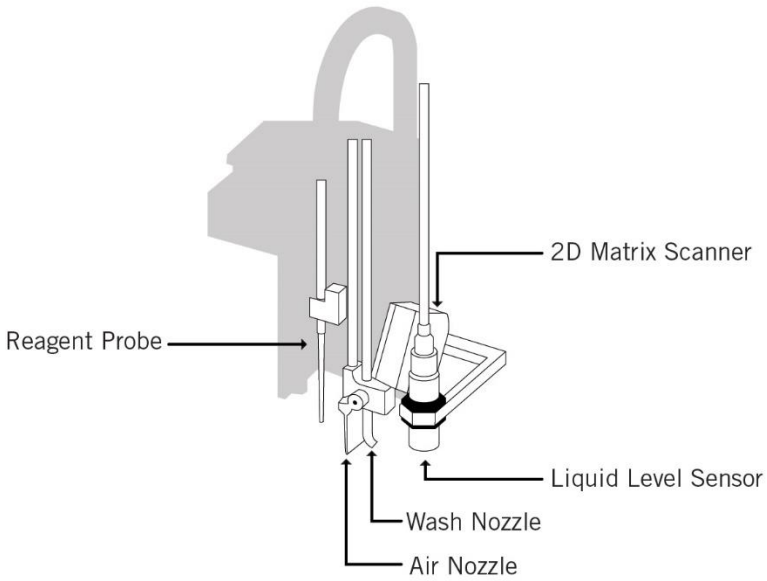


Any serious incidents associated with a Biocare Medical product that has resulted in, or could potentially result in, the death of a patient or user or in the temporary or permanent deterioration of a patient or user's health, report the incident(s) to a local representative of Biocare Medical and the appropriate local Regulatory Authority.

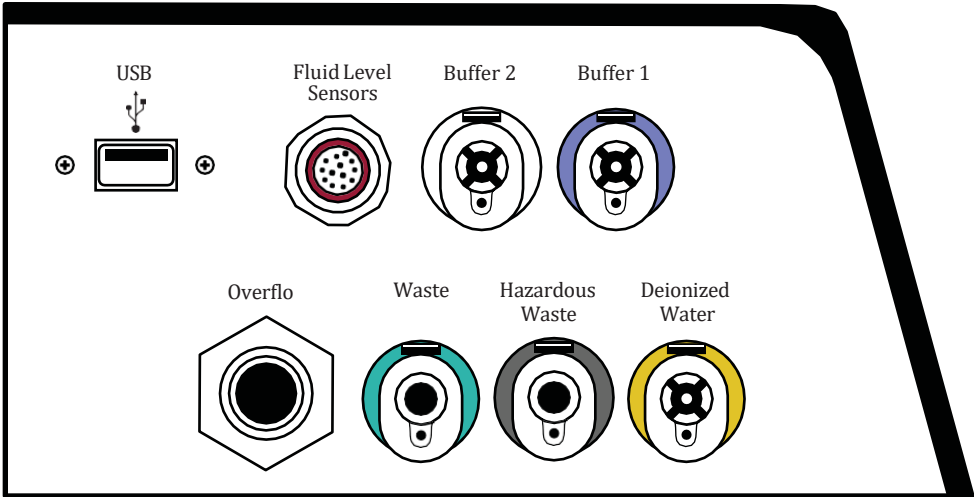
Instrument Components



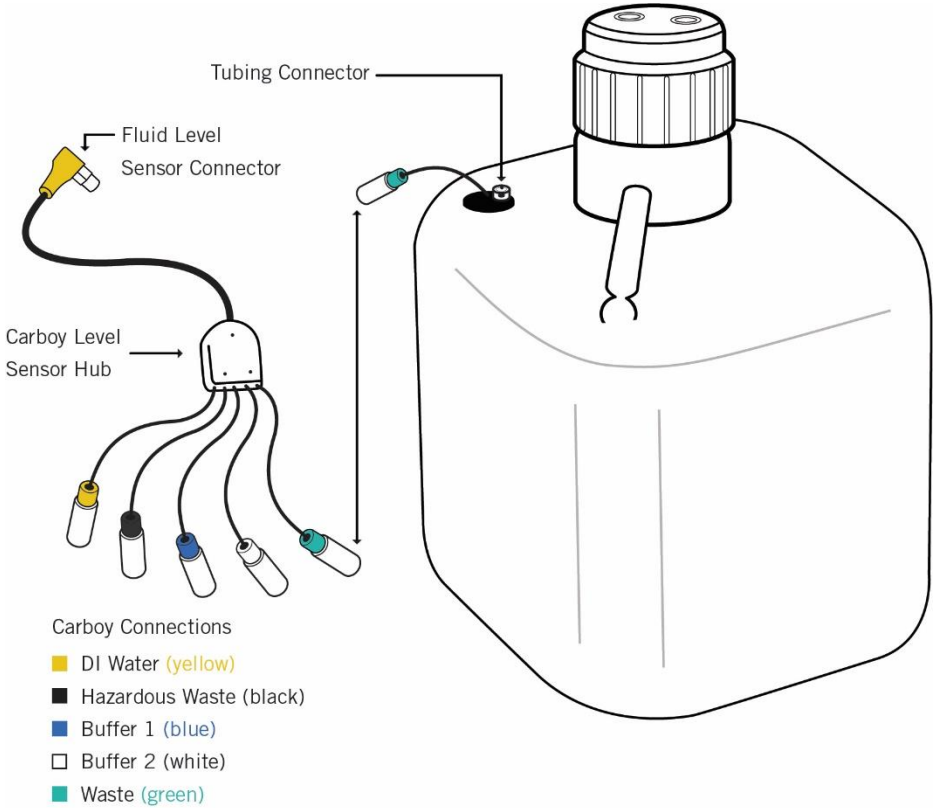
Z-head Components



Carboy Tubing Connections



Carboy





## Description of Parts

Parts	Description
Slide racks	The IntelliPATH PLUS includes five removable slide racks, each with a 10-slide capacity. The IntelliPATH MAX includes five removable slide racks, each with a 5-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 PLUS and IntelliPATH MAX 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 Screen.
Cold Spot	The IntelliPATH PLUS and IntelliPATH MAX Cold Spot is capable of holding two vials of heat labile reagents at 2-8°C during the staining process.
Mixing vials	The IntelliPATH PLUS and IntelliPATH MAX have 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. At minimum, vials must be filled with the volume requested during reagent preparation. All reagent vials have a 300 µL dead volume.
Z-head	<p>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:</p> <p>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.</p> <p>Liquid Level Sensor: The contactless ultrasonic level sensor detects the reagent volume level and sends a signal to the software. 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.</p> <p>Air Nozzle / Wash Nozzle: The wash nozzle applies buffer or DI water to the slides at each rinse step and at preset intervals to keep slides moist during the holding time before the start of a run. The air nozzle applies an air blow step used to remove excess liquid from a slide before applying reagents.</p> <p>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 PLUS/IntelliPATH MAX software.</p>
Buffer and distilled/deionized water storage	<p>The buffer and water carboy assemblies have liquid level sensors. The IntelliPATH PLUS and IntelliPATH MAX use 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.</p> <p>A secondary containment system for each of the buffer and distilled water carboys is recommended. Selected secondary containment systems must accommodate at least the full capacity of their respective carboys.</p>
Waste Storage	<p>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 slides run, reagents used, and the number of wash cycles.</p> <p>A secondary containment system for each of the waste carboys is recommended. Selected secondary containment systems must accommodate at least the full capacity of their respective carboys.</p>

## Storage and Handling

### Reagents

Always follow the manufacturer's instructions for storage and handling. To prevent contamination, follow good laboratory practices and techniques when opening, diluting, and decanting all solutions. Store Biocare reagents as specified in the reagent data sheets to maintain reagent stability.

### Waste Disposal

Some of the reagents used on the IntelliPATH PLUS and IntelliPATH MAX may be hazardous and must be disposed of properly in accordance with local regulations. It can be determined from the SDS sheet for a given reagent if a reagent is hazardous. The IntelliPATH PLUS and IntelliPATH MAX 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 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, it must be selected and designated as such 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.

Note: A full 20-liter carboy weighs approximately 45-pounds and a full 10-liter carboy weighs approximately 22.5 pounds and must be handled with caution to prevent user injury and spills.

### Instrument Disposal

If the IntelliPATH PLUS or IntelliPATH MAX 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.

In the European Union, all electronic waste must be disposed of in accordance with Directive 2012/19/EU on waste electrical and electronic equipment. In regions outside the European Union, follow local procedures and regulations for e-waste disposal.

Contact your local technical service if you require assistance.

## 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 PLUS or IntelliPATH MAX. 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 PLUS and IntelliPATH MAX 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.

Requirement	Requirement Description
Laboratory bench counter space requirements	<p>Solid, vibration-free laboratory bench with a flat area, capable of safely supporting the weight of the instrument (145lbs/66kg) and any peripherals or power conditioning equipment which are desired to place at instrument level</p> <p>Minimum recommended counter space:            With computer, keyboard, and mouse on bench: 66" x 27" (W x D)            Instrument only: 44" x 27" (W x D)</p>
Instrument Footprint and Clearance	<p>Lid closed: 40" X 24" X 27" (WxHxD)            Lid open: 40" x 40" x 27" (WxHxD)</p> <p>Note: With the lid open, the 11" of the instrument closest to the back side of the instrument have a vertical clearance of 24" – the remaining 16" have a vertical clearance of 40" at maximum</p> <p>A minimum clearance of 5.0 cm (2") on all sides for ventilation and room for the computer and peripherals next to the instrument</p>
Minimum recommended space for carboys	28" x 42" space, below instrument level
Printer Space Requirements	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	<p>Surge protection is required.</p> <p>The backup power supply (UPS) 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.</p>
Circuit Requirements	<p>The use of a dedicated 15A circuit is recommended for the instrument.</p> <p>Warning: Avoid connecting the instrument on the same circuit as the ARC- Antigen Retrieval Chamber or similar equipment used for antigen retrieval, as they often use up to 10A and performance of both instruments can be affected when run simultaneously.</p>

## Environmental Conditions

Placement	Indoor, away from direct sunlight and extreme hot or cold
Operating temperature range	15-30°C (59-86°F). Recommended temperature for optimal staining is 68-75°F
Storage temperature	10-40°C (50-104°F)
Transportation temperature	0-50°C (32-122°F)
Min. to Max. Temperature range	10-40°C (50-104°F)
Humidity	Avoid humidity extremes. Low humidity can cause electrostatic problems that may affect the computer. High humidity may create condensation.
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 instrument 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.
Recommended maximum altitude	3000M
Pollution degree	2
Main supply voltage fluctuations	±10%
Overvoltage category	Category II

## Support

To contact Biocare Medical Technical Support by telephone, please call 1-800-799-9499, Option 3.

Alternatively, email Technical Support at [techsupport@biocare.net](mailto:techsupport@biocare.net) or submit a message online at [www.biocare.net](http://www.biocare.net)

## Safety Precautions

The IntelliPATH PLUS and IntelliPATH MAX are 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 PLUS or IntelliPATH MAX 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 PLUS or IntelliPATH MAX. 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 PLUS or IntelliPATH MAX dedicated computer system. This may cause unexpected operation of the automated slide stainer or corrupt the operating software and will void the instrument warranty.

Shutdown the software through the log-out button.

Do not turn off the 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 the carboy assemblies below the level of the stainer, preferably at ground level.

Proper cleaning is important for the reliable operation of the instrument. Follow the recommended cleaning procedures in the Instrument Maintenance section.

Do not open the instrument door until the robotic arm has stopped moving. The system door status can be observed from the IntelliPATH PLUS or IntelliPATH MAX software screen.















To bring the robotic arm to the home position select Log Out/ Shut Down to shut down the computer, then re-start computer and log back in.

### 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 PLUS and IntelliPATH MAX provide 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.

## Symbols

The following symbols may appear on the instrument or its documentation:

	Warning. Biohazardous materials may be present. Personal Protection is required
	CE marking
	Manufacturer
	Serial number
	Consult instructions for use (consult operating instruction)
	Electrical Earth Ground
	Main Power (ON/OFF)
	Pinch/Crush Hazard
	Hazardous voltage
	Consult accompanying documents
	Authorized representative in European country
	In vitro diagnostic medical device
	ETL Listed Mark for compliance with US and Canadian standards
	Directive 2012/19/EU: Waste electrical and electronic equipment (WEEE)

# Software Features & Functions

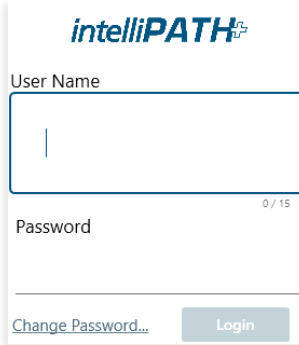
This section is intended to familiarize the user with key software features, providing details of all operations available to Administrative and Regular Users.

## User Access

There are two levels of access for users of the IntelliPATH PLUS 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 available to both user access levels are described in this section.

## Login

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

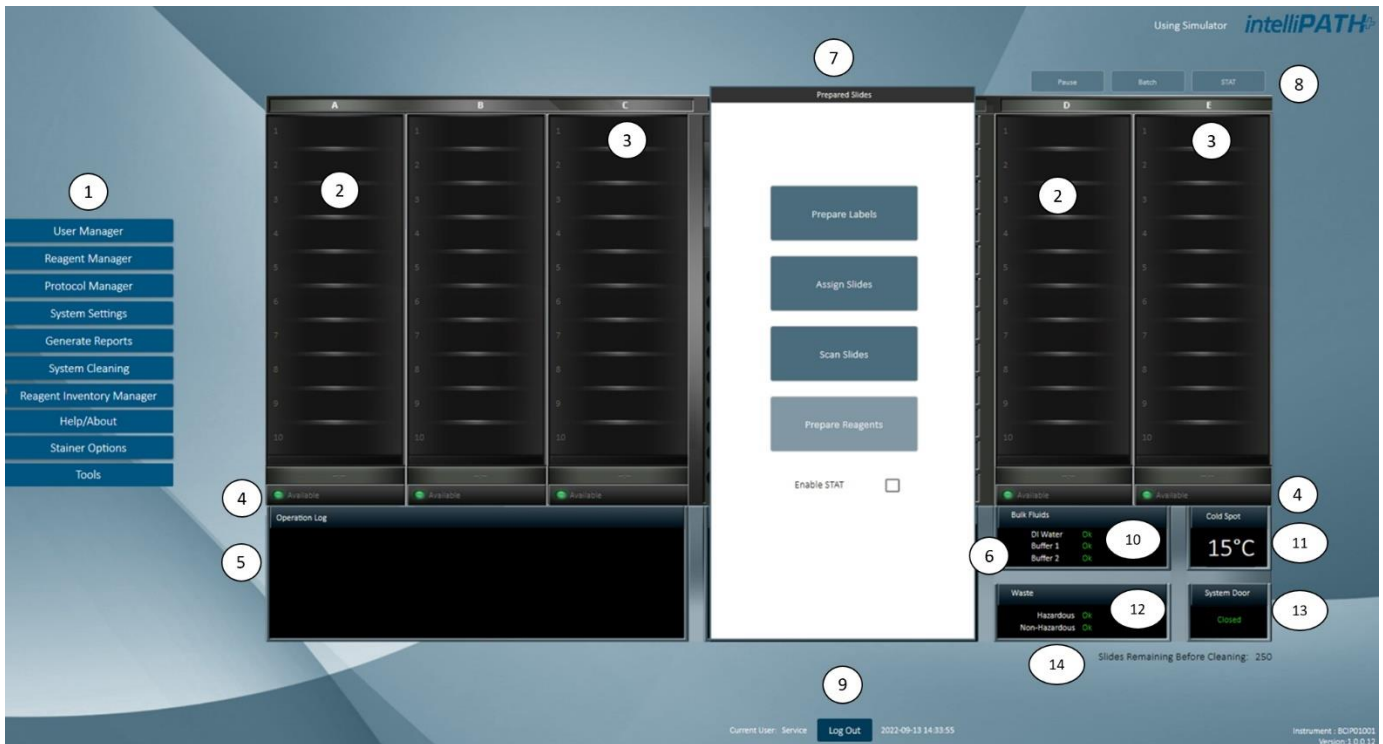


The image shows a login dialog box for IntelliPATH PLUS. At the top, the logo "intelliPATH<sup>+</sup>" is displayed in blue. Below the logo, the text "User Name" is followed by a text input field containing a vertical cursor. To the right of the input field, the text "0 / 15" indicates the character limit. Below the "User Name" field, the text "Password" is followed by a password input field. At the bottom of the dialog, there is a link "Change Password..." and a "Login" button.

## Stainer Application Home Screen

Use the Stainer Application to program, run, and manage slide staining operations. The Stainer Application home screen for both IntelliPATH PLUS and IntelliPATH MAX are below with a diagram and description of each function.

### IntelliPATH PLUS



1. Menu
2. Slide position
3. Slide tray position
4. Slide tray status
5. Operation Log
6. System Status
7. Slide Preparation
8. Run Designation Buttons
9. Log Out
10. Bulk Fluid Status
11. Current Cold Spot Temperature
12. Hazardous & Non-Hazardous Waste Status
13. System Door Status
14. Slide Remaining Before Cleaning Count

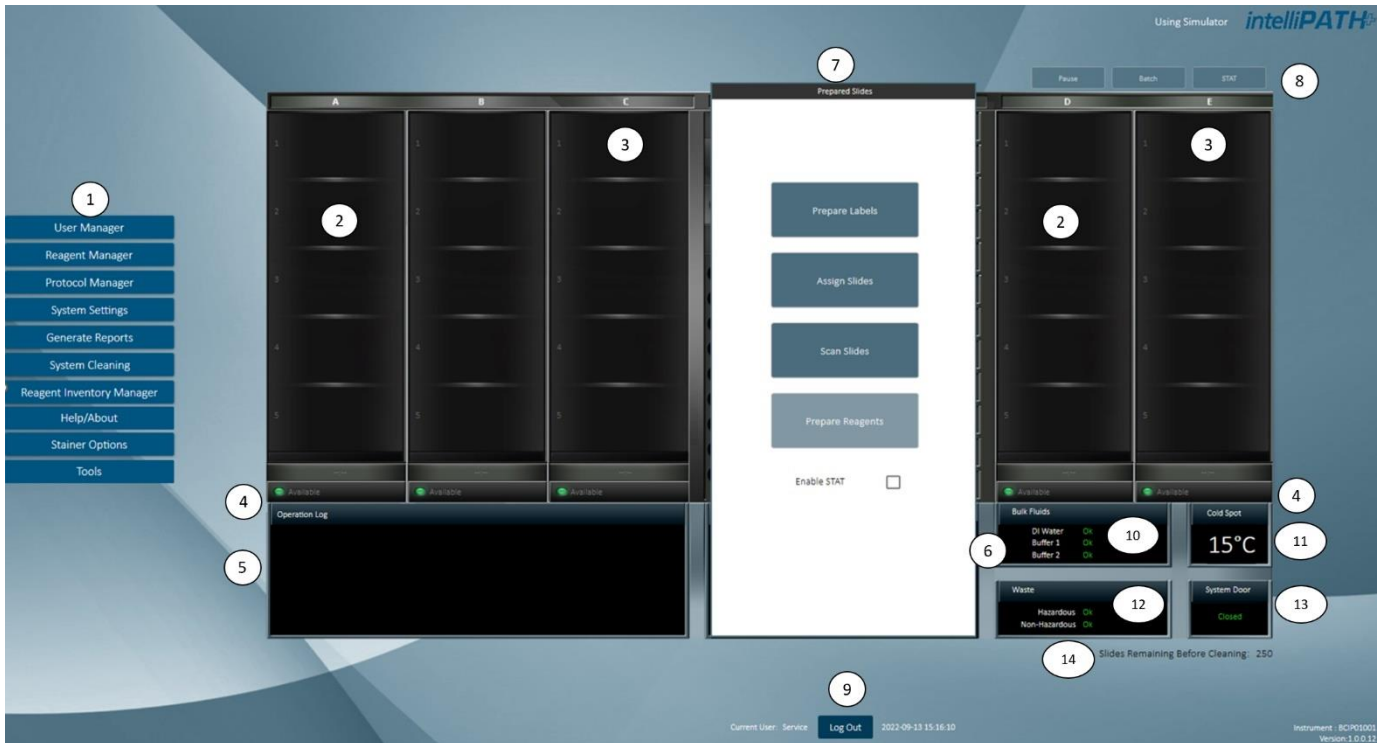


# intelliPATH MAX

The intelliPATH MAX allows for processing of double wide slides.

The instructions in this user manual apply for both intelliPATH PLUS and intelliPATH MAX.

Where applicable, intelliPATH MAX specific instructions will be called out in detail if they deviate from the intelliPATH PLUS instructions.



1. Menu

2. Slide position

3. Slide tray position

4. Slide tray status

5. Operation Log

6. System Status

7. Slide Preparation

8. Run Designation Buttons

9. Log Out

10. Bulk Fluid Status

11. Current Cold Spot Temperature

12. Hazardous & Non-Hazardous Waste Status

13. System Door Status

14. Slide Remaining Before Cleaning Count

## Menu Bar

The menu bar on the left side of the Stainer Application's main screen provides access to a number of other functions:

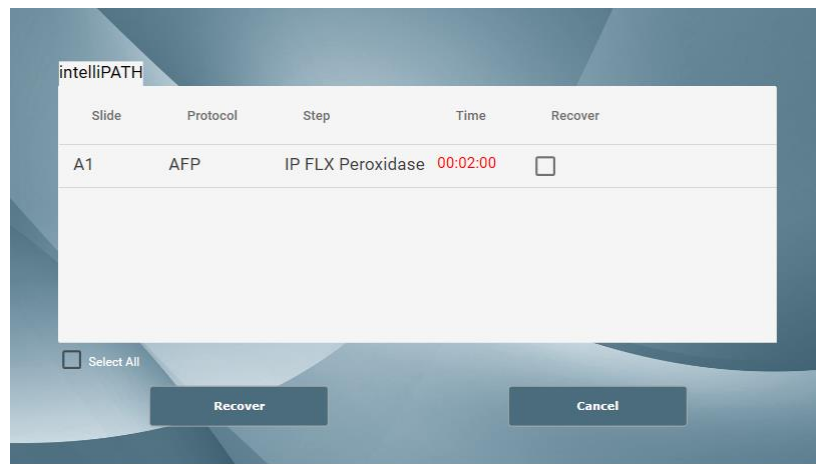
	Description	User	Admin
Stainer Application	Program and run staining protocols. Manage cases, slide staining protocols, and slide stainer operations. Access Reagent Manager, Protocol Manager, Reagent Inventory, and User Manager.	+	+
User Manager	Create new user accounts and modify existing accounts.	-	+
Reagent Manager	Create new/modify existing reagents and reagent groups.	+	+
Protocol Manager	Save, design, and manage protocols.	+	+
System Settings	Set preferences and defaults; save system software operating parameters for labels and onboard mixing, configure language settings and LIS connections.	-	+
Generate Reports	Used to generate and print reports.	+	+
System Cleaning	Enables manual and automatic cleaning of instrument parts.	+	+
Reagent Inventory Manager	Track reagent lot numbers, expiration dates, and reagent volume.	+	+
Help/About	View the IntelliPATH PLUS and IntelliPATH MAX User Manual and device information.	+	+
Stainer Options	Allows the Administrative user to set preference and default parameters.	+	+
Tools	The Tools Button allows user to access Reset Carboys, Drain Waste/ Prime Buffers, Prime Probe, Label Designer, Print Reports (Run Log Report, Slide Layout Report, Reagent Layout Report, Reagent Worksheet), Reagent List (Contamination List, Prep Wash List and DI Wash List), and Design Slide Fields	+	+

## 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, if a power outage/surge that exceeds the power buffering capacity of the UPS, or if a Windows Operating System error occurs.

After an incident, when the user logs back in to the IntelliPATH PLUS or IntelliPATH MAX and executes the Stainer Application, this screen is displayed.

This screen lists all the slides that were used in the previous run with the following information:

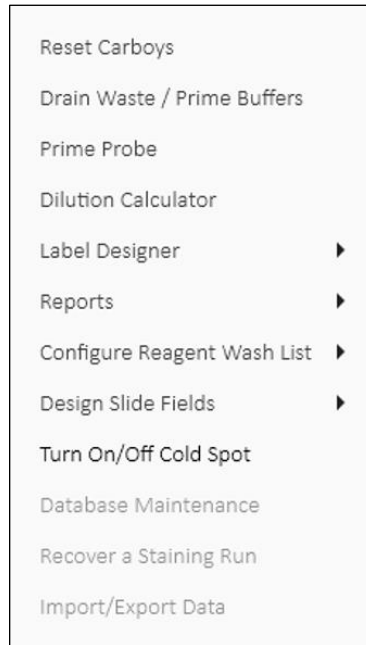


Check all of the slides to be recovered and click on the Recover button. The checked slides are loaded, and staining run begins where the interrupted run left off. However, the user must assess the incubation time that has occurred during the delay as well as the reagent step(s) the slides were paused in during the delay, prior to deciding whether to continue the run or to repeat the run with new slides.

Note: While the software is recovering a run, do not click the back button, this will result in the software requiring the re-verification of reagent volumes prior to resuming the run.

## Tools Menu

The Tools button under the Stainer Application Screen allows user to access Reset Carboys, Drain Waste/ Prime Buffers, Prime Probe, Label Designer, Print Reports (Run Log Report, Slide Layout Report, Reagent Layout Report, Reagent Worksheet), Reagent List (Contamination List, Prep Wash List, and DI Wash List), and Design Slide Fields.



## Reset Carboys

If the instrument's sensors detect that a buffer carboy is empty or a waste carboy is full select Reset Carboys from the Tools drop down menu of the Stainer Application Screen.

A screenshot of a dialog box titled 'Reset Carboys' with a close button 'X' in the top right corner. The dialog is split into two columns. The left column is titled 'Buffer Carboys' and contains three checkboxes: 'DI water', 'Buffer 1', and 'Buffer 2'. The right column is titled 'Reset Waste' and contains two checkboxes: 'Hazardous' and 'Non Hazardous'. Below the columns is a red text instruction: 'Check the Carboys that need to be reset. Replace the Carboys with fresh bulk fluids (or empty the waste carboys) and click on 'Reset' button.' At the bottom of the dialog are two buttons: 'Reset' and 'Done'.

Once the carboy issue has been remedied, check the carboy that needs to be reset and click Reset. This will tell the software that the input carboys are filled, and the waste carboys are emptied.

Click Done when finished.

## Drain Waste & Prime Buffers

This screen can be accessed through the Tools drop down menu of the Stainer Application Screen.

X

**Drain Waste**

Non Hazardous

Hazardous

**Prime Buffer**

DI water

Buffer 1

Buffer 2

Close Start

There are 2 sets of radio buttons: one for Drain Waste and one for Prime Buffers and DI water.

To drain Non-Hazardous waste, select the Non-Hazardous radio button and click the Start button (the Start button will change to Stop). Once draining is complete, click the Stop button.

To drain Hazardous waste, select the Hazardous radio button and click the Start button (the Start button will change to Stop). Once draining is complete, click the Stop button.

To prime DI Water, select the DI Water radio button and click the Start button (the Start button will change to Stop). Once priming is complete, click the Stop button.

To prime Buffer 1, select the Buffer 1 radio button and click the Start button (the Start button will change to Stop). Once priming is complete, click the Stop button.

To prime Buffer 2, select the Buffer 2 radio button and click the Start button (the Start button will change to Stop). Once priming is complete, click the Stop button.

## Prime Probe

This screen can be accessed through the Tools drop down menu of the Stainer Application Screen. Select Start Prime to prime the probe. Click Stop Prime to stop priming.

## Dilution Calculator

The Dilution Calculator is a useful tool which allows the user to calculate how to dilute a stock solution of known concentration. The Dilution Calculator is located under the Tools drop down menu of the Stainer Application Screen.

Dilution Calculator X

**Input Parameters**

Total Final Volume (mL) \_\_\_\_\_

Dilution Ratio \_\_\_\_\_ : \_\_\_\_\_

Volume Conversion  
1000  $\mu\text{L}$  = 1 mL; 0.001 mL = 1  $\mu\text{L}$

Calculate

## Label Designer

The Label Designers allow the user to edit slide and reagent labels. The Label Designers are located under Tools, where the Slide Label Designer or Reagent Label Designer can be opened individually.

## Slide Label Designer

The slide label displays information to be printed and affixed onto the slide. The Slide Label Designer is located under Label Designer in the Tools drop down menu.

#	Field	Type	Font
1	Case #	Text	10
2	Block ID	Text	10
3	Protocol Name	Text	9
4	Pre-Treatment	Text	8
5	Antibody	Text	8
6	Case#+TestID+SlideID	Text	8

Case #  
Block ID  
Protocol Name  
Pre-Treatment  
Antibody  
Case#+TestID+SlideID

Slide Printer

Printer Intensity

**Label Dimension**

Height

Width

**Print Offsets**

Text Offsets

X  Y

2D Matrix Offsets

X  Y

Print 2D Matrix

**Label Type**

Regular

Flap

**Label Orientation**

Horizontal

Vertical

Flip

**Test Print**

**Save**

There are 4 columns in the Label Fields section:

- The first column is the Line number (#), indicating the order in which the information will appear on the label.
- The second column is the field displayed in that line. There are six Label Field lines which are configurable by the user. The available options in each drop-down menu are as follows:
  - Case #
  - Case # + Test ID + Slide ID
  - Case # + Block ID
  - Antibody
  - Institution + Date
  - Protocol Name
  - Block ID
  - Slide ID (Note: Will not fully show in human readable form)
  - Institution
  - Pretreatment
  - Patient Name
  - Pathologist
- The Type of field (i.e., Text) is displayed in the third column.
- The fourth column is the font size. This ranges from 8 (smallest) to 10 (largest). If not, all fields print on a slide label, the font may be too large. Decreasing the font size should resolve this.

- A preview of the label is available in the upper right.
- Several printer settings can be adjusted in the Printer Offsets box.
- Click Test Print to test and confirm that desired settings have been achieved.
- Click Save & Close to save changes.
- Visually inspect the test label print to confirm acceptable alignment of the printed content. Adjust Printer Offsets to move text block.
- Decreasing the X-offset will lower the text block from the top of the label.
- Decreasing the Y-offset will shift the text block away from the 2D matrix.

1. Several settings are visible in the lower right. The table below provides default settings established by Biocare Personnel.

Slide Printer	ZD621 (model of label printer)
Printer Intensity	5 (light) to 30 (dark)
Label Dimensions	Height: 190 to 210 Width: 210
Print Offsets- Text Offsets	X: 500 to 780 Y: 10 to 220
Print Offsets- 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	Horizontal (default) or Vertical

2. Click Test Print to test and confirm desired settings have been achieved.
3. Click Save & Close to save changes.



## Reagent Label Designer

The reagent label displays reagent information and is to be printed and affixed onto reagent vials. The Reagent Label Designer is located under Label Designer in the Tools dropdown menu.

Label Fields	#	Field	Type
	1	Short Name	Text
	2	Catalog #	Text

Slide Printer

Printer Intensity

DPM

Horizontal Offset

Vertical Offset

**Test Print**

**Save**

- The first column is the Line # on the label.
- The second column is the field displayed in that line. There are three Label Field lines which are configurable by the user. The available options in the dropdown menu are Reagent Name, Short Name, Catalog #, Lot #, Expiration Date, and Lot + Expiration Date.
- Upon choosing a Label Field option from the Field drop down menu, the Type (i.e., Text) will be displayed in the third column.
- A preview of the label is available in the upper right of the screen.
- Several Settings are visible in the lower right; these are set up by Biocare Medical Personnel.
- Click Test Print to test and confirm desired settings have been achieved.
- Click Save & Close to save changes.
  1. Several settings are visible in the lower right. The table below provides default settings established by Biocare Personnel.

Reagent Printer	ZD621 (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)

2. Click Test Print to test and confirm desired settings have been achieved.
3. Click Save & Close to save changes.

## Reports

Reports allows the user to print out Slide Layout, Reagent Layout, Run Logs, and Reagent Worksheets. The user can also print to PDF. Several IHC Reports and Protocol Validation can be accessed through the Report Generator.

## Configure Reagent Wash Lists

The Reagent Wash Lists are used to configure the Contamination List, PrepWash List, and DI Wash List. Adding reagents to these lists according to the three conditions explained below will prompt the probe to undergo an IntelliPrep or DI water washing. The washing will ensure the probe is clean to prevent contamination. IntelliPrep is a cleaning reagent that is required when using Alkaline Phosphatase (AP) labeled detection systems and compatible chromogens.

To access Configure Reagent Wash Lists from the Stainer Application Screen, select Tools, then click Configure Reagent Wash Lists and select from Contamination Lists, PrepWash List, or DI Wash List.

## Contamination List and PrepWash List Explanation

The Contamination List and PrepWash List work together to ensure the probe is thoroughly cleaned with IntelliPrep to wash off AP Polymer residue. After it aspirates each reagent that was added to the Contamination List, the probe will immediately wash with IntelliPrep.

To activate the IntelliPrep wash, the three conditions below must be met:

1. The reagent that will cause contamination, any Alkaline Phosphatase (AP) polymer needs to be added to the Contamination List.
2. The mixing component that has the potential for contamination, typically the Alkaline Phosphatase (AP) chromogen buffer used to dilute the Alkaline Phosphatase (AP) chromogen needs to be added to the Prep Wash List.
3. Set the end product chromogen in the Reagent Manager to unstable.

## Contamination List

Use the Contamination List to identify AP Polymer reagents, which leave residue and can cause contamination and can lead to a deterioration in staining quality.

To add reagents to the Contamination List, select the reagent to be added from the Reagent List and click the Right Arrow (→) to add to Contamination List.

To delete a reagent from the list, select the reagent to be deleted and click the Left Arrow (←).

## PrepWash List

Use the PrepWash List to identify reagents that require the probe to be pre-washed with IntelliPrep Solution before it aspirates a reagent on this list. Reagents that have potential for contamination, typically the buffer used to dilute the chromogen, should be added to the PrepWash List.

To add reagents to the PrepWash List, select the reagent to be added from the Reagent List and click the Right Arrow (→) to add to the PrepWash List.

To delete a reagent from the list, select the reagent to be deleted and click the Left Arrow (←).

## DI Wash List

The DI Wash List is intended for reagents that may have staining quality affected when exposed to buffer before aspiration (examples include, but are not limited to, enzyme/enzyme components like Pepsin and Trypsin). When a reagent is added to the DI Wash List, the probe is primed with DI before aspirating the reagent in the DI Wash List.

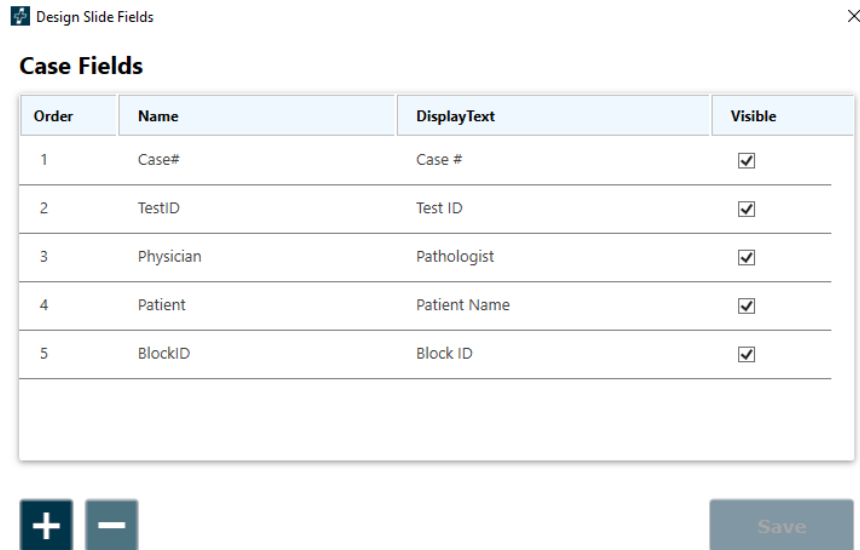
To add reagents to the DI Wash List, go to Tools-> Configure Reagent Wash Lists-> DI Wash List and select the reagent to be added from the Reagent List and click the Right Arrow (→) to add to DI Wash List.

To delete a reagent from the list, select the reagent to be deleted and click the Left Arrow (←).

## Design Slide Fields

Setup Slide Fields allows the user to choose the fields to display in the Slide Details sections of the Slide Manager window and Add Slides window when preparing slides.

- Click the Tools drop down menu on the Stainer Application Screen, choose Design Slide Fields then Setup Slide Fields.



The screenshot shows a window titled "Design Slide Fields" with a close button (X) in the top right corner. Below the title is the heading "Case Fields". A table with four columns: "Order", "Name", "DisplayText", and "Visible" is displayed. The table contains five rows of data. Below the table are two buttons: a plus sign (+) and a minus sign (-), and a "Save" button.

Order	Name	DisplayText	Visible
1	Case#	Case #	<input checked="" type="checkbox"/>
2	TestID	Test ID	<input checked="" type="checkbox"/>
3	Physician	Pathologist	<input checked="" type="checkbox"/>
4	Patient	Patient Name	<input checked="" type="checkbox"/>
5	BlockID	Block ID	<input checked="" type="checkbox"/>

- Use the Add (+) button to add fields.
  - Use the Delete (-) button to delete fields.
  - Each Case Field has the following user-configurable 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.
- Slide Fields are displayed in the Slide Details section of the Add Slides window. Slide Fields are also displayed in the Slide Details section of the Slide Manager window.
- Visible: Item is displayed in the Slide Details list when creating slides.

Note: The Order field represents the order in which custom slide fields were created and has no effect on the stainer application

## Slide Display Fields

Slide Display Fields is located in the Tools drop down menu of the Stainer Application Screen, select Design Slide Fields The Slide Display Field has two configurable fields:

- Top Line
- Bottom

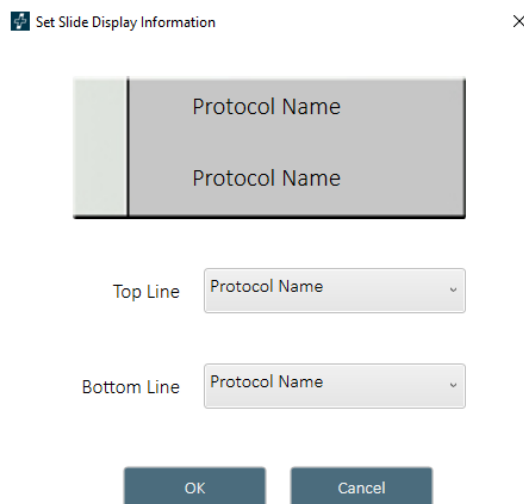
Line

The user can select from five options:

- Case #
- Test ID
- Physician
- Block ID
- Protocol Name

Click OK when done.

These fields refer to the text that is displayed in the 2-3 lines of the Slide Image of a mapped slide on the Stainer Application Screen.



## Turn On/Off 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 System Status Box in the lower right corner of the Stainer Application Screen.

The Cold Spot can be turned on and off from the Tools drop down menu on the Stainer Application Screen.

## Display Error List

If a problem occurs during the run, the software notifies the user to correct the issue.

When an Attention message is displayed on the Stainer Application Screen, perform the action requested or click 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 a scheduled manual reagent application.

## Run Time Estimates

When a staining run is started or when a new Batch/STAT is started, the Run Time is estimated for each slide tray along with time completion of the run. These estimates can be viewed from the Stainer Application Screen. The estimated tray completion time and overall run completion time are periodically re-estimated and updated throughout the run. Estimations become more accurate the closer the run is to completion.

The screenshot displays the Stainer Application Screen interface, which is divided into several sections:

- Slide Trays (A-E):** A grid of 10x5 trays (A-E) showing the status of each slide. Trays A and B are marked as "In Process" with a green background and a red arrow pointing to the estimated completion time of 13:56. Trays C, D, and E are marked as "Available" with a gray background.
- Reagent Dispensing (A-D):** A central panel showing the dispensing sequence for each tray. It lists reagents such as IP Pepsin, IP Hem, ADH-S, Purifier, CA125, Bcl-6, Multiplex2, Mouse IgG, IP410, Univ HRP, IP Peroxid, and IP DAB Buff. The sequence is numbered 1 through 12.
- Operation Log:** A scrollable log at the bottom left showing the sequence of operations, including dispensing and blowing steps for each tray.
- Run Time Summary:** A central panel displaying the Start Time (10:52), Current Time (10:56:43), and Estimated End Time (13:56). A red arrow points to the Estimated End Time.
- System Status:** A panel at the bottom right showing the status of Bulk Fluids (DI Water, Buffer 1, Buffer 2), Waste (Toxic, Non Toxic), Cold Spot (15°C), and System Door (Closed).

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

## System Settings

System Settings can be selected from the Stainer Application Screen. Under User Settings, the user can select password, language, report, printer, and LIS settings.

The screenshot shows a 'System Settings' dialog box with the following sections and controls:

- Application Settings:** A dropdown menu for 'Select Language'.
- User Management Settings:** Two dropdown menus: 'Retention Expiration' set to 'every 60 days' and 'Max Login Attempts' set to '3'.
- Report Settings:** Two dropdown menus: 'Report Printer' set to '\\spec1print01\60 Berry Cust Serv Copier - Sharp' and 'Paper Size' set to 'Letter'.
- LIS Settings:** A dropdown menu for 'Connection Type' set to 'None'. Below it are text input fields for 'Host Name', 'Port', and 'Activation Code'. There are two checkboxes: 'Auto Release Slide' (unchecked) and 'Allow Slide Order Polling' (unchecked). A text input field for 'Slide Order Polling Frequency (minutes)' is set to '5'.

At the bottom of the dialog, there is a 'Connection Status' indicator showing 'Not Connected'. To the right of this indicator are buttons for 'Test Connection' and 'Download Slides'. Below these are 'Apply' and 'Cancel' buttons.

## 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 resume the run, click Resume.

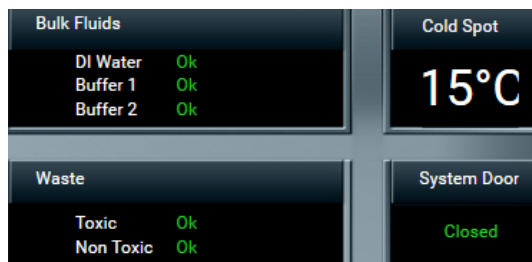
Note: The instrument will initiate a count down with a notification message that slides may over-incubate if the pause is prolonged.

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.

## System Status

The System Status area indicates if there is sufficient DI Water, Buffer 1, and Buffer 2 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.



## 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.

## 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.

## 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.

## 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.

## User Manager

The User Manager is used to create new user accounts and to modify (edit or deactivate) existing user accounts.

The screenshot displays the 'User Management' interface. On the left, a 'Users' table lists user accounts. The table has columns for 'User ID', 'Name', and 'Active'. One user, 'biocare', is listed with an active status. A 'Show Inactive Users' checkbox is present above the table. On the right, the 'User Properties' form is open, showing fields for 'User ID', 'First Name', 'Last Name', 'Title', 'Password', and 'Confirm Password'. The 'Access Level' is set to 'Regular'. A red error message is displayed at the bottom of the form: 'Password must be between 3 and 15 characters. Operator first name must be between 1 and 23 characters. Operator last name must be between 1 and 20 characters. User title must be between 1 and 20 characters. Operator user name must be between 3 and 15 characters. A valid password is required.' At the bottom of the form, there are '+', '-', 'Save', 'Cancel', and 'Edit' buttons.

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. A Regular user may change their password.

### Full Name

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

### Title

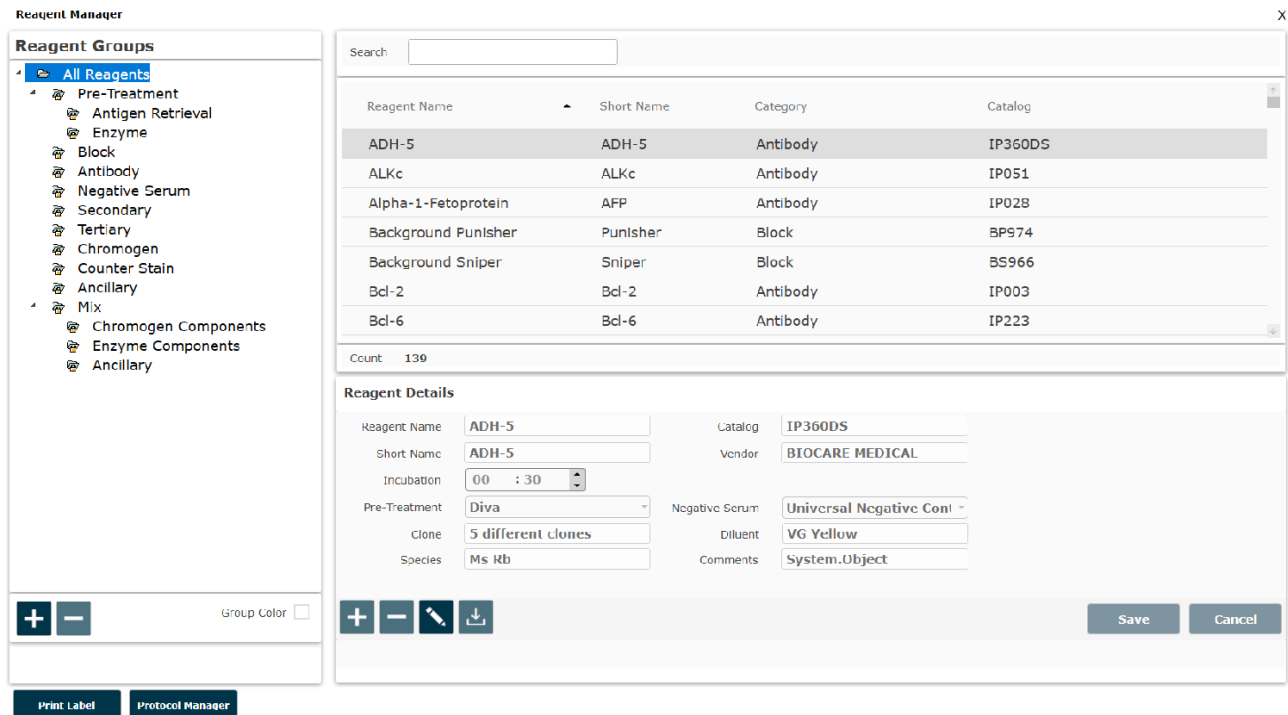
List end-user title. This is a free form text field.

### Access Level

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

# Reagent Manager

The Reagent Manager is used to create new reagents or to modify existing reagents.



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 PLUS and IntelliPATH MAX software: Pre-Treatment, Block, Antibody, Negative Serum, Secondary, Tertiary, Chromogen, Counter Stain, Ancillary, and Mix. Click to highlight the reagent field of choice.

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

The software assigns default colors to the standard Reagent Groups. For custom groups, users can customize group colors to their own preferences.

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

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.

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.

Use the buttons at the bottom of the screen to Add (add sign), Delete (minus sign), Edit (pencil icon) custom reagents. To change the information about a particular reagent, make the changes in the Reagent Details section. Click Save.

Use the Import button (down arrow) to display the non-IP Reagent Master window, which contains a list of all reagents in the Biocare catalog which are not pre-optimized for the IntelliPATH line of instruments. To import the reagents from the non-IP Reagent Master list, check the reagents to be imported and click on Add Selected Reagents button.

## 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 Subgroup (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. Optionally, it is possible to indicate the Clone, Species, Diluent and Comments associated with the antibody of interest for reference purposes.

### 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 selected 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 PLUS and IntelliPATH MAX to perform on-board mixing of these reagents.

Reagent Name	Short Name	Category	Catalog
IP Ferangi Blue Buffer	IP FB Buffer	Chromogen Components	IPBF5026
IP Ferangi Blue Chromogen	IP FB Chrom	Chromogen Components	IPC5025
IP FLX DAB Buffer	IP DAB Buff	Chromogen Components	IPBF5009
IP FLX DAB Chromogen	IP DAB Chrom	Chromogen Components	IPC5008
IP FLX Fast Red Buffer	IP FR Buff	Chromogen Components	IPBF5016
IP FLX Fast Red Chromogen	IP FR Chrom	Chromogen Components	IPC5015
IP Warp Red Buffer	IP WR Buffer	Chromogen Components	IPBF5023

1. To add a mixing component reagent, click the desired subgroup category. (Chromogen Components, Enzyme Components, or 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.

- 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.

**Reagent Manager**

**Reagent Groups**

- All Reagents
  - Pre-Treatment
    - Antigen Retrieval
    - Enzyme
    - Block
    - Antibody
    - Negative Serum
    - Secondary
    - Tertiary
    - Chromogen
    - Counter Stain
    - Ancillary
  - Mix
    - Chromogen Components
    - Enzyme Components
    - Ancillary

Count: 4

Reagent Name	Short Name	Category	Catalog
IP FAST RED	IP FAST RED	Chromogen	IPK5017
IP Ferangi Blue	IP Ferangi	Chromogen	IPK5027
IP FLX DAB	IP FLX DAB	Chromogen	IPK5010
IP Warp Red	IP Warp Red	Chromogen	IPK5024

**Reagent Details**

Reagent Name: IP Ferangi Blue      Catalog: IPK5027

Short Name: IP Ferangi      Vendor: BIOCARE MEDICAL

Incubation: 00 : 05      Type: Mix

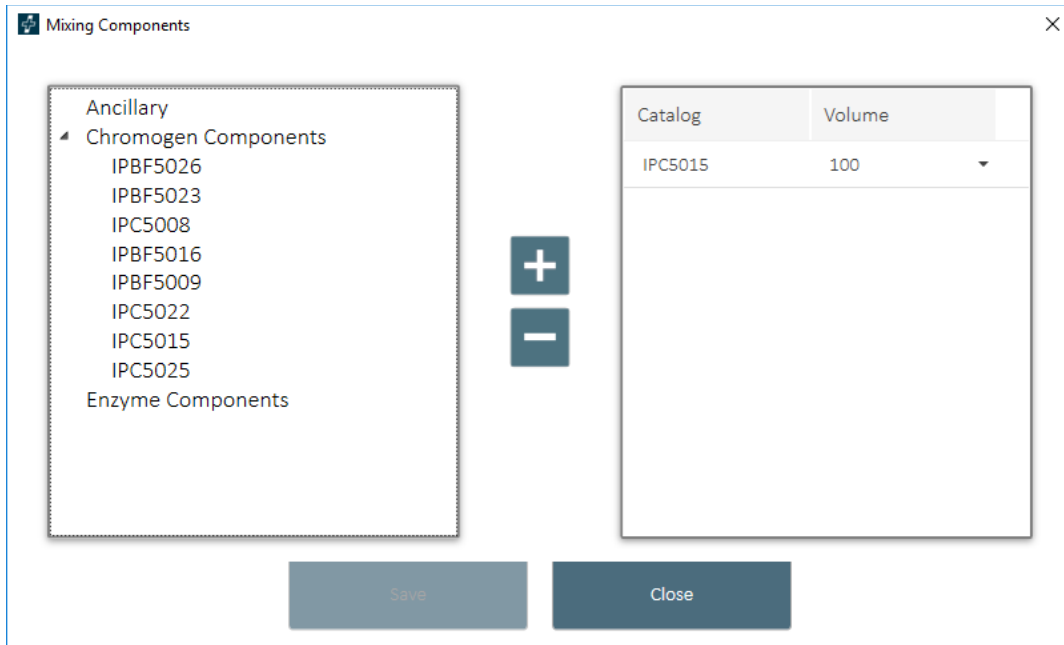
Waste Disposal Properties:  Hazardous  Non-Hazardous

Mixing Properties:  Online  Offline

Stability:  Stable  Unstable

Buttons: +, -, Erase, Download, Save, Cancel

Example: Chromogen. Use the Mixing Components screen to designate the volume (in  $\mu\text{L}$ ) of chromogen buffer and the volume (in  $\mu\text{L}$ ) 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.
2. Click the Add button to add to the list on the right.  
 Note: Mixing components are added to the mixing vial in the sequence they are added to and displayed in the list. For a more accurate mix add the buffer first then the concentrate.
3. Click on the Volume field drop-down menu to select the desired volume (in  $\mu\text{L}$ ) of buffer.
4. Add Chromogen (concentrate) to the mix in the same way. The minimum volume which may be selected is 100  $\mu\text{L}$ .
5. To delete a component from the list on the right of the screen, highlight it in either list, and then click the Subtract button.
6. 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, two conditions must occur:

1. The buffer component of any chromogen mix which can be affected or prematurely activated by AP polymers must be included on the Prep Wash List.
2. All AP polymers must be included on the Contamination List.

By default, the Prep Wash List contains at minimum: IPBF5016, IPBF5023, or IPBF5026.

By default, the Contamination List contains at minimum: IPSC5004, MRCT525, MM624, RALP525, AP605, MRT623, MRCT523, MALP521, RMR625, and RDS513.

Review the Reagent List (Configure Reagent Wash Lists) section for more information regarding list configuration.

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

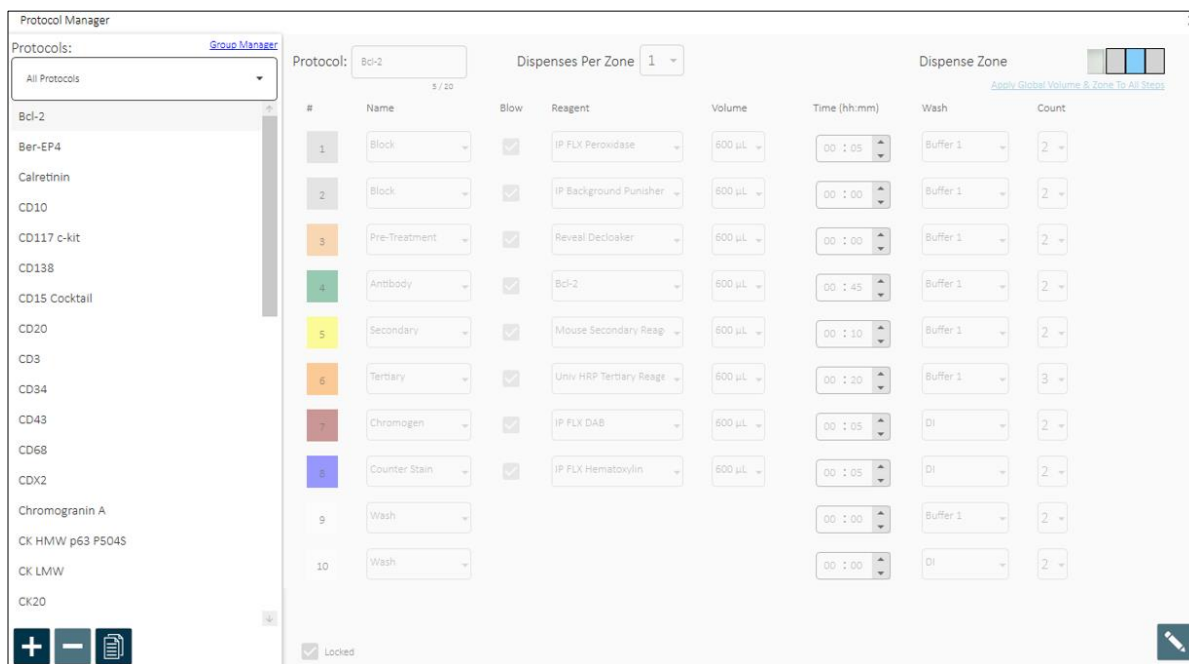
## Assigned Reagent Incubation Requirements

### Important Note:

The intelliPATH PLUS and intelliPATH MAX incubation processing is optimized for reagent incubation times of 5 minutes or longer. Assigning less than 5-minute reagent incubations can over- or under-incubate the assigned reagent leading to less-than-optimal results. Therefore, Biocare recommends all reagent incubation times be a minimum of 5 minutes for optimal results.

## Protocol Manager

Protocol Manager can be accessed from the Stainer Application Screen or from a link in the Reagent Manager. Use Protocol Manager to save, design, and manage protocols.






The list of protocols can be filtered by choosing All Protocols or by choosing a Custom Group in the Protocols: drop down menu.

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

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).

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

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.
- For IntelliPATH MAX only: Dispenses Per Zone (1 or 2)
- 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.
  - Minimum selectable Dispense Volume varies with the number of Dispense Zones selected:

Dispense Zones Selected	IntelliPATH Plus - Min. Disp. Volume (µL)	IntelliPATH MAX - Min. Disp. Volume (µL)
1	100	200
2	150	300
3	200	400

- All steps of the protocol are viewable including all details associated with those steps.

The Edit button (pencil icon) allows a user to change the following items in a protocol:

- Modify existing protocol name.
- For IntelliPATH MAX only: Modify the number of dispenses per zone (1 or 2).
- 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.
- To exit, click the Close button.

## Stainer Options






















Stainer Options allows the Administrator to set preference and default parameters. The system software settings will be accessible from drop down menus.

The screenshot shows the 'Stainer Options' configuration window. It includes the following fields and options:

- Institution Name:** Text input field with a character count of 0 / 30.
- Default Reagent Vendor:** Text input field with a character count of 0 / 30.
- Dispenses Per Zone:** Dropdown menu set to 1.
- Reagent Dispense Zone:** Dropdown menu set to Full Slide.
- Reagent Dispense Volume:** Dropdown menu set to 400 µL.
- Default Dispense Property:** Dropdown menu set to Global.
- Will Apply Buffer To Keep Slides Wet After Slide Is Complete:** Dropdown menu set to Yes.
- Buffer Type Used To Keep Slide Wet After Slide Is Complete:** Dropdown menu set to DI.
- Buffer Interval Used To Keep Slide Wet After Slide Is Complete (Units Are in Minutes):** Dropdown menu set to 30.
- Buffer Interval Used To Keep Slides Wet Before Slide Is Complete (Units Are in Minutes):** Text input field set to 25.
- Default Delay Used for Delayed Runs (Units Are in Hours):** Dropdown menu set to 2.

A 'Close' button is located at the bottom center of the window.

When an option is selected, a description of this option will appear on the bottom of the screen. The table below describes selections available under Stainer Options.

Stainer Options	Description																		
Institution Name	Institution Name can be displayed on the Slide Label. See Slide Label Designer section for details.																		
Default Reagent Vendor	Default Reagent Vendor will be prepopulated when new reagents are created in the Reagent Manager. See Reagent Manager section for details.																		
Dispenses Per Zone	Only available for IntelliPATH MAX: Defines the number of dispenses per Zone, either one (1) in the center or two (2) left and right of the center line.																		
Reagent Dispense Zone	<p>Set the default dispense zone for the slides. Dispense zone options are:</p> <table border="1"> <tbody> <tr> <td>Bottom</td> <td></td> <td>Middle</td> <td></td> <td>Top</td> <td></td> </tr> <tr> <td>Bottom Middle</td> <td></td> <td>Full Slide</td> <td></td> <td>Top Middle</td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td>Top Bottom</td> <td></td> </tr> </tbody> </table> <p>The selected zone is used as the default dispense zone when editing protocols and can be applied as the dispense zone for protocols added via the Assign Slides menu.</p>	Bottom		Middle		Top		Bottom Middle		Full Slide		Top Middle						Top Bottom	
Bottom		Middle		Top															
Bottom Middle		Full Slide		Top Middle															
				Top Bottom															
Reagent Dispense Volume	Global default reagent dispense volume value. The selected value is used as the default dispense volume when editing protocols and the dispense volume for protocols added via the Assign Slides menu when Default Volume Property is set to Global.																		
Default Dispense Property	<p>This setting determines the dispense volume used for protocols added to the trays via the Assign Slides menu.</p> <p>The Global setting causes the dispense volume in protocols mapped through Assign Slides to be changed to the global Reagent Dispense Volume.</p> <p>The Protocol setting causes the dispense volume for protocols mapped through Assign Slides to match the values set in the protocol.</p> <p>Note: this value can also be set by checking Apply Global Volume and Zone to Assigned Slides in Assign Slides.</p>																		
Will Apply Buffer To Keep Slides Wet After Slide is Complete	This setting determines whether automatic slide buffering takes place after run completion. Yes enables post-completion buffering, No disables automatic post-completion buffering.																		
Buffer Type Used To Keep Slide Wet After Slide is Complete	Sets the buffer (DI water, Buffer 1, or Buffer 2) which is used during post-completion buffering. Note: Post-completion buffering only takes place when Buffer Slides after Completion is set to Yes.																		
Buffer Interval Used To Keep Slide Wet After Slide is Complete (Units Are in Minutes)	Sets the interval at which buffering after a run is complete occurs. Note: Post-completion buffering only takes place when Buffer Slides after Completion is set to Yes.																		
Buffer Interval Used To Keep Slides Wet Before Slide Is Complete (Units Are in Minutes)	Sets the interval at which buffering occurs before the slide is complete. Note: The buffer type is determined by the protocol.																		
Delay Run	Sets the default run delay period. The option to delay the start of a run is available on the Pre-Start Checklist.																		

# Generate Reports

Generate Reports is accessible through the Stainer Application Screen.

To print a report, highlight it in the list on the left side of the Generate Reports screen. Any additional report parameters which must be set are displayed in the bottom section of the Generate Reports screen as drop-down menus. Click Generate Report to generate and view the report.

**Generate Reports** X

**Select a Report**

Reagent List	Slide Volume (for a Date Range)
Protocol List	IHC Report (by Batch)
Protocol Validation	IHC Report (by Run)
Reagent Usage (by Catalog)	IHC Summary
Reagent Usage (by Run)	Slide Report
Reagent Usage	Slide Layout Report
User Login Information	Reagent Layout Report
Slide Volume (by Protocol)	Troubleshooting

Displays a list of all the reagents grouped by Vendor with a Vendor specific reagent count

**Generate Report**

Report Types	Description
Reagents List	Generates a list of all reagents grouped by vendor.
Protocol List	Generates a list of all protocols.
Protocol Validation	Provides a report for a protocol indicating all the steps performed, a comment section, and sign off section for the pathologist.
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.
Reagent Usage	Provides the total volume of all the reagents used for the various runs.
User Login Information	States the user activities, including user ID and Login Date/Time.
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.
IHC Report (by Batch)	Provides a summary of all the slides in a batch with the protocol and details for each slide.
IHC Report (by Run)	Provides a summary of all the slides in a run with the protocol and details for each slide.
IHC Summary	Provides a summary of all the slides in a run with the protocol for each slide.
Slide Report	Provides details of the slides that were stained.
Slide Layout Report	Graphical descriptions of slides in their slide carrier positions.
Reagent Layout Report	Graphical descriptions of vials in the reagent, cold spot, and mixing racks.
Troubleshooting	Creates an exportable log pack for technical service

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 Stainer Application Screen.

**Note:** For reports where date range input is required, ensure that a valid date range is selected. Invalid date ranges (i.e., start date is after end date) result in the software generating blank reports.

## System Cleaning

System Cleaning provides instructions for performing the instrument cleaning protocol. It is recommended that the instrument be cleaned after every 250 stained slides or once a week. During the cleaning protocol, do not allow the Buffer and Water intake filters to touch unclean surfaces. System Cleaning is available from the Stainer Application Screen.

1. Perform each of the Pre-Requisites for Cleaning listed on the screen below, in the specified order, and check the boxes as tasks are completed.
  - Mix 5 mL hydrochloric acid (0.25%-0.5%) with 95 mL of ethanol. Pour the mixture into the waste sink. Wait for 30 minutes.
  - Fill a minimum of 4 liters of deionized (DI) water into the DI Water carboy.
  - Fill a minimum of 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.

Please Note: To ensure efficient cleaning of the system, A1 and A2 vials should contain sufficient volume of 5mL for A1 and 5mL for A2.

### System Cleaning

X

Mix 5 mL of 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 of 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).

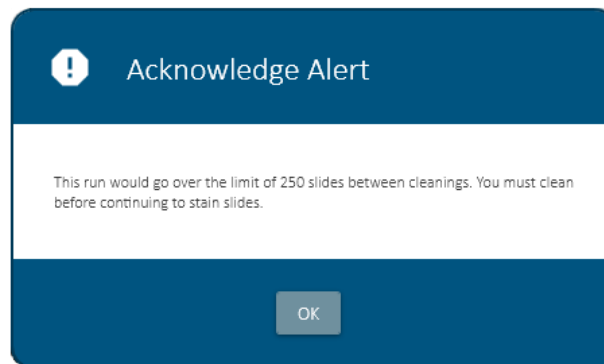
1. Click Verify Carboys & Reagents.
2. Close the instrument lid.
3. Click Start Cleaning.
4. Click Cancel Cleaning if needed.
5. To exit the System Cleaning, click X to close the window .
6. The Cleaning Log is accessible by clicking the View Cleaning Log link in the System Cleaning screen.

intelliPATH (BCIP01001)			
Cleaning Log for intelliPATH (BCIP01001)			
Clean Date	Slides	Status	User
06/23/2022	0	Cleaning Complete	biocare

[Print Log](#)

**Exit**

- The following information is displayed:
    - Clean Date - Date of the cleaning
    - Slides - Number of slides run before cleaning.
    - Status - Completed or Canceled
    - User - Logged in User
  - To print the cleaning log, click the Print Log link.
1. If Slides remaining before Cleaning has reached zero or less than zero, the following window will appear upon attempting to scan reagents:



- Select System Cleaning from the Stainer Application Screen at this time.

## Reagent Inventory Manager

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.

Catalog	Lot	Expiration	Starting Volume	Current Volume	Serial Number
IP028			8720	8720	
BP974			8720	8720	
IPK5010	202200		1990	4310	
IPK5010	202200	2022/09	1990	4310	
IPBF5009			8720	8720	
IPC5008			8720	8600	
IPC5008			8720	8720	
IPC5006			8720	8720	
IPB5000			8720	8420	
IPB5000			8720	8720	
IPBF5023			8720	8720	
IPSC5004			8720	8720	
IPT5002			8720	8720	
IP498			8720	8720	
IPT5002			8720	8720	
IPC5022			1930	1930	

Count : 28

Clean Inventory

+ Print

Reagent Inventory Manager is accessible from the Stainer Application Screen. The list of reagents can be sorted by any field by clicking on Reagent Steps.

Clicking Clean Inventory will remove any reagents that have no more usable volume and those which have expired.

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

Add a New Reagent

Catalog  →

Lot

Expiration

Starting Volume

Serial Number

Save Close

- Enter the information in the input fields. All inventoried (registered) reagents require a 4-digit serial number. Use the Browse feature (blue arrow) located on the top right of the Add a New Reagent window to find an existing Catalog Number. The Reagent Lookup window will be displayed.

**Add a New Reagent**

Catalog

Lot

Expiration

Starting Volume

Serial Number

**Save** **Close**

→

Catalog	Reagent Name
7898	test bb
abc	Test
AG100001	IP Peroxidase
AG100002	Bcl2
BP974	Background Punisher
BS966	Background Sniper
IP001	Smooth Muscle Actin - SMA
IP003	Bcl-2
IP004	CD20-L26
IP005	CD43
IP006	CD45RO - UCHI1

- 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 PLUS/IntelliPATH MAX software as the reagent is used up during staining runs.

Use the Print icon 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 section 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 on the instrument login screen.

1. From the Stainer Application Screen select User Manager.

Assign a user account

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

The screenshot displays the 'User Management' interface. On the left, a table titled 'Users' lists existing users. The table has columns for 'User ID', 'Name', and 'Active'. One user, 'biocare', is listed with a checked 'Active' checkbox. Above the table is a checkbox labeled 'Show Inactive Users'. Below the table are '+' and '-' buttons. On the right, the 'User Properties' form is shown, which includes fields for 'User ID' (with a character count of 8/15), 'Access Level' (a dropdown menu), 'First Name' (8/20), 'Last Name' (8/20), and 'Title' (8/40). There is also an 'Active' checkbox at the bottom of the form. A pencil icon for editing is located at the bottom right of the form area.

User ID	Name	Active
biocare		<input checked="" type="checkbox"/>

Show Inactive Users

**User Properties**

User ID: \_\_\_\_\_ 8 / 15      Access Level: \_\_\_\_\_

First Name: \_\_\_\_\_ 8 / 20

Last Name: \_\_\_\_\_ 8 / 20

Title: \_\_\_\_\_ 8 / 40

Active

**+** **-**

1. Enter the appropriate user information and press Save.

## Modify a user account

1. To modify an account or password, select the appropriate account and press Delete or Edit button at the bottom left side of the screen.
2. The system will not allow the deletion of the most current Administrator account.

## Change password

1. To change a user password, select Change Password located on the bottom left of the Log-in screen.



2. Enter username, current password, and new password when prompted.

## Assign or Modify Reagents

### Example Setup

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

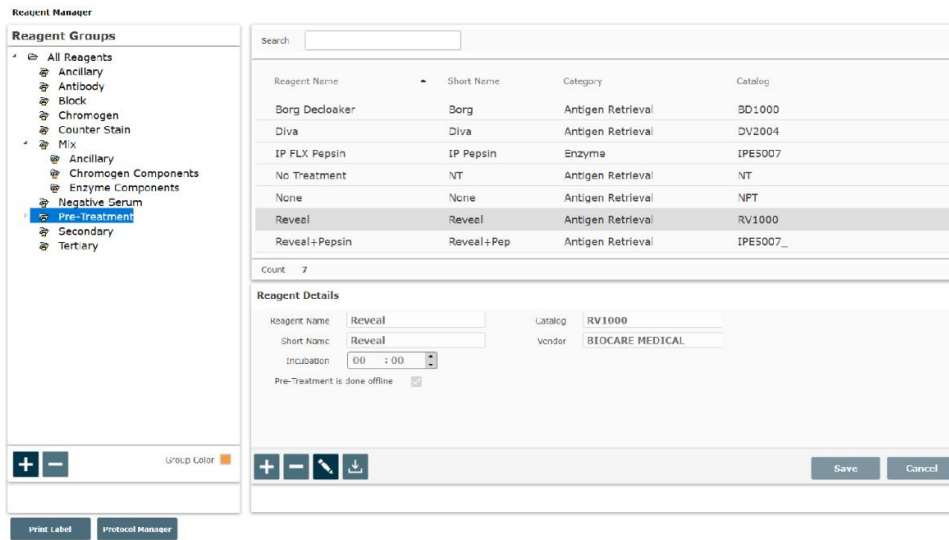
- **Pre-Treatment:** Reveal Decloaker
- **Block:** Peroxidized 1 (Cat. No. PX968) for 5 min
- **Antibody:** Ki-67 (M) (Cat. No. IP375) for 30 min
- **Detection:** MACH 3 Mouse AP Polymer Detection (Cat. No. M3M532)
  - Secondary: MACH 3 Mouse Probe (MP530) for 10 min
  - Tertiary: MACH 3 Mouse AP-Polymer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

1. From the Stainer Application Screen select Reagent Manager.
2. Go through each Reagent Group and confirm that the desired reagent exists or set up the appropriate reagents and conditions.

Note: Reagent Groups provided with the instrument have pre-defined Group Colors which align with coloring of Biocare reagents. Custom reagent groups can be assigned any color during or after creation (highlight the group and select the group color) by utilizing the color picker.

### 2a. Pre-Treatment Group

- Select Pre-Treatment from Reagent Group at the left side of the screen.

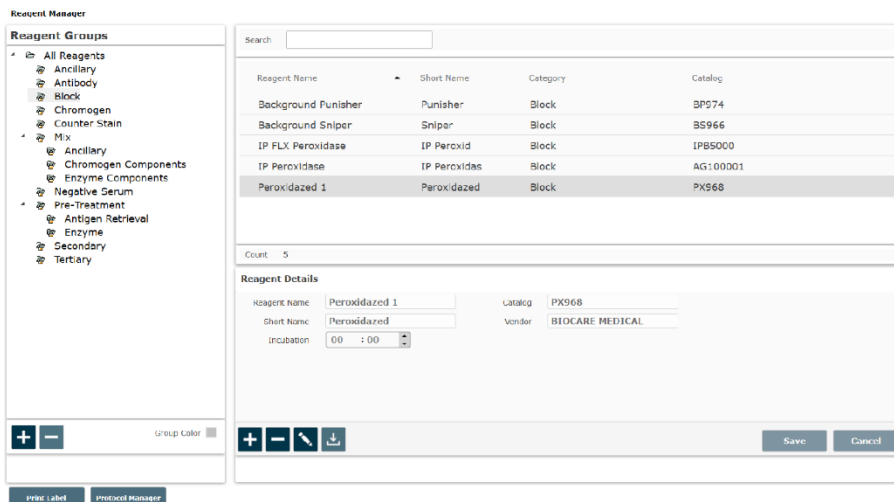


- Note: To add a new pretreatment reagent which is not in the list, select the desired subgroup (Antigen Retrieval or Enzyme) under Pre-Treatment in the Reagent Group list. Then click the Add new Reagent (+) button in the lower center of the window. Enter the appropriate Name, Catalog Number, Short Name 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 Subgroup, 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  $\mu\text{L}$ ) 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 Peroxidized 1 does not exist.
- To add Peroxidized 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. Antibody Titers

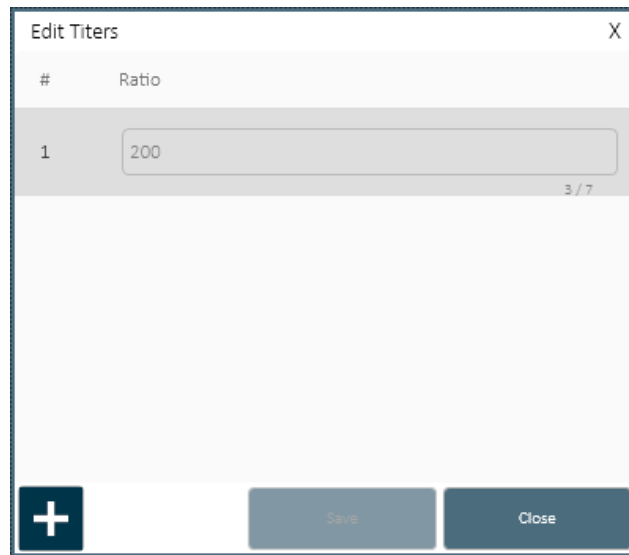
Use the Create Titers/View Titers screen to view or change the titer ratios for a particular reagent.

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

The screenshot displays the Reagent Manager interface. On the left, a tree view shows the 'Antibody' group selected. The main area shows a table of reagents with columns for Reagent Name, Short Name, Category, and Catalog. Below the table, there is a 'Reagent Details' form with fields for Reagent Name, Short Name, Incubation, Pre-Treatment, Clone, Species, Catalog, Vendor, Negative Serum, Diluent, and Comments. The 'Save' and 'Cancel' buttons are visible at the bottom right of the form.

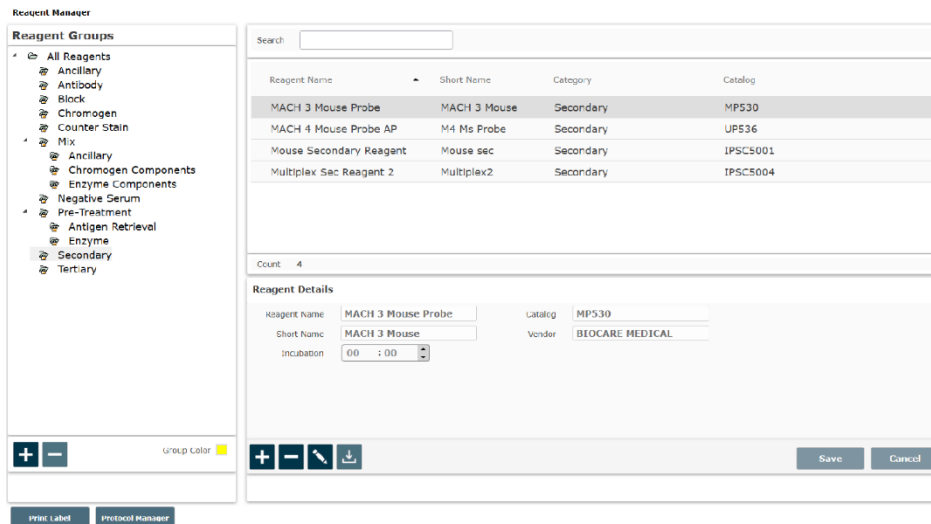
Reagent Name	Short Name	Category	Catalog
ADH-5	ADH-5	Antibody	IP360DS
ALKc	ALKc	Antibody	IP051
Alpha-1-Fetoprotein	AFP	Antibody	IP028
Bcl-2	Bcl-2	Antibody	IP003
Bcl-6	Bcl-6	Antibody	IP223
Bcl-6 LN22	Bcl-6	Antibody	IP410
BerEP4	BerEP4	Antibody	IP107
CA125	CA125	Antibody	IP101
Calcitonin	Calcitonin	Antibody	IP072

- 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).
- Click Save.
- 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.
- To delete a titration, click on gray area on the left side of the unwanted row, then click Delete.
- Click Save to save changes or Close to exit.



## 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.

The screenshot shows the 'Reagent Manager' application window. On the left, the 'Reagent Groups' sidebar is expanded to show the 'Tertiary' group. The main area displays a table of reagents with the following data:

Reagent Name	Short Name	Category	Catalog
MACH 3 Mouse AP-Polymer	MACH 3 Mouse	Tertiary	MAP532
MACH 4 AP-Polymer	M4 AP	Tertiary	MRAP536
Univ HRP Tertiary Reagent	Univ HRP	Tertiary	IPT5002

Below the table, the 'Reagent Details' form is visible, with the following fields filled:

- Reagent Name: MACH 3 Mouse AP-Polymer
- Short Name: MACH 3 Mouse
- Catalog: MAP532
- Vendor: BIOCARE MEDICAL
- Incubation: 00 : 00

At the bottom of the form, there are buttons for '+', '-', a pencil icon, a download icon, 'Save', and 'Cancel'. At the very bottom of the window, there are buttons for 'Print Label' and 'Protocol Manager'.

## 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 (+) button.
  - Enter the appropriate Name, Catalog Number, Short Name, Vendor, and Incubation information in the Reagent Details section.
  - Choose Regular (if mixed offline) or Mix (if mixed online) from the drop-down menu.
  - 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).
  - Click the Mixing Components link, choose a component from the left window, click the Add (+) 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.
  - Click Save to close the Mixing Components window. Click Save.
- For more information, refer to the Reagent Manager section.

Reagent Manager X

**Reagent Groups**

- [-] All Reagents
- [-] Ancillary
- [-] Antibody
- [-] Block
- [-] Chromogen
- [-] Counter Stain
- [-] Mix
  - [-] Ancillary
  - [-] Chromogen Components
  - [-] Enzyme Components
- [-] Negative Serum
- [-] Pre-Treatment
- [-] Antigen Retrieval
  - [-] Enzyme
  - [-] Secondary
  - [-] Tertiary

Group Color ■

+ -

Search:

Reagent Name	Short Name	Category	Catalog
IP FAST RED	IP FAST RED	Chromogen	IPK5017
IP Ferangi Blue	IP Ferangi	Chromogen	IPK5027
IP FLX DAB	IP FLX DAB	Chromogen	IPK5010
IP Warp Red	IP Warp Red	Chromogen	IPK5024

Count: 4

**Reagent Details**

Reagent Name:

Short Name:

Incubation:

Waste Disposal Properties:  Hazardous  Non Hazardous

Mixing Properties:  Online  Offline

Stability:  Stable  Unstable

Mixing Components

Catalog:

Vendor:

Type:

+ - [edit] [download] Save Cancel

Print Label

Protocol Manager

## 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.

The screenshot shows the 'Reagent Manager' application window. On the left, a sidebar titled 'Reagent Groups' lists various categories, with 'Counter Stain' highlighted in blue. The main area features a search bar and a table of reagents. The table has columns for 'Reagent Name', 'Short Name', 'Category', and 'Catalog'. One entry is visible: 'IP FLX Hematoxylin' with a short name of 'IP Hem', category of 'Counter Stain', and catalog number 'IPCS5006'. Below the table, the 'Reagent Details' section contains input fields for 'Reagent Name' (IP FLX Hematoxylin), 'Short Name' (IP Hem), 'Catalog' (IPCS5006), 'Vendor' (BIOCARE MEDICAL), and 'Incubation' (00 : 05). There are also radio buttons for 'Waste Disposal Properties' with 'Non Hazardous' selected. At the bottom, there are '+', '-', and 'x' icons, a 'Group Color' selector, and 'Save' and 'Cancel' buttons. A 'Print Label' and 'Protocol Manager' button are located at the very bottom left.

## 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 located to the bottom left to continue.



## Assign or Modify Protocols

### Example Setup

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

- **Pre-Treatment:** Reveal
- **Block:** Peroxidized 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

### Create a New Protocol

From the Stainer Application Screen, select Protocol Manager. Alternatively, select Protocol Manager from the bottom right side of the Reagent Manager screen.

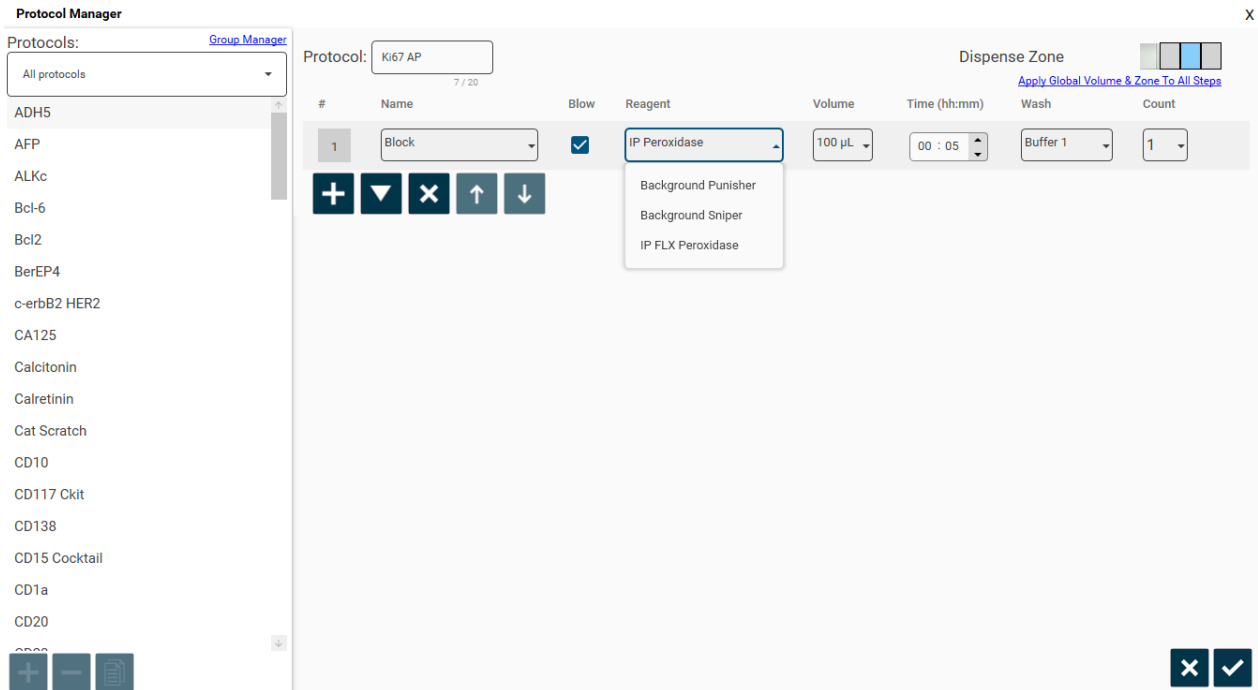
#### a. Create a new protocol not based on an existing protocol

The screenshot shows the Protocol Manager interface. On the left, there is a list of protocols including Bcl-2, Ber-EP4, Calretinin, CD10, CD117 c-kit, CD138, CD15 Cocktail, CD20, CD3, CD34, CD43, CD68, CDX2, Chromogranin A, CK HMW p63 P504S, CK LMW, and CK20. The main area displays the details for the 'Bcl-2' protocol, which is currently set to 1 dispense per zone. The protocol steps are as follows:

#	Name	Blow	Reagent	Volume	Time (h:mm)	Wash	Count
1	Block	<input checked="" type="checkbox"/>	IP FLX Peroxidase	600 µL	00 : 05	Buffer 1	2
2	Block	<input checked="" type="checkbox"/>	IP Background Punisher	600 µL	00 : 00	Buffer 1	2
3	Pre-Treatment	<input checked="" type="checkbox"/>	Reveal Decloaker	600 µL	00 : 00	Buffer 1	2
4	Antibody	<input checked="" type="checkbox"/>	Bcl-2	600 µL	00 : 45	Buffer 1	2
5	Secondary	<input checked="" type="checkbox"/>	Mouse Secondary Reag	600 µL	00 : 10	Buffer 1	2
6	Tertiary	<input checked="" type="checkbox"/>	Univ HRP Tertiary Reage	600 µL	00 : 20	Buffer 1	3
7	Chromogen	<input checked="" type="checkbox"/>	IP FLX DAB	600 µL	00 : 05	DI	2
8	Counter Stain	<input checked="" type="checkbox"/>	IP FLX Hematoxylin	600 µL	00 : 05	DI	2
9	Wash				00 : 00	Buffer 1	2
10	Wash				00 : 00	DI	2

- Click Add (+) Sign to create a new protocol.
- Enter the new protocol name, Ki67 AP, in the Protocol field.
- For intelliPATH MAX only: Select the number of Dispenses Per Zone (1 or 2)

- Select desired Dispense Zone. (Note that this will only be activated if Stainer Options section is set to Protocol for Default Dispense Property.)
- Click Add (+) Sign to add a step. In the Name column, choose Block from the drop-down menu of Reagent Group names.
- 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 Peroxidized 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.
  - 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.
  - The type of Wash may also be changed to DI Water or Buffer 2 or may remain Buffer 1.
  - 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 Add (+) Sign to add a new step and repeat the above process until all steps have been programmed.
  - The downward triangle allows the user to insert a step above the currently selected step.
  - The X allows the user to delete a step.
  - The Up Arrow (↑) will move the currently selected step up in the protocol.
  - The Down Arrow (↓) will move the currently selected step down in the protocol.
- Click Check Mark located on the bottom right to save the protocol.
- Click the X button located on the bottom right to close the window.

b. Edit a Protocol

- Choose an existing protocol on the left side of the Protocol Manager window from which to base the new protocol from.
- Select the protocol to be used as the template located to the left of the Protocol Manager and click edit (pencil icon) located on the bottom right.

Note: It is not possible to edit Biocare Clinical Protocols (protocols provided with the instrument from Biocare) – these protocols can be used directly or as templates for user optimization or copied, renamed, and edited for modification.

**Protocol Manager** X

Protocols: [Group Manager](#)

All protocols

ADH5

AFP

AFP Copy (1)

ALKc

Bcl-6

Bcl2

BerEP4

c-erbB2 HER2

CA125

Calcitonin

Calretinin

Cat Scratch

CD10

CD117 Ckit

CD138

CD15 Cocktail

CD1a

+

-

📄

Protocol: ALKc 4 / 20

Dispense Zone Apply Global Volume & Zone To All Steps

#	Name	Blow	Reagent	Volume	Time (h:mm)	Wash	Count
1	Block	<input checked="" type="checkbox"/>	IP FLX Peroxidase	300 µL	00 : 05	Buffer 1	1
2	Block	<input checked="" type="checkbox"/>	Background Punisher	300 µL	00 : 10	Buffer 1	1
3	Pre-Treatment	<input checked="" type="checkbox"/>	Reveal	300 µL	00 : 00	Buffer 1	1
4	Antibody	<input checked="" type="checkbox"/>	ALKc	300 µL	00 : 30	Buffer 1	1
5	Secondary	<input checked="" type="checkbox"/>	Mouse Secondary Reage	300 µL	00 : 10	Buffer 1	1
6	Tertiary	<input checked="" type="checkbox"/>	Univ HRP Tertiary Reager	300 µL	00 : 10	Buffer 1	2
7	Chromogen	<input checked="" type="checkbox"/>	IP FLX DAB	300 µL	00 : 05	Dt	1
8	Counter Stain	<input checked="" type="checkbox"/>	IP FLX Hematoxylin	300 µL	00 : 05	Dt	1
9	Wash				00 : 00	Buffer 1	1
10	Wash				00 : 00	Dt	1

🖋️

- Edit the Protocol Name located on the top and edit to existing selections as needed.

**Protocol Manager** X

Protocols: [Group Manager](#) Protocol:  4 / 20

Dispense Zone

[Apply Global Volume & Zone To All Steps](#)

#	Name	Blow	Reagent	Volume	Time (hh:mm)	Wash	Count
1	Block	<input checked="" type="checkbox"/>	IP FLX Peroxidase	300 µL	00 : 05	Buffer 1	1
2	Block	<input checked="" type="checkbox"/>	Background Punisher	300 µL	00 : 10	Buffer 1	1
3	Pre-Treatment	<input checked="" type="checkbox"/>	Diva	300 µL	00 : 00	Buffer 1	1
4	Antibody	<input checked="" type="checkbox"/>	ADH-5	300 µL	00 : 30	Buffer 1	1
5	Secondary	<input checked="" type="checkbox"/>	Multiplex Sec Reagent 2	300 µL	00 : 30	Buffer 1	2
6	Chromogen	<input checked="" type="checkbox"/>	IP FLX DAB	300 µL	00 : 05	DI	1
7	Chromogen	<input checked="" type="checkbox"/>	IP Warp Red	300 µL	00 : 07	DI	1
8	Counter Stain	<input checked="" type="checkbox"/>	IP FLX Hematoxylin	300 µL	00 : 05	DI	1
9	Wash				00 : 00	Buffer 1	1
10	Wash				00 : 00	DI	1

- Utilize any of the available options:
  - The Add (+) Sign allows the user to add a new step.
  - The X allows the user to delete a step.
  - The downward triangle allows the user to insert a step above the currently selected step.
  - The Up Arrow (↑) will move the currently selected step up in the protocol.
  - The Down Arrow (↓) will move the currently selected step down in the protocol.
  - Click Check Mark to save the protocol.
- Click the X button located on the bottom right to close the window

\*Note: The original protocol will be lost and overwritten with the newly created protocol. To keep original/existing protocol while still creating an additional new protocol, follow the Copy a Protocol section below then save the edited copy under the new desired protocol's name.

### c. Copy a Protocol

- To Copy a protocol, select the protocol to be copied, then click the copy icon (📄) located on the bottom left of the Protocol Manager
- A copy of the original protocol is created by the software and automatically assigned a sequentially numbered name based on the copied protocol. For example, copying the "CD20" protocol yields a copy of the CD20 protocol named "CD20-1". If a "CD20-1" protocol already exists, a "CD20-2" protocol is created. The software will follow this pattern and append the lowest possible unused sequential number to the original protocol name.
- Edit the copied protocol as needed. The protocol name and its steps can be adjusted.
- Click Check Mark to save the protocol.
- Click the X button located on the bottom right to close the window

\*Note: Biocare Clinical Protocols (the protocols provided as defaults with the instrument) cannot be edited directly - copying allows their use as templates for user optimization.

d. 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.
  - Choosing Cancel Slide will cancel the slide.
  - Choosing Resume Operation will resume the slide process.

## Additional Program Preparation & Setup

### Creating Custom Groups

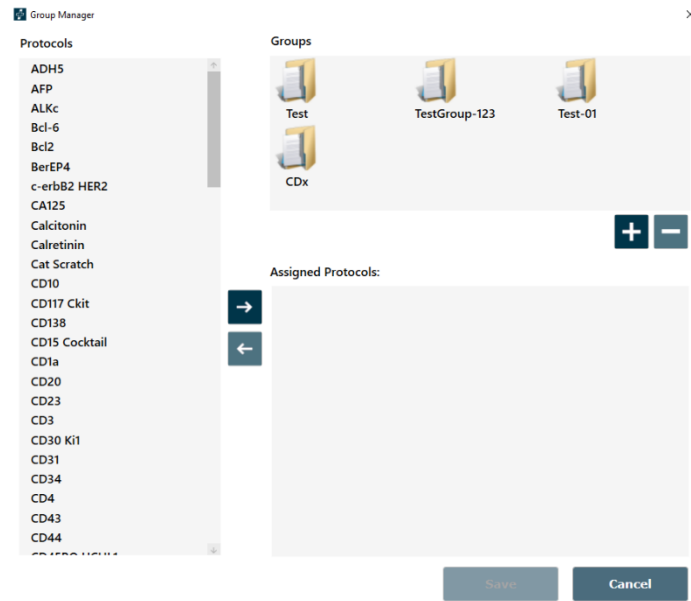
The creation of Custom Groups allows the laboratory to create groups of Protocols utilized by the laboratory rather than having to scroll through the list of All Protocols. A protocol must be first created under All Protocols to add or delete protocols under a Custom Group.

1. Select Group Manager link from the top left of the Protocol Manager window.

The screenshot shows the 'Protocol Manager' window. On the left, there is a 'Protocols:' dropdown menu set to 'All protocols'. Below it is a scrollable list of protocols including ADH5, AFP, ALKc, Bcl-6, Bcl2, BerEP4, c-erbB2 HER2, CA125, Calcitonin, Calretinin, Cat Scratch, CD10, CD117 Ckit, CD138, CD15 Cocktail, CD1a, and CD20. At the bottom left of this list are three icons: a plus sign, a minus sign, and a refresh icon. On the right, the 'Protocol:' field is set to 'ADH5'. Below this is a table with 10 rows representing protocol steps. The table has columns for '#', 'Name', 'Blow', 'Reagent', 'Volume', 'Time (h:mm)', 'Wash', and 'Count'. The 'Blow' column contains checkmarks for steps 1 through 8. The 'Wash' column contains 'Buffer 1' for steps 1-5 and 'DI' for steps 6-10. The 'Count' column contains values 1, 1, 1, 1, 2, 1, 1, 1, 1, and 1 respectively. At the top right of the table area, there is a 'Dispense Zone' section with a color-coded bar and a link that says 'Apply Global Volume & Zone To All Steps'. At the bottom right of the table area is a trash can icon.

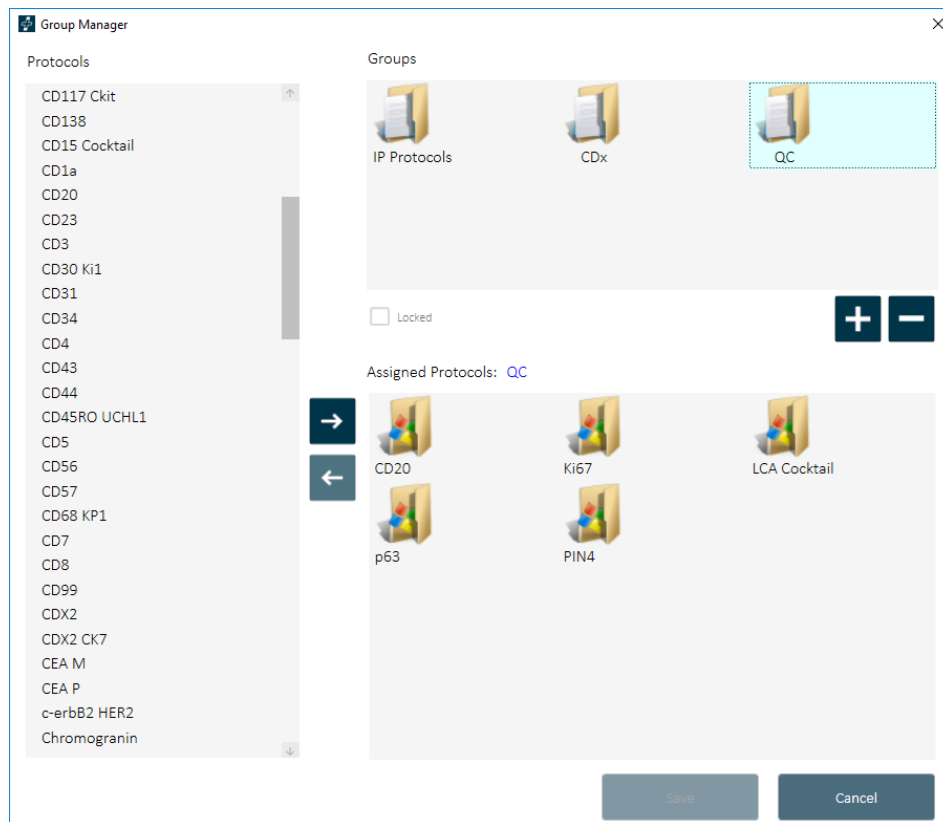
#	Name	Blow	Reagent	Volume	Time (h:mm)	Wash	Count
1	Block	✓	IP FLX Peroxidase	300 uL	00 : 05	Buffer 1	1
2	Block	✓	Background Punisher	300 uL	00 : 10	Buffer 1	1
3	Pre-Treatment	✓		300 uL	00 : 00	Buffer 1	1
4	Antibody	✓	ADH-5	300 uL	00 : 30	Buffer 1	1
5	Secondary	✓	Multiplex Sec Reagent 2	300 uL	00 : 30	Buffer 1	2
6	Chromogen	✓	IP FLX DAB	300 uL	00 : 05	DI	1
7	Chromogen	✓	IP Warp Red	300 uL	00 : 07	DI	1
8	Counter Stain	✓	IP FLX Hematoxylin	300 uL	00 : 05	DI	1
9	Wash				00 : 00	Buffer 1	1
10	Wash				00 : 00	DI	1

2. Click Add (+) Sign under Groups 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.

Note: This feature can be used to create panels of antibodies in one group.



## Laboratory Information System (LIS)

After activation of the LIS feature, the IntelliPATH PLUS and IntelliPATH MAX system is capable of interfacing with LIS systems capable of HL7 or LIS2-A2 (ASTM) transmissions. This allows the IntelliPATH PLUS and IntelliPATH MAX to request slides from the LIS for processing and to automatically report slide completion results to the LIS.

For detailed LIS specifications and setup information, refer to the IntelliPATH PLUS and IntelliPATH MAX LIS Integration Guide.

# Before Starting a Run

This section contains general guidelines for preparing samples for the IntelliPATH PLUS and IntelliPATH MAX prior to starting a run.

## Reagent Preparation

### Buffer 1

Add 500mL of Automation Wash Buffer, 20X (Cat. No. TWB945 M) to 9.5L of deionized water or add 1000ml of Automation Wash Buffer, two bottles of 20X (Cat. No. TWB945 M) to 19L of deionized water.

### DI Water

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

## Tissue and Slide Preparation

1. Deparaffinize tissue sections through 3 changes of xylene at 5 minutes each, 3 changes of 100% ROH at 1 minute each or 20 dips, and one 95% alcohol at 1 minute or 20 dips. Wash in DI water.
2. If applicable, ensure that the slides have been through the appropriate Heat Induced Epitope Retrieval (HIER) process offline after deparaffinization. Enzyme Induced Epitope Retrieval (EIER) can be performed online after offline deparaffinization by adding an enzyme incubation step to the protocol.
3. Hydrate in DI water and soak in buffer for 5 minutes 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 on the slide, preferably with variable levels of reactivity. 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

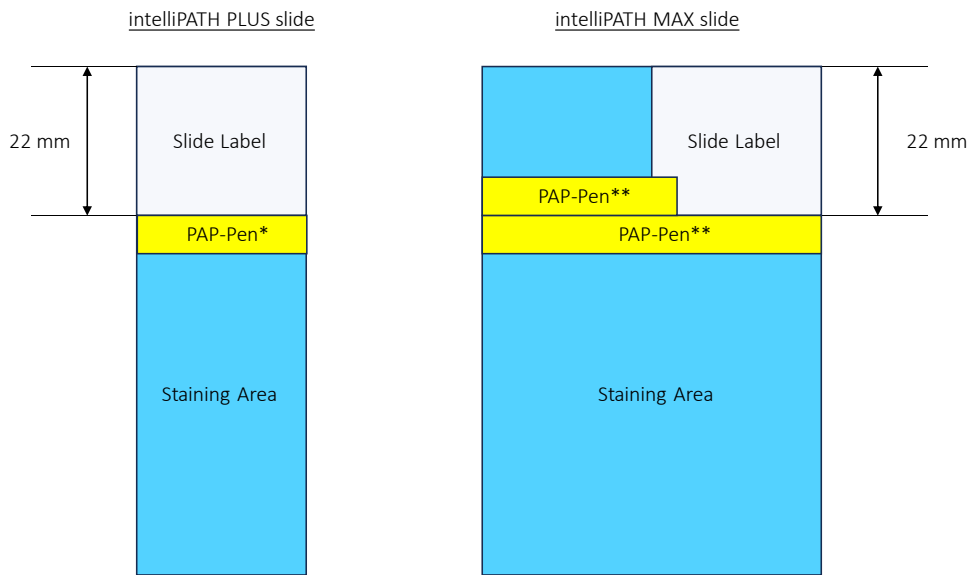
Include more than one antibody and its control: If one is positive, the process worked.

## 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. Verify the bulk container lines are not kinked or pinched, which would prevent proper rinsing.
4. Make sure there are no obstructions to the movement of the robotic arm.
5. 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.
6. If the instrument is off:
  - a. Turn the instrument on using the main power switch located above the power cord on the right side of the instrument.
7. If the computer is on, and the instrument was turned off at least once after the computer was turned on:
  - a. Turn off the computer. This can be done by clicking "Log Out" then clicking "Shutdown". This can also be done by holding down the power button on the front of the PC.



8. If the computer is off:
  - a. Turn on the computer and login to the IntelliPATH Plus program after the program and instrument initialize.
9. Load the reagent rack with filled reagent vials in the correct orientation: the label "FRONT" must be positioned toward the front of the instrument.
10. Confirm the slides are leveled. If the slides are not leveled call Technical Support.
11. If you will print labels, make sure the label printer is attached to the computer.
12. If you want to use the 2-D Matrix programming feature, affix the 2-D matrix labels to the slides and reagent vials.  
 Note: The slide labels must be applied as indicated in the graphic below.
13. Make sure to apply a PAP-Pen line across the slide as shown in the graphic below.
  - \* For standard wide slides (IntelliPATH PLUS) only use PAP-Pen when no slide label is used.
  - \*\* For double wide slides (IntelliPATH MAX) always use PAP-Pen (2x).



Important Note: Be sure to turn on the instrument before turning on the PC. Otherwise, software will fail to communicate with the instrument and automatically open in demo mode and runs will not start.

To bring the robotic arm to the home position select Log Out/ Shut Down to shut down the computer then re-start and log back in.

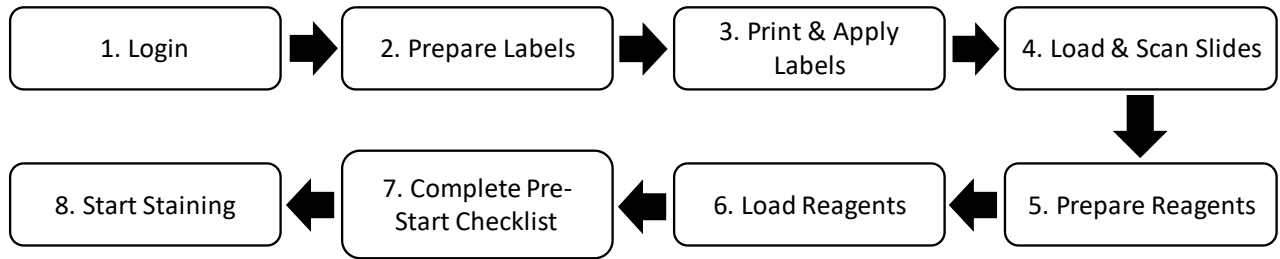
## Prepare and Start a Run

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

Important Note: Before starting this chapter, be sure to follow the instrument preparation section. Specifically, ensure to turn on the instrument before logging into the IntelliPATH PLUS/IntelliPATH MAX software, otherwise, software will automatically open in demo mode, not allowing an actual run to start. Also, be sure to shut down the PC in step 7 if the instrument has been shut down at least one time since the PC was started. Otherwise, the instrument will not be initialized when the run is performed, and the run will fail.

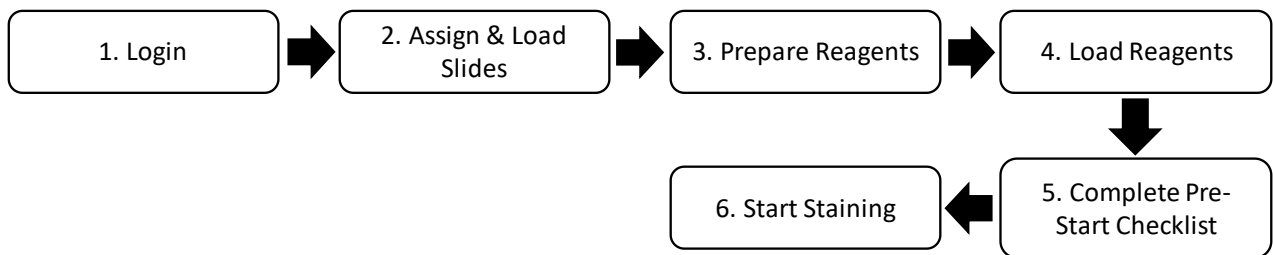
### Process Overview (Option 1)

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



### Process Overview (Option 2)

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



# Login to IntelliPATH PLUS / IntelliPATH MAX Software

Close the instrument lid, then turn on the instrument and control PC.

Note: During initialization, the robotic arm in the instrument moves. Keep the instrument lid closed during initialization.

Login to IntelliPATH PLUS/ IntelliPATH MAX software. Enter a valid username and password in the dialog box.



The image shows a login dialog box for IntelliPATH+ software. At the top, the logo "intelliPATH+" is displayed in blue. Below the logo, the text "User Name" is positioned above a rectangular text input field. The input field contains a single vertical cursor line. To the right of the bottom of the input field, the text "0 / 15" indicates the character count. Below the input field, the text "Password" is positioned above another rectangular text input field, which is currently empty. At the bottom of the dialog box, there are two elements: a blue hyperlink labeled "Change Password..." on the left, and a grey button labeled "Login" on the right.

## Select Slide Preparation

Prepare Slides window located on the Stainer Application Screen 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

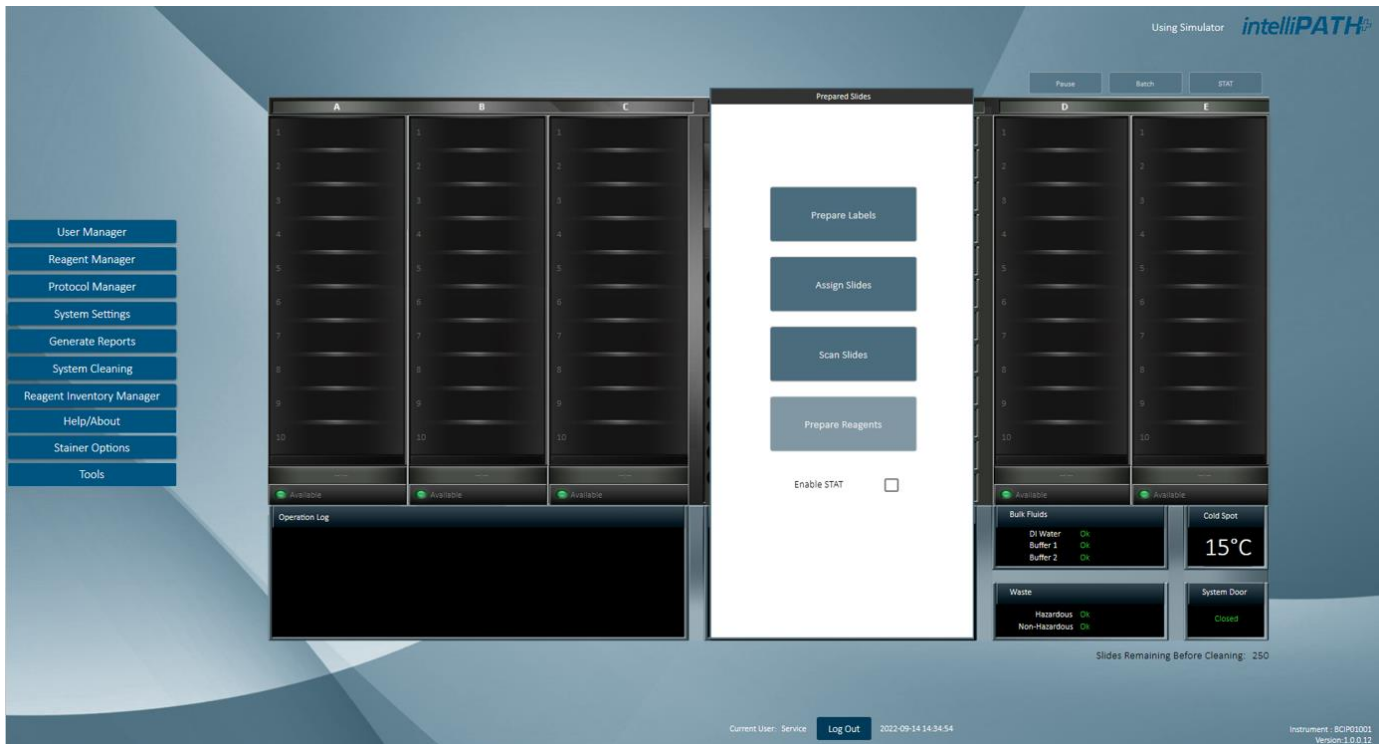
Labels that have been printed with 2D Matrix codes (either from Slide Manager or from an LIS System) can be scanned in the Scan Slides section.

### Prepare Reagents

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

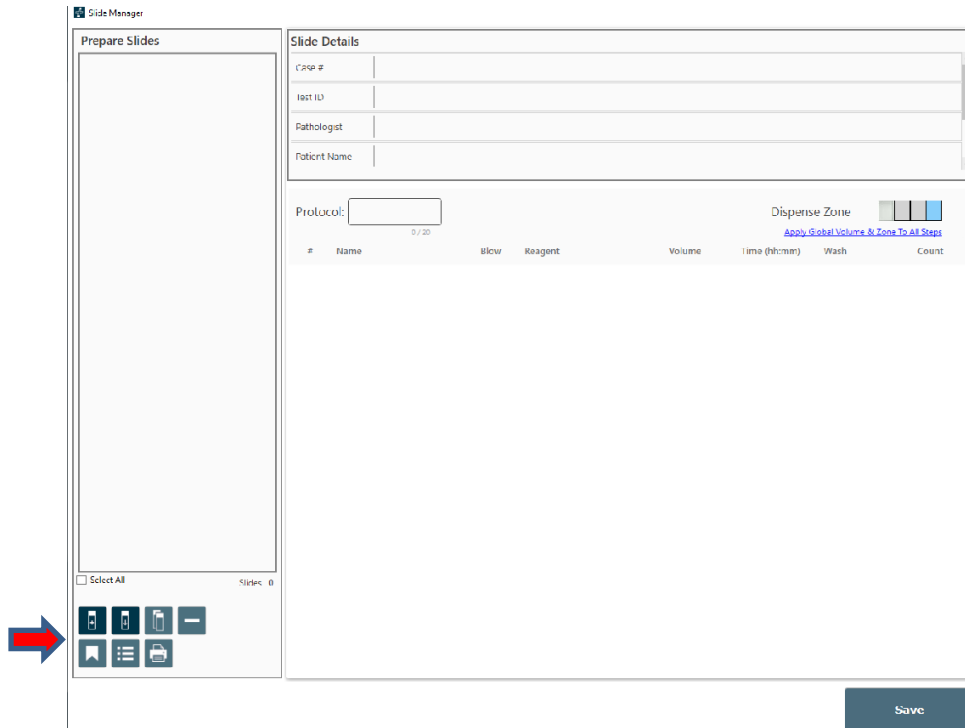
### Enable STAT

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, the user will not be able to add slides to this rack.

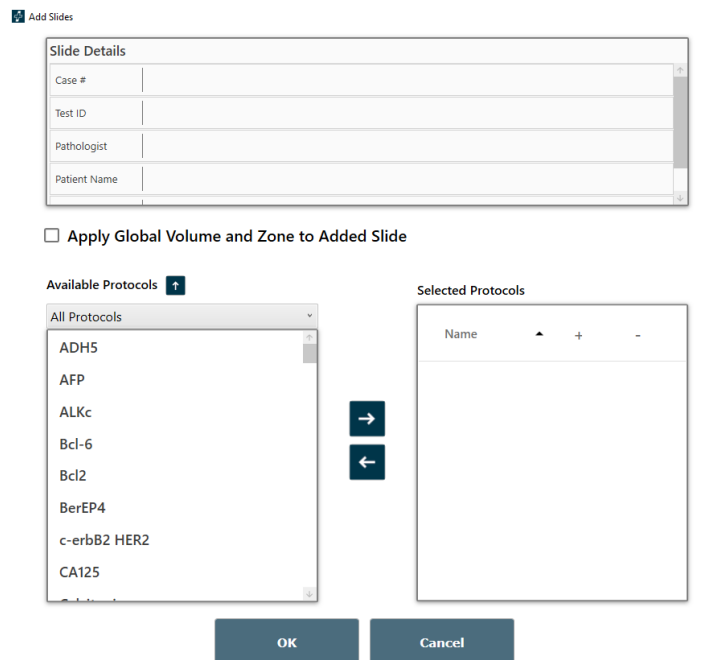


## Prepare Labels

1. Prepare Labels in the Prepare Slides window.
2. To add a new slide, click the Add icon (icon with the slide and + sign) located to the bottom of the Slide Manager screen.



1. The Add Slides screen will appear.



1. Enter the patient case in the Slide Details section. The software automatically assigns a Test ID. The other fields under Slide Details are optional.

- Under All Protocols (or a User defined/User selected Custom Group) select the desired protocol and click the right blue arrow. Click the + or – squares to add positive (+) or negative (-) controls. Repeat steps until all protocols have been added.
- To delete a protocol, under Selected Protocols, click on the protocol to delete and click the left blue arrow.
- Click OK once all protocols have been selected.

The screenshot displays the Slide Manager interface, divided into two main sections: 'Prepare Slides' and 'Slide Details'.

**Prepare Slides:** This section on the left contains a list of protocols with checkboxes. The protocols listed are: AFP (test 567), AFP- (test 567), AFP+ (test 567), BerEP4 (test 567), c-erbB2 HER2 (test 567), and CA125 (test 567). Below the list are 'Select All' and 'Clear All' buttons, along with a set of navigation icons.













**Slide Details:** This section on the right provides configuration options for a specific slide. It includes fields for 'Case #', 'Hist ID', 'Pathologist', and 'Patient Name'. The 'Protocol' is set to 'AFP'. A 'Dispense Zone' indicator shows three active zones. A table below lists the steps of the protocol:

#	Name	Blow	Reagent	Volume	Time (hh:mm)	Wash	Count
1	Block	✓	IP FLX Peroxidase	300 uL	00 : 05	Buffer 1	1
2	Block	✓	Background Pursher	300 uL	00 : 10	Buffer 1	1
3	Antigen Retrieval	✓	Reveal	400 uL	00 : 00	Buffer 1	1
4	Antibody	✓	Alpha-1-fetoprotein	100 uL	00 : 30	Buffer 1	1
5	Tertiary	✓	Univ HRP Tertiary Reagent	300 uL	00 : 30	Buffer 1	2
6	Chromogen	✓	IP FLX DAB	300 uL	00 : 05	DH	1
7	Counter Stain	✓	IP FLX Hematoxylin	300 uL	00 : 05	DH	1
8	Wash				00 : 00	Buffer 1	1
9	Wash				00 : 00	DH	1

At the bottom right of the interface is a prominent blue 'Save' button.

- The Slide Manager screen will re-appear with the protocols selected.
- Click Save once all slides have been added.

## Description of Slide Manager Icons

Icon	Function	Icon	Function
	Add new slides to the Prepared Slides.		Print slide labels for all checked slides.
	Opens the Import Slides window to select Recently Run, Processed, Saved, or Pending slides for import into the Slide Manager.		Add a new step at the end of the protocol for the currently selected slide.
	Make copies of the currently selected slide.		Add a new step before the selected step in the protocol for the currently selected slide.
	Deletes all checked slides in the prepared slides list.		Delete the selected step in the protocol for the currently selected slide.
	Opens the Save Slides window to store created slides for later use.		Move up the selected step in the protocol for the currently selected slide.
	Opens the Reagent Worksheet to estimate reagent usage for slides selected on the worksheet Note: this feature requires slides to be unmapped		Move down the selected step in the protocol for the currently selected slide.

- Click Select All to select all slides under Prepared Slides if all slides are desired.
- Slide Detail and Protocol information can be modified by clicking the slide to be edited.
- 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).
- Protocol information such as Protocol Name, Dispense Zone, and reagent steps and their properties can be deleted, added, inserted or moved. Use the icons to add or subtract steps (see Slide Manager Icon Table.)
- Click Save once all updates are complete.
- Additional slides can be added by clicking the Add (+) 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.

## Import Slides

To Import Slides during slide set up, click Prepare Labels from the Stainer Application Screen select the Import icon located to the bottom left.

The screenshot displays the 'Slide Manager' application window, divided into two main sections: 'Prepare Slides' on the left and 'Slide Details' on the right.

**Prepare Slides:** This section contains a list of slide sets with checkboxes and labels: ADH5 (456), Bcl-6 (456), and BerEP4 (999). A red arrow points to the 'Select' button at the bottom left of this panel.

**Slide Details:** This section provides a comprehensive overview of the current slide's configuration. It includes fields for Case # (456), test ID (abc123), Pathologist, and Patient Name (281082122202144130673). The Protocol is set to 'ADH5'. A 'Dispense Zone' indicator shows three active zones. A table below lists the 10 steps of the protocol, including reagents, volumes, times, and washes.

#	Name	Blow	Reagent	Volume	Time (h:mm)	Wash	Count
1	Block	<input checked="" type="checkbox"/>	IF FLX Peroxidase	300 µL	00 : 05	Buffer 1	1
2	Block	<input checked="" type="checkbox"/>	Background Puncher	300 µL	00 : 10	Buffer 1	1
3		<input checked="" type="checkbox"/>		300 µL	00 : 00	Buffer 1	1
4	Antibody	<input checked="" type="checkbox"/>	ADH-5	300 µL	00 : 30	Buffer 1	1
5	Secondary	<input checked="" type="checkbox"/>	Multiplex Sec Reagent 2	300 µL	00 : 30	Buffer 1	2
6	Chromogen	<input checked="" type="checkbox"/>	IF FLX DAB	300 µL	00 : 05	D1	1
7	Chromogen	<input checked="" type="checkbox"/>	IF Warp Red	300 µL	00 : 07	D1	1
8	Counter stain	<input checked="" type="checkbox"/>	IF FLX Hematoxylin	300 µL	00 : 05	L1	1
9	Wash				00 : 00	Buffer 1	1
10	Wash				00 : 00	D1	1

Navigation icons are located at the bottom left, and a 'Save' button is at the bottom right.



The Prepare Slides screen will appear. Under Filter By, slides can be filtered by Processed Slides, Recent Slides, Saved Slides, and Pending Slides using a dropdown menu. For Processed Slides, there will be an option to select a date range.

**Selection Criterion**

Filter By: **Processed Slides** | Date Range From: | Date Range To: | **Apply**

**Slide Details**

Case # **test 567**

Test ID

Pathologist

Patient Name

Protocol: **AHP** | Dispense Zone: [Zone 1] [Zone 2] [Zone 3]

#	Name	Blow	Reagent	Volume	Time (hh:mm)	Wash	Count
1	Fixative	✓	IP FLX Peroxidase	500 uL	00 : 05	Buffer 1	1
2	Block	✓	Background Punisher	300 uL	00 : 10	Buffer 1	1
3	Antigen Retrieval	✓	Reveal	300 uL	00 : 00	Buffer 1	1
4	Antibody	✓	alpha-1-Fetoprotein	300 uL	00 : 30	Buffer 1	1
5	Tertiary	✓	Univ HRP Tertiary Reagent	300 uL	00 : 30	Buffer 1	2
6	Chromogen	✓	IP FLX DAB	500 uL	00 : 05	D1	1
7	Counter Stain	✓	IP FLX Hematoxylin	300 uL	00 : 05	D1	1
8	Wash				00 : 00	Buffer 1	1
9	Wash				00 : 00	D1	1

**Close** | **Import Slides**

Once slides have been selected click Import Slides. The selected slides will appear in the Slide Manager window.

**Selection Criterion**

Filter By: **Pending Slides**

**Slide Details**

Case # **test 567**

Test ID

Pathologist

Patient Name

Protocol: **AFP** | Dispense Zone: [Zone 1] [Zone 2] [Zone 3]


- Pending Slides
- BerEP4
- AFP
- c erbB2 HER2
- CA125
- AFP+
- AFP-

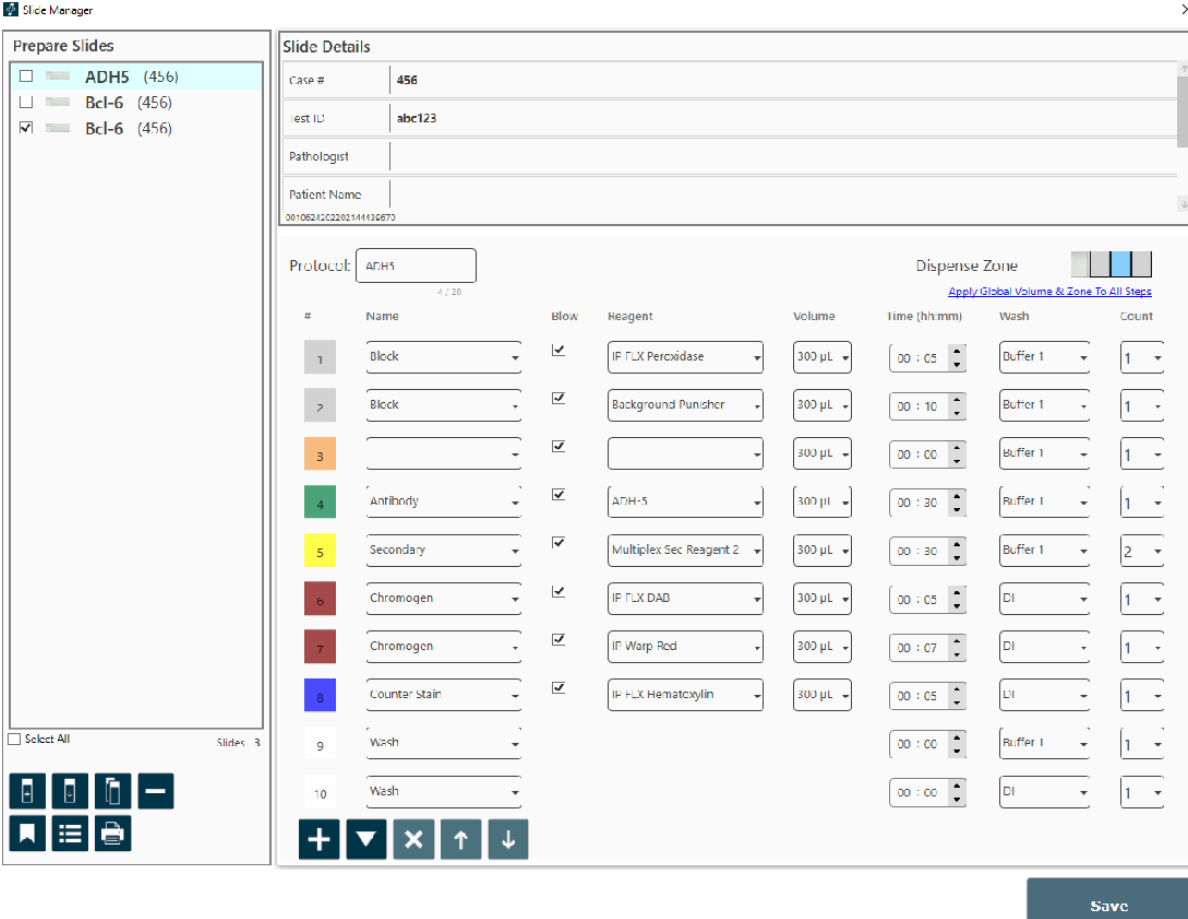
#	Name	Blow	Reagent	Volume	Time (hh:mm)	Wash	Count
1	Block	✓	IP FLX Peroxidase	300 uL	00 : 05	Buffer 1	1
2	Block	✓	Background Punisher	300 uL	00 : 10	Buffer 1	1
3	Antigen Retrieval	✓	Reveal	300 uL	00 : 00	Buffer 1	1
4	Antibody	✓	alpha-1-Fetoprotein	300 uL	00 : 30	Buffer 1	1
5	Tertiary	✓	Univ HRP Tertiary Reagent	300 uL	00 : 30	Buffer 1	2
6	Chromogen	✓	IP FLX DAB	300 uL	00 : 05	D1	1
7	Counter Stain	✓	IP FLX Hematoxylin	300 uL	00 : 05	D1	1
8	Wash				00 : 00	Buffer 1	1
9	Wash				00 : 00	D1	1

**Close** | **Import Slides**

Print Labels

Slide Manager window will open to allow for additional features including printing labels.

- To print slide labels, select the slide (s) and click the Print Slides (  ) icon.



The Slide Manager window is divided into two main sections: 'Prepare Slides' and 'Slide Details'.


**Prepare Slides:** A list of slides is shown with checkboxes. Slide 3 (Bcl-6) is selected. Below the list are icons for 'Select All', 'Print', 'Copy', and 'Delete'.

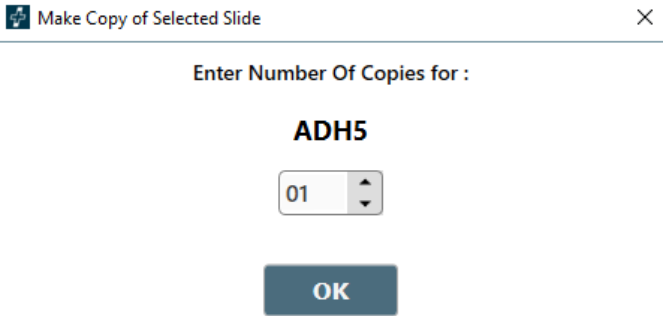
**Slide Details:** Contains fields for Case # (456), Test ID (abc123), Pathologist, and Patient Name (001062420202141130670). The Protocol is set to ADH5. A 'Dispense Zone' selector is visible. Below is a table of steps:

#	Name	Blow	Reagent	Volume	Time (h:mm)	Wash	Count
1	Block	<input checked="" type="checkbox"/>	IF FLX Peroxidase	300 µL	00 : 05	Buffer 1	1
2	Block	<input checked="" type="checkbox"/>	Background Punisher	300 µL	00 : 10	Buffer 1	1
3		<input checked="" type="checkbox"/>		300 µL	00 : 00	Buffer 1	1
4	Antibody	<input checked="" type="checkbox"/>	ADH-5	300 µL	00 : 30	Buffer 1	1
5	Secondary	<input checked="" type="checkbox"/>	Multiplex Sec Reagent 2	300 µL	00 : 30	Buffer 1	2
6	Chromogen	<input checked="" type="checkbox"/>	IF FLX DAB	300 µL	00 : 05	DI	1
7	Chromogen	<input checked="" type="checkbox"/>	IF Warp Red	300 µL	00 : 07	DI	1
8	Counter Stain	<input checked="" type="checkbox"/>	IF FLX Hematoxylin	300 µL	00 : 05	L1	1
9	Wash				00 : 00	Buffer 1	1
10	Wash				00 : 00	DI	1

At the bottom right of the window is a 'Save' button.

Copy Prepared Slides

- 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).



The dialog box is titled 'Make Copy of Selected Slide' and contains the following elements:

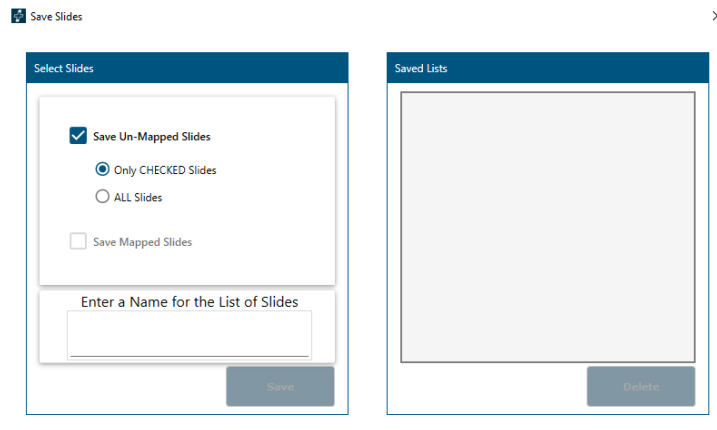
- A close button (X) in the top right corner.
- The text 'Enter Number Of Copies for :'
- The slide name 'ADH5' displayed in large bold text.
- A numeric input field containing '01' with up and down arrow buttons.
- An 'OK' button at the bottom.

Delete Prepared Slides

- A Prepared Slide can be deleted by checking the box next to the slide to be deleted and clicking the minus (-) sign.

## Save Prepared Slides

- To save slides to run later, select the slide (s) and click the Save Slides (  ) icon. (The Save Slides To Run Later window will open.



- 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.
- To save only mapped slides, check the box next to Save Mapped Slides.
- Enter a name for the list of slides in the box.
- Click Save.
- A representation for each existing list appears on the right. To delete an existing list, select and click Delete.
- To map a saved list, go to Assign Slides. To scan saved slides, utilize Scan Slides feature in Prepare Slides window.

## Reagent Worksheet

- Reagent Worksheet can be viewed and printed by clicking the Bulleted List (☰) button. The Reagent Worksheet window will open.

Show Reagent Worksheet ×

**Slides List**

Prepare Slides ▾

- ALL Slides
- Bcl-6

**Reagent List**

	Reagent Name	Short Name	Category	Catalog	Volume
<input type="checkbox"/>	IP FLX Peroxidase	IP Peroxid	Block	IPR5000	300
<input type="checkbox"/>	Background Punisher	Punisher	Block	BP974	300
<input type="checkbox"/>	Reveal	Reveal	Antigen Retrieval	RV1000	300
<input type="checkbox"/>	Bcl-6 LN22	Bcl-6	Antibody	IP410	300
<input type="checkbox"/>	Mouse Secondary Reagent	Mouse sec	Secondary	IPSC5001	300
<input type="checkbox"/>	Unlv HRP Tertiary Reagent	Unlv HRP	Tertiary	IPT5002	300
<input type="checkbox"/>	IP FLX DAB	IP FLX DAB	Chromogen	IPK5010	300
<input type="checkbox"/>	IP FLX Hematoxylin	IP Hem	Counter Stain	IPCS5006	300

\_ Select All

Count 8

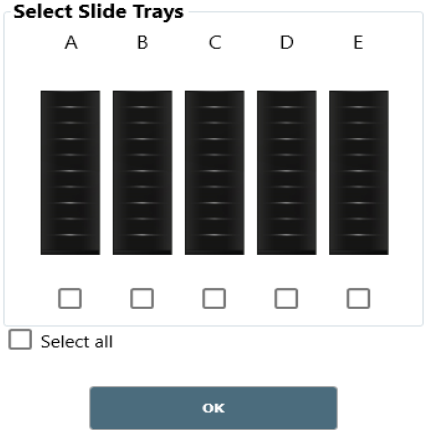
Print Worksheet
Print Label
Close

- Choose from the drop down: Prepared Slides or Mapped Slides.  
All slides from the chosen drop-down menu are listed on the left.
  - All reagents required to run these slides are listed on the right.
  - Selecting specific slides from the Slides List will show only the reagents needed for those slides in the Reagent List on the right.
  - To print the Reagent List, click Print Reagent Worksheet.
  - To print reagent labels, check the boxes next to the reagents needing labels and click Print Labels. Select All checkbox is located to the bottom right.
  - Reagent Worksheet may also be printed from the Tools drop down menu of the Stainer Application Screen.
- Click Close when finished.

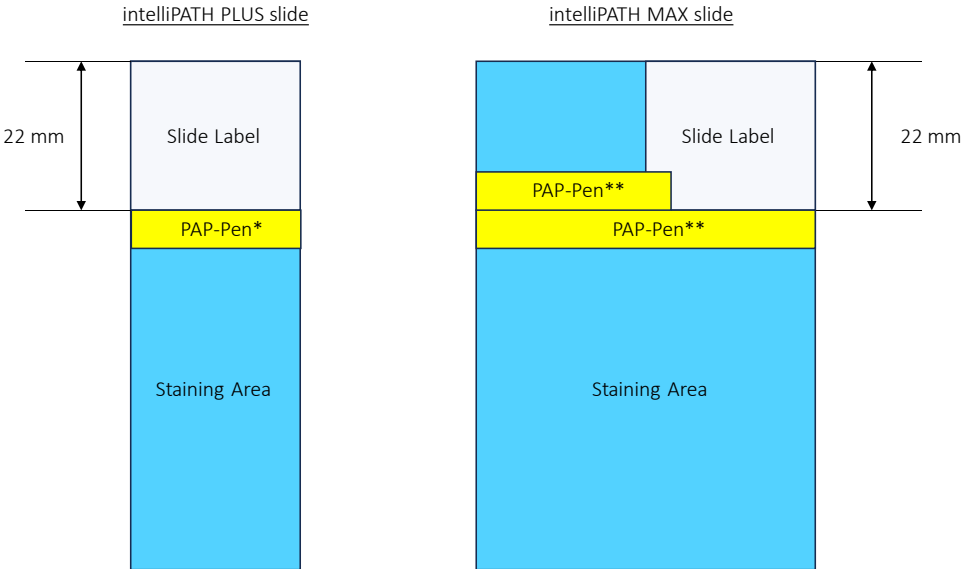
# Scan Slides

1. Click Scan Slides to open the Select Slide Tray to Scan window.

X

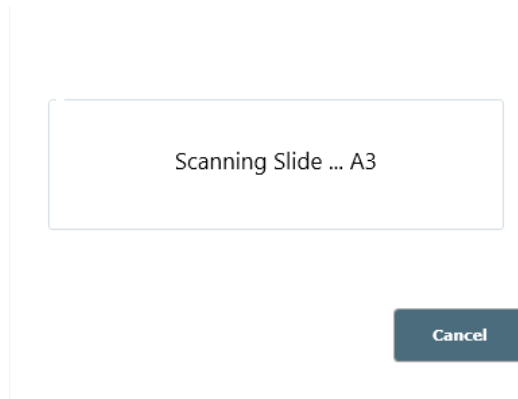


- Place labels on the slides and physically load the slides onto the instrument after slides have been deparaffinized and retrieved if necessary. Alternatively, slides may be labeled prior to deparaffinization and retrieval.  
 Note: The slide labels must be applied as indicated in the graphic below.



- Check the box for each tray that contains slides (the Select all checkbox may be utilized if all 5 trays contain slides)
- Close the instrument lid and click OK to begin slide scanning.  
 Note: selecting OK causes the robotic arm in the instrument to move to the selected trays for scanning.

- The Scanning Labels...intelliPATH PLUS 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.

2. Scanned Slides can be viewed, edited, or unloaded.

- Hover the mouse over a scanned slide for the Slide Information window to appear.

**Slide Information**

Slide ID : 0010624202202144439670  
Slide Position : 3 [Show Details](#)  
Case # : 456  
Protocol : ADH5

Reagent	Cat#	Volume	Time	Wa ↑
IP FLX Peroxidase	IPB5000	300 µL	00:05	Bu
Background Punisher	BP974	300 µL	00:10	Bu
Diva	DV2004	300 µL	00:00	Bu
ADH-5	IP360DS	300 µL	00:30	Bu ↓

- Slide Details and Protocol information can be viewed.
  - Additional Slide Details can be viewed by clicking the Show Details link.
  - 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

3 ADH5  
ADH5

**View/Edit**  
**Copy Slide**  
**Unload Slide**

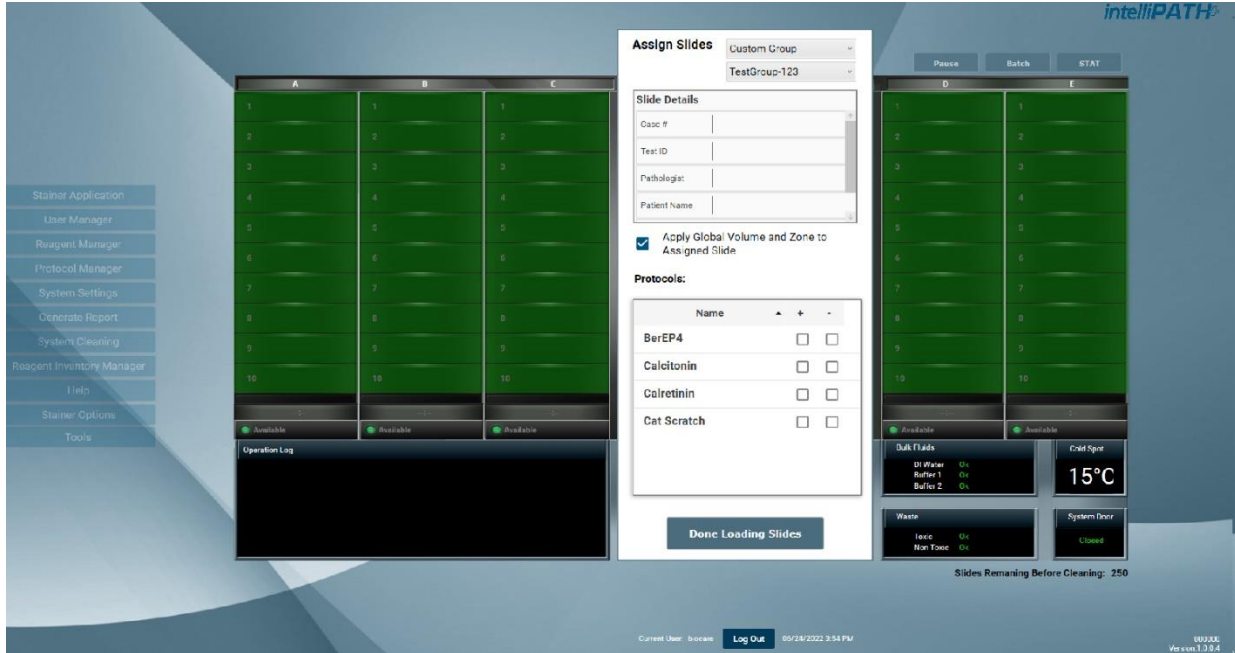
- View/Edit opens the Slide Manager window.  
Note: editing protocols in this window is restricted to custom user protocols.
- Copy Slide is designed for a single slide, to copy multiple slides go to Add Slides view.
- Unload Slide is designed for a single slide, to unload multiple slides go to Assign Slides view.

Note: Copy Slide and Unload Slide function are for single slides

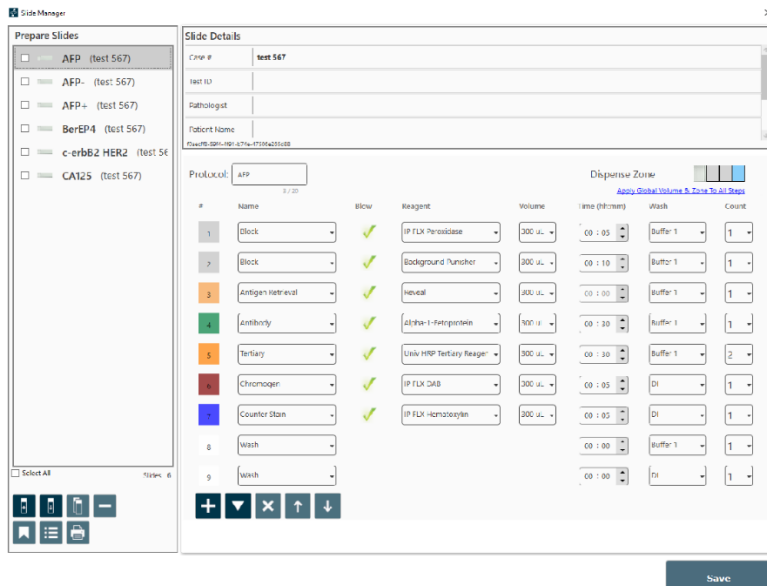
# Assign Slides

As an alternative to Scanning Slides the user can also Assign Slides...

- Click Assign Slides and the Assign Slides window will appear.



- Multiple view options are available from the Select Protocols drop down menus.
  - All Protocols lists every protocol in the system.
  - Custom Group only shows the Protocols from a particular Custom Group.
    - An additional drop down exists to filter by specific Custom Group
  - 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).





- LIS Slides lists all LIS imported slides.
- Saved Slides only shows the Protocols from a particular Saved List.
  - An additional drop-down exists to filter by specific Saved List.
  - If a Saved Slide is mapped on a slide tray, then unmapped from the slide tray, the slide will automatically be deleted from the Saved Slide list. The user will need to add the slide again to the Saved Slide list if it desired to retain it in the list.
 

Note: if a Saved Slide will potentially be unmapped and remapped by the user, it is recommended to import the Saved Slide into the Prepared Slides list through the workflow described in the Prepare Labels section of this manual to prevent deletion.
- 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.
  - 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).
  - 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).
  - If positive and/or negative controls are desired, check the box under the Add (+) 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).
  - 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

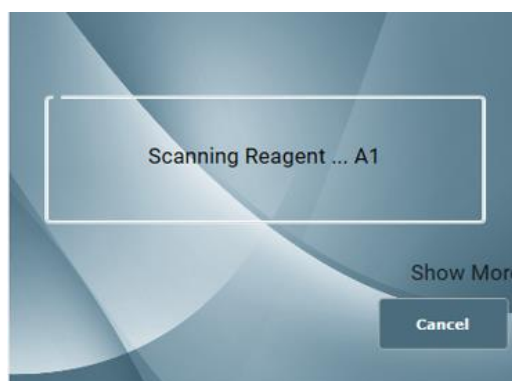
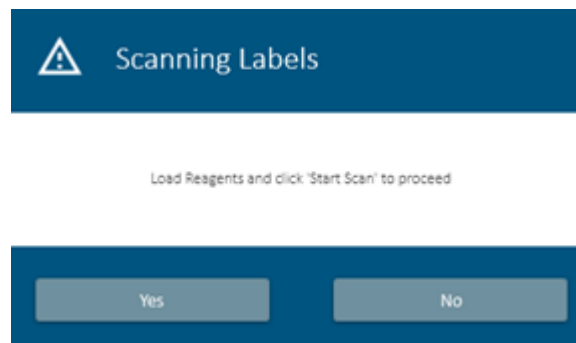
Once desired slides have been loaded and scanned, click Prepare Reagents to open the Load Reagents window

- 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.

Catalog	Reagent Name	Lot Number	Expiration (YYYY/...
IPB5000	IP FLX Peroxidase	<input type="text"/>	<input type="text"/>
IPCS5006	IP FLX Hematoxylin	<input type="text"/>	<input type="text"/>
IPT5002	Univ HRP Tertiary Reagent	<input type="text"/>	<input type="text"/>
IP410	Bcl-6 LN22	<input type="text"/>	<input type="text"/>
IP360DS	ADH-5	<input type="text"/>	<input type="text"/>

- 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.  
Note: ensure reagent vials are free of microbubbles, as microbubbles have the potential to reduce pipetting accuracy if they pulled from the vial.  
Note 2: Loading reagent vials into descending positions from A1 to D12 without leaving any empty locations in the tray will speed up the reagent scanning process.
- Be sure to load all required Mixing Vials as depicted by a gray circle in the Mixing Vial Rack with a number in the center.  
Note: ensure mixing vials are free of microbubbles, as microbubbles have the potential to reduce pipetting accuracy if they pulled from the vial.
- Click Load Reagents and choose from three options: Auto Map, , Scan Reagents.
  - 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.
  - 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.
  - Scan Reagents will cause the 2D Matrix Scanner to scan the Reagent Rack until all required reagents have been located.
  - Click Scan Reagents. The Scanning Labels window will display the actions of the 2D Matrix Scanner and allow to cancel using the Cancel button.
  - Close the instrument lid and click Yes to Start Scanning reagent labels.  
Note: selecting Yes causes the robotic arm in the instrument to move to the reagent rack and cold spot for scanning.



- When using the Auto Map or the Manual Map feature, if a reagent exists in inventory, the Select from Inventory window will appear.
- Choose from the list and click Use Selected Vial if the inventoried vial will be used.
- Choose Use New if a non-inventoried vial will be used.

IPCS5006 IP FLX Hematoxylin

Lot #	Expiry Date	Serial ID	Volume
			8120 µL
			8420 µL

Use Selected Vial      Use New

After all the required reagents have been loaded, click Next to proceed. The Reagent Verification window will appear.

**Reagent Verification** X

Position	Reagent	Required Vol.	Actual Vol.

Reagent and Mixing vials are loaded as specified

Load the Reagents and click on "Verify Reagents" to proceed

Verify Reagents      Proceed >

- 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 Proceed 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.  
**Note:** selecting Proceed > causes the robotic arm in the instrument to move to the reagent rack, cold spot, and mixing vials for level detection.
- 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.

Reagent Verification X

Position	Reagent	Required Vol.	Actual Vol.
R-A1	IP FLX Hematoxylin	600 µL	8720 µL
R-A2	ADH-5	600 µL	8720 µL
R-A3	Background Punisher	600 µL	8720 µL
R-A4	Multiplex Sec Reagent 2	600 µL	8720 µL
R-A5	IP FLX Peroxidase	600 µL	8720 µL
R-A6	IP FLX DAB Buffer	2300 µL	8720 µL
R-A7	IP FLX DAB Chromogen	420 µL	8720 µL
R-A8	IP Warp Red Buffer	2300 µL	8720 µL

Reagent and Mixing vials are loaded as specified
  Override Sensor

Load the Reagents and click on "Verify Reagents" to proceed

Proceed >

- Once all reagents and mixing vials have been accepted, click Proceed.

# Pre-Start Checklist

1. The Pre-Start Checklist provides information on the instrument status, estimated buffer usage and waste generation, along with additional options that may be required for a run. Using the Buffer & Waste Estimate section as a guide, ensure that all buffer carboys contain the required volume for the run and that all waste carboys have sufficient space for waste generated during the run. Check off each item in the Waste Carboy Status section upon confirmation.
2. The Delayed Run checkbox on the top right side of the Pre-Start 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. Prime adequately, until lines are free of air or bubble streams.
4. Click Prime Probe, located at the bottom right side of the screen. Ensure the auto-prime cleared air bubbles from probe coil. If air bubbles remain, repeat prime.
5. The Pre-Start Checklist includes buttons to Estimate Run Time, Home Arm, Drain Waste, Prime Probe, and Print Layout Maps (for slides and reagents).
6. It is recommended that the user selects the Rinse Slides before the Run checkbox to ensure that the slides will be hydrated to allow the reagents to adequately spread across the slide.

**Pre-Start Checklist**
X

**Buffer & Waste Estimate**

DI Water -	200 µL	OK
Buffer 1 -	1260 µL	OK
Buffer 2 -	0 µL	OK
Hazardous -	440 µL	OK
NonHazardous -	1020 µL	OK

**Run Estimate**

06:42 PM	-	-	-	-
A	B	C	D	E

**Estimate Run Time**

**Delayed Run**

Default Delay: 2

Current Time 06/24/2022 04:24:20 PM

Start Time 6/24/2022 18 : 24

Rinse Slides

Rinse Buffer, Interval DI 00 : 30

Delay Allowed: 24 hr.

**Waste Carboy Status**

- Required buffer carboys have been filled
- Hazardous carboy has been Emptied
- NonHazardous carboy has been Emptied
- Slides and Reagents are loaded as shown in the Maps

**Operations**

**Home Arm**

**Prime Buffers**

**Drain Waste**

**Prime Probe**

**Print Layout Maps**

Rinse Slides before the Run

< Back

Start Staining

## 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 run, to start immediately or Cancel Run.

Use of the Delayed Run feature on slides retrieved via HIER offline may result in staining inconsistencies. An increase in delay may increase chances of the slides drying which may cause a weakening of signal intensity. The implementation of multiple washes to a Delayed Run may compromise the tissue or the slide preparation.

2. While a run is in progress, a new Batch staining run may be started if there are available trays, or a STAT staining run may be started if slide tray E is available.

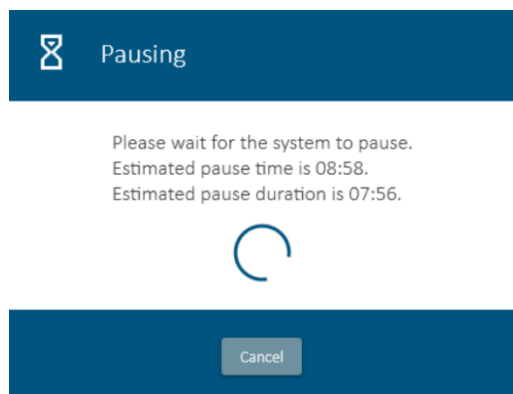
During a run, a Prepare Slides button will appear next to the run designation buttons. This button will open the Prepare Labels interface, which can be used to prepare slide labels for future processing. See the Prepare Labels section for details.



## 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 PLUS/IntelliPATH MAX window.
2. The dialog "Do you want to Add more Slides?" is displayed. Select Yes to proceed.
3. If the instrument is in the middle of an operation that cannot be stopped, the message below will appear notifying the user of the following:
  - i. Estimated pause time: The specified time the instrument will pause to allow user to load and scan reagents.
  - ii. Estimated pause duration- The total time the user has to load and scan reagents.



4. The instrument will allow the user to batch directly if it is not busy with an operation that cannot be paused:
  - i. A countdown of the Remaining Pause Duration will appear at the top of the screen. This is the allotted time to load and scan reagents.
  - ii. Going over the Remaining Pause Duration may cause over incubation of slides, when this occurs the Remaining Pause Duration time will turn red and start tracking elapsed time after the Remaining Pause Duration countdown.
  - iii. The user should plan accordingly to avoid going over the Remaining Pause Duration time.
5. The Prepare Slides window will appear, and the user will follow the prompts.
6. After the slides are scanned and Prepare Reagents has been selected, the system door will open, allowing the user to load reagents. The system door will lock when Scan Reagents is clicked. The user should have reagents ready to load to prevent slides in process from over-incubating.

Please Note: During a batching run, the system may require for mixing vials in which the last vial may not be used due to dispensing efficiencies utilized during the run.

## 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 PLUS /IntelliPATH MAX window.
2. The dialog Add STAT Slides. is displayed. Select Yes to proceed.
3. The Prepare Slides window 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 after the instrument safely gets all slides to a stopping point that will not affect staining, allowing the user to load additional reagents. System Door will lock when Scan Reagents is clicked. The User should have reagents ready to load to prevent slides in process from over-incubating.

## Cancel a Run

1. To abort a run, click the Stop button located on the center bottom of the Stainer Application Screen.
2. Select Yes when asked "Are you sure you want to abort a run."
3. After stopping the run, wait for the system to finish its current operations and display that the run is cancelled before proceeding.
4. Once a run is completely cancelled, the Stainer Application Screen will display in red "Run Cancelled on IntelliPATH."



Pause Batch Start

- User Manager
- Reagent Manager
- Protocol Manager
- System Settings
- Generate Reports
- System Cleaning
- Reagent Inventory Manager
- Help/About
- Stainer Options
- Tools

	A	B	C	D	E
1	IP Peroxidase IPBS000				
2	ADH-S IPBS002				
3	BC-B P410				
4	Punisher bingta				
5	Multiplex2 IPCS004				
6	W item IPCS006				
7	Mouse sec IPCS002				
8	Univ HRP PTS002				
9	IP DAB CV IPCS008				
10	IP DAB B IPFS009				
11	IP WB B IPFS002				
12					

Completed Available Available

Operation Log  
2022-09-21 14:59:09 - Dispensing - ReagentName: IP FLX Peroxidase, ReagentCatalog: IPBS000, SlidePosition: A1, SlideBarcode: , CaseNumber: unassigned, Volume: 300, DispenseZone: Middle  
2022-09-21 14:59:27 - Blowing - SlidePosition: A2, SlideBarcode: , CaseNumber: unassigned, Count: 1  
2022-09-21 14:59:29 - Dispensing - ReagentName: IP FLX Peroxidase, ReagentCatalog: IPBS000, SlidePosition: A2, SlideBarcode: , CaseNumber: unassigned, Volume: 300, DispenseZone: Middle  
2022-09-21 14:59:30 - RunCompleted -  
2022-09-21 14:59:30 - RunCompleted -

**Run Cancelled on intelliPATH**

Print Reports

Start a New Run

Bulk Fluids: DI Water , Buffer 1 , Buffer 2   
Waste: Hazardous , Non-Hazardous   
Cold Spot: 15°C  
System Door: Closed

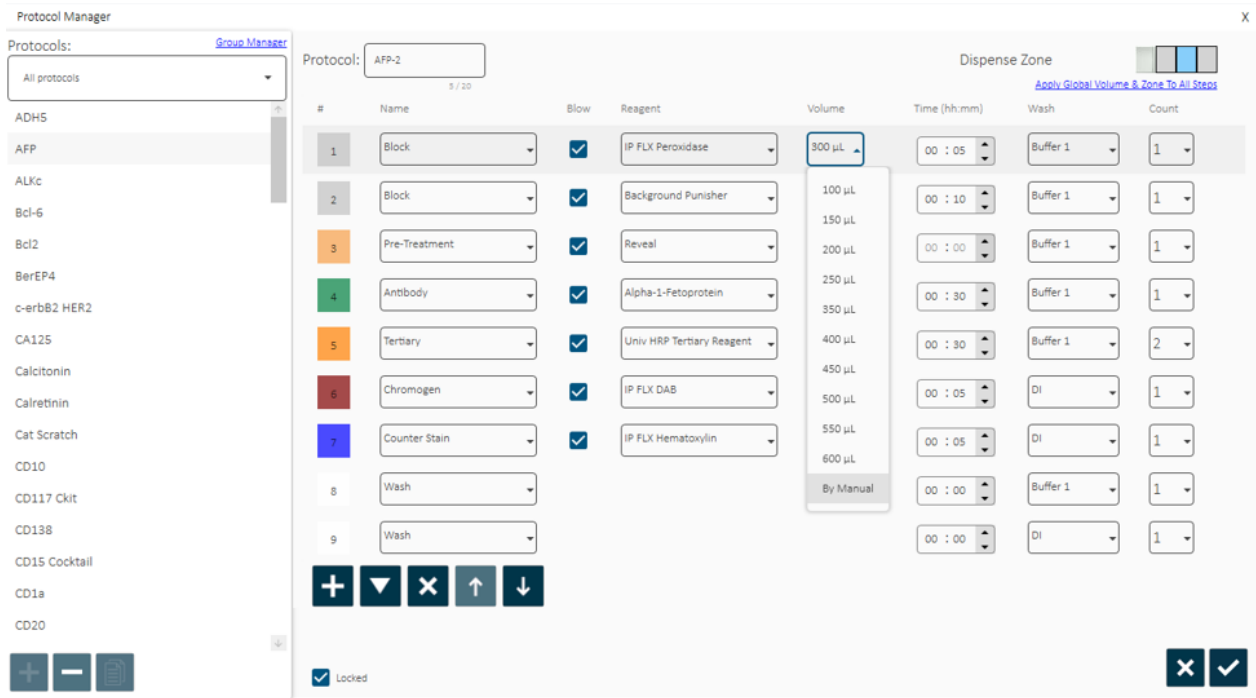
Slides Remaining Before Cleaning: 250

Current User: Service [Log Out](#) 2022-09-21 14:59:37

Instrument: BCIPO1001  
Version: 1.0.0.12

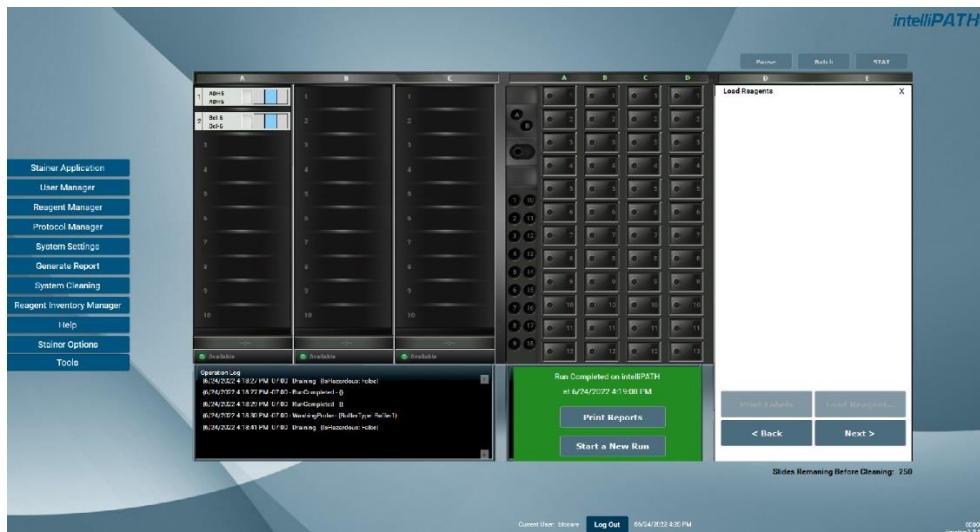
## Manual Application of Reagent

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.

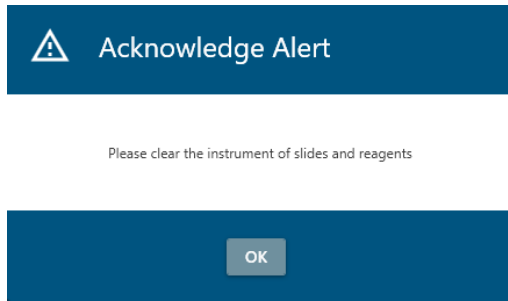


## Run Completion

Once the run is completed the user can Print Reports or Start a New Run. If Print Reports is chosen, the Generate Reports window will open.



If Start a New Run is chosen, the system will prompt the user to Clear Trays and Clear Reagents.



# Instrument Maintenance

## System Cleaning

When the IntelliPATH PLUS/ IntelliPATH MAX software notifies the operator that cleaning is necessary, follow the 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.

Refer to the Software Features & Function - System Cleaning section for further details.

## Daily

- Rinse the used racks in tap water after every run.
- Using a DI squirt bottle, 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 under Protocol Manager. (One of the most effective ways to keep the instrument clean.)
- Always use DI water with Tween 20 (Biocare's Automation Tween 20 – Cat: TWA 20).

## Weekly

Note: This procedure cleans the reagent 'probe' (pipettor), slide racks, the Liquid Level Sensor, the Barcode Reader and the waste-reservoir drain.

- Weekly or every 250 slides. Perform the 'System Cleaning'/DAB Away 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 the process.
- Shut down the computer and turn off the instrument, then 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 PLUS/intelliPATH MAX 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 ensures the 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.
- Clean the splash guard dividers (vertical sheet metal parts between the Slide trays) with 10% Lysol 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 instrument.
- 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, problems may arise 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, the way in which it is processed prior to staining, and the staining process.

Problem	Possible Causes & Solutions
<p>No staining, weak or inconsistent staining, false negatives</p>	<p>Cause: Programming errors. Resolution: Review programming and correct errors.</p> <p>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.</p> <p>Cause: Buffer and deionized water, in their respective carboys, are not at proper capacity. Resolution: Fill carboys.</p> <p>Cause: Slides positioned incorrectly in slide racks. Instrument and slides must be horizontal, verified by level gauge. Resolution: Reposition slides.</p> <p>Cause: Protocol did not include rinse step between reagent steps. Resolution: Add rinse steps to protocol using the Protocol Manager.</p>
<p>Slides dry out</p>	<p>Cause: Buffer and deionized water are not at proper capacity. Resolution: Fill carboys.</p> <p>Cause: Slides positioned incorrectly on the IntelliPATH. Resolution: Position slides correctly. Position must be verified by level gauge. Inspect slides positioned at back of instrument.</p> <p>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.</p>

## Fluid Handling

Problem	Possible Causes & Solutions
Drops form on probe	<p>Multiple causes, call Technical Support with details on which step/s drops appear on probe:</p> <p>E.g.:</p> <ul style="list-style-type: none"> <li>When the probe moves from the wash station to reagent vials?</li> <li>When the probe moves from the wash station to slide for rinse step?</li> <li>When the probe moves from the reagent vial to slide?</li> <li>When the probe moves from slide to slide?</li> </ul>
Buffer not operating at optimal flow	<p>Cause: Buffer container is not at proper capacity. Resolution: Fill the container and prime the pump.</p> <p>Cause: Tubing between pump and Z head is obstructed or bent. Resolution: Inspect tubing and clear obstruction.</p>
Reagent dropped on slides spreads in H-shaped pattern	<p>Cause: Buffer container is not at proper capacity. Resolution: Fill the container and prime the pump.</p> <p>Cause: Slides' surfaces are hydrophilic. Resolution: Immerse slides in buffer for 15 minutes (minimum) before placing them in the IntelliPATH.</p> <p>Cause: Buffer has incorrect concentration of Tween 20. Resolution: Remix buffer to contain Tween 20 in prescribed concentration of 0.1%.</p> <p>Cause: De-paraffinizing procedure not followed properly. Resolution: Review procedure and results for possible errors.</p> <p>Cause: Slide level is inaccurate. Resolution: Verify by level gauge. If unable to level instrument, contact Technical Support.</p> <p>Cause: Buffer nozzle is obstructed. Resolution: Remove obstruction and confirm flow.</p> <p>Cause: Air nozzle outlet is obstructed. Resolution: Rinse nozzle and use small brush to clear passage.</p> <p>Cause: Compressor is not operating. Machine emits no sound during operation. Resolution: Contact Technical Support.</p>
Buffer or deionized/ distilled water not flowing from buffer head	<p>Cause: Carboys are empty. Resolution: Fill carboys.</p> <p>Cause: Tubing between containers and instrument is obstructed, bent, or damaged. Resolution: Re-route tubing and clear obstructions.</p> <p>Cause: Standard priming procedures for buffer and deionized water pump not followed properly. Resolution: Repeat priming procedures. If problem not solved contact Technical Support.</p>

## Fluid Handling (continued)

Problem	Possible Causes & Solutions
Reagent dosage uneven across slides	<p>Cause: Deionized water does not have the proper concentration of Tween 20. Resolution: Adjust the deionized water and Tween 20 formula and prime the deionized water pump. Repeat run.</p> <p>Cause: Air bubbles in the clear plastic tubing from reagent probe. Resolution: Call Technical Support for instructions on how to remove bubbles.</p> <p>Cause: Leaks in syringe. Resolution: Call Technical Support for instructions.</p>
Waste backs up in the sink	<p>Cause: Overflow tubing kinked or obstructed. Resolution: Check overflow tubing for obstructions or kinks.</p> <p>Cause: Waste pump filter obstructed, waste pump failed, waste level sensor failed. 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.</p>

## Electrical

Problem	Possible Causes & Solutions
The Power On LED (green light) is off, indicating no power to instrument	<p>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.</p> <p>Cause: Fuse has failed (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 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.</p> <p>Fuse Specifications: 100-120 Units: 250VAC, 8A, 20mmx5mm (1 fuse) 200-240 Units: 250VAC, 4A, 20mmx5mm (2 fuses)</p> <p>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.</p>

## Mechanical

Problem	Possible Causes & Solutions
Bent pipette	<p>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.</p> <p>Cause: Stainer out of calibration Resolution: Contact Technical Support</p>
Toxic and non-toxic waste pumped to single, external waste container	<p>Cause: Waste diverter valve malfunctioned. Resolution: Call Technical Support to have valve changed.</p> <p>Note: that despite the inconvenience of mixed waste streams, the instrument continues to function and remains safe to operate.</p>
Waste is flowing out of overflow tube (large diameter, clear tube)	<p>Cause: Waste pump has malfunctioned, or level of waste generated during the staining process reaches level of overflow tubing. Resolution: Call Technical Support to confirm malfunction and to change pumps.</p>
Probe or wash-blow head misaligned	<p>Cause: Stainer is out of calibration. Resolution: Call Technical Support to calibrate the instrument.</p>



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