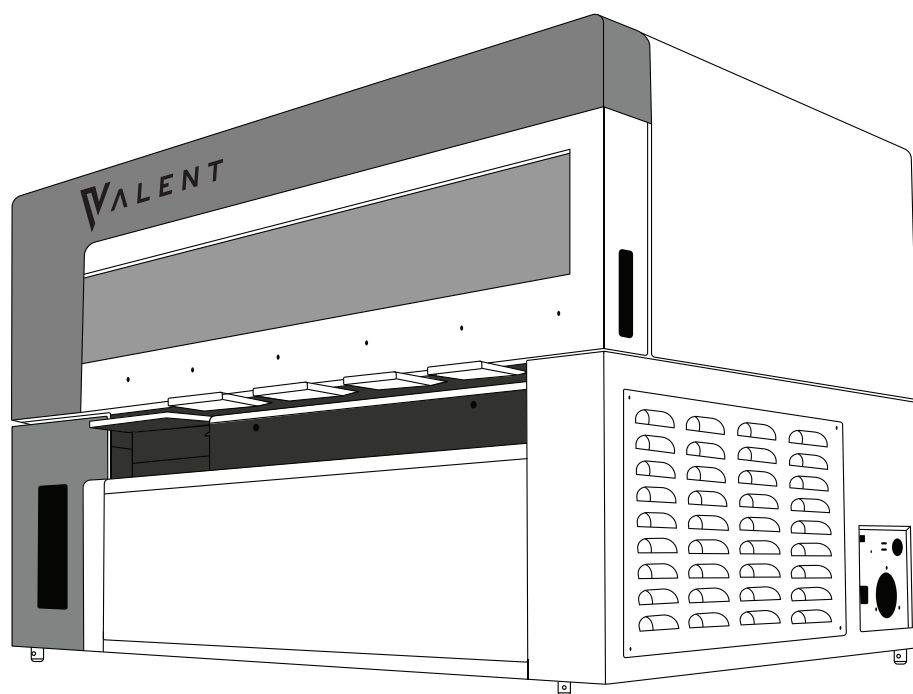


VALENT[®] Manual

Automated Slide Staining Platform User Manual



Biocare Medical

Technical Support:
800-799-9499 Option 3

Customer Service:
800-799-9499 Option 2

Fax:
925-603-8080

Corporate Office:
60 Berry Drive
Pacheco, CA 94553

www.biocare.net

Table of Contents

Chapter 1: Introduction	1
Intended Use.....	1
About the VALENT Automated Staining Platform.....	1
Limitation of Use.....	1
VALENT Specifications.....	1
VALENT Cart Specifications.....	2
Reagent Vial Label and Slide Label Printers.....	2
Report Printer.....	2
USB Flash Drive.....	2
Warranty.....	2
VALENT Components.....	3
Z-Head Schematic.....	4
VALENT Cart Components.....	4
Carboy Connections.....	4
VALENT Description of Parts.....	6
Storage and Handling.....	8
Reagents.....	8
Humidity.....	9
Waste Disposal.....	9
Instrument Disposal.....	9
Site Installation Requirements.....	9
Support.....	9
Chapter 2: Safety Precautions	10
Recommended Use.....	10
Reagents and Chemicals.....	10
Reagent Rack.....	10
Instrument Safety Guidelines.....	10
Programming Cautions.....	10
Lithium Battery.....	11
Safely Turning on the Cart.....	11
Turn ON the Cart.....	11
Turn OFF the instrument.....	12
Symbols Glossary.....	13
Chapter 3: VALENT Software Features & Functions	14
User Access.....	14
Login.....	14
Home Screen.....	14
Home Screen Features.....	15
Run Designation Buttons.....	16
Menu Bar.....	16
Staining Run.....	16
Data Manager.....	17
Tools.....	18
Print Reports.....	19
Configure Reagent Wash Lists.....	20

Contamination List	20
PrepWash List.....	20
Aqua Rinse Wash List.....	20
View Menu.....	21
Notifications.....	21
Run Time Estimates	21
Cleaning Log.....	22
Run Log	22
Help	22
Chapter 4: Program Preparation & Setup	23
Administrator Program Preparation & Setup	23
Summary of Administrator vs. Regular User Profile.....	23
Assign or Modify Users	23
User Information Guideline	24
Modify a User Account.....	24
Software Settings	25
System Parameters.....	26
Instrument Parameters	26
Reagent Manager.....	27
Reagent Groups	27
DePar.....	27
Antigen Retrieval	27
Enzyme	27
Block	27
Antibody.....	27
At the bottom of the Reagent Details box:.....	28
Negative Serum Group.....	28
Secondary Group.....	28
Tertiary Group	28
Chromogen Group.....	28
Counter Stain Group.....	28
Ancillary Group	28
Mix Group	28
Display Reagent Information.....	28
Template Manager	30
Description of Template Manager Icons	30
Creating a Template from a Blank Template	30
Create a Template from an Existing Template	32
Delete and Modify Templates	32
Additional Program Preparation & Setup	33
Custom Groups	33
How to Create a Custom Group	33
Delete a Custom Group	34
Edit a Custom Group	34
Slide Fields	35
Slide Map Fields	36
Slide Label Designer.....	37
Reagent Label Designer	38

Report Field	39
Chapter 5: Before Starting a Run	40
Slide Preparation	40
Slide Specifications.....	40
Slide Labels.....	40
Tissue Placement on Slide	40
Slide Trays	41
Inserting Slides into the Slide Tray.....	41
Removing Slides from the Slide Tray	41
Tissue Preparation	42
Positive and Negative Controls.....	42
Bulk Reagent Preparation.....	42
Instrument Preparation	43
Drain Waste & Prime Buffers	44
Prime Probe.....	44
Prime Buffers	44
Prime DePar	45
Prime Troughs and Manifold	45
Drain Waste	46
Reagent Manager.....	47
Add, Delete, and Modify Reagents	47
Add a New Reagent	47
Delete a Reagent	48
Modify a Reagent	48
Import a Reagent from Reagent Manager.....	49
Add a Reagent in Mix Group	51
Specify Mixing Properties	52
Volume Calculation for Mixing Reagents	53
Inventory Manager	55
View Reagents	55
Add Reagents	56
Delete Reagents and Clean Inventory	57
Print Labels in Inventory Manager	57
Register Reagents in Inventory Manager	58
Protocol Manager	59
Protocol Manager Features	60
Create a Protocol.....	61
Create a New Protocol.....	61
Create a Protocol from a Template.....	62
Create a Protocol from a Selected Protocol.....	63
Chapter 6: Prepare and Start a Run.....	64
Process Overview 1.....	64
Process Overview 2.....	64
1. Login	65
Home Screen.....	65
2. Prepare Slides.....	66
Prepare and Edit Slides	66
Add, Delete and Copy Slides from Slide Manager	67

Import Slides from Slide Manager	69
Save Slides for a Later Run	70
3. Print Labels	71
View and Print Reagent Worksheet	72
4. Scan Slides.....	73
5. Prepare and Load Reagents	75
6. Scan or Map Reagents	76
7. Pre-Start Checklist.....	77
8. Start Staining	79
Slide and Reagent Information	79
Reagent Information.....	80
Run Complete.....	80
Clear the Completed Trays.....	81
Map Slides.....	82
1. Login	82
2. Map Slides	83
3. Manually Assign Slides	84
4. Load Labeled Slides	85
5. Prepare and Load Reagents	85
6. Scan or Map Reagents.....	86
7. Pre-Start Checklist	88
8. Start Staining	89
Chapter 7: System Cleaning.....	90
Daily	90
Weekly	90
Program Cleaning	91
Weekly Slide Tray Cleaning	92
Monthly.....	93
Clean AR Carboys.....	95
Drain the Secondary Containment Sump.....	95
Additional Cleaning of the Instrument	95
Chapter 8: Troubleshooting	96
Printer Port Connections	96
Changing Printer Labels and Ribbons.....	96
Staining Performance	97
Mechanical.....	97
Electrical.....	99
Operating Errors.....	99
Appendix- Quick Start Guides.....	102
Quick Start Guide 1-Instrument Preparation	102
Instrument Preparation	102
Quick Start Guide 2-Creating a Protocol	103
Quick Start Guide 3-Preparing Slides	104
Quick Start Guide 4-Process Overview	105
Process Overview 1.....	105
Process Overview 2.....	105
Appendix- Electrical Labels	106

Definitions, Acronyms and Abbreviations:

Name	Description
AR	Antigen Retrieval
DAB	3, 3' Diaminobenzidine
DePar	Deparaffinization (also called Dewaxing).
DI Water	Deionized Water
FFPE	Formalin Fixed Paraffin Embedded
HIER	Heat Induced Epitope Retrieval
HRP	Horseradish Peroxidase
IHC	Immunohistochemistry
IF	Immunofluorescence
L	Liters
LED	Light Emitting Diode
mL	Milliliter
mm	Millimeter
Probe dispense range	The minimum and maximum reagent volume that can be dispensed by an instrument.
PPE	Personal Protective Equipment
Pollution degree	Pollution degree measures how much conductivity is in the air including dry pollution and condensation which determines how close to each other conductive parts can be in the instrument.
RT	Room Temperature (20°C-25°C)
µL	Microliters
UE	Unhandled Exception

Chapter 1: Introduction

Intended Use

This manual is intended for use by clinical, research, industry and reference laboratory personnel who use the VALENT Automated Staining Platform to perform immunohistochemistry (IHC) staining. This manual describes how to operate the VALENT using the VALENT Software and will assume users have been trained and have a basic understanding of IHC procedures.

About the VALENT Automated Staining Platform

The VALENT is Biocare Medical's highest-capacity, fully-automated, open-architecture slide stainer designed to perform high-quality and consistent IHC staining in lieu of manual staining methods without the variability. However, the VALENT retains the ability to integrate established manual staining protocols with an automated platform for ease of use with minimal optimization. The VALENT incorporates on-board deparaffinization and heat-induced antigen retrieval, while expanding capacity to 48 slides and shortening turn-around-time compared with other auto-stainers.

Limitation of Use

The optimum antibody dilution and protocol for a specific application can vary due to different factors. These may include, but are not limited to: tissue fixation, antigen retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of Biocare Medical's reagents, the recommended incubation times and titers listed in product data sheets are not applicable to other detection systems as results may vary and will have to be optimized by the user. The datasheet recommendations and protocols are based on exclusive use of Biocare Medical products. Ultimately, it is the responsibility of the investigator to determine optimal staining protocol conditions. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

VALENT Specifications

Catalog Number	VLT8101
Slide capacity	48
Independent slide trays	4 trays, 12 slides per tray
Refrigerated reagent & mixing vial rack	44 positions, 20mL vials; Temperature range: room temperature to 10°C below room temperature
Antigen retrieval temperature range	Room temperature to 98°C at sea level
Reagent dispensing volume	300µL
Probe dispense capacity	300µL -14.4mL (48 slides x 300µL/slide)
DePar dispense volume per slide	1mL
Bulk reagent carboys	4
Waste carboys	2
Waste separation	Separates hazardous and non-hazardous
Unit control	One instrument per computer
Electrical requirements	Power input: 1800W (1800VA) / Power source: 100-120 VAC, 50/60Hz The VALENT cannot be used without the VALENT Cart. Power supplied to the VALENT from the VALENT Cart may reach 3600W@ 120V. The use of a dedicated circuit capable of delivering a minimum of 1850W continuously with less than 5% voltage sag is required for the instrument.
Instrument dimensions	40"W X 24"D X 26"H / 102cm W X 61cm D X 66cm H
Instrument weight	245lbs / 111.1 kg

VALENT Cart Specifications

Catalog Number	VLT8102 (50Hz), VLT8103 (60Hz)
Bulk reagent carboys	Six carboys, 8L capacity per carboy.
Secondary containment capacity	11L maximum capacity
Electrical requirements	Power output: 3600W(3600VA) Power source: 100-120 VAC 50/60 Hz Requires a step-down transformer rated for 2kW for operation using 220V mains (not supplied). Cart must be factory-configured for 50Hz operation. Do not plug anything into the VALENT Cart besides the computer and label printers.
VALENT Cart dimensions	40"W X 24"D X 30"H / 102cm W X 61cm D X 77cm H
Cart weight	250lbs / 113.4 kg
Undervoltage and overvoltage protection	The VALENT Cart is protected from undervoltage/overvoltage conditions by internal relays built into the inverter/charger which will limit input voltage to 85-140VAC. Operation is prevented if input voltage is outside the specified range. NOTE: All cart circuit breakers must be in the OFF (down) position before disconnecting the power cord from the cart or the wall outlet. Failure to do so may cause the batteries to run down and necessitate a service call.

Reagent Vial Label and Slide Label Printers

The VALENT Software is compatible with Microsoft Windows 10 and will have all computer system software pre-installed. The system also includes two TSC TC310 Thermal Transfer Printers. One printer is required for slide labels and the second printer is required for reagent vial labels.

Report Printer

Please see manufacturer's specifications.

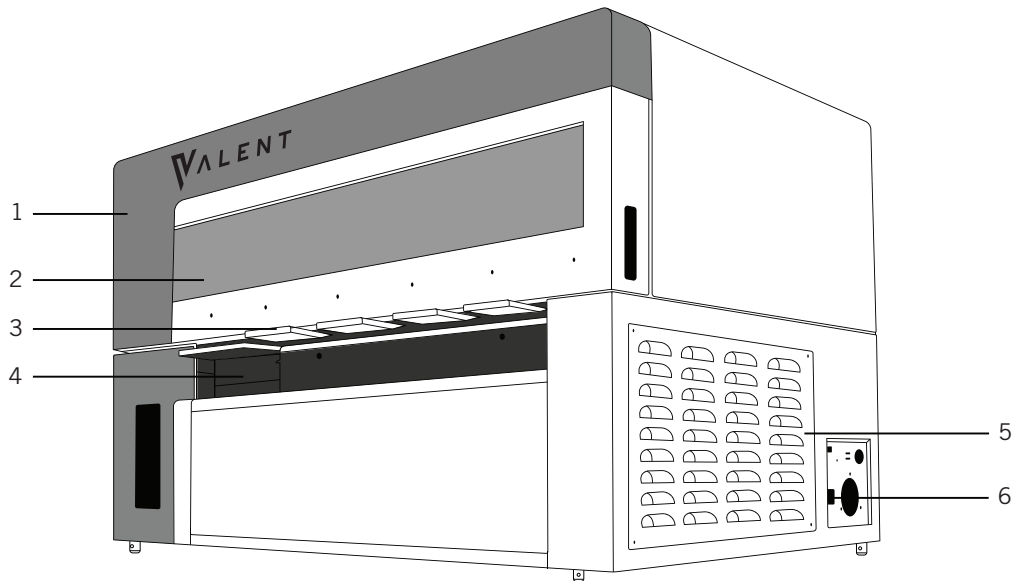
USB Flash Drive

The VALENT Software allows for the transfer of data to a USB external drive.

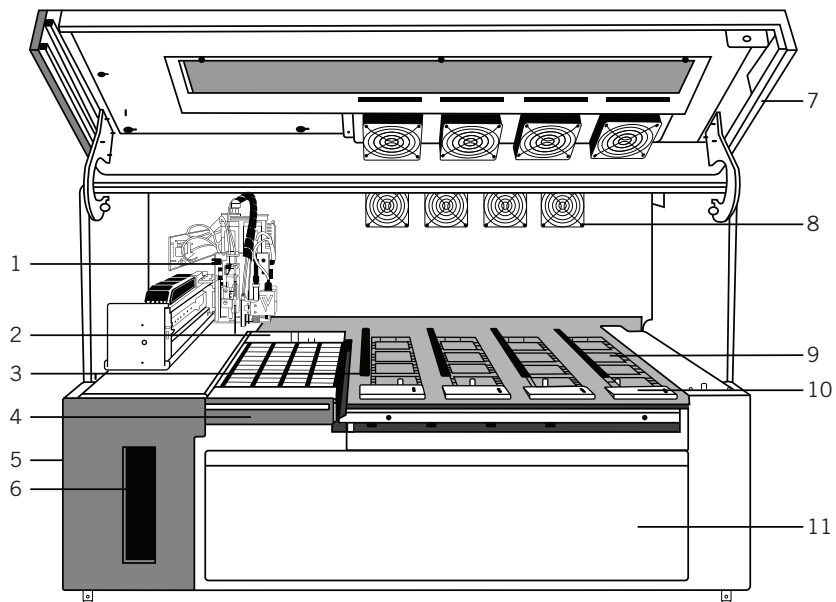
Warranty

The VALENT warranty is for one year from date of installation and covers all parts and labor when service is performed solely by Biocare Medical Field Services Personnel. The warranty is invalidated if equipment is abused, damaged, misused, or improperly maintained by the customer, as determined by Biocare Medical at its sole discretion. The 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.

VALENT Components



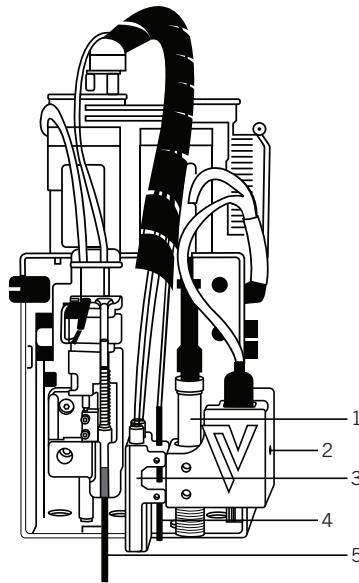
- 1. System Lid
- 2. Window
- 3. Slide Trays
- 4. Reagent Rack
- 5. System Board Cover
- 6. Power Switch



- 1. Z-head
- 2. Probe Wash Station
- 3. Dispense Manifold
- 4. Reagent Rack
- 5. Val DePar (Side)
- 6. Syringe Pump

- 7. System Lid
- 8. Fans (8 Total)
- 9. Troughs (Below Slide Tray)
- 10. Slide Trays (4 Total)
- 11. Service Panel

Z-Head Schematic



A probe schematic which includes a separate probe for Val DePar, reagent and Wash-Blow-Wash.

1. Liquid Level Sensor
2. Barcode Camera
3. Wash-Blow-Wash
4. Val DePar Probe
5. Reagent Probe

VALENT Cart Components

Carboy Connections



Image of carboy connection panel.

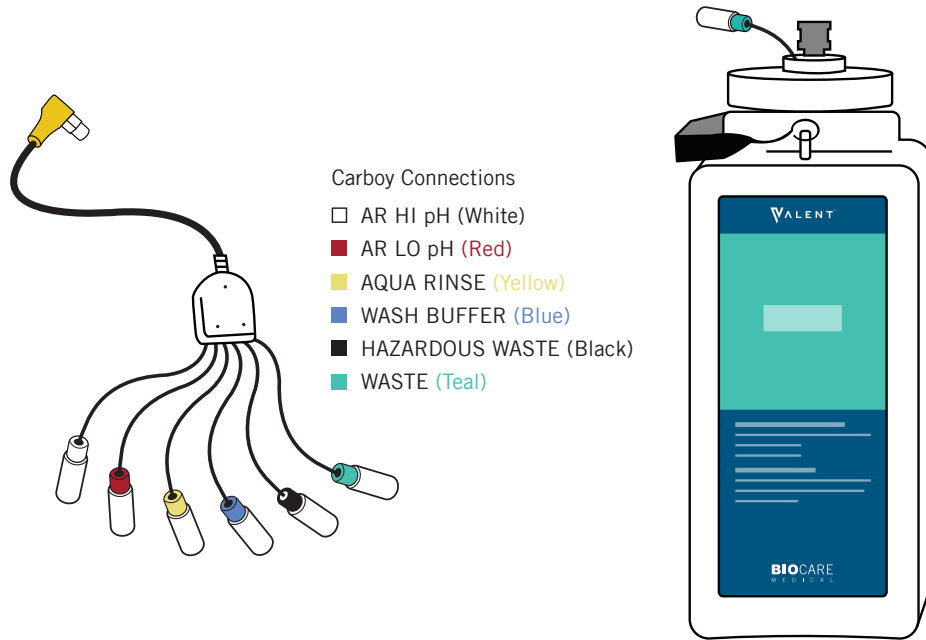
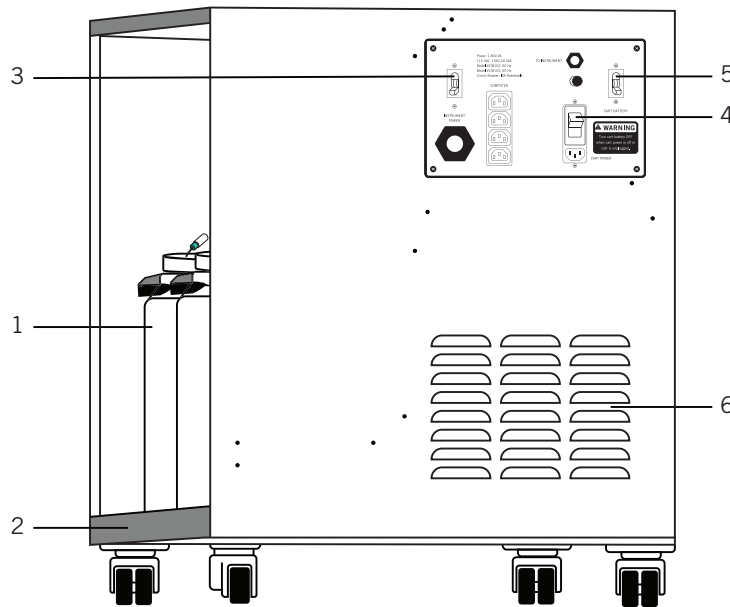


Image of a carboy and carboy sensor cables



Side view of the VALENT Cart displaying electrical connections.

1. Carboys
2. Secondary Containment
3. Instrument Power Circuit Breaker
4. Cart Power Circuit Breaker
5. Battery Circuit Breaker
6. Air Vents

NOTE: All cart circuit breakers must be in the OFF (down) position before disconnecting the power cord from the cart or the wall outlet. Failure to do so may cause the batteries to run down and necessitate a service call.

VALENT Description of Parts

Parts	Description
Independent slide trays	<p>The VALENT includes four removable stainless steel slide trays, each with a 12-slide capacity. The slide trays secure the slides firmly in a horizontal position at all times during the staining run. The slide trays can be removed from the instrument for loading slides, and then reinserted, without opening the system lid.</p> <p>There is an LED sensor which, when RED, indicates the slide tray is locked in place and may not be removed. When the LED turns green, the slide tray may be removed or reinserted. The LED is off when a slide tray is removed from the instrument.</p>
System lid	<p>The VALENT system lid operates with a gas strut motion control system which allows access to the work surface. The system lid automatically locks at the start of a run. The lid must be closed during the operation of the instrument. The system lid status can be viewed from the VALENT Software Home Screen or by the LED light (red if locked, green if unlocked).</p>
Syringe pump	<p>The syringe pump is a positive displacement pump used for aspiration and dispensing of reagents on slides, for mixing reagent components and probe washing.</p>
Fans	<p>The internal fans are designed to reduce humidity and temperature during heated antigen retrieval. There are a total of 8 fans in the upper chassis, 4 intake fans are located on the VALENT system lid and 4 exhaust fans are located on the back panel of the VALENT. The fans operate in different combinations and automatically turn on and off during AR. In addition, there are five fans in the lower chassis to cool the componentry following AR.</p>
Reagent rack	<p>The reagent rack is a stainless steel rack with 44 vial positions for 20mL VALENT vials, this rack can slide in and out of the instrument without opening the system lid. The reagent rack is cooled throughout the run keeping reagents below room temperature. Each reagent rack is calibrated to a specific instrument and can't be substituted for another reagent rack.</p>
Reagent vials	<p>All vials have a 20mL capacity with a screw cap and a 50µL dead volume. Vials can be filled with the volume specified by the selected protocol or with excess volume in preparation for use in a subsequent run.</p> <p>The VALENT will mix designated reagents in empty 20mL VALENT vials when online mixing is selected. Do not re-use mixing vials; always use new, clean mixing vials to prevent contamination and/or staining artifacts. The VALENT Software automatically calculates a 50µL dead volume for all mixing vial reagents.</p>

Z-head	<p>The Z-head, (see Figure 1c), is mounted on the Y-arm that moves along the horizontal left/right X-axis inside 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. The reagent probe employs a high-accuracy dispense mechanism which gently dispenses reagents across a slide in a manner that avoids any tissue disruption.</p> <p>Liquid Level Sensor: The ultrasonic level sensor detects the reagent volume level. The system will provide a visual alarm 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>Barcode camera: The barcode camera, is used for scanning slide and reagent barcodes and is capable of Optical Character Recognition (OCR) and image recognition. The barcode camera ensures that the correct vials and slides are in place to prevent errors. Additionally, the barcode camera allows the software to alert the user if reagent vial caps are still mistakenly left in place before a run starts.</p> <p>Wash-Blow-Wash Nozzle: In a single pass, the nozzle applies a layer of Aqua Rinse or Wash Buffer, followed immediately by a curtain of air to blow off the wash, and then a second layer of Aqua Rinse or Wash Buffer to wash a second time. This occurs at each rinse step and also at preset intervals to keep slides from drying out during the holding time before the start of a run. The air nozzle removes excess liquid from a slide before applying reagents by blowing air across the entire width of the slide.</p>
Probe wash station	The probe wash station is located next to the Z-head park position and is used to wash the reagent probe. The reagent probe is cleaned in the wash station throughout a run.
Bulk reagents and carboys: Antigen Retrieval (AR), Aqua Rinse and Wash Buffer	<p>AR-Hi pH, AR-Lo pH, Wash Buffer and Aqua Rinse Carboy assemblies have liquid level sensors to detect volume levels. The carboys allow for a nominal volume of 8L with 1L of dead volume. If there is insufficient Wash Buffer or Aqua Rinse in the carboy assemblies, the instrument will not initiate the staining process.</p> <p>Check the levels of the bulk reagents before each run, replenish and reset if indicated by the VALENT Software during the staining process. The required volumes for each run are calculated by the VALENT Software and displayed during the programming process.</p>
Bulk mixing carboys	10L bulk mixing carboys are used for preparing bulk reagents which include Wash Buffer, Aqua Rinse and Antigen Retrieval. Bulk reagents prepared in these bulk mixing carboys will be transferred to the 8L bulk reagent carboys on the VALENT Cart.
Waste storage	The VALENT separates hazardous and non-hazardous waste. A non-hazardous waste 8L carboy and a hazardous waste 8L carboy are provided for accumulated waste collection. The actual amount of waste volume generated will depend on the number of slides programmed per run and staining protocol. The required available volumes for each run are calculated by the VALENT Software and displayed during the programming process. Both waste carboy volumes should be checked and emptied as needed before starting a staining run.
Dispense Manifold	There is a dispense manifold for each trough that dispenses AR and Aqua Rinse onto the slide.
Troughs	There are four troughs on the VALENT, located below the slide trays, that are used for the antigen retrieval step and draining reagents to waste.
DePar	A mineral oil based deparaffinization reagent is held in a 500mL bottle located to on the left side of the VALENT.
Window	The VALENT has a red window to prevent photobleaching of fluorochromes.

Storage and Handling

Reagents

Always follow manufacturers' instructions for storage and handling of reagents. To prevent contamination, follow good laboratory practices of sterile technique when opening, diluting, and decanting all solutions. When not in use, store Biocare Medical reagents at the recommended storage conditions as specified in the data sheets to maintain reagent stability.

Instrument Environmental Conditions

Placement	Indoors, away from direct sunlight and extreme heat or cold.
Operating temperature range	15-30°C (59-86°F); Recommended: 20-24°C (68-75°F) for optimal staining results.
Storage temperature range	10-40°C (50-104°F)
Transport temperature range	0-50°C (32-122°F)
Maximum relative humidity	80%, non-condensing
Humidity	Maximum relative humidity 80%, non-condensing
Ventilation	Do not block the vent openings on the VALENT. Leave a minimum of 2 inches 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 reagents not specified by Biocare Medical.
Recommended maximum altitude	6562 feet Lower boiling temperature and a higher evaporation rate must be considered for labs in a higher elevation. For example, if the optimal temperature for antigen retrieval is 98°C with an elevation below 1500 feet, the antigen retrieval temperature may have to be optimized if the elevation is above 3750 feet.
Pollution degree 2	Normally only nonconductive pollution occurs. Temporary conductivity caused by condensation is to be expected.
Positioning the VALENT	The right side of the instrument and VALENT Cart must be positioned at a minimum of 8 inches from any wall or other obstruction to allow access to all power switches and cables. There must also be adequate clearance to allow disconnecting of the cart power cable from the main wall receptacle.
Main supply voltage fluctuations	±5%
Overvoltage category	Category II
Specification of heat transfer media suitable for use	All heat transfer media are water-based reagents with high or low pH buffer salts and a mineral oil based DePar reagent. No other media is allowed during heat cycle.

Humidity

During Antigen Retrieval humidity levels may increase and create condensation, to prevent this the lab should have an operational HVAC system.

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

Waste Disposal

Some of the reagents used on the VALENT may be hazardous, and must be disposed of properly in accordance with local regulations. The lab should determine from the Safety Data Sheets (SDS) for a given reagent whether the reagent is hazardous. The VALENT can be programmed to separate waste streams for chromogens considered to be hazardous. The carboy used for this waste stream is marked "Hazardous Waste." This carboy must only be used solely for hazardous waste in order to avoid unnecessarily increasing the volume of any hazardous waste.

In the event a spill of hazardous materials occurs inside the instrument, unplug instrument from the cart and unplug the VALENT Cart from the wall outlet. **NOTE: All cart circuit breakers must be in the OFF (down) position before disconnecting the power cord from the cart or the wall outlet. Failure to do so may cause the batteries to run down and necessitate a service call.** The user is required to use PPE which may include a lab coat, gloves, and safety glasses. Use disposable absorbent material to soak up small spills. Follow approved lab procedures for handling larger spills. Refer to appropriate Safety Data Sheets for proper handling of reagents. The VALENT Cart has built-in secondary containment for bulk reagent spills with a 11L maximum capacity. If spills occur inside the instrument contact Biocare Medical's Technical Support before reconnecting the power.

Instrument Disposal

If the VALENT is to be removed from service and disposed of, the instrument must be disinfected using Lysol IC Quaternary Disinfectant Cleaner through the fluid delivery and waste systems. Similarly, all exposed surfaces must be disinfected using 10% Professional Lysol IC Quaternary Disinfectant Cleaner before it is disposed of in accordance with local, state and federal regulations.

The VALENT Cart batteries should be re-cycled or properly disposed of in accordance with local regulations.

Site Installation Requirements

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

Note: The VALENT weighs approximately 245lbs and must be handled from the bottom of each side of the chassis by two people or more who are safely capable of lifting the specified weight. Do not lift the instrument from the system lid, doing so will cause damage to the VALENT and void the warranty.

If the VALENT is placed on a laboratory bench, the bench must be solid, vibration-free with a flat area, capable of safely supporting the weight of the instrument. Additional consideration must be made for a minimum clearance of 2 inches on all sides for ventilation and room for an all in one computer, keyboard and mouse next to the instrument. The label and report printers for the VALENT may be located anywhere that allows them to be connected to the instrument. Biocare Medical will provide a cart for the computer and printers. Nothing may be placed on top of the VALENT.

The use of a dedicated circuit capable of supplying a minimum of 1850W continuously is required for proper operation. Do not connect the cart to the same circuit as other equipment, lighting, or any other electrically operated devices.

Support

To contact Biocare Medical Technical Support by telephone, please call 1-800-799-9499, Option 3 or email Technical Support at techsupport@biocare.net.

Chapter 2: Safety Precautions

Recommended Use

The VALENT is designed for use with FFPE tissue samples. Fresh (unfixed) tissue may contain infectious organisms, infectious sample use is limited to tissues/specimens that are specified in Biocare Medical's product data sheets. Handle control slides and test 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 Medical for use on the VALENT are classified as hazardous. These must always be used according to the manufacturer's instructions and good laboratory practices. Always wear PPE such as gloves, eye protection and a protective lab coat when handling any chemical solution used on the VALENT, and when cleaning the VALENT or emptying waste carboys. Obtain a Safety Datasheet (SDS) from the manufacturer for each reagent. Do not use any chemicals on the VALENT other than those specified. Biocare Medical offers Val Clean, an acid alcohol-based cleaning solution for the removal of hematoxylin residue. Danger from hazardous fumes, fire or explosion may result with the possibility of injury to the operator or damage to the instrument.

It is the user's responsibility not to use decontamination or cleaning agents, other than specified in this manual. Contact Biocare Medical Technical Support before using unspecified cleaning agents.

Reagent Rack

Always use both hands when loading and unloading the reagent rack. Using both hands, one hand holding reagent rack from the front and the other hand from the bottom, load the reagent rack with filled reagent vials in the correct orientation; the reagent rack handle should be towards the front of instrument, facing the user. Reagent vials must have the label positioned toward the front of the VALENT, facing the user. When unloading a reagent rack once a run is complete, the bottom of the reagent rack may be cold, use a paper towel or other absorbent material to hold the reagent rack from the bottom. Tipping of the reagent rack may result in injury if the rack is not securely placed in its designated position, or handled securely during transport.

Instrument Safety Guidelines

1.	Use only the authorized VALENT Software program that is supplied with the instrument, or authorized software updates.
2.	Do not install any other software applications onto the VALENT's dedicated computer system. This may cause an unexpected operation of the VALENT or corrupt the operating software and will void the instrument warranty.
3.	Do not switch off power to the computer until the VALENT Software is properly closed.
4.	Do not turn off power to the VALENT until all motion has stopped and the robotic arm is in the home position.
5.	The system lid of the VALENT must be closed before operation will begin.
6.	Do not attempt to remove reagent rack or slide trays while the system lid is locked during a run.
7.	Keep carboy assemblies below the level of the VALENT.
8.	Proper cleaning is important for the reliable operation of the VALENT. Follow the recommended cleaning procedures in Chapter 7.
9.	The robotic arm must be stopped before the VALENT's system lid can be opened. The status of the system lid can be viewed from the VALENT Software Home Screen.
10.	Do not place your hands, fingers or other body parts underneath the VALENT, this may cause injury.

Programming Cautions

To help prevent false positive or false negative results ensure all staining protocols are programmed correctly. If unexpected results occur, check the programming first. The VALENT provides the option to enter patient information for each slide. Make sure to enter the correct patient identifier information for each slide.

Lithium Battery

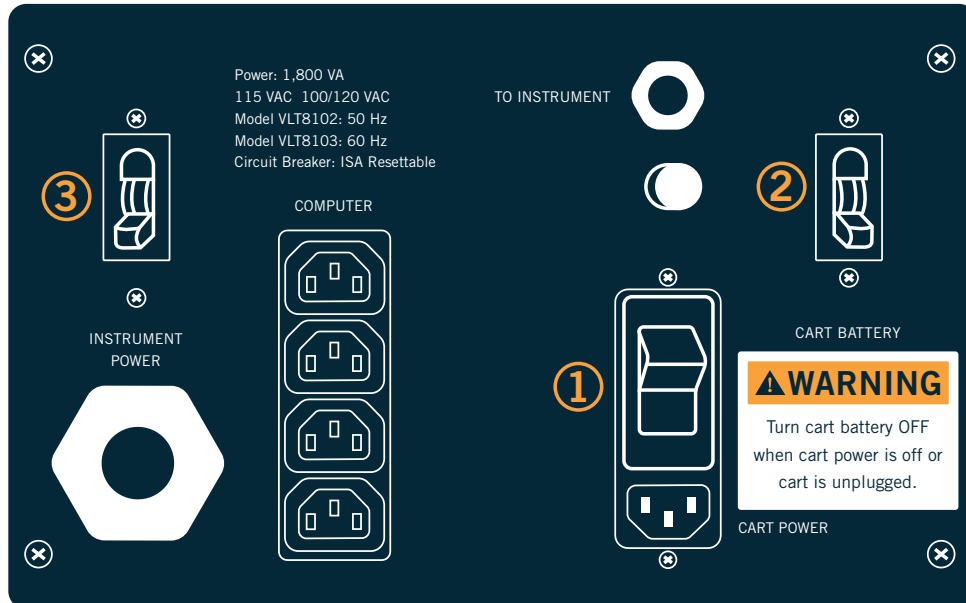
This device contains one or more Lithium Iron Magnesium Phosphate Batteries. The batteries should not be opened or burned. The batteries are safe with normal use. Exposure to the ingredients contained within and or their combustion products could be harmful. Risk of exposure occurs only if the battery is mechanically, thermally, or electrically abused to the point of compromising the battery enclosure. If the battery enclosure is compromised, exposure to the electrolyte solution contained within can occur by inhalation, ingestion, eye contact and skin contact. More information is available from the manufacture of the battery, LithiumWerks.

Safely Turning on the Cart

If the VALENT Cart has to be switched on or off, the instrument must be switched on or off in a specific order to avoid system failure. Instances where the instrument cart may need to be turned on or off include:

- When moving the instrument to a different location.
- If there has been a power outage and the instrument requires proper shut down.
- When the user does not plan to use the instrument for at least two weeks or longer a week or more.
- If the VALENT Software and/or printers are not functioning appropriately.

Turn ON the Cart



1. Turn On the Cart Power Circuit Breaker
 2. Turn On the Cart Battery Circuit Breaker
 3. Turn On the Instrument Power Switch Circuit Breaker
- Confirm that all circuit breakers on the side of the cart are in the OFF (down) position, (refer to the diagram above.)
 - Confirm that the cart is plugged into a dedicated electrical outlet capable of supply at least 1850W continuously.
 - Confirm that the 30A instrument power umbilical from the cart is connected to the receptacle on the right side of the instrument.
 - Confirm that the battery sense cable from the cart is connected to the receptacle on the right side of the instrument.
 - Turn on the cart power circuit breaker, which is the white switch located on the electrical panel on the right side of the cart.
 - Wait 60 seconds for the battery charger to sense wall power.
 - Turn on the cart battery circuit breaker, which is the black switch located on the right side of the panel.
 - Immediately after the cart battery circuit breaker is turned on, the battery charger fan inside the cart will be audible for approximately 5 seconds, indicating the charger has turned on.
 - If the charger does not turn on, toggle the cart battery circuit breaker off and then back on again until the charger turns on.
 - Turn on the instrument power switch circuit breaker, which is the black switch located to left of on the left side of the panel.
 - Turn on the instrument using the large white power switch on the right side of the instrument.
 - Turn on the computer.

Turn OFF the instrument

















Turning off the instrument is the reverse order as turning on instrument:

- Exit out of software, then turn off the computer.
- Turn off the instrument using the large white power switch on the right side of the instrument.
- Turn off the instrument power circuit breaker which is the black switch located on the left side of the cart panel.
- Turn off the cart battery circuit breaker which is the black switch, located on the right side of the panel.
- Turn off the cart power circuit breaker, which is the white switch on the cart panel.

NOTE: All cart circuit breakers must be in the OFF (down) position before disconnecting the power cord from the cart or the wall outlet. Failure to do so may cause the batteries to run down and necessitate a service call.

Symbols Glossary

The following symbols may appear on the instrument label:

	Warning. Biohazardous materials may be present. Personal protection is required.	Attention. Des matières biologiques dangereuses peuvent être présentes. Une protection individuelle est requise.
	Warning. Electrical shock hazard.	Attention. Risque de choc électrique.
	CE Marking	Marquage CE
	In-Vitro Diagnostic Medical Device	Dispositif médical de diagnostic in vitro
	Manufacturer	Fabricant
	Serial number	Numéro de série
	Consult instructions for use (consult operating instruction).	Consultez les instructions d'utilisation (consultez le mode d'emploi).
	Electrical Earth Ground	Terre électrique
	Main Power (ON/OFF)	Interrupteur Principal (ON / OFF)
	Caution. Surface may be hot.	Attention. La surface peut être chaude.
	Warning. Pinch Point. Keep hands and fingers clear.	Attention. Risque de pincement. Gardez les mains et les doigts éloignés.
	Caution, consult accompanying documents.	Attention. Reportez-vous au manuel de l'utilisateur.
	On (Power)	Allumer
	Off (Power)	Éteindre
	Identification of Authorized Representative in the European Community.	Identification du représentant autorisé dans la Communauté européenne
	Caution, 3 kg, potential heavy equipment.	Attention, 3 kg, équipement lourd potentiel.
	Heavy object.	Objet lourd.

Chapter 3: VALENT Software Features & Functions

This chapter is intended to familiarize the user with the VALENT Software's key features, providing details of all operation modules available to administrators and regular users.

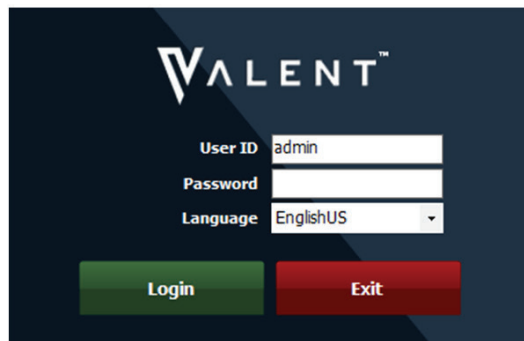
User Access

There are two levels of access for users of the VALENT Software: regular user and administrator. Users with administrator privileges have access to all screens available to regular users, but have some additional privileges that will be discussed in this chapter. Screens used by both users are described in this chapter. The VALENT Software can only have one administrator with an 'Admin' user id but there can be many administrator level users.

Login

To log in, double-click the VALENT icon on the desktop, enter the User ID and Password in the dialog box, select Language, and click Login to continue.

Note: Default User ID is **admin**, default password is **valent**.



Home Screen



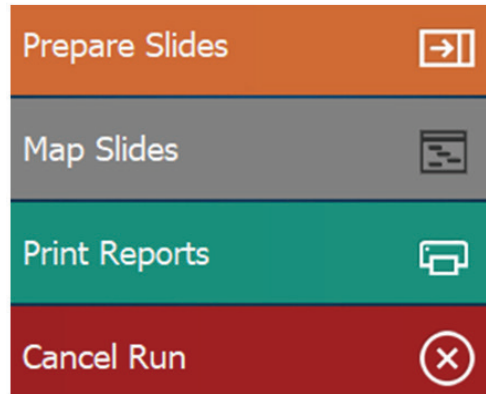
1. Menu Bar
2. Run Designation Buttons
3. Run End Time
4. Reagent Rack
5. System Lid Status
6. Reagent Rack Lock/Unlock Status
7. Reagent Rack Temperature
8. Carboy Status
9. Slide Tray Position
10. Slide Tray Lock/Unlock Status
11. Slide Tray Status

Home Screen Features

	Name	Function
1.	Menu Bar	Select from the menu bar to navigate instrumental functions and access information.
2.	Run Designation Buttons	Allows user to Prepare Slides, Map Slides, Print Reports or Cancel Run.
3.	Run End Time	Displays the run end time.
4.	Reagent Rack	The reagent rack is a stainless steel rack with 44 positions for 20mL vials that can easily slide in and out of the instrument. The reagent rack remains below room temperature throughout a run. Use the mouse cursor to hover over a reagent vial to view reagent information during a run.
5.	System Lid	Displays whether system lid is opened or closed.
6.	Reagent Rack Lock/Unlock Status	Displays whether the reagent rack is locked or unlocked.
7.	Reagent Rack Temperature	Displays the temperature of the reagent rack to ensure reagents are stored at an acceptable temperature range.
8.	Carboy Status	<p>The carboy status indicates if there is sufficient DePar, Aqua Rinse, Antigen Retrieval (AR) and Wash Buffer available in the bulk reagent carboys. The carboy status also displays the amount of non-hazardous waste and hazardous waste in the carboy.</p> <p>A reminder will be displayed when bulk reagent carboys are low and when waste carboys need to be emptied.</p>
9.	Slide Tray Position	The VALENT Software displays the location of each slide on the slide tray numbered from 1-12. Hovering over a mapped slide allows the user to view slide information and protocol during a run.
10.	Slide Tray Lock/Unlock Status	Displays whether a slide tray is locked or unlocked. Slide trays are locked during a run.
11.	Slide Tray Status	The VALENT Software displays the slide trays and the slide positions graphically on the user interface. The slide trays are designated A-D. Tray status indicates whether the tray is in process (red) or available (green).

Run Designation Buttons

Run Designation Buttons on the Home Screen provides access to Prepare Slides, Map Slides, Print Reports and Cancel Run. These options allow the user to quickly and seamlessly start a run.



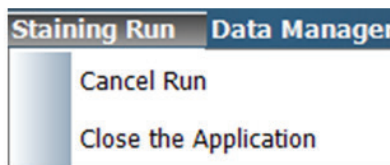
Action Buttons	Description
Prepare Slides	This option is the starting point to preparing a run; add, copy, delete or import slides for a run, and select or modify protocols.
Map Slides	Allow assignment of protocol or prepared slides by manually mapping to a specific tray location.
Print Reports	View and print IHC Summary, IHC Report, IHC Short Report and Protocol Validation.
Cancel Run	Allows user to abort a run. This button is red when a run is in process.

Menu Bar

The menu bar in the upper left corner of the VALENT application's main screen and provides access to a number of functions.

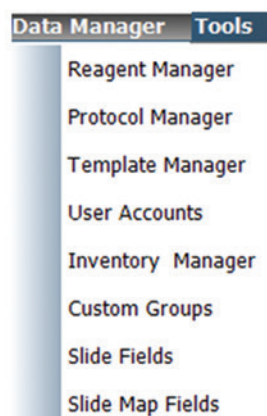
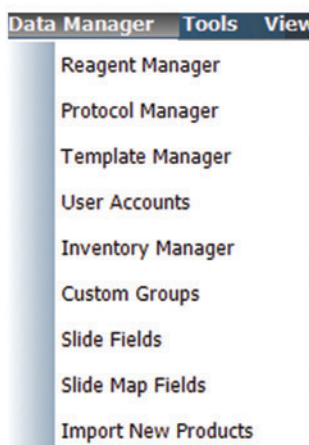
Staining Run

Staining Run allows the user to Cancel Run or Close the Application.



Data Manager

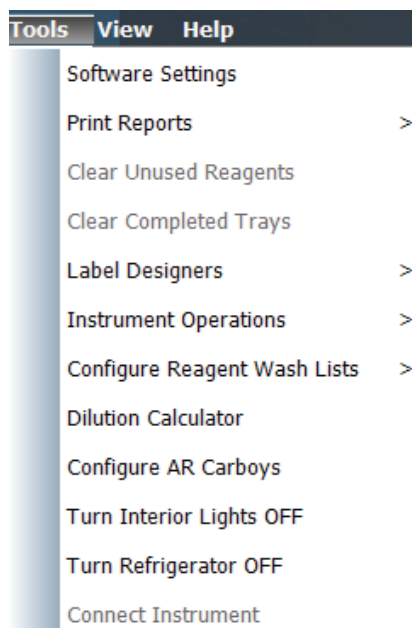
Data Manager allows the user to access reagent lists, inventory, protocols, templates, user accounts, custom groups, and slide information.



Function	Description
Reagent Manager	Add new reagents, modify existing reagents and print reagent labels.
Protocol Manager	Design, edit and manage protocols.
Template Manager	Design, edit and manage detection templates.
User Accounts	Create new user accounts and modify existing accounts.
Inventory Manager	Enter and track reagent lot, expiration, starting volume, current volume, and lot number to be used on the instrument.
Custom Groups	Allows the laboratory to create groups of protocols under Group Manage, frequently used by the laboratory rather than having to scroll through all the protocols.
Slide Fields	Slide Fields allows the user to create, edit and manage data fields that may be associated with a slide.
Slide Map Fields	Slide Map Fields is the information that shows up on mapped slides on the Home Screen.
Import New Products	Upload new Biocare product data to the VALENT software. Please contact your local Biocare Medical representative for details on new product availability.

Tools

Tools allows the user to access the instrument functions listed below.



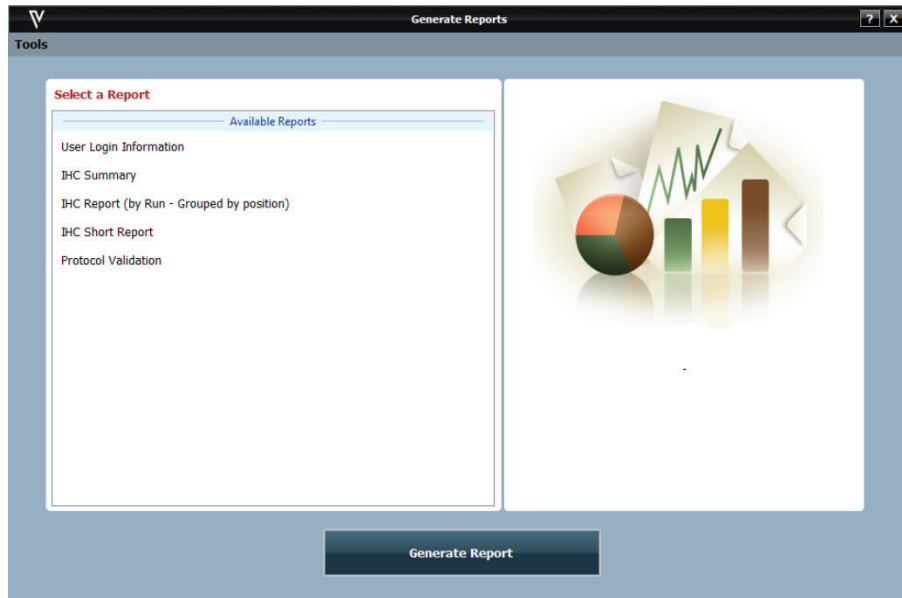
Function	Description
Software Settings	This feature allows the administrator to set preference and default parameters. VALENT Software settings can be entered manually or accessible from a dropdown menu.
Print Reports	Print Reports allows the user to print out Slide Layouts, Reagent Layouts, Run Logs, and Reagent Worksheets. The user can also print to PDF. Several IHC Reports and Protocol Validation can be accessed through the Report Generator.
Clear Unused Reagents	Removes reagent vials from the reagent rack that are no longer needed for the staining run. This option is only accessible after a run is complete.
Clear Completed Trays	Releases the slide tray from instrument and allows the user to remove the slide trays.
Label Designers	Slide and reagent labels can be edited under Label Designers.
Instrument Operations	Allows the user to perform routine maintenance such as: Drain Waste, Prime Buffers, System Cleaning, Reset Carboys and Read Sensors.
Configure Reagent Wash Lists	The user can add reagents that require special handling for decontamination to the Configure Reagent Wash List to signal a cleaning step to help prevent contamination in the probe.
Dilution Calculator	Automatically calculates how to dilute a stock solution of known concentration to the required working concentration.
Configure AR Carboys	Allows the user to assign an antigen retrieval (AR) solution to the two designated AR Carboys. Biocare Medical's antigen retrieval solutions include AR-Lo pH 6.2 and AR-Hi pH 9.5.
Turn Interior Lights On/Off	Select this function to turn interior lights on or off.
Turn Refrigerator On	Allows user to turn reagent rack refrigeration on. The refrigerated rack keeps reagents below room temperature throughout a run.
Connect to Computer	Allows computer and instrument to communicate.

Print Reports

Use the Print Reports button to view and print the following reports: IHC Summary, IHC Report, IHC Short Report and Protocol Validation.

There are two ways to print reports:

- The Print Report button is displayed on the left side of the Home Screen.
- Print Reports can be accessed through the Tools dropdown menu.
 - From Tools select Print Reports then go to Report Generator. Click the desired report parameter then click the Generate Report button.



Report	Description
IHC Summary Report	Provides a summary of all the slides that were stained in a run along with the protocol used for each slide.
IHC Report	Provides a detailed summary of all the slides within a case with the protocol for each slide.
IHC Short Report	Provides a brief summary of all the slides within a case with the protocol for each slide.
Protocol Validation Report	Provides a report for a protocol indicating all the steps, along with the reagents used, a comment section, and a sign off section for pathologists.

Configure Reagent Wash Lists

The Configure Reagent Wash Lists is composed of a Contamination List, PrepWash List and Aqua Rinse Wash List. Adding reagents to these lists according to the three conditions explained below will prompt the probe to undergo a ValPrep washing to ensure the probe is clean in order to prevent contamination. ValPrep 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 Home Screen, go to the menu bar and select Tools, then click Configure Reagent Wash Lists and select from Contamination Lists, PrepWash List or Aqua Rinse Wash List.

Contamination List and PrepWash List

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

Use the PrepWash List to add reagents that require the probe to be pre-washed with ValPrep 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 activate the ValPrep 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

To add reagents to the Contamination List, select the reagent to be added from the Reagent List and click the green arrow facing right to add to Contamination List. To delete a reagent from the list, select the reagent to be deleted and green arrow facing left.

PrepWash List

To add reagents to the PrepWash List, select the reagent to be added from the Reagent List and click the green arrow facing right to add to the PrepWash List. To delete a reagent from the list, select the reagent to be deleted and click the green arrow facing left.

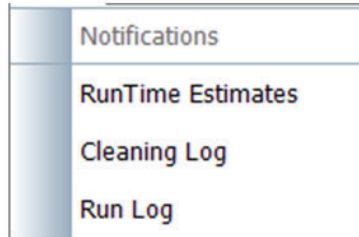
Aqua Rinse Wash List

The Aqua Rinse Wash List is intended for reagents that may have staining quality affected when exposed to buffer before aspiration. When a reagent is added to the Aqua Rinse Wash List, the probe is primed with Aqua Rinse before aspirating the reagent in the Aqua Rinse Wash List.

To add reagents to the Aqua Rinse Wash List, go to Tools-> Configure Reagent Wash Lists-> Aqua Rinse Wash List and select the reagent to be added from the Reagent List and click the green arrow facing right to add to Aqua Rinse Wash List. To delete a reagent from the list, select the reagent to be deleted and click the green arrow facing left.

View Menu

The View dropdown menu allows access to Notifications, Run Time Estimates, Cleaning Log and Run Log. Notifications is not accessible unless there is a notification to view.



Notifications

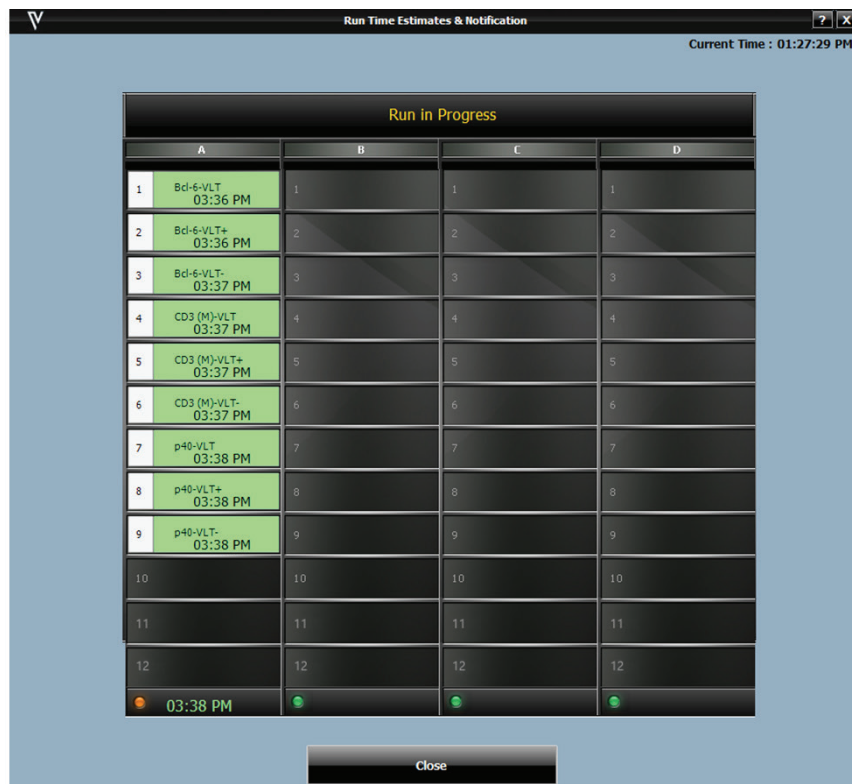
If a problem occurs during the run, the VALENT Software will display a notification. The Notification Details window will appear with a description of the action required and the slide(s) affected. Follow prompts on the screen to clear the notification.

Run Time Estimates

When a staining run is started the run end time is estimated.

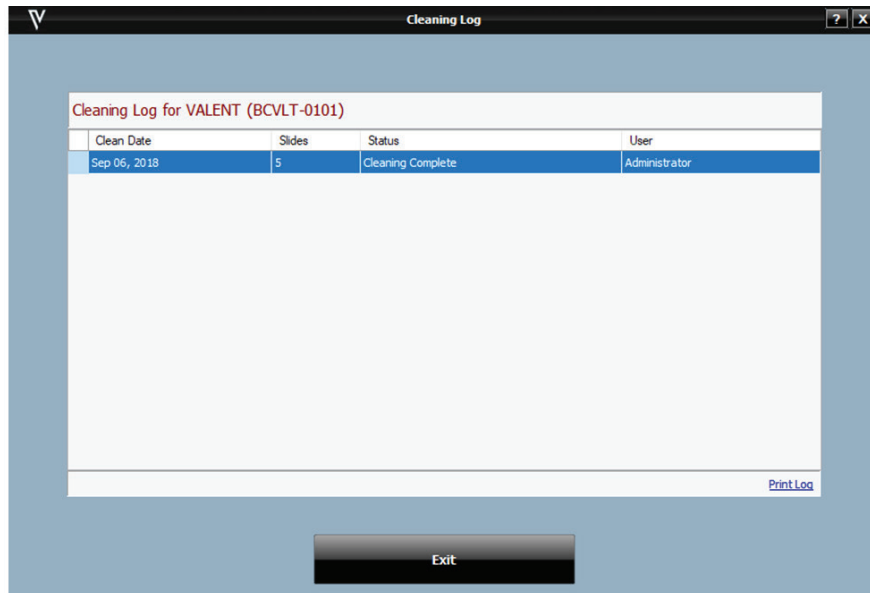
Run time estimates can be viewed two ways:

- Run Time Estimates can be found on the top of the main screen, above the reagent rack display. The time the run is expected to end is displayed. Separate run end times for each slide tray can be found above each slide tray.
- Run Time Estimates can also be viewed via the menu bar by selecting View and Run Time Estimates. This will display the estimated run end time for each slide and for each slide tray.



Cleaning Log

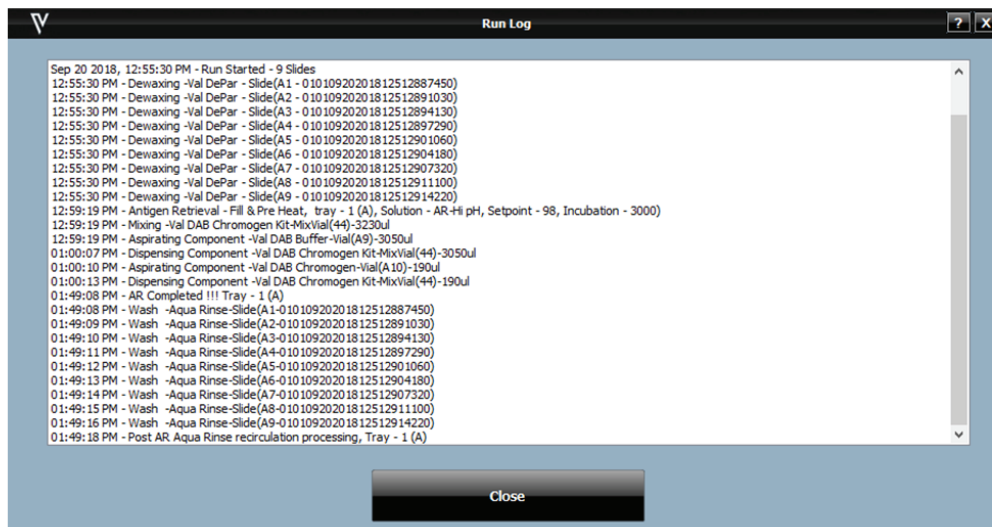
The cleaning log displays the date the system was cleaned, how many slides since its last cleaning and the user who performed the cleaning. Click Print Log, located at the bottom right of Cleaning Log window for a copy of the Cleaning Log.



Run Log

The Run Log documents the time, date, instrument ID & serial number, VALENT Software version, and run name. The Run Log also displays all operations performed by the instrument. As an operation is performed, the log is updated.

The Run Log can be viewed during a run or immediately after a run is completed otherwise the Run Log option will be grayed out not allowing access until the next VALENT run.



Help

The Help dropdown menu allows the user to:

- View the product name and product version.
- Access the VALENT User Manual.
- Provide Technical Support contact information.

Chapter 4: Program Preparation & Setup

Administrator Program Preparation & Setup

Administrators can follow the detailed steps in this chapter to add or change users, passwords, reagents, and protocols.

Summary of Administrator vs. Regular User Profile

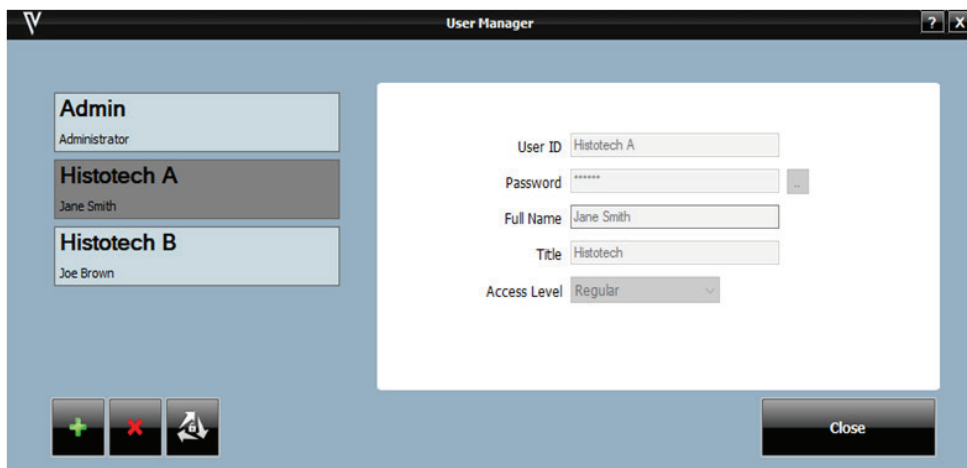
Below is a summary of the features that are available for an administrator and a regular user.

Action Buttons	Administrator	Regular User
Reagent Manager	Add, modify or delete reagents.	Add, modify or delete reagents.
Template Manager	Add, modify or delete template protocols.	Modify templates only, adding and deleting templates is restricted.
Software Settings	Set Instrument Parameters, Notifications and Alarms.	No Access Allowed.
User Accounts	Add, delete or modify accounts including passwords.	Change password.

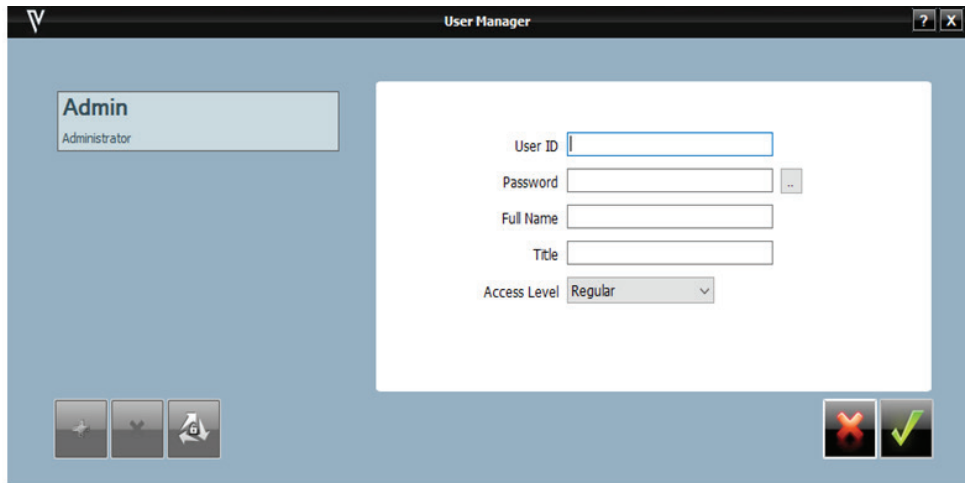
Assign or Modify Users

Only administrators can assign or modify user accounts. Regular users can only modify their passwords.

- From the Home Screen select Data Manager and click User Accounts.
- The User Manager window will appear.
- To add a new user, press the green Add (+) button at the bottom left side of the screen.



- Enter the appropriate user information and click Save (green check mark).

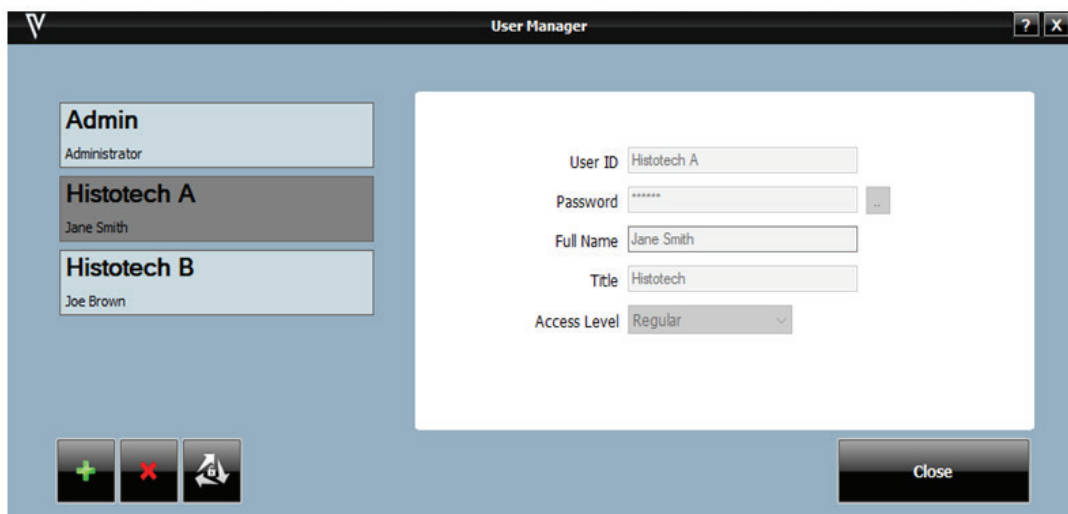


User Information Guideline

User Information	Description
User ID	This must be unique. The system does not require a specific naming convention and is at the discretion of the user.
Password	This must be unique. The system does not require a specific naming convention and is at the discretion of the user. There is a minimum of 6 characters required and a maximum of 15 characters.
Full Name	Enter user's first and last name. 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 to administrator or regular user.

Modify a User Account

To modify an account or password, select the appropriate account and press Delete (X) or Edit (3 gray arrows) button at the bottom left side of the screen.



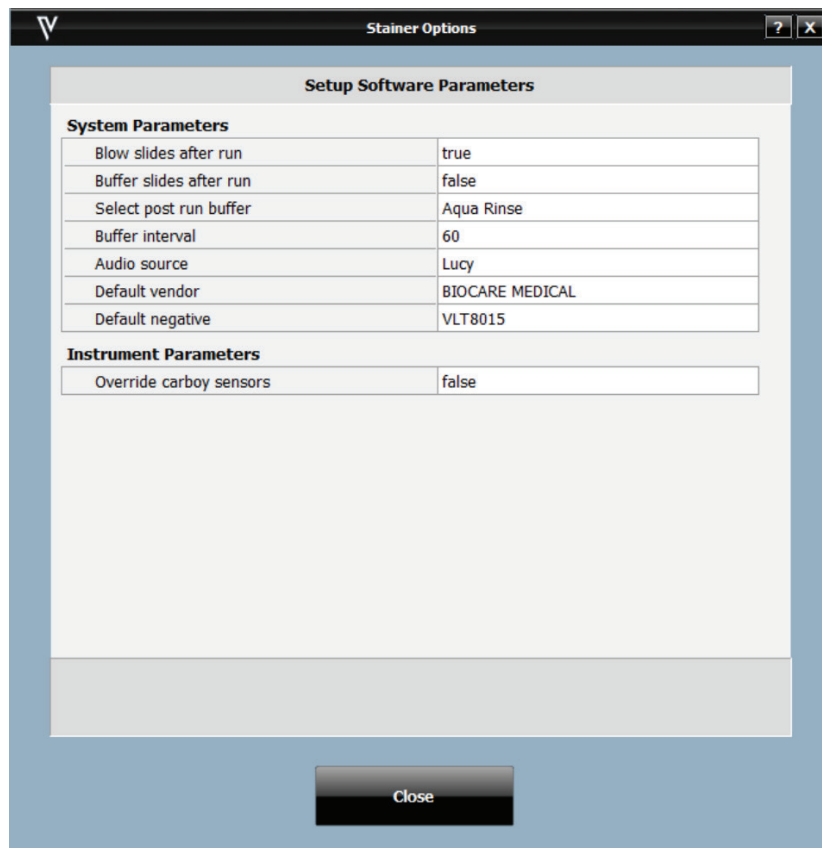
Modify Passwords

Administrators and regular users may change their password through User Accounts.

- From the top right side of the Data Manger dropdown menu select User Accounts.
- From the User Manager window, select the edit button located at the bottom left (3 gray arrows) button.
- Update the password information and click Save (green check mark) to proceed.
- Click Close to close window.

Software Settings

Software Settings can be accessed from the menu bar under Tools. This feature allows the administrator to set preferences and default parameters. Software settings are selected from dropdown menus. There are two parameters listed: System Parameters and Instrument Parameters. When the user clicks on a parameter, a description of it will appear at the bottom of the window.



System Parameters

Under System Parameters, the user can adjust the parameters listed below.

Parameter	Description
Slides After Run	Select True or False. If True is selected, slides are air dried after a run. If False is selected, slides will not be air dried.
Buffer Slides After Run	Select True or False. If True is selected, buffer will be applied to slides after the run completes at the designated interval. If False is selected, slides will air dry after the run completes.
Select Post Run Buffer	Designates either Buffer or Aqua Rinse to be applied if Buffer Slides After Run is set to True.
Buffer Interval	Time in minutes between buffering of slides after run completion. Valid range is between 15 and 30 minutes.
Default Vendor	Default Vendor is Biocare Medical. This is displayed when creating a new reagent in Reagent Manager.
Default Negative	The Val Universal Negative Control is catalog number VLT8015

Instrument Parameters

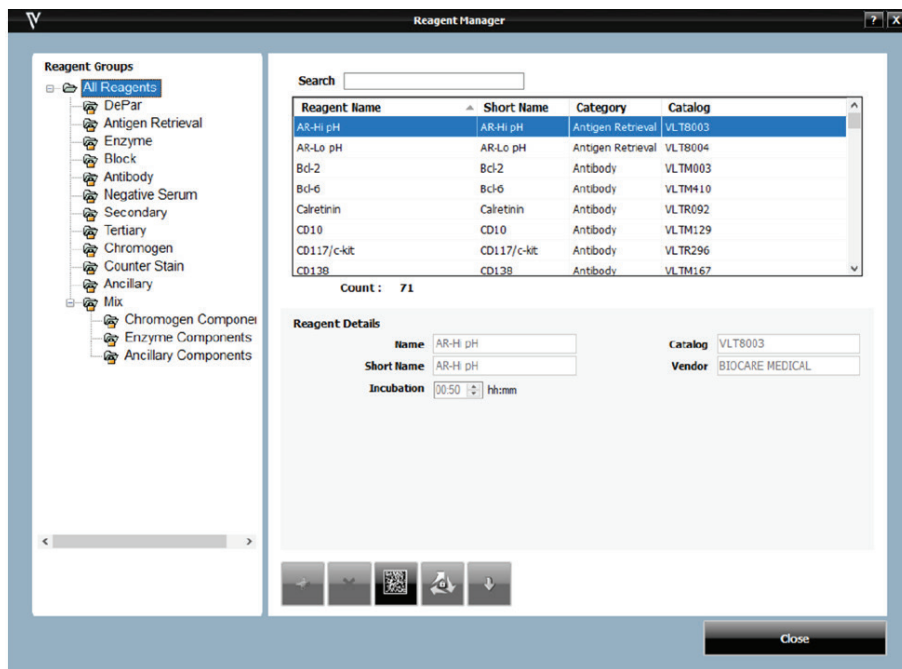
Instrument parameters should not be modified by the user. Please call Technical Support for assistance.

Reagent Manager

Reagent Manager is used to add new reagents, modify or delete existing reagents by both regular users and administrators. Reagent Manager can be accessed from the menu bar.

Reagent Groups

Reagent Groups, listed on the left side of the screen, are reagent categories including: DePar, Antigen Retrieval, Enzyme, Block, Antibody, Negative Serum, Secondary, Tertiary, Chromogen, Counter Stain, Ancillary and Mix.



DePar

The user is required to use Biocare Medical's DePar and cannot edit this group

Antigen Retrieval

The user is required to use Biocare Medical's Antigen Retrieval Solution and cannot edit this group

Enzyme

This group is used to add, modify and delete enzymes.

Block

This group is used to add, modify and delete blocking solutions.

Antibody

The antibody reagent group allows the user to enter new primary antibodies. This selection will allow the addition, modification and deletion of antibodies.

At the bottom of the Reagent Details box:

Designate the appropriate fields that are linked to the primary antibody of interest. For reference purposes, the user has the option to indicate the Clone, Species, Diluent and Comments associated with the antibody of interest.

Negative Serum Group

The Negative Serum reagent group is used 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 using the negative serum linked to the antibody.

Secondary Group

This group is used to add, modify, and delete secondary reagents.

Tertiary Group

This group is used to add, modify, and delete tertiary reagents.

Chromogen Group

The Chromogen reagent group is used to add, modify, and delete chromogens. The Chromogen reagent group offers greater detail than other reagent groups, and allows the user to program mixing of chromogens online. The user can also specify if a reagent is stable or unstable if added under Chromogen Components under the Mix Group.

Counter Stain Group

The Counter Stain reagent group includes all counter stains. This screen will allow the addition, modification, and deletion of counterstains.

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 if added under Ancillary Components under the Mix Group.

Mix Group

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

Display Reagent Information

- Use the search field at the top of the Reagent Manager window to quickly find a reagent under the selected Reagent Group.
- 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.

Reagent Manager

Reagent Groups

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

Search

Reagent Name	Short Name	Category	Catalog
AR-Hi pH	AR-Hi pH	Antigen Retrieval	VLT8003
AR-Lo pH	AR-Lo pH	Antigen Retrieval	VLT8004
Bcl-2	Bcl-2	Antibody	VLTM003
Bcl-6	Bcl-6	Antibody	VLTMM10
Calretinin	Calretinin	Antibody	VLTR092
CD10	CD10	Antibody	VLTM129
CD117/c-kit	CD117/c-kit	Antibody	VLTR296
CD138	CD138	Antibody	VLTM167

Count : 71

Reagent Details

Name: Catalog:

Short Name: Vendor:

Incubation: h:mm

←
→
📄
🔄
↓






Close

Template Manager

Template Manager allows an administrator to modify or delete templates. Regular users can edit current templates under Template Manager but cannot add or delete templates.

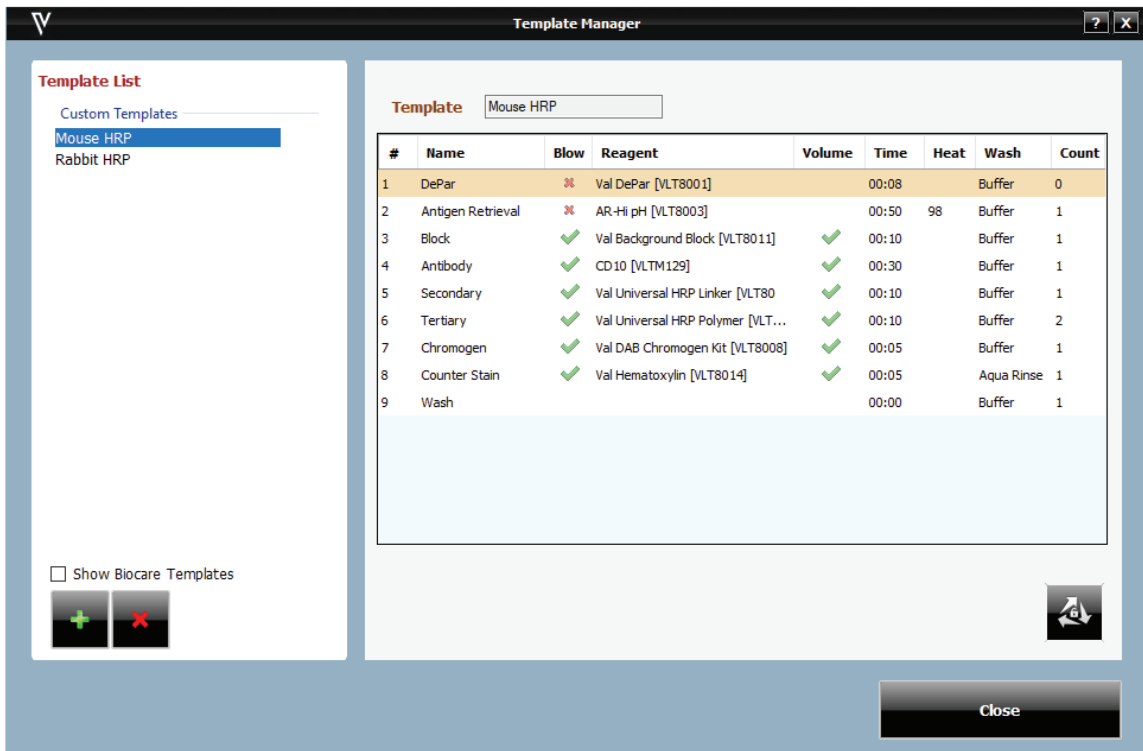
Important Note: When creating or editing a protocol from an existing template, click out of the current cell and to a different cell to lock in the changes.

Description of Template Manager Icons

Icon	Description	Icon	Description
	Add a new step at the end of a protocol.		Move up the selected step in a protocol.
	Delete a step at the end of the protocol.		Move down the selected step in a protocol.
	Insert a new step before the selected step in a protocol.		

Creating a Template from a Blank Template

- From the Home Screen, go to Data Manager, then select Template Manager.
- To the bottom left under Protocols, select Add (+), to add new template.

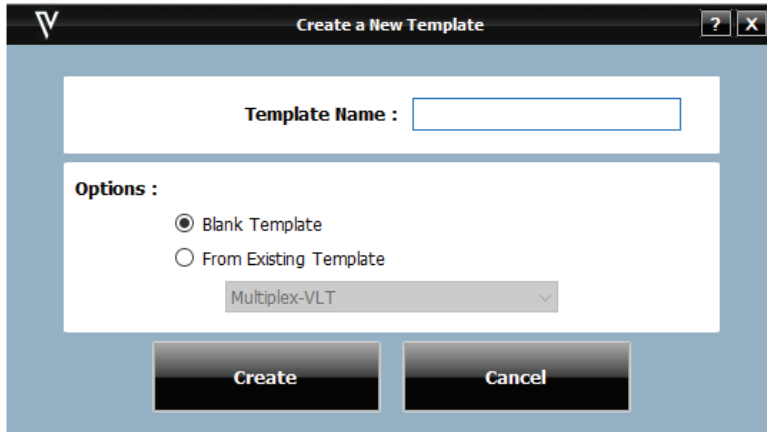


The screenshot shows the 'Template Manager' window. On the left, there is a 'Template List' section with a search bar and a list of templates: 'Custom Templates', 'Mouse HRP' (selected), and 'Rabbit HRP'. Below the list are two icons: a green plus sign and a red minus sign, and a checkbox labeled 'Show Biocare Templates'. The main area displays the details for the 'Mouse HRP' template. At the top, there is a 'Template' dropdown menu with 'Mouse HRP' selected. Below this is a table with the following columns: '#', 'Name', 'Blow', 'Reagent', 'Volume', 'Time', 'Heat', 'Wash', and 'Count'.

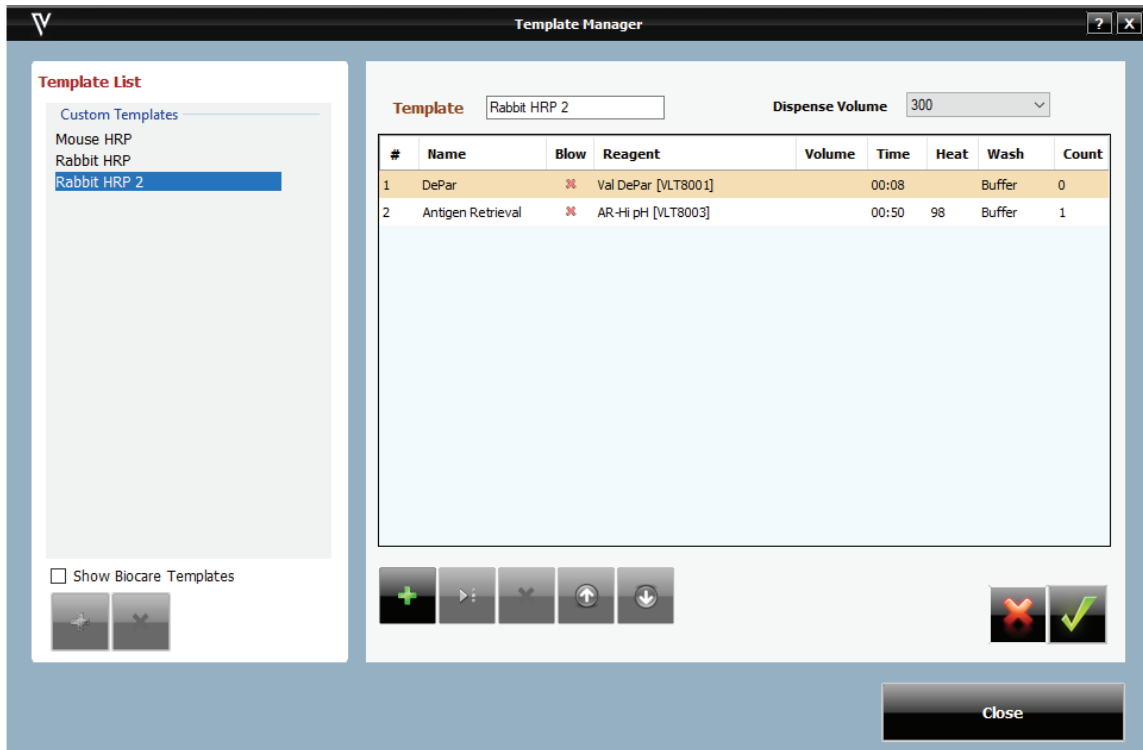
#	Name	Blow	Reagent	Volume	Time	Heat	Wash	Count
1	DePar	✘	Val DePar [VLT8001]		00:08		Buffer	0
2	Antigen Retrieval	✘	AR-Hi pH [VLT8003]		00:50	98	Buffer	1
3	Block	✔	Val Background Block [VLT8011]	✔	00:10		Buffer	1
4	Antibody	✔	CD10 [VLT80129]	✔	00:30		Buffer	1
5	Secondary	✔	Val Universal HRP Linker [VLT80	✔	00:10		Buffer	1
6	Tertiary	✔	Val Universal HRP Polymer [VLT...	✔	00:10		Buffer	2
7	Chromogen	✔	Val DAB Chromogen Kit [VLT8008]	✔	00:05		Buffer	1
8	Counter Stain	✔	Val Hematoxylin [VLT8014]	✔	00:05		Aqua Rinse	1
9	Wash				00:00		Buffer	1

At the bottom right of the main area, there is a 'Close' button.

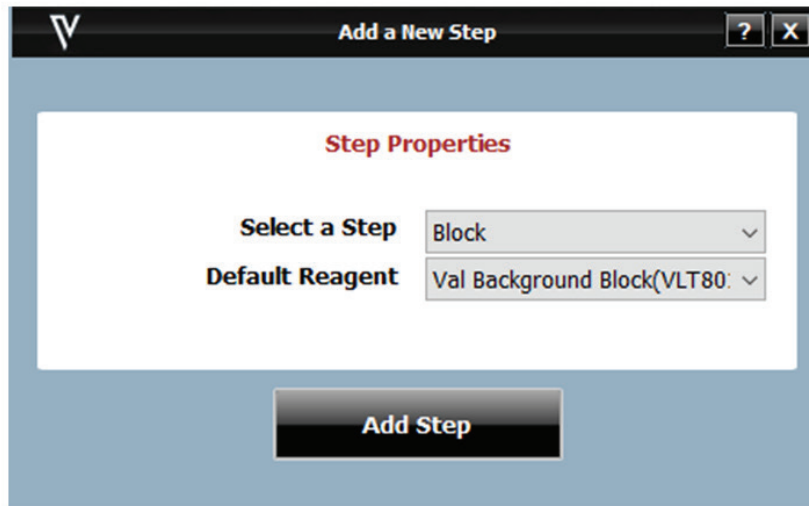
- A Create New Template window will appear.



- In the Template Name field, type in the name of the new template.
- Under Options, select Blank Template.
- Click Create.



- Select Add (+) located at the bottom of the window, this opens the Add a New Step window.



- Using the dropdown menu Select a Step along with the reagent required for this step, then click Add Step.
- Continue adding steps to protocol by selecting Add (+) button. Use the icons to create a template.
- Once all steps are added, the user can program time, select reagents from a dropdown menu, (to add reagents go to Reagent Manager). The user can select the number of washes required in each step under Count. Blow can be switched on or off by selecting the red (X) for OFF or the green check mark for ON. Turning off Blow will leave any fluid from the previous step on the slide (including Pre-Rinse).
- When finished editing protocol, click Save (green check mark) and Close.

Create a Template from an Existing Template

- From the Home Screen, go to Data Manager, then select Template Manager.
- To the left under Protocols, select Add (+), to add new template.
- Under Options, select From Existing Template to use a current template and make modifications. A dropdown menu is provided to allow the user to select a template.
- In the Template Name field, type in the name of the new template.
- Click create and use the icons to create a template.
- Once all steps are added, the user can program time, select reagents from a dropdown menu, (to add reagents go to Reagent Manager). The user can select the number of washes required in each step under Count, with a maximum of 3 washes per step. Blow can be switched on or off by selecting the red (X) for OFF or the green check mark for ON. Turning off Blow will leave any fluid from the previous step on the slide (including Pre-Rinse).
- When finished editing the template click Save (green check mark) and Close.

Delete and Modify Templates

- From the Home Screen, go to Data Manager, then select Template Manager.
- To delete a template, under Custom Templates, select the template to be deleted then click the (X) button to delete.
- Click Yes in the Confirm window.
- To edit a template, under Custom Templates, select the template to be edited then click Edit (3 gray arrows) button to make the necessary edits.

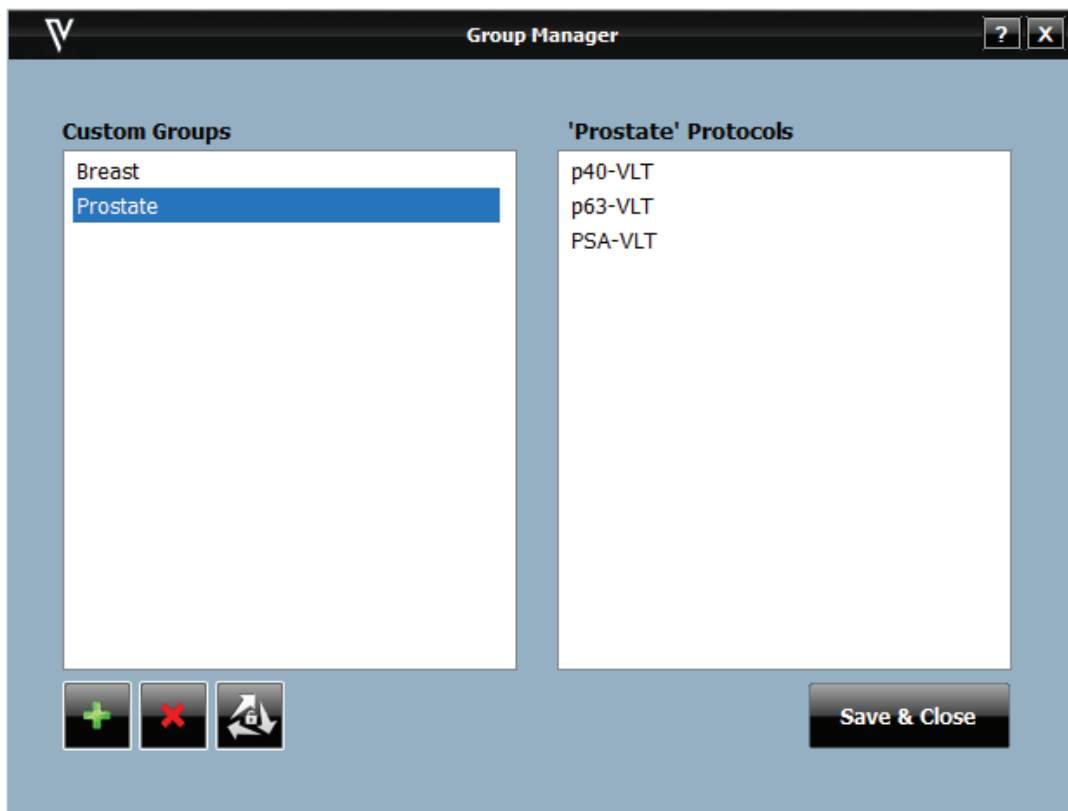
Additional Program Preparation & Setup

Custom Groups

Custom Groups allows the laboratory to create groups of protocols frequently used by the laboratory rather than having to scroll through a list of protocols

How to Create a Custom Group

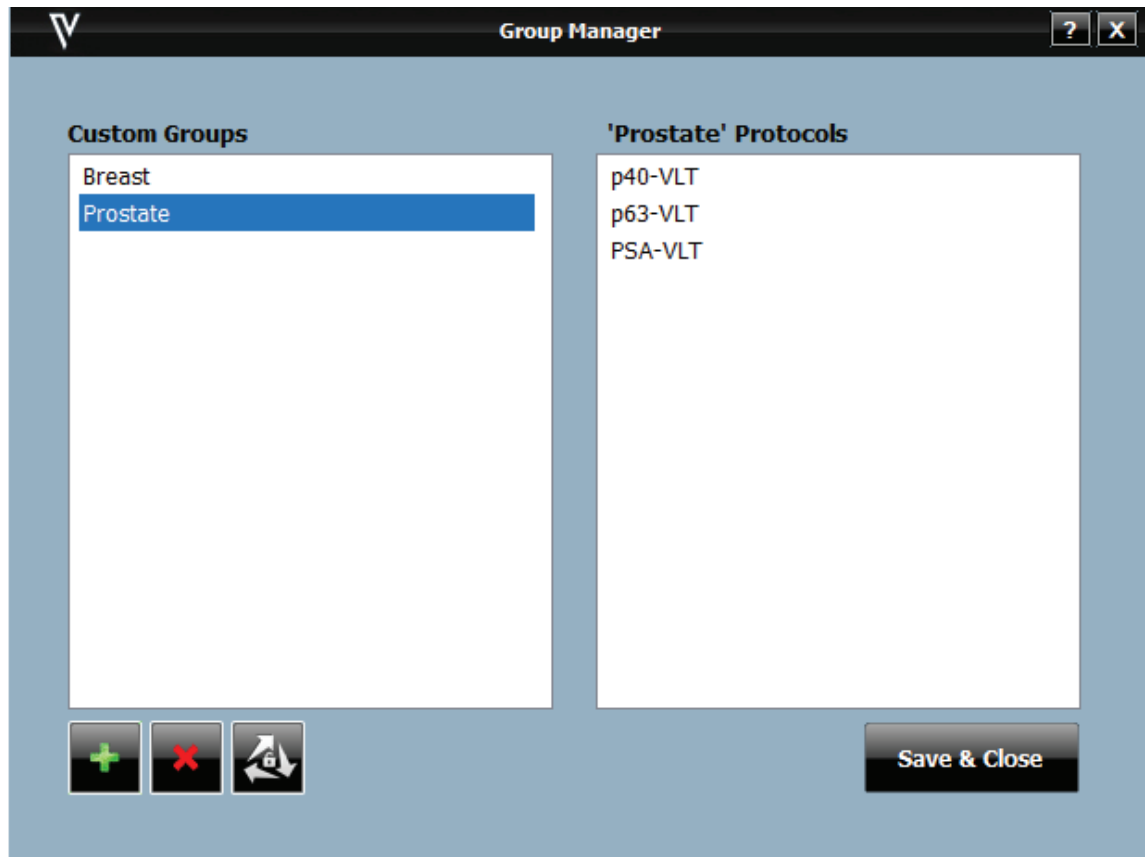
- From the Home Screen, go to Data Manager, then select Custom Groups.
- The Group Manager window will appear.
- On the bottom left of the screen click the Add (+) button and name the Custom Group.



- Name the Custom Group in the group tab.
- From Master Protocols list, select the protocols to be added to the Custom Group and click the arrow facing right to add to Assigned Protocols.
- To remove a protocol from the Assigned Protocols list, select the protocol then click the left arrow.
- Click Close to save and exit the window.

Delete a Custom Group

- From the Home Screen, go to Data Manager, then select Custom Groups.
- The Group Manager window will appear.
- From the Group Manager window the user can delete a Custom Group by selecting the Custom Group and clicking the red X button.



Edit a Custom Group

- The user can also edit a Custom Group by selecting the Custom Group and clicking Edit(3 gray arrows) button.
- Use the green arrows to add and delete protocols in the Custom Group. Select the protocol to be added then click the green arrow button pointing right. To delete, select the protocol to be deleted then the green arrow button pointing left.
- Click Close to exit and save.

Slide Fields

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.

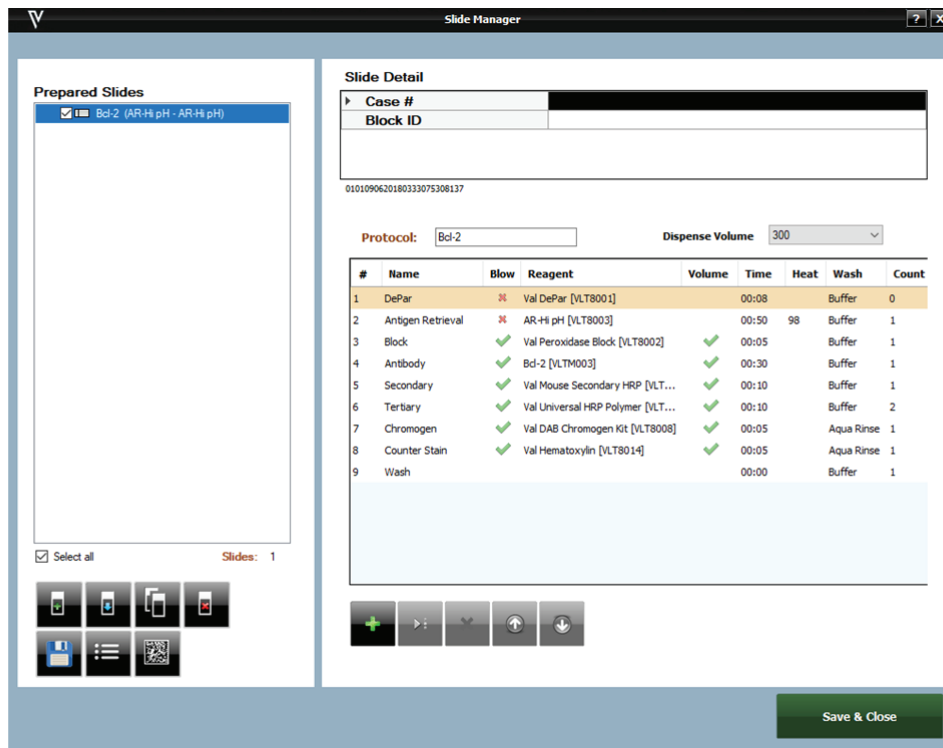
- From Data Manager on the Home Screen, choose Slide Fields. The Design Slide Fields window will open.



- Use the Add (+) button to add fields.
- Use the Delete (X) button to delete fields.
- Each Case Field has the following properties:
 - o Name: The name of the field that can be referenced by other parts of the program.
 - o Display Text: The text that appears in the Slide Details section of Add Slides, Slide Manager and Assign Slides to identify the field.

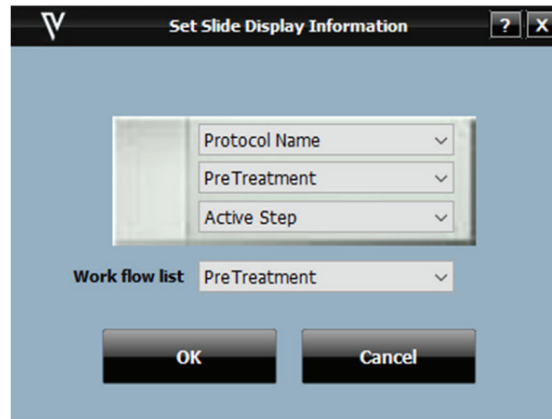
Slide Fields are displayed in the Slide Details section of the Add Slides window.

Slide Fields are also displayed in the Slide Details section of the Slide Manager window.

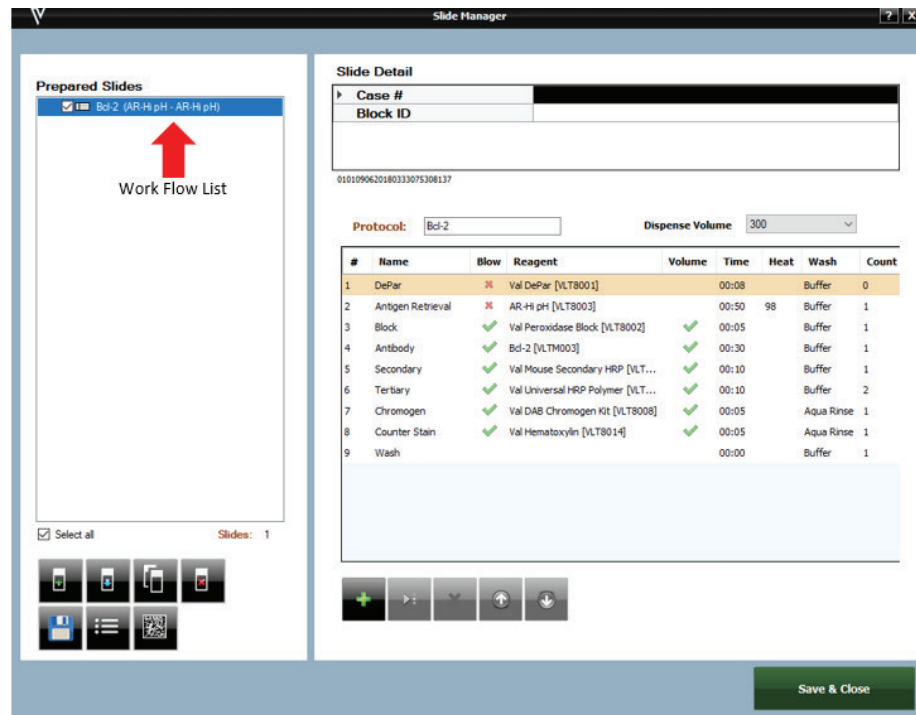


Slide Map Fields

- Slide Map Fields is located in the Data Manager dropdown menu of the Home Screen. Upon selection, the Set Slide Display Information window will open.
- There are 4 configurable fields:
 - Top Line
 - Middle Line
 - Bottom Line
 - Work flow list
- These fields refer to the text that is displayed in the 2 or 3 lines of the Slide Image of a mapped slide on the Staining Main Screen.



- In each of the 4 fields, choose from the following options in the drop down menu: Case#, Protocol Name, Primary Antibody, PreTreatment, Active Step or Block ID.
- The Work Flow List is a display option that will appear in parenthesis by the slide's protocol under Prepared Slides in both Slide Manager and Assign Slides windows. When the user is preparing slides or manual mapping several protocols, the Work Flow List is a way for the user to view and keep track of information such as Case#, Block ID, Protocol Name, Primary Ab or PreTreatment (based on what is selected to view).

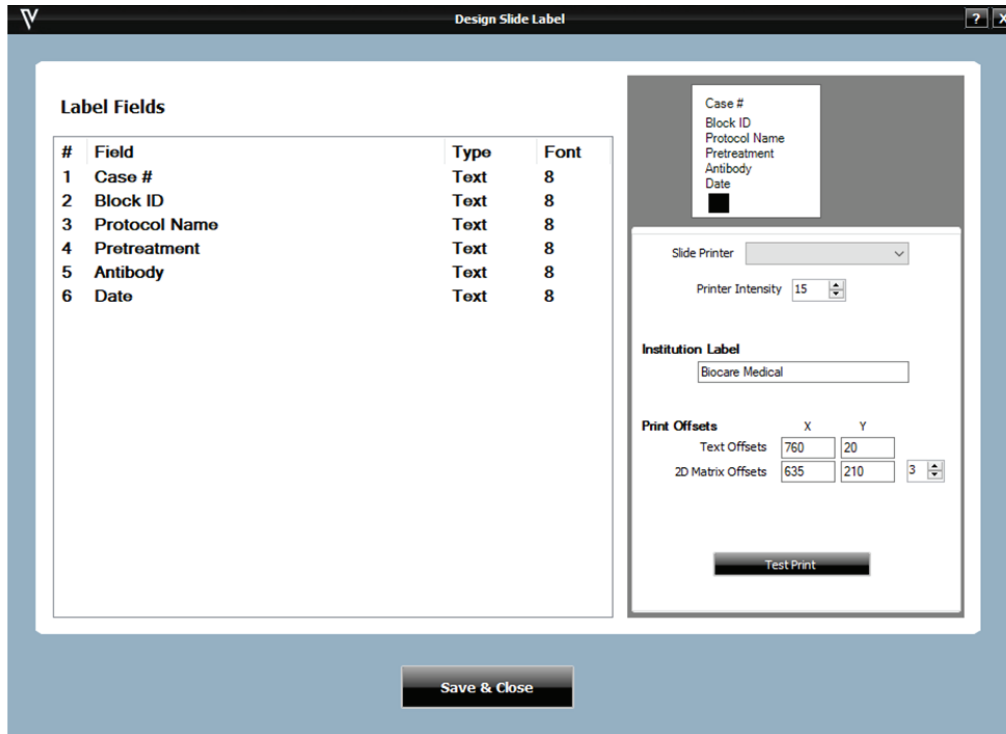


- Click OK when finished.

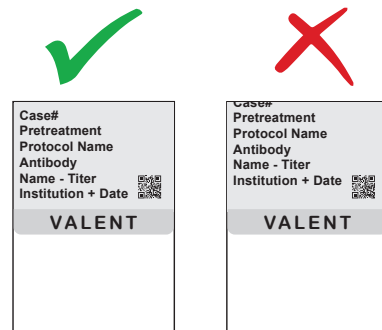
Slide Label Designer

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 dropdown menu of the Home Screen. Upon selection, the Design Slide Label window will open.



- 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 6 Label Field lines which are configurable by the user. The available options in each drop down menu are:
 - Instrument + Date
 - Slide ID
 - Protocol Name
 - Pretreatment
 - Antibody
 - Case#
 - Block ID
 - Case # + Block ID
 - Institution
 - Date
 - 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.



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 of the Home Screen.

#	Field	Type
1	Reagent Name	Text
2	Catalog #	Text
3	Lot + Exp	Text

Reagent Name
Catalog #
[Barcode]
Lot + Exp

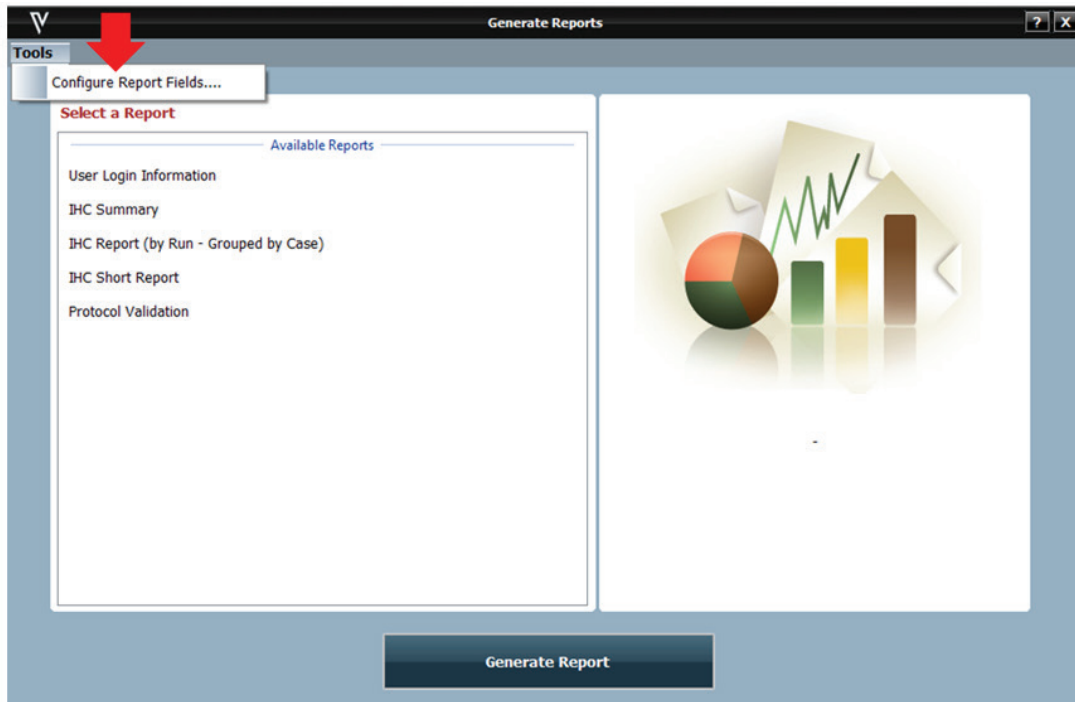
Reagent Printer [Dropdown]
Printer Intensity 10 [Slider]
Text Offset X: 680 Y: 0 DPM
Barcode Offset X: 555 Y: 30 DPM: 2
Test Print
Save & Close

- 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, 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.

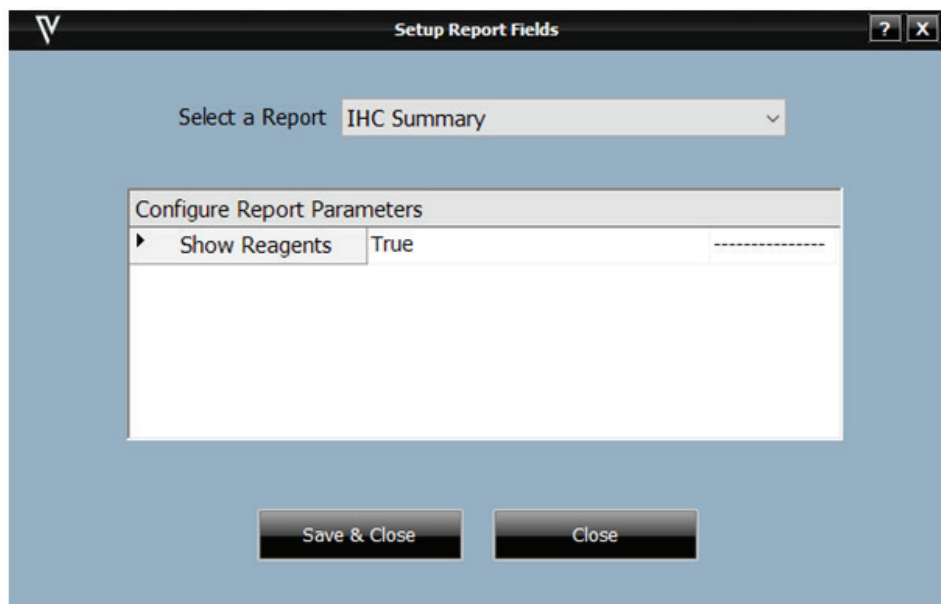
Report Field

The system allows a user to configure an IHC Summary report and add or delete information based on lab requirements.

- From the Home Screen select Tools and go to Print Reports then click Report Generator.
- The Generate Reports window will appear, go to Tools and click Configure Report Fields.



- Select a report from the Select a Report dropdown menu.
- After selecting IHC Summary, the following appears in the window:



- Select True to display reagents in IHC Summary report or False to not display reagents in the report.
- Click Close.

Chapter 5: Before Starting a Run

This chapter contains general guidelines for preparing samples, reagents, protocols on the VALENT prior to starting a run.

Slide Preparation

Slide Specifications

The VALENT works best with slides that do not contain a logo under the frost. If a slide with a logo is used, cover the logo with the slide label. Below are slide specifications for the VALENT.

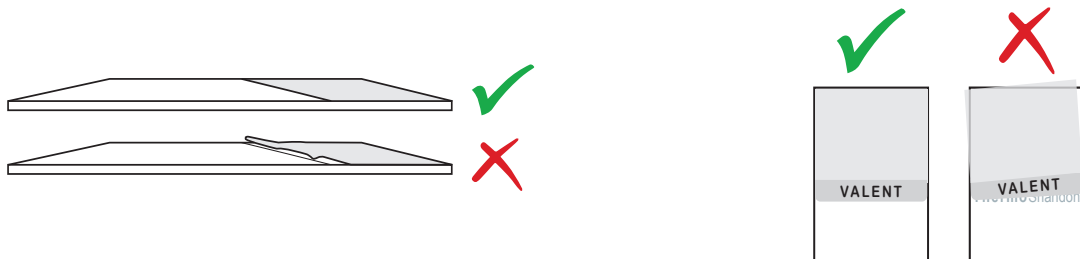
Material	Glass, ISO 8037/1
Dimensions	Length: 74.9-76.0 mm (2.95-2.99 in) Width: 24.64-26.00 mm (0.97-1.02 in) Thickness: 0.8-1.3 mm (0.03-0.05 in)
Label Area	Width: 24.64-26.0 mm (0.97-1.02 in) Length: 16.9-21.0 mm (0.67-0.83 in)

Important Note: Pap pens are not required when running slides on the VALENT. Barrier slides should not be used on the VALENT, it will obstruct the flow of antigen retrieval solution and dispensing of reagents onto the slide resulting in less than optimal staining results.

Slide Labels

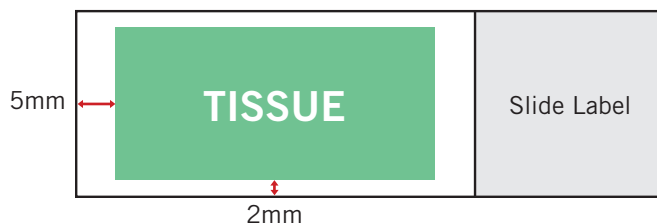
All slides require a water-repellant/hydrophobic tab label for engineered continuous flow of Val DePar and antigen retrieval solution. If manually mapping slides, use a VALENT slide label. Failing to use a slide label may yield poor staining quality. The lack of slide labels may introduce issues such as slide cracking, as the slide may not load easily without the slide label, and frosted paint from slide melting off and mixing with antigen retrieval solution.

When placing the slide label on the slide make sure the whole label is completely flattened and adhered to the slide, especially the bottom of the label. If the slide label is not properly placed and sticks up even slightly, liquid flow will be impeded, and reagents will wick and yield poor staining quality. Please see diagram below.



Tissue Placement on Slide

The tissue should be placed in the center of the slide and should not be at the edge or border of slides. Avoid placing the tissue 2mm to the left or right edge of the slide. The tissue should be placed 3mm below the VALENT slide label and 5mm above the bottom edge of the slide. Please see the reference diagram below.



Slide Trays

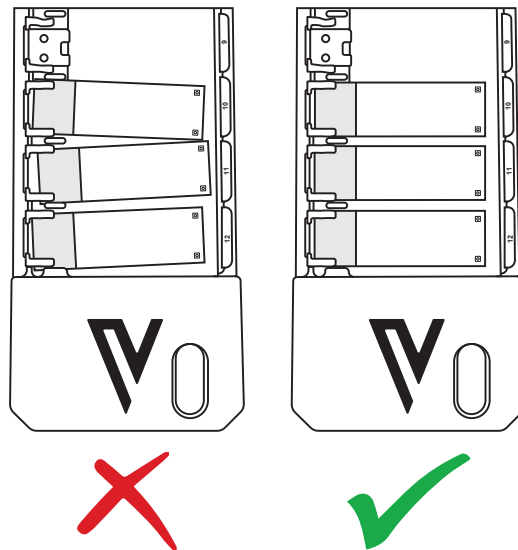
Run Requirements

Although most runs will have similar protocol conditions and can be processed in the same slide tray, there are certain conditions where protocols cannot be processed in the same tray or the same run.

1.	DePar and non-DePar slides cannot be on the same slide tray.
2.	Non-DePar slides with antigen retrieval require a different slide tray.
3.	Varying DePar times requires a separate run.
4.	All slides in a slide tray require the same antigen retrieval temperature.
5.	All slides in a slide tray require the same antigen retrieval solution.

Inserting Slides into the Slide Tray

- Lay slide tray on a flat clean surface.
- Ensure that all slides have a slide label.
- Place the slide flat, directly below the slide clip making sure it's centered.
- Gently push the slide inward so slide is under the slide clip.
- Slides should be inserted in a straight horizontal motion, do not insert slide at an angle, this may cause the slide to crack.
- Slides should be straight and evenly spaced between each other.
- If a slide is not straight, it may affect staining due to possible reagent wicking.



Removing Slides from the Slide Tray

- Gently pull the slide out of the slide tray in a straight horizontal motion.
- Do not pull slides out at an angle, this may cause the slide to crack.

Note: If removing the slide tray immediately after a run completes, residual Aqua Rinse may still be on the slide tray. To eliminate residual Aqua Rinse, lift the slide tray at 90 degree angle over the trough to allow Aqua Rinse to spill into the trough.

Tissue Preparation

Deparaffinization and antigen retrieval are performed onboard the VALENT to streamline the IHC workflow.

Positive and Negative Controls

To ensure accurate, reliable staining and prevent patient misdiagnosis, quality control is recommended by any or all of the following:

- **Positive Tissue Control**
Include a tissue sample known to test positive for the marker that requires detection, preferably a sample with a gradient/range of reactivity. Test results should indicate positive staining for the given marker if the run was successfully executed.
- **Positive Reagent Control**
Include more than one antibody and its' control; if one is positive, the process worked.
- **Negative Tissue Control**
Include a known negative tissue and apply primary antibody. Test result should indicate negative staining with no background.
- **Negative Reagent Control**
Replace primary antibody with negative control serum. Test result should indicate negative staining with no background.

Bulk Reagent Preparation

Bulk reagents can be prepared in 8L bulk reagent carboys or 10L bulk reagent mixing carboys. See the table below for reagent preparation instructions. Refer to data sheets as needed.

Reagent	8L Bulk Reagent Carboys	10L Bulk Reagent Mixing Carboys
Wash Buffer	Add 400mL of 20X Wash Buffer, (VLT8013 MX) to 7.6L DI water.	Add 500mL of 20X Wash Buffer, (VLT8013 MX) to 9.5L DI water.
Aqua Rinse	Add 400mL of 20X Aqua Rinse, (VLT8012 MX) to 7.6L DI water.	Add 500mL of 20X Aqua Rinse, (VLT8012 MX) to 9.5L DI water.
AR-Hi pH	Add 1L of AR-Hi pH, (VLT8003 MM) to 4L DI water.	Add 1L of AR-Hi pH, (VLT8003 MM) to 4L DI water.
AR-Lo pH	Add 1L of AR-Lo pH, (VLT8004 MM) to 4L DI water.	Add 1L of AR-Lo pH, (VLT8004 MM) to 4L DI water.

Instrument Preparation

1. Turn the VALENT on using the main power switch (white switch) found in the electrical panel of the instrument, on the right side.
2. Turn on the computer and open the VALENT application.
3. Double check that both waste carboys are empty and properly connected to the VALENT.
4. Double check that bulk reagent carboys are filled appropriately and properly connected to the VALENT.
5. **Remove all slide trays from instrument before priming.** The user should prime until there are no remaining bubbles in the carboy tubing or probe coil. When priming the dispense manifold, prime until the stream coming from the port is steady and even across the 12 ports.
6. Priming should also be done when refilling the carboys, priming the manifold is not required for this.
7. Rinse the slide racks with water, and carefully brush away any residual deposits of dried buffer that may be present. This will prevent contamination from previous runs.
8. Using both hands, one hand holding reagent rack from front and the other hand from the bottom, load the reagent rack with filled reagent vials in the correct orientation; the reagent rack handle should be towards the front of instrument, facing the user. Reagent vials must be positioned toward the front of the VALENT, facing the user.
9. To print slide or reagent labels, make sure the slide label printer, reagent label printer, and report printer are attached to the computer.
10. When placing the slide label on the slide, the whole label should be completely flattened and adhered to the slide, especially the bottom of the slide label. A slide label that is not completely flat and sticks up even slightly will cause liquid flow to be interrupted. When liquid flow is affected, reagents will wick and may yield poor staining quality.
11. All slides require a label. If manually mapping, use a VALENT slide label. Failing to use a slide label may yield poor staining quality.
12. Confirm that all slides are inserted all the way under the slide clips, placed securely in the slide clips, and centered. It is important that slide labels are viewable by the barcode camera.

Important Note: Be sure to turn on the instrument before logging into the VALENT Software.

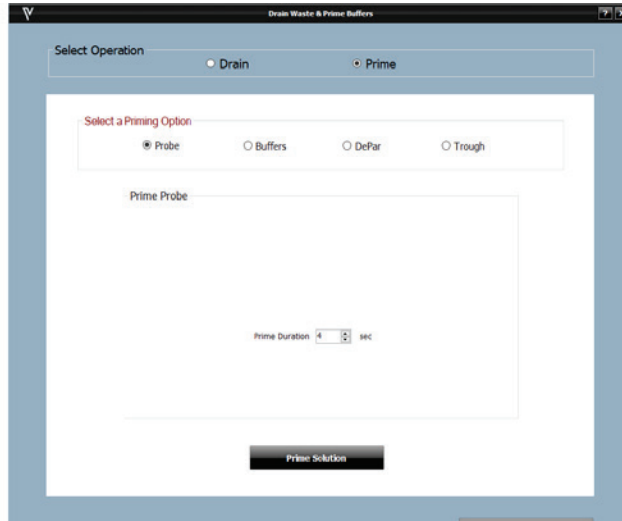
Otherwise, the VALENT Software will automatically be opened in demo mode and the run will not start.

Drain Waste & Prime Buffers

Remove all slide trays from instrument before priming. The user should prime until there are no remaining bubbles in the carboy tubing or probe coil. When priming the manifold, prime until the stream coming from the port is steady and even across the 12 ports. Priming should also be done after refilling the carboys, this does not require priming the manifold. This function is found under Tools-> Instrument Operations-> Drain Waste & Prime Buffers

Prime Probe

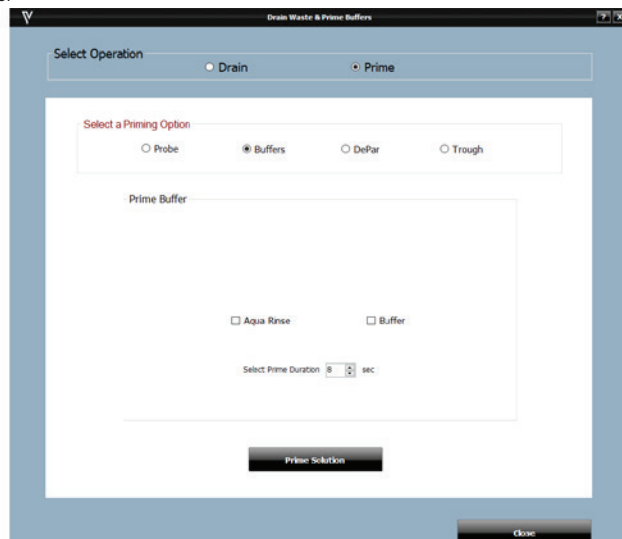
- Select Prime from the Select Operation section.
- When Prime is selected, the following are enabled: Probe, Buffers, DePar and Trough.



- To prime probe, select Probe and adjust the duration of prime in seconds as needed, then click Prime Solution.
- When priming is complete, click Close or select another priming option.

Prime Buffers

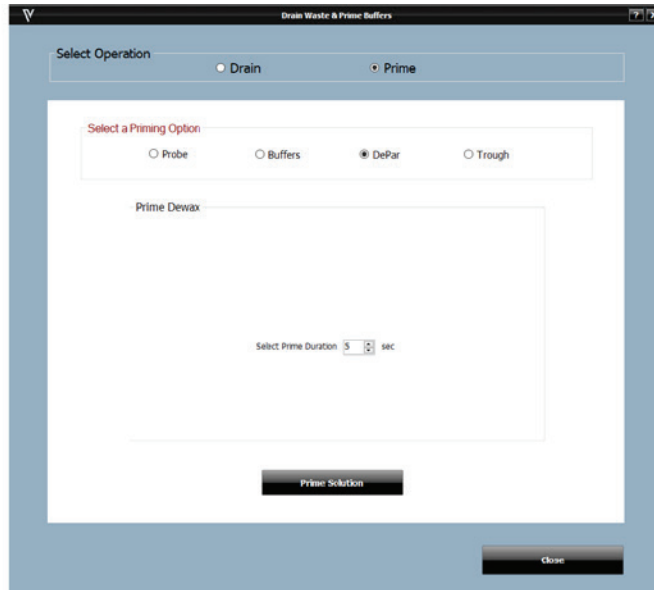
- To prime, select Prime under Select Operation, then click Buffers under Select a Priming Option.
- Select Aqua Rinse or Buffer



- Adjust the duration of prime in seconds as needed and click Prime Solution.
- When priming is complete, click Close or select another priming option.

Prime DePar

- To prime, select Prime under Select Operation, then click DePar under Select a Priming Option.

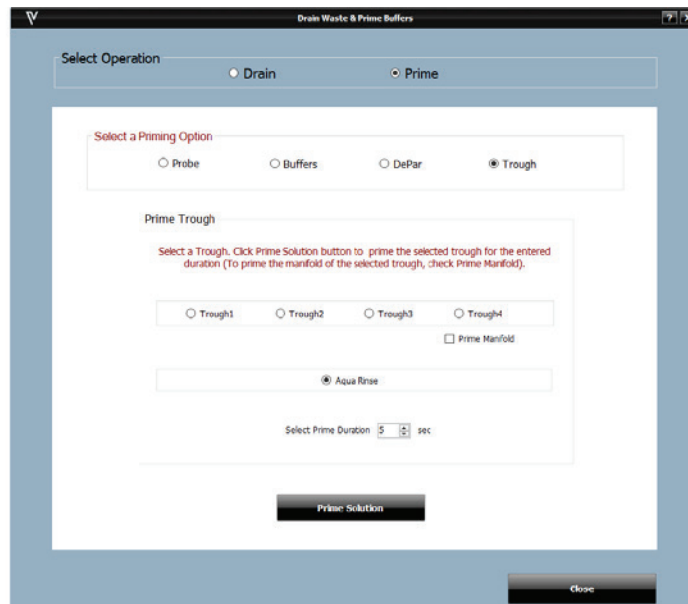


The screenshot shows a software interface titled "Drain Waste & Prime Buffers". At the top, there are two radio buttons for "Select Operation": "Drain" (unselected) and "Prime" (selected). Below this is a section titled "Select a Priming Option" with four radio buttons: "Probe" (unselected), "Buffers" (unselected), "DePar" (selected), and "Trough" (unselected). Underneath is a "Prime Dewax" section with a large empty rectangular area. At the bottom of this area is a label "Select Prime Duration" followed by a text input field containing the number "5" and the unit "sec". At the very bottom of the interface are two buttons: "Prime Solution" and "Close".

- Adjust the duration of prime in seconds as needed and click Prime Solution.
- When priming is complete, click Close or select another priming option.

Prime Troughs and Manifold

- To prime, select Prime under Select Operation, then click Troughs under Select a Priming Option.
- Select the Trough to be primed.



The screenshot shows the same software interface as above, but with "Trough" selected under "Select a Priming Option". Below this, there is a "Prime Trough" section. It contains a red instruction: "Select a Trough. Click Prime Solution button to prime the selected trough for the entered duration (To prime the manifold of the selected trough, check Prime Manifold)". Below the instruction are four radio buttons for "Trough1", "Trough2", "Trough3", and "Trough4", all of which are unselected. To the right of these buttons is a checkbox labeled "Prime Manifold", which is also unselected. Below the radio buttons is a text input field containing "Aqua Rnae" and a radio button next to it. At the bottom of this section is a label "Select Prime Duration" followed by a text input field containing "5" and the unit "sec". At the very bottom of the interface are two buttons: "Prime Solution" and "Close".

- To prime the manifold for the selected trough, check the Prime Manifold box.
- Adjust the duration of prime in seconds, as needed, and click Prime Solution.
- When priming is complete, click Close or select another priming option.

Drain Waste

- This screen can be reached from the Tools and then selecting Instrument Operations.
- There are 2 selections: Drain Waste or Prime Buffers.
- Select Drain under Select Operation, then click the trough to be drained under Select Trough or Wash Station

The screenshot shows a software window titled "Drain Waste & Prime Buffers". At the top, there is a "Select Operation" section with two radio buttons: "Drain" (which is selected) and "Prime". Below this is a "Drain Solution" section. Inside this section, there is a "Select Trough or Wash Station" area with five radio buttons: "Trough1" (selected), "Trough2", "Trough3", "Trough4", and "Wash Station". Below the trough selection, there is another section with two radio buttons: "Non-Hazardous Waste" (selected) and "Hazardous Waste". At the bottom center of the "Drain Solution" area is a "Start Drain" button. At the bottom right of the entire window is a "Close" button.

- To drain into non-hazardous waste, select Non-Hazardous and click Start Drain.
- To drain into hazardous waste, select Hazardous and click Start Drain.

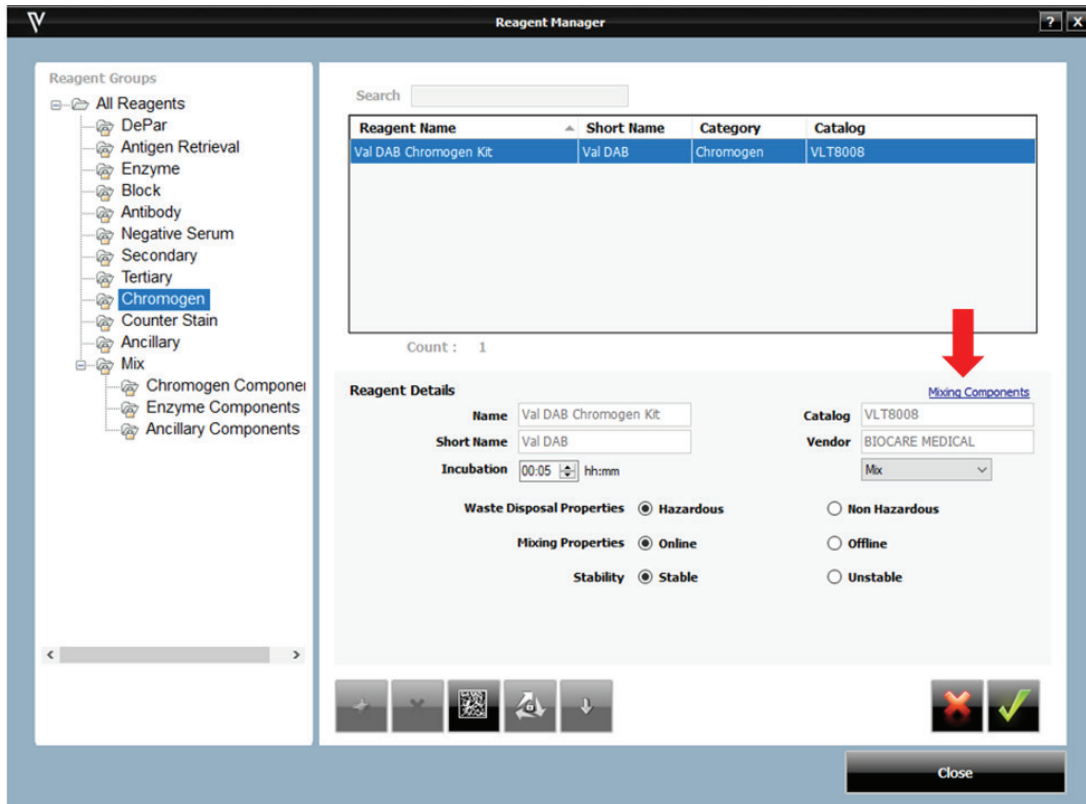
Reagent Manager

Add, Delete, and Modify Reagents

Users can add delete and modify reagents under Reagent Manager.

Add a New Reagent

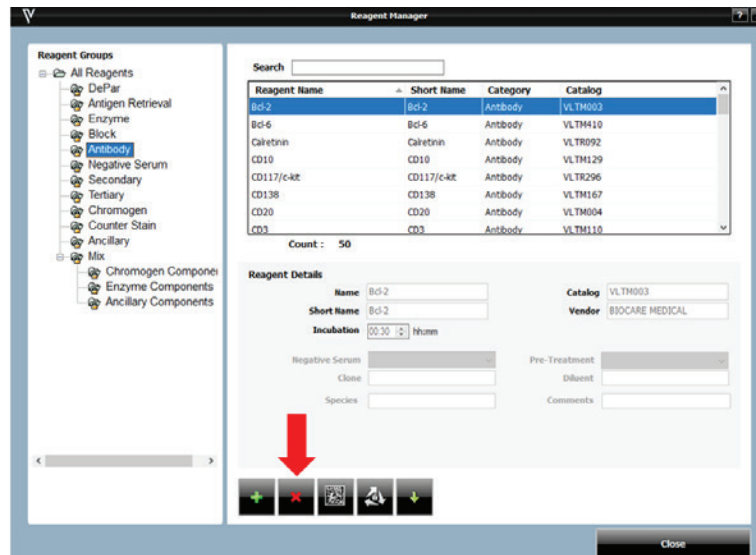
- From the Home Screen, select Data Manger, then go to Reagent Manager.
- To the left of the screen, under Reagent Groups, highlight the Reagent Group to which the new reagent belongs.
- Use the add button under Reagent Details to add a new reagent.



- Enter the Name, Short Name, Catalog Number, Vendor, Incubation Time, etc. of the new reagent.
- Select Save (green plus) and Close to save the information.
- When a reagent is added to this screen it will be added to Inventory Manager as a reagent for selection.

Delete a Reagent

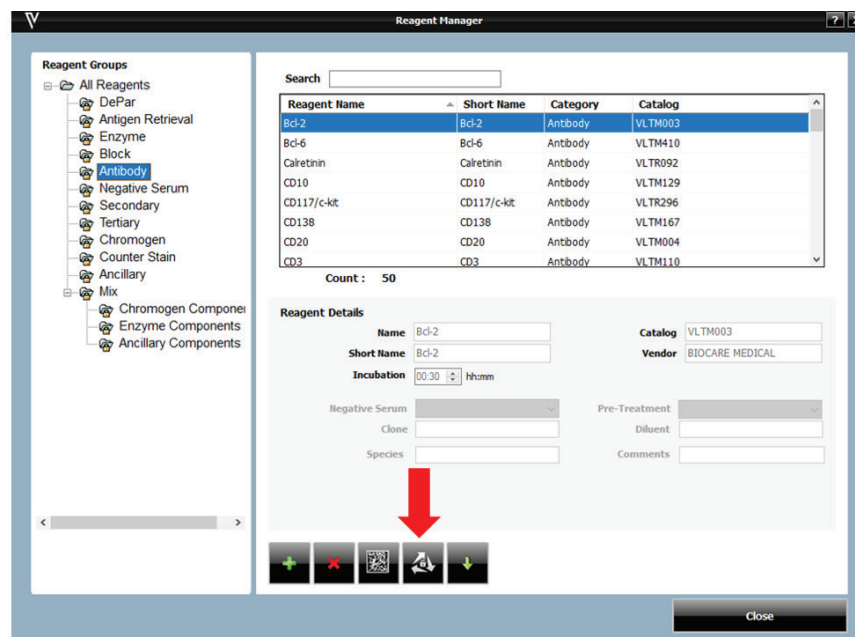
- From the Home Screen, select Data Manager, then go to Reagent Manager.
- To the left side of the screen, under Reagent Groups, click the Reagent Group to which the new reagent belongs.
- From the reagent table, click the reagent to be deleted.
- Use the delete button (X), under Reagent Details to delete a reagent.



- Select Close to save the information.

Modify a Reagent

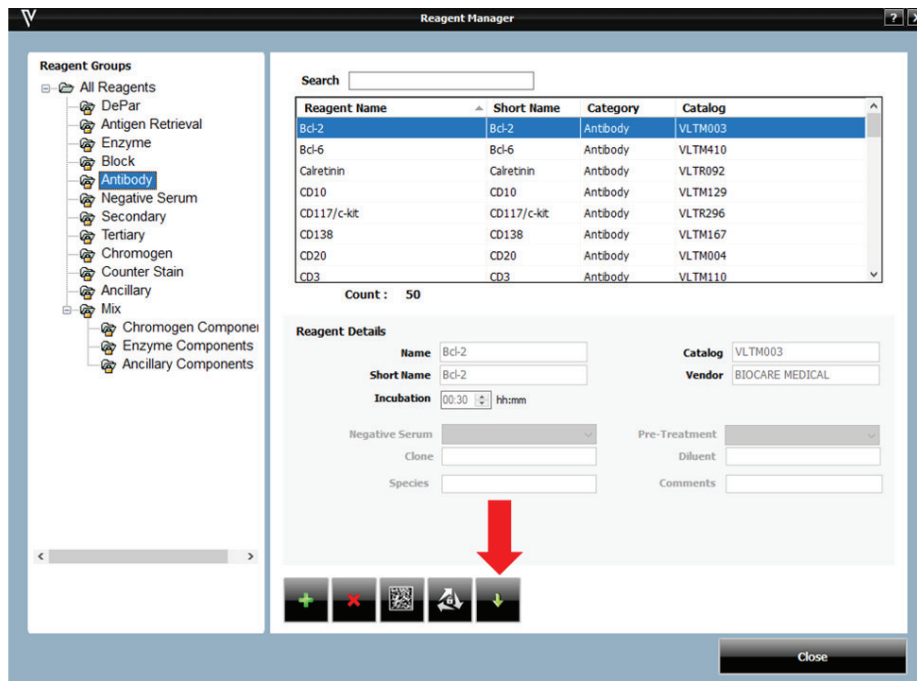
- From the Home Screen, select Data Manager, then go to Reagent Manager.
- Under Reagent Groups, click the Reagent Group under which the reagent is categorized.
- From the reagent table, click the reagent to be modified.
- Use the Edit (3 gray arrows) button under Reagent Details to modify a reagent.



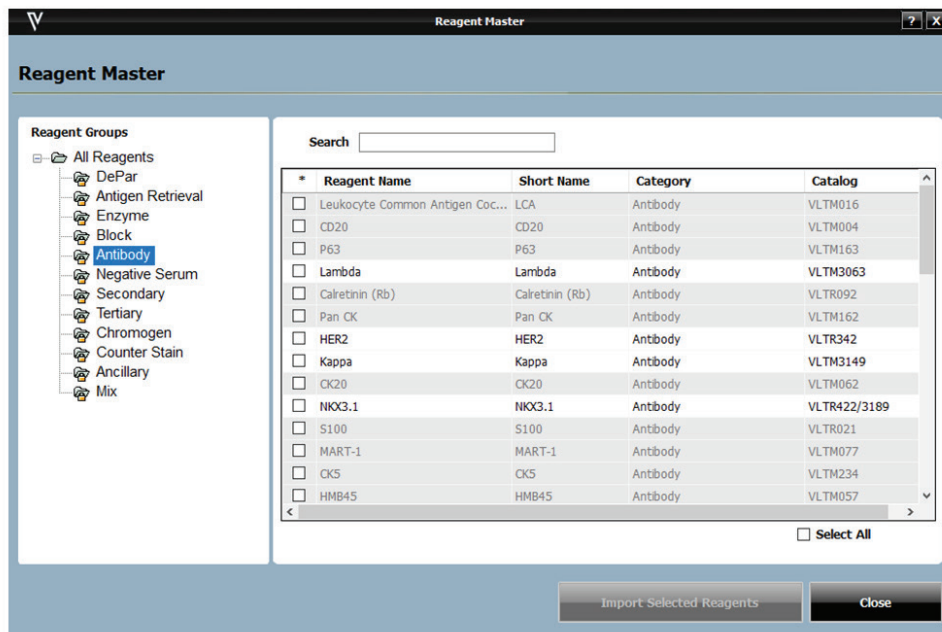
- Make the necessary changes then click Save (green check mark) and Close to exit.

Import a Reagent from Reagent Manager

- From the Home Screen, select Data Manger, then go to Reagent Manager.
- To the left side of the screen, under Reagent Groups, click the Reagent Group under which the reagent is categorized.
- Use the Import (green arrow) button under Reagent Details to import a reagent.



- The Reagent Master List window will appear.

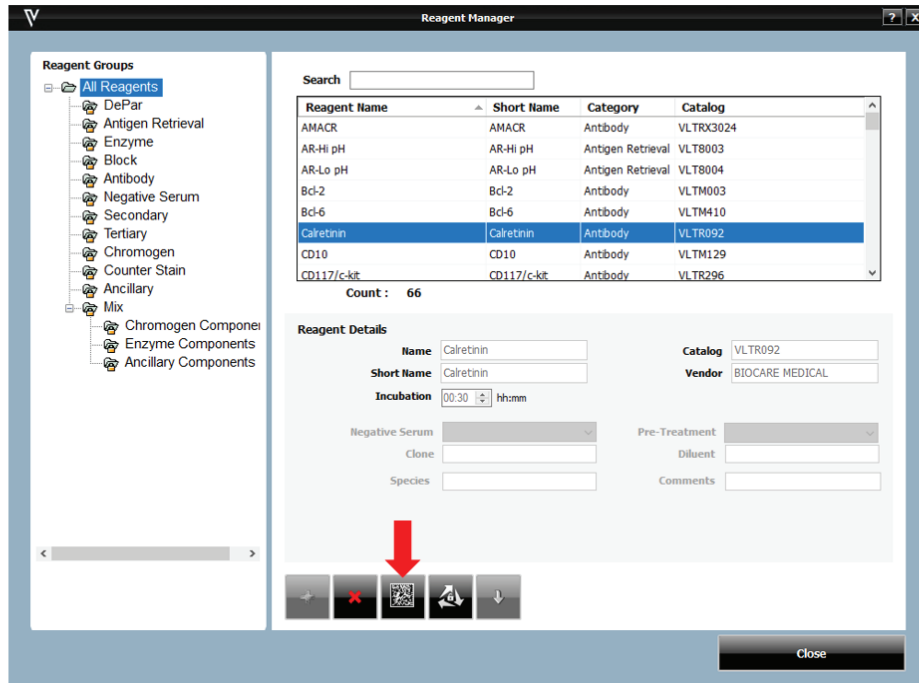


- Select the reagent to be imported and click Import Selected Reagents
- Select Close to save the information and exit out of window.

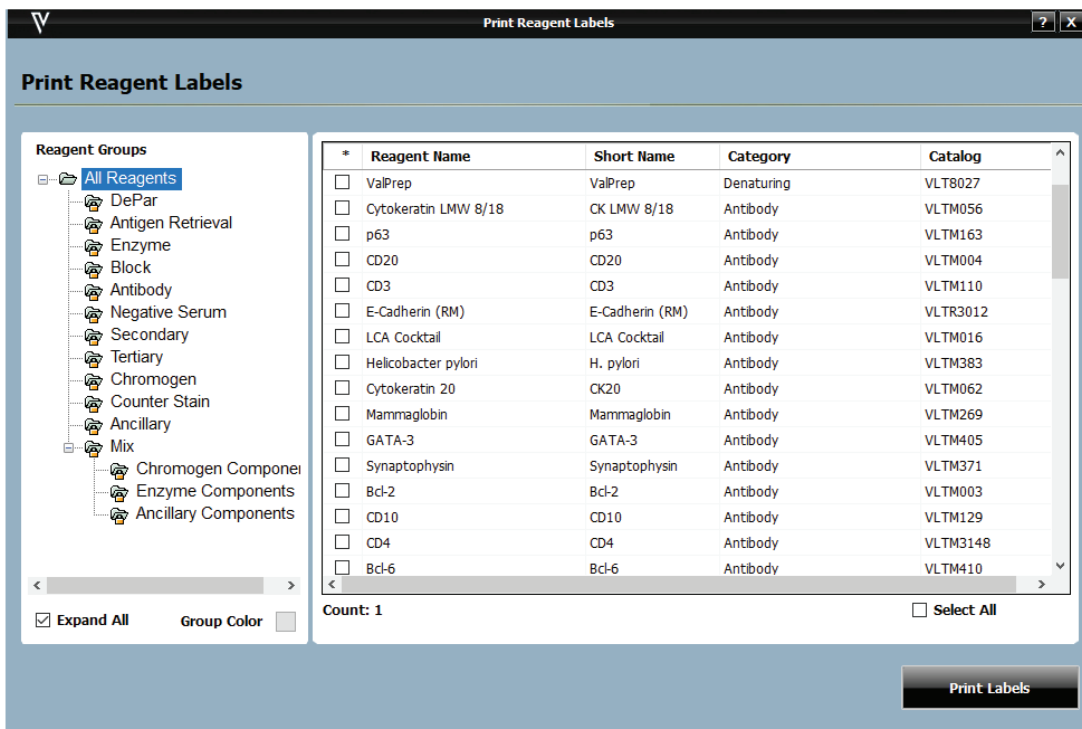
Note: Reagents in gray signify that they are already part of the Reagent Master List and do not need to be imported, while reagents in black have not been imported to Reagent Master List. Only Biocare Medical Reagents can be added to the Reagent Master List.

Print a Reagent Label

- From the Home Screen, select Data Manager, then go to Reagent Manager.
- Use the Print button under Reagent Details to open the Print Reagent Labels window.



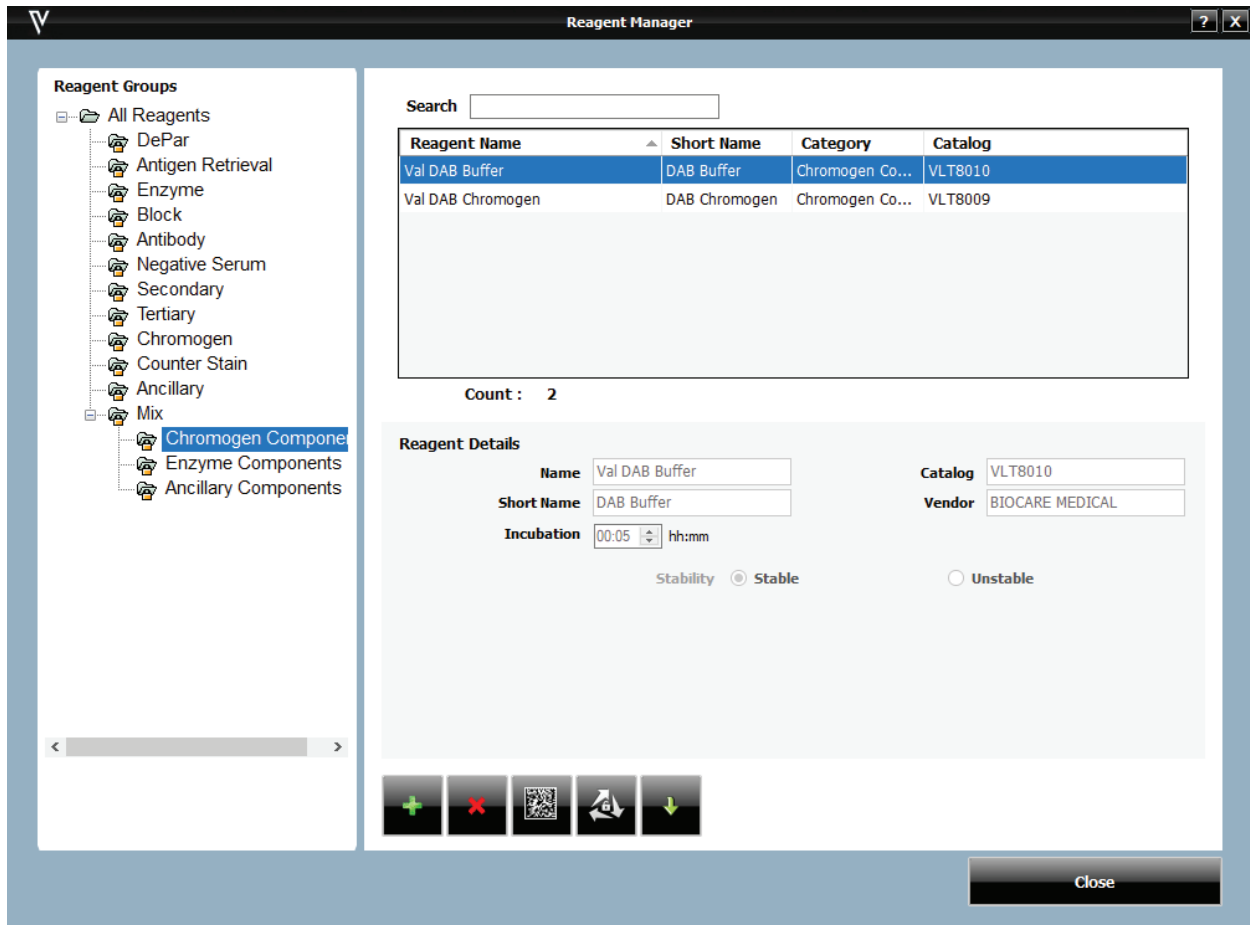
- To the left of the screen, under Reagent Groups, click the Reagent Group under which the reagent is to be categorized.



- In the reagent table, click and highlight reagent to be printed or choose Select All to print out all reagent labels.
- Click Print Labels.

Add a Reagent in Mix Group

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



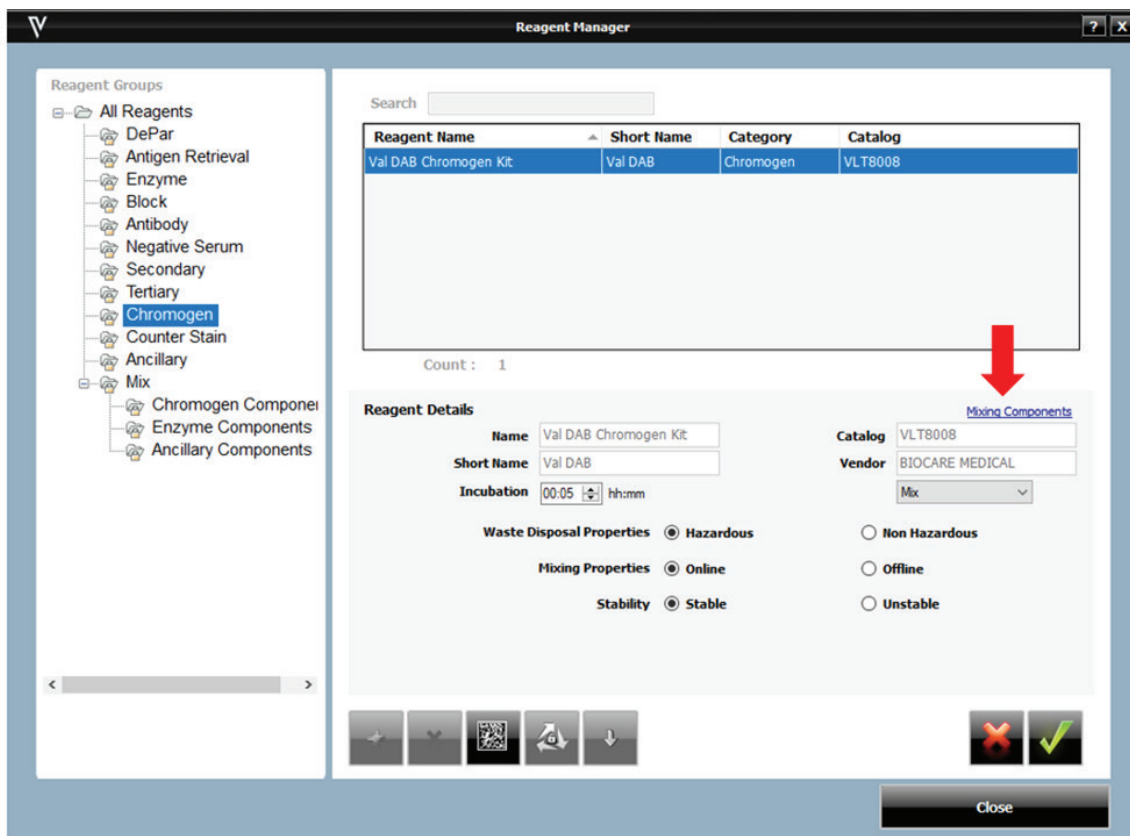
- From the Home Screen, select Data Manger, then go to Reagent Manager.
- To add a mixing component reagent under Mix, click the desired subgroup category. (Chromogen Components, Enzyme Components, Ancillary).
- Click the Add (+) button below Reagent Details box to add a new reagent.
- Enter the Name, Catalog Number, Short Name, Vendor, and Incubation Time.
- Select Stability (Stable or Unstable) to designate whether the reagent needs to be made just before being dispensed or can be made at the beginning of the run.
 - Stable and unstable reagents are loaded in a 20mL reagent vial.
- Once all information has been entered, click Save (green check mark) and click Close.

Specify Mixing Properties

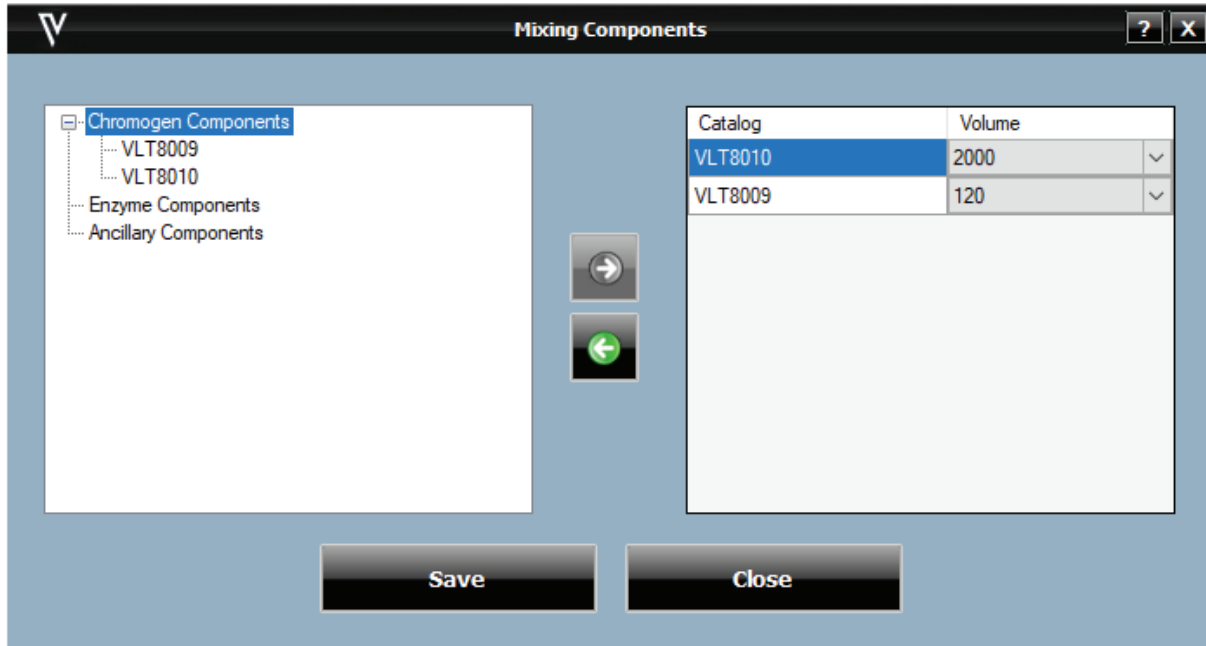
The user can specify whether mixing of available Enzyme, Chromogen, and Ancillary Reagent Groups is performed online, by the instrument during a run, or offline manually. Once set to Mix, the Mixing Components link will be available in the top right corner of the Reagent Details box.

Chromogen Example

- From the Home Screen, select Data Manger, then go to Reagent Manager.
- Under Reagent Groups, select from either Chromogen, Ancillary, or Enzyme Components.
- Click the Add (+) button under Reagent Details and fill out Reagent Details such as Name, Short Name, Catalog Number, Vendor, Mix or Regular, Waste Disposal Properties, Mixing Properties and Stability.
- For Stability, Stable means the mix is stable, Unstable means the mix is unstable and must be used immediately by the instrument.
- Once Mix is selected from a dropdown menu, Mixing Components can be accessed.



- Use the Mixing Components window to designate the volume (in μL) of chromogen buffer and the volume (in μL) of chromogen substrate.



Volume Calculation for Mixing Reagents

There are 2 dead volumes to consider when mixing reagents online that is determined by the VALENT Software:

- About 300 μ L is lost during the mixing process itself, which should be accounted for in the sample calculations below.
- There is a 50 μ L dead volume for all reagent and mixing vials due to the limitation of probe.

Below is an example of how dead volumes work for mixing reagents.

DAB Reagent = DAB Chromogen + DAB Buffer

The dispense volume per slide is 300 μ L with an extra 20 μ L needed, (the extra 20 μ L volume is to compensate for lost volume during slide application) for a total of 320 μ L.

DAB Reagent

Volume for 12 slides= 12 * 320 μ L= 3840 μ L

Dead volume = 50 μ L

Total DAB Reagent required for 12 sides = 3890 μ L

a. DAB Chromogen

Volume needed for 12 slides = 240 μ L

Dead volume = 50 μ L

Total volume = 290 μ L

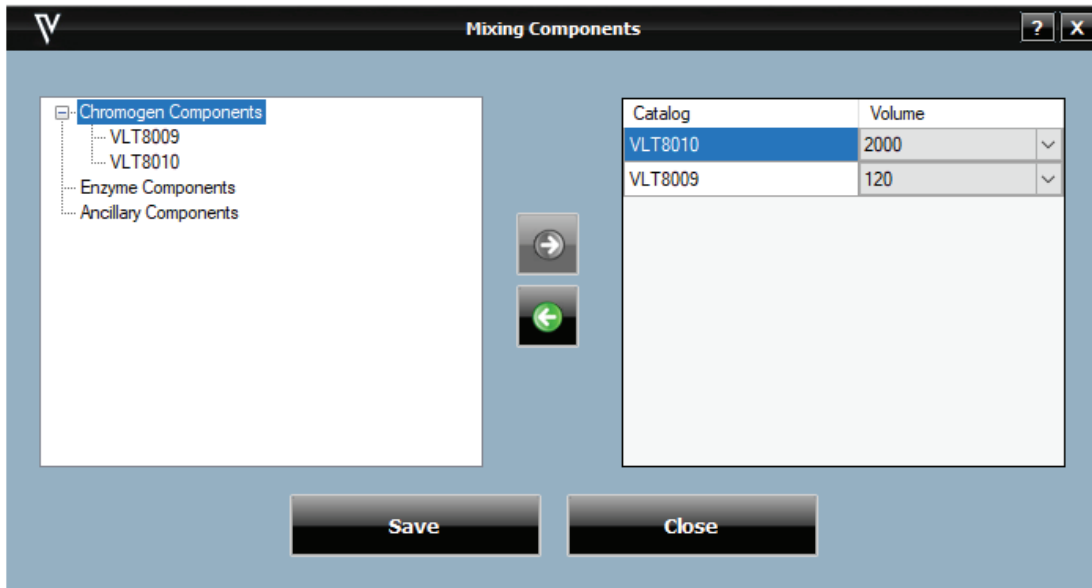
b. DAB Buffer

Volume for mixing 12 slides = 3950 μ L

Dead volume = 50 μ L

Total = 4000 μ L

After mixing buffer and chromogen, the total volume of DAB Reagent will be 4190 μ L (240 μ L + 3950 μ L). During the mixing process, 300 μ L is lost leaving 3890 μ L, (4190 μ L -300 μ L).



- From the Chromogen Components list on the left, highlight the catalog number for the chromogen buffer and click the right arrow button to add to the list on the right.
- Click the Volume field dropdown menu to select the desired volume (in μL) of buffer.
- Add Chromogen (concentrate) to the mix in the same way. The minimum volume required is $100\mu\text{L}$.
- To delete a component from the list on the right of the screen, highlight it in either list and click the back arrow button.
- Click Save, then Close to exit.

Important Note: When setting up mixing components, reagents that require larger volumes should be added first.

Inventory Manager

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.

View Reagents

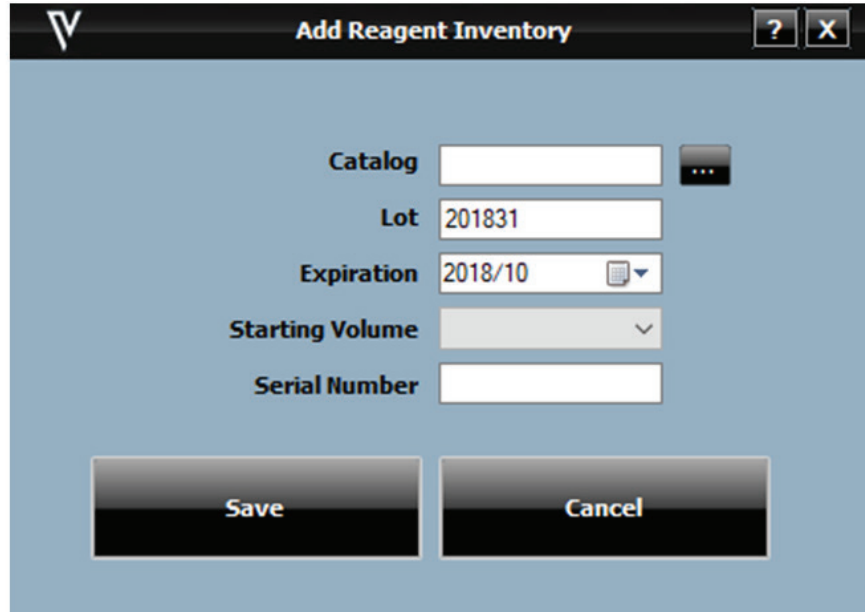
- Inventory Manager can be opened from the Data Manager dropdown menu from the Home Screen. When Inventory Manager is chosen, the Reagent Inventory Manager window is displayed.

Catalog	Lot #	Expiration (YYYY/MM)	Initial Volume	Current Volume	Serial
VLTM163	20180044	2018/12	20000	20000	000001
VLTM004	20180111	2018/12	20000	20000	000001
VLT8015	20180117	2018/12	20000	20000	000001

- The list of reagents can be sorted by any field by clicking on the header. Reagents can also be sorted by the Reagent Step dropdown menu, located to the top left of the screen.
- A search field is provided to quickly find a reagent.

Add Reagents

- When Inventory Manager is chosen, the Reagent Inventory Manager window is displayed.
- Select the Add (+) button to add a reagent.
- The Add Reagent Inventory window will allow the user to enter reagent information such as Catalog Number, Lot Number, Expiration Date, Starting Volume and Serial Number.

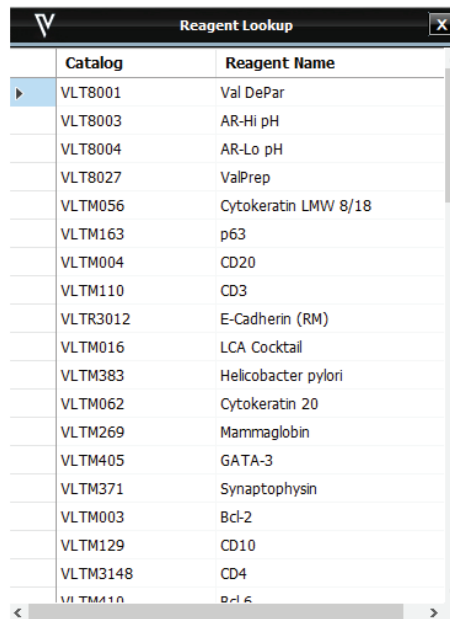


The screenshot shows the 'Add Reagent Inventory' window. The title bar includes a logo and window control buttons. The main area contains the following fields:

- Catalog:** A text box with a dropdown arrow icon to its right.
- Lot:** A text box containing the value '201831'.
- Expiration:** A text box containing the value '2018/10' and a calendar icon to its right.
- Starting Volume:** A text box with a dropdown arrow icon to its right.
- Serial Number:** An empty text box.

At the bottom of the window are two large buttons: 'Save' and 'Cancel'.

- The Reagent Lookup button is located next to Catalog field to quickly pull up reagents already in inventory.



The screenshot shows the 'Reagent Lookup' window, which displays a list of reagents in a table format. The table has two columns: 'Catalog' and 'Reagent Name'. The first row is selected, showing 'VLT8001' and 'Val DePar'.

Catalog	Reagent Name
VLT8001	Val DePar
VLT8003	AR-Hi pH
VLT8004	AR-Lo pH
VLT8027	ValPrep
VLTM056	Cytokeratin LMW 8/18
VLTM163	p63
VLTM004	CD20
VLTM110	CD3
VLTR3012	E-Cadherin (RM)
VLTM016	LCA Cocktail
VLTM383	Helicobacter pylori
VLTM062	Cytokeratin 20
VLTM269	Mammaglobin
VLTM405	GATA-3
VLTM371	Synaptophysin
VLTM003	Bcl-2
VLTM129	CD10
VLTM3148	CD4
VLTM410	p16

- Click Close to exit.

Important Note: When Inventory Manager is opened from the Data Manager dropdown menu in the Home Screen, the Register Reagents button is displayed.

Delete Reagents and Clean Inventory

- Select Inventory Manager.
- To delete a reagent, select the reagent to be deleted and click the Delete (X) button.

Catalog	Lot #	Expiration (YYYY/MM)	Initial Volume	Current Volume	Serial
VLTM163	20180044	2018/12	20000	20000	000001
VLTM004	20180111	2018/12	20000	20000	000001
VLT8015	20180117	2018/12	20000	20000	000001

- The user can click Clean Inventory to clear a list of inventory. The system will only allow the user to Clean Inventory if the reagent is expired and contains a volume below 350 μ L.
- The Current Volume of reagents is calculated by the VALENT Software as the reagent is used up during staining runs.
- Click Close to exit.

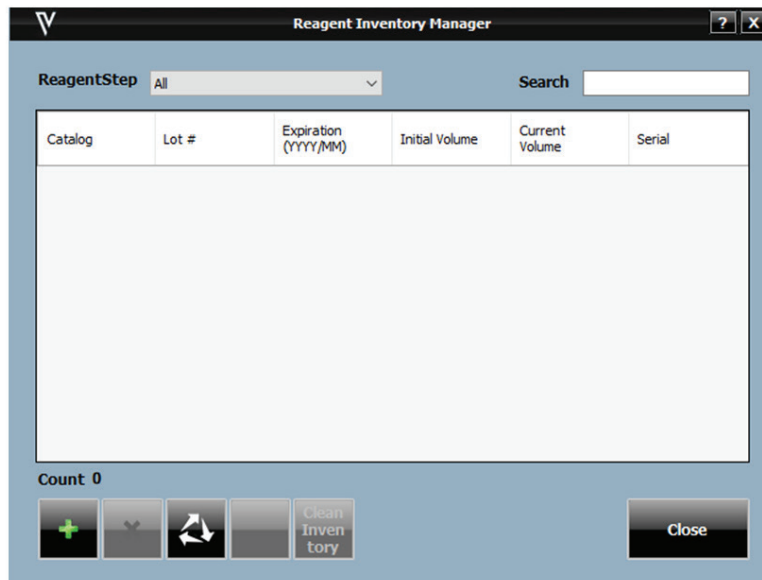
Print Labels in Inventory Manager

- Select Inventory Manager.
- Select the reagent that requires a print label and click the barcode button.
- Click Close to exit.

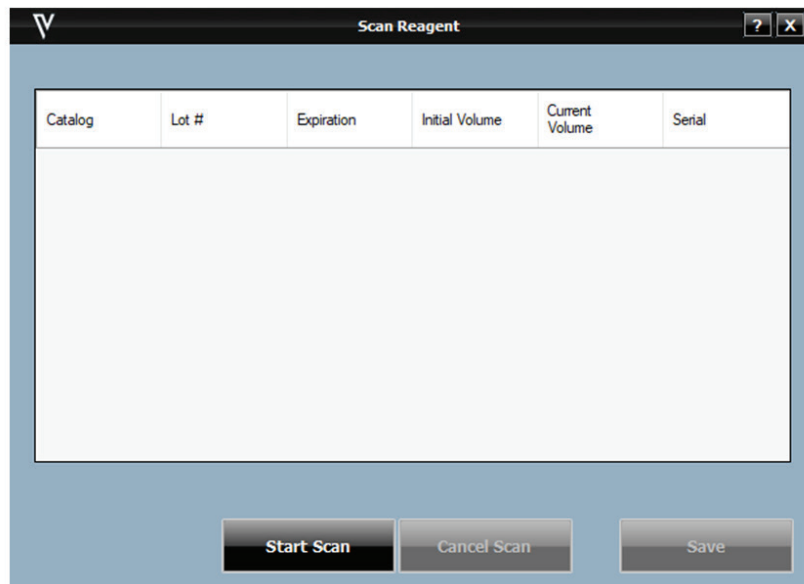
Register Reagents in Inventory Manager

New reagents can only be scanned into inventory when the user initially logs into the system. For example, if a protocol has been run or system cleaning executed, the user won't be able to scan reagents into inventory. To scan reagents into inventory, the user will have to exit the software and log in again. The user has the option of manually entering reagents into inventory.

- Select Inventory Manager.
- Select the Register Reagent (3 gray arrows) button to scan.



- To scan the reagents, click Start Scan.



- To save these listed reagents to the inventory, click the Save button. Reagents with valid lot numbers and expiration dates are saved to the inventory and this window is closed.
- To cancel scanning, click Cancel.
- Click OK once scanning is completed.






Important Note: The use of expired reagents is strongly discouraged in a clinical environment. Refer to the reagent label description and data sheets.

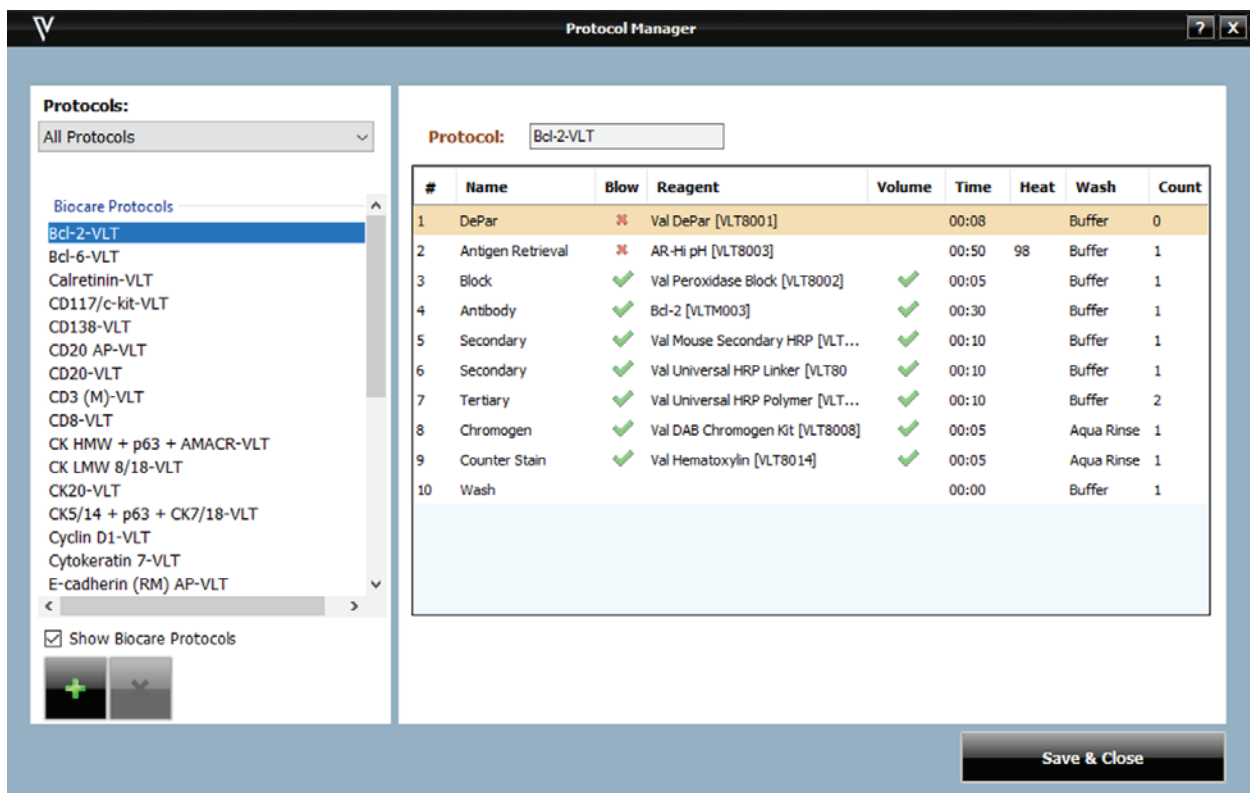
Protocol Manager

Protocol Manager can be reached from the Data Manager dropdown menu of the Home Screen. Use the Protocol Manger module to save, design, and manage protocols.

Important Note: When programming protocols, it is important to consider environmental conditions. Lower boiling temperatures and higher evaporation rates must be evaluated for labs at a higher elevation. If the optimal temperature for antigen retrieval is 98°C with an elevation of 1500 feet, the temperature for antigen retrieval may need to be adjusted to 95°C if the elevation is above 3750 feet. Please call Technical Support if you have further questions.

Description of Template Manager Icons

Icon	Description	Icon	Description
	Add a new step at the end of a protocol.		Move up the selected step in a protocol.
	Delete a step at the end of the protocol.		Move down the selected step in a protocol.
	Insert a new step before the selected step in a protocol.		



The screenshot shows the Protocol Manager interface. On the left, a list of protocols is shown under 'Biocare Protocols', with 'Bcl-2-VLT' selected. The main area displays the details for the 'Bcl-2-VLT' protocol, including a table of steps.

#	Name	Blow	Reagent	Volume	Time	Heat	Wash	Count
1	DePar	✘	Val DePar [VLT8001]		00:08		Buffer	0
2	Antigen Retrieval	✘	AR-Hi pH [VLT8003]		00:50	98	Buffer	1
3	Block	✔	Val Peroxidase Block [VLT8002]	✔	00:05		Buffer	1
4	Antibody	✔	Bcl-2 [VLT0003]	✔	00:30		Buffer	1
5	Secondary	✔	Val Mouse Secondary HRP [VLT...	✔	00:10		Buffer	1
6	Secondary	✔	Val Universal HRP Linker [VLT80...	✔	00:10		Buffer	1
7	Tertiary	✔	Val Universal HRP Polymer [VLT...	✔	00:10		Buffer	2
8	Chromogen	✔	Val DAB Chromogen Kit [VLT8008]	✔	00:05		Aqua Rinse	1
9	Counter Stain	✔	Val Hematoxylin [VLT8014]	✔	00:05		Aqua Rinse	1
10	Wash				00:00		Buffer	1

At the bottom right of the interface, there is a 'Save & Close' button.

Protocol Manager Features

- The user can filter the list of protocols by choosing All Protocols or by choosing a Custom Group in the Protocol's dropdown menu.
- A filtered list of protocols will appear below the Protocol's dropdown menu based on the dropdown choice. The user can check the Show Biocare Protocols box to only view additional Biocare Protocols. This is located to the bottom left of the window.
- Biocare Protocols cannot be edited, only Custom Protocols can be edited.
- Use the buttons to the bottom left of the window to add or delete a protocol. To create a New Protocol select the Add (+) button, the following selection is available: Create New Protocol, Create from a Template, and Create from a Selected Protocol.

#	Name	Blow	Reagent	Volume	Time	Heat	Wash	Count
1	DePar	✘	Val DePar [VLT8001]		00:08		Buffer	0
2	Antigen Retrieval	✘	AR-Hi pH [VLT8003]		00:50	98	Buffer	1
3	Block	✔	Val Peroxidase Block [VLT8002]	✔	00:05		Buffer	1
4	Antibody	✔	Bcl-2 [VLTM003]	✔	00:30		Buffer	1
5	Secondary	✔	Val Mouse Secondary HRP [VLT...	✔	00:10		Buffer	1
6	Secondary	✔	Val Universal HRP Linker [VLT80	✔	00:10		Buffer	1
7	Tertiary	✔	Val Universal HRP Polymer [VLT...	✔	00:10		Buffer	2
8	Chromogen	✔	Val DAB Chromogen Kit [VLT8008]	✔	00:05		Aqua Rinse	1
9	Counter Stain	✔	Val Hematoxylin [VLT8014]	✔	00:05		Aqua Rinse	1
10	Wash				00:00		Buffer	1

- To delete a protocol, highlight the protocol and click Delete Selected Protocol (X), located to the bottom left of the window.

Important Note: There are two delete (X) buttons, select the one under Show Biocare Protocols

- The information about the selected protocol will appear in the Protocols section on the right half of the window including the name of the protocol, dispense volume and protocol steps.
- Use the buttons located on the bottom of screen to edit the protocol along with clicking on the particular step that requires changes. The user can change the following items in a protocol:
 - o Modify existing protocol name.
 - o Modify existing reagent, blow, volume, time, wash type and wash count for any step in a protocol.
 - o Use buttons to add, insert, delete or move steps in the protocol.

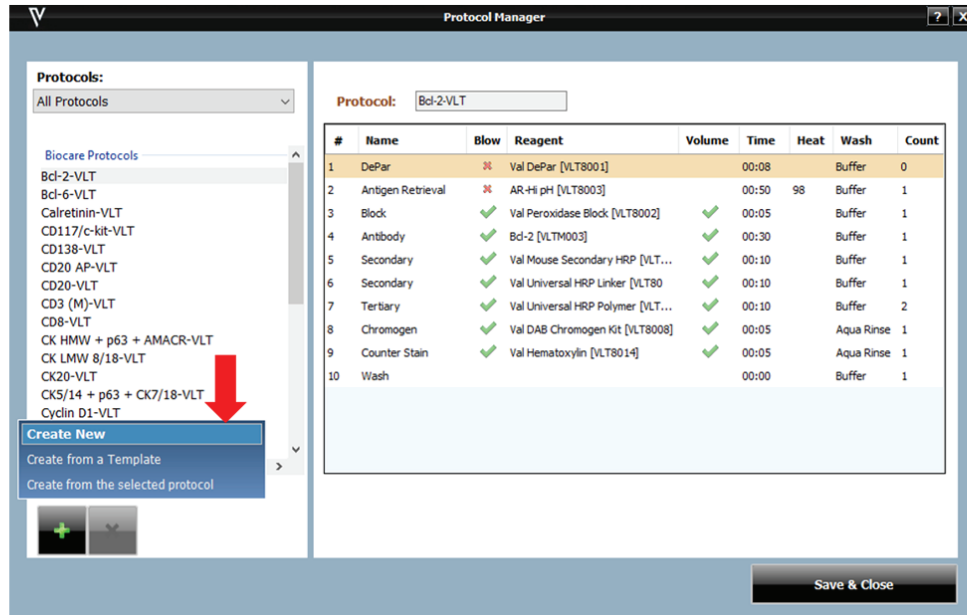
Important Note: When creating or editing a protocol from a Template or a Selected Protocol, click out of current cell and to a different cell to lock in the changes.

Create a Protocol

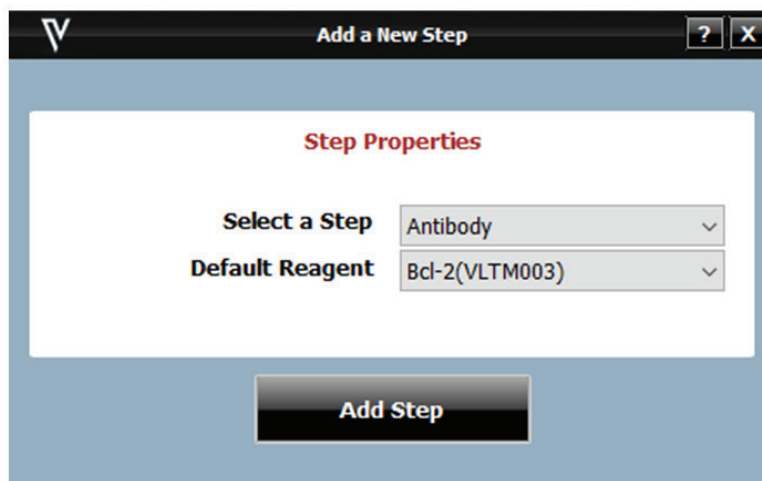
There are three ways to create a protocol; the user can either Create a New Protocol, Create from a Template or Create from a Selected Protocol.

Create a New Protocol

- From the Home Screen, go to Data Manager, then select Protocol Manager.
- To the bottom left of Protocol Manager window select the Add (+) icon located to the bottom left of the screen.



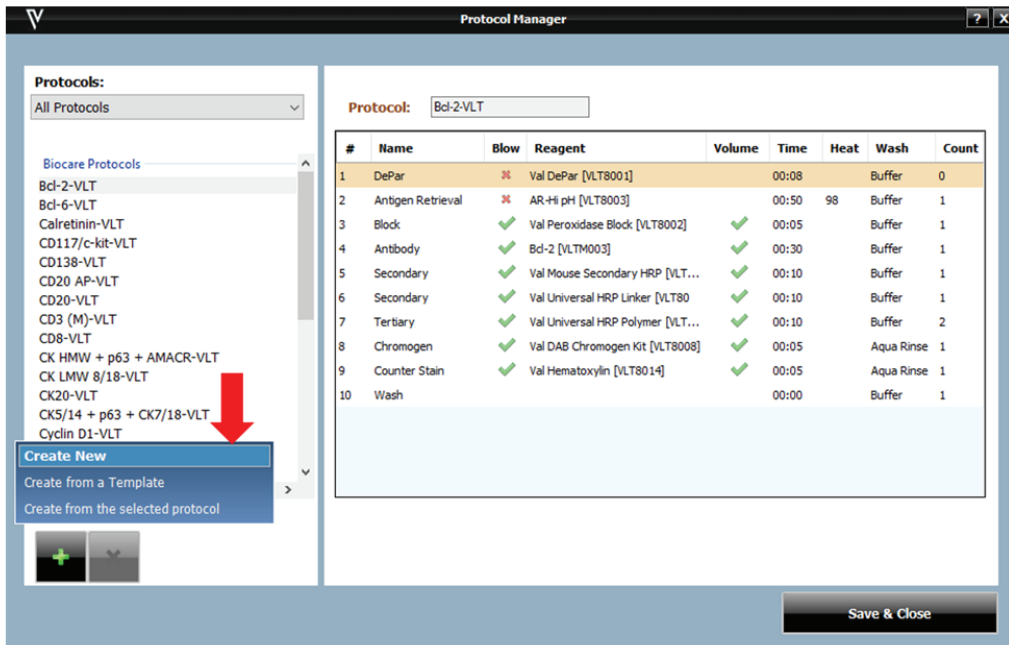
- Once Add (+) is selected, select Create New from the options.
- On the top right side of the window, add the protocol name.
- The dispense volume is 300µL for all protocols.
- Select Add (+) located at the bottom of the window, this opens the Add a New Step window.



- Using the dropdown menu Select a Step along with the reagent required for this step, then click Add Step.
- Use the icons provided to finish creating a protocol.
- Once all steps are added, the user can program time and select reagents from a dropdown menu (to add reagents go to Reagent Manager). The user can select the number of washes required in each step under Count, with a maximum of three washes allowed per step. Blow can be switched on or off by selecting the red (X) for OFF or the green check mark for ON. Turning Blow off will leave any fluid from the previous step on the slide (including Pre-Rinse).

Create a Protocol from a Template

- From the Home Screen, go to Data Manager, then select Protocol Manager.



- To the bottom left of Protocol Manager window select the green Add (+) icon.
- Once Add (+) is selected, select the Create from a Template option.
- A Select an Item window will appear, select the template required, and click OK.
- On the top right side of the window, edit the protocol name if needed.
- The dispense volume is 300µL.
- Use the icons provided to finish creating a protocol.
- Once all steps are added, the user can program time and select reagents from a dropdown menu (to add reagents got to Reagent Manager). The user can select the number of washes required in each step under Count, with a maximum of 3 washes per step allowed. Blow can be switched on or off by selecting the red X for OFF or the green check mark for ON. Turning off Blow will leave any fluid from the previous step on the slide (including Pre-Rinse).
- When finished editing protocol, click Save & Close.

Create a Protocol from a Selected Protocol

- From the Home Screen, go to Data Manager, then select Protocol Manager.
- To the left under Protocols, find the protocol to be copied. In the Protocol field, use the dropdown filters to select All Protocols or Custom Groups. Custom Groups are the user's preferred list of protocols.
- To find Biocare Medical Protocols, click Show Biocare Protocols located on the bottom left.
- Select desired protocol to create a new protocol.
- To the bottom left of Protocol Manager window select the green Add (+) icon located below Show Biocare Medical Protocols.

- Once the green Add (+) icon is selected, select the Create from the Selected Protocol option.
- On the top right side of the window, under Protocol name, COPY will be added at end of the protocol name, edit the Protocol name if needed.
- The dispense volume is 300µL.
- Use the icons provided to finish creating a protocol.
- Once all steps are added, the user can program time and select reagents from a dropdown menu (to add reagents go to Reagent Manager). The user can select the number of washes required in each step under Count, with a maximum of 3 washes per step allowed. Blow can be switched on or off by selecting the red (X) for OFF or the green check mark for ON. Turning off Blow will leave any fluid from the previous step on the slide (including Pre-Rinse).
- When finished editing, click Save & Close.

Chapter 6: Prepare and Start a Run

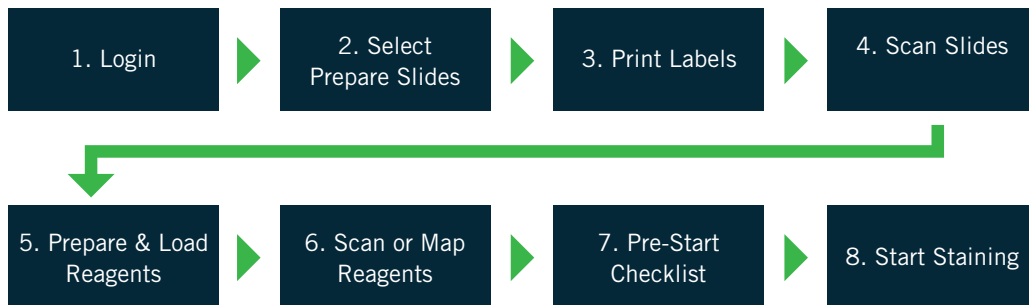
Once all required reagents and protocols have been entered into the VALENT Software by the administrator, both administrators and regular users can use this chapter as a guide to setup and begin their staining run.

Important Note: Before starting this chapter, be sure to follow the instrument preparation section. In particular, be sure to turn on the instrument before logging in to the VALENT Software, otherwise, the VALENT Software will automatically open in demo mode, not allowing the user to start the run.

There are two ways to process slides described below.

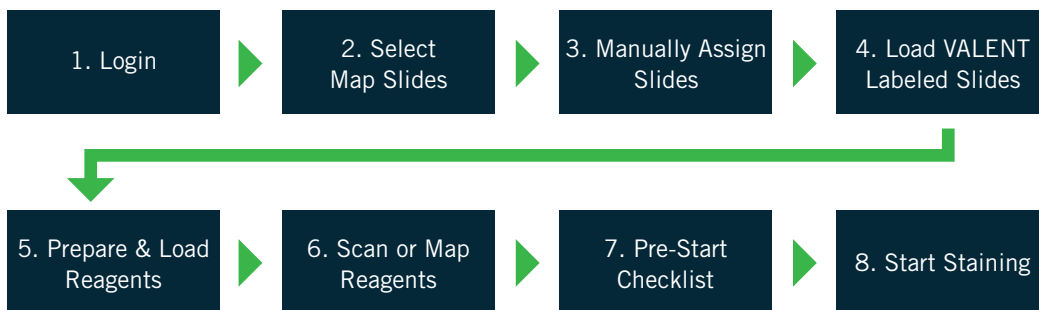
Process Overview 1

Summary of the run setup process by Scanning Slide Labels. Details of each step are provided within this chapter.



Process Overview 2

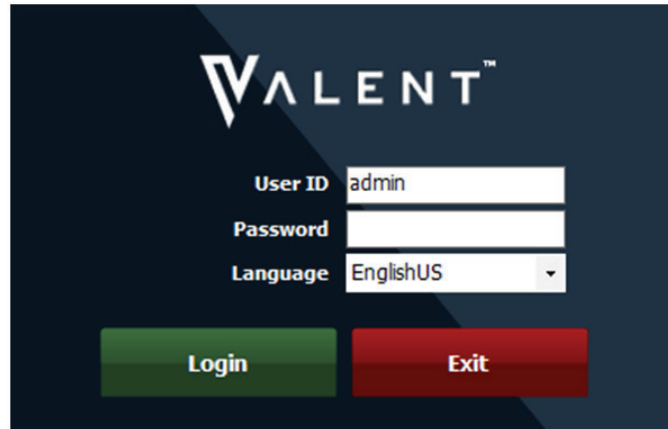
Summary of the run setup process using Manual Mapping of Slides. Details of each step are provided within this chapter.



1. Login

Login to the VALENT Software. Enter username and password in the dialog box.

Note: Default User ID is **admin**, default password is **valent**.



Home Screen



1. Menu Bar
2. Run Designation Buttons
3. Run End Time
4. Reagent Rack
5. System Lid Status
6. Reagent Rack Lock/Unlock Status
7. Reagent Rack Temperature
8. Carboy Reagent Levels
9. Slide Tray Position
10. Slide Tray Lock/Unlock Status
11. Slide Tray Status

2. Prepare Slides

Prepare Slides is the orange Run Designation Button that is located to the top left of the Home Screen. It is the starting point to begin a staining run. Prepare Slide functions are listed below.

Prepare and Edit Slides

- From the Home Screen select Prepare Slides.
- The Add Slides window will allow the user to enter Slide Details, such as Case #, Pathologist, Patient Name, etc.
- All slides added in the Add Slides window will be labeled with the same Slide Details such as Case # or Block ID. To enter different Slide Details, go to the Data Manager-> Slide Fields and enter slide details desired. See Slide Fields section of Chapter 4 for more information.
- Choose from a list of protocols under Available Protocols dropdown menu. Filter by All Protocols or Custom Groups.
- Select the desired protocol from the list of Available Protocols (hold the CTRL button down to select more than one protocol).
- Click the green right arrow to select the protocol.
- If positive and/or negative controls are desired, check the box under the plus (+) sign to order a positive control and check the box under the minus (-) sign to order a negative control.
- Click OK.
- The Slide Manager window will open for additional features including printing slide labels, copying slides, importing slides, saving slides, deleting slides, and viewing a reagent worksheet.

- Slide Detail, such as Case#, Pathologist, Patient Name, Block ID, etc. can be modified by clicking on the cell to be modified.
- Protocol information, such as protocol name, reagent steps and their properties, can be deleted, inserted, added or moved by clicking on the cell to be modified.
- Skip to Print Labels of Chapter 5 of the Protocol Manager section if the user does not need further instruction on how to add, modify, copy, print slides and reagent worksheet, etc.

Important Note: When modifying Protocol and Slide Detail information, click out of the current cell and to a different cell to lock in the changes.

Add, Delete and Copy Slides from Slide Manager

- From the Slide Manager window, there are several buttons to the bottom left of the window.
- Additional slides can be added by clicking the plus (+) sign slide icon.

Slide Manager

Prepared Slides

- CD10 (AR-H pH - AR-H pH)
- CD10+ (AR-H pH - AR-H pH)
- CD10- (AR-H pH - AR-H pH)
- CD3 (M) (AR-H pH - AR-H pH)
- CD3 (M)+ (AR-H pH - AR-H pH)
- CD3 (M)- (AR-H pH - AR-H pH)
- p40 (M) (AR-H pH - AR-H pH)
- p40 (M)+ (AR-H pH - AR-H pH)
- p40 (M)- (AR-H pH - AR-H pH)
- p63 (AR-H pH - AR-H pH)
- p63+ (AR-H pH - AR-H pH)
- p63- (AR-H pH - AR-H pH)

Slides: 12

Slide Detail

Case # BCM123
Block ID 45678

0010905201805195163160

Protocol: p63- Dispense Volume: 300

#	Name	Blow	Reagent	Volume	Time	Heat	Wash	Count
1	DePar	✘	Val DePar [VLT8001]		00:08		Buffer	0
2	Antigen Retrieval	✘	AR-H pH [VLT8003]		00:50	98	Buffer	1
3	Block	✔	Val Peroxidase Block [VLT8002]	✔	00:05		Buffer	1
4	Block	✔	Val Background Block [VLT8011]	✔	00:10		Buffer	1
5	Antibody	✔	Val Universal Negative Control ...	✔	00:30		Buffer	1
6	Secondary	✔	Val Mouse Secondary HRP [VLT...	✔	00:10		Buffer	1
7	Tertiary	✔	Val Universal HRP Polymer [VLT...	✔	00:20		Buffer	2
8	Chromogen	✔	Val DAB Chromogen Kit [VLT8008]	✔	00:05		Aqua Rinse	1
9	Counter Stain	✔	Val Hematoxylin [VLT8014]	✔	00:05		Aqua Rinse	1
10	Wash				00:00		Buffer	1

Save & Close

- This will bring the user back to the Add Slides window. The user can then select additional slides for processing.
- The user can make copies of a Prepared Slide by highlighting the slide to be copied and clicking the multiple slide icon from the Slide Manager.

Slide Manager

Prepared Slides

- CD10 (AR-H pH - AR-H pH)
- CD10+ (AR-H pH - AR-H pH)
- CD10- (AR-H pH - AR-H pH)
- CD3 (M) (AR-H pH - AR-H pH)
- CD3 (M)+ (AR-H pH - AR-H pH)
- CD3 (M)- (AR-H pH - AR-H pH)
- p40 (M) (AR-H pH - AR-H pH)
- p40 (M)+ (AR-H pH - AR-H pH)
- p40 (M)- (AR-H pH - AR-H pH)
- p63 (AR-H pH - AR-H pH)
- p63+ (AR-H pH - AR-H pH)
- p63- (AR-H pH - AR-H pH)

Slides: 12

Slide Detail

Case # BCM123
Block ID 45678

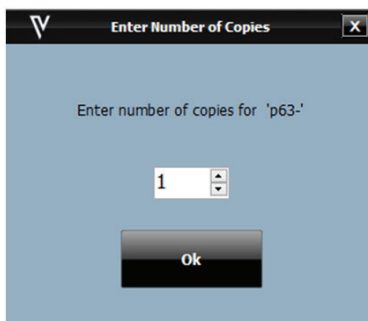
0010905201805195163160

Protocol: p63- Dispense Volume: 300

#	Name	Blow	Reagent	Volume	Time	Heat	Wash	Count
1	DePar	✘	Val DePar [VLT8001]		00:08		Buffer	0
2	Antigen Retrieval	✘	AR-H pH [VLT8003]		00:50	98	Buffer	1
3	Block	✔	Val Peroxidase Block [VLT8002]	✔	00:05		Buffer	1
4	Block	✔	Val Background Block [VLT8011]	✔	00:10		Buffer	1
5	Antibody	✔	Val Universal Negative Control ...	✔	00:30		Buffer	1
6	Secondary	✔	Val Mouse Secondary HRP [VLT...	✔	00:10		Buffer	1
7	Tertiary	✔	Val Universal HRP Polymer [VLT...	✔	00:20		Buffer	2
8	Chromogen	✔	Val DAB Chromogen Kit [VLT8008]	✔	00:05		Aqua Rinse	1
9	Counter Stain	✔	Val Hematoxylin [VLT8014]	✔	00:05		Aqua Rinse	1
10	Wash				00:00		Buffer	1

Save & Close

- Enter the number of copies.



- A prepared slide can be deleted by checking the box next to the slide to be deleted and clicking the red (X) sign slide icon.

Slide Manager

Prepared Slides

- CD10 (AR-Hi pH - AR-Hi pH)
- CD10+ (AR-Hi pH - AR-Hi pH)
- CD10- (AR-Hi pH - AR-Hi pH)
- CD3 (M) (AR-Hi pH - AR-Hi pH)
- CD3 (M)+ (AR-Hi pH - AR-Hi pH)
- CD3 (M)- (AR-Hi pH - AR-Hi pH)
- p40 (M) (AR-Hi pH - AR-Hi pH)
- p40 (M)+ (AR-Hi pH - AR-Hi pH)
- p40 (M)- (AR-Hi pH - AR-Hi pH)
- p63 (AR-Hi pH - AR-Hi pH)
- p63+ (AR-Hi pH - AR-Hi pH)
- p63- (AR-Hi pH - AR-Hi pH)

Select all 12 slides

Slide Detail

Case # **BCM123**
Block ID **45678**

01010905201805195163160

Protocol: **p63-** Dispense Volume: **300**

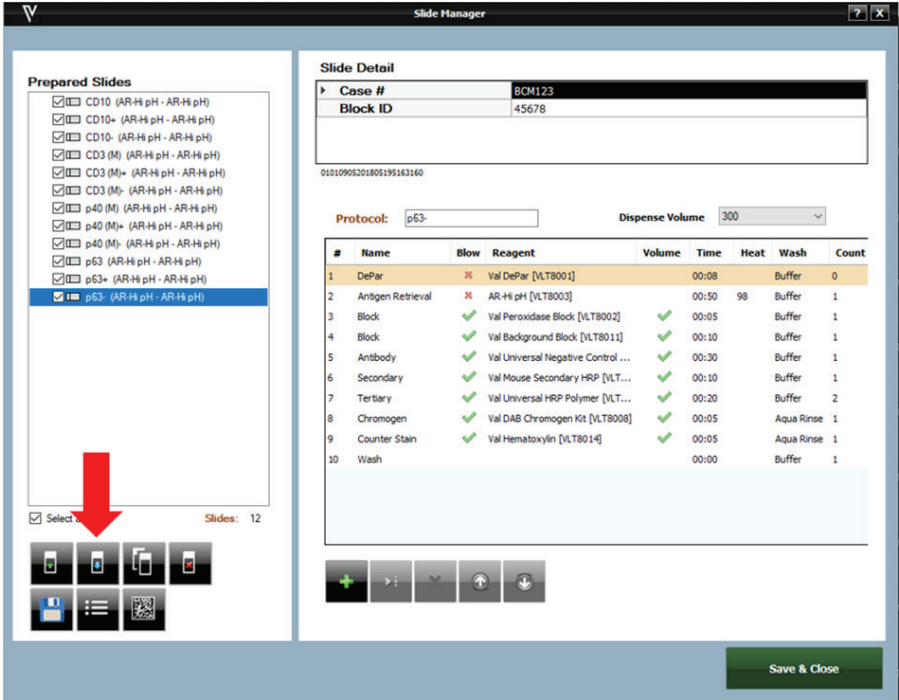
#	Name	Blow	Reagent	Volume	Time	Heat	Wash	Count
1	DePar	✗	Val DePar [VLT8001]		00:08		Buffer	0
2	Antigen Retrieval	✗	AR-Hi pH [VLT8003]		00:50	98	Buffer	1
3	Block	✓	Val Peroxidase Block [VLT8002]	✓	00:05		Buffer	1
4	Block	✓	Val Background Block [VLT8011]	✓	00:10		Buffer	1
5	Antibody	✓	Val Universal Negative Control ...	✓	00:30		Buffer	1
6	Secondary	✓	Val Mouse Secondary HRP [VLT...	✓	00:10		Buffer	1
7	Tertiary	✓	Val Universal HRP Polymer [VLT...	✓	00:20		Buffer	2
8	Chromogen	✓	Val DAB Chromogen Kit [VLT8008]	✓	00:05		Aqua Rinse	1
9	Counter Stain	✓	Val Hematoxylin [VLT8014]	✓	00:05		Aqua Rinse	1
10	Wash				00:00		Buffer	1

Save & Close

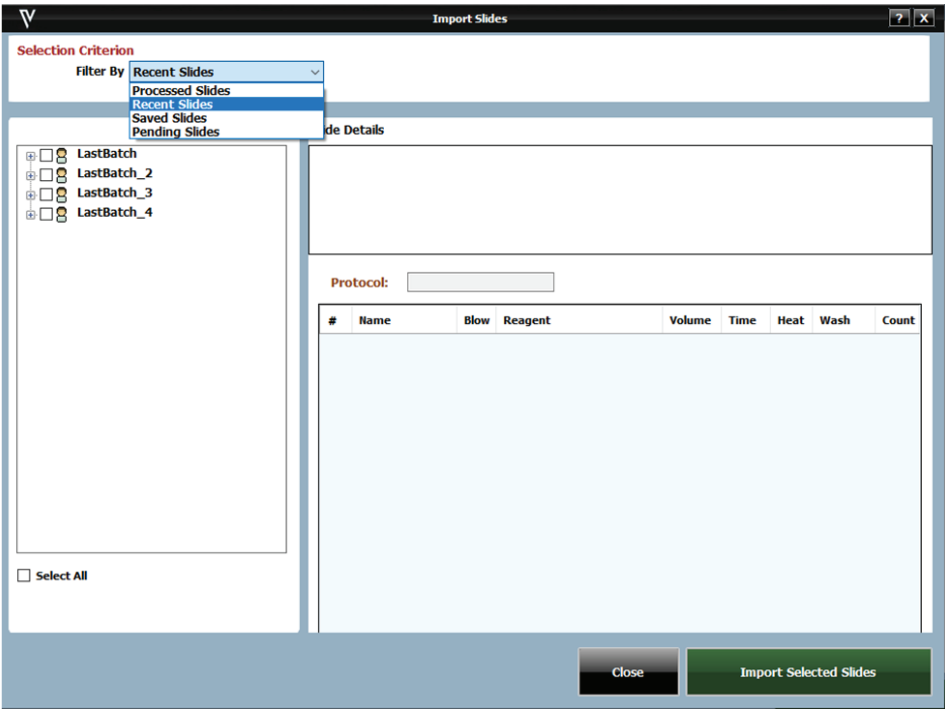
Important Note: Make sure only the slides desired to be deleted are check-marked or everything will be deleted.

Import Slides from Slide Manager

- From the Slide Manager window, there are several buttons to the bottom left of window.
- Processed Slides, Recent Slides, Pending Slides and Saved Slides can be imported by clicking the Import Slides (blue arrow pointing down) sign slide icon.



- The Import Slides Window will appear.

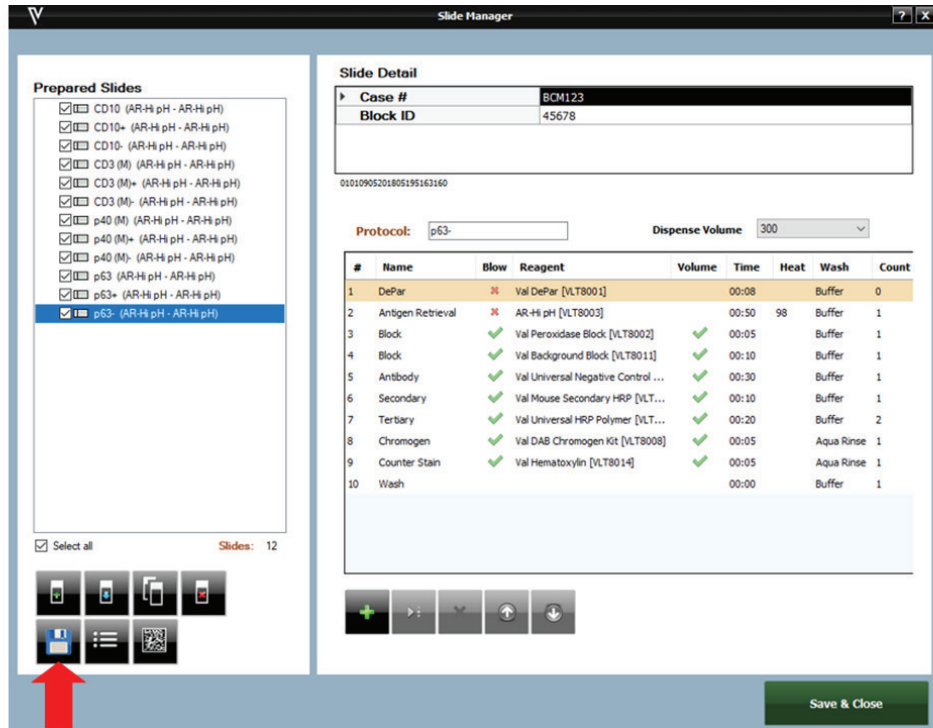


- Select which set of slides are to be imported from the dropdown menu, check the box for each required slide and click Import Selected Slides.

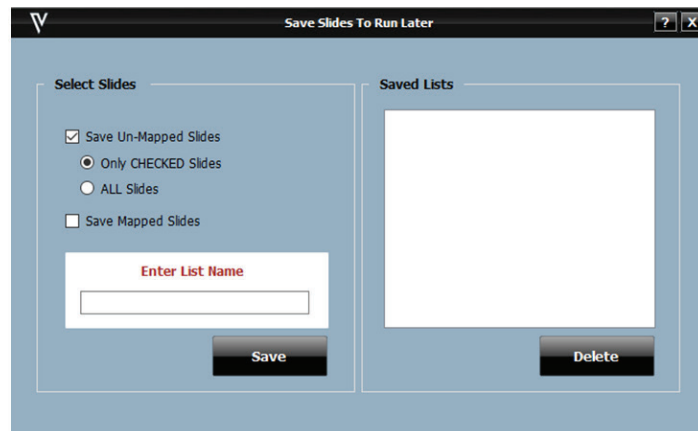
Save Slides for a Later Run

The user can prepare slides for a future run when the instrument is not running or while a run is in progress.

- To save slides to run later, click the Save Slides button on the Prepared Slide screen.



- The Save Slides To Run Later window will open.

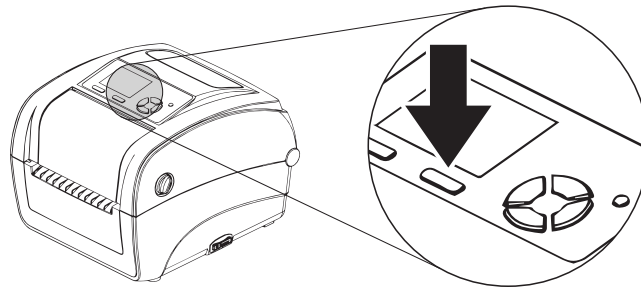


- To save only Un-Mapped Slides (slides that are still in the list), check the box next to Save Un-Mapped Slides.
- To save only the checked slides under Un-Mapped slides, select Only CHECKED Slides.
- To save both checked and unchecked slides within unmapped slides, select ALL Slides.
- To save only 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.

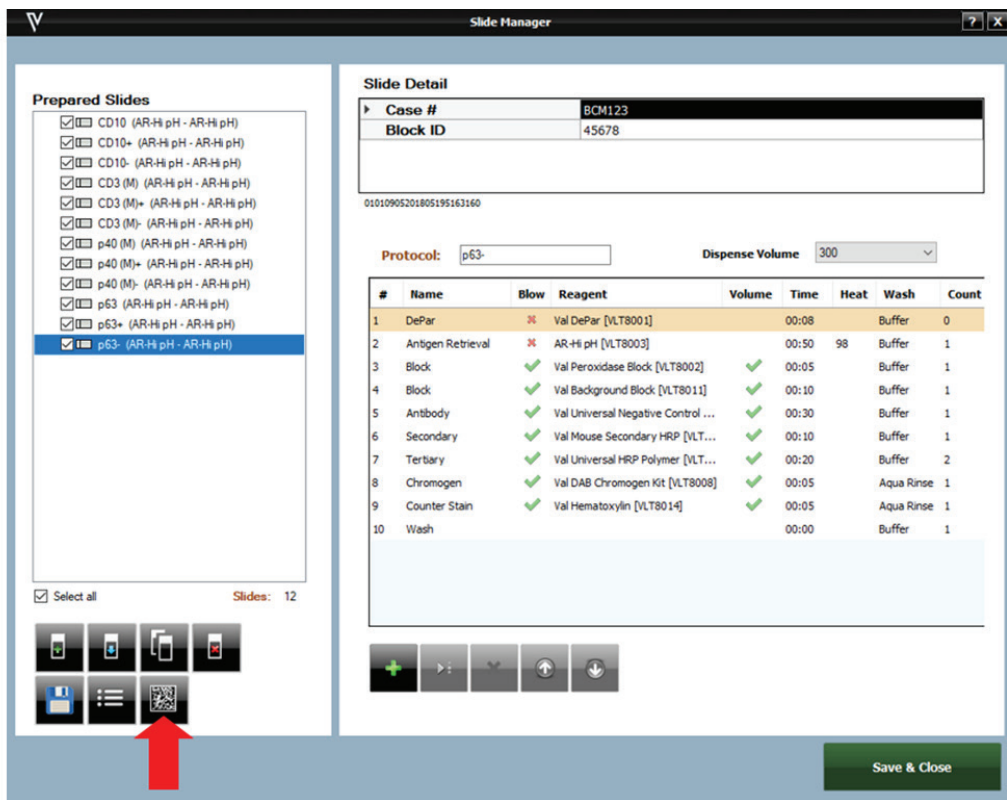
3. Print Labels

Once the user has set up slides from Prepared Slides in the Slide Manager window, follow the steps to start a run.

Important Note: Prior to printing a new batch of slide labels for a run, use the "FEED" button on the top of the label printer to advance the slide label roll, and discard the first, blank label. See section on how to Prepare and Edit Slides in the beginning of this chapter to obtain detailed information on how to set up slides and protocols.



- From the Slide Manager Window under Prepared Slides, once all slides have been ordered and information is correct, select the print button to print slide labels, located to the bottom right.



- Make sure each slide that requires printing has a check mark next to its box.
- Once the labels are printed, place the labels on the slides and load the slides onto the slide tray.
- Select Save and Close.
- The Assign Slides window will appear which is required to start scanning.

Important Note: When placing the slide label on the slide make sure the whole label is completely flattened and adhered to the slide, especially the bottom of the label. If the slide label sticks up even slightly, current flow will be impeded and reagents will wick and yield poor staining quality.

View and Print Reagent Worksheet

- From the Slide Manager window, select the slides to be processed then click Show Reagent Worksheet button, located to the bottom left under Prepared Slides.

The screenshot shows the Slide Manager interface. On the left, the 'Prepared Slides' panel lists 12 slides, with 'p63- (AR-Hi pH - AR-Hi pH)' selected. A red arrow points to a button with a printer icon in the bottom left of this panel. On the right, the 'Slide Detail' panel shows Case # BCM123 and Block ID 45678. Below this, a table lists reagents for protocol 'p63-' with a dispense volume of 300. The table includes columns for #, Name, Blow, Reagent, Volume, Time, Heat, Wash, and Count.

#	Name	Blow	Reagent	Volume	Time	Heat	Wash	Count
1	DePar	✘	Val DePar [VLT8001]		00:08		Buffer	0
2	Antigen Retrieval	✘	AR-Hi pH [VLT8003]		00:50	98	Buffer	1
3	Block	✔	Val Peroxidase Block [VLT8002]	✔	00:05		Buffer	1
4	Block	✔	Val Background Block [VLT8011]	✔	00:10		Buffer	1
5	Antibody	✔	Val Universal Negative Control ...	✔	00:30		Buffer	1
6	Secondary	✔	Val Mouse Secondary HRP [VLT...	✔	00:10		Buffer	1
7	Tertiary	✔	Val Universal HRP Polymer [VLT...	✔	00:20		Buffer	2
8	Chromogen	✔	Val DAB Chromogen Kit [VLT8008]	✔	00:05		Aqua Rinse	1
9	Counter Stain	✔	Val Hematoxylin [VLT8014]	✔	00:05		Aqua Rinse	1
10	Wash				00:00		Buffer	1

- Choose from the drop down: Prepared Slides or All Slides to view Mapped Slides.
- All slides from the chosen dropdown menu are listed on the left, under Slide List.
- All reagents required to run these slides are listed on the right.
- Selecting specific slides from the Slides List will only show the reagents needed for those slides in the Reagent List on the right.
- To print the Reagent List, click Print Reagent Worksheet.
- To print labels, check the boxes next to the reagents that require labels and click Print Labels. Select All is available if required.
- Reagent Worksheet may also be printed from the Tools dropdown menu of the Home Screen, once reagents are mapped.
- Click Save & Close when finished.

4. Scan Slides

Once the user has set up slides from Prepared Slides in the Slide Manager window, follow the steps to start a run.

Important Note: See section on how to Prepare and Edit Slides in the beginning of this chapter to obtain detailed information on how to set up slides and protocols.

- From the Slide Manager Window under Prepared Slides, once all slides have been ordered and information is correct, select the print button to print slide labels, located to the bottom right.
- Click Save + Close

Prepared Slides

- CD10 (AR-Hi pH - AR-Hi pH)
- CD10+ (AR-Hi pH - AR-Hi pH)
- CD10- (AR-Hi pH - AR-Hi pH)
- CD3 (M) (AR-Hi pH - AR-Hi pH)
- CD3 (M)+ (AR-Hi pH - AR-Hi pH)
- CD3 (M)- (AR-Hi pH - AR-Hi pH)
- p40 (M) (AR-Hi pH - AR-Hi pH)
- p40 (M)+ (AR-Hi pH - AR-Hi pH)
- p40 (M)- (AR-Hi pH - AR-Hi pH)
- p63 (AR-Hi pH - AR-Hi pH)
- p63+ (AR-Hi pH - AR-Hi pH)

Select all Slides: 12

Slide Detail

Case # BCM123
Block ID 45678

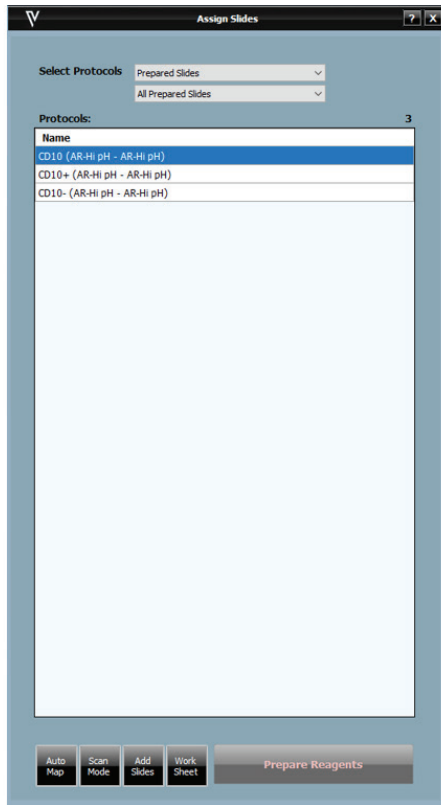
01010905201805195163160

Protocol: p63- Dispense Volume: 300

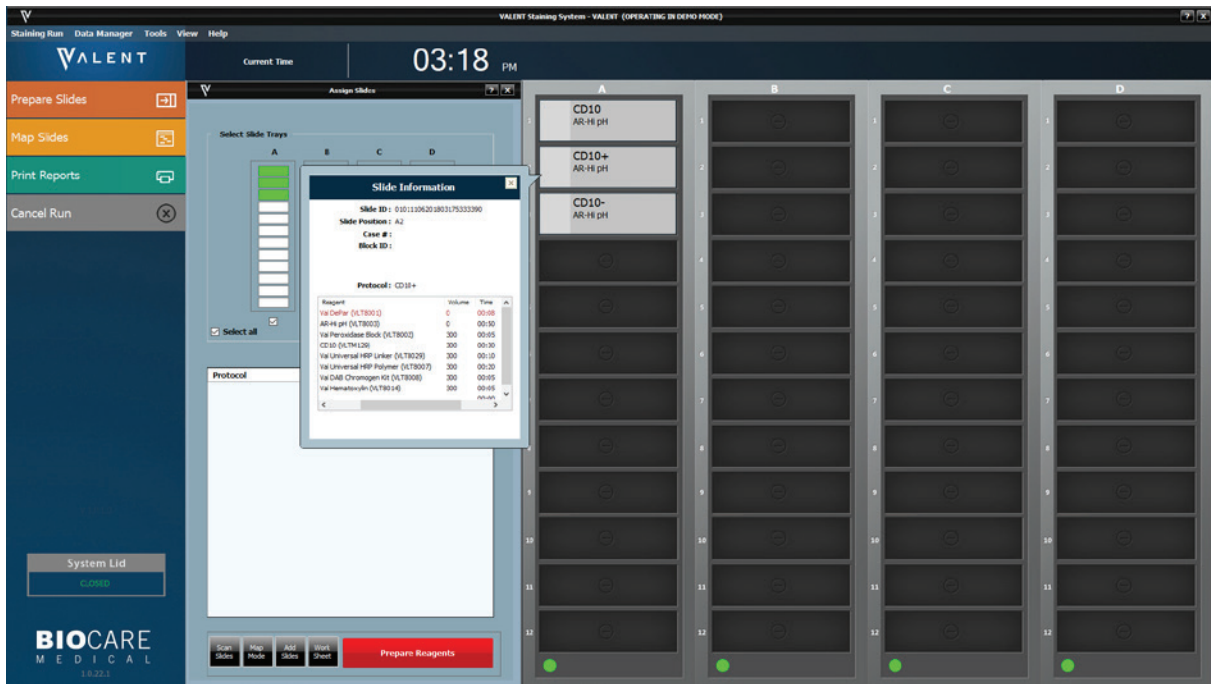
#	Name	Blow	Reagent	Volume	Time	Heat	Wash	Count
1	DePar	✘	Val DePar [VLT8001]		00:08		Buffer	0
2	Antigen Retrieval	✘	AR-Hi pH [VLT8003]		00:50	98	Buffer	1
3	Block	✔	Val Peroxidase Block [VLT8002]	✔	00:05		Buffer	1
4	Block	✔	Val Background Block [VLT8011]	✔	00:10		Buffer	1
5	Antibody	✔	Val Universal Negative Control ...	✔	00:30		Buffer	1
6	Secondary	✔	Val Mouse Secondary HRP [VLT...	✔	00:10		Buffer	1
7	Tertiary	✔	Val Universal HRP Polymer [VLT...	✔	00:20		Buffer	2
8	Chromogen	✔	Val DAB Chromogen Kit [VLT8008]	✔	00:05		Aqua Rinse	1
9	Counter Stain	✔	Val Hematoxylin [VLT8014]	✔	00:05		Aqua Rinse	1
10	Wash				00:00		Buffer	1

Save & Close

- The Assign Slides window will appear. Select Scan Mode.
- Check the box for each slide tray that contains slides, the Select All checkbox is available if all 4 slide trays contain slides.
- Click Scan Slides to begin slide scanning. Scanning will cease once all printed slide labels have been detected.



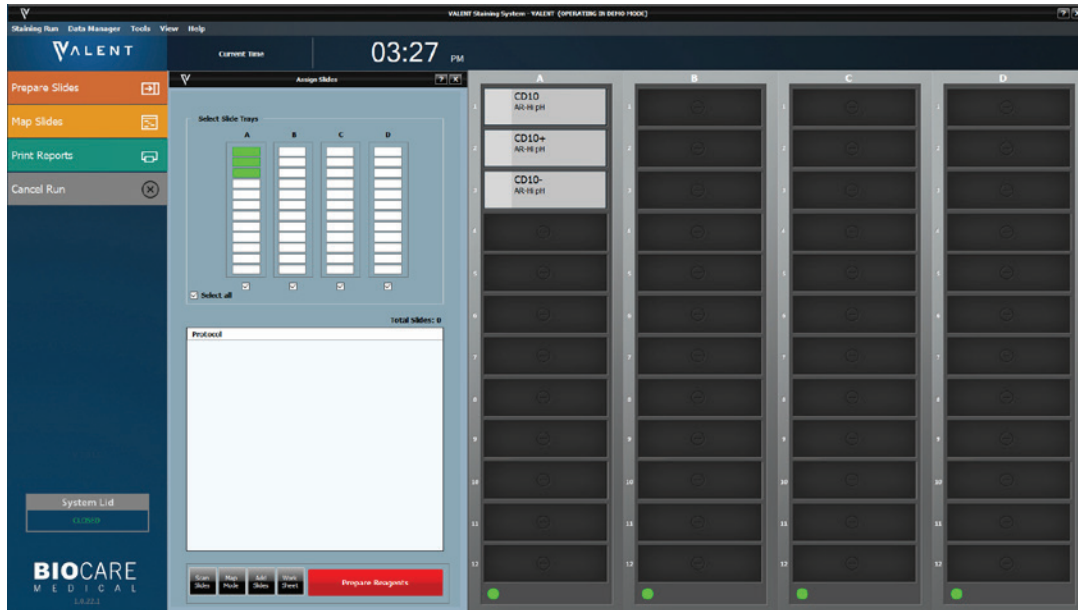
- If the user requires more slides, the Add Slides button is located to the bottom of the Assign Slides window.
- The Home Screen will display all scanned slides in the Slide Tray. Slide Positions will appear green under Assign Slides, once slides have been detected.
- Use the mouse to hover over a scanned slide for the Slide Information window to appear.



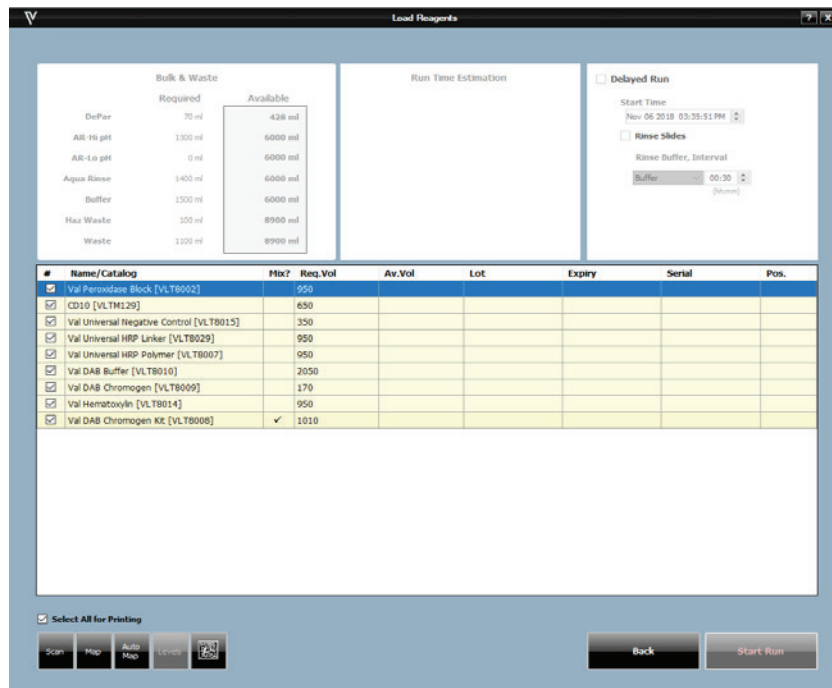
- Once all slides have been scanned, the Prepare Reagent button will be accessible.

5. Prepare and Load Reagents

- Once desired slides have been loaded and scanned, click Prepare Reagents from the Assigned Slide window 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 enter 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 the Inventory Manager.
- If reagent labels are needed, check the box for each reagent that a label is needed or check Select All for Printing and click Print Label.
- Label reagent vials. Reagent labels should be placed next to opening of vial and centered.
- If using hematoxylin, gently mix the reagent by inverting the vial twice before loading onto the reagent rack.

6. Scan or Map Reagents

Ensure all reagent vials are properly labeled and load all reagents listed in the reagent rack in order of use, to facilitate optimal reagent dispensing time.

- Choose from three loading reagent options: Auto Map, Manual Map, and Scan Reagents.
 - o Auto Map will load reagents in the reagent rack in the order listed in the Load Reagents screen. Load Reagents is based on which slides were assigned first. For example, if TTF-1 is entered manually in positions A6-A12 first and then CD20 is added in A1-A5. Load Reagents will list TTF-1 first before CD20. It is the user's responsibility to physically load the reagent vials in the auto mapped locations correctly.
 - o Manual Map allows the user to choose a reagent from the Load Reagents list and then choose the position in the reagent rack to which the user desires it to be loaded. Repeat until all reagents in the Load Reagents list have been mapped. It is the user's responsibility to physically load the reagent vials in the manually mapped locations correctly.
 - o Scan Reagents will instruct the barcode camera to scan the reagent rack until all required reagents have been located. It will automatically detect reagent levels.
- After all of the required reagents have been loaded and scanned, mapped or auto-mapped reagents require the user click Levels to detect reagent levels are sufficient for the run.

7. Pre-Start Checklist

Use the Load Reagents screen as a Pre-Start Checklist to verify that the appropriate carboys have been filled, and hazardous and non-hazardous carboys have been emptied. Check the carboy status categories under Bulk & Waste.

Bulk & Waste

	Required	Available
DePar	70 ml	500 ml
AR-Hi pH	1300 ml	6000 ml
AR-Lo pH	0 ml	6000 ml
Aqua Rinse	1900 ml	6000 ml
Buffer	1500 ml	6000 ml
Haz Waste	100 ml	8900 ml
Waste	1500 ml	8900 ml

Confirm DePar Volume

Run Time Estimation

A	08:31 PM
B	-
C	-
D	-
Total Run	08:31 PM

Delayed Run

Start Time
May 28 2019 05:50:13 PM

Rinse Slides

Rinse Buffer, Interval
Buffer 00:30 (h:mm)

#	Name/Catalog	Mix?	Req. Vol	Av. Vol	Lot	Expiry	Serial	Pos.
<input type="checkbox"/>	Val Peroxidase Block [VLT8002]		950	20050		2019/12		A1
<input type="checkbox"/>	CD10 [VLT80129]		650	20050		2019/12		A2
<input type="checkbox"/>	Val Universal Negative Control [VLT8015]		350	20050		2019/12		A3
<input type="checkbox"/>	Val Mouse Secondary HRP [VLT8006]		950	20050		2019/12		A4
<input type="checkbox"/>	Val Universal HRP Linker [VLT8029]		950	20050		2019/12		A5
<input type="checkbox"/>	Val Universal HRP Polymer [VLT8007]		950	20050		2019/12		A6
<input type="checkbox"/>	Val DAB Buffer [VLT8010]		2050	20050		2019/12		A7
<input type="checkbox"/>	Val DAB Chromogen [VLT8009]		170	20050		2019/12		A8
<input type="checkbox"/>	Val Hematoxylin [VLT8014]		950	20050		2019/12		A9
<input type="checkbox"/>	Val DAB Chromogen Kit [VLT8008]	✓	1010	0		2019/12		D11

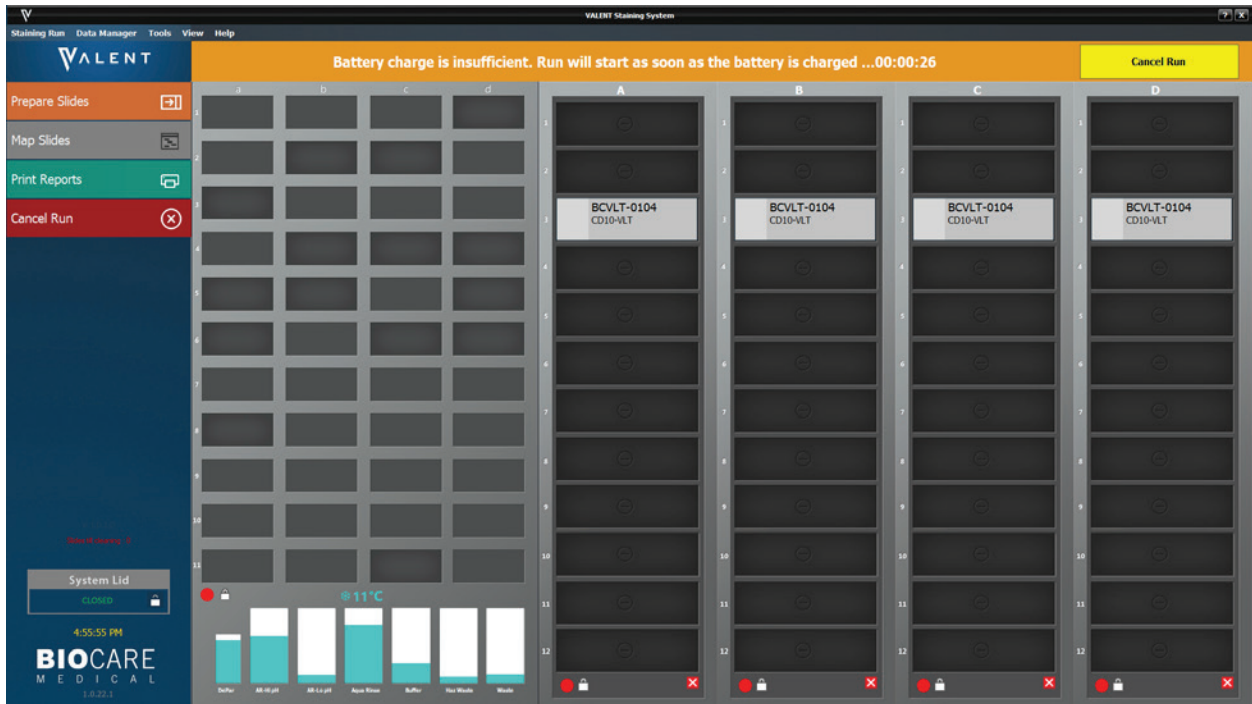
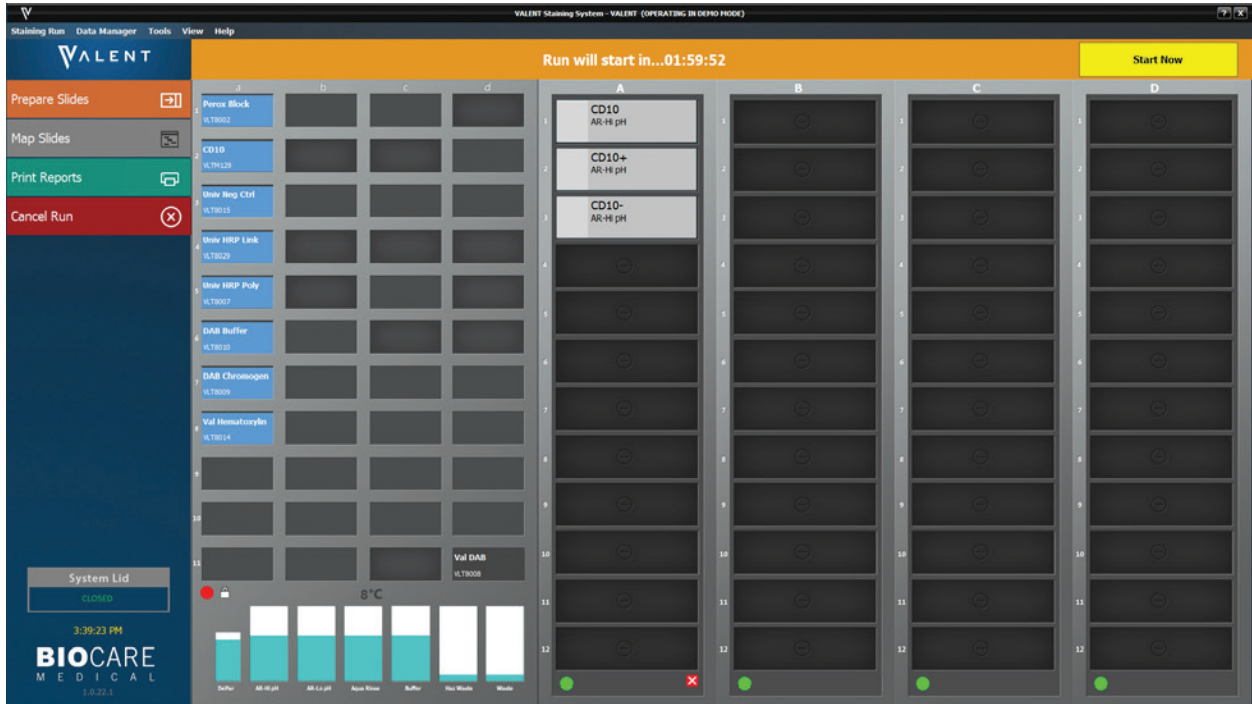
Select All for Printing

Scan Map Auto Map Levels

Check and Confirm DePar volume Back Start Run

- Make sure that all reagents and mixing vials have been loaded as shown on the screen and volumes are sufficient. Do not re-use mixing vials, always use new, clean mixing vials. The Bulk & Waste section of Load Reagents window provides information about the required volumes and waste capacities for each carboy in support of the programmed run.
- Confirm that sufficient DePar Solution is available for the upcoming run, then check the Confirm DePar Volume box.
- Check the buffer lines above the Z-head for air bubbles, if air bubbles are present refer to Drain Waste and Prime Buffers of Chapter 5 for instructions on how to remove air bubbles.
- 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. To set Delayed Run:
 - o Check the Delayed Run box under Load Reagents
 - o Select the Start Time
 - o Optional: If required select Rinse Slides, Rinse Buffer Interval Time and Aqua Rinse/Buffer

Important Note: The Delayed Run box will only appear once the reagent levels have been checked.



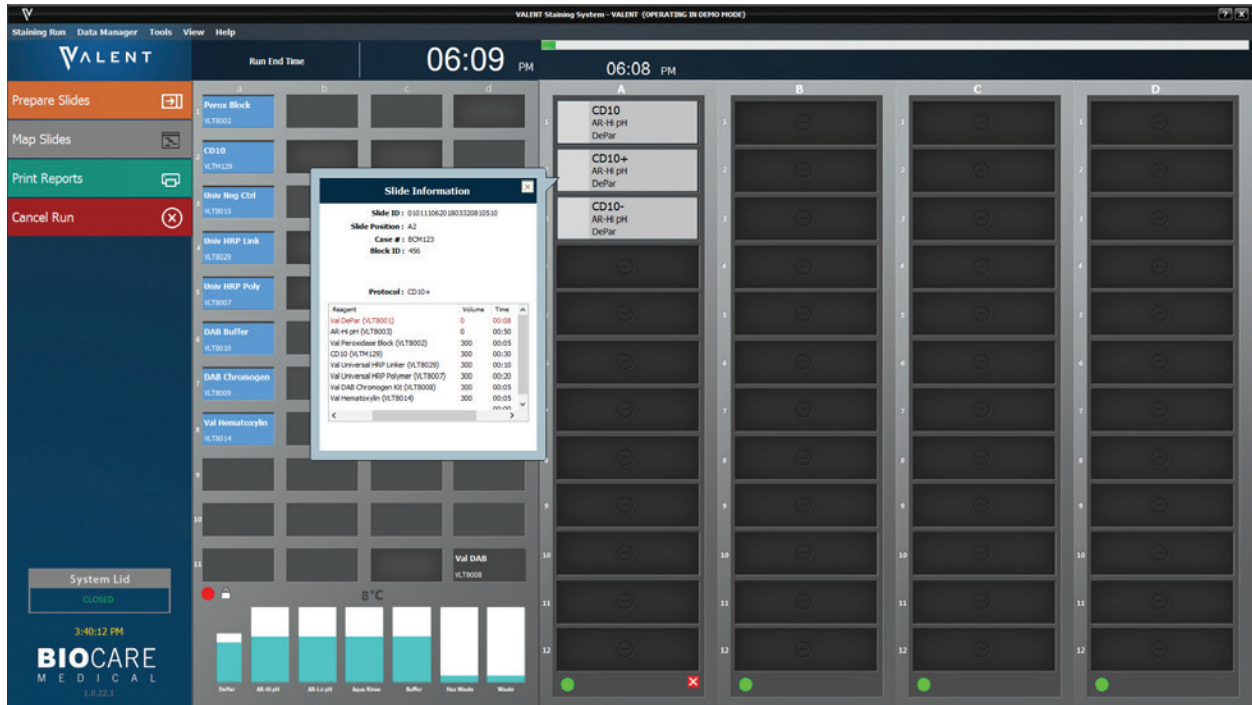
If the VALENT Cart Battery is not fully charged, the software will display a notification message with an estimation of the additional delay, as shown above.

8. Start Staining

- Once everything has been checked, select Start Run.
- **Note:** If the Delayed Run box was selected in the Pre-Start Checklist screen, after clicking Start Run, the Run will start in... countdown clock will appear in orange at the top of the Home Screen. The run automatically begins after the countdown is completed. Alternatively, the user may select Start Now or Cancel Run.

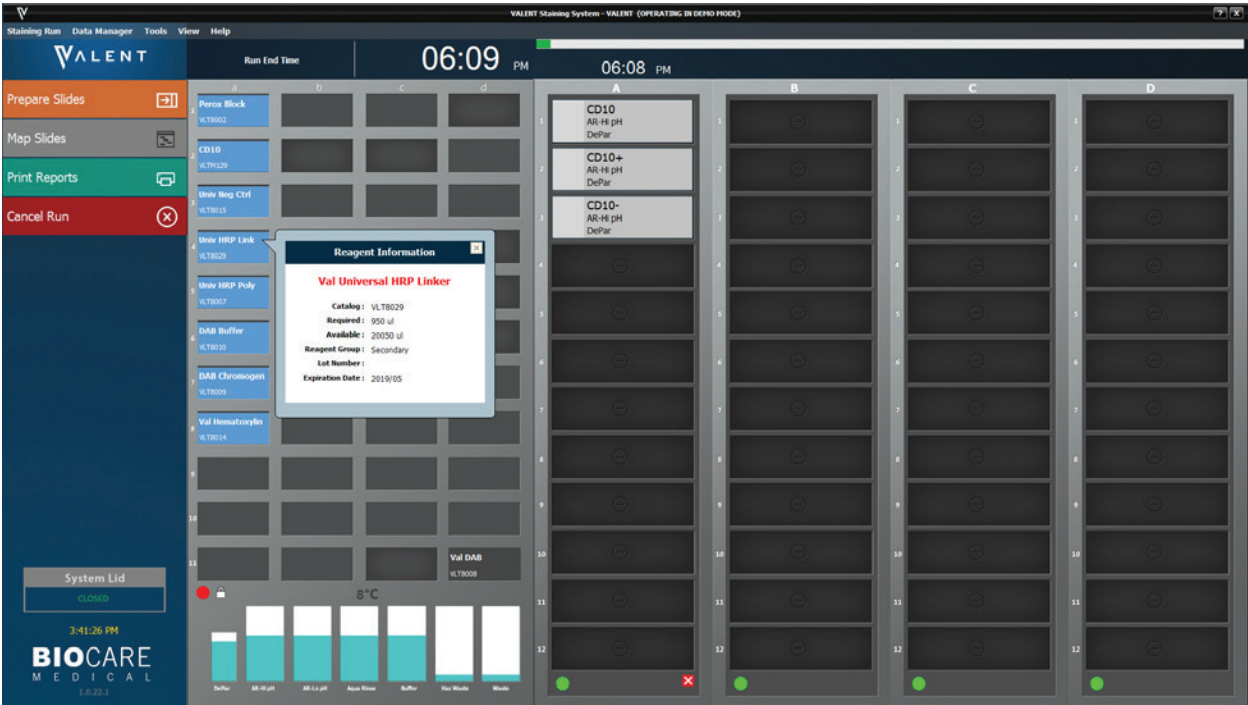
Slide and Reagent Information

Once the run has started, the user can view Slide Information by using the mouse cursor to hover over a slide.



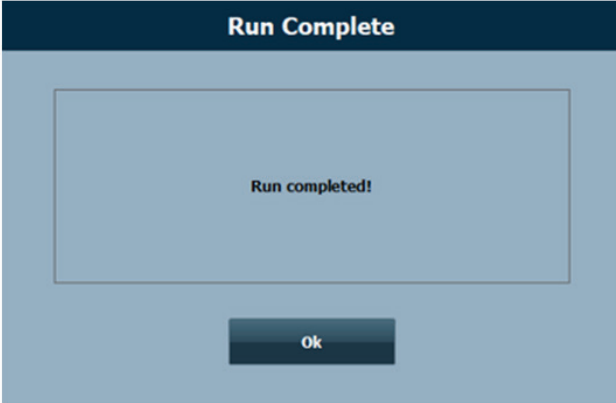
Reagent Information

Once the run has started, the user can view Reagent Information by using the mouse cursor to hover over a reagent.



Run Complete

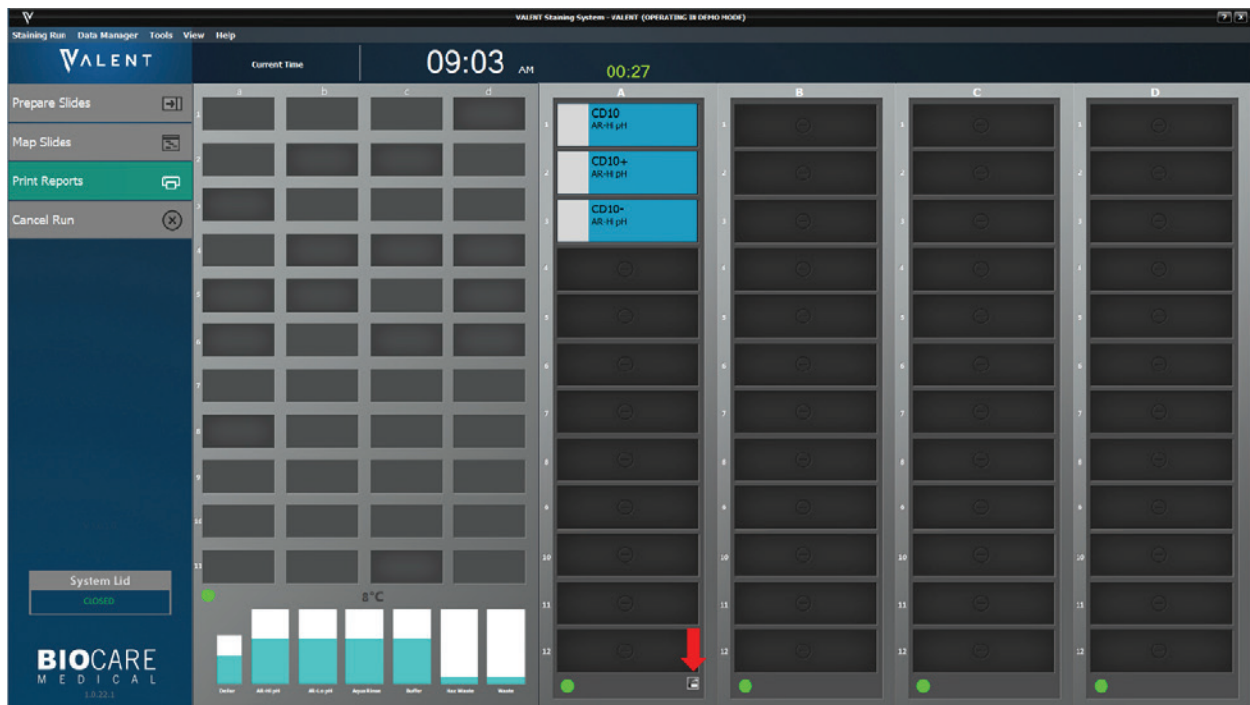
When a run is complete, slides will turn blue and a Run completed notification will appear.



Clear the Completed Trays

Once a run is complete the user can clear tray. There are two ways to do this:

- Select Clear the Completed Trays from the Tools dropdown menu of the main screen. This will release, or unlock, the slide tray from the instrument to allow the user to remove the slides.



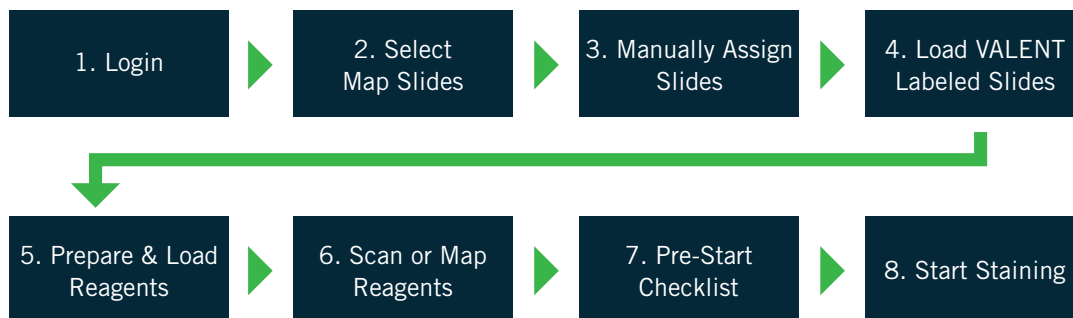
- At the end of run an icon appears below the slide trays. Clicking this icon allows the user to clear reagents and the slides in the VALENT Software.
- Reagents are automatically cleared after the run completes.

Map Slides

The VALENT allows manual mapping of slides under Map Slides.

Process Overview 2

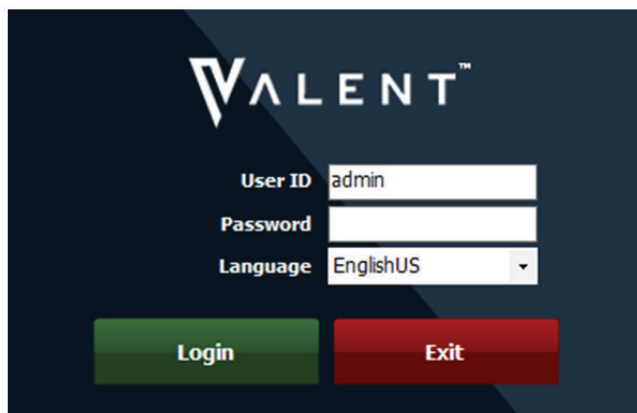
Summary of the run setup process using Manual Mapping of Slides. Details of each step are provided within this chapter.



1. Login

Login to VALENT Software. Enter username and password in the dialog box.

Note: Default User ID is **admin**, default password is **valent**.



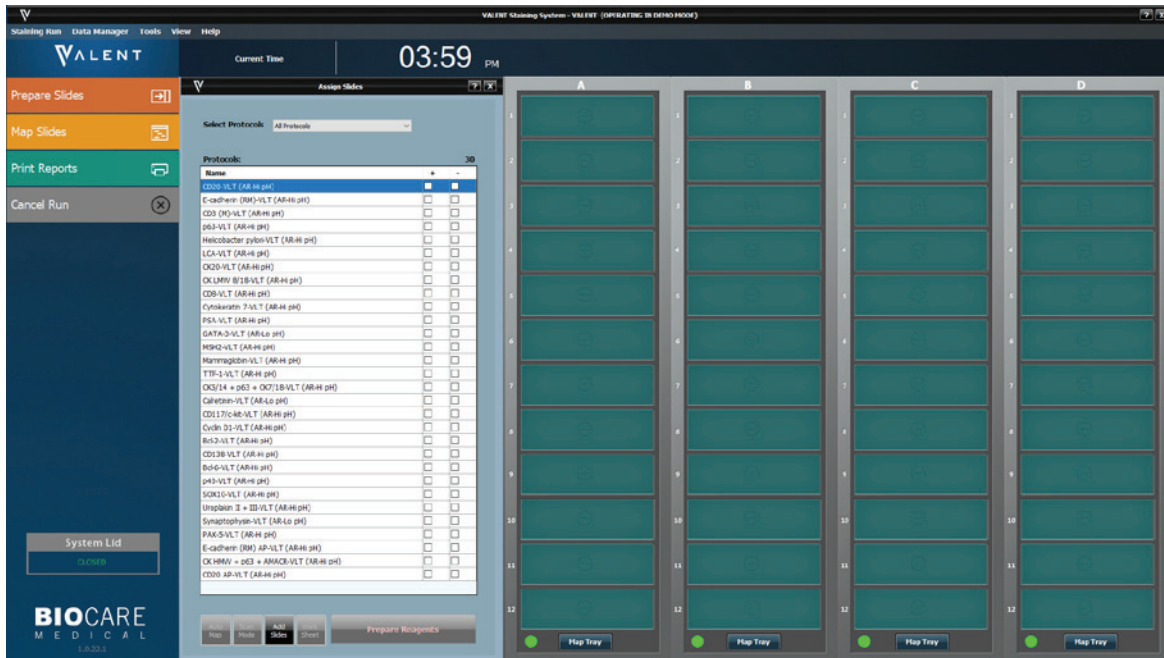
2. Map Slides

- From the Home Screen select Map Slides and the Assign Slides window will appear.
- Multiple view options are available from the Select Protocols dropdown menus. Below is a description of each protocol group.

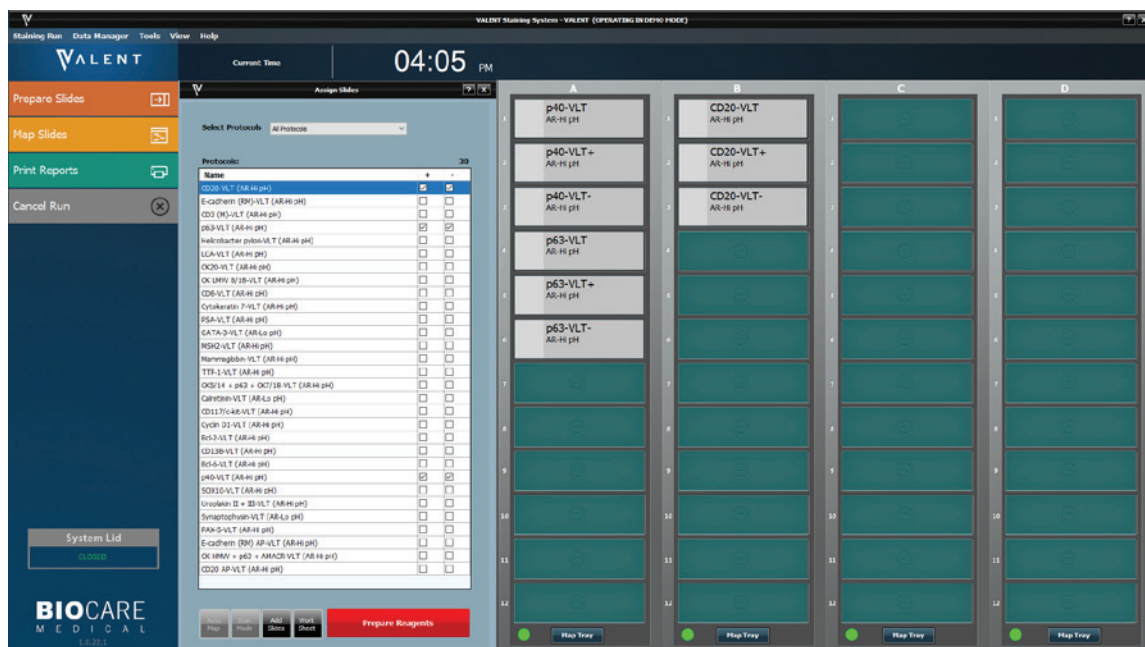
Protocol	Description
All Protocols	Lists every protocol in the system.
Custom Group	Displays protocols from a particular Custom Group. An additional dropdown exists to filter by specific Custom Group.
Prepared Slides	Only shows the Protocols from the Prepared Slides section of the Slide Manager Window. An additional dropdown menu allows the user 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).

3. Manually Assign Slides

- From the list of protocols, choose the protocol to assign and then click the slide position where the user will load the slide, the protocol will be assigned to that slide position.
- To assign the same protocol to an entire tray, choose the protocol and click Map Tray.



- If positive and/or negative controls are desired, check the box under the plus (+) sign to order a positive control and check the box under the minus (-) sign to order a negative control.
- After mapping slides to slide tray, print a copy of the Slide Layout Report to keep track of each slide's location.
- To Print the Slide Layout Report go to Tools -> Print Reports -> Slide Layout Report.



- To remove a slide from the slide tray click the slide to be deleted.
- Add Slides is available if more protocols are needed.

4. Load Labeled Slides

- All slides require a VALENT Slide Label. If slide does not have a label, use a VALENT Slide Label. Failing to use a slide label may yield poor staining quality.

5. Prepare and Load Reagents

- Once desired slides have been loaded and scanned, click Prepare Reagents from the Assigned Slide window to open Load Reagents window.
- A list of all reagents required for the run will be displayed.

#	Name/Catalog	Mix?	Req.Vol	Av.Vol	Lot	Expiry	Serial	Pos.
<input checked="" type="checkbox"/>	p40 (M) [VLTM3066]		950					
<input checked="" type="checkbox"/>	Val Universal Negative Control [VLT8015]		950					
<input checked="" type="checkbox"/>	p63 [VLTM163]		950					
<input checked="" type="checkbox"/>	CD20 [VLTM004]		950					
<input checked="" type="checkbox"/>	Val Mouse Secondary HRP [VLT8006]		3650					
<input checked="" type="checkbox"/>	Val Universal HRP Linker [VLT8029]		3650					
<input checked="" type="checkbox"/>	Val Universal HRP Polymer [VLT8007]		3650					
<input checked="" type="checkbox"/>	Val DAB Buffer [VLT8010]		4010					
<input checked="" type="checkbox"/>	Val DAB Chromogen [VLT8009]		290					
<input checked="" type="checkbox"/>	Val Hematoxylin [VLT8014]		3650					
<input checked="" type="checkbox"/>	Val DAB Chromogen Kit [VLT8008]	<input checked="" type="checkbox"/>	3890					

- A lot and expiration link is available to view and enter lot number along with the expiration date for the reagents listed. This information will only be tracked for this run. If a permanent entry is needed, go to the Inventory Manager.
- If reagent labels are needed, check the box for each reagent that a label is needed or use the Select All for Printing checkbox.
- Label reagent vials. Reagent label should be placed next to opening of vial and centered.
- If using hematoxylin, gently mix the reagent by inverting the vial twice before loading onto the reagent rack.

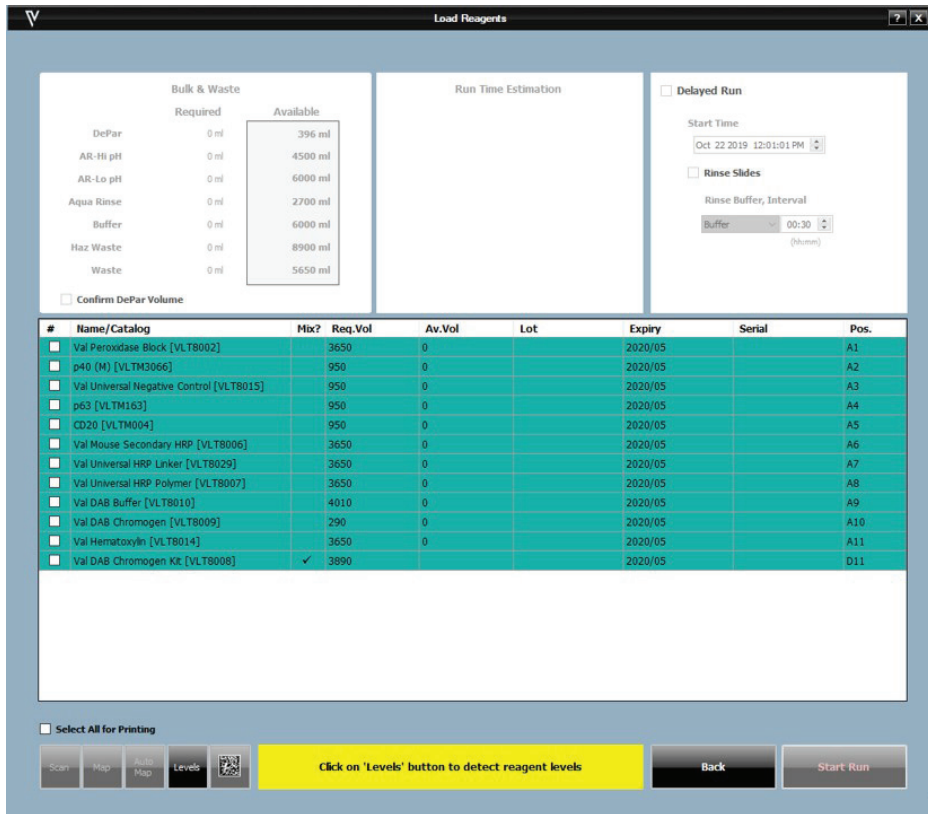
6. Scan or Map Reagents

- Ensure all reagent vials are properly labeled and load all reagents listed in the reagent rack in order of use, to facilitate optimal reagent dispensing time.
- Choose from three loading reagent options: Auto Map, Manual Map, and Scan Reagents.
 - o Auto Map will load reagents in the reagent rack in the order listed in the Load Reagents screen. Load Reagents is based on which slides were assigned first. For example, if TTF-1 is entered manually in positions A6-A12 first and then CD20 is added in A1-A5. Load Reagents will list TTF-1 first before CD20. It is the user's responsibility to physically load the reagent vials in the auto mapped locations.
 - o Manual Map allows the user to choose a reagent from the Load Reagents list and then choose the position in the reagent rack to which the user desires it to be loaded. Repeat until all reagents in the Load Reagents list have been mapped. It is the user's responsibility to physically to physically load the reagent vials in the manually mapped locations.
 - o Scan Reagents will instruct the barcode camera to scan the reagent rack until all required reagents have been located. It will automatically detect reagent levels.

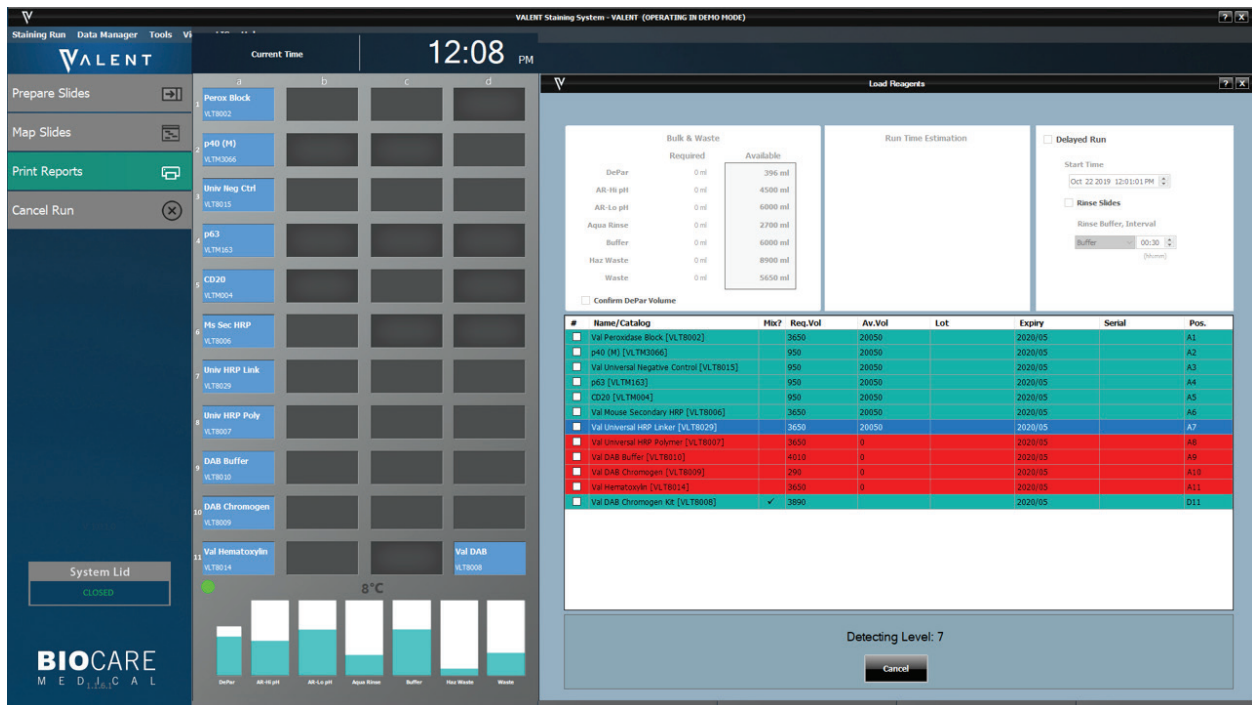
The screenshot displays the VALENT software interface. On the left, there is a sidebar with options: 'Prepare Slides', 'Map Slides', 'Print Reports', and 'Cancel Run'. The main area shows a reagent rack grid with columns for 'Required' and 'Available' volumes. Below the grid are temperature indicators for 'Buffer', 'pH 7.4', 'pH 8.0', 'pH 9.0', 'pH 10.0', 'pH 11.0', and 'pH 12.0'. On the right, the 'Load Reagents' screen is active, showing a table of reagents with columns for Name/Catalog, Map?, Req. Vol, Av. Vol, Lot, Expiry, Serial, and Pos. Below the table are buttons for 'Select All for Preloading' and 'Start Run'.

Name/Catalog	Map?	Req. Vol	Av. Vol	Lot	Expiry	Serial	Pos.
VA Peroxidase Block [VA.T8002]		3000	0		2020/05		A1
p48 (M) [VA.T8006]		900	0		2020/05		A2
VA Universal Negative Control [VA.T8012]		900	0		2020/05		A3
p40 [VA.T8007]		900	0		2020/05		A4
CD20 [VA.T8008]		900	0		2020/05		A5
VA Protein Secondary HRP [VA.T8004]		3000	0		2020/05		A6
VA Universal HRP Linear [VA.T8003]		3000	0		2020/05		A7
VA Universal HRP Polymer [VA.T8005]		3000	0		2020/05		A8
VA Universal HRP Polymer [VA.T8007]		3000	0		2020/05		A9
VA DAB Buffer [VA.T8010]		4000	0				
VA DAB Chromagen [VA.T8009]		250	0				
VA Diaminobenzidine [VA.T8014]		3000	0				
VA DAB Chromagen Kit [VA.T8008]		3000	0				

- If reagents are manually mapped or auto mapped, the user is required to click the Levels button to detect reagent levels before starting a run.



- If reagents are scanned, the VALENT will automatically detect reagents levels without having to click Levels.



- Manual override of reagents is available. Once the vials have been checked, if a reagent is highlighted in red indicating the volume is low, the user can manually override the system and enter the correct volume in the vial.
- Once reagent levels have been manually entered or scanned, the user can enter reagent lot numbers.

7. Pre-Start Checklist

Use the Load Reagents screen as a Pre-Start Checklist to verify that carboys have been filled, hazardous and non-hazardous carboys have been emptied. Check the carboy status categories under Bulk & Waste.

The screenshot shows the 'Load Reagents' window with the following sections:

- Bulk & Waste:** A table comparing Required vs. Available volumes for various reagents.

	Required	Available
DePar	70 ml	396 ml
AR-Hi pH	1300 ml	4500 ml
AR-Lo pH	0 ml	6000 ml
Aqua Rinse	2200 ml	2700 ml
Buffer	1700 ml	6000 ml
Haz Waste	200 ml	8900 ml
Waste	2500 ml	5650 ml
- Run Time Estimation:** Shows a total run time of 03:08 PM.
- Delayed Run:** Includes a Start Time dropdown (Oct 22 2019 12:01:01 PM), a Rinse Slides checkbox, and a Rinse Buffer Interval dropdown (Buffer, 00:30).
- Reagent Table:** A table with columns: #, Name/Catalog, Mix?, Req.Vol, Av.Vol, Lot, Expiry, Serial, Pos.

#	Name/Catalog	Mix?	Req.Vol	Av.Vol	Lot	Expiry	Serial	Pos.
<input type="checkbox"/>	Val Peroxidase Block [VLT8002]		3650	20050		2020/05		A1
<input type="checkbox"/>	p40 (M) [VLTM3066]		950	20050		2020/05		A2
<input type="checkbox"/>	Val Universal Negative Control [VLT8015]		950	20050		2020/05		A3
<input type="checkbox"/>	p63 [VLTM163]		950	20050		2020/05		A4
<input type="checkbox"/>	CD20 [VLTM004]		950	20050		2020/05		A5
<input type="checkbox"/>	Val Mouse Secondary HRP [VLT8006]		3650	20050		2020/05		A6
<input type="checkbox"/>	Val Universal HRP Linker [VLT8029]		3650	20050		2020/05		A7
<input type="checkbox"/>	Val Universal HRP Polymer [VLT8007]		3650	20050		2020/05		A8
<input type="checkbox"/>	Val DAB Buffer [VLT8010]		4010	20050		2020/05		A9
<input type="checkbox"/>	Val DAB Chromogen [VLT8009]		290	20050		2020/05		A10
<input type="checkbox"/>	Val Hematoxylin [VLT8014]		3650	20050		2020/05		A11
<input type="checkbox"/>	Val DAB Chromogen Kit [VLT8008]	<input checked="" type="checkbox"/>	3890	0		2020/05		D11

- Make sure that all reagents and mixing vials have been loaded as shown on the screen and volumes are sufficient. Do not re-use mixing vials, always use new, clean mixing vials.
- The Bulk & Waste section of Load Reagents window informs the user that carboys have adequate bulk reagent and waste capacity for the run.
- Confirm that sufficient DePar Solution is available for the upcoming run, then check the Confirm DePar Volume box.
- Check the buffer lines above the Z-head for air bubbles, if air bubbles are present refer to Drain Waste & Prime Buffers of Chapter 5 for instructions on how to remove air bubbles.
- 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. To set Delayed Run:
 - Check the Delayed Run box under Load Reagents
 - Select the Start Time
 - Select Rinse Slides, and Rinse Buffer Interval Time
 - Select Aqua Rinse or Wash Buffer

Important Note: The Delayed Run box only appears once the reagent levels have been checked

- Once everything has been checked, the user can either Start Run or select Delayed Run.

8. Start Staining

- Once everything has been checked, select Start Run.
- Note: If the Delayed Run box was selected in the Pre-Start Checklist screen, after clicking Start Run, the Run will start in... countdown clock will appear in orange at the top of the Home Screen. The run automatically begins after the countdown is completed. Alternatively, the user may select Start Now or Cancel Run.

Chapter 7: System Cleaning

The VALENT should be cleaned on a daily, weekly, and monthly basis. The use of appropriate personal protective equipment (PPE) is recommended during all instrument cleaning procedures. Failing to clean the instrument may result in poor quality staining.

Daily

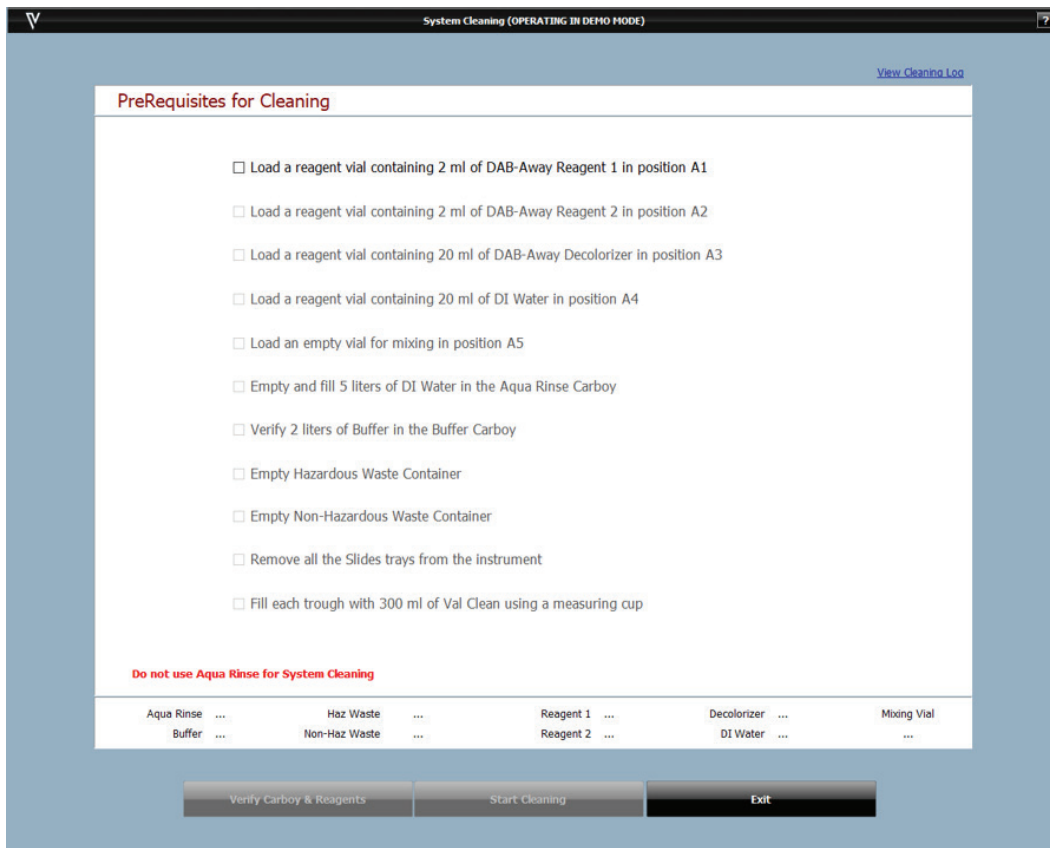
- Rinse the used slide racks in tap water and dab (do not wipe) dry with a paper towel after every run. Always wear gloves while performing this cleaning step.
- Inspect slide trays for residue from DAB, hematoxylin or other unwanted debris. If debris or residue is observed, perform weekly slide tray cleaning as described in the "Weekly Slide Tray Cleaning" section on page 92 of this manual.
- Place the empty slide racks on a clean, dry surface for storage until the next use.

Weekly

Perform Val DAB Away and Val Clean cleaning at least once a week or every 250 slides to clean the reagent probe followed by Weekly Slide Tray cleaning to remove residue from slide trays, trough surfaces, trough level sensors, and trough filters.

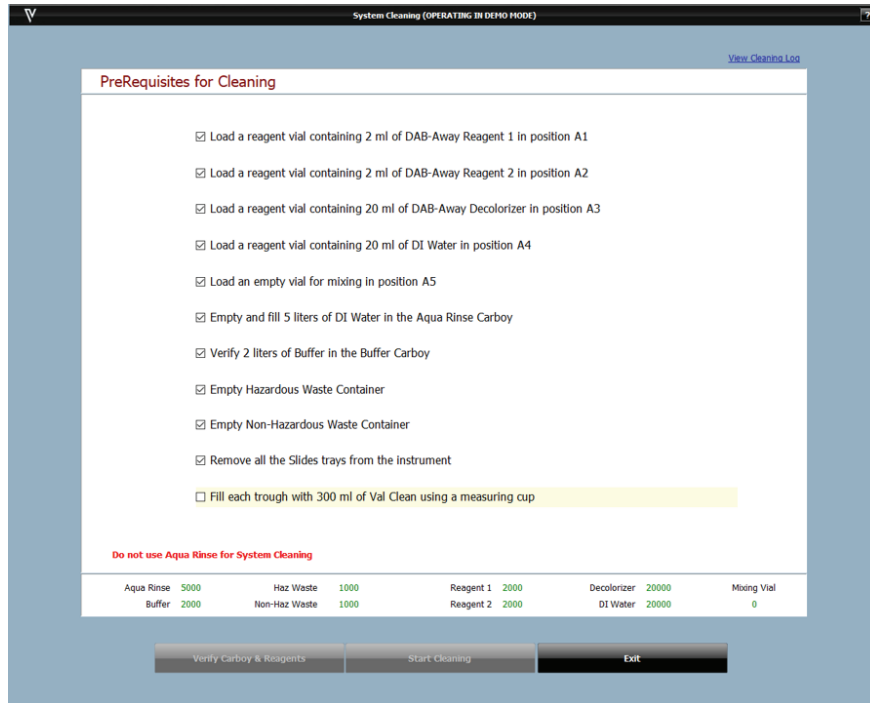
Procedure for DAB away cleaning:

- From the Home Screen select Tools -> Instrument Operations -> System Cleaning.
- The Clear Trays reminder message will appear. Click Ok to confirm the trays have been removed from the instrument.
- The Clear Reagents reminder message will appear. Click Ok to confirm the IHC reagents have been removed from the rack.
- Next, the Cleaning Routines summary window will appear. To proceed with system cleaning or carboy cleaning, click the corresponding Clean Now button.
- The System Cleaning Window will appear. Follow each instruction and check mark each box for Prerequisites for Cleaning once the task is complete.

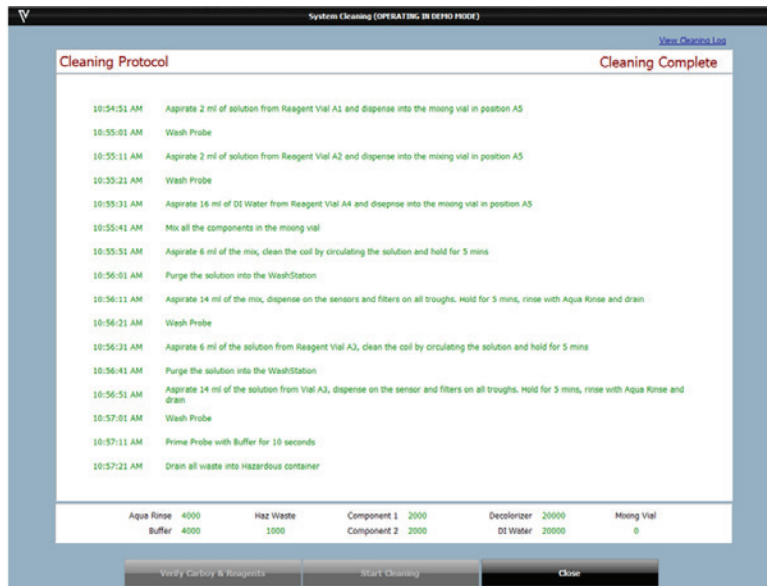


Program Cleaning

- Once all boxes have been check marked, click Verify Carboy & Reagents and ensure there is sufficient reagent in the bulk reagent carboys and waste carboys have capacity for waste.
- Complete the final checklist step as described in the PreRequisites for Cleaning checklist.



- Click Start Cleaning when carboys have been verified.



- The user can select View Cleaning Log on the top right-hand side and print the log if needed.
- Close the window.
- Proceed to Monthly Carboy Cleaning if required, or click Exit.
- If no additional cleaning is required at this time, close the Stainer Application before beginning a new staining run.

Cleaning Routine	Last Cleaning	Slides # used cleaning	Days # until cleaning	Clean	Extend cleaning	Available extension #
System Cleaning	5/29/2019	250	-	Clean Now		
Carboy Cleaning	5/29/2019	-	30	Clean Now		

Exit

Weekly Slide Tray Cleaning

Residue and/or debris that accumulates on the slide racks of the VALENT can be easily removed by application of a sodium bicarbonate based paste. It is recommended that the slide trays are cleaned at least once per week to avoid build up of unwanted residue.

- For each tray to be cleaned, begin by mixing approximately 10 grams of sodium bicarbonate with 15 ml of water to form a soft paste. (i.e. Combine 40 grams of sodium bicarbonate with 60ml of water to clean all 4 trays at once.)
- Use a soft, short bristled brush to apply the sodium bicarbonate paste to all surfaces of the slide tray, including the bottom surface of the slide trays.
- If needed, the paste may be left to sit for up to 5 minutes to aid with residue and debris removal.
- Gently agitate the brush and paste over the slide trays surfaces, paying extra attention to the area around the slide clips. Re-apply and repeat as needed in areas where visible residue persists.
- Rinse slide trays thoroughly under cool tap water to remove all paste.
- Pat dry with a soft cloth, and allow to air dry thoroughly before next use.
- With all the slide trays removed, clean the interior of the VALENT troughs by wiping the following surfaces with a 70% Isopropyl alcohol lint free wipe.
 - interior bottom of all four troughs
 - interior rail guides for slide trays

After all trough surfaces have been wiped clean, rinse the interior surfaces and trough filters by pouring 200 ml of Aqua Rinse into each trough. Ensure that the top surfaces of each trough filter is rinsed with Aqua Rinse.

Monthly

Perform Carboy Cleaning monthly to disinfect carboys and internal supply lines. Diltued Lysol® I.C. Quaternary Disinfectant Cleaner is used for this procedure. Follow the dilution directions specified on the Lysol bottle. A minimum of 8 liters of diluted Lysol cleaner are needed for this procedure.

- From the Home Screen select Tools -> Instrument Operations -> System Cleaning.
- The Clear Trays reminder message will appear. Click Ok to confirm the trays have been removed from the instrument.
- The Clear Reagents reminder message will appear. Click Ok to confirm the IHC reagents have been removed from the rack.
- Next, the Cleaning Routines summary window will appear. To proceed with carboy cleaning, click the corresponding Clean Now button.
- The Carboy Cleaning with Lysol window will appear. Follow each instruction and check mark each box in the list once the task is complete.

Carboy Cleaning with Lysol (OPERATING IN DEMO MODE)

[View Cleaning Log](#)

PreRequisites for Carboy Cleaning

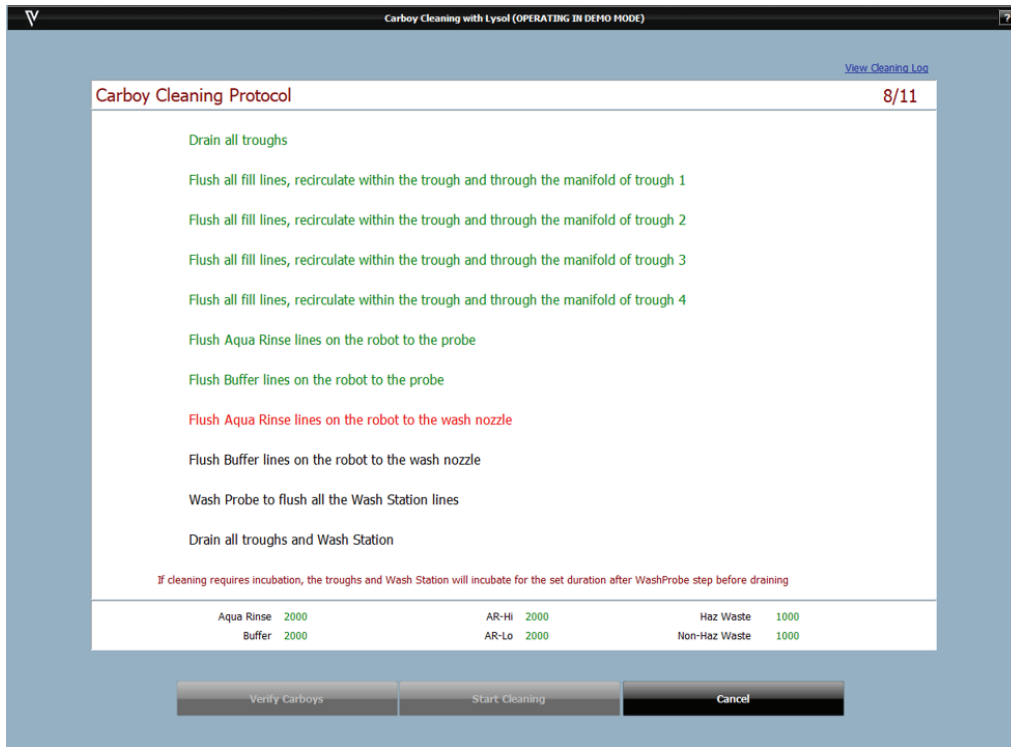
- Empty carboy and fill 2 liters of diluted Lysol in Aqua Rinse carboy
- Empty carboy and fill 2 liters of diluted Lysol in Buffer carboy
- Empty carboy and fill 2 liters of diluted Lysol in AR-Hi carboy
- Empty carboy and fill 2 liters of diluted Lysol in AR-Lo carboy
- Empty Waste Container
- Empty Hazardous Waste Container

Lysol ® I.C. Quaternary Disinfectant Cleaner should be diluted according to directions specified on bottle

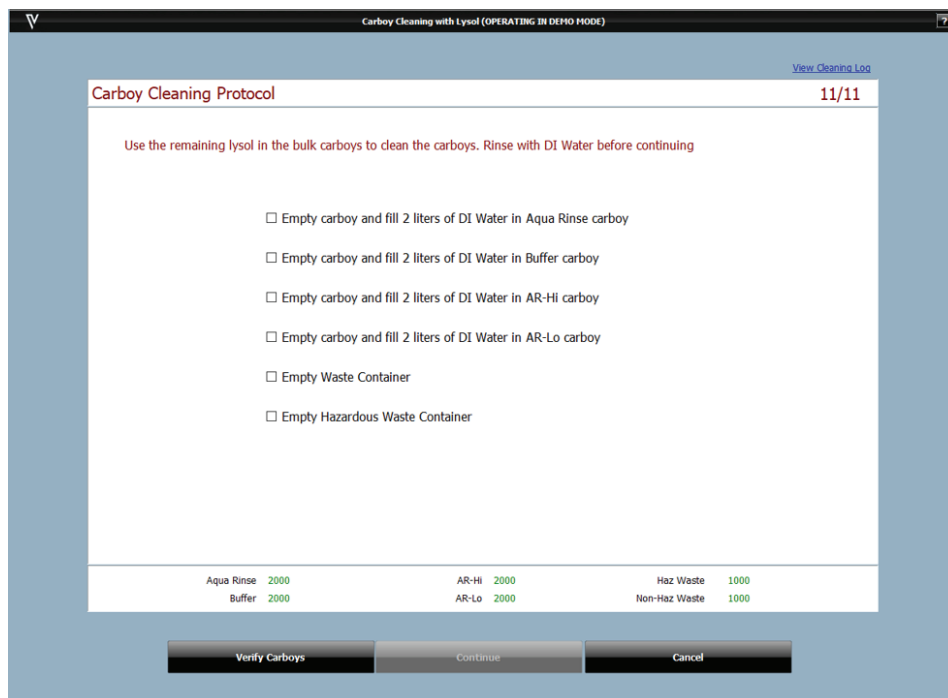
Aqua Rinse	...	AR-Hi	...	Haz Waste	...
Buffer	...	AR-Lo	...	Non-Haz Waste	...

Verify Carboys Start Cleaning Exit

- Once all boxes have been check marked, click Verify Carboy to initiate Carboy Cleaning Protocol.



- Once Lysol cleaning is complete, the Carboy Cleaning Protocol will pause and a new checklist will appear.
- Empty remaining Lysol solution from the bulk carboys and initiate rinsing with DI water as prompted in the checklist.
- Click Verify Carboys, then Continue to complete the Carboy Cleaning Protocol.



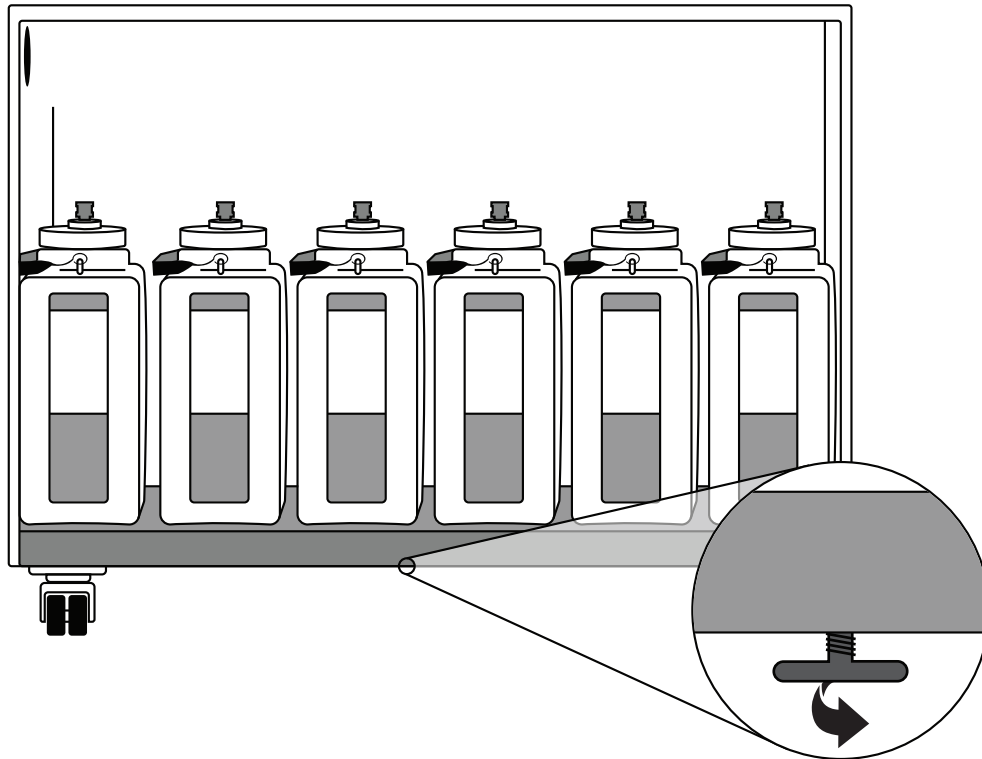
Carboy Cleaning Continued

- Once cleaning is completed, the System Cleaning Screen will show Cleaning Complete.
- The user can select View Cleaning Log on the top right-hand side to view or print the logs if needed.
- Close the window.
- The Cleaning Routines summary window will appear. Click Exit. Close the stainer application before beginning a new staining run.

Drain the Secondary Containment Sump

Drain the secondary containment sump on a monthly basis or if a large spill is caught by the sump.

- To drain the secondary containment sump, take an empty container that will fit under the VALENT Cart and place it below the drain plug, located underneath the VALENT Cart towards the middle front (see diagram).
- Unscrew the drain plug by turning the knob clockwise as viewed from above.
- Allow the liquid to drain into the empty container.
- Re-seal the secondary container sump by screwing the plug back in.
- Dispose of the liquid collected into the appropriate container.



Additional Cleaning of the Instrument

- Remove the slide racks and soak using Lysol® I.C. Quaternary Disinfectant Cleaner, wiping if necessary, being careful not to bend the slide clips.
- With all the slide trays removed, clean the interior of the VALENT by wiping the troughs, with 70% Isopropyl alcohol lint free wipe, being careful to avoid the filters in the troughs.
- Wash Buffer salt buildup is typical and can be wiped down with a lint free cloth and DI water to dissolve the salt deposits as needed.

Chapter 8: Troubleshooting

Occasionally, you may encounter problems while obtaining staining results or performing associated procedures. This chapter describes the most commonly reported issues, 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.

Printer Port Connections

If slide or reagent labels are not printing, check for the following:

- Power cables are plugged into the printers and VALENT Cart
- USB cables are plugged into the printers and VALENT Cart
- Printers are switched on

If printers are connected properly and powered on, and still no labels are print, log into the VALENT software and go to Tools-> Label Designers-> Slide Label Designer.

- Select the drop-down menu next to Slide Printer.
- Choose one of the options in the list.
- Select Test Print. Repeat the last 2 steps until a slide label successfully prints.
- Select the Save & Close button.
- Repeat the same steps for the Reagent Label Designer.

Important Note: There should only be TSC TC310 and TSC TC310 (Copy 1), but if the printers lose connection to a port, the computer might create a new port pathway. Therefore, there may be TSC TC310 (Copy 2), TSC TC310 (Copy 3), and so on in the drop down menu).

Changing Printer Labels and Ribbons

The reagent and slide label printers, TSC TC310 Thermal Transfer Printers, are manufactured by TSC. Please refer to TSC's website for instructions on how to change printer labels and ribbons at www.tscprinters.com.

Staining Performance

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

Problem	Possible Causes & Solutions
<p>No staining, weak or inconsistent staining, false negatives.</p>	<p>Cause: Programming errors. Solution: Review programming and correct errors.</p> <p>Cause: Slides positioned incorrectly in slide racks. Instruments and slides must be horizontal, verified by level gauge. Resolution: Reposition slides.</p> <p>Cause: Slide labels positioned incorrectly onto the slide. If the slide label is not properly placed and sticks up even slightly, liquid flow will be impeded and reagents will wick and yield poor staining quality. Please see the diagram in the Slide Preparation section of chapter 5. Resolution: Reposition slide labels.</p>
<p>Slides have dried out.</p>	<p>Cause: Slides positioned incorrectly on the VALENT Resolution: Visually inspect the slides from the front of the instrument, making sure they are positioned correctly.</p> <p>Cause: Prolonged incubation requires continued dispensing of reagent on each slide. Resolution: For incubation time exceeding one hour, divide protocol step into two, consecutive steps with the same reagent.</p>
<p>Tissue lifting off slide.</p>	<p>Cause: Tissue section has not properly adhered.</p> <p>Resolution: Ensure that positively charged slides are used on the VALENT and FFPE tissue samples are adequately dried in the oven before loading onto the instrument.</p>
<p>Need access to a previous run log to help determine root cause of weak staining or failed run.</p>	<p>Cause: The VALENT Software only displays a run log for the most current run, access to previous run is not available in the VALENT Software. Resolution: Call Technical Support.</p>

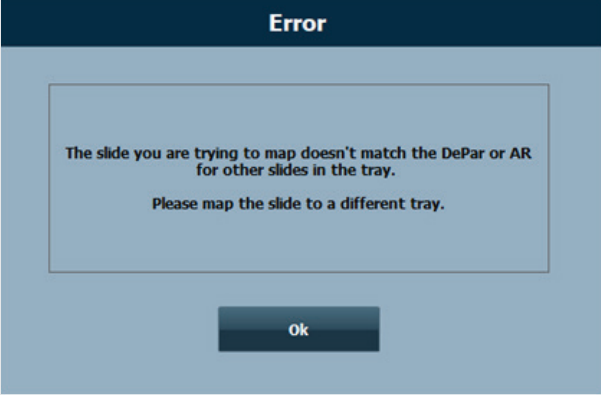
Mechanical

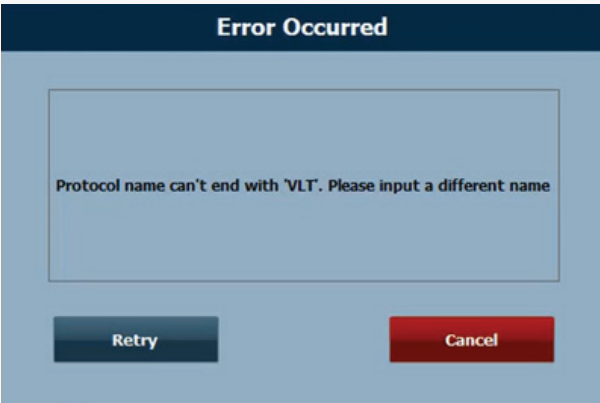
Problem	Possible Causes & Solutions
<p>DePar not dispensing correctly.</p>	<p>Cause: DePar container may be empty. Resolution: Check the DePar container on the left side of the instrument and confirm that there is sufficient DePar reagent. Under Tools-> Instrument Operations -> Drain Waste & Prime Buffers, prime DePar until a steady stream is flowing through the DePar probe into the Wash Station. If DePar is still not flowing correctly after priming 3 times, call Technical Support.</p>
<p>AR/DePar not flowing correctly.</p>	<p>Cause: Ports in the manifold are obstructed. Resolution: Under Tools-> Instrument Operations -> Drain Waste & Prime Buffers to prime manifold with Aqua Rinse for 10 seconds, repeat as necessary. If AR is still not flowing correctly, does not clear after priming 3 times, call Technical Support.</p>
<p>Probe or wash-blow head misaligned.</p>	<p>Cause: VALENT is out of calibration. Resolution: Call Technical Support to calibrate the instrument.</p>
<p>Map of slide layout disappears once the corresponding slide tray is removed from the VALENT.</p>	<p>Cause: When a user is manually mapping slides, if the user removes the slide tray from the VALENT, that particular slide tray will disappear from the Home Screen not allowing the user to map slides. The slide tray needs to be loaded into the VALENT to allow slides to be manually mapped in the software. Resolution: Place slide tray back into the VALENT to allow manually mapping and wait 30 seconds for the Home Screen to reflect that the slide tray has been replaced. Once slides have been manually mapped, a Slide Layout Report should be printed so the user does not lose track of where slides are located.</p>
<p>The reagent rack, slide tray, or system lid does not physically unlock.</p>	<p>Cause: Mechanical issue. Resolution: Call Technical Support. DO NOT ATTEMPT TO UNLOCK WITHOUT BIOCARE PERSONNEL ASSISTANCE.</p>

Electrical

Problem	Possible Causes & Solutions
Reagent label printer, slide label printer or report printers are not working.	<p>Cause: Printers are not connected to correct port. Resolution: Check the printer ports to make sure the each printer connection is properly connected to the correct port.</p> <p>Cause: Printers are not communicating with instrument. Resolution: Re-start your instrument and computer by following directions on how to Safely Turn Instrument On/Off found and Printer Port Connection section in this chapter. If problems still persist, contact Technical Support for further assistance.</p>
Power outage.	<p>Cause: Power outages may cause the instrument to unexpectedly shut down. If the instrument is not properly shut down system failure can occur. Resolution: Re-start your instrument by following directions on how to Safely Turn Instrument On/Off found in this chapter. If problems still persist, contact Technical Support for further assistance.</p>

Operating Errors

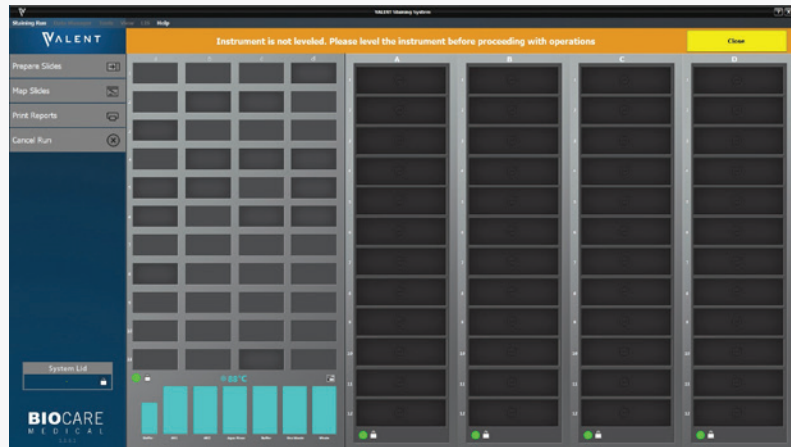
Problem	Possible Causes & Solutions
Carboy Details window shows required volume from the previous run after a run is complete.	<p>Cause: If a user hovers over the carboys from the Home Screen, the required volume from the previous run will be displayed. Required volume is not reset once a run is complete. Resolution: This does not affect a future run. Once the user starts a new run, carboy details show required volume correctly.</p>
The VALENT is in demo mode.	<p>Cause: The instrument and software are not connected. Resolution: Be sure to turn on the instrument before logging into the VALENT Software.</p>
The software will not allow you to map a slide to a particular slide tray.	<p>Cause: There are run requirements that limit what protocol can be processed in the same slide tray. Please see Chapter 5 of the Slide Tray section for more information. Resolution: Move the slide that has a different set of AR or DePar conditions and add to another slide tray.</p> 

<p>An error message appears when editing protocols.</p>	<p>Cause: Biocare Medical Protocols cannot be edited, doing so will cause the message below to appear.</p> <p>Resolution: The user can copy and rename a selected Biocare Medical protocol to make edits, refer to the Protocol Manager section in Chapter 5.</p> 
<p>New reagents can't be scanned into Inventory Manager.</p>	<p>Cause: New reagents can only be scanned into inventory when the user initially logs into the system. For example, if a protocol has been run or system cleaning executed, the user won't be able to scan reagents into inventory.</p> <p>Resolution: To scan reagents into inventory, exit the system and log in again. There is also an option of manually entering reagents into inventory.</p>
<p>The barcode camera is not detecting slide labels or reagent labels</p>	<p>Cause: Slide labels or reagent labels are positioned incorrectly onto the slide. Please see the diagram in the Slide Preparation section of chapter 5.</p> <p>Resolution: Reposition slide label or reagent label.</p> <p>Cause: This may be caused by splashes of reagents or residual oil from the user's fingerprints during preparation inhibiting the barcode camera.</p> <p>Resolution: Use a paper towel to gently wipe the slide label or reagent label to remove residual oil.</p>
<p>Reagent level scan is not working properly.</p>	<p>Cause: The reagent vial is obstructed.</p> <p>Resolution: Reposition the vial so that it sits flush in the reagent rack. Make sure the cap is removed.</p> <p>Cause: The liquid level sensor is obstructed with debris.</p> <p>Resolution: Gently wipe any debris from the liquid level sensor with a 70% Isopropyl alcohol lint free wipe.</p>

Cause: The instrument is out of level and needs to be re-leveled.

Resolution: Call Technical Support for instructions on how to re-level the VALENT.

Notification that instrument is not level.



Cause: Trough not filling for AR step.

Resolution: Check carboy tubing connections. Use the Drain Waste & Prime buffers tool to confirm proper connection (even flow of solution with minimal bubbles in the line). If all tubing is connected properly and solution is not flowing as expected, call Technical support.

Cause: Temperature did not reach set point.

Resolution: Call Technical Support.

Slide tray cancellations.



Appendix- Quick Start Guides

Quick Start Guide 1-Instrument Preparation










Instrument Preparation

1. Turn the VALENT on using the main power switch (white switch) found in the electrical panel of the instrument, on the right side.
2. Turn on the computer and open the VALENT application.
3. Double check that both waste carboys are empty and properly connected to the VALENT.
4. Double check that bulk reagent carboys are filled appropriately and properly connected to the VALENT.
5. Priming the instrument should be done before every run without slide trays. The user should prime until there are no remaining bubbles in the carboy tubing or probe coil. When priming the dispense manifold, prime until the stream coming from the port is steady and even across the 12 ports.
6. Priming should also be done when refilling the carboys, priming the manifold is not required for this.
7. 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.
8. Using both hands, one hand holding reagent rack from front and the other hand from the bottom, load the reagent rack with filled reagent vials in the correct orientation; the reagent rack handle should be towards the front of instrument, facing the user. Reagent vials must be positioned toward the front of the VALENT, facing the user.
9. To print slide or reagent vial labels, make sure the slide label printer, reagent label printer and report printer are attached to the computer.
10. When placing the slide label on the slide, the whole label should be completely flattened and adhered to the slide especially the bottom of the slide label. A slide label that is not completely flat and sticks up even slightly will cause liquid flow to be interrupted. When current flow is affected, reagents will wick and may yield poor staining quality.
11. All slides require a label. If manually mapping, use a VALENT slide label. Failing to use a slide label may yield poor staining quality.
12. Confirm that all slides are inserted all the way under the slide clips, placed securely in the slide clips, and centered. It is important that slide labels are viewable by the barcode camera.



Important Note: Be sure to turn on the instrument before logging into the VALENT Software.

Otherwise, the VALENT Software will automatically be opened in demo mode and the run will not start.

Quick Start Guide 2-Creating a Protocol

1. Log in to the VALENT Software.
2. Find Data Manager from the menu bar and Click **Reagent Manager**.
3. Select which reagent group the new reagent is classified under and click .
4. Add the reagent information and click  to **Save** and click  **Close**.
5. From the menu bar select **Data Manager** and then **Protocol Manager**.
6. To create a new protocol click  and select **New Protocol** to create from “de novo”, **Create from Template** or **Create from a Selected Protocol**.
7. Name the Protocol.
8. Use the buttons      to Add, Insert, Delete or Move steps within a protocol.
9. Click **Save & Close**.

Quick Start Guide 3-Preparing Slides

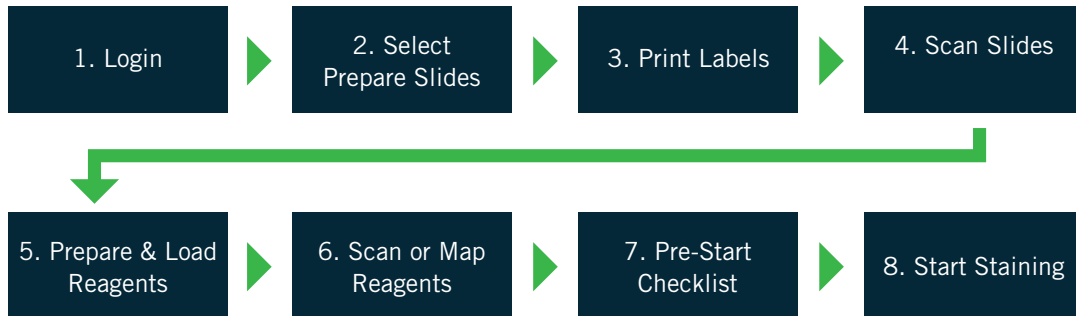
1. Log in to the VALENT Software.
2. Click **Prepare Slides**.
3. In the **Add Slides** window enter Slide Details.
4. Highlight the required protocol and click the green **Right Arrow**. Repeat until all required protocols have been selected.
5. If positive and negative controls are needed, highlight the boxes next to each protocol that require positive and negative controls.
6. Click OK.
7. In the **Slide Manager** window, ensure all information is correct including Slide Details and Protocol.
8. Add, Delete or Copy Slides as needed by selecting the appropriate button.
9. Make sure all slides are checked and then click **Print Slide Labels** .
10. To print reagent labels, click **Show Reagent Worksheet** .
11. Click **Save & Close**.
12. Affix labels to reagent vials and slides, making sure slide labels are flat and completely adhere to slide.
13. Load slides and reagents onto the instrument.
14. In the **Assign Slides** window click **Scan Mode** and select all slide trays that apply.
15. Click **Scan Slides**.
16. After slides have been scanned, click **Prepare Reagents**.
17. Click Scan to scan reagents and then **Levels** to detect reagent levels.
18. Check Bulk and Waste Carboys and Prime Buffers if needed.
19. Click **Start Run** or (**Delayed Run** can also be selected).

Quick Start Guide 4-Process Overview

There are two ways to process slides described below.

Process Overview 1

Summary of the run setup process by Scanning Slide Labels. Details of each step are provided within in Chapter 6.



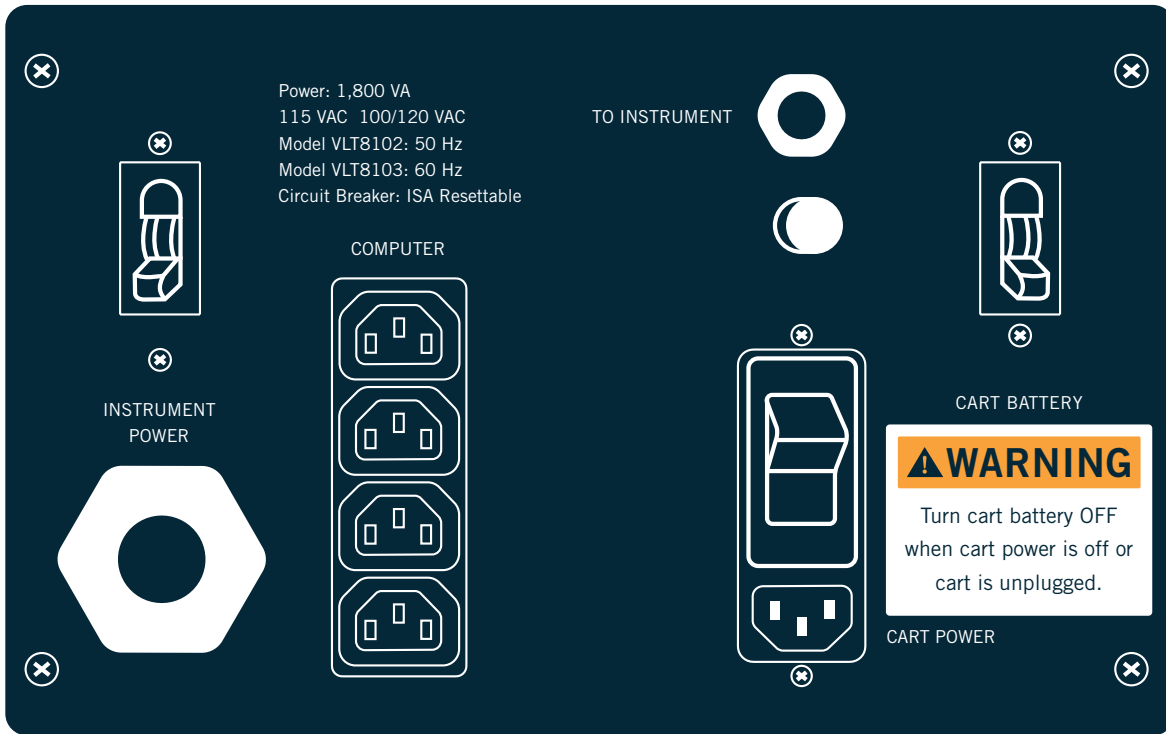
Process Overview 2

Summary of the run setup process using Manual Mapping of Slides. Details of each step are provided in Chapter 6.

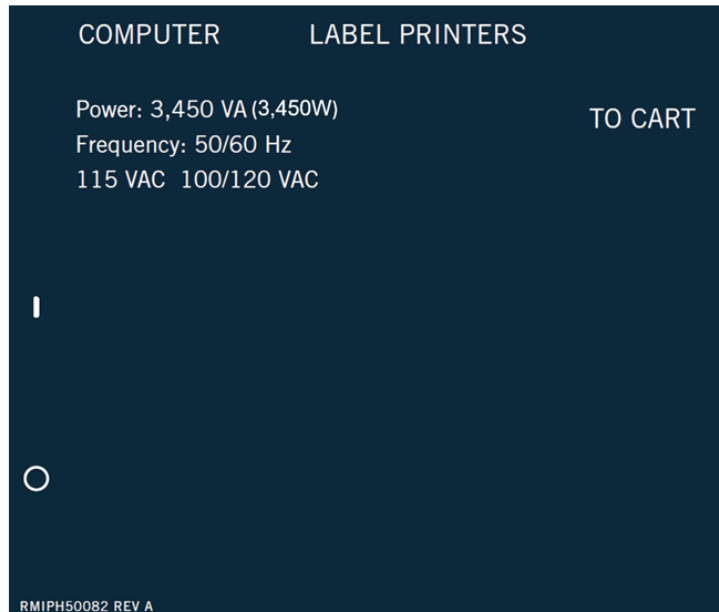


Appendix- Electrical Labels

Electrical Label for the VALENT Cart



Electrical Label for the VALENT



BIOCARE
M E D I C A L

800.799.9499
60 Berry Drive
Pacheco, CA 94553

www.biocare.net

VLT8118
112219