



**SPIFE Nexus**  
**Automated Electrophoresis**



**Operator's Manual**  
**Catalog Number 1650 (120/230V)**

**SPIFE Nexus**  
**Automated Electrophoresis System**  
**Operator's Manual**

**WARNING!**  
**DO NOT ATTEMPT TO MOVE, INSTALL, OR  
OPERATE THIS INSTRUMENT BEFORE  
READING AND UNDERSTANDING THE  
CONTENTS OF THIS MANUAL, PARTICULARLY  
THE PRECAUTIONS, LIMITATIONS AND  
HAZARDS IN SECTIONS THREE AND FOUR.**

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## Section 1 - Instrument Use and Function

Helena's **SPIFE Nexus** (Figure 1-1) is an automated electrophoresis system with a built-in Sample Handler, as well as Sample Applicator, destain/wash vat area, Stain/Reagent Dispenser and Spreader, Antisera/Reagent Applicator, Dryer Chamber, and Scanner. Once the sample tubes are loaded, the instrument automatically loads samples from test tubes to sample cups, applies samples from sample cups to associated gels, electrophoreses at a programmable voltage, applies antisera, stain, destains, blots, and scans each finished gel. Once the gel is finished and scanned, it slides out of the front of the instrument. The touch screen facilitates entering or changing procedure parameters and operation of the instrument.

The SPIFE Nexus contains preprogrammed parameters for Split Beta Serum Protein Electrophoresis, Serum Immunofixation, Acid Hemoglobin, Alkaline Hemoglobin, Urine Proteins, and Urine Immunofixation; however, the end user may alter the parameters for these tests, if desired, and create unlimited new test procedures. In the future, additional test procedures will become available from Helena Laboratories.

Stored results can be retrieved in seconds and full editing features are provided with the QuickScan Touch *plus* software program so fractions may be selected, comments added to the file, etc.

Refer to the procedure supplied with the gel kits for information on the following areas:

- Summary
- Principle
- Reagents
- Instruments
- Specimen Collection and Handling
- Step-by-Step Method
- Evaluation of the Bands
- Stability of End Product
- Results
- Expected Values
- Reagent Preparation
- Sample Application
- Test Procedure
- Performance Characteristics
- Expected Results
- References
- Reference Values
- Interpretation of Results
- Bibliography



**Figure 1-1 SPIFE Nexus System**

## Section 2 - Principles of Operation

The functional units of the SPIFE Nexus are shown in Figure 2-1. Operation is controlled by a computer and microcontrollers.

Software updates are provided via portable USB storage media.

### 2.1. Principles of Operation – User Interface

The SPIFE Nexus is powered on by pressing the round silver button on the front of the instrument. Holding this button down for 20 seconds will cause a hard reboot of the instrument.

The button on left-hand side is an emergency breaker. If the instrument draws more than 15 Amps, it will shut off the instrument. This should be used for EMERGENCY only. Using this button on a regular basis will cause computer errors.

The computer runs a self-test at power initialization to detect error conditions or potential problems.

On the touch screen, the user can open the software by double tapping the SPIFE Nexus icon on the screen or by double clicking the mouse.

The user may select the test types, start or stop the automatic sequence of operations, prime the Sample Handler and Pump Tubing, select test parameters, and change displayed menus.

On the right-hand side of the instrument, there are four USB ports, one serial port, one LIS port, one network port, one AC outlet, one display outlet, six fluid ports as well as a waste full sensor interconnector.

Once a run has begun, the SPIFE Nexus will scan the barcodes on the following items and will alert the user if one of these items is incorrect or missing for the current run: Sample Tray, Gel Cassette, Platen

Cover (with correct Electrode insert), Applicator Blade Template, Reagent Chiller, as well as the Blotter Holder.

### 2.2. Principles of Operation – Sample Handler System

The Sampler Handler portion of the SPIFE Nexus consists of the Tube Transport area, Sample Tray Platform, and Electrophoresis Platform.

The test tube racks are loaded into the Tube Transport area in the front of the instrument. The door folds down and the user can load up to ten racks ensuring the recessed notch on the back of the test tube rack has the metal bar slid into it. The instrument will identify the samples by reading a barcode on the sample tube and will send that information to the SPIFE Nexus software. Once all the samples in the rack have been processed, it will be shifted to the left. To prevent jams, a sensor on the far left-hand side will alert the instrument if the area is full.

The pipette pulls the sample from the test tube and aliquots the required volume into the Disposable Sample Cups that have been loaded within the reusable sample tray and placed onto the Sample Tray Platform. The pipette will also make the appropriate dilutions for the various Immunofixation lanes and then transfer a predetermined amount of sample from the dilution well into the appropriate sample cups.

Once all the samples have been transferred to the Sample Tray, the instrument will pick up the Applicator Holder and position it over the Sample Tray. Once the Applicator Holder is in position, the instrument will lower and immerse the applicator blades into the sample cups. After that, the Applicator Holder will move over and apply the samples onto the gel that is located on

the electrophoresis platen. Once the samples have been applied, the motor driven claw will place the Applicator Holder back into the Consumables Tray.

### 2.3. Principles of Operation – Electrophoresis and Staining

The relationship of the functional units of the SPIFE Nexus are shown in Figure 2-1. Operation is controlled by the main controller, slave microprocessors, their hardware interfaces, and user selections of control parameters displayed on the monitor and selected using the keyboard, mouse, or touch screen.

The Electrophoresis Station consists of a programmable temperature controlled platen. A microprocessor controls the electrophoresis voltage supply and monitors the status of the electrophoresis voltage, current, as well as platen temperature.

From this station, the following actions may be carried out: electrophoresis, staining, antisera/reagent application, as well as blotting, and drying. The type of test that is being run dictates which actions will occur here and in what order.

For electrophoresis, the instrument positions the Platen Cover with the appropriate Electrode Insert in contact with the gel surface and applies the preprogrammed temperature and voltage ranges for the desired amount of time.

Once electrophoresis has occurred, the instrument removes the Platen Cover and replaces it in its storage area.

For IFE plates, there is storage for Antisera and Fixative located within the onboard Reagent Storage area. The Reagent Chiller consists of the onboard storage area and a motor driven pipette, which applies the antisera to the gel. After antisera has been applied to the gel and the selected absorption time has elapsed, the gel will be blotted

with a disposable blotter. The Blotter Holder, which has a disposable adhesive blotter on the bottom, is stored in the Consumables Tray. The motor driven claw will pick up the Blotter Holder and place the loaded Blotter Holder onto the top of the gel to remove excess antisera from the gel surface.

Pre-drying is accomplished by utilizing the electrophoresis platform set to heating mode.

Stain is applied by using the Stain/Reagent Dispenser and a borosilicate glass Reagent Roller. The Stain/Reagent Dispenser moves over the gel and pours a small amount of stain onto the gel surface. Once the stain has been applied, a roller rolls back and forth over the gel, evenly dispersing the liquid.

At this stage, the gel is moved to the Wash/Destain Station. A vertical vat is filled with either Wash or Destain that can be circulated bottom to top or top to bottom. After this step, the vat is emptied.

The master microprocessor then signals the heater in the Drying Chamber to heat the chamber to drying temperature. The Dryer Station consists of a vertical forced air dryer with programmable temperature settings and air temperature monitoring. The gel is placed into the dryer and a Dryer Cover is placed on top of the dryer opening.

Once the gel has completed all program-selected operations, the gel is transferred into the scanner. The gel is scanned and then pushed out of the front of the instrument signaling to the user that the gel has been completed.

#### 2.3.1. QuickScan Touch *plus*

Finished gel images are viewed in the QuickScan Touch *plus* software. Using this software, scans can be edited if so desired. All user input is through the touch screen,

mouse, or keyboard. For more information on how to edit a scan, reference the QuickScan Touch *plus* Operator's Manual.

### **2.3.2. Instrument Shutdown**

**Note:** *Before shutting down the instrument, ensure **any** USB drives have been removed from the right-hand side of the instrument.*

*Failure to do this will cause the instrument to not power down properly and it will still be drawing power. Additionally, when the user attempts to press the silver power button on the front of the instrument, it will not power back on.*

To properly shut down the instrument, click the X in the upper right-hand corner to close out the SPIFE Nexus software. The computer and main instrument can be turned off by selecting the Windows logo in the lower left-hand side of the monitor. Select *Power* then *Shut down*.

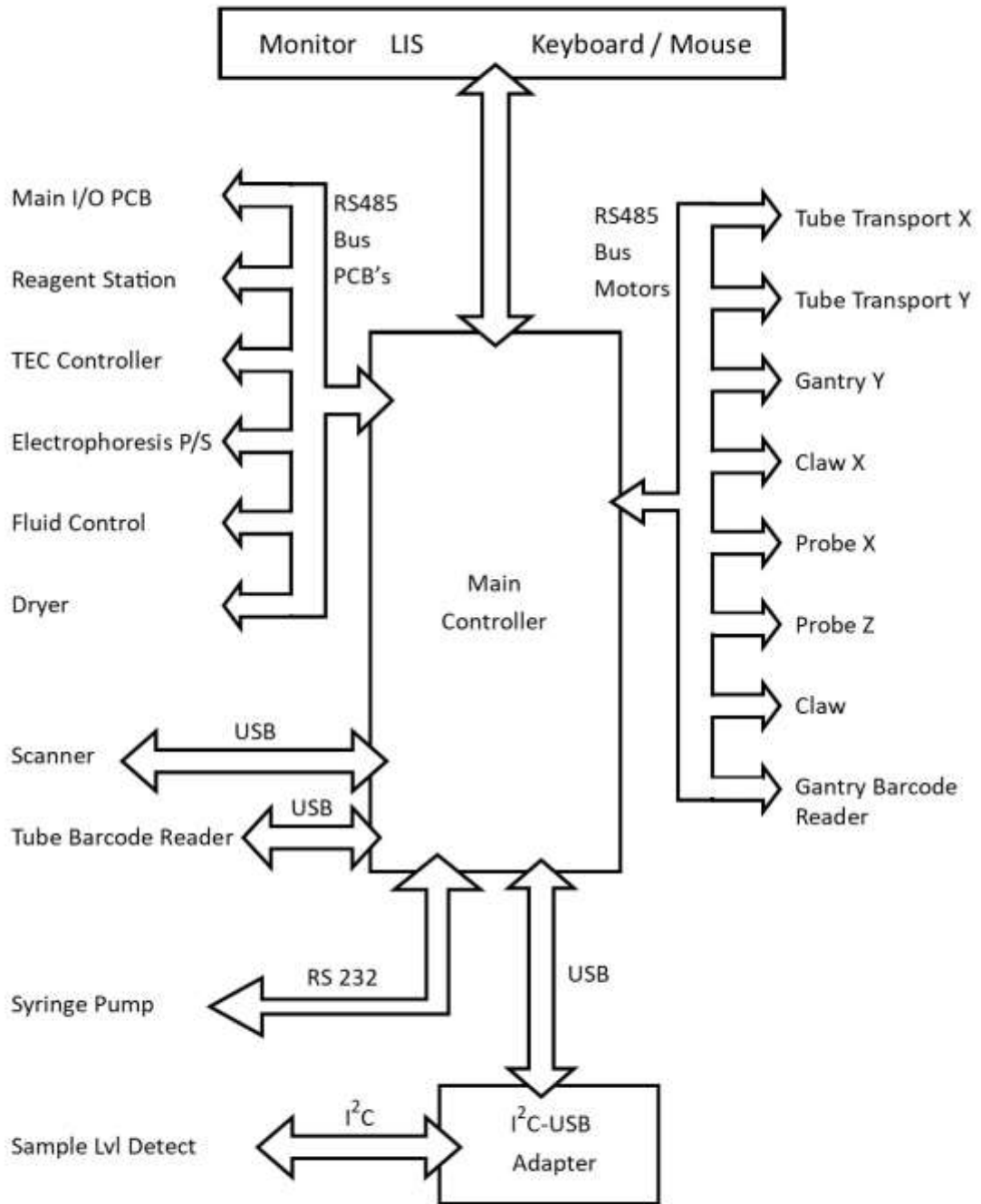


Figure 2-1 Flow diagram

### Section 3 - Precautions and Limitations

3.1. For emergency shutdown, turn off the instrument using the main power switch on the left-hand side of the instrument or disconnect the main power cord from the wall outlet.

3.2. Refer to the procedure supplied with the gels and reagents for proper gel orientation, diluent and reagent preparation, specimen collection and handling, and other information.

3.3. Use only diluents, reagents and gels made specifically for use with the SPIFE Nexus. Refer to the procedures supplied with the reagents for precautions and limitations specific to the reagents.

3.4. Use only hardware and software accessories made specifically for the instrument.

3.5. Storage and transport environmental requirements:

Storage and shipping temperatures: 5 - 40°C (41- 104°F).

Relative Humidity: 10 - 80%, non-condensing.

3.6. Do not expose the instrument to drafts or operate the instrument in direct sunlight. Do not operate the instrument at temperatures below 15°C (59°F) or above 27°C (80.6°F).

3.7. Provide adequate room (2" minimum [5 cm]) at the sides and back of the instrument for good air circulation.

3.8. Do not attempt to operate the instrument until the entire Operator's Manual, and the manuals provided with the scanner, monitor and printer, have been read and understood. Section 11 contains all the warning symbols that may be found throughout the manual and on the instrument.

3.9. Do not place any objects inside the scanning slot other than items to be scanned.

3.10. This instrument should not be connected to any other devices or instruments in any way not described in this manual.

3.11. Do not expose the Gel Cassette to temperatures above 70°C (158°F), or severe warping of the Cassette may result, making it unsuitable for use.

3.12. The instrument should not be moved once the Helena Laboratories approved representative has installed the instrument. If the instrument must be moved, it should be recalibrated and checked before use.

3.13. This instrument meets the leakage current specifications of directive EN 61010-1.

3.14. All tubing must be securely connected to fittings to prevent leaks.

3.15. Due to high heat, do not touch the areas including the Pre-Dry and Dryer stations.

3.16. The instrument should be kept dust free if possible. Harsh cleansers, acids or bases should never be used either on the inside or outside of the instrument. See Section 10.9.3 for more detail. **NOTE: Always unplug the main power cord before cleaning.**

3.17. Should an instrument be contaminated by blood or blood derivative, spray any contaminated surface with a commercial virucidal and germicidal agent. Observe where the specimens are used inside the instrument and confine cleaning to that area. Wipe up the residue. These materials contain corrosives and are harmful to metal surfaces.

Harsh cleansers, acids or bases should never be used either on the inside or outside of the instrument. See Section 10.9.3

for more detail. **NOTE: Always unplug the main power cord before cleaning.**

3.18. Do not place the instrument near a strong source of electromagnetic interference, such as a centrifuge, x-ray machine, etc.

3.19. Do not block air vents and intakes. They are located on the front and rear of the instrument.

3.20. Keep hands and clothing away from the motor driven arm when in operation.

3.21. Installation should not be attempted unless a representative of Helena Laboratories or of its subsidiaries or distributors is present, or unless verbal or written permission to proceed has been given by Helena Laboratories, its subsidiaries or distributors.

3.22. Instructions for the "responsible body\*" (\*Under IEC 61010-2-101:2002 -- the person(s) responsible for the use and maintenance of equipment and for ensuring that operators are adequately trained for eliminating and reducing hazards involved in removal from use, transportation, or disposal.)

3.23. Requirements for handling biohazards: Due to potential biohazard risk from human blood, guidelines pertaining to Universal Precautions shall be adhered to when handling the samples and operating this instrument. This includes the use of protective gloves and any other protective equipment as warranted for safe handling and disposal of test tubes and use, transportation and disposal of this device. For more information on precautions that should be used when handling human blood, reference CLSI Standard GP Protection of Lab Workers from Occupationally Acquired Infections. M29-A4 (Clinical Lab Safety).

3.24. The Helena Laboratories representative/distributor shall provide a power cord or adapter of the proper configuration for the country in which the instrument is to be installed. The power cord or adapter will comply with IEC 60227, IEC 60245, or be certified as rated for the power specified in Section 9 of this manual.

3.25. For disposal, send this instrument to a proper recycling center in accordance with applicable federal, state, and local requirements.

3.26. Although the SPIFE Nexus is factory programmed for some procedures, the operator may alter scanning parameters if desired. If scanning problems occur, return to default parameters.

3.27. Gel Cassettes are fragile and will break if dropped.

3.28. Do not include additional software programs on the SPIFE Nexus without first consulting Helena Laboratories Service personnel.

3.29. To prevent software failure, properly eject any storage devices before removing them from USB ports.

3.30. It is recommended that the user refrain from changing display settings (font, size, color, resolution, etc.) while operating the SPIFE Nexus in order to prevent software failure.

3.31. Operators should follow all instructions within the manual regarding priming the instrument and monitoring fluid levels. Failure to perform these maintenances and monitor fluid levels could result in possible carryover by contamination from one sample to another.

3.32. If a severe fluid/reagent spill should occur, possibly leaking into the instrument, call Helena Laboratories Service department before attempting use.

3.33. Lift the instrument manually or with multiple people, as it weighs approximately 113.4 kg (250 pounds).

3.34. On the right-hand side of the instrument, the display power port is to only be used for the power cord that is connected to the computer monitor (display).

3.35. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generating of droplets of these substances. Blood specimens or other potentially infectious materials shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

Equipment that may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the user can demonstrate that decontamination of such equipment or portions of such equipment are not feasible. Gloves shall be worn when it can be reasonably anticipated that the user may have contact with blood or other potentially infectious materials, as well as touching contaminated surfaces. Other personal protective equipment (eye protection, gowns, etc.) shall be worn, as appropriate.

All equipment, environmental, and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials. Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after

any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

**Warning labels** (with “**Biohazard**” symbol) are affixed to containers of regulated waste and other components of the instrument likely to be contaminated with potentially infectious materials.

3.36. The instrument main door uses an interlock to control access to the inside of the instrument as a means to prevent access to hazards presented by operation of the instrument. If the interlock fails permitting access to the instrument during operation, cease using the instrument and call Helena Laboratories Service department before attempting use.

## Section 4 - Hazards

Section 11 contains all the warning symbols that may be found throughout the manual and on the instrument. If the instrument is used in a manner not specified by this manual, the protection provided by equipment design may be impaired.

4.1. Many safety features have been built into the instrument. Do not attempt to defeat or bypass any of these safety features.

4.2. These devices contain high voltages, which can be extremely dangerous. Turn off the system power, disconnect the main power cord and use extreme care when attempting disassembly for cleaning, repair or adjustments. Do not operate any instrument with the cover off unless instructed to do so by a qualified service technician directly representing Helena Laboratories, its subsidiaries, or its distributors.

4.3. Do not attempt to operate the instrument unless the power cords are plugged into grounded wall outlets of the proper voltage and frequency. This information is contained on the serial number plate located on the left side of the instrument.

4.4. Do not lubricate the instrument.

4.5. Do not place fingers near any moving parts when the instrument is in use.

4.6. Requirements for handling biohazards: Due to potential biohazard risk from human based components, guidelines pertaining to Universal Precautions shall be adhered to when handling the samples and operating this instrument. This includes the use of protective gloves and any other personal protective equipment as warranted for safe handling and disposal of test tubes, reagents, applicators, or other items containing or contaminated by biohazards.

4.7. Use only diluents and reagents specified by the Helena Laboratories procedure

in use. Damage to the instrument may result from introducing some types of solutions into the instrument.

4.8. Follow safe handling and disposal procedures for diluents and reagents used with this instrument.

4.9. In case of power loss during operation, the instrument will reset and the test will need to be restarted.

4.10. Shock hazard. Never touch the cables at the rear of the unit during operation.

4.11. Do not touch the Dryer Station area. Surfaces can reach temperatures of approximately 65°C (149°F).

4.12. Keep flammable liquids and flammable vapors away from the instrument at all times.

4.13. Do not use poisonous or injurious gases near or in the instrument.

## Section 5 - Installation

Installation is to be performed by qualified Helena personnel. The customer will be required to verify that a functional instrument has been installed to completion.

**WARNING: Read Section 3 (Precautions and Limitations) & Section 4 (Hazards) before attempting to move or turn on the instrument.**

**WARNING: Do not attempt to lift instrument manually.**

**Note:** The SPIFE Nexus is an “Overvoltage Category II, Appliance Class I – Protective Earth Connected” device under EN 61010-1 and is for use in a laboratory or similar environment.

### 5.1. Unpacking and Inspection

1. Check all shipping containers for signs of damage. If damage is found, immediately notify the shipping carrier.

2. Carefully unpack the instrument and accessories and remove them from the shipping cartons. The packing material should be removed undamaged, if possible, should repacking be necessary.

**CAUTION: The instrument and its components are heavy. Use a minimum of two people to lift the instrument. Lift only from the bottom surface of the instrument. Use approved lifting techniques when moving the instrument.**

3. Remove plastic wrappings from the instrument and accessories. If scissors or a knife are used to cut the plastic or binding tape, take care not to scratch the instrument.

4. Inspect the instrument for any obvious signs of damage. If damage is found, notify the shipping carrier and Helena Laboratories.

5. Inventory all items. If any parts are missing, recheck the packing materials before notifying Helena Laboratories.

### Table 5-1 Inventory

- 1 SPIFE Nexus\_
- 1 SPIFE Nexus Container Kit
  - 3 2½ gallon bottles (Wash, DI Water, and Saline)
  - 2 2 gallon Waste containers
  - 1 13 liter Destain jerrican
  - 3 Wash Cap Assemblies with tubing
  - 1 Destain Cap Assembly with tubing
  - 1 Waste Vat Cap Assembly with tubing and shorting plug
  - 6 Pigtail Tubing Ports
  - DI Tubing Assembly
  - Tubing
- 1 SPIFE Nexus Applicator Blade Weights, Cat. No. 2572
- 1 SPIFE Nexus Applicator Holder
- 1 Line Cord, Shielded, 20 AWG
- 1 Line Cord, Jumper Cordset C13, 10 AMP
- 1 Level
- 1 SPIFE Nexus Blotter Holder
- 1 SPIFE Nexus Platen Cover
- 1 SPIFE Nexus Dryer Chamber Cover
- 2 Dilution Bottle with caps
- 1 Stylus
- 1 Tube Racks package (10/pkg)
- 1 SPIFE Nexus Applicator Blade Templates (set of 8), Cat. No. 2570
- 1 SPIFE Nexus Antisera Spreader Tips (10/pkg), Cat. No.2574
- 1 SPIFE Nexus A22 Short Electrode Insert, Cat. No. 2577
- 2 SPIFE Nexus Cassettes, Cat. No. 2580
- 2 SPIFE Nexus Reagent Roller, Cat. No. 2583

1 SPIFE Gel Block Remover, Cat. No. 1115	2584 SPIFE Nexus Contact Sheets (5/pkg)
1 SPIFE Maintenance Swabs, 5/pkg, Cat. No. 1113	2420 SPIFE Nexus Split Beta SPE-60 Kit (600 tests)
1 SPIFE Nexus Contact Sheets, 5/pkg, Cat. No. 2584	2421 SPIFE Nexus Split Beta SPE-40 Kit (400 tests)
1 SPIFE Nexus Consumables Tray	2422 SPIFE Nexus Split Beta SPE-20 Kit (200 tests)
1 SPIFE Nexus Blotter Guide	2408 SPIFE Nexus IFE-15 Kit (10 gels, consumables, antisera)
1 Installation Report	2409 SPIFE Nexus IFE-9 Kit (10 gels, consumables, antisera)
1 Installation Flash Drive, SPIFE Nexus software	2401 SPIFE Nexus IFE-6 Kit (10 gels, consumables, antisera)
1 SPIFE Nexus Operator's Manual	3360 SPIFE Disposable Sample Cups, Deep Well
1 QuickScan Touch <i>plus</i> Operator's Manual	3362 SPIFE IFE-15 Disposable Cup Tray
1 Customer Maintenance Form	3363 SPIFE-IFE-9/15 Disposable Cups
1 Tray, Spill Vat	3368 SPIFE-IFE-3/6 Disposable Cups
1 NDDC for SPIFE Nexus, Cat. No. 1034	3370 SPIFE 20, 40, 60 Disposable Cup Tray
1 Optical Density Step Tablet, Cat. No. 1047	3377 SPIFE-IFE-3/6 Disposable Cup Tray
1 Guard, Justinari Anti-Splash	3378 SPIFE-IFE-9 Cup Tray

**Available Supplies**

<u>Cat #</u>	<u>Product Description</u>
2582	SPIFE Nexus Ready Run Kit (contains Consumables Tray, Reagent Roller, Applicator Holder, Blotter Holder, Blade Weights, and Applicator Guide Template set)
2575	SPIFE Nexus Disposable Stain Cups (100/pkg)
2570	SPIFE Nexus Applicator Blade Templates (set of 8)
2572	SPIFE Nexus Applicator Blade Weights (5/pkg)
2574	SPIFE Nexus Antisera Spreader Tips (10/pkg)
2576	SPIFE Nexus Carbon Electrode Insert
2583	SPIFE Nexus Reagent Roller
1696	Pos. ID Barcode Labels for Touch and SPIFE Nexus Systems (1000/pkg)
9173	Service Manual for SPIFE Nexus
1184	Extended Warranty
1185	Consolidated Service for SPIFE Nexus
2580	SPIFE Nexus Cassette
1694	Color Printer, Laser
1422	Black and White Printer, Laser
1652	SPIFE Nexus Cart

- 2577 SPIFE Nexus A22 Short Electrode Insert
- 2398 SPIFE Nexus Split Beta SPE-100 Kit (1000 tests)
- 2399 SPIFE Nexus Split Beta SPE-80 Kit (800 tests)
- 2415 SPIFE Nexus Alkaline Hemoglobin-20 (200 tests)
- 2418 SPIFE Nexus Acid Hemoglobin-20 (200 tests)
- 3369 SPIFE Disposable Sample Cups, Shallow Well
- 3100 REP Prep
- 3366 SPIFE 80,100 Disposable Cup Tray
- 3427 SPIFE Urine Protein Accessories
- 3380 SPIFE Urine Alignment Guide
- 3391 SPIFE Urine IFE-9 Accessories
- 1034 NDDC for SPIFE Nexus
- 1114 SPIFE Maintenance Swabs Small (10/pkg)

**5.2. Unpacking and Inspection**

**5.2.1. Instrument Location**

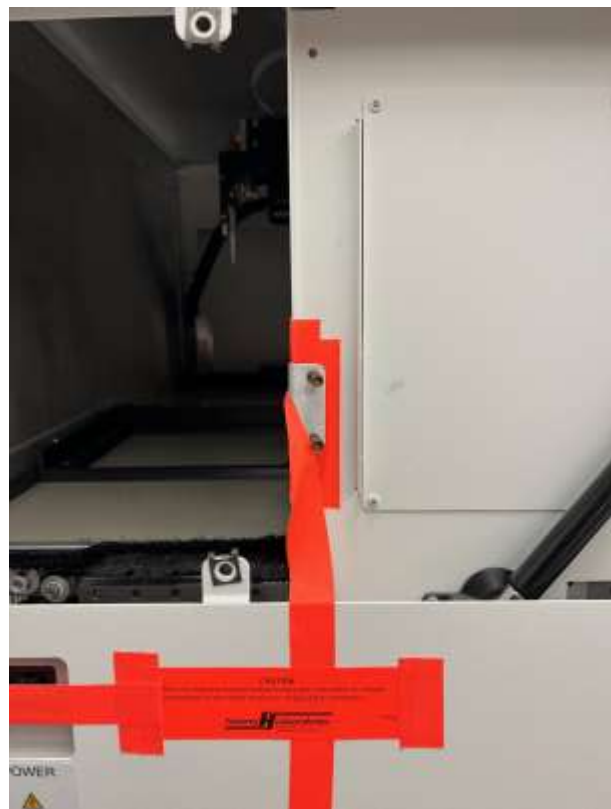
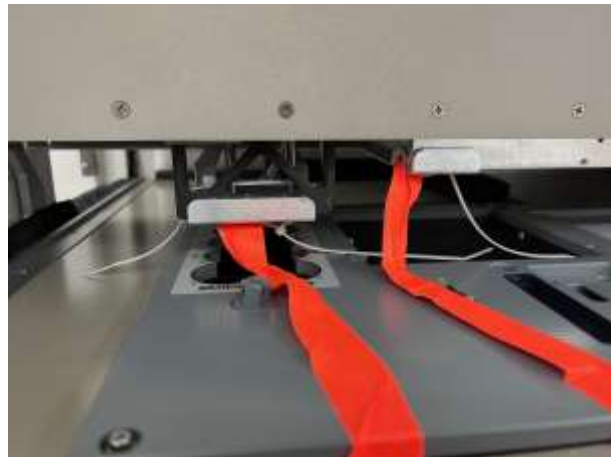
1. Select an environment free of drafts, direct sunlight, excessive humidity and dust, and large temperature fluctuations. Ambient temperature should be between 59 to 80°F (15 to 27°C).
2. Locate the instrument on a level, flat surface, near an easily accessible wall outlet.
3. The location needs to be large enough to allow proper air circulation around the instrument and provide space to place the vats. All reagent vats connected to the instrument must be vented to the atmosphere. The waste vat must be placed below the instrument.

4. Refer to *Section 9: Performance Specifications* for instrument dimensions and weight

**NOTE: At least 2” (5.1 cm) of clearance are necessary for all sides of instrument to prevent overheating.**

**5.2.2. Removing Shipping Bracket and Leveling Instrument**

1. There will be shipping brackets.



2. Unscrew the brackets.
3. Place a level in the center of the electrophoresis chamber and adjust the two feet on the lower right side to level the chamber floor. The floor should be level both from side-to-side and front-to-back.

### 5.2.3. Connecting Vats & Instrument

1. Only remove the port cap when installing the tubing to that port.

**Note: Only use containers and fittings supplied with the instrument. Do not connect the instrument to pressurized supplies. Use only tubing, fittings, and containers rated for a minimum of 16.5 PSI.**

2. Attach the six pigtails to each of the bottle caps.



3. From the length of tubing provided, cut appropriate lengths for each of the Destain, Wash, Overflow Wash line, and Waste containers. The tubing should be long enough to reach the bottle but not so long so there are kinks or excessive amounts draped across the floor.
4. Attach the Saline Tubing Assembling to the pigtail on the Saline vat cap. Fill vat with saline. Attach the other end of the Tubing Assembly from the Saline vat to Port 1.

Ports are located on the right side of the instrument (see Figure 5-3).

5. Attach the length of tubing to the pigtail on the Destain vat cap. Fill vat with Destain. Attach the other end of the tubing from the Saline vat to Port 2.

6. Attach the length of tubing to the pigtail on the Wash vat cap. Fill vat with Wash. Attach the other end of the tubing from the Wash vat to Port 3.

7. Attach the DI Tubing Assembly to the pigtail on the DI Water vat cap. Fill vat with DI water. Attach the other end of the tubing of the Tubing Assembly from the DI Water vat to Port 4.

8. For the Overflow Wash line, attach the length of tubing to the cap that will be used on the Waste vat. Attach the other end of the tubing to Port 5. This catches any overflow from the Wash cycles and channels it into the Waste vat.

9. For the Waste line, attach the length of tubing to the cap that will be used on the Waste vat. Attach the other end of the tubing from the Waste vat to Port 6.

**Note:** Port 6 can only be used for waste.

10. If using the Waste vat, connect the other end of the sensor into the receptacle located on the right hand side of the instrument, labeled "Waste Full Flow Sensor Interconnector".

11. The tubing from ports 5 and 6 may be run to a sink for waste disposal, instead of the Waste vat. When using a sink, use the Shorting Plug instead of the level sensor. Plug the Shorting Plug into the receptacle located on the right side of the instrument, labeled "Waste Full Sensor Interconnector". The waste tubing should always remain unrestricted between the instrument and waste drain or vat.



12. Check that any ports on the instrument not used are left capped. Insure that all tubing is securely connected to fittings to prevent leaks.

13. Install the Spill Tray as shown in Figure 5-6.

#### 5.2.4. Power Cord and Parts Handling

1. Confirm that the main power switch is off and plug the SPIFE Nexus power cord into the outlet provided on the left side of the instrument (Figure 5-4).

**NOTE: Keep area around main inlet and power switch clear and readily accessible for emergency disconnection of equipment.**

2. Plug the power cord into a grounded wall outlet of the proper voltage and frequency. These specifications can be found on the serial number plate located on the left side of the instrument.

3. The wall outlet should not be on the same circuit as any large load device such as a refrigerator, compressor, centrifuge, etc. The instrument's circuitry contains filters to reduce the effect of line voltage fluctuations; however, they should still be avoided. If the operator experiences difficulty, it may be necessary to install an isolation transformer.

**NOTE:** A detachable power cord used with this instrument must have been selected by an agent of Helena Laboratories that is an approved type suitable for application and acceptance by local registry authorities in the country which it is used, based on the serial tag specifications for voltage and current.

**NOTE:** The SPIFE Nexus meets the leakage current specifications of directive EN 61010-1. To meet standards more stringent than this, we recommend the purchase of an isolation transformer. Specifications for this transformer are given in Section 9.

4. The barcode reader, an optional accessory, is used for positive patient ID and plugs into the outlet provided on the right side of the instrument Figure 5-3.

5. Turn on the Main power switch on the left hand side of the instrument. Power on the instrument by pressing the large silver button on the front bottom of the instrument.

**Note:** *Ensure the digital audio input option is selected by using the silver dial on the right side of the monitor. This will allow sounds to be heard through the DisplayPort connection.*

The SPIFE Nexus software is ready to operate once the desired test(s) and the worklist(s) have been created. Setup instructions are in Section 6 - User Setup.



**Figure 5-1 Front view of the SPIFE Nexus**



**Figure 5-2 Back view of the SPIFE Nexus**



**Figure 5-3 Right side view of the SPIFE Nexus**

**Table 5-2 Instrument Ports**

1	USB Ports	Monitor, Mouse/Keyboard, optional Barcode Reader, Data Drives
2	Serial Port	Not Used or Functional
3	Network Port	Ethernet port for system networking
4	LIS Port	RS-232 serial port for interfacing to a <u>L</u> aboratory <u>I</u> nformation <u>S</u> ystem (LIS).
5	Fluid Ports	These ports are used to connect the tubing to the vat containers. 1 – Saline 2 – Destain 3 – Wash Vat 4 – DI Water 5 – Overflow Wash 6 – Waste
6	Display Power	AC outlet for connected Display/Monitor, IEC 60320-1 C13
7	Display Port	Display/Monitor interface port
8	Waste Full Sensor Interconnector	Input from Waste Container to detect a full Waste Vat



**Figure 5-1 Left side view of the SPIFE Nexus**



**Figure 5-2 Hose placement**



**Figure 5-3 Spill Tray placement**

## Section 6 - User Setup

This section will describe the step-by-step process in creating tests containing multiple samples that may also require dilution schemes for specific immunoglobulins.

The SPIFE Nexus will automatically track test setup changes by the user.

1. Turn the power on for the instrument by pressing the large silver button on the front of the instrument.

2. The Microsoft® Windows® program opens and displays the SPIFE Nexus icon.

3. Upon first use, a serial number must be entered. Right click and select, *Run as Administrator*.

4. The User Account Control will display prompting the user for an administrator name and password. After the password has been entered, the software will prompt the user for the serial number.

5. Once the serial number has been entered, this screen will not show again.

**Note:** *If the SPIFE Nexus is being used with the QuickScan Touch plus software and users were created, the logon prompt will be displayed. If QuickScan Touch plus will not be used in conjunction with the SPIFE Nexus, a User's icon will be included on the menu bar as well as the SPIFE Nexus Setup window. See Section 6.5 for more details.*

6. Once the software has initialized and the user has logged in, it will display a prompt to the operator stating, "*Priming is recommended at the beginning of each day as well as after refilling DI Water or Saline. Would you like to Prime?*" with Yes and No buttons.

- a. Select *Yes* to prime the instrument.

- b. Select *No* to proceed to the main menu.

7. The main menu will be displayed. There are eight icons displayed on the menu bar: *Start, Stop, Prime, Unlock Door, Light, Setup, Maint, and About* (Figure 6-1).

8. Select *Setup*.

9. The *SPIFE Nexus Setup* window opens and displays three tabs: *Tests, Instrument, and Language*. There are also *OK* and *Cancel* buttons (Figure 6-2).

### 6.1. Tests

1. The *Tests* window displays all the current tests as well as options to *Edit, Add, Delete, Print, Export, and Import* (Figure 6-2).

2. *Edit* - To edit an existing test, highlight the needed test and select *Edit*. The *Edit Test* window appears and contains the test name and its current parameters (Figure 6-3). See Sections 6.1.1 through 6.1.5 for instructions on using this window. Note that once a test has been edited and saved, the **new test will overwrite the original test**.

3. *Add* - To add a new test, select *Add* and the *Add Test* window (Figure 6-4) displays with blank fields (see Sections 6.1.1 through 6.1.7 for further detail).

4. *Delete* - To delete an existing test, highlight the needed test and select *Delete*. A *Confirm Delete* prompt displays:

- a. Select *Yes* to delete the test.

- b. Select *No* to retain the test.

**Note:** *Custom deleted tests cannot be restored after deleting. They can only be recreated using default settings and then altering the parameters back to the custom settings.*

5. *Print* – select to print the highlighted test's settings.

6. *Export* – select to export the highlighted test to another location.

- a. The *Export Test* window will appear.
- b. Select the location to save the test and click *Save*.
- c. The window will close automatically and return to the *Tests* window.

7. *Import* - select to import a test from another location.

- a. The *Import Test* window will appear.
- b. Select the location where the test is located and select *Open*.
- c. The window will close automatically and return to the *Tests* window.

8. Once all the tests have been set up and/or altered as desired:

- a. *OK* - to save all the changes made to setup and exit setup, select *OK*.

- b. *Cancel* - to exit setup without saving any changes made, even those made to different portions of setup, select *Cancel*.

- i. If changes were made, a *Confirm Cancel* prompt displays.

- 1) To exit without saving changes, select *Yes*.

- 2) To save changes, select *No* in response to the prompt and then select *OK*.

### 6.1.1. Test Type and Test Name

1. *Test Type* – On the *SPIFE Nexus Add Test* window, use the drop down list to select the appropriate test type. If editing, this step may be skipped. (Figure 6-5).

2. *Test Name* - Prior to naming the test, or altering specific parameters, click on the *Default Settings* button at the upper right of the screen. The appropriate default settings for the test type selected will automatically be displayed by test name. The test name may be entered/altered as needed; however, each test setup must have a unique test name. The complete

test name will automatically include the name entered here, the maximum number of samples setup for this test as well as the stain type.

3. On the same screen, below *Test Type* and *Test Name*, there are five tabs; *Sample Loading* (Section 6.1.2), *Gel Preparation* (Section 6.1.3), and *Scan* (Section 6.1.4), *Pre-Start Checklist* (Section 6.1.5), and *Instrument Setup* (6.1.6). Each of these contains menus for setting up test-specific parameters and processes.

**Note:** When naming a test, in order for the gel to be scanned in *QuickScan Touch plus*, the test name must be the same in both the *SPIFE Nexus* software as well as the *QuickScan Touch* software. The test name is case-sensitive.

### 6.1.2. Sample Loading

The following parameters may be altered as needed. Note that only parameters specific to the test type selected are available for modification. For example, dilutions are not a default setting for Serum Proteins.

1. When *Tests* is selected in the *Setup* menu, and the *Add (or Edit) Test* menu is opened, the *Sample Loading* tab is selected first by default.

- a. *Sample Load Enabled* – enable to have the sample tray loaded with onboard samples pulled from the onboard test tube racks.

- b. *Tray* – use the dropdown arrow to select the necessary sample tray.

- c. *Volumes* – from this section, the volumes may be individually customized for each row.

- i. *Row* – use the dropdown arrow to select the desired row.

ii. *Required Volume ( $\mu\text{L}$ )* – the minimum volume required to be in the sample cup for the test to occur.

iii. *Dispense Volume ( $\mu\text{L}$ )* – the volume dispensed into the sample tray before leaving the required volume behind.

d. *Primary Wash Time (sec)* – the amount of time of the wash between sample tubes.

e. *Primary Wash Cycles* – the number of washes between sample tubes.

f. *Secondary Wash time (sec)* – the amount of time of the wash between dilutions of the same sample.

g. *Secondary Wash Cycles* – the number of washes between dilutions of the same sample.

h. *Samples Per Gel* – the number of samples per gel that will be processed.

i. *Lanes Per Sample* – the number of lanes per sample.

j. *Dilution Mix Cycles* – select the number of times to have the system aspirate and dispense the dilution mix. This feature is only available for Immunofixation Electrophoresis (IFE) tests.

k. *Cover gel while loading sample* – select *Yes* for the platen cover to be placed over the gel while the sample tray is being loaded to prevent the gel from drying out.

l. *Temperature ( $^{\circ}\text{C}$ )* – select the temperature of the electrophoresis platen during sample loading. The default value is  $12^{\circ}\text{C}$  with a maximum setting of  $30^{\circ}\text{C}$ .

m. *Dilutions* – Dilutions are available only with Immunofixation Electrophoresis (IFE) tests.

i. Dilutions may be individually set for each sample (or for the entire row by clicking on the header and highlighting the

column) and each specificity. Available dilutions are Neat; 1 in 2; 1 in 3; 1 in 4; 1 in 5; 1 in 6; 1 in 7; 1 in 8; 1 in 10; 1 in 12; 1 in 14; 1 in 16; 1 in 18, and 1 in 20 (Figure 6-6).

### 6.1.3. Gel Preparation

The Gel Preparation tab allows the user to customize the different operations for the gel, such as Sample Application or Electrophoresis Time creating a unique testing process.

#### 6.1.3.1. Stain Type

*Stain Type* – Using the dropdown menu, select from the following stain types: *Acid Blue*, *Acid Violet*, *Amido Black*, *Fat Red 7B*, *Fetal Tek*, or *Ponceau S*.

#### 6.1.3.2. Gel Preparation Processes

From this section, gel processes can be added or deleted and then reordered depending on the necessary requirements.

1. *Add* – select to add a new process to the test chronologically. The *Add Gel Preparation Process* window will appear with the processes detailed in 6.1.3.2.1 through 6.1.3.2.10 (Figure 6-7).

2. *Insert* – select to add a new process at a selected place. The *Insert Gel Preparation Process* window will appear with the processes detailed in 6.1.3.2.1 through 6.1.3.2.10 (Figure 6-8).

3. *Delete* – To delete an existing process, highlight the unneeded process and select *Delete*. A *Confirm Delete* prompt displays:

a. Select *Yes* to delete the process.

b. Select *No* to not delete the process.

4. *Move Up* – select to move the highlighted process up in the list.

5. *Move Down* – select to move the highlighted process down in the list

### 6.1.3.2.1. Applicator Load

Enter the parameters to configure how the applicator blades will be loaded with samples from the sample tray wells.

1. *Applicator Load Enabled* – select *Yes* to have the instrument automatically load the applicator blades with sample from the onboard sample tray wells or *No* to disable this process.

2. *Applicator Load Time (mm:ss)* – the length of time the blade remains immersed in the sample.

3. *Applicator Load Speed (mm/ss)* – the speed at which the blade is removed from the sample (measured in millimeters per second).

4. *Application Load Offset (mm from center)* – set to center the blades over the sample wells. Selecting a positive number will move the blades toward the front of the machine, while selecting a negative number moves the blades toward the back of the instrument. The default value is 0.

### 6.1.3.2.2. Sample Application

Enter the parameters to configure how sample will be applied to the gel.

1. *Sample Application Enabled* – select *Yes* to have sample applied to the gel or *No* if sample application is not necessary.

2. *Apply Time (mm:ss)* – the length of time the blades remain in the gel.

3. *Absorption Time (mm:ss)* – the length of time the gel is allowed to sit after sample has been applied.

4. *Application Offset (mm from center)* – set to center the blades over the gel. Selecting a positive number will move the blades toward the front of the machine, while selecting a negative number moves the blades toward the back of the instrument. The default value is 0.

### 6.1.3.2.3. Electrophoresis

Enter the parameters to configure how electrophoresis will occur.

1. *Electrophoresis Enabled* – select *Yes* to enable electrophoresis or *No* to disable this process.

2. *Operating Mode* – select from *Constant Voltage*, *Constant Current*, or *Constant Power*.

**Note:** Currently, only *Constant Voltage* is available for use.

3. *Voltage (volts)* – set the required voltage to be applied during electrophoresis.

4. *Temperature (°C)* – set the platen temperature to be maintained during electrophoresis.

5. *Time (hh:mm:ss)* – set the length of time for electrophoresis to occur.

6. *Safety Limits* - Set the performance limits for the test using the arrows to make the required selection. If the instrument should fall outside these limits, the run will be aborted.

a. *Minimum Voltage (volts)* – the minimum voltage allowed for the test to continue.

b. *Maximum Voltage (volts)* – the maximum voltage allowed for the test to continue.

c. *Minimum Current (mA)* – the minimum current allowed for the test to continue.

d. *Maximum Current (mA)* – the maximum current allowed for the test to continue.

e. *Minimum Temperature (°C)* – the minimum temperature allowed for the test to continue.

f. *Maximum Temperature (°C)* – the maximum temperature allowed for the test to continue.

#### 6.1.3.2.4. Fixative /Antiserum Application

Enter the parameters to configure how fixative, antiserum, or other reagent will be applied onto the gel by pipette application.

1. *Fixative / Antiserum Application Enabled* – select *Yes* to have reagent applied to the gel or *No* to bypass this process.

2. *Absorption Time (mm:ss)* – the length of time the gel is allowed to rest after reagent is applied.

3. *Lane 1 Position (mm from calibration point)* – the offset point (from left to right) from the calibration point.

4. *Row 1 Start (mm from calibration point)* – the starting point (from back to front) of the lane where the application begins.

5. *Row 1 End (mm from calibration point)* – the ending point (from back to front) of the lane where the application ends.

6. *Lane to Lane Spacing (mm)* – the center lines spacing between the lanes.

7. *Row to Row spacing (mm)* – the distance between rows, measured from center line to center line.

8. *Sample to Sample Spacing (mm)*: - the center line spacing between the first lane of each sample on the same row.

9. *Spreader Tip Needed* - select *Yes* to have reagent applied with the Spreader Tip or *No* to not use the Spreader Tip.

10. *Apply To All Samples* – select *Yes* to apply reagent to all samples regardless of what was loaded during Sample Loading. Selecting *No* will alert the SPIFE Nexus to only apply to one sample past the last loaded sample.

11. *Application Position Check* –

a. Select from the following dropdown menu options:

i. *Row 1 Lane 1 Start*

ii. *Row 1 Lane 1 End*

iii. *Last Lane*

iv. *Last Row End*

b. *Move To* – click to move to the selected application position to verify correct position.

c. *Home* – click to return the pipette to the Home position.

d. *Apply Settings* – select to view and set up specific sample lane settings.

**Note:** *The Apply Settings option is available in the User permissions menu.*

#### 6.1.3.2.5. Reagent / Stain Application

Enter the parameters to configure how reagent will be applied to the gel using the roller bar.

1. *Reagent / Stain Application Enabled* – select *Yes* to have the Reagent/Stain dispenser apply reagent/stain to the gel or *No* for no reagent/stain application.

2. *Spread Cycles* – select the number of times to have the roller spread reagent/stain across the gel. A full spread cycle involves rolling from the top gel block to the bottom and back.

3. *Half Cycle Spread* – select *Yes* to have the roller finish in the middle of the gel or *No* to have the roller continue to the top gel block.

4. *Temperature (°C)* – set platen temperature to be maintained during reagent/stain application.

5. *Absorption Time (hh:mm:ss)* – the length of time the gel is allowed to rest after reagent/stain is applied.

6. *Pour Position (mm from cal point)* – the position where the reagent/stain is poured onto the gel.

7. *Spread Start (mm from cal. point)* – the position where the roller begins to spread the reagent/stain.

8. *Spread Length (mm)* – the total distance the roller will travel to spread the reagent/stain across the gel.

9. *End of Roll Pause (sec)* – enter the number of seconds for the roller to pause after stopping.

#### 6.1.3.2.6. Pre-Dry / Incubate

Enter the parameters to configure how the gel will be pre-dried/incubated on the platen.

1. *Incubate / Pre-Dry Enabled* – select *Yes* to Pre-dry/Incubate the plate or *No* if it is not necessary.

2. *Temperature (°C)* – set the platen temperature to be maintained during the Pre-Dry/Incubate process.

3. *Time (hh:mm:ss)* – set the length of time for Pre-Dry/Incubate to occur.

4. *Cover Gel:* - select *Yes* to cover the gel during Pre-dry/Incubate or *No* if it is not necessary.

5. *Ep Cover Type:* if Cover Gel is enabled, the selected Electrophoresis Plate from Test Setup is displayed.

6. *Layer Number:* if Cover Gel is enabled, use dropdown menu to select specific layer where the specified Electrophoresis Cover is stored.

#### 6.1.3.2.7. Wash / Destain

Enter the parameters to configure the wash cycles. For the SPIFE Nexus, there

is one vat, but multiple wash processes can be set up by selecting the process type below in Step 1.

1. *Process type* – choose from *DI Water Wash*, *Buffer Wash*, or *Destain*.

2. *Wash / Destain Enabled* – *Yes* to include a Wash/Destain step or *No* to not include the wash or destain cycle.

3. *Recirculate* – select from the dropdown menu:

a. *No Recirculate* – the vat is filled only and then drained, allowing the fluid to remain motionless.

b. *Recirculate Bottom to Top* – the fluid is kept moving by pumping it from the top of the vat to the bottom; causing the fluid in the vat to travel from the bottom to the top

c. *Recirculate Top to Bottom* – the fluid is kept moving by pumping it from the bottom of the vat to the top; causing the fluid in the vat to travel from the top to the bottom.

4. *Recirculation Speed* – use dropdown menu to set speed from 1 to 10.

5. *Time (hh:mm:ss)* – set the length of time for the Wash / Destain process.

6. *Pulse Cycles* – use the up and down arrows to select the number of pulse cycles to include. A pulse cycle is when the Nexus switches the direction of the fluid in the vat and creates a “pulse”.

7. *Pulse Time(sec)* – enter the number of seconds for the SPIFE Nexus to “pulse” the fluid.

#### 6.1.3.2.8. Dry

Enter the parameters to configure how the plate will be dried within the dryer chamber.

1. *Dry Enabled* – select *Yes* to move the plate to the dryer chamber or *No* to not dry the plate.

2. *Temperature (°C)* – set the dryer chamber temperature to be maintained during the Dry process.

3. *Time (hh:mm:ss)* – set the length of time for the Dry process.

#### 6.1.3.2.9. Blot

Enter the parameters to configure blotting the gel.

1. *Blot Enabled* – select *Yes* to have the gel blotted or *No* for no blotting.

2. *Temperature (°C)* – set platen temperature to be maintained during blotting.

3. *Time (hh:mm:ss)* – set the required length of time for the gel to be blotted.

4. *Blotter Type:* – the selected Blotter from Test Setup is displayed.

5. *Layer Number:* – displays the Layer number where the specified Blotter is stored.

#### 6.1.3.2.10. Manual Process

This has been incorporated to give the user the freedom for assay development. Enter the parameters to configure the process.

Once the user is notified onscreen by a manual process message, a countdown timer of five minutes begins and will be displayed in the bottom right hand corner. If the actions are not completed with the user clicking OK to move to the next process before the timer elapses, ending the test becomes the only option.

1. *Manual Process Enabled* – select *Yes* to include a manual process in the test or *No* for no manual process to be included.

2. *Process Name* – add a descriptive name for the process.

3. *Start Message* – the message that will be displayed when it is time for the manual process to occur.

4. *Time (hh:mm:ss)* – the length of time the manual process is allotted. This time begins after the user clicks or taps *OK* in the start message to alert the Nexus the process has been started.

5. *End Message* – the message that will be displayed when the manual process has ended. To proceed, the user closes out whatever they were doing, shuts the machine door, and clicks *OK* to proceed to the next step of automation.

#### 6.1.4. Scan

Select *Yes* to enable plate scanning or *No* for the plate to not be scanned (Figure 6-9).

#### 6.1.5. Pre-Start Checklist

A checklist, specific to the test selected, can be displayed before the test starts to help the user ensure all the necessary supplies have been collected and placed onto the instrument (Figure 6-10).

1. *Show Pre-Start Checklist* – select *Yes* to have the Pre-Start Checklist display before the test begins or *No* to skip it. For example, a serum protein run could include the following:

- Sufficient DI, Saline, and Destain
- Primed Instrument
- 20-tooth Applicator Blade with Blade Weights
- 3 x 700uL SPIFE Nexus Blue Stain
- Clean Roller Bar
- Gel Barcode
- Sample Racks

#### 6.1.6. Instrument Setup

From this tab, the required consumables for the test are listed. Default settings will auto populate these fields (Figure 6-11).

1. *Cassette* – select from the following:

- a. *C01: Standard Cassette*
- b. *C02: Quick Gel Cassette*
- c. *C03: Standard Cassette2*
- d. *C04: Standard Cassette3*
- e. *C05: Standard Cassette3*

2. *Applicator Template* – select from the following:

- a. *A01: IFE 3, 6, 9 / CK / SPE / Split Beta (60)*
- b. *A02: LD / Alkaline Phosphatase*
- c. *A03: Acid HB / SPE HiRes (20) / QG Alk HB / QG Cholesterol / QG Lipo*
- d. *A04: IFE (15) / Split Beta-100 / Cholesterol*
- e. *A05: Lipoprotein*
- f. *A06: QG (CK, IFE, LD, SPE, Split Beta, Acid HB)*
- g. *A07: A1AT*
- h. *A08: Alkaline HB*

3. *Reagent Applique* – select from the following:

- a. *R01: Antisera Storage*
- b. *R02: Antisera Applique2*
- c. *R03: Antisera Applique3*
- d. *R04: Antisera Applique4*
- e. *R05: Antisera Applique5*

4. *Electrophoresis Plate* – select from the following:

- a. *E01: Standard 2 Carbon Electrodes*
- b. *E02: Standard 1 Carbon, 1 Stainless electrode*
- c. *E03: Quick Gel*
- d. *E04: Standard 3*
- e. *E05: Standard 4*

f. *E06: Standard 5*

5. *Blotter Holder* – select from the following:

- a. *B01: Standard Blotter*
- b. *B02: Quick Gel Blotter*
- c. *B03: Standard Blotter2*
- d. *B04: Standard Blotter3*
- e. *B05: Standard Blotter4*

### 6.1.7. OK and Cancel

1. *OK* - to save all the changes made and return to the Setup menu, select *OK*.

2. *Cancel* - to exit setup without saving any changes made, select *Cancel*.

a. If changes were made, a *Confirm Cancel* prompt displays.

i. To exit without saving changes, select *Yes*.

ii. To save changes, select *No* in response to the prompt and then select *OK*.

### 6.2. Instrument

This tab allows the user to customize error and status messages (Figure 6-12).

1. *Sample ID for no tube* – the text to be displayed if no tube is detected.

2. *Sample ID for no bar code* – the text to be displayed if no sample ID is detected

3. *Platen idle temperature (°C)* – the idle temperature of the electrophoresis platen.

4. *Reagent Chiller* – select *On* to initiate the reagent chiller or *Off* to disable the reagent chiller.

5. *Interior Lights* – select *On* to turn on the Interior Lights or *Off* to disable the Interior Lights.

6. *Status Indicator Lights* – customize which warning lights to enable and be shown on the status light.

a. *Show Red on Error* – select *Yes* to show red for a critical error or *No* for no light to be displayed.

b. *Show Yellow on Warning* – select *Yes* to show yellow for a warning message or *No* for no light to be displayed.

c. *Show Blue on Attention Required* – select *Yes* to display blue when a material or item is required or *No* for no light to be displayed.

d. *Show Green when Running* – select *Yes* to display green for when the status is satisfactory or *No* for no light to be displayed.

e. *Flash Green on Test Completion* – select *Yes* to flash green when the current run has been completed or *No* for the light to not flash when the current run has been completed.

7. *Alarm Volume* – use the slide bar and select from 0 to 100 for the alarm volume.

### 6.3. Language

All available languages are displayed. At this time, only English is available (Figure 6-13).

### 6.4. Unlock Door

A safety interlock feature automatically locks the main instrument door when it is off as well as when the door has been shut. Select to unlock the main door of the instrument.

### 6.5. About

The *About* icon displays all the current information for the SPIFE Nexus instrument, including the software version, firmware versions, and Helena Laboratories contact information (Figure 6-14).

### 6.6. Users

In the event the SPIFE Nexus will not be used with Helena's QuickScan Touch *plus*

software, users and passwords may still be created. If this is the case, the display will have a slightly different look to it (Figure 6-15).

After double clicking the SPIFE Nexus icon on the desktop, the instrument will display the SPIFE Nexus Sign In window. Log into the software using the default username 'Administrator' and the password 'Adm1n'.

SPIFE Nexus Sign In

User Name: Administrator

Password:

Keep me signed in until I sign out.

Sign In Exit Program

Located on the Main Menu bar is the *Users* icon. Selecting it will display which user is currently logged into the system.

SPIFE Nexus User

User 'Administrator' is signed in.

Sign Out Close

Selecting *Sign Out* will sign out the current user and display the *Sign In* window again.

Selecting *Close* will close the dialog box and return to the Main Menu.

#### 6.6.1. User setup

1. From the Main Menu, select *Setup*.
2. The *SPIFE Nexus Setup* window opens and displays four tabs: *Tests*, *Sample trays*, *Instrument*, *Language*, and *Users*. There are also *OK* and *Cancel* buttons.
3. Select the *Users* tab (Figure 6-16). The *Users* tab is displayed as well as options to

*Edit, Add, Delete, and Print.* Any current users will be listed.

4. *Edit* - To edit an existing user, highlight the needed user and select *Edit*. The *Edit User* window appears and contains the user name, password, and the user permissions (Figure 6-17).

a. *User Name* – enter the desired user name.

b. *Password* – enter the desired password.

c. *This user has permission to* – select each of the following which will apply to the current user

- i. *Change Setup*
- ii. *Change Calibration*
- iii. *Clear Log Files*
- iv. *Setup Users*

5. *Add* - To add a new user, select *Add* and the *Add User* window (Figure 6-18) displays with blank fields.

a. *User Name* – enter the desired user name.

b. *Password* – enter the desired password.

c. *This user has permission to* – select each of the following which will apply to the current user.

- i. *Change Setup*
- ii. *Change Calibration*
- iii. *Clear Log Files*
- iv. *Setup Users*

6. *Delete* - To delete an existing user, highlight the needed user and select *Delete*. A *Confirm Delete* prompt displays:

- a. Select *Yes* to delete the user.
- b. Select *No* to retain the user.

7. *Print* – select to print the highlighted user name and information.

8. When the editing is completed:

a. *OK* - to save all the changes made to setup and exit setup, select *OK*.

b. *Cancel* - to exit setup without saving any changes made, even those made to different portions of setup, select *Cancel*.

i. If changes were made, a *Confirm Cancel* prompt displays.

1) To exit without saving changes, select *Yes*.

2) To save changes, select *No* in response to the prompt and then select *OK*.

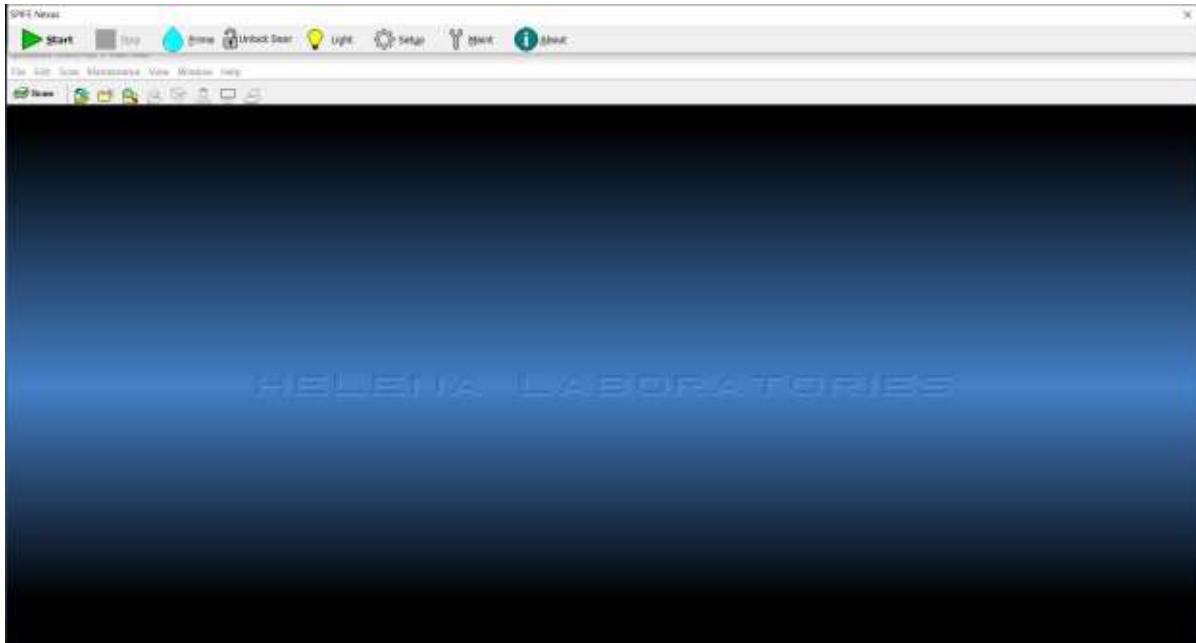


Figure 6-1 Main Menu

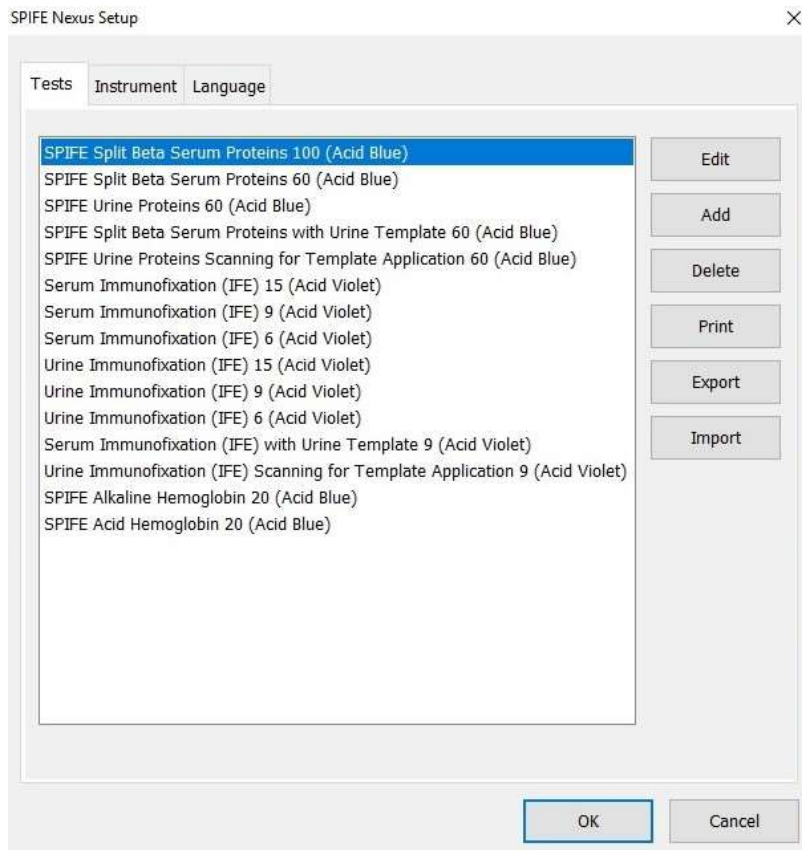


Figure 6-2 SPIFE Nexus Setup, Tests

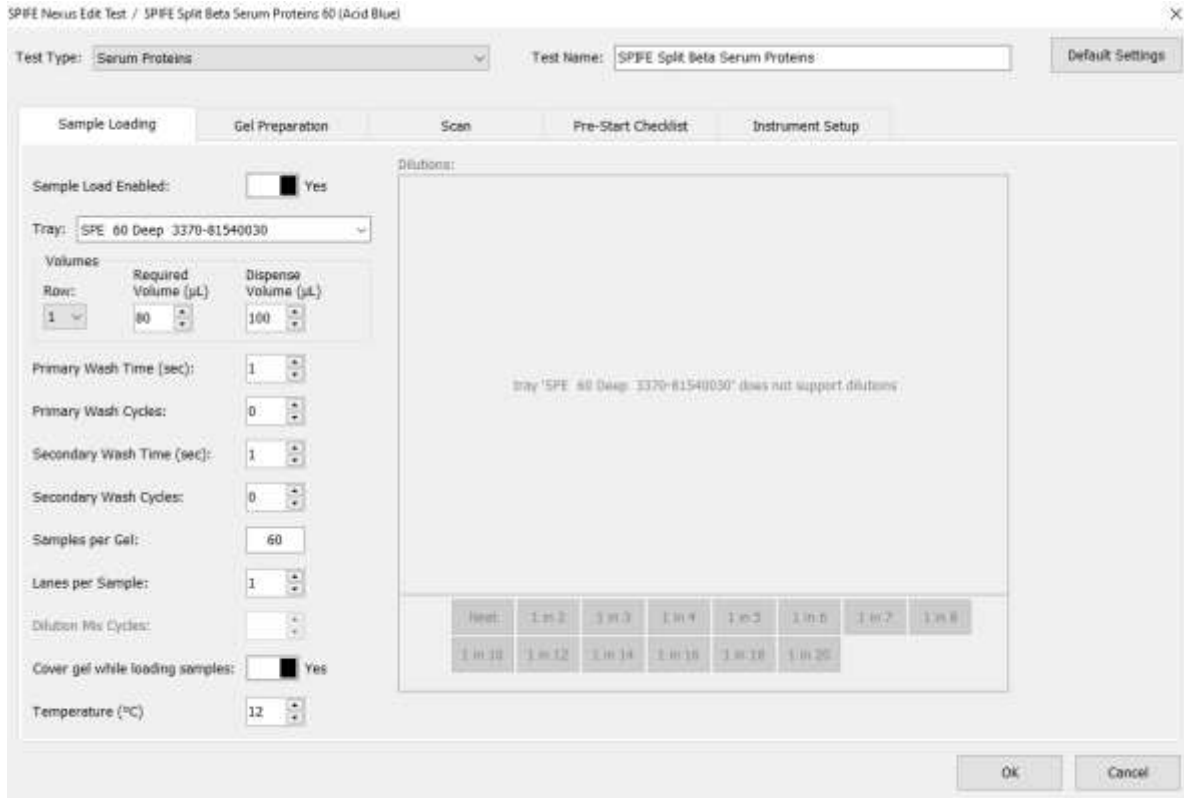


Figure 6-3 SPIFE Nexus Setup, Edit Test

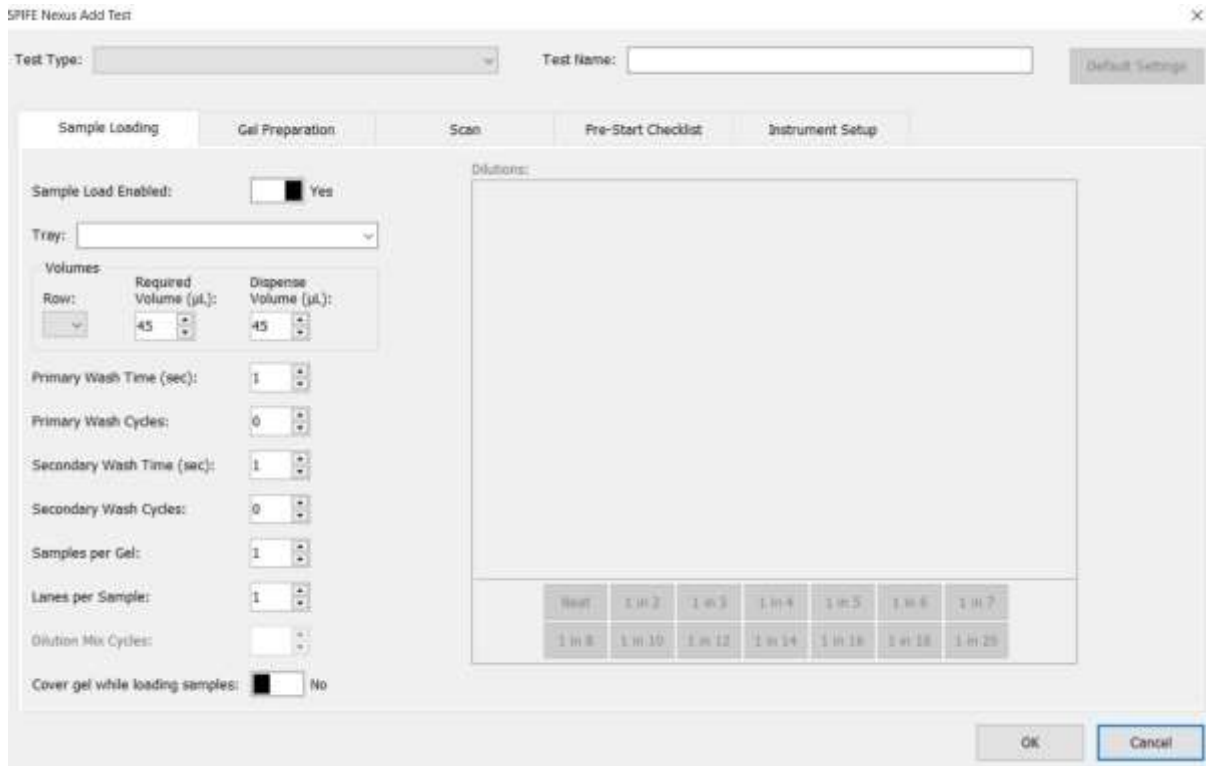


Figure 6-4 SPIFE Nexus Setup, Add Test

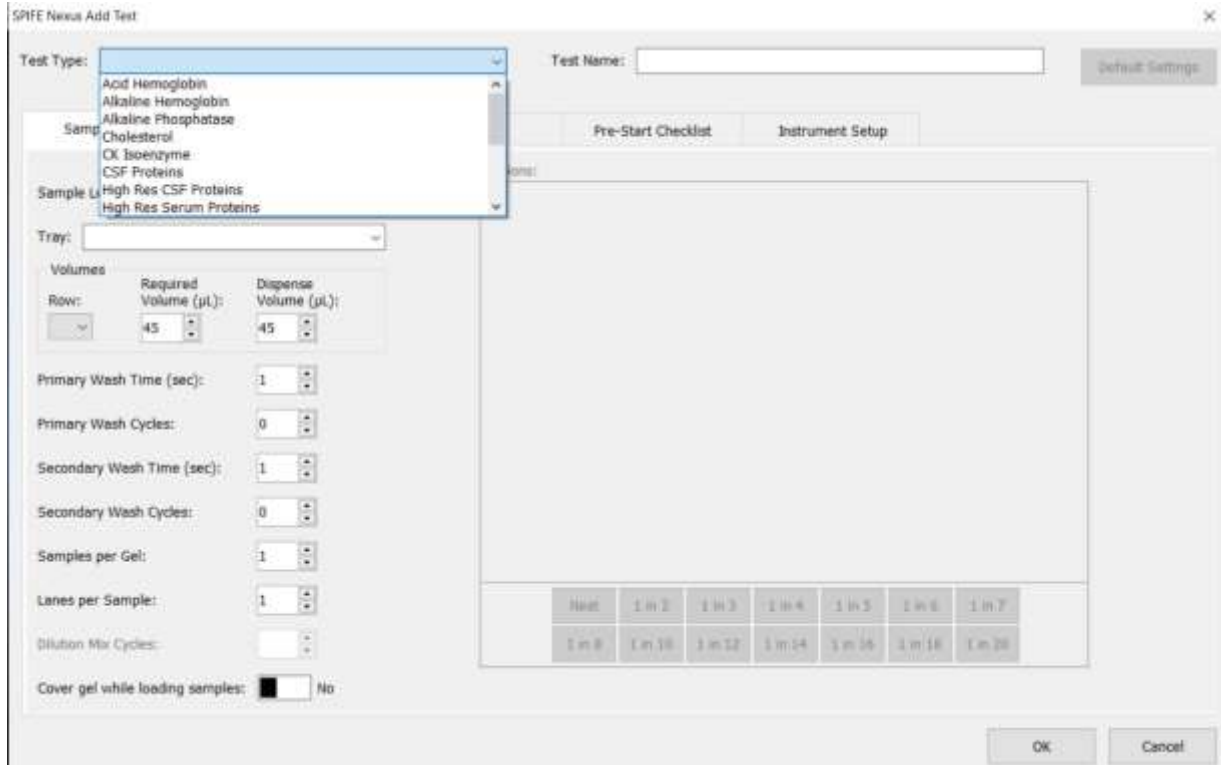


Figure 6-5 Test Type Drop Down List

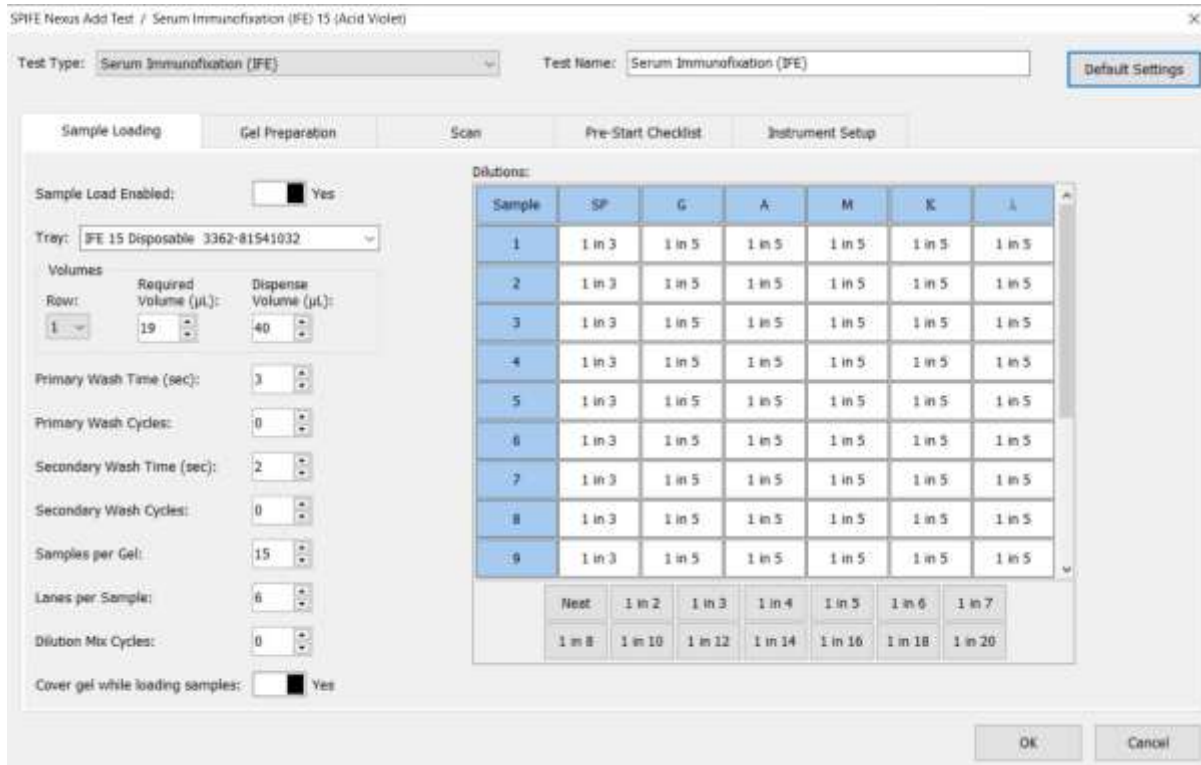


Figure 6-6 Dilutions

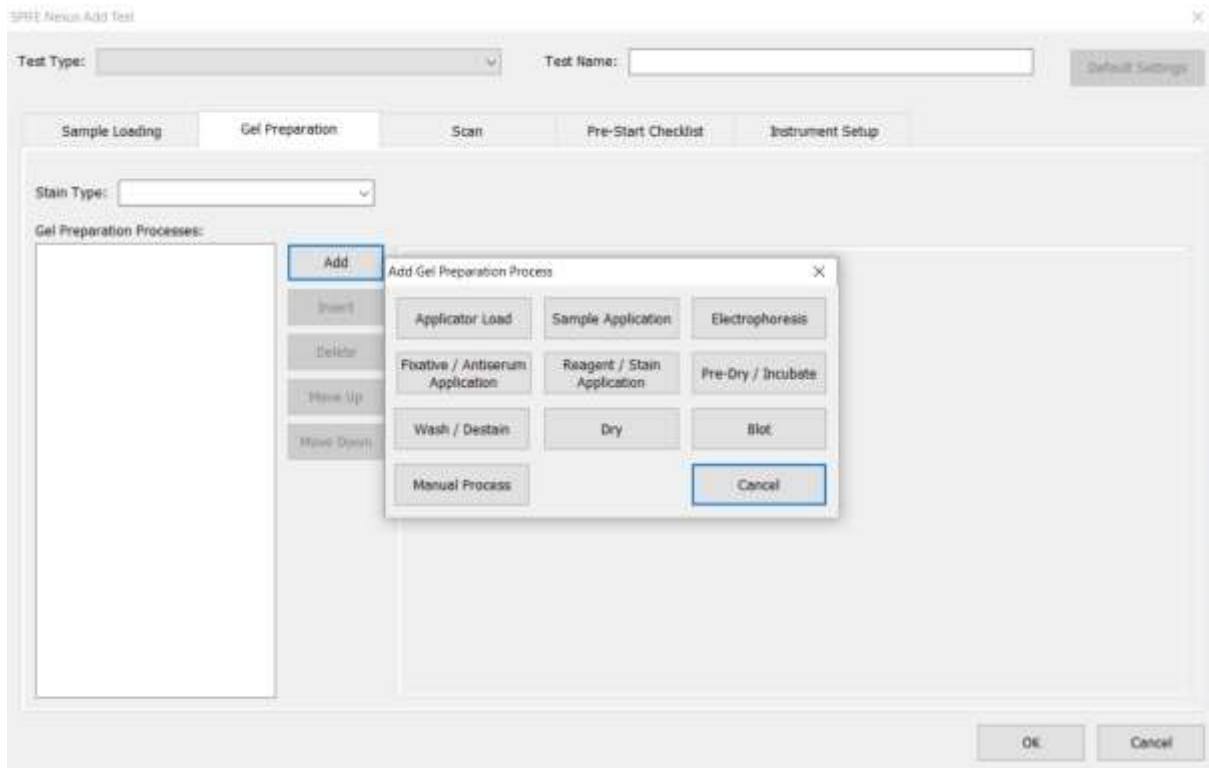


Figure 6-7 Add Gel Prep Process

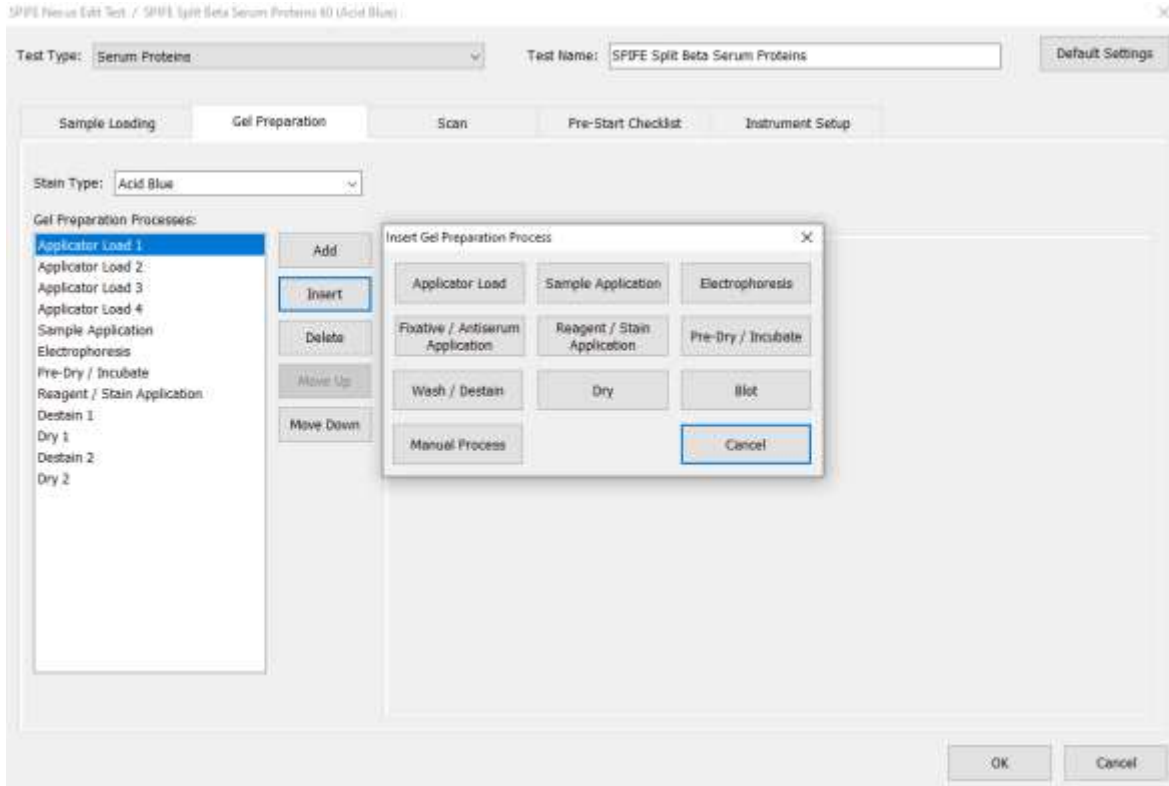


Figure 6-8 Insert Gel Prep Process

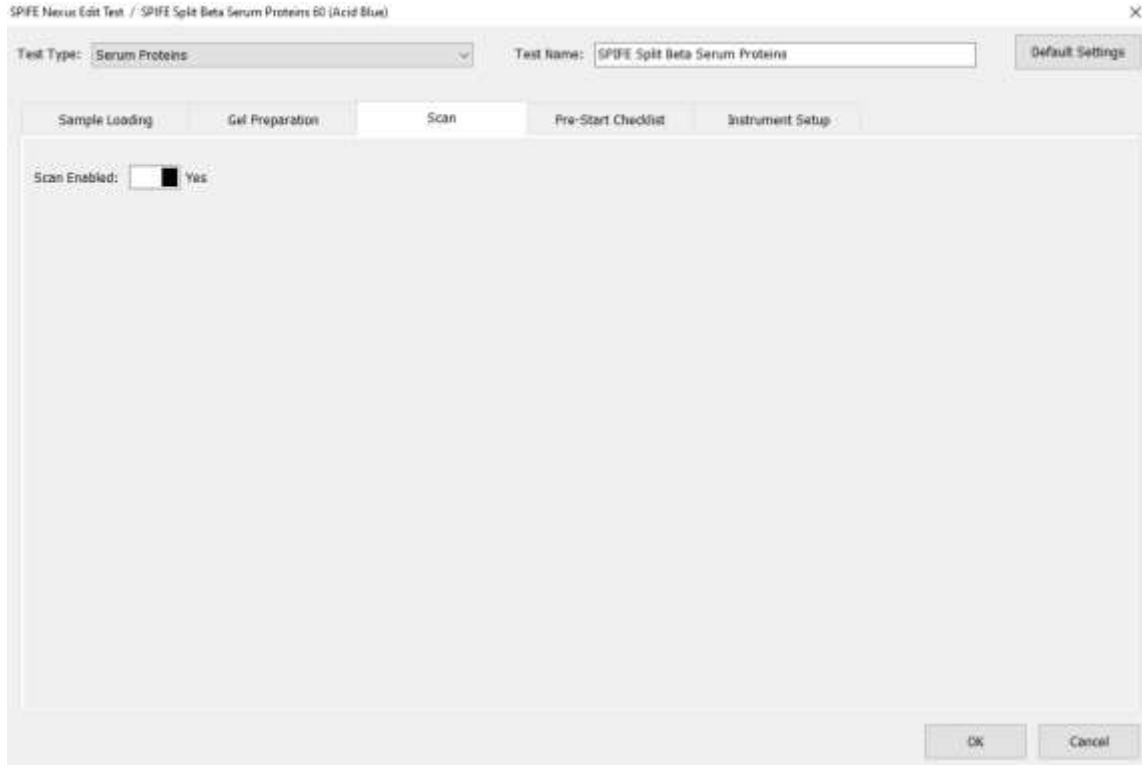


Figure 6-9 Scan

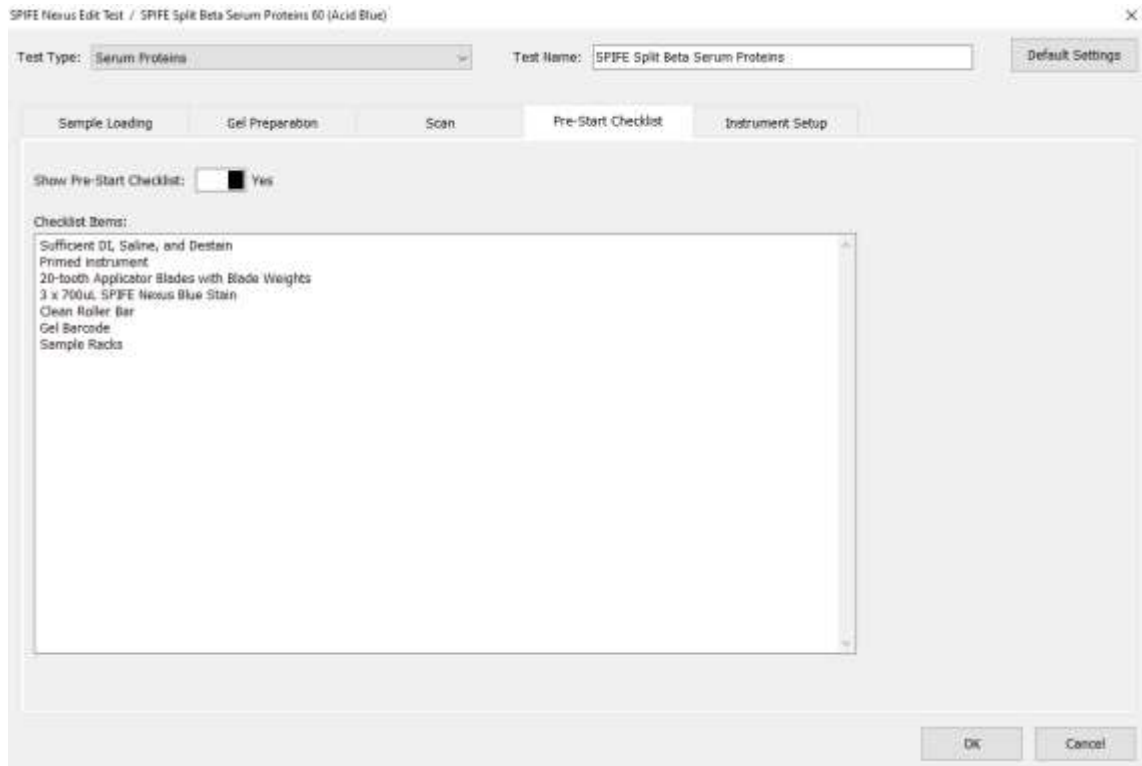


Figure 6-10 Pre-Start Checklist

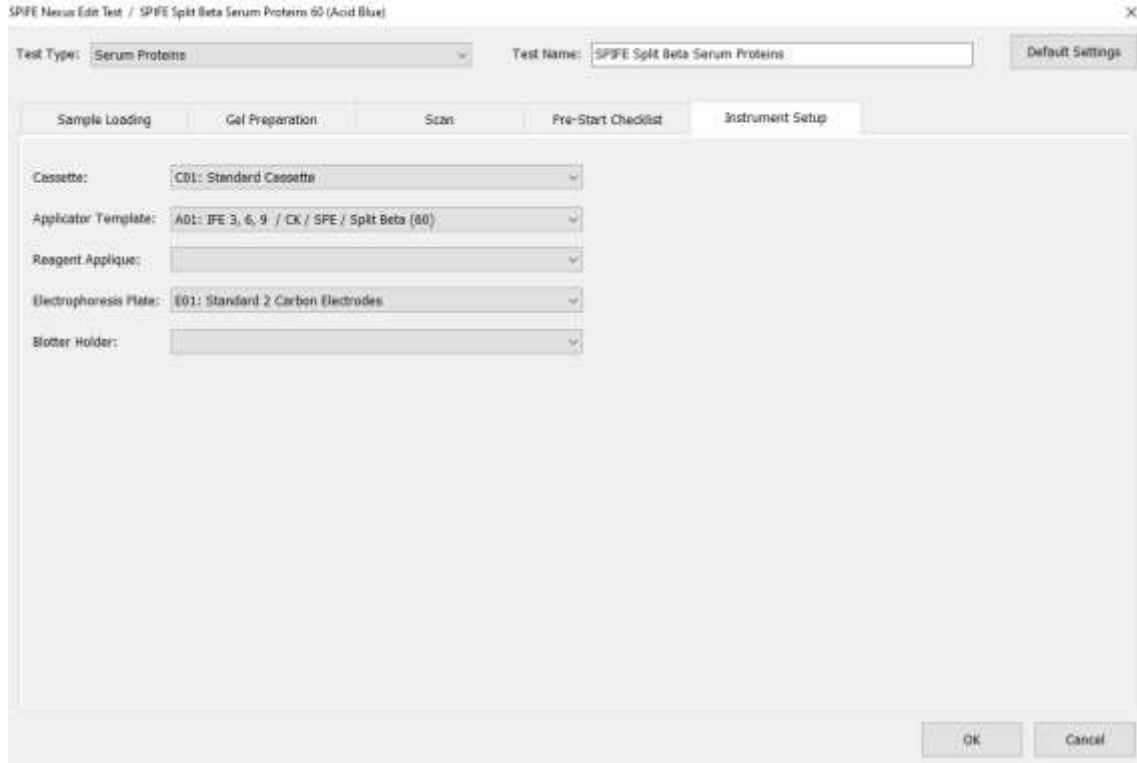


Figure 6-11 Instrument Setup

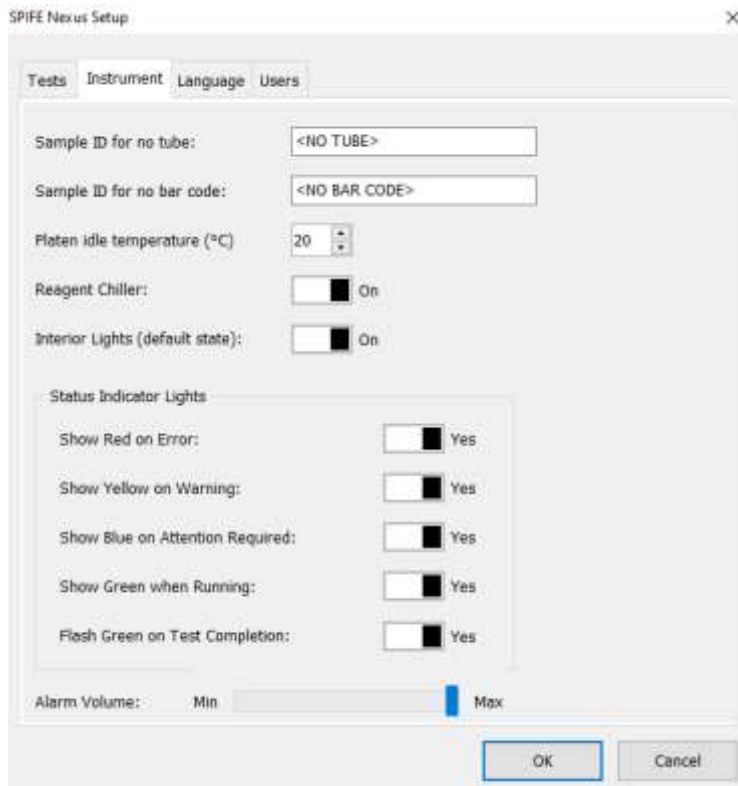


Figure 6-12 Instrument

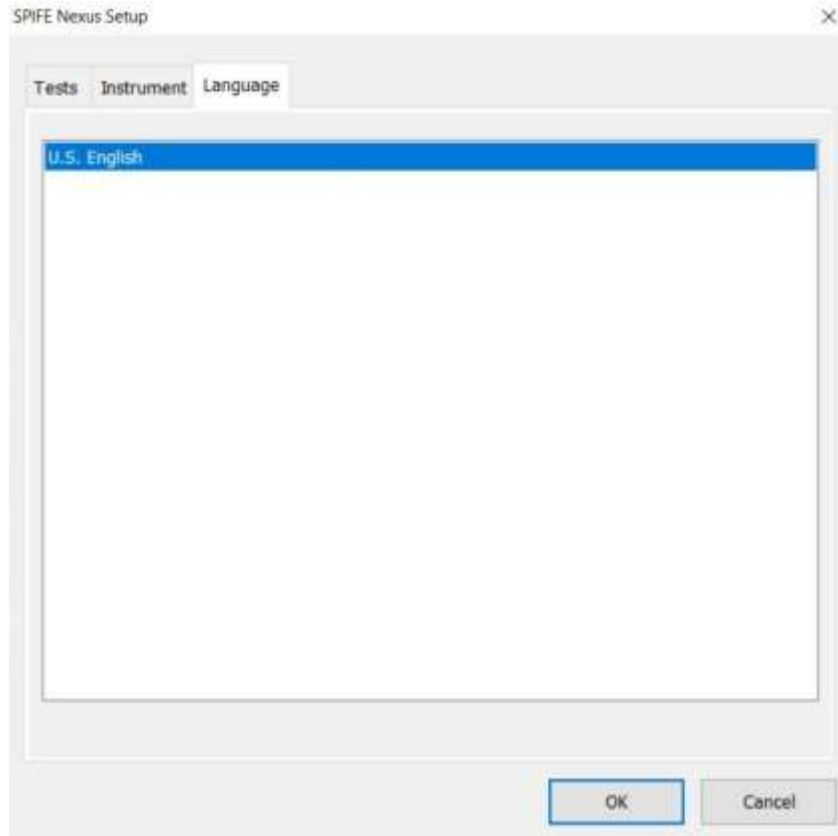


Figure 6-13 Language

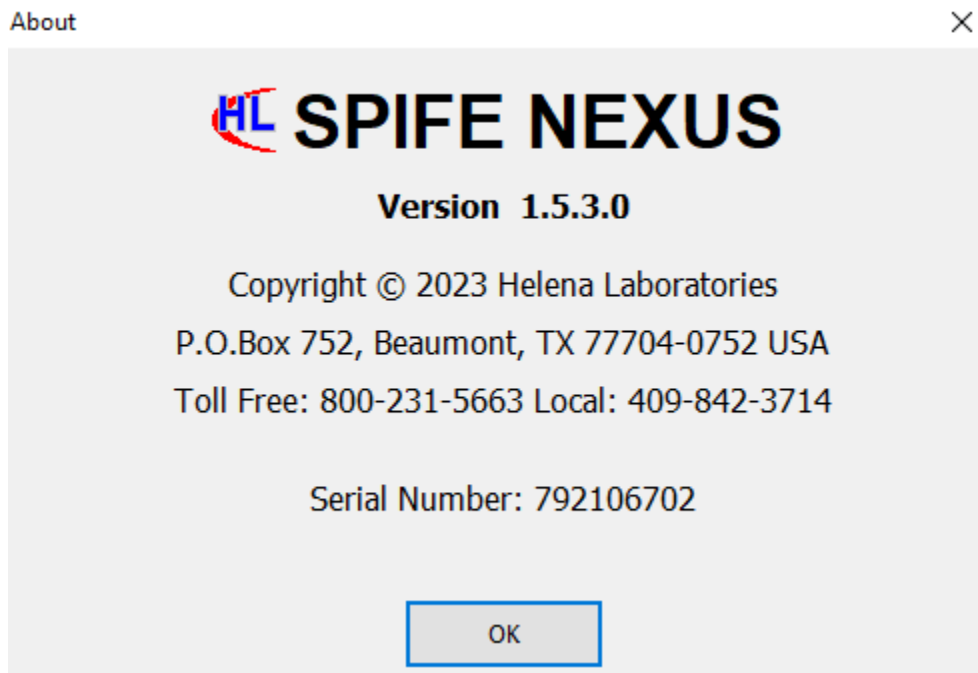


Figure 6-14 About

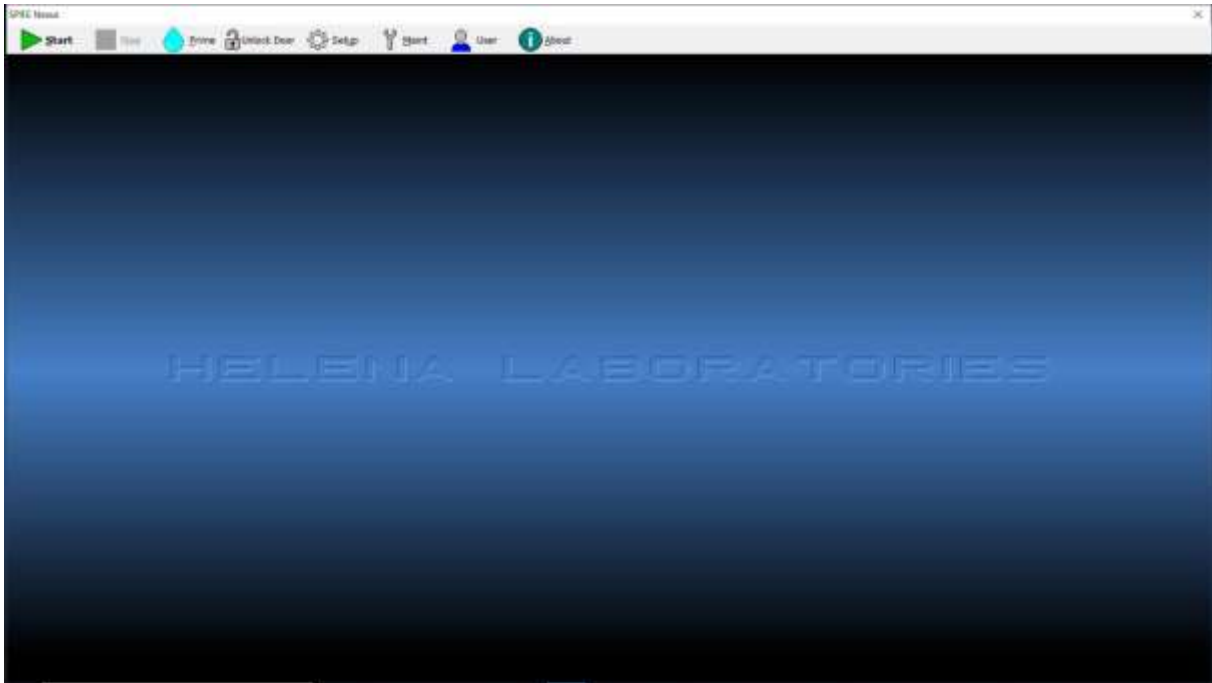


Figure 6-15 Main Menu with Users Icon

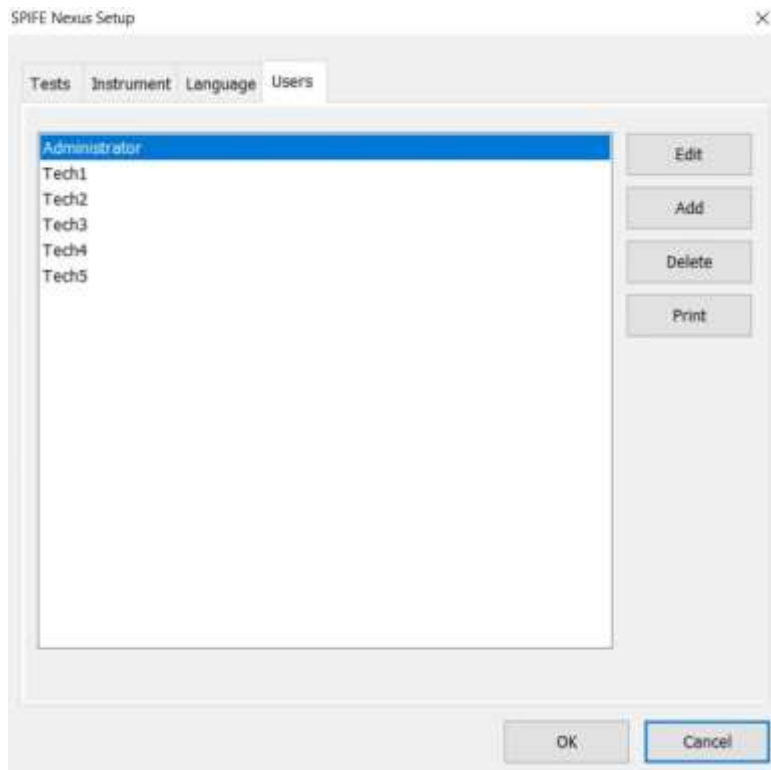


Figure 6-16 Users

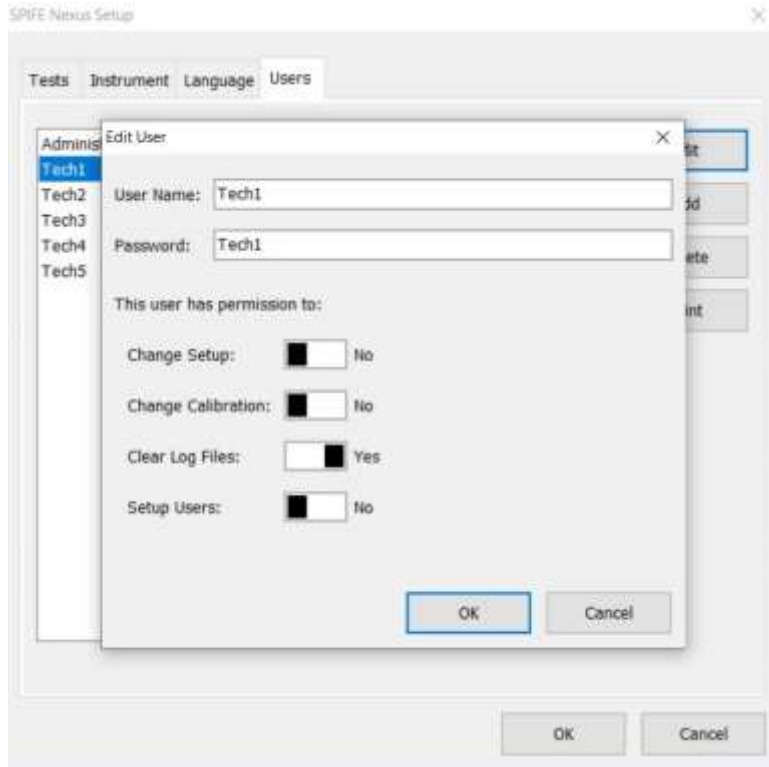


Figure 6-17 Edit Users

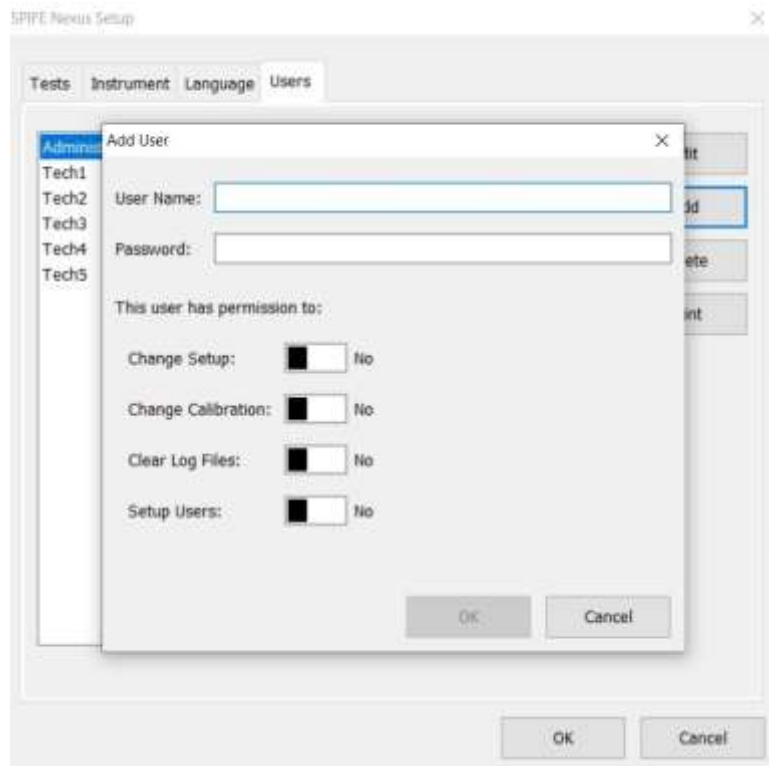


Figure 6-18 Add Users

## Section 7 - Operating Instructions

**CAUTION: Do not attempt to operate this instrument until after reading the Operator’s Manual. This includes Section 4, which incorporates safe biohazard practices.**

If the system has not been set up, go through Section 6 before proceeding. Proceeding without completing test and instrument setup may result in difficulty in completing the instructions contained in this section. This section is a broad overview of the components used in a typical test. For test-specific setup instructions, consult the package insert for that assay type.

When the power is off, a safety interlock feature locks the main instrument door. To access the inside of the instrument, it must be turned on first.

### 7.1. Power On, Initialization, and Power Off

To power on the instrument, first switch on the main power on the left hand side of the instrument. Once the large silver button on the front of the instrument begins to glow red, press it to turn on the instrument. The Microsoft® Windows® program will open and displays the SPIFE Nexus icon on the desktop.

Double click the SPIFE Nexus icon and the QuickScan Touch *plus* Sign In window will appear.

If no username and password has been created, call Helena Laboratories for instructions on logging in.

Once the software has initialized and the user has logged in, a prompt will be displayed stating, “*Priming is recommended at the beginning of each day as well as after refilling DI Water or Saline. Would you like to Prime?*” with Yes and No buttons. If this prompt appears, and the Main Menu (Figure 7-1) is visible at the top of the screen, the system is operating correctly. If an error message appears, or the instrument does not perform as described in this Operator’s Manual, refer to the message, and perform the actions required in the message. For further assistance, or if the error recurs, record the message and call Helena Laboratories (Table 10-2-Troubleshooting).

If the instrument will not be in use for an extended period of time (one or more shifts), the computer should be turned off. Exit the SPIFE Nexus software by clicking the X in the upper right hand corner. Once the SPIFE Nexus software is closed, power off the computer by selecting the Windows icon in the bottom left hand corner, then selecting the Power icon, then the Shut down icon. If the instrument is in continuous use, instrument should be shut down using this process at least once per day.

The SPIFE Nexus software has a timer feature. After one hour and forty-five minutes of software inactivity, a small timer will appear with an Abort Shutdown button. Clicking the Abort Shutdown button will prevent the software from being closed out.

**Note:** Do not power off the instrument using the side switch on the left hand side. This is for emergency shut off only. For standard shutdown, use the Windows Menu.

## 7.2. General Component Setup

This section is a broad overview for general preparation of the instrument components. For test-specific setup instructions, consult the package insert for that assay type.

Operators must follow all instructions within the Operator's Manual regarding priming the instrument, monitoring fluid levels, and cleaning. Failure to perform these maintenance procedures and monitor fluid levels could result in possible carryover by contamination from one sample to another or compromised results.

### 7.2.1. Fluid Bottles

Ensure there is sufficient fluid in the bottles below the instrument to complete the chosen test type. If the Wash, or Destain bottles do not contain enough fluid to fill the Wash/Destain Vat, an error message will occur during the run to prompt the user to refill the bottles (See section 7.4.1).

### 7.2.2. Liquid Waste

Fluid Ports 5 and 6 should be connected to the waste vat or to a drain. Check that the waste tubing is unrestricted. If using a waste vat, check that the waste level and empty if necessary before beginning a run. The waste vat includes an overflow sensor, and a message will appear when the waste vat needs emptying during operation (see section 7.4.1).

### 7.2.3. Reagents and Diluents

Uncap reagents and diluents for the chosen test type and insert into the designated wells of the Reagent Chiller. Ensure that the correct Reagent Chiller Applique for the chosen test type has been applied to the Reagent Chiller.

### 7.2.4. Platen Cover and Electrode Insert

Ensure that the Platen Cover with the correct Electrode Insert for the chosen test

type is located in the storage position on the instrument. Refer to Section 10 of the Operator's Manual for instructions on cleaning, changing, and replacing the Platen Cover and Electrode Insert.

### 7.2.5. Consumables Tray

Slide the Consumables Tray forward, and prepare with Applicator Template, clean Applicator Blades, and install a SPIFE Nexus Blotter D onto the Blotter Holder if necessary for the chosen test type. Remove any unnecessary objects from the Consumables Tray before sliding it into the home position—pushing until it snaps into place.

### 7.2.6. Stain/Reagent Dispenser

Place Stain Cups with liquid stain or reagent into the holes of the Stain/Reagent Dispenser according to the chosen test type. Place the Reagent Roller bar for the chosen test type between the hooks at the bottom of the Stain/Reagent Dispenser.

### 7.2.7. Dryer Cover

Ensure that the Dryer Cover is stored to the right of the dryer with the red sticker toward the back of the instrument

### 7.2.8. Sample Cup Tray

Slide the correct Disposable Sample Cups into the appropriate Sample Cup Tray for the chosen test type, ensuring that the sample cups are inserted completely. Seat the Sample Tray snugly over the pegs in the Sample Tray station. If the patient samples are loaded into the tray by hand before the run, the Sample Load process should be toggled to "No" in the SPIFE Nexus Run menu (see section 7.3.1.4).

### 7.2.9. Test Tube Racks

If the patient samples are to be loaded into the Sample Cup Tray by the instrument, remove any previous test tube racks before

loading the tube racks into the tube transport area.

Each tube rack holds ten tubes and the SPIFE Nexus can hold up to 10 racks at a time for a maximum load of 100 samples. Position 1 is the back left corner. The instrument starts at the first position of the left most test tube rack. It then samples the entire rack and moves to the first position of the second rack.

Load the samples in the test tube rack in the same order as is desired on the corresponding QuickScan Touch *plus* worklist, beginning at position 1. It is best to load consecutively without skipping positions. If a position is skipped in the test tube rack, the corresponding position on the worklist will be skipped.

When using bar coded sample tubes, position the tubes in the tube rack so that the bar code label is positioned facing out of the vertical slot of the test tube rack (Figure 7-18). Ensure that the entire bar code label is visible in the vertical slot and the tube is straight up and down.

When inserting tube racks into the tube transport area, ensure the racks are inserted so that the recessed notch on the tube rack fits around the rail at the back of the tube transport area. This will prevent the racks from falling over or jamming the instrument (see Figure 7-16)

**Low Sample Volume:** If there is insufficient sample volume (less than 500 µl) for a urine Immunofixation test, 20 µl of sample may be pipetted by hand into the sample cups. The prepared sample tray would then be placed into the instrument, and the test programmed as usual with the exception of toggling the Sample Load process to “No” in the SPIFE Nexus Run menu (see section 7.3.1.4.

**7.2.10. Gel and Gel Cassette**

Place the bottom half of the Gel Cassette on the electrophoresis platen with the two pins lined up on the left side. Dispense 2 mL of REP Prep on the platen.

Remove the gel from the protective packaging and discard the overlay. Gently blot the gel per the directions in the package insert for the assay. Dispose of the blotter afterwards.

Place the left edge of the gel into the bottom of the cassette fitting the round hole over the upper pin and the obround hole over the lower pin. Gently lay the gel down over the REP Prep making sure no bubbles remain.

Place a Positive ID barcode label (Cat. No. 1696) on the upper right hand side of the gel backing (Figure 7-14). Select the barcode that starts with the letter “G”



Place the top half of the Gel Cassette over the gel. Make sure the 2D barcode is located in the upper right corner of the cassette .



### 7.3. Beginning a Test

To start a test, with all components prepared according to assay specifications, close the main door of the instrument and select the START icon on the touch screen. The SPIFE Nexus Run window will appear (Figure 7-2).

#### 7.3.1. SPIFE Nexus Run Menu

*Test* - Using the dropdown menu, select the preprogrammed test to be run. The default Run Processes associated with the selected test will be displayed .

*Tray* - The tray associated with the selected test will be displayed.

*Dilutions* – If the chosen test type uses a Sample Tray with dilution options, dilutions may be individually set for each lane of each sample. The dilution can be changed by selecting the individual box, the sample number, or the lane type, then selecting from the available list of dilutions (Figure 7-4). Dilutions changed in the Run Menu will only be changed for the current run. To make a permanent change to the dilution scheme for the chosen test type, make the

change in the Setup Menu (see section 6.1.2).

*Run Processes* – Run Processes can be enabled or disabled before running by toggling to Yes or No, thus altering the test for the current run .

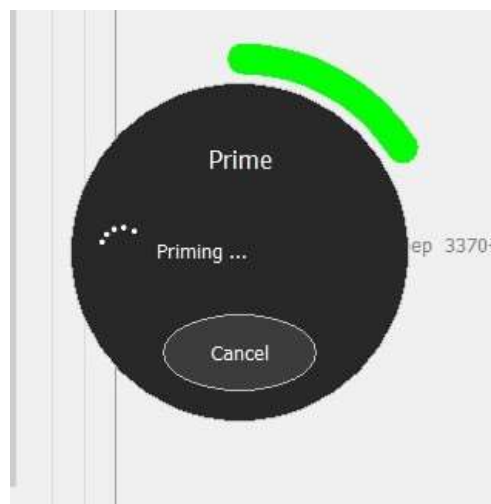
*Unlock Door* – select to unlock the main door.

*Prime* – Select to prime the sample and reagent handling system. This should be done on a daily basis.

A prompt alerts the user “Prime, moving to wash.....”. A *Cancel* button is also displayed which will immediately stop the operation.



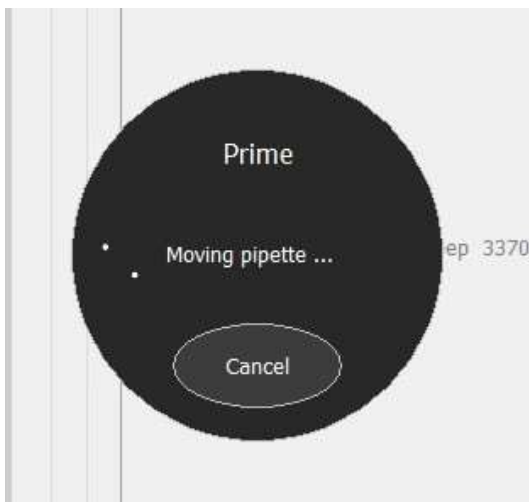
Next it will alert the user, “Priming...”.



Next it will alert the user, “Priming completed...”.



Next it will alert the user, “Moving pipette...”.



Once complete, the window will close and return to the *SPIFE Nexus Run* window.

*Start Run* – select to start the run.

*Rescan* – select to rescan the plate.

*Cancel* – select to cancel the run and return to the Main Menu.

### 7.3.2. Pre-Start Checks

When the operator presses Start Run on the Start Menu, the instrument immediately goes through a system of checks to ensure onboard components are of the correct

type and in the correct location for the chosen test type. Checks include a user-programmed checklist, sensor checks for the presence of necessary accessories, and 2D barcode scanning of assay-specific components.

#### 7.3.2.1. Pre-Start Checklist

If a Pre-Start Checklist has been configured for the selected test type, it will appear on screen immediately after pressing the Start Run button. Each item on the list must be checked before the Continue button becomes available.



For information on setting up and editing the Pre-Start Checklist, see Section 6.1.5.

#### 7.3.2.2. Sensor Checks

After the Pre-Start Checklist, then the instrument checks for the presence and location of components, which will be used in the selected test. The checked components include:

- Gel Cassette
- Platen Cover
- Consumables Tray
- Spreader Tip
- Dryer Cover

If a warning appears for any of these items, check for the presence and correct placement of these items before proceeding with the run. Incorrect placement of these items

can cause damage to the instrument. If correct placement of these items has been confirmed but warnings persist, contact Helena Laboratories.

Additional warnings are given if:

- The waste vat is full
- The tube rack removal area is full
- The door is open

### 7.3.2.3. Barcode Checks

After checking for the correct placement of components, the instrument will check for:

- Gel Cassette
- Sample Tray
- Reagent Chiller Applique
- Electrode Insert
- Applicator Template
- Blotter Holder

If a warning appears for any of these items, check for the presence and correct placement of these items before proceeding with the run. Incorrect placement of these items can cause damage to the instrument. If correct placement of these items has been confirmed but warnings persist, contact Helena Laboratories.

9. When this check has been completed, the run will begin.

### 7.3.3. Progress Indicators

When a Run is in progress, a black circle will be displayed in the middle of the screen with the name of the test being executed as well as the estimated time remain.



A green circle will track clockwise around the outer edge of the black circle in relation with the Estimated Time Remaining.

Displayed below the Estimated Time Remaining is the Current Process. This displays the process that is actively occurring. A blue circle will track clockwise in relation with the progress of the current process. Below it, the Time Remaining for it is displayed as well as the current action of the instrument and/or temperature.

A Stop button is at the bottom of the black circle. If Stop is selected, the instrument will prompt the user with, “All processing for gel [ID#] will be stopped. Are you sure you want to stop gel [ID#]?” as well as Yes and No buttons. Selecting No will cancel the Stop request, and the instrument will continue to process the gel. Selecting Yes will stop the current process, and all components will be moved to their storage locations before the main door unlocks.

### 7.4. Errors

During a Run, errors of two types may occur. Recoverable errors are caused by depleted fluids/reagents or by accumulated waste. Non Recoverable critical errors occur when a movement, temperature, communication, or electrical.

### 7.4.1. Recoverable Errors

If an error for any of these conditions is given, the instrument will pause all operations until the operator presses the OK button to continue, or until 5 minutes has elapsed. After 5 minutes, the error becomes Non Recoverable. Be sure to correct the condition before responding to the error message. When the OK button is pressed, the instrument will re-attempt the failed operation. If the Cancel button is pressed, the run will end.

Conditions which give Recoverable errors include:

- No Saline Detected
- No DI water detected
- No Reagent detected
- Wash Station overflow
- The Wash/Destain vat failed to fill
- Waste vat is full
- Lower door is open

### 7.4.2. Non Recoverable Critical Errors

If an error for any of these conditions is given, the run must be terminated to prevent damage to the instrument. Take note of the error dialogue and click the Stop button to end the test. If prompted, use the Safe Start menu to guide components to a safe location to end the test (Section 10.10.15):

Conditions which give Non Recoverable errors include:

- Fluid Detect Read Failure
- Gel is not in the correct location
- No sample racks or tubes detected
- Electrophoresis parameters exceeded limits
- Temperatures exceed limits
- Unable to reach target position
- Pump failure
- Communication failure

### 7.5. Results

Once the gel has been completely processed by the instrument, the Gel Cassette containing the finished gel will be located in the scanner port of the front side of the instrument, where it can be removed by the user.

The worklist will automatically be displayed on the screen in the QuickScan Touch *plus* software for review and editing.

For more information on its entirety of available features, consult the QuickScan Touch *plus* Operator's Manual.

Dispose of any consumables such as Sample Cups, Applicator Blades, Stain Cups, and blotters as biohazardous waste. Refer to Section 10 for the maintenance required after every test.

### 7.6. Rescan

**Note:** Any open worklists must be closed before a rescan can occur.

**Note:** Rescans may only be performed on gels that have a Positive ID Barcode Label affixed to the gel.

Place the cassette containing the gel onto the electrophoresis platen.

Click the Start icon.

Select Rescan.

The SPIFE Nexus claw will pick up the cassette and place it into the scanning slot.

If a Positive ID Barcode Label has been detected, once the instrument has placed the gel in the slot the QuickScan Touch *plus* software will prompt the user and ask if this is a rescan. Select Yes if the gel needs to be rescanned. The QuickScan Touch *plus* software opens the original worklist and

rescans the gel into it. Select No if rescanning is not desired.

If a Positive ID Barcode Label cannot be detected, once the instrument has placed the gel in the slot the QuickScan Touch *plus* software will alert the user that the gel barcode scan failed and will display a text box allowing the user to enter the information. Enter the Positive ID Barcode Label number and click Yes. The QuickScan Touch *plus* software opens the original worklist and rescans the gel into it. Select No if no Positive ID Barcode Label number is available. QuickScan Touch *plus* cannot rescan the gel without an ID Barcode number as a reference to find the original worklist

### **7.7. About**

Select the *About* and a window will display containing the current software version and system serial number, as well as the software version numbers of the software for each of the instrument components.

The system serial number should be the same as the handwritten serial number on the Helena labels located on the computer, scanner, and transparency lid.

*OK* - select to exit the window.

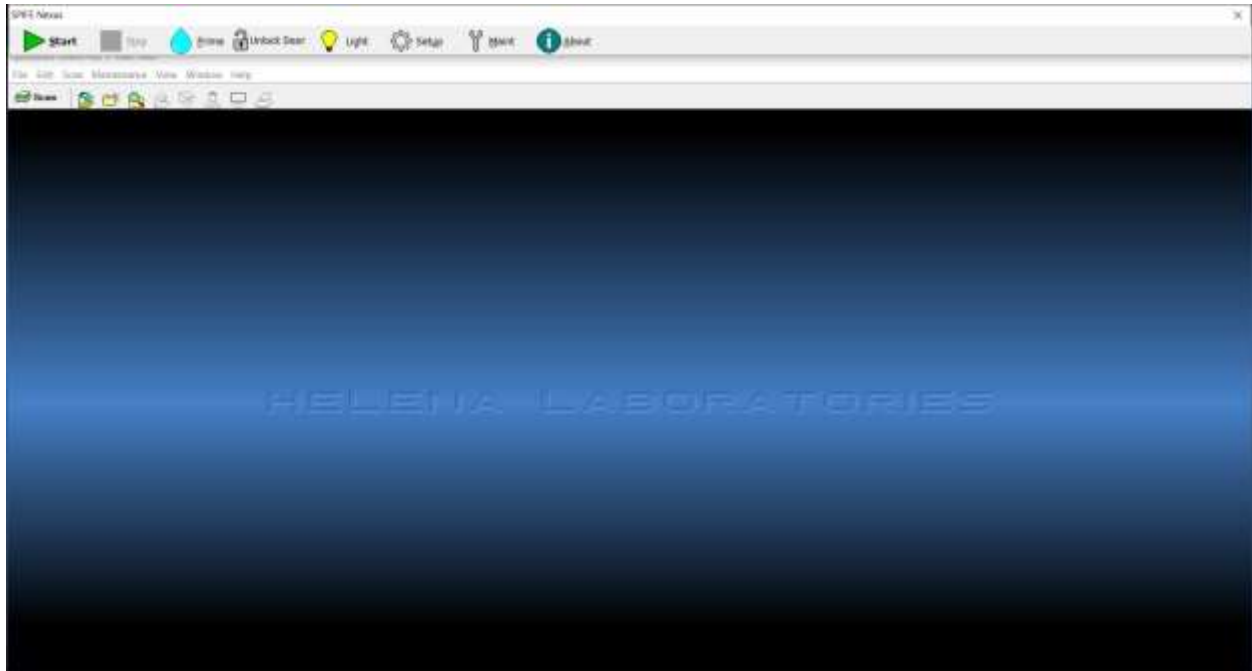


Figure 7-1 Main Menu

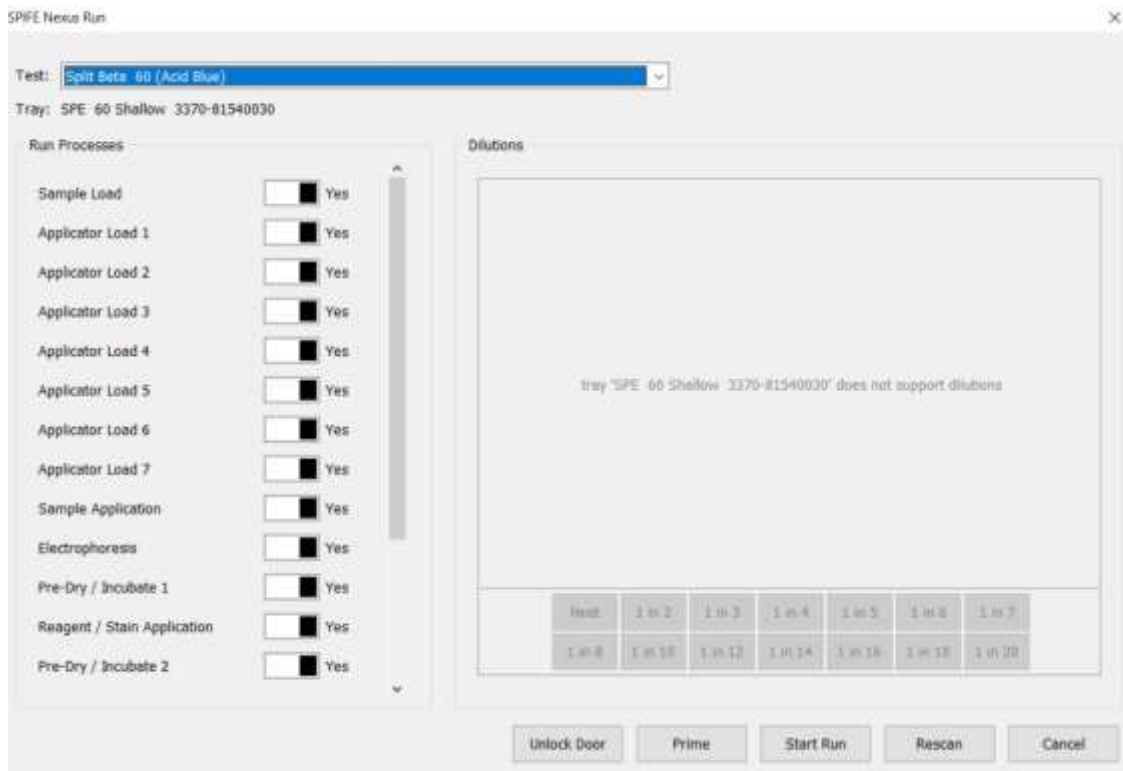


Figure 7-2 Run Screen, Split Beta

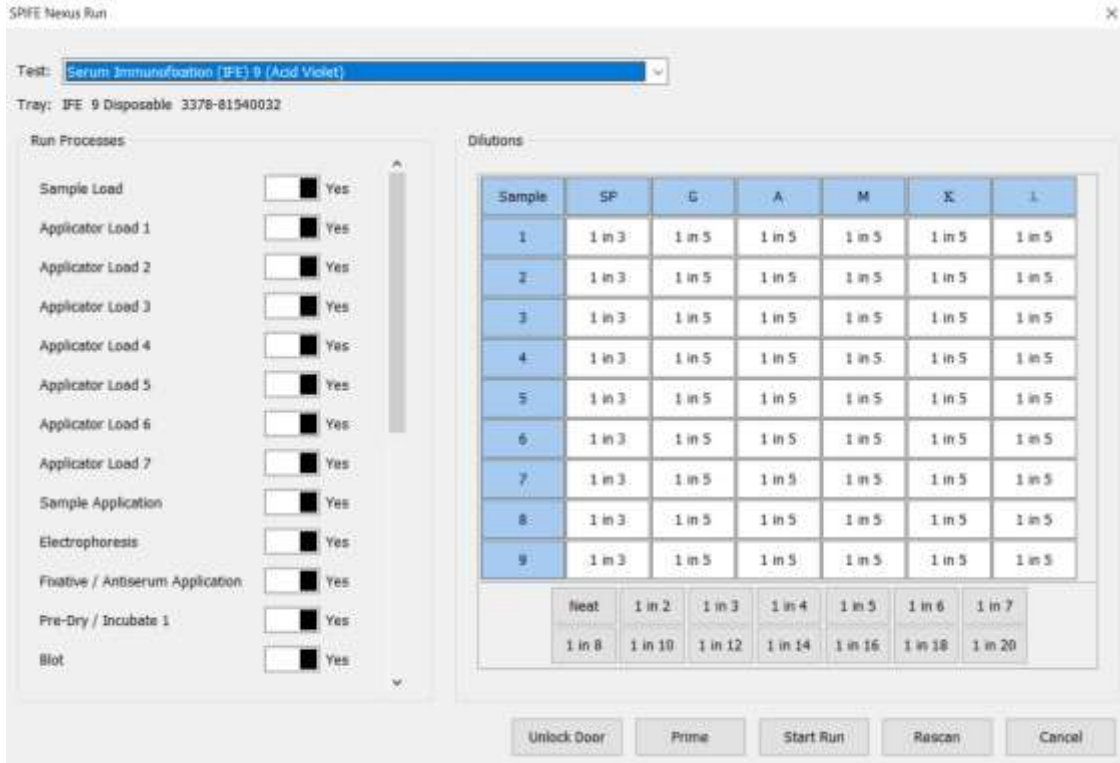


Figure 7-3 Run Screen, IFE

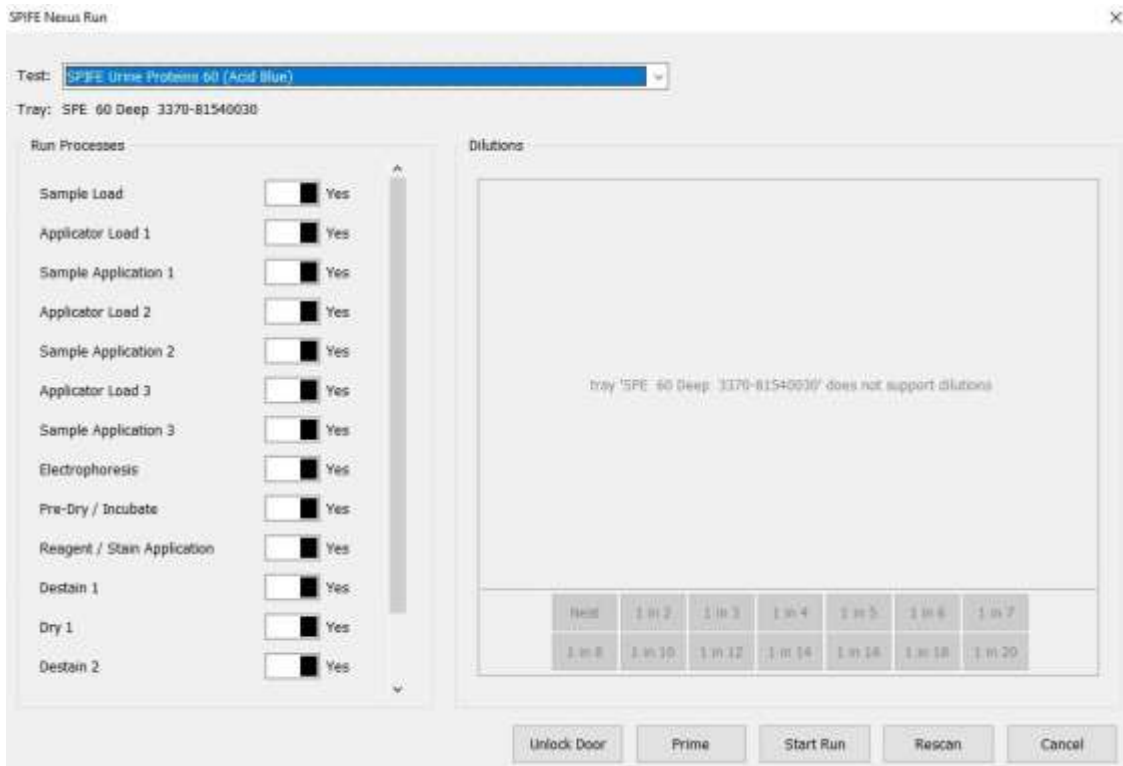


Figure 7-4 Run Screen, Urine Proteins

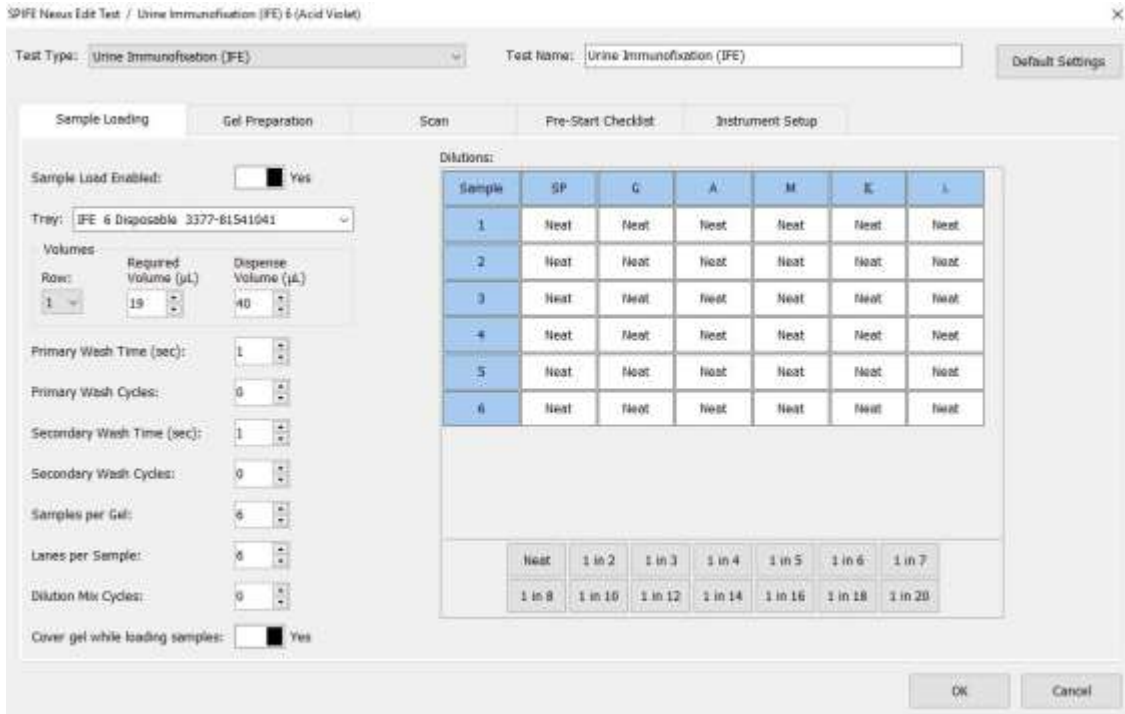


Figure 7-5 Run Screen, Urine IFE

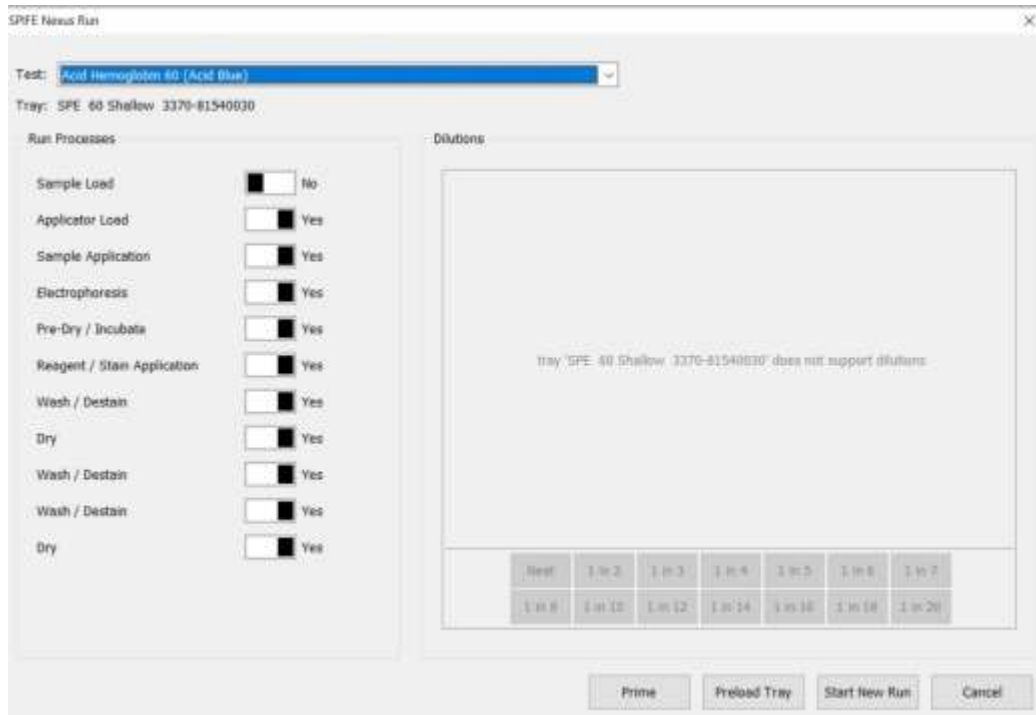


Figure 7-6 Run Screen, Acid Hemoglobin

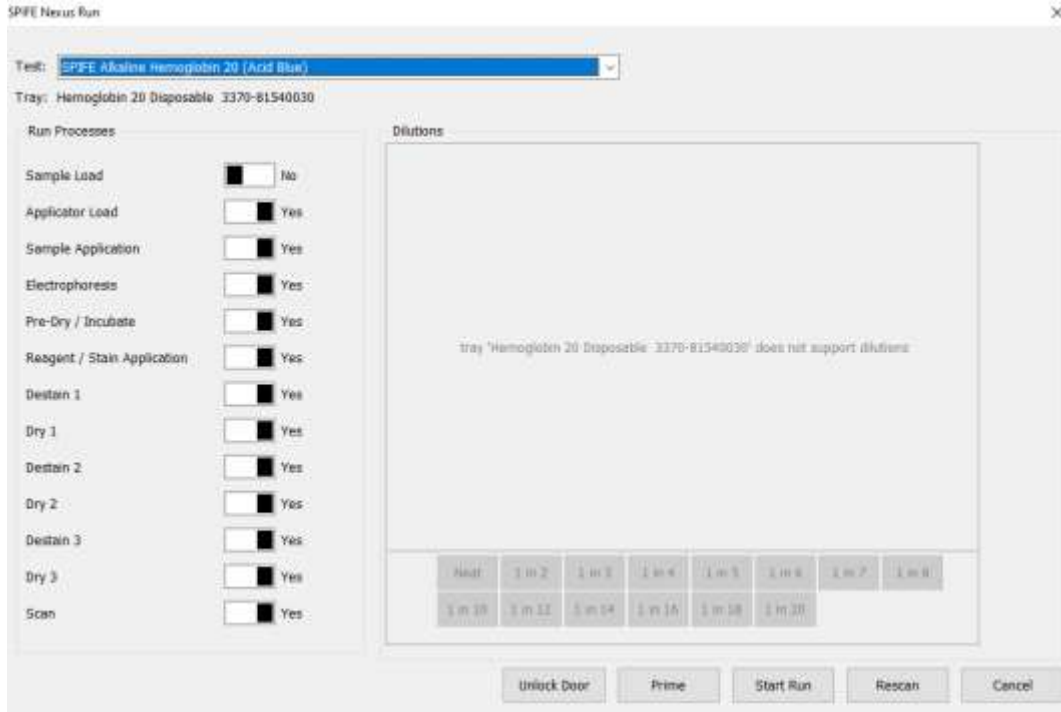


Figure 7-7 Run Screen, Alkaline Hemoglobin

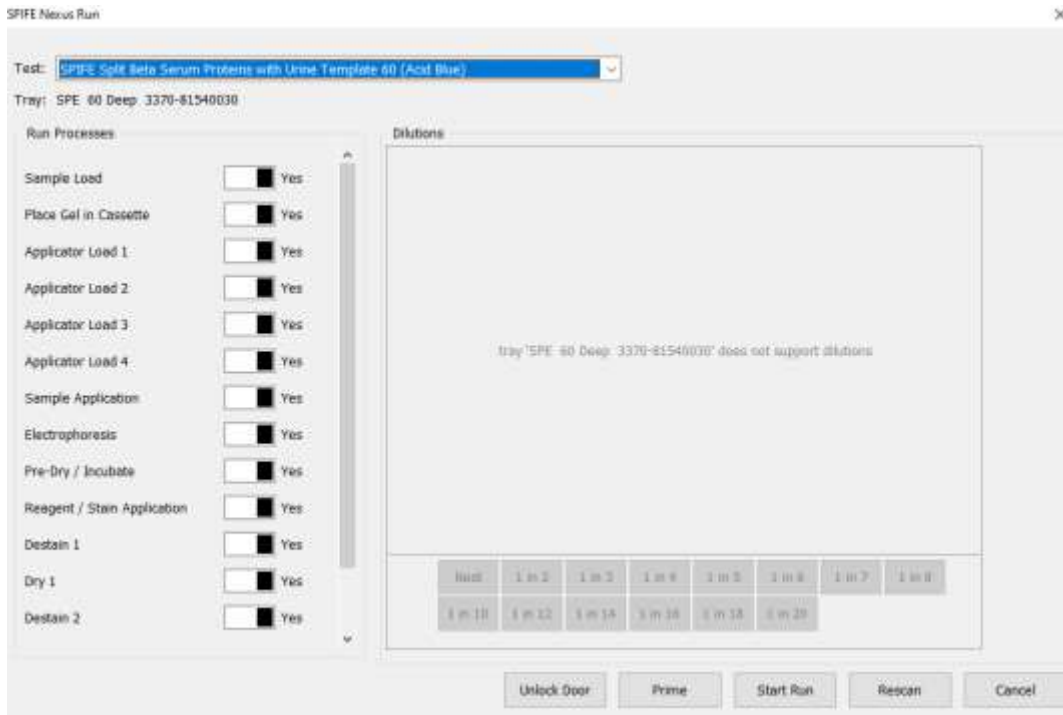


Figure 7-8 Run Screen, Split Beta Serum Proteins with Urine Application 60

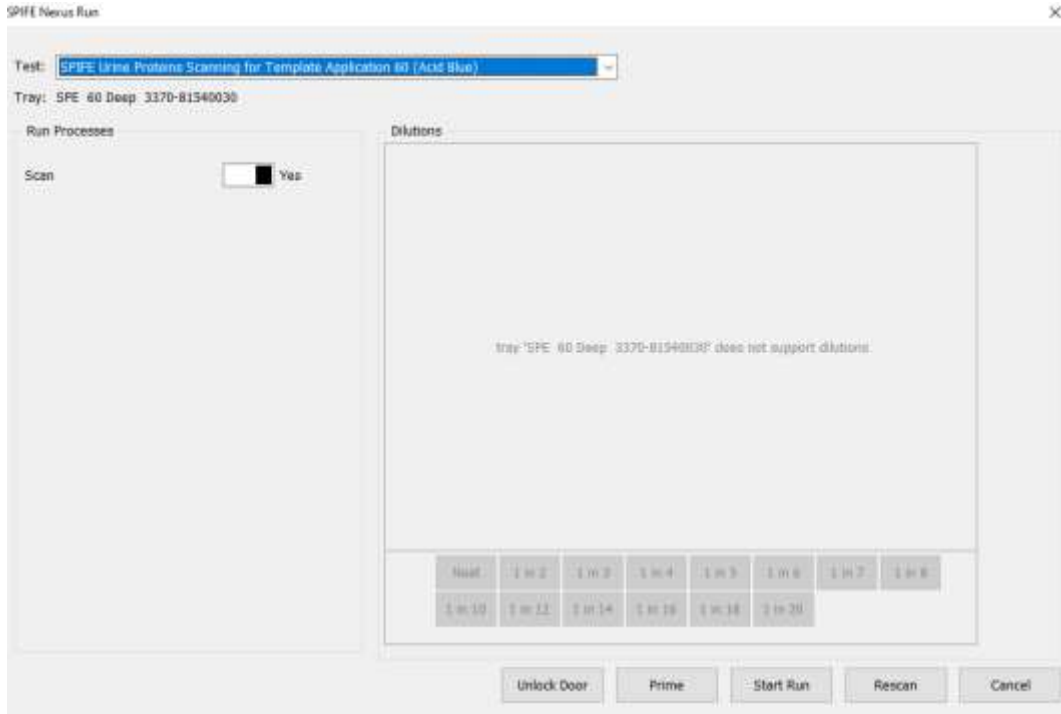


Figure 7-9 Run Screen, Urine Proteins for Template Application 60

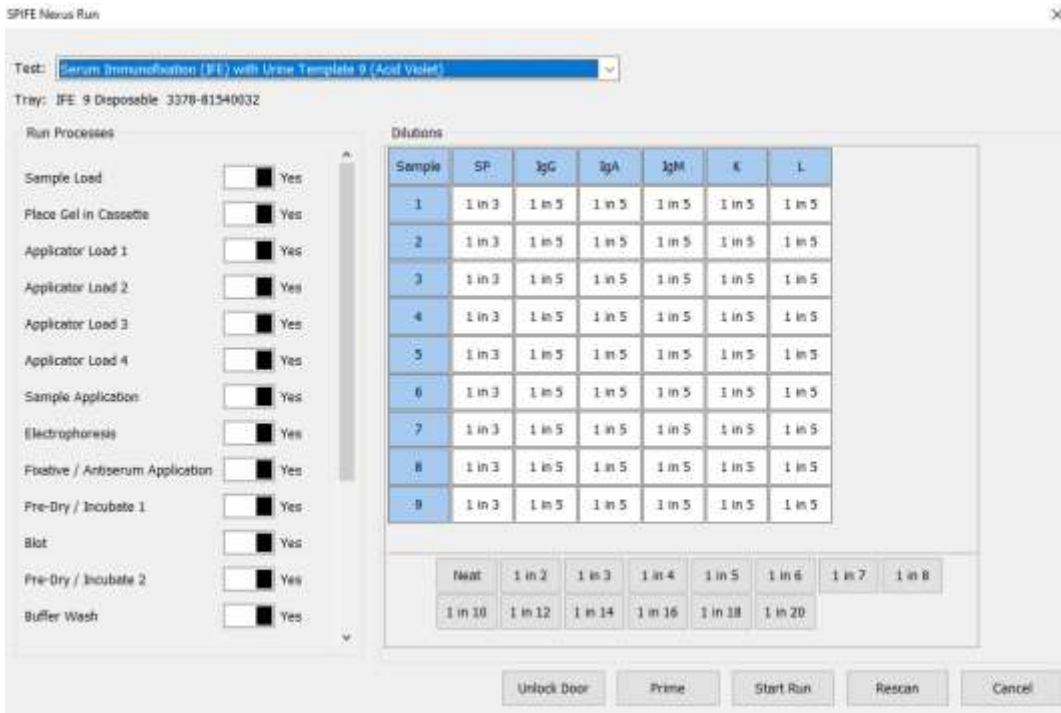


Figure 7-10 Run Screen, Serum IFE with Urine Template 9

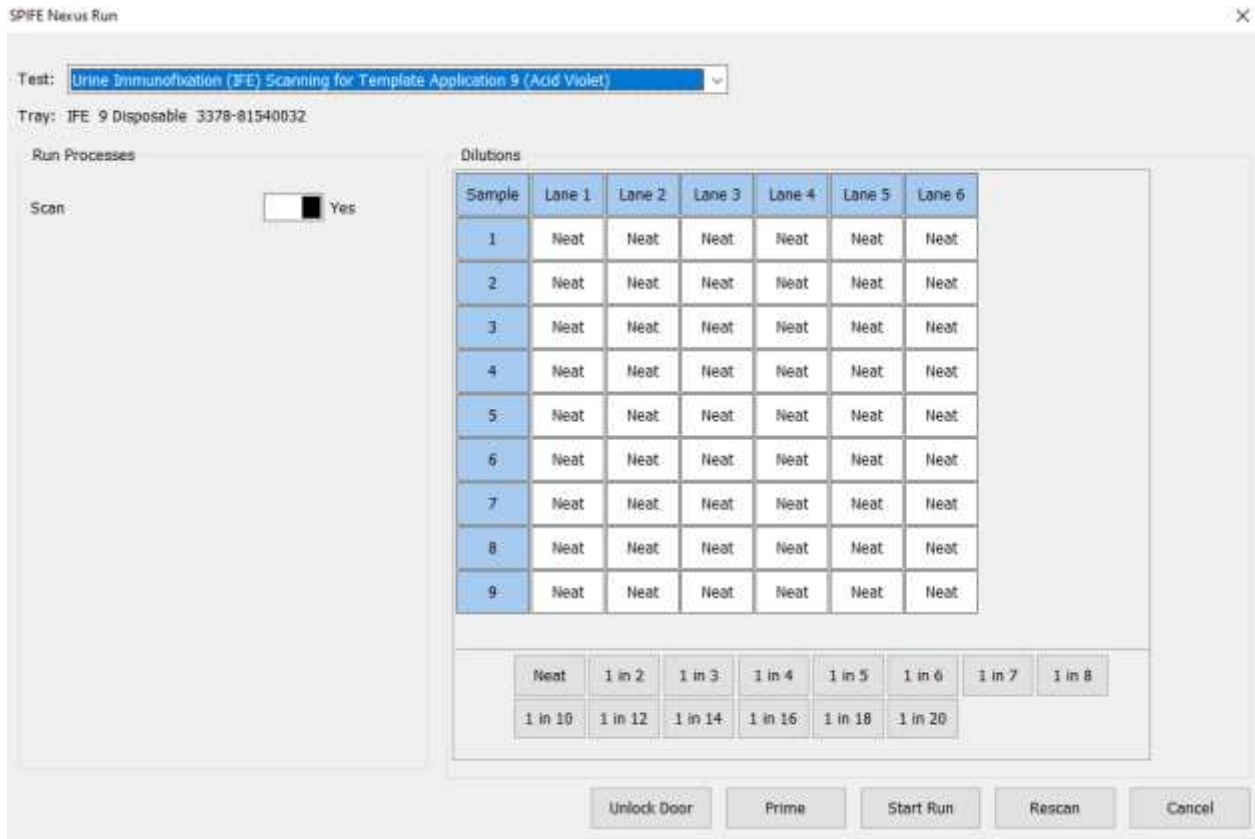


Figure 7-11 Run Screen, Urine IFE for Template Application 9



Figure 7-12 Instrument, Front View



Figure 7-13 Reagent Chiller

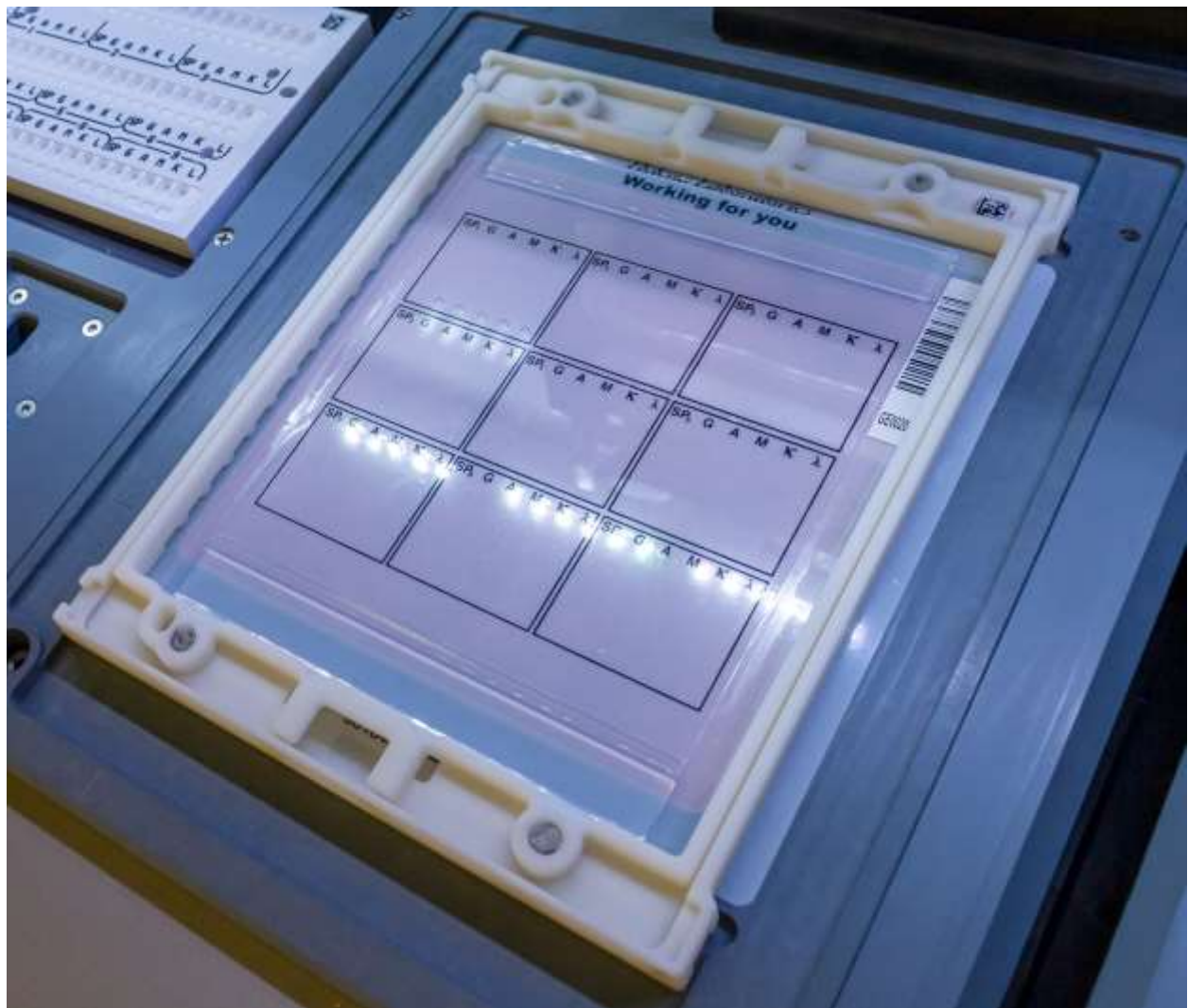
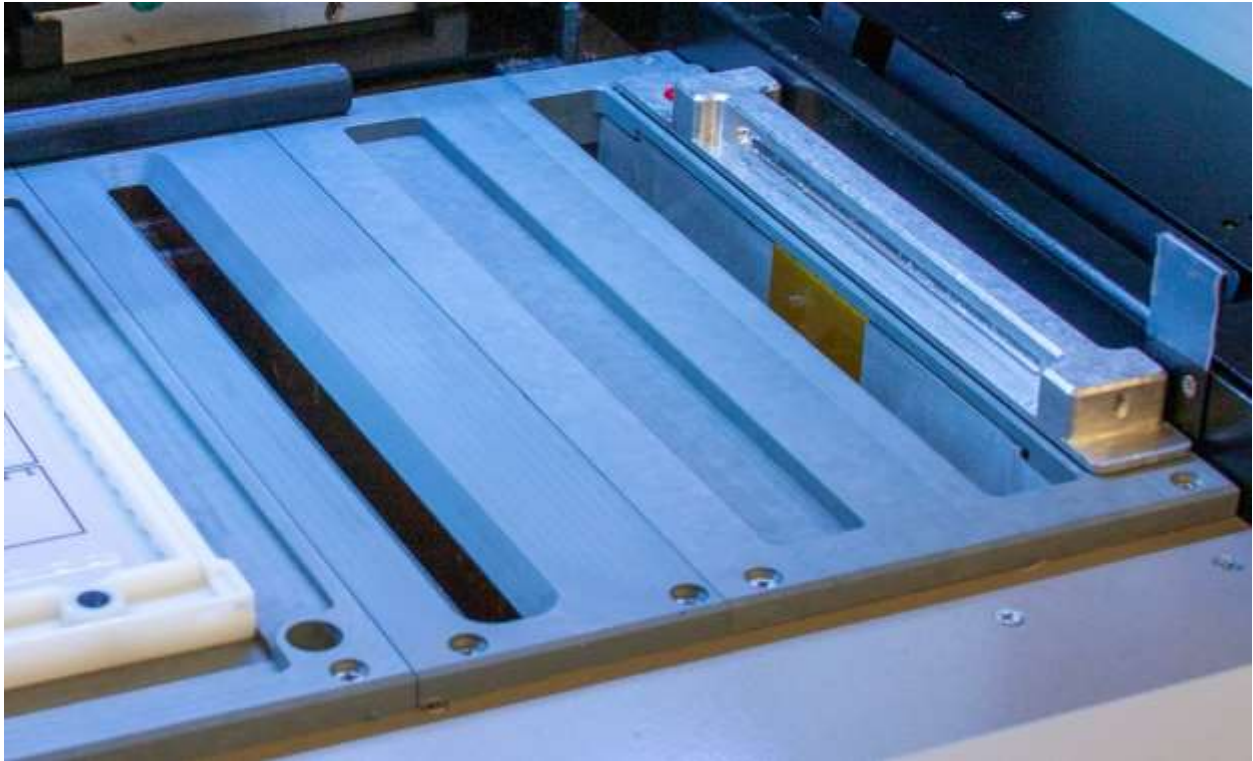


Figure 7-14 Electrophoresis Platen



**Figure 7-15 Wash Vat and Dryer Chamber**



**Figure 7-16 Tube Transport**

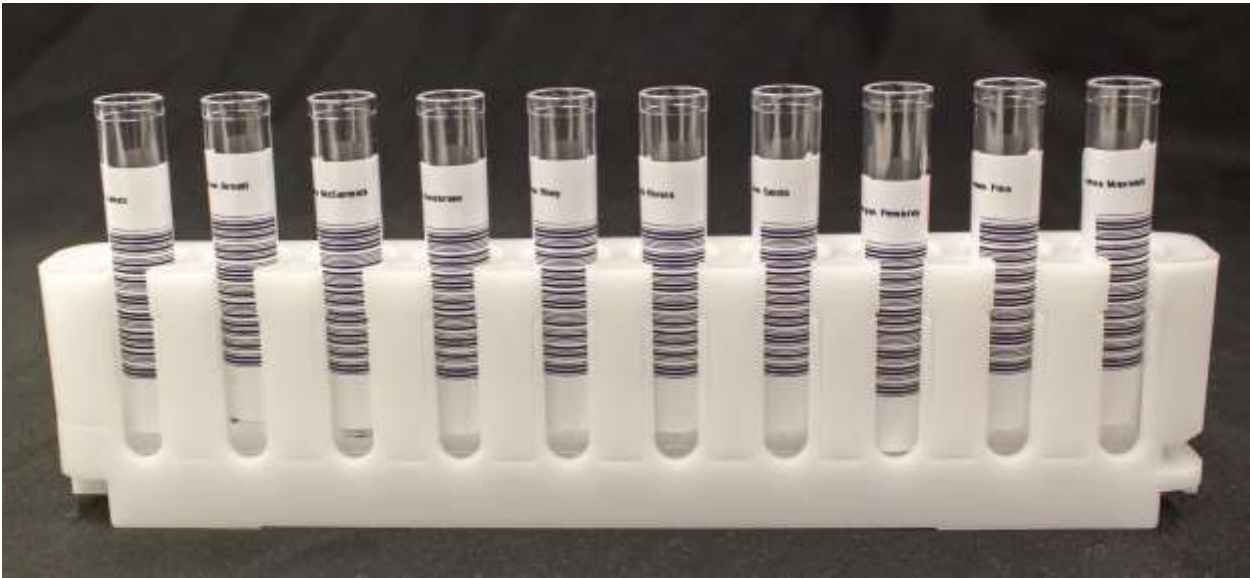
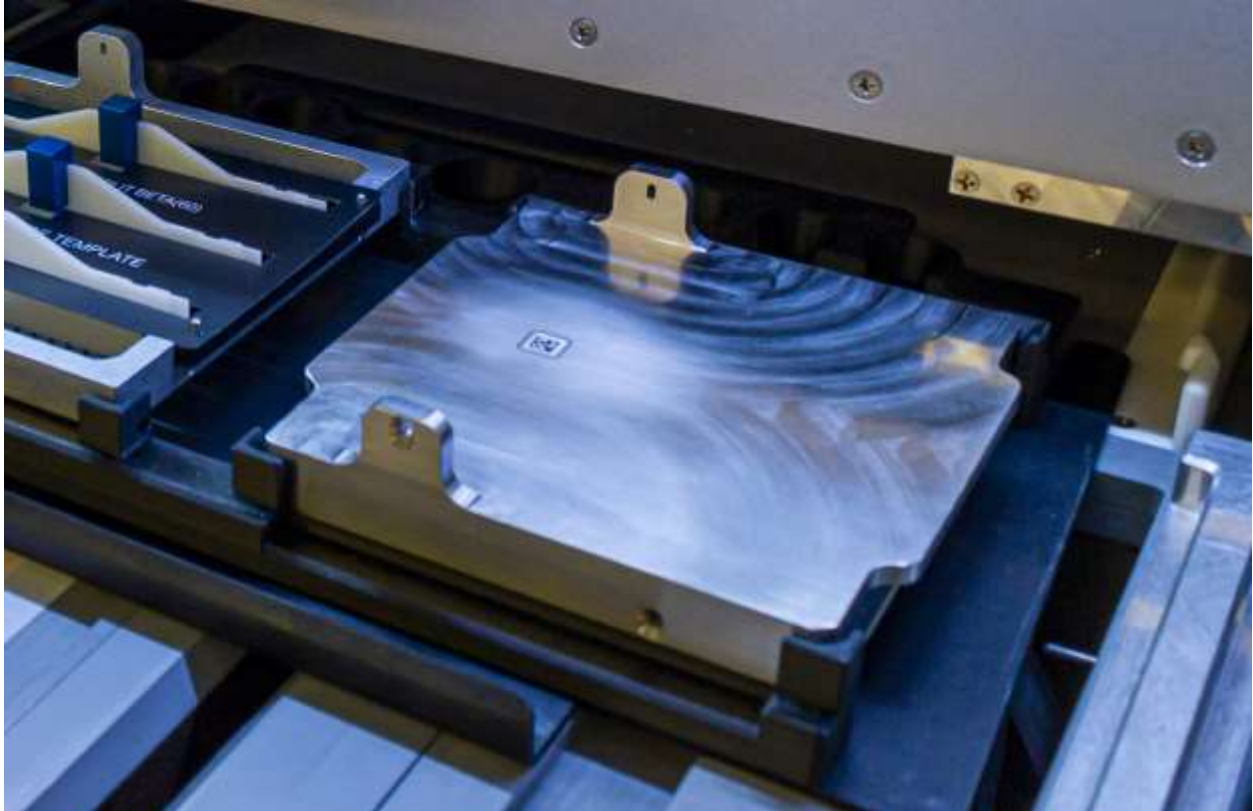


Figure 7-17 Barcode Placement



Figure 7-18 Sample Tray (with Cups)



**Figure 7-19 Placement of Blotter Holder in Consumables Tray**



**Figure 7-20** Applicator Holder with Applicator Blades, Applicator Blade Template, and Blade Weights

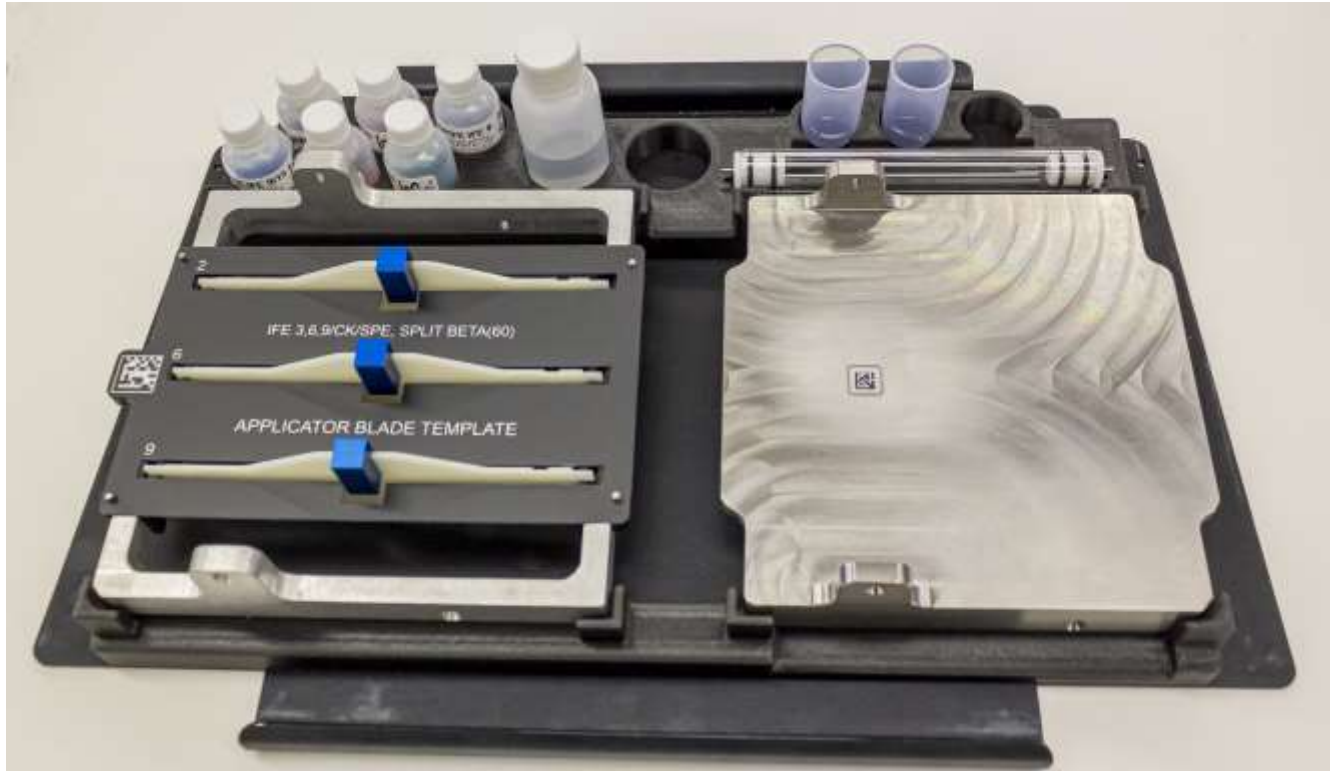


Figure 7-21 Consumables Tray

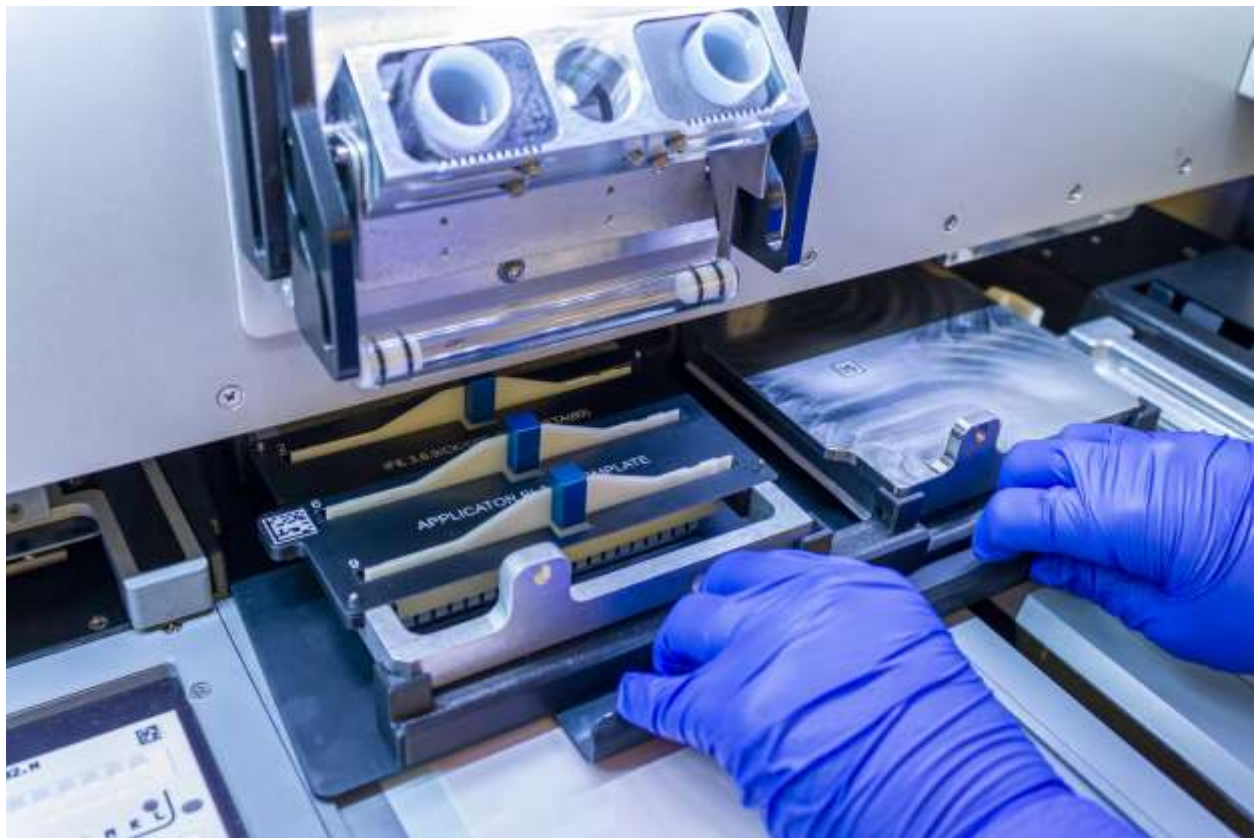
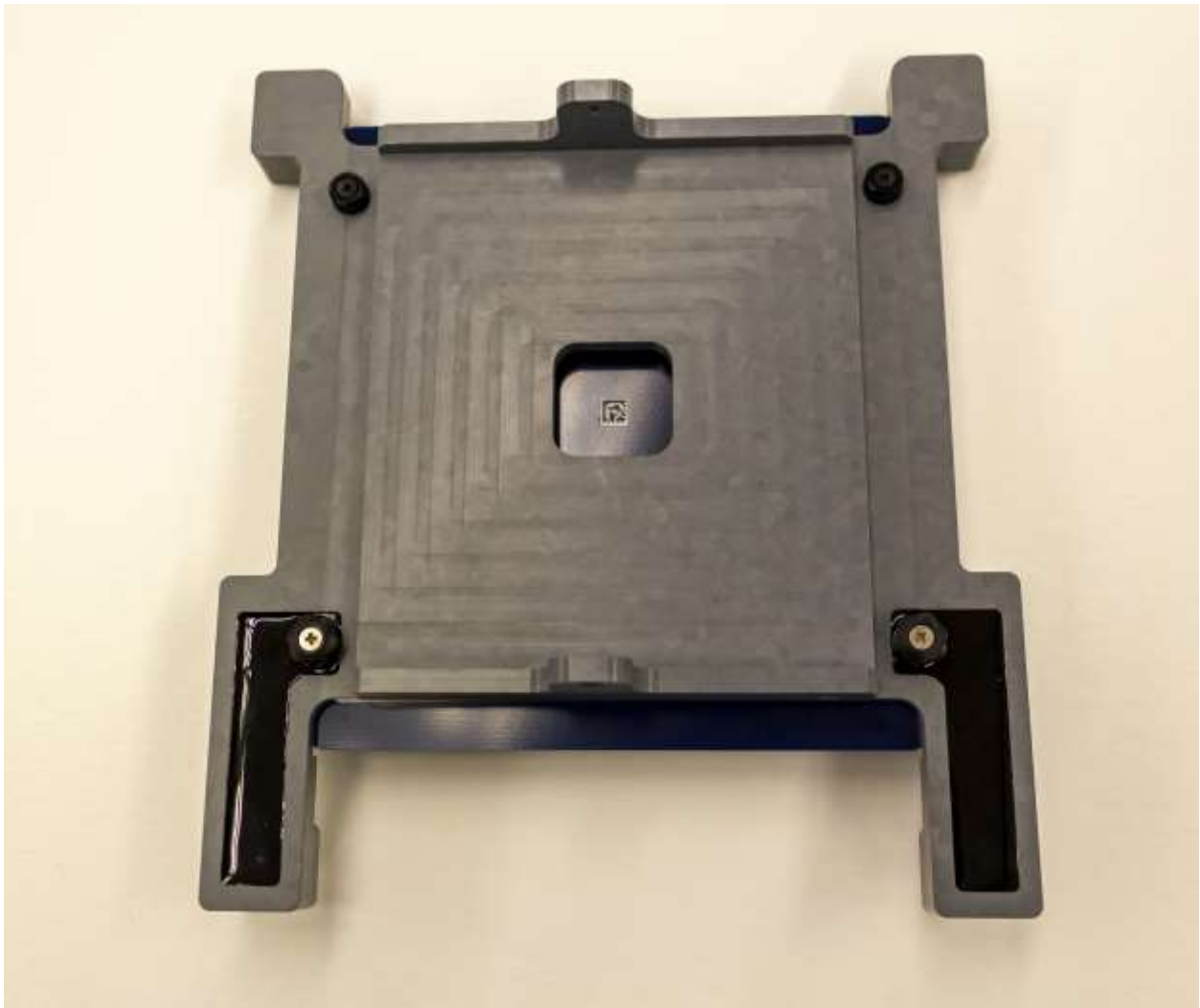


Figure 7-22 Sliding Consumables Tray into Place



**Figure 7-23 Platen Cover with Electrode Insert**

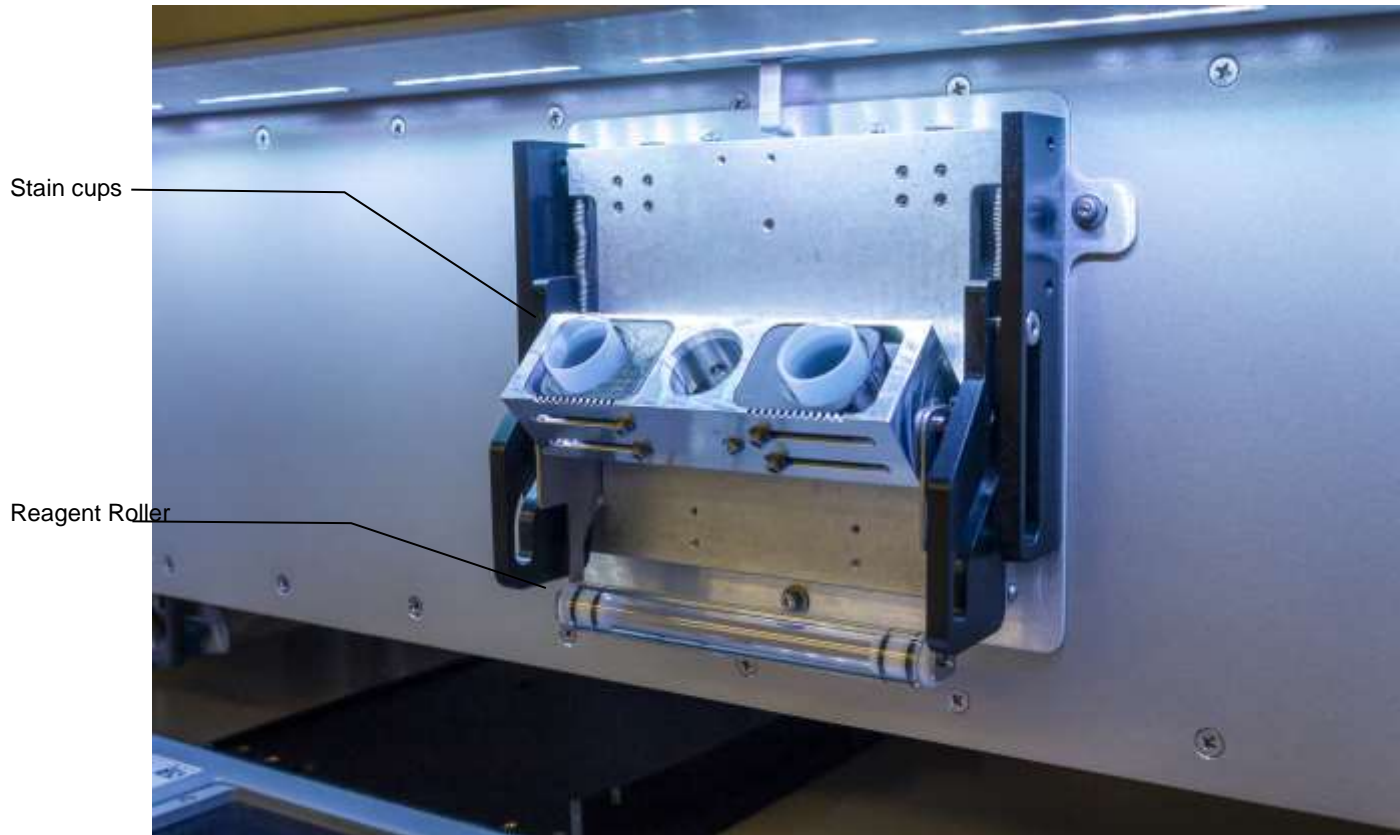


Figure 7-24 Stain / Reagent Dispenser Bar

## Section 8 - Test Functions and Quality Control

### 8.1. Startup

The instrument automatically initializes and performs a self-test any time the power is turned on or a test is aborted. Should an error message appear on the display, see section 10.2, Troubleshooting.

### 8.2. Quality Control

#### 8.2.1. Controls

1. For quantitative gels, a normal control should be run in scan position 1 and/or abnormal control in the last position, with samples in between. The control data should be compared to the ranges printed on the assay sheet provided with the control.

2. Each laboratory should establish its own normal range of expected values for the procedures in use. Refer to the procedure supplied with the reagents for further information.

3. It is recommended that each laboratory set up an effective quality control program based on licensing requirements.

### 8.3. Instrument Performance Check

#### 8.3.1. Neutral Density Densitometer Control (NDDC)

**Note:** In order to run an NDDC check, the SPIFE Nexus must be used in conjunction with the QuickScan Touch plus software system.

1. The QC plate contains a Neutral Density Densitometer Control (NDDC) containing 5 bands of known quantitation, and a 10 Step Optical Density (OD) Step Tablet with an OD Range of .05 to 3.05 in .30 increments. Scan the QC plate at frequent, regular intervals.

#### 8.3.2. 10 Step Optical Density (OD) Step Tablet

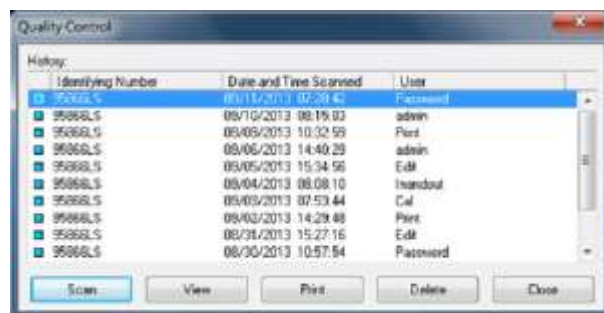
1. The OD Step Tablet checks linearity and analog response of the visible light source and detector.

2. A list of the quantitative ranges for the NDDC bands should have been entered during QC setup.

3. To QC using the NDDC and OD Step Tablet and/or to manage previous QC results, select *Maintenance* and then *Quality Control*. The QC window displays. A list of all saved QC scans is displayed, with the options to View, Print, Scan, Delete, and Cancel.

#### 8.3.3. QC Main Menu

1. The History of all saved QC scans is available from the main QC menu. The availability of previous QC results is dependent upon selections made in setup. The list of previous results includes the NDDC Identifying Number and the date and time the QC was run.



2. Highlight the desired QC and select from the following:

a. *View* - A single scan may be selected from the list for view.

b. *Print* - Select and the *Print QC Results* window displays. As needed, select the appropriate *Printer* and *Number of Copies*. Select *Print* to print the scan. Select *Cancel* to exit without printing. It is recommended that a permanent record of the QC results be kept.

c. *Delete* – Select to delete to selected QC. An *Alert* displays with Yes and No options. Select Yes to exit and delete the selected QC scan, or No to exit without deleting the scan.

d. *Close* – Select to close the *Quality Control* window.

#### 8.3.4. Scan

1. To run a new QC scan using the NDDC/OD Step Tablet, select *Scan*, click on *Maintenance*, then *QC*, then *Scan*. The message “*Place the Neutral Density Density Control in the scanner. Click ‘OK’ to continue*” displays.

2. The obround hole of the QC plate slides over the bottom left pin of the cassette. The round hole of the QC plate slides over the round pin of the cassette. Snap the two pieces of the cassette together and place it into the scanning slot of the SPIFE Nexus.

3. Select *OK* and “Scanning in Progress” displays.

4. The NDDC results are automatically compared to and displayed with the *Assayed Value* and *Expected Range* entered in setup. Out of range values are indicated by a *plus* or *minus* on the display and report.

5. The OD Step Tablet shows proper linearity when, on the QC printout, a straight line can be drawn which connects the vertical points from the bottom step through **at least six peaks**.

#### 8.3.5. Unacceptable results

##### If the results are not acceptable:

Optics alignment or instrument servicing may be required. Contact Helena Laboratories for assistance.

#### 8.3.6. Print QC History Report

1. *Print* - From the main QC window, the *Print* function may be used to print a report containing all previously run QC. The report includes for each previously run QC the NDDC identifying number, the date and time of the run, and each of the five NDDC fraction results.

2. The report also includes, for each of the five NDDC fractions, the mean, standard deviation, and coefficient of variation, determined from the results of each previously run QC. Select *Print*, the report prints and the display returns to the *QC History* window. Select *Cancel* to return to the window without printing.

#### 8.3.7. Delete

1. From the *Quality Control* window, use the delete function to delete the indicated QC.

2. Select *Delete*.

3. A *Confirm Delete* prompt displays:

a. Select *Yes* to delete the selected QC scan.

b. Select *Yes to All* to delete the multi-selected QC scans.

4. Select *No* or *Cancel* to retain the QC scan and return to the *Quality Control* window.

#### 8.3.8. Cancel

*Cancel* - select to exit the QC History window.

#### 8.3.9. Exit

To exit the QC window, select the X located on the top right of the window.

**Section 9 - Performance Specifications****FOR INDOOR USE ONLY****Media Types:**

Agarose and cellulose acetate gels

**Maximum Gel Size:**

7.8 x 6 in. (12.7 x 12.7 cm)

**Input Power:**

100 to 120 VAC at 16 Amps Max / 240 VAC at 10 Amps Max

50/60 Hz

Max Mains Supply Voltage Fluctuation 10%

**Appliance Class: I****Over Voltage Category: II****Circuit Protection/Fuses:**

Circuit Protection: 20 amp breaker

**Display Power AC outlet Fuse:**  
T3.15AH250V

**Line Cords:** Line cords used must meet regulatory requirements of installation jurisdiction and have an insulation rating of 250 VAC

**Leakage Current:**

< 3.5 mA. sinusoidal

**Dimensions: Height x Width x Depth:****SPIFE Nexus Instrument:**

29" (53.3 cm) x 41" (104.1 cm) x

31" (78.8 cm)

41" (104.1 cm) wide without the monitor pole

44" (111.8) wide with the monitor pole.

**Computer, Monitor, and Keyboard:**

23" (58.4 cm) H x 14" (35.6 cm) W x 16" (40.6 cm) D

**Total Weight:** ~ 250 lbs (113.4 kg)

**Operating Environment:**

Pollution Degree 2

15 to 27°C (59 to 80.6°F) 20% - 80% non-condensing relative humidity

Max Altitude 2000 m

**Storage / Shipping Environment:**

5 to 40°C (41 to 104°F) 10%-80% non-condensing relative humidity

Complete specifications for the scanner, monitor, and printer can be found in their respective owner's guides.

**Operating System:**

Microsoft® Windows® 10

\*Windows is a registered trademark of Microsoft Inc.

**Electrophoresis Timer Range:** 1 sec. to 20 min. in 1-second increments @1100 V and 150 mA

**Chamber:**

**Electrophoresis Temperature Range:** 10 to 32°C (50 to 89.6°F)

**Pre-Drying Temperature Range:** 30 to 62°C (86 to 143.6°F)

**Final Drying Temperature Range:** 30 to 65°C (86 to 149°F)

**Circuit Protection:** 20 A Breaker

**Pump System:** 1 gear pump, 1 syringe pump, 2 peristaltic pumps

**Test Tubes:** 12-16 mm diameter, 75-100 mm height (Minimum sample volume 500 uL)

Table 9-1 Bar Codes

Type	Character Density Minimum Bar Width	Ratio Thin to Thick	Maximum Characters Bar Width
Code 3 of 9 (Code 39) (alphanumeric)	0.0075	3:1	10
EAN	0.014	n/a	13
Codabar (numeric)	0.0098	n/a	10
UPC - 12 (numeric)	0.014	n/a	13
CODE 128 (alphanumeric)	0.0075	3:1	25

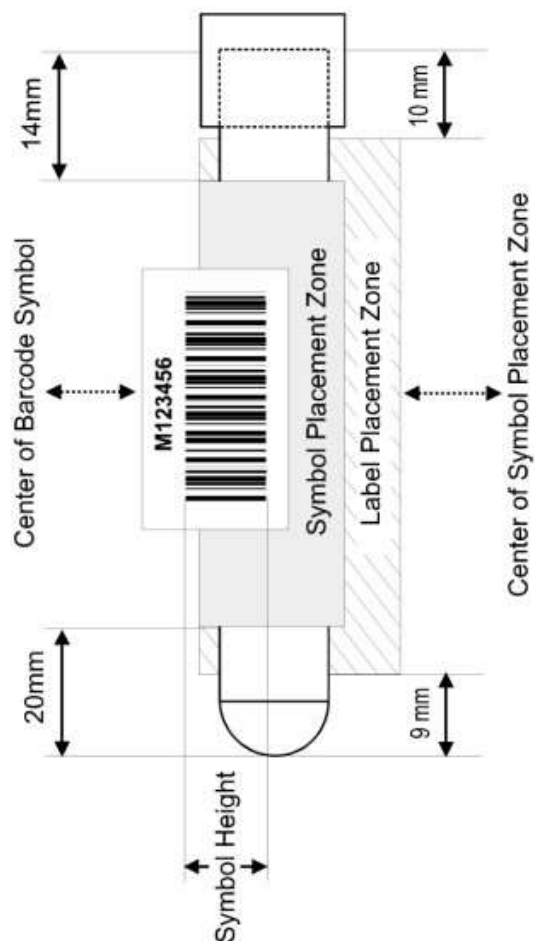


Table 9-2 Test Tube Type and Minimum Volume Table

Test Tube Type	Minimum volume (SPE / UPE)	Minimum volume (Serum IFE)	Minimum volume (Urine IFE)
13 X 75 mm round bottom	215 µL	190 µL	370 µL
16 X 100 mm round bottom	365 µL	340 µL	520 µL
13 mm conical bottom	140 µL	115 µL	295 µL
13 mm serum separator	565 µL	540 µL	---
16 mm serum separator	865 µL above plug	840 µL above plug	---

The size of the placement zone varies depending on the length of the tube. See CLSI's AUTO02-A2, Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard – Second Edition, December 2005 for more detailed information.

**Bandwidth Specifications:**

The recommendation for QuickScan Touch plus customers is allowing a minimum of 10 MB/s for each client. For the server, the recommendation is 10 MB/s for up to five connected clients and an additional 0.5 MB/s for each additional client.

**Table 9-3 UPS Specifications:**

A UPS of the double inversion type is recommended.

Line voltage	100 VAC @ 50 Hz	120 VAC @ 60 Hz	240 VAC @ 50 Hz
Peak VA Requirement	1750	2040	2400
VA requirement for 5 minutes	1250	1620	1310
Watt requirement for complete run*	530	485	620

\*Watt requirement must be referenced against the UPS manufacturer's run time specifications to determine the number of batteries needed to provide power of sufficient duration to allow the instrument to complete a full run for the desired assay

**Group Policies:**

If the SPIFE Nexus is connected to a network and institute has domain control on the instrument, group policies should only be updated at the beginning or end of the day, not while the instrument is running. Group policy updates that occur during a test can prevent the scanning process from occurring after the cassette is placed into the scanner.

## Section 10 - Maintenance, Troubleshooting and Warranty

This section describes routine operator maintenance procedures as well as detailed calibration instructions.

**Note:** The SPIFE Nexus Maintenance Sheet, Document No. D7000011, is available for download on the Helena Laboratories website to aid customers in documenting maintenance procedures.

The flow of this chapter will follow the SPIFE Nexus Maintenance window. After each of the windows have been detailed, the different instrument maintenance procedures will be listed. For instrument calibration or for maintenance not described in this manual, call Helena Laboratories for assistance.

From the Main Menu, select the *Maint* icon. The SPIFE Nexus Maintenance window appears displaying the following options: *Inspect Flow*, *Maintenance Wash*, *Test / Calibrate*, *Archive Service Files*, *View Logs*, *Backup*, *Restore*, and *Close* (Figure 10-1).

\*Contact a Helena Service Representative for assistance with replacing and calibrating the sample handler pipette. **Incorrect pipette calibration may result in severe pipette damage.**

### 10.1. Inspect Flow

Select to wash the pipette system.

1. Click the *Inspect Flow* button.

a. A prompt alerts the user “Wash, moving to wash.....”. A *Cancel* button is also displayed which will immediately stop the operation.



b. Next it will alert the user, “Wash, washing pipette...”.



c. Next it will alert the user, “Wash, washing completed...”



d. Next it will alert the user, “Wash, moving pipette...”.



2. Once complete, the window will close and return to the SPIFE Nexus Main Menu.

## 10.2. Maintenance Wash

1. The Maintenance Wash is designed to flush the three different lines from the reagent bottles into the vat in the instrument. Each different wash fills the vat with the chosen fluid, recirculates it, and then drains the fluid from the vat.

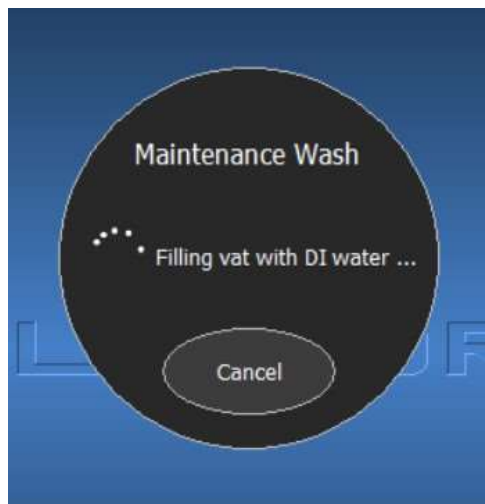
2. Click the *Maintenance Wash* button. The *Maintenance Wash* tab opens displaying the following options: *DI Water*

*Wash, Destain Wash, Buffer Wash, Bleach Wash, and Cancel* (Figure 10-2).



3. *DI Water Wash* – Select to perform a DI Water Wash of the vat and flush the DI Water line to the instrument.

a. A prompt alerts the user “*Maintenance Wash, Filling vat with DI Water...*”. A *Cancel* button is also displayed which will immediately stop filling the vat and drain it.



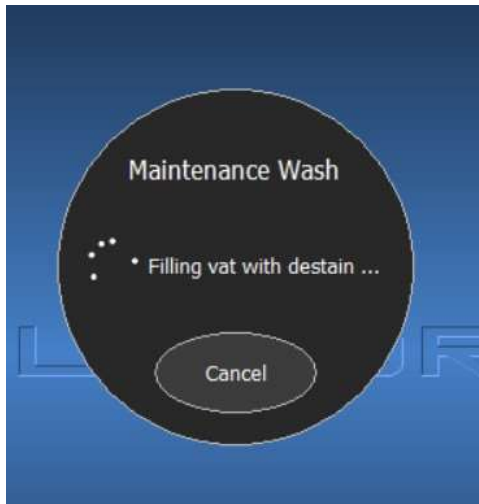
b. Next, it will alert the user “*Draining vat...*”.

c. Once complete, the window will close and return to the main menu.

4. *Destain Wash* – Select to perform a Destain Wash of the vat and flush the Destain line to the instrument.

a. A prompt alerts the user “*Maintenance Wash, Filling vat with destain...*”.

A *Cancel* button is also displayed which will immediately stop filling the vat and drain it.

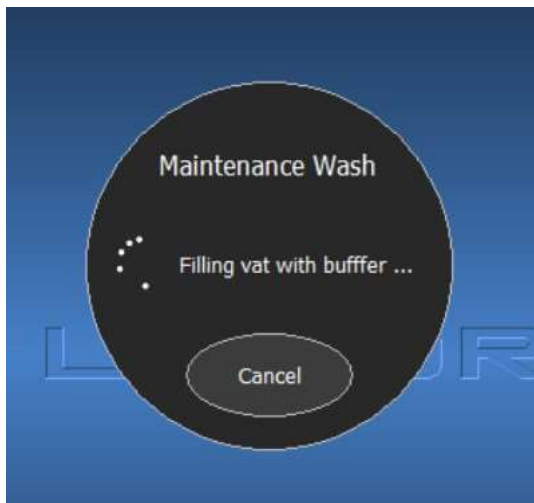


b. Next, it will alert the user “*Draining vat...*”

c. Once complete, the window will close and return to the main menu.

5. *Buffer Wash* – Select to perform a Buffer Wash of the vat and flush the Buffer Wash line to the instrument.

a. A prompt alerts the user “*Maintenance Wash, Filling vat with buffer...*”. A *Cancel* button is also displayed which will immediately stop filling the vat and drain it.



b. Next, it will alert the user “*Draining vat...*”

c. Once complete, the window will close and return to the main menu.

6. *Bleach Wash* – select to perform a series of washes to bleach, rinse, and prime tubing within the instrument. Before pressing, have 3L of 10% Bleach solution and 3L of DI water ready.

**Note:** It is *VERY* important to empty the waste vat before starting to avoid potential chemical interaction.

**Note:** Cancelling a *Bleach Wash* before completion may not drain the vat completely. If for any reason the *Bleach Wash* cycle is cancelled, select the *DI Water Wash* and then immediately cancel it. This will prompt the vat to drain.

a. A prompt alerts the user to empty the waste vat, then move fluid straws into the bleach solution. Press ‘OK’ to continue.

b. The instrument proceeds to cycle through the maintenance washes, then gives a new prompt to move straws to DI water. Press ‘OK’ to continue.

c. The instrument proceeds to cycle through the maintenance washes, rinsing the bleached components with DI water. Then the instrument gives a prompt to place fluid straws back into their respective containers. Press ‘OK’ to continue.

d. The instrument proceeds to prime the washed systems with their respective fluids so that they are ready for the next test.

e. Dispose of used bleach solution from the Waste Vat before proceeding to the next test.

7. *Cancel* – click to return to the SPIFE Nexus Main Menu.

### 10.3. Clean Platen Cover

1. From the SPIFE Nexus Maintenance window, select the *Clean Platen Cover* button to have the Platen Cover brought from its home position to the front of the instrument

2. Remove the Platen Cover, dampen a lint-free tissue with DI water and wash the surface of the electrophoresis chamber. Using a cotton-tipped applicator moistened with DI water, clean the surrounding trough (all four sides) and the entire under side of the lid.

3. Replace the Platen Cover and select OK on the onscreen prompt.

4. The SPIFE Nexus replaces the Platen Cover and closes the SPIFE Nexus Maintenance window.

### 10.4. Test / Calibrate

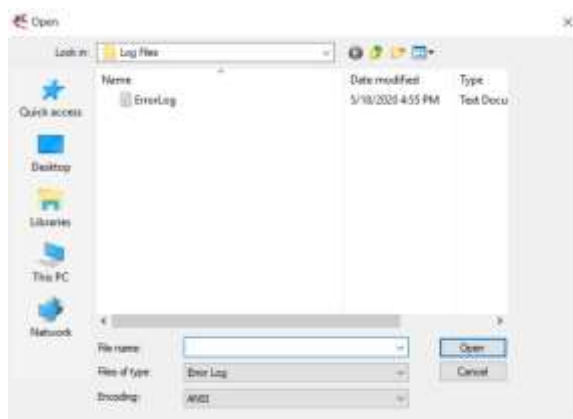
The SPIFE Nexus Test / Calibrate menu should only be accessed by or at the request of a Helena Service Representative (Figure 10-3).

### 10.5. View Logs

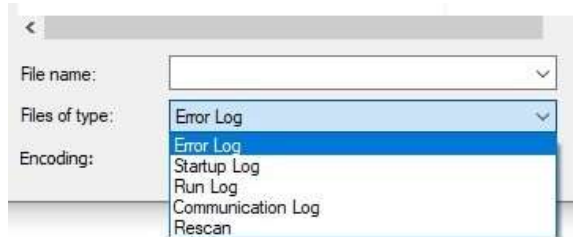
The View Logs option allows the user to search all the different types of logs generated by the SPIFE Nexus. After opening the necessary log file, it can be viewed, printed, or even deleted.

1. Select the *View Logs* button. The *SPIFE Nexus View Log* window is displayed (Figure 10-3).

2. *Open Log* – select to open a log file from the *Log Files* folder.



a. From Files of type dropdown menu, select from *Error Log*, *Startup Log*, *Run Log*, *Communication Log*, or *Rescan*.



b. Once the type of file has been selected, all files of that category will be displayed.

c. Select the necessary file and click *Open*.

d. The file is now displayed in the *SPIFE Nexus View Log* window.

3. *Clear Log* – select to clear the log.

a. A *Confirm Clear* prompt displays.

i. Select *Yes* to clear the log and display a blank screen.

ii. Select *No* to keep the log and cancel the clear request.

4. *Close Log* – select to close the log and display a blank screen.

5. *Find* – select to find a word or phrase.

a. Click the *Find* button. The *Find* dialog box is displayed.

b. *Find what* – add a text or phrase to search for

c. *Match whole words only* – select to match whole words and not partial ones.

d. *Match case* – select to make a case sensitive search.

e. *Find* – once all the options have been added, click to search the log and return to the *SPIFE Nexus View Log* window. Any results will be highlighted in blue.

f. *Cancel* – select to exit the window.

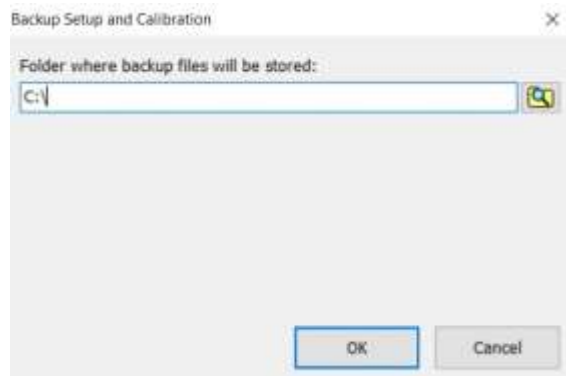
6. *Find Next* – once *Find* has been utilized, select *Find Next* to move to the next finding.

7. *Print* – select to print the log.

8. *Close* – select to close the window and return to the *SPIFE Nexus Maintenance* window.

## 10.6. Backup

1. Press the *Backup* button. The *Backup Setup and Calibration* window is displayed.



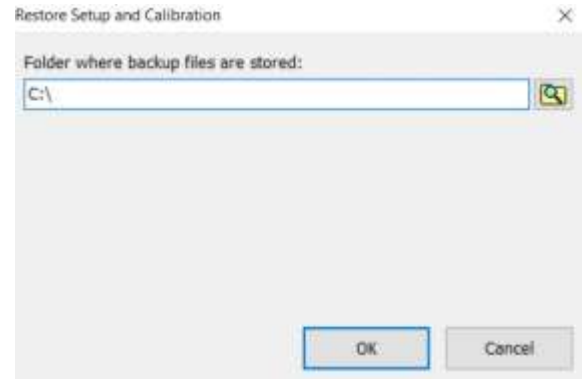
2. Select the folder to save the backup using the *Find Files* icon or by typing the file location in the text box.

3. Click *OK* to back up the files and return to the *SPIFE Nexus Maintenance* window.

4. Click *Cancel* to not back up anything and return to the *SPIFE Nexus Maintenance* window.

## 10.7. Restore

1. Press the *Restore* button. The *Restore Setup and Calibration* window is displayed.



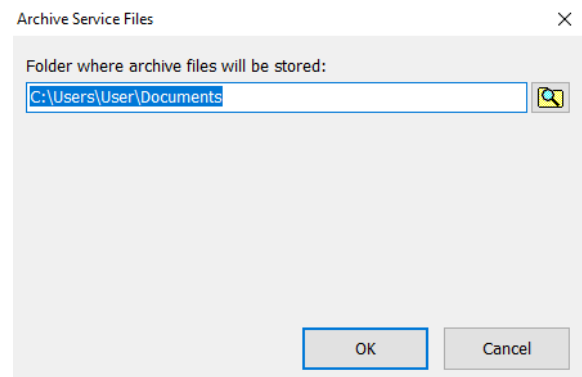
2. Select the folder where the files to be restored are located using the *Find Files* icon or by typing the file location in the text box.

3. Click *OK* to restore the files and return to the *SPIFE Nexus Maintenance* window.

4. Click *Cancel* to not restore any files and return to the *SPIFE Nexus Maintenance* window.

## 10.8. Archive Service Files

1. Select the *Archive Service Files* button.



2. Select the folder to archive the instrument files using the *Find Files* icon or by typing the file location in the text box.

3. Click OK to archive the files to the desired file location and return to the *SPIFE Nexus Maintenance* window.

4. Click Cancel to not archive the files and return to the *SPIFE Nexus Maintenance* window.

### 10.9. Close

Select *Close* to exit out of the *SPIFE Nexus Maintenance* menu.

### 10.10. Instrument Care

This section describes the physical maintenance procedures that need to be performed as part of the Calibration and Maintenance program.

**Note:** *If the instrument must be powered off for a maintenance procedure, open the main instrument door before turning off the power. When the power is off, a safety interlock feature locks the main instrument door.*

#### 10.10.1. Clean Cassettes

1. Rinse and dry Gel Cassettes between each use to remove stain spots.

#### 10.10.2. Clean Reagent Roller

1. Remove the Reagent Roller from the instrument.

2. Wipe clean with an isopropyl prep pad and allow to air dry.

#### 10.10.3. Clean Visible Spills and General Instrument Cleaning

1. Wipe all visible fluid and particles from the surfaces of the instrument with a slightly damp lint-free tissue. For dried stain spots, re-hydrate with water before wiping and wipe with isopropyl alcohol if stain persists. If a large volume of liquid has spilled, shut down and unplug instrument before absorbing liquid with paper

towels and calling Helena Laboratories Electronics Customer Service.

**Warning:** Never reach inside of the Dryer chamber without first checking that the heating elements have cooled

#### 10.10.4. Clean Blotter Holder

1. Remove the used SPIFE Nexus Blotter D from the Blotter Holder.

2. Wipe with a clean dry towel to absorb any remaining moisture from the Blotter Holder and blotter pad.

#### 10.10.5. Inspect Platen Contact Sheet

3. After wiping away any spilled fluids from the Platen surface, inspect the Platen Contact Sheet for bubbles forming beneath, for peeling edges, and for injury and gouging. If any of these issues are found, call a Helena Laboratories Service Representative to schedule a Contact Sheet replacement (Figure 10-16).

#### 10.10.6. Prime Fluid System

1. The instrument should be primed on a daily basis, preferably at the beginning of a shift before any runs have been started.

2. From the Main Menu, select the *Prime* icon.

3. A prompt alerts the user "Prime, moving to wash...". A *Cancel* button is also displayed which will immediately stop the operation.



4. Next it will alert the user, “Priming...”.



5. Next, it will alert the user, “Priming completed...”



6. Next it will alert the user, “Moving pipette...”.



7. Once complete, the window will close and return to the SPIFE Nexus Main Menu.

#### 10.10.7. Clean Reagent/Sample Tray Stations

1. Dampen a lint-free tissue with DI water and wash the surfaces of the Antisera and Sample Tray stations.
2. Using a second tissue, wipe dry all areas that were cleaned.

#### 10.10.8. Clean Platen Cover

1. From the SPIFE Nexus Maintenance window, select the Clean Platen Cover button to have the Platen Cover brought from its home position to the front of the instrument.

Clean Platen Cover



2. Remove the Platen Cover, wipe any moisture from the chamber with a clean lint-free towel.
3. Wipe each of the electrodes with a lint-free cloth and isopropyl alcohol.
4. Replace the Platen Cover onto the platen and select OK on the onscreen prompt.

Clean Platen Cover



5. The SPIFE Nexus replaces the Platen Cover and closes the SPIFE Nexus Maintenance window.

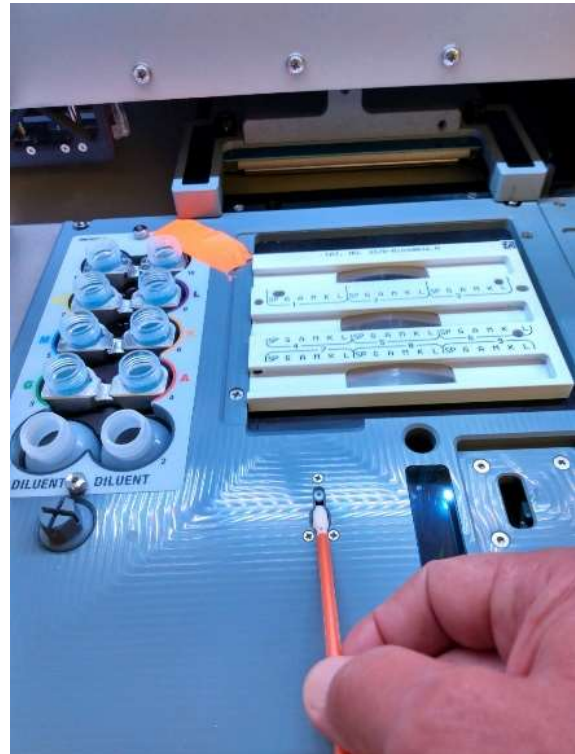
Clean Platen Cover



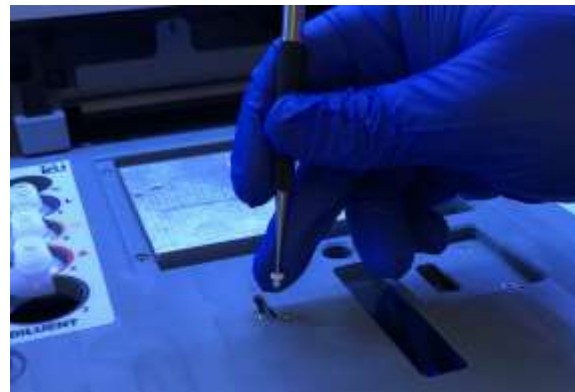
**10.10.9. Inspect and clean Antisera Spreader Tip**

1. Using the spreader tip tool, remove the Antisera Spreader Tip from the storage location by inserting the tool and sliding the Antisera Spreader Tip forward (Figure 10-5).
2. Carefully lift the Antisera Spreader Tip from the storage track using the tool.
3. Dispose of used Antisera Spreader Tip in biohazard waste.
4. Using a SPIFE Maintenance Swab (Cat. No. 1114), gently clean around the insertion area to remove any debris or

fluid. Dispose of the swab in biohazard waste when finished.



5. Place a new Antisera Spreader Tip on the end of the tool. The new Spreader Tip may be a tighter fit than the used spreader tip.



6. Slide the new Antisera Spreader Tip all the way to the back of the storage track where it should snap into place.
7. Replace the Antisera Spreader Tip monthly or if it appears damaged.

### 10.10.10. Clean/Bleach DI Water and Saline Bottles

**Note:** This procedure should also be used for the Saline, Buffer Wash, and Destain Bottles.

1. Empty the DI Wash, Saline Wash, Wash, and Destain Wash bottles, located below the instrument.
2. Clean the bottles with a 10% bleach solution to prevent bacterial or fungal contamination.
3. Rinse the bottles thoroughly with DI water to remove the bleach solution.
4. Refill and replace the bottles, placing the correct straw cap on each bottle.
5. From the Main Menu, select Prime. The priming operation will ensure that no bubbles are in the lines.

### 10.10.11. Clean Sample Pipette Wash Block

**Note:** If errors for Wash Station Overflow continue to occur, follow these steps to clean the Pipette Wash station.

1. With a damp cloth, wipe any debris from the inset area around the wash station.
2. Inspect the drainage hole at the bottom of the wash station for any blockage.
3. Insert a Maintenance Swab (Cat. No. 1113) into the wash station and wipe the optical sensor located on the back wall of the wash station followed by the other interior surfaces.
4. Use the *Inspect Flow* button (Section 10.1) to check pipette for blockage.



### 10.10.12. Clean Scanner

1. Open the Main Door and then turn off the instrument.
2. After the power has been turned off, dampen a maintenance swab (Cat. No. 1113) with distilled water and insert it into the front scanner port.



3. Swipe the swab back and forth along the bottom of the scanner. This will remove any buildup. Do not attempt to clean the sides of the scanner. If buildup exists further back into the scanner, the top scanner opening can be used to access the back of the scanning track.
4. The picture below details before cleaning.



1. Once cleaned, allow time for the distilled water to dry before powering the instrument back on for use.

#### 10.10.13. Clean Optical Fluid Sensors

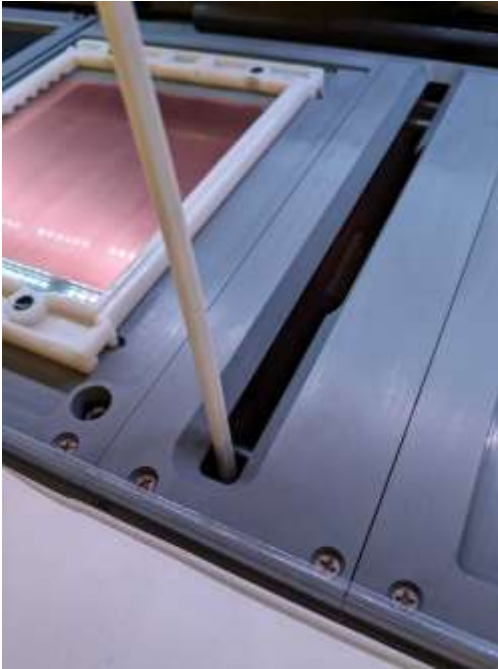
1. Using a maintenance swab (Cat. No. 1113), wipe the sensor at the top right side of the main section of the Wash/Destain vat.



5. The picture below details after cleaning.



2. Wipe the overflow sensor in the overflow chamber at the front of the Wash/Destain vat. The sensor is located about mid-way down the right wall of the overflow chamber.



#### 10.10.14. Clean Waste Level Sensor

1. Unscrew the Waste vat cap and remove it from the Waste vat. Unplug the sensor from the AUX port of the instrument.
2. Remove the two pieces of tubing from the vat cap.
3. Turn the vat cap over and hold the waste level detect sensor under running tap water, removing any residue. Ensure that the sensor cable does not get wet.
4. Screw the waste vat cap back onto the Waste vat and replace the two pieces of tubing. Plug the sensor cord back into the AUX port of the instrument.

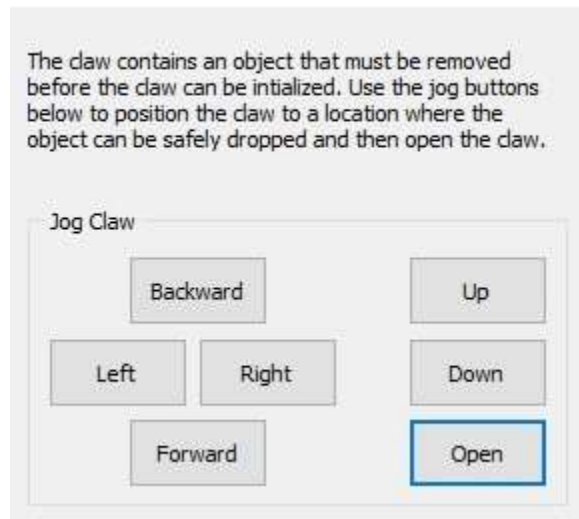
#### 10.10.15. Safe Start Instructions

In the event of a test ending prematurely, the SPIFE Nexus has a Safe Start window that will be displayed if the claw is currently holding an object. The jog buttons on the menu help the user maneuver the claw to a position where it can safely release the object without

damaging itself or the instrument with automated movement.

1. *Jog claw* – This allows the user to select which direction to slightly move the claw's position.
  - a. *Backward* – select to jog the claw backwards.
  - b. *Left* – select to jog the claw left.
  - c. *Right* – select to jog the claw right.
  - d. *Forward* – select to jog the claw forward.
  - e. *Up* – select to jog the claw up.
  - f. *Down* – select to move the claw down.
  - g. *Open* – select to open the claw, which will release anything the claw is holding.

SPIFE Nexus Initialize Error



2. Use the jog buttons on the menu to guide the claw containing the object to a flat surface within the machine, preferably towards the front of the instrument.
3. Lower the object and ensure the height of the object will not prevent the gantry from passing over it. If the gantry hits the object, it can damage the instrument and possibly require recalibration.

4. When the object is in a safe position, click the *Open* button. The claw will open, and all motors will return to their home positions.

5. If this occurs during the execution of a run, the SPIFE Nexus will end the run at this point.

6. If this occurs during initialization before the run has begun, the SPIFE Nexus will continue initialization.

7. After the main door unlocks, the item which was released by the claw can be moved back to its storage location by the operator.

#### **10.10.16. Replace Electrode Insert**

Electrode Inserts will need to be replaced periodically depending on use. Indications that an Electrode Insert needs to be replaced include shortened patterns on one side of the gel, current errors during electrophoresis, and migration abnormalities in the corners of the top row of the gel.

1. Click the “Clean Platen Cover” button in the Maint Menu, and allow the instrument to bring the Platen Cover forward to the platen.

2. Remove the Platen Cover from the instrument.

3. Unscrew the four corner screws of the Platen Cover to release the Electrode Insert.

4. Screw in the new insert. If the screw holes of the Electrode Insert do not align with the screws of the Platen Cover, rotate the insert by 180°; the screws are keyed to only allow the correct orientation of the insert.

5. Place Platen Cover with new insert onto the platen and follow instrument prompts of the cleaning routine to replace the Platen Cover in the storage position.

#### **10.10.17. Switch Platen Covers**

For customers who use two different Platen Covers containing different Electrode Inserts for different assay types, use the Clean Platen Cover button (Section 10.3) in the Maint Menu to bring the current Platen Cover forward from the storage position.

1. When the prompt to remove and clean the Platen Cover appears, replace the Platen Cover on the platen with the correct Platen Cover for the assay type and allow the instrument to move it to the storage position.

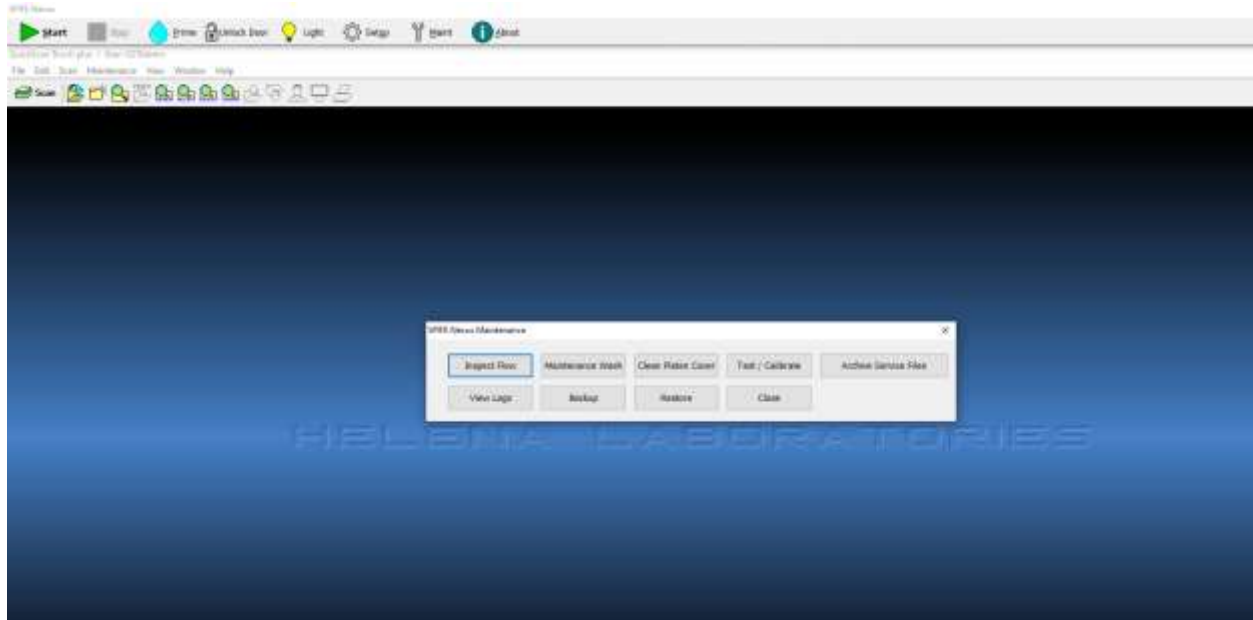


Figure 10-1 Nexus Maintenance

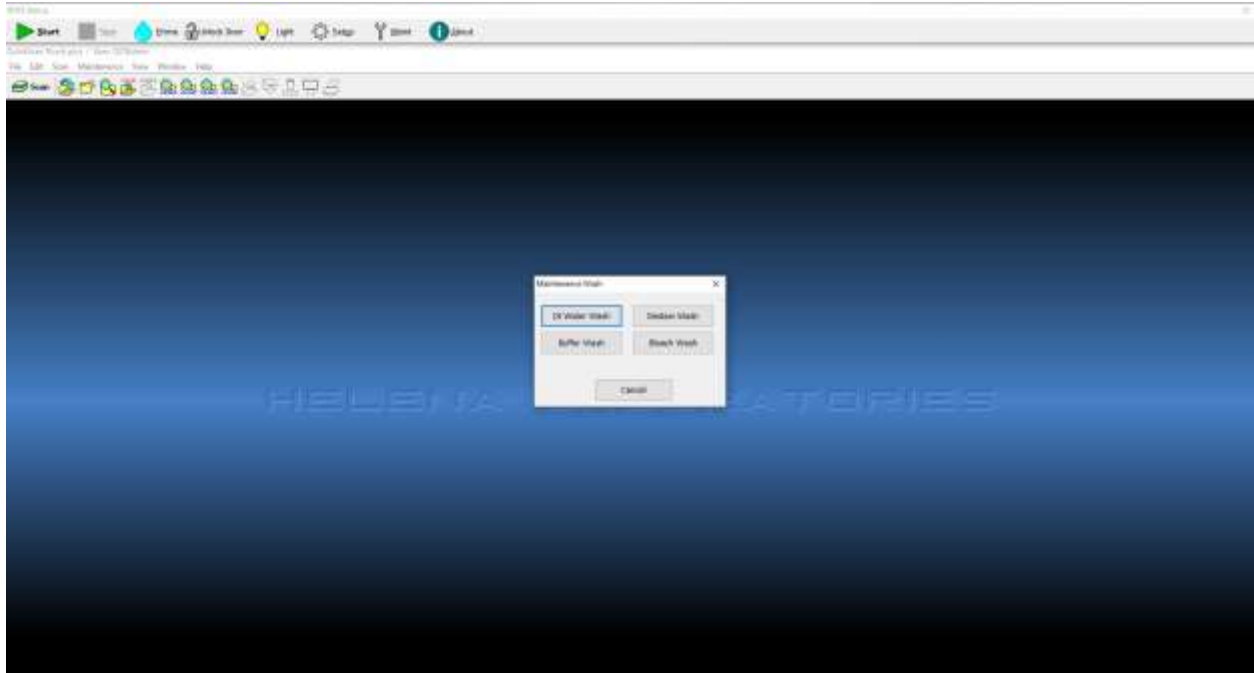


Figure 10-2 Maintenance Menu

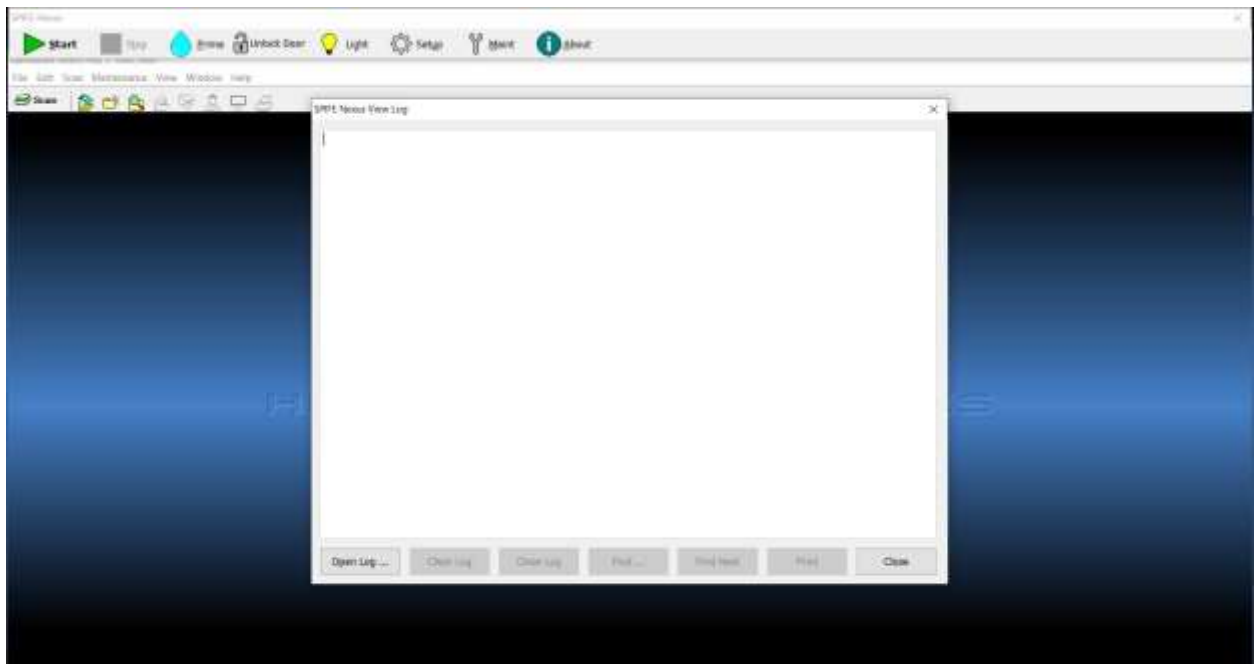
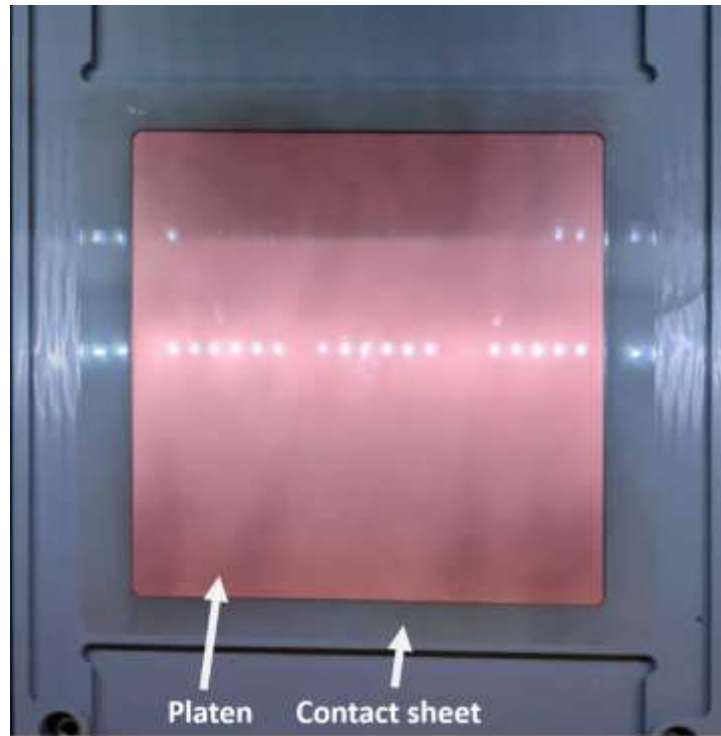


Figure 10-3 View Log



**Figure 10-4 Inspect Contact Sheet**

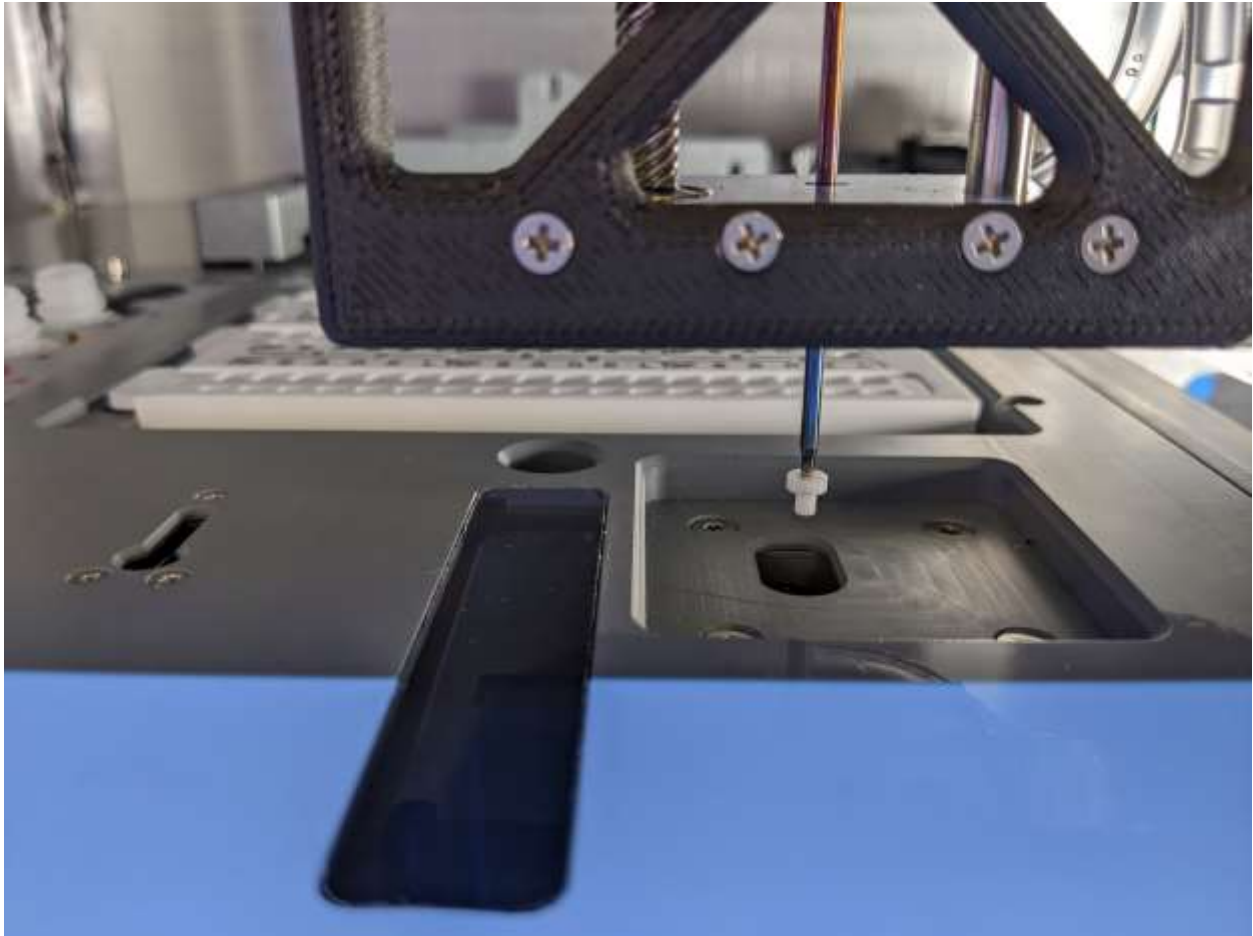


Figure 10-5 Antisera Spreader Tip

## Troubleshooting

When using the SPIFE Nexus software, error messages may appear. If corrective action is not obvious, call Helena Laboratories for assistance. For system problems, refer to the following table. If the recommended solutions should fail to solve a problem, call Helena Laboratories for assistance.

**Table 10-1 Troubleshooting**

PROBLEM	POSSIBLE CAUSE	SOLUTION
SPIFE Nexus screen disappears when user selects an item in the QuickScan Touch <i>plus</i> software.	When the QuickScan Touch <i>plus</i> software is being used, the SPIFE Nexus screen is hidden.	Select the top bar of the SPIFE Nexus window to bring it forward in front of the QuickScan Touch <i>plus</i> window.
No power to instrument	Power cord unplugged	Plug cord into proper wall outlet.
	Fuse blown	Call Helena Laboratories for assistance.
Error message is displayed	Error found during self-test or operation	Do as directed by the message. If message returns, call Helena Laboratories for assistance.
No sample dispensing into sample tray	Empty DI water bottle	Refill DI Water bottle.
	Bent or clogged pipette	Inspect pipette then prime instrument (see Inspect Flow, Section 10.1)
	No sample in tube	Add sample to tube.
	Low sample volume	Minimum sample volume is 500 $\mu$ l. User may hand-pipette samples with low sample volume directly into cups if necessary (see 7.1).
	Air bubbles in DI water tubing	Prime instrument (see 10.10.6).
	Air bubbles, foam in sample	Examine sample tube.
	Sample tube not seated corrected	Examine sample tube.
	Tubing/Pump failure	Call Helena Laboratories for assistance.
No sample applied to plate	Test not programmed for correct number of samples.	Check test parameters (see 6.1).
	Incorrect applicator blade used	Check blades, check for application mark on plate.
	No sample in tube	Examine sample tube. Also see "No sample dispensing into sample tray".

PROBLEM	POSSIBLE CAUSE	SOLUTION
Sample in wrong well	Incorrect tube order or wrong test loaded	Verify tube order in racks and verify correct test has been selected.
Level detect failure	Saline in pipette	Peristaltic pump tubing reversed. Verify tubing is piped correctly.
Pipette wasn't washed Cross contamination	Tubing/Pump failure	Call Helena Laboratories for assistance.
Pipette stops before aspirating or doesn't pipette sample	Blockage of pipette Sensor failure	Call Helena Laboratories for assistance
	DI bottle and Saline bottle are reversed.	Verify saline bottle tubing is connected to the wash station and DI water tubing is connected to the syringe.
Failed to Initialize: Pipette X Pipette Z Gantry Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service for assistance.
Failed to home: Pipette X Pipette Gantry Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service for assistance.
Failed to get to target position: Pipette X Pipette Z Gantry Y Rack X Rack Y	Mechanical or Electrical problem	Turn off instrument and call Helena Laboratories Service for assistance.
Electrophoresis chamber not reaching programmed temperature	Fuse blown	Call Helena Laboratories for assistance.
	Electrical problem	Call Helena Laboratories for assistance.
Fan does not run	Restricted air flow	Remove obstructions and ensure enough air space surrounds instrument.
	Electrical problem	Call Helena Laboratories for assistance.

PROBLEM	POSSIBLE CAUSE	SOLUTION
Gel Cassette does not eject	Mechanical or Electrical problem	Push cassette out manually Call Helena Laboratories for assistance
Dryer too hot	Electrical problem	Call Helena Laboratories for assistance.
Vat level detector failures	Dirty stainer chamber	Use Maintenance Swab soaked in Destain solution to clean inside of stainer chamber, especially around level detector sensors.
	No fluid in chamber	Ensure that wash vat is correctly connected to the instrument and that the vat(s) contain fluid.
Reagent does not dump	No stain added to cups	Check for stain.
	Programming Problem	Check programming for the test against the IFU (see 6.1) and reenter, if parameters have been changed.
	Electrical Problem	Call Helena Laboratories for assistance.
Unable to communicate with the bar code imager	Connection Problem	Call Helena Laboratories for assistance.
"No diluent" error	Diluent needs to be refilled.	Add diluent and tap 'OK' to continue.
	Level detect failure.	Call Helena Laboratories for assistance.
Incorrect sample volume	Tubing/Pump failure	Call Helena Laboratories for assistance
	Bent or plugged pipette	Inspect pipette (see Inspect Flow, section 10.1)
	Leaks in delivery system	Check for loose fittings or breaks in tubing line.
Pipette wasn't washed Cross contamination	Peristaltic pump failure	Prime instrument (see 10.10.6). Check peristaltic pumps.
Board communication Failure. Contact Helena Service	No response was detected from one of the following boards: Fluid Control, EP Power Supply, or Dryer	Call Helena Laboratories for assistance.

**10.11. Warranty**

Helena Laboratories warrants its products to meet Helena's published specifications and to be free from defects in materials and workmanship. Helena's liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price attributable to the goods as to which such claim is made. These alternatives shall be the buyer's exclusive remedies.

In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages.
















The foregoing warranties are in lieu of all warranties expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.






**Warranty Duration**

This warranty is provided to the original purchaser for six months from date of sale.

**Section 11 - Symbology**

The following symbols may be used in this manual, or on the instrument, to provide information necessary to the user, if applicable. To prevent the operator from gaining access to the machine while it is running, sensors and locks have been put in place. If access is gained, please contact Helena Laboratories Support.

	Caution, electric shock hazard, high voltages capable of causing personal injury - shut down the instrument and unplug the power cord before touching - do not operate with the cover(s) removed
	Caution, heat hazard - allow heated components to cool before handling
	Caution, general hazard – reference applicable section of Operator’s Manual before proceeding
	Direct current
	Alternating current
	Both direct and alternating current
	Ground (earth) terminal
	Protective conductor terminal (grounded conductors)
	Frame or chassis terminal
	Equipotentiality (conductor with all parts at a single potential)
	On (power switch)
	Off (power switch)
	Consult instructions
	European authorized representative
	Manufacturer

	<p>Indicates "do not place in trash" in countries or regions requiring recycling and other specific handling, such as in Europe, under the WEEE (Waste Electrical and Electronic Equipment) Directive, 2002/96/EC</p>
	<p>Caution, biohazard: this symbol applies where potential biohazards exist and universal precautions should be exercised. Note: An orange label is for domestic orders &amp; a yellow is for foreign orders.</p>
	<p>Caution, crush hazard: Do not place fingers near any moving parts when the instrument is in use. Do not operate with the cover(s) removed.</p>
	<p>Caution, puncture hazard: Do not place fingers near any moving parts when the instrument is in use. Do not operate with the cover(s) removed.</p>
	<p>Attention, warning. Refer to the Operator's Manual for more information about the area of the instrument.</p>

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## **SPIFE Nexus**

**Operator's Manual**

**Software Version 1.6.0.0**

**For additional information, call  
Helena Laboratories at 800-231-5663, toll free.**



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