ASI Evolution® SR

OPERATOR'S MANUAL

ARLINGTON SCIENTIFIC, INC.®

#2800-015

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1.0 Introduction

The **ASI Evolution® SR** system automates measurement of RPR agglutination tests for syphilis which are analyzed through an image processing algorithm from images taken with an internal CCD camera.

The instrument automatically dispenses serum samples and ASI Evolution® RPR reagent into 48 well plates.

The system uses high quality pictures of the reaction in each well in the microplates. The software has been developed with an optical recognition feature that identifies each well boundary and ensures it is in the correct position. An error message will display on the screen indicating if the well boundary is unable to be identified.

Additionally, there is a preview window which shows the current view field of the camera. The pictures are stored on the hard drive. Results are labeled reactive or nonreactive.

Barcode labeled patient samples can be imported with the use of a hand-held barcode scanner.

The Analyzer automates the various stages of the RPR test, including:

+ Fluid Handling—aspirating and dispensing fluid volumes between 2µL and 500µL
+ Mixing—the plate carriers mix in a circular motion at two speeds (~400 rpm and ~109 rpm)
+ Timing—the instrument will process the tests in a prescribed time allotment, with each step timed appropriately
+ Image Capture—the instrument's camera will record images of each completed test
+ Image processing—the software processes and stores data of the test result image
+ Reporting—the software reports and records the numerical and qualitative results of each test

Reactions occur in plastic 48 well plates. To operate the machine most efficiently, user procedure is as follows:

1. Load sample tubes into the sample rack
2. Load the sample rack into the unit
3. Refill the prime bottle with D.I. Water
4. Place the reagent in the proper position in the permanent rack
5. Loading and unloading micro well test plates

The machine can process up to 192 samples.

After measurement, the data is stored on the system for later use and display. A printout or file export is provided.

Using a second mode of operation, the positive samples can be batched for determination of titers.

1.1 Intended Use

FOR invitro DIAGNOSTIC USE

The ASI Automated RPR (rapid plasma reagin) Test for Syphilis for use on the ASI Evolution® SR, is a qualitative and semiquantitative nontreponemal flocculation test for the detection of reagin antibodies in human serum and plasma as a screening test for serological evidence of syphilis.

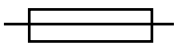
The ASI Evolution® SR is intended to be used as a fully automated analyzer to objectively interpret the results of the ASI Automated RPR Test for Syphilis. The ASI Evolution® SR is designed to provide standardized test interpretation and to provide for storage, retrieval, and transmittal of the test results.

The ASI Automated RPR Test for Syphilis for use on the ASI Evolution® SR is for professional use only. The test is intended to be used for *invitro* diagnostic testing.

1.2 Warning Markings

1.2.1 Safety Symbols

Symbols that may appear on the product

			
WARNING	**Protective Ground**	**CAUTION**	**BIOHAZARD**
Risk of Shock	**(Earth) Terminal**	**Refer to Manual**	**Risk of Infection**
	**FUSE:** For continued protection against risk of fire, replace only with fuse of the specified type and current ratings. Disconnect equipment from supply before replacing fuses.		
	**DANGER:** Pinch points, sharp points, and moving parts—mechanisms may operate without warning.		

1.2.2 Safety Terms

These terms may appear on the product or in this manual:

TERM	MEANING
DANGER	Indicates an injury immediately accessible as you read this marking.
WARNING	WARNING statements identify conditions or practices that could result in injury or loss of life. WARNING indicates an injury hazard not immediately accessible as you read this marking.
CAUTION	CAUTION statements identify conditions or practices that could result in damage to this product or other property.
BIOHAZARD	BIOHAZARDS are biological agents that can cause disease in humans. Lab workers handling potentially infectious materials must use universal precautions to reduce the risk of exposure to these agents.
 **BIOHAZARD** 	
	**WARNING:** If any materials are overturned during operation, immediately set the power switch to OFF (0). This material should be treated as potentially biohazardous. Appropriate cleanup and disposal of biohazardous waste should be used.

1.2.3 Disposal and Storage

Dispose of according to local regulations. Laptop's hard drive must be destroyed.

Before the instrument is removed from the laboratory for storage, disposal, transporting, or servicing, it must be decontaminated.

Decontamination should be performed by a well-trained authorized person, observing all necessary safety precautions. Instruments to be returned must be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing center or from any authority's intervention.

BIOHAZARD	
	**WARNING:** Treat all components during use and disposal as you would any biohazardous material.
	**WARNING:** If any materials are overturned during operation, immediately set the power switch to OFF (0). This material should be treated as potentially biohazardous. Appropriate cleanup and disposal of biohazardous waste should be used.

1.3 Safety Precautions

Review the following safety precautions to avoid injury and prevent damage to this instrument or any products connected to it. To avoid potential hazards, use this instrument only as specified.

 **WARNING**	Only qualified personnel should perform service procedures. Contact your dealer to arrange factory training.
 **WARNING**	Hazardous line voltages are present behind the AC cover and on the power supplies. Always disconnect the external AC power cable before servicing the instrument.
 **BIOHAZARD**	The operation of the ASI Evolution® SR analyzer may involve the use of biohazardous material. Refer to Sections 1.2.2 and 1.2.3 in this manual for biohazard warnings.
To assure operator safety and prolong the life of your instrument, carefully follow all instructions outlined below.	
Read Instructions	Take time to read this manual carefully before using this instrument. Review the following safety precautions to avoid injury and prevent damage to this instrument or any products connected to it. To avoid potential hazards, use this instrument only as specified. For best results, familiarize yourself with the instrument and its capabilities before attempting any clinical diagnostic tests. Refer any questions to your instrument service provider.
Instrument Familiarity	For the best results, familiarize yourself with the instrument and its capabilities before attempting to use the instrument. Refer any questions to the proper Field Service Engineer.
Servicing	There are no user-serviceable parts inside the instrument. Refer servicing to qualified service personnel. Use only factory-authorized parts. Failure to do so may void the warranty.
Wear Protective Apparel	Many diagnostic assays utilize materials that are potential biohazards. **WARNING:** Always wear protective apparel and eye protection while using this instrument.
Follow Operating Instructions	**WARNING:** Do not use this instrument in a manner not specified by the manual, or the protection provided by the instrument may be impaired.
Use Proper Power Cord	**WARNING:** Use only the power cord specified for this product and certified for the country of use.
Observe All Terminal Ratings	**WARNING:** To avoid fire or shock hazard, observe all ratings and markings on the instrument. Consult this manual for further ratings information before making connections to the instrument.
Install as Directed	The instrument should be installed on a sturdy, level surface capable of safely supporting the instrument's weight of 35 kg. The mounting surface should be free of vibrations. The instrument does not require fastening to the bench top.
Use Proper Fuse	Use only the fuse type and rating specified for this instrument.
Provide Proper Ventilation	Refer to the installation instructions for details on installing the product so it has proper ventilation. The instrument should be surrounded by the following clearances: 46cm on each side, 117cm on top, 15cm in front, and 18cm in back.
Do Not Operate Without Protective Covers	**WARNING:** Do not operate this instrument with covers and panels removed.
Avoid Exposed Circuitry	**WARNING:** Do not touch exposed connections and components when power is present.

1.3 Safety Precautions (Continued)

Do Not Operate in An Explosive Atmosphere	**WARNING:** Do not operate instrument in an explosive atmosphere.
Do Not Operate with Suspected Failures	**WARNING:** If you suspect there is damage to this instrument, have it inspected by a qualified service person.
Do Not Operate in Wet/ Damp Conditions	**WARNING:** Do not operate instrument in wet/damp conditions.
Avoid Excessive Dust	Do not operate in an area with excessive dust.
Keep Instrument Surfaces Clean and Dry	**CAUTION:** Solvents such as acetone or thinner will damage the instrument. • Do not use solvents to clean the unit. Avoid abrasive cleaners; the ASI Evolution® SR Analyzer top cover is liquid-resistant, but easily scratched. • Clean the exterior of the instrument with a soft cloth using plain water. If needed, a mild all-purpose or nonabrasive cleaner may be used. • Use as a disinfectant a 1:10 dilution solution of chlorine bleach (5.25% Sodium Hypochlorite) or 70% isopropyl alcohol. • Take special care not to spill liquid inside the instrument
Transporting	**CAUTION!** Treat instrument and components as you would any biohazardous material. See Section 1.2.3 Disposal and Storage for decontamination recommendations. When shipping the instrument, it is important that the instrument be anchored using the original shipping screws and packaging. Pack the instrument in the original manner to prevent shipping damage.
Degree of protection IEC60529)	IPXO – Not Rated/No Protection **NOTE:** The manufacturer or his agent is to be consulted if there is any doubt about the compatibility of decontamination or cleaning agents.

Limitations of the Procedure:

- The device should not be used for syphilis testing with the Reverse Testing Algorithm (when treponemal testing is conducted first). This device should only be used when RPR testing is conducted before any follow up treponemal assays.
- Do not use tapered tubes.
- All reactive results should be reviewed.
- Do not use plasma that has been frozen more than 2 times.
- Prozone reactions can occur in patients with secondary syphilis. False negative nontreponemal test results, arising from prozone, can also be seen in incubating primary and in late syphilis. The nonreactive pattern is slightly granular or "rough" with specimens exhibiting prozone. When this pattern is exhibited, a dilution of the specimen should be prepared. Titer the diluted specimen until endpoint is reached or until no reactivity is observed. All tests exhibiting a rough appearance should be further evaluated.
- Biological false positive reactions occur occasionally with the carbon antigen. Such reactions sometimes occur in samples from individuals with a history of drug abuse, pregnancy or with diseases such as lupus erythematosus, malaria, vaccinia, mononucleosis, leprosy, viral pneumonia, and after small-pox vaccinations.
- Pinta, yaws, bejel and other treponemal diseases produce positive reactions in this test.
- Contaminated, lipemic, icteric or grossly hemolyzed sera should not be used because of the possibility of nonspecific reactions. A specimen is too hemolyzed for testing when printed matter cannot be read through it.
- The cover of the ASI Evolution® SR should be closed while tests are being performed to avoid glare from outside lighting sources.
- Reactive RPR test samples should be followed up with treponemal antibody testing as recommended in the Manual of Tests for Syphilis.
- Temperature of the reagents and samples is crucial to test outcome; it should be between 20-30°C.
- A final diagnosis should not be made on the result of a single test but should be based on a correlation of test results with other clinical findings.

1.4 Operating Precautions

WARNING: Insufficient RAM will adversely affect the performance of your instrument. The minimum RAM required is 16GB.

The ASI Evolution® SR Analyzer is intended to be used by laboratory professionals who are trained and capable of handling biohazardous material, such as patient samples. Some diagnostic assays utilize materials which are potentially biohazardous.

- Always wear protective apparel and eye protection while using this instrument.
- Always operate the instrument with the aerosol shield lowered.
- Do not use the instrument in a manner not specified by the manual, or the protection provided by the instrument may be impaired.
- Probe tips are sharp and may cause bodily injury. Do not place hands or fingers under the probe while instrument is in operation. Always set the power switch to OFF (O) before working on the probe. Never touch the probe while the instrument is operating.

⚠ **WARNING**	The probe performs a self-clean periodically while the probe is idle. Always keep hands away from the probe and probe pathway when the instrument is ON.

- Watch the instrument during "Start of Day" operation to ensure that the probe functions are operating properly.
- Always operate the instrument with the top cover down, except during "Start of Day" operation.
- Do not operate the instrument if the probe is damaged.
- Only use reagent bottle that is designated for the Evolution. Do not overfill or refill the reagent bottle past the neck of the bottle. Doing so may cause the system to inadvertently aspirate air.

⚠ **CAUTION!** ⚠	
⚠	**CAUTION!** To avoid waste fluid backing up into the instrument, ensure that the drain tube is positioned such that the flow of gravity allows waste fluid to drain directly into the waste container. The end of the drain tube should not rest in the waste fluid nor should it rest against any wall or the bottom of the waste container.

1.5 Expected Values

A comparison of the digital interpretation of the results from the ASI Evolution® SR using the original interpretation algorithm (BK20048A, K201438, and BK200539) to establish substantial equivalence to the interpretation made by the ASI Evolution® SR using the new interpretation algorithm was conducted.

The ASI Evolution® SR was evaluated for equivalence, in its pattern of reactivity using a total of 1,762 individual retrospective samples, with identifiers removed, that had been collected from different Departments of Public Health Labs and Blood Banks. Reactive, Weak Reactive and Nonreactive controls were run on each day of testing.

Retrospective Serum Sample Testing – 870 Samples

Retrospective Serum Sample Testing – 870 Samples		ASI Evolution New Algorithm	
		Reactive	Nonreactive
ASI Evolution Original Algorithm	Reactive	100	2
	Nonreactive	3	765

Note: *The five discordant results were investigated and the three samples that were called reactive by the new algorithm and nonreactive by the original algorithm were tested with a treponemal test and found to be reactive. The two samples that were called nonreactive by the new algorithm and reactive by the original algorithm had bubbles or artifacts in the test well.*

Serum positive agreement is calculated as:

103/(103 + 0) = 100%

95% CI = 96.48%- 100%

Serum negative agreement is calculated as:

767/(767 + 0) = 100%

95% CI = 99.52%- 100%

Serum samples were from both SST and Red Top tubes.

Retrospective Plasma Sample Testing – 892 Samples

Retrospective Plasma Sample Testing – 892 Samples		ASI Evolution New Algorithm	
		Reactive	Nonreactive
ASI Evolution Original Algorithm	Reactive	117	3
	Nonreactive	4	768

Note: *The seven discordant results were investigated and the four samples that were called reactive by the new algorithm and nonreactive by the original algorithm were tested with a treponemal test and found to be reactive. The three samples that were called nonreactive by the new algorithm and reactive by the original algorithm had bubbles or artifacts in the test well.*

Total Plasma positive agreement is calculated as:

121/(121 + 0) = 100%

95% CI = 97.00%- 100%

Total Plasma negative agreement is calculated as:

771/(711 + 0) = 100%

95% CI = 99.52%- 100%

Sodium Citrate positive agreement is calculated as:

56/(56 + 0) = 100%

95% CI = 93.62%- 100%

Sodium Citrate negative agreement is calculated as:

350/(350 + 0) = 100%

95% CI = 98.95%- 100%

EDTA positive agreement is calculated as:

65/(65 + 0) = 100%

95% CI = 94.48%- 100%

EDTA negative agreement is calculated as:

421/(421 + 0) = 100%

95% CI = 99.13%- 100%

Conclusion:

The positive and negative percent agreement for the two algorithms demonstrate that they have a very similar performance.

Reproducibility

Reproducibility testing was conducted. The testing consisted of:

- Testing seven (7) samples
  - 2- RPR nonreactive samples
  - 2- RPR reactive 1:2 titered samples
  - 1- RPR reactive 1:4 titered sample
  - 1- RPR reactive 1:8 titered sample
  - 1- RPR reactive 1:16 titered sample
- Each sample was run in duplicate within the panel.
- Each sample was tested each day for five non-consecutive days by an operator with experience in performing the ASI Automated RPR Test for Syphilis
- Each sample was tested a second time on each of the days referenced above separated by approximately 2 hours.

Rapid Plasma Reagin (RPR)				
Sample	**Sample #**	**N**	**Expected Result**	**95% Confidence Interval**
RPR nonreactive	10159A	60	100% (60/60)	94.04–100
RPR nonreactive	06127	60	100% (60/60)	94.04–100
RPR reactive 1:2	10159D	60	100% (60/60)	94.04–100
RPR reactive 1:2	W9P19R	60	100% (60/60)	94.04–100
RPR reactive 1:4	10159C	60	100% (60/60)	94.04–100
RPR reactive 1:8	10159E	60	100% (60/60)	94.04–100
RPR reactive 1:16	R0B03R	60	100% (60/60)	94.04–100

The data shows a very high degree of reproducibility.

Testing was done comparing cadaveric donor samples and living tissue donor samples. The results were as follows:

A total of 164 serum samples, collected in SST (90) and red top tubes (74), with identifiers removed were tested to determine patterns of reactivity using the qualitative RPR test with the ASI Automated RPR Test procedure on the ASI Evolution.

The results of the qualitative analysis of the samples collected from serum collected in red top tubes (prior to and after spiking with reactive sample) are shown below:

Serum Sample (Red Top) Testing - 74 Samples Known Nonreactive		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	0	0	0
	Nonreactive	0	74	74
	Total	0	74	74

Results of red top tube serum testing with known nonreactive

Serum Sample (Red Top) Testing - 74 Samples Spiked Samples		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	74	0	74
	Nonreactive	0	0	0
	Total	74	0	74

Results of red top tube serum testing with spiked samples

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

The results of the qualitative analysis of the samples collected from serum collected in SST tubes (prior to and after spiking with reactive sample) are shown below:

Serum Sample (SST) Testing - 90 Samples Known Nonreactive		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	0	0	0
	Nonreactive	0	90	90
	Total	0	90	90

Results of SST serum sample testing with known nonreactive

Serum Sample (SST) Testing - 90 Samples Spiked Samples		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	90	0	90
	Nonreactive	0	0	0
	Total	90	0	90

Results of SST serum samples testing with spiked samples

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

A total of 84 EDTA plasma samples, with identifiers removed were tested to determine patterns of reactivity using the qualitative RPR test with the ASI Automated RPR Test procedure on the ASI Evolution® SR.

The results of the qualitative analysis of the samples collected from EDTA plasma tubes (prior to and after spiking with reactive sample) are shown in below:

EDTA Plasma Sample Testing 84 Samples Known Nonreactive		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	0	0	0
	Nonreactive	0	84	84
	Total	0	84	84

Results of EDTA plasma sample testing with known nonreactive

EDTA Plasma Sample Testing 84 Samples Spiked Samples		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	0	0	0
	Nonreactive	0	84	84
	Total	0	84	84

Results of EDTA plasma sample testing with spiked samples

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

Living Donor Specimens

A total of 126 serum samples, collected in SST (51) and red top (75) tubes, with identifiers removed were tested to determine patterns of reactivity using the qualitative RPR test with the ASI Automated RPR Test procedure on the ASI Evolution.

The results of the qualitative analysis of the samples collected from serum collected in red top tubes (prior to and after spiking with reactive sample) are shown in below:

Serum Sample (Red Top) Testing - 75 Samples Known Nonreactive		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	0	0	0
	Nonreactive	0	75	75
	Total	0	75	75

Results of living donor serum testing in red top tubes with known nonreactive

Serum Sample (Red Top) Testing - 75 Samples Spiked Samples		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	75	0	75
	Nonreactive	0	0	0
	Total	75	0	75

Results of living donor serum testing in red top tubes with spiked samples

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

The results of the qualitative analysis of the samples collected from serum collected in SST tubes (prior to and after spiking with reactive sample) are shown in below:

Serum Sample (SST) Testing 51 Samples Known Nonreactive		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	0	0	0
	Nonreactive	0	51	51
	Total	0	51	51

Results of living donor serum testing in red top tubes with known nonreactive

Serum Sample (SST) Testing 51 Samples Spiked Samples		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	0	0	0
	Nonreactive	0	51	51
	Total	0	51	51

Results of living donor serum testing in red top tubes with spiked samples

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

A total of 76 EDTA plasma samples, with identifiers removed were tested to determine patterns of reactivity using the qualitative RPR test with the ASI Automated RPR Test procedure on the ASI Evolution.

The results of the qualitative analysis of the samples collected from EDTA plasma tubes (prior to and after spiking with reactive sample) are shown in below:

EDTA Plasma Sample Testing 76 Samples Known Nonreactive		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	0	0	0
	Nonreactive	0	76	76
	Total	0	76	76

Results of EDTA plasma sample testing with known nonreactive

EDTA Plasma Sample Testing 76 Samples Spiked Samples		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager—AT Results	Reactive	76	0	76
	Nonreactive	0	0	0
	Total	76	0	76

Results of EDTA plasma sample testing with spiked samples

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

ASiManager-AT Performance Characteristics

Positive Agreement

Using the data from the composite performance results above, the positive agreement of the ASI Evolution SR can be calculated:

Cadaveric Donor Serum (Red Top)	Cadaveric Donor Serum (SST)	Cadaveric Donor Plasma (EDTA)
74/(74+0) = 100%	90/(90+0) = 100%	84/(84+0) = 100%
95% CI = 95.14%- 100%	95% CI = 95.98%- 100%	95% CI = 95.70%- 100%

Living Donor Serum (Red Top)	Living Donor Serum (SST)	Living Donor Plasma (EDTA)
75/(75+0) = 100%	51/(51+0) = 100%	76/(76+0) = 100%
95% CI = 95.20%- 100%	95% CI = 93.02%- 100%	95% CI = 95.26%- 100%

Negative Agreement

Using the data from the composite performance results above, the negative agreement of the ASI Evolution SR can be calculated:

Cadaveric Donor Serum (Red Top)	Cadaveric Donor Serum (SST)	Cadaveric Donor Plasma (EDTA)
74/(74+0) = 100%	90/(90+0) = 100%	84/(84+0) = 100%
95% CI = 95.14%- 100%	95% CI = 95.98%- 100%	95% CI = 95.70%- 100%

Living Donor Serum (Red Top)	Living Donor Serum (SST)	Living Donor Plasma (EDTA)
75/(75+0) = 100%	51/(51+0) = 100%	76/(76+0) = 100%
95% CI = 95.20%- 100%	95% CI = 93.02%- 100%	95% CI = 95.26%- 100%

Sensitivity

Using the data from the performance results of the spiked samples the sensitivity of the ASI Evolution SR using cadaveric and living donor samples can be calculated:

The sensitivity was determined by spiking the nonreactive specimens with one of five RPR reactive samples.

Cadaveric Donor Serum (Red Top)	Cadaveric Donor Serum (SST)	Cadaveric Donor Plasma (EDTA)
74/(74+0) = 100%	90/(90+0) = 100%	84/(84+0) = 100%
95% CI = 95.14%- 100%	95% CI = 95.98%- 100%	95% CI = 95.70%- 100%

Living Donor Serum (Red Top)	Living Donor Serum (SST)	Living Donor Plasma (EDTA)
75/(75+0) = 100%	51/(51+0) = 100%	76/(76+0) = 100%
95% CI = 95.20%- 100%	95% CI = 93.02%- 100%	95% CI = 95.26%- 100%

Specificity

Using the data from the performance results of the nonreactive samples the specificity of the ASI Evolution SR using cadaveric and living donor samples can be calculated:

Cadaveric Donor Serum (Red Top)	Cadaveric Donor Serum (SST)	Cadaveric Donor Plasma (EDTA)
74/(74+0) = 100%	90/(90+0) = 100%	84/(84+0) = 100%
95% CI = 95.14%- 100%	95% CI = 95.98%- 100%	95% CI = 95.70%- 100%

Living Donor Serum (Red Top)	Living Donor Serum (SST)	Living Donor Plasma (EDTA)
75/(75+0) = 100%	51/(51+0) = 100%	76/(76+0) = 100%
95% CI = 95.20%- 100%	95% CI = 93.02%- 100%	95% CI = 95.26%- 100%

Conclusion:

The sensitivity and specificity for cadaveric donor specimens and living donor specimens are *substantially equivalent.*

The conclusions drawn from the nonclinical and clinical studies demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

NOTES

2.0 Technical Specifications

Overall

Typical throughput	*Up to 190 RPR agglutination tests per hour*
Minimum reaction volume	*110 µL*
Minimum Volume for performing titers between 1:1 – 1:32	*800 µL*
Minimum volume for performing titers between 1:64 – 1:2048	*520 µl*
Total Minimum volume for performing qualitative, low end point titers and high endpoint titers	*950 µla*
Minimum sample requirement to perform qualitative testing	*500 µL*
Dimensions and weight	*36.25” (92.1cm) width, 18.75” (47.6cm) height, 21.5” (54.6cm) depth, 78lbs (35kg)*

Reagent and Sample Dispensing

Capabilities	*Process qualitative syphilis RPR tests*
Pump	*One syringe pump, sized: 500µL*
Probe	*316 stainless steel for maximum reagent compatibility, level sensing*
Minimum and maximum volume	*2µl –450µl*
Maximum number of specimens	*192 (including controls)*
Maximum number of reagents	*One carbon reagent bottle, one diluent bottle*
Reaction vessel	*Standard 48 well plates (4 total)*
Instrument bottles	*1L Priming bottle*

Reading

Detection mode	*Image Processing*
Detector	*Built-in Machine Camera*
Optical design	*Camera with lens to focus on wells, adjustable exposure time and aperture*
Light source	*LED lit light panel backing the reaction plate, adjustable brightness*

Software

Format	*USB and Internet upgrades*
Operating system	*Microsoft Windows® 11 Pro*
Minimum system	*64-bit Windows® 11 Pro, 16 GB RAM, minimum 1GB free drive space, USB port*
Recommended system	*64-bit Windows® 11 Pro, Intel® Core™ i5 or higher, 16 GB RAM, USB port*
Secondary menu options	*Import/export data, etc., Control, Run, and Setup*
Calculation modes	*Algorithm for image analysis, titer testing to determine strength of reactive samples*
Self-monitoring modes	*Mechanical function and more*
QC options	*Stores control data, Patient results and reaction images*
USB port	*USB cable provided*

Power

Voltage range	*100-240VAC*
Frequency range	*50-60Hz*
Power maximum	*160W*
Installation category	*CAT II*

ASI Automated RPR test kits for Syphilis

480 test kit	*900480AD*
4800 test kit	*9004800AD*
5ml control set	*905005A*
RPR Dilution Buffer	*5300-905A*

Recommended environmental conditions

Indoor use

Main supply voltage	*Fluctuations not to exceed ±10% of the nominal voltage*
Operating temperature	*18-35°C recommended*
Operating humidity	*Less than 60% recommended*

ⓘ ***NOTE:*** *Although it may be safe to operate in these conditions, it may not be suitable for the performance of your tests. Check with your reagent supplier.*

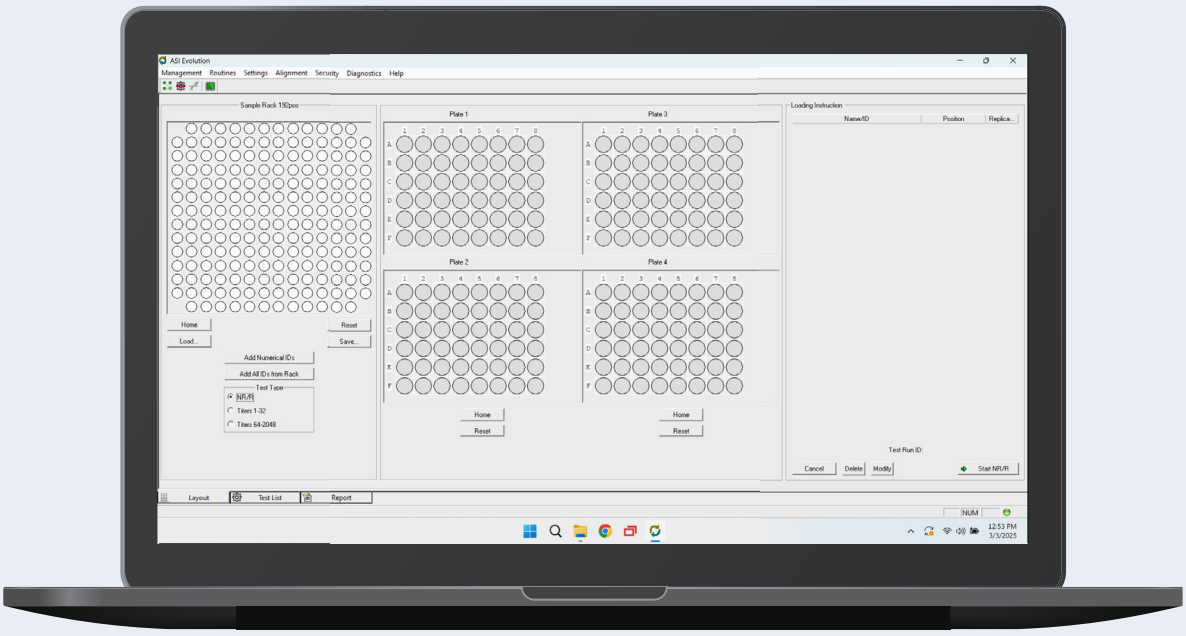
Certifications

NRTL Listed, CE Marked, FDA-Cleared for Blood Donor Testing BK170114 and BK200488, FDA-Cleared for in-vitro diagnostic Testing K173376, K182391 and K201438. Cadaveric (Non-heart beating) tissue screening BK200539.

3.0 ASI Evolution® Software

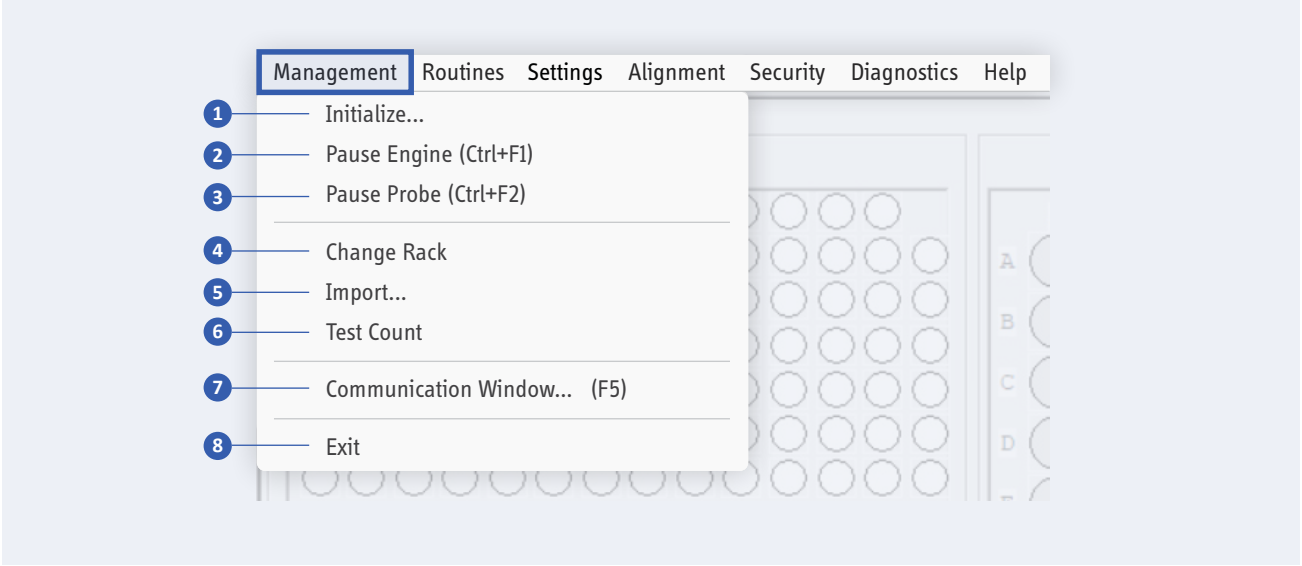
Launch ASI Evolution® Software.

Laptop Desktop with ASI Evolution® Software Application Icon



ASI Evolution® Software Screen

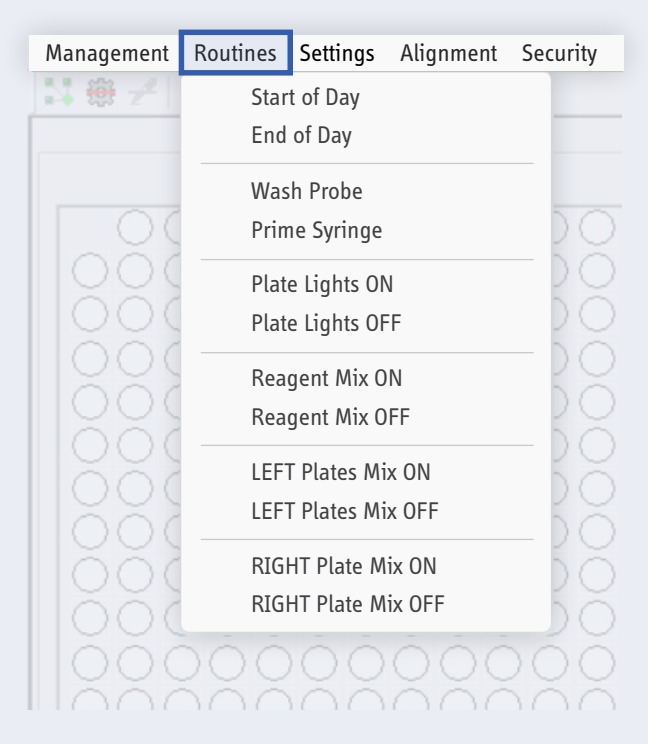
3.1 MANAGEMENT MENU



Management Menu Options

Management Menu Options	
OPTION	**DESCRIPTION**
1 Initialize	Establish or re-establish communication between the software and the instrument without restarting the software.
2 Pause Engine	Press Pause Engine all currently running tasks will finish then the engine will pause; press Pause Engine again and the instrument will resume from the point it was paused.
3 Pause Probe	Press Pause Probe and the probe will finish pipetting and wash the probe before pausing. Probe will be paused until Pause Probe is selected again; in the meanwhile, other tasks will continue.
4 Change Rack	This feature allows the user to switch between the standard 192 sample rack and a custom 100 sample rack.
5 Import	This feature will populate the Sample Rack locations with names or IDs that are located in a .txt file or .csv. The .txt or .csv file can be created manually or using an external bar code reader. The first line of either the .txt or .csv file is reserved for the Test Run ID. Patient sample #1 will be located on the second line of the txt file, sample #2 will be on the third line, and so on.
6 Test Count	Test count data can be retrieved, printed, and exported, either for a range of dates, or for a specific month.
7 Communication Window (F5)	Used for Service Purposes ONLY.
8 Exit	Exit the software.

3.2 ROUTINES



Routines Menu Options

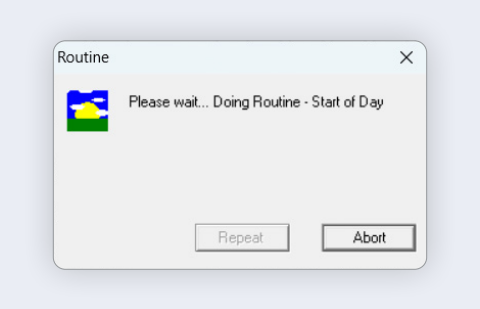
3.2.1 Start of Day

Running "Start of Day" at the beginning of every workday is required.

Reference section *8.3 – Routine Maintenance for the ASI Evolution.*

1. Check the bottle volume levels: empty the Waste bottle if necessary; empty the Prime bottle and refill it with fresh deionized water.
2. From the Routines Menu, select *Start of Day.*
3. The sample handling system will be primed with deionized water.

ⓘ *NOTE: Observe the fluid handling system and ensure there are no leaks.*



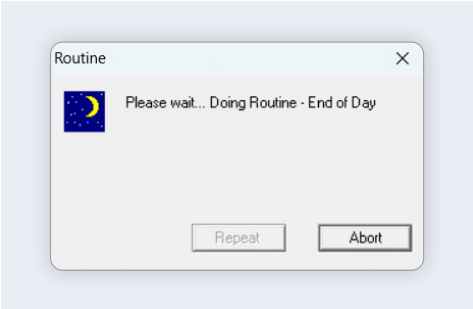
Start of Day Loading Window

3.2.2 End of Day

Running "End of Day" at the end of every workday is required.

1. Place a 12 x 75 tube of approximately 1:10 dilution of chlorine bleach (chlorine bleach=5.25% Sodium Hypochlorite) in Rack1 Position1.
2. From the Routines Menu, select *End of Day* and follow the prompts.

This will completely disinfect the sample handling system.



End of Day Loading Window

3.2.3 Wash Probe

The "Wash Probe" option is used to decontaminate.

3.2.4 Prime Syringes

This option ensures the fluid path is full of water.

3.2.5 Plate Lights ON/OFF

Manually turns the plate lights on and off.

3.2.6 Reagent Mix ON/OFF

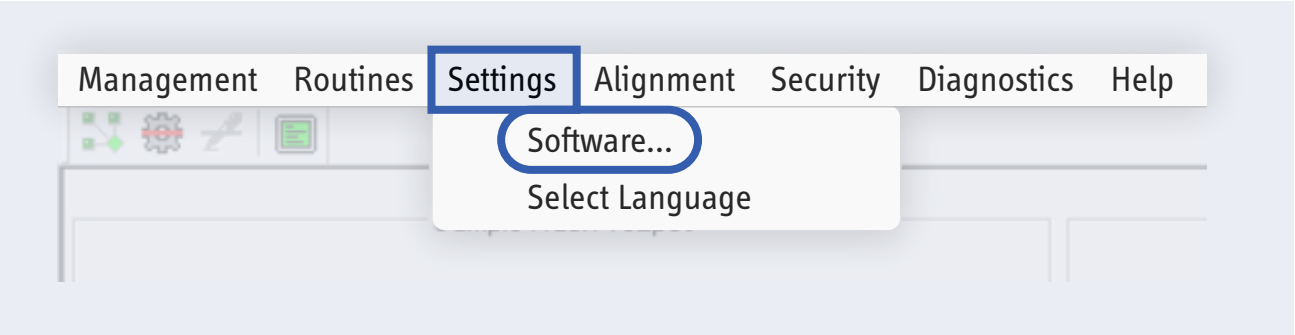
Manually turns the reagent mixing system on and off.

3.2.7 LEFT Plates Mix ON/OFF and RIGHT Plates Mix ON/OFF

Manually turns the plate mixer on and off.

3.3 SETTINGS

Selecting the Software option in the Settings Menu allows users to determine how long records are kept, adjust COM ports, import worklists, export results, arrange report appearance and to designate what information is included in reports. Only the **ADMIN** user role can enable these functions. All other roles should see these options grayed out.



Settings Menu > Software Option

3.3.1.1 Shrink Test Database

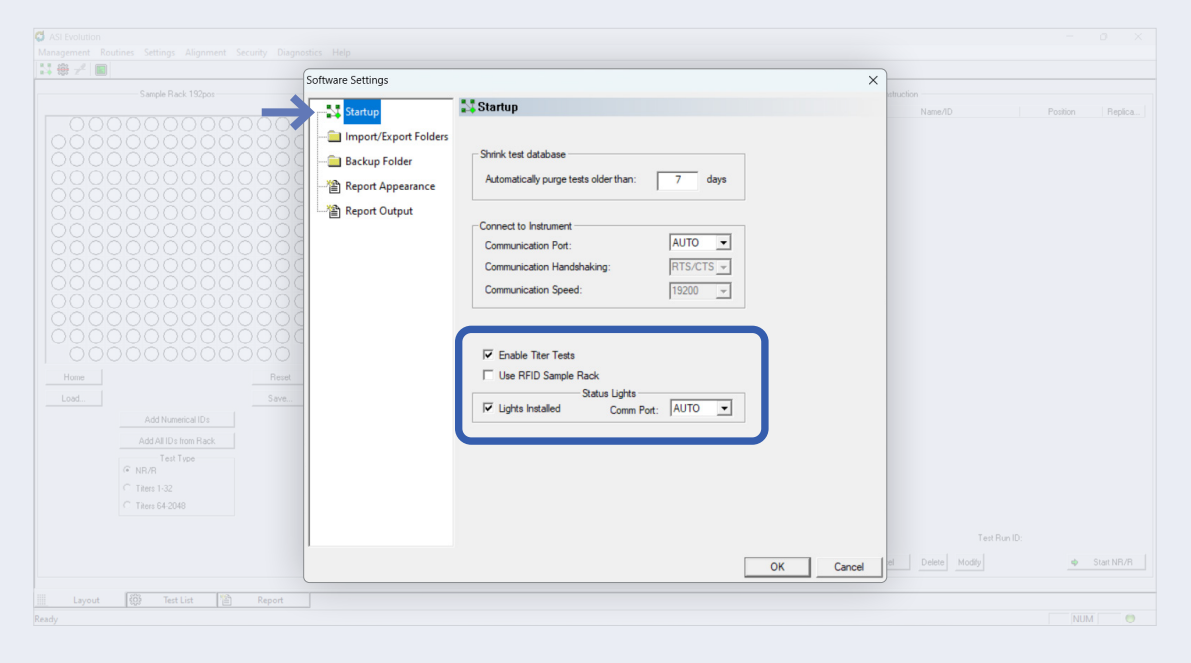
This feature allows users to decide how long to retain records. The database will automatically purge tests that are older than the retention setting. The default retention setting is 365 days, although the feature is designed to accommodate setting a retention range from 7 to 500 days. The Database Purge process will automatically execute every time the ASI Evolution software starts.

3.3.1.2 Connect to Instrument

This feature is automatically accomplished by the software. Laptop must be connected directly to the instrument.

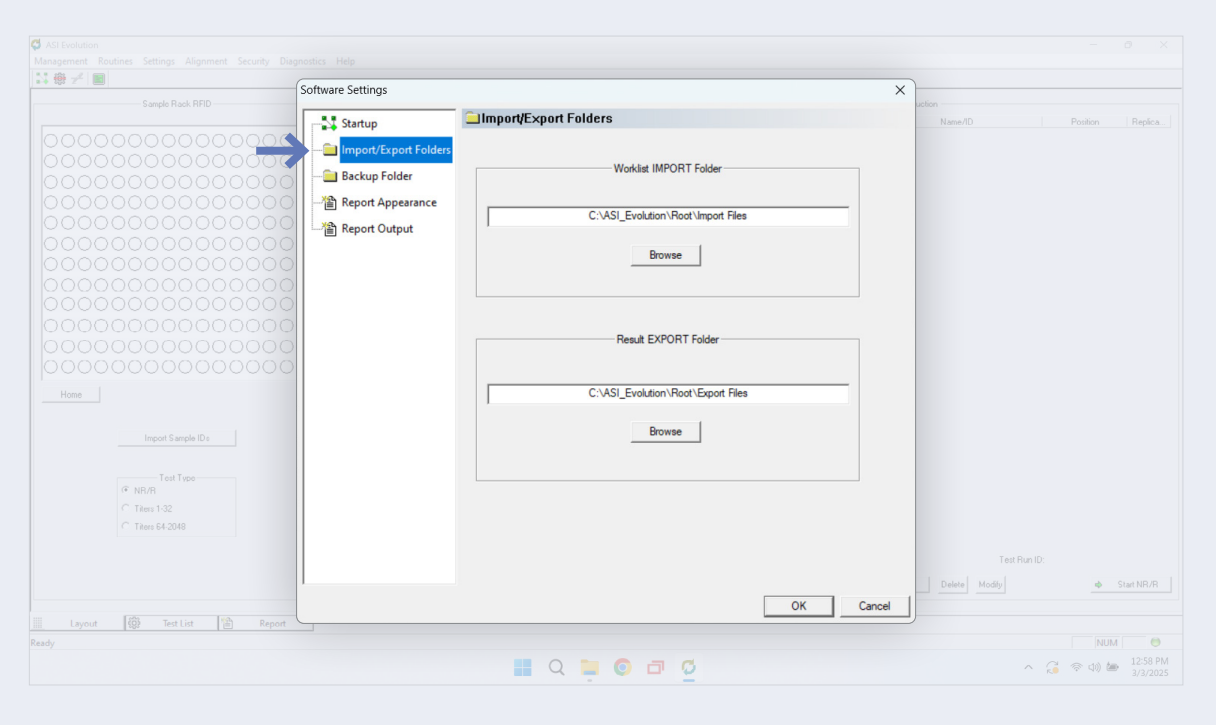
3.3.1.3 Enable Titer Tests

1. Ensure "Enable Titer Tests" is selected.
   - └— When running titrations "Use RFID rack" will not be selected. RFID rack refers to the Smart Rack system, which is unavailable for titration samples.
2. Select "Lights Installed" if unit is equipped with Status Light.



Software Settings > Startup Tab

3.3.2 Import/Export Folders Tab



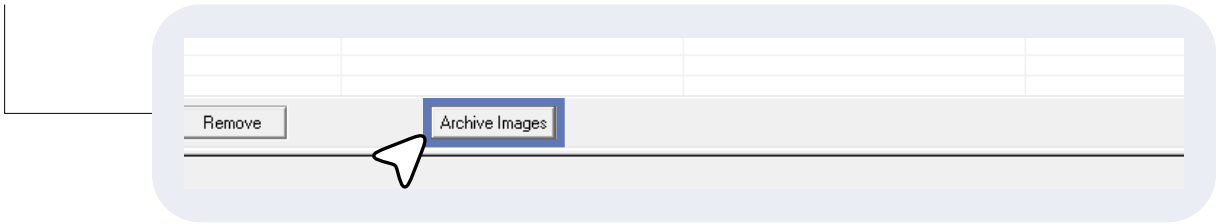
Software Settings > Import/Export Folders Tab

Files can be quickly imported from or exported to the ASI Evolution® SR root folder on the C: Drive of the computer being used to run the instrument.

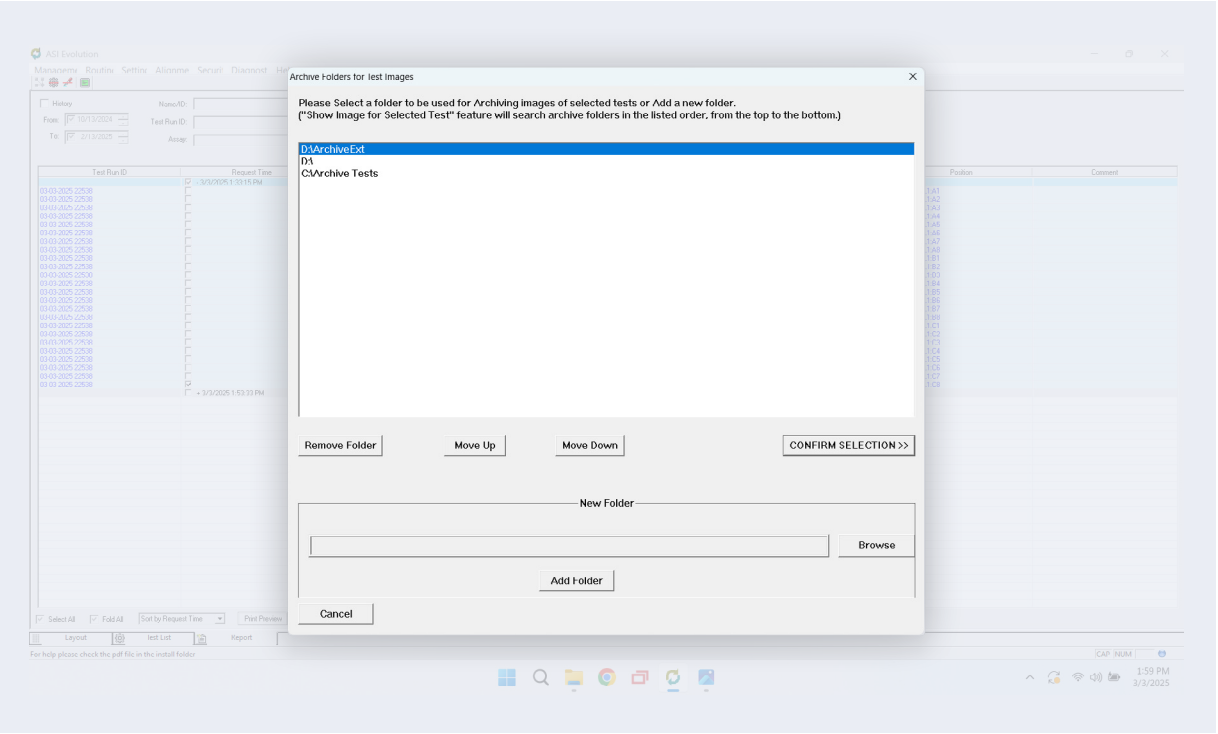
3.3.3 Archiving Images

Select the images to be archived.

Press the **“Archive Images”** button on the “Report” page.



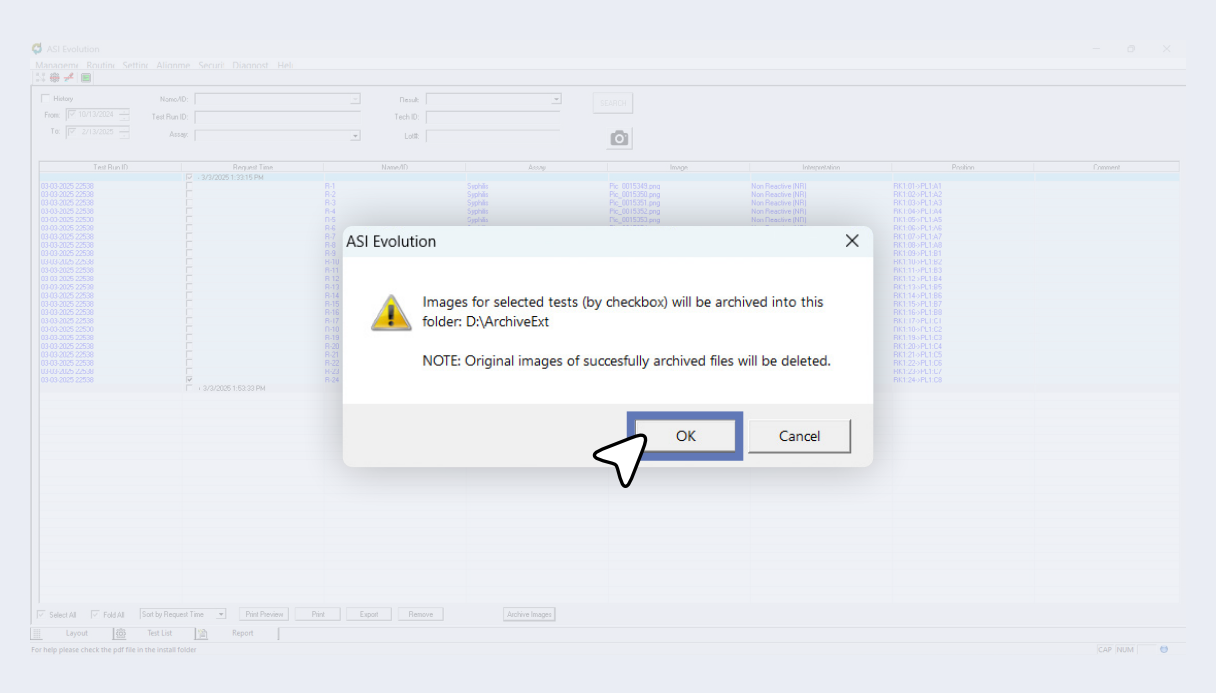
The following window will open:



Select the folder to archive the images to.

Add a new folder to the list of archive folders (those folders would probably be on the network).

- To add a new archive folder to the list use the “New Folder” group at the bottom part of the window. For simplicity/safety a folder can be selected only by the Browse button, cannot be typed in.
- Browse to selected folder, use the Add Folder button to add the folder to the list.
- Select a folder for archiving images of selected tests and click CONFIRM SELECTION.



Click OK, all existing pictures of selected tests will be copied to the selected archive under a new extended name. Extended name is comprised of Original Image Name + Instrument ID (Serial Number + ASI-Evolution) + Date_Time of tests request.

A message box was added after archiving is finished to tell the summary.

This message box contains the following information:

- Number of images that were archived (if any).
- Number of images that were chosen to be archived but were archived previously (if any).
- Number of images that were not found but belong to Rejected runs (if any).
- Number of images that were not found nor were previously archived (if any, should not happen).
- Number of images for which File Copy failed (archive folder does not exist or lacking privileges).

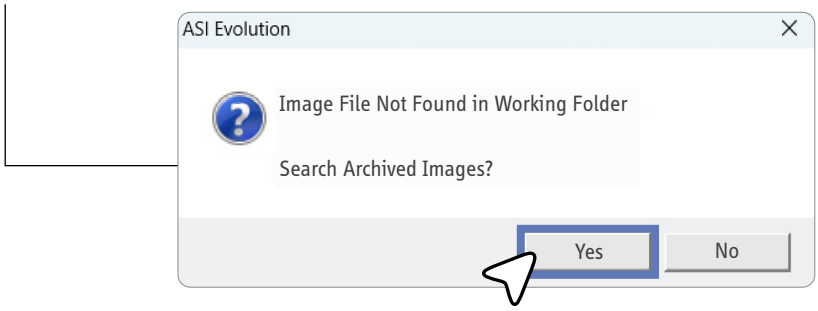
Viewing the archived images

Select a test for viewing (Report tab).

Click the Camera Icon (or double click on the test).

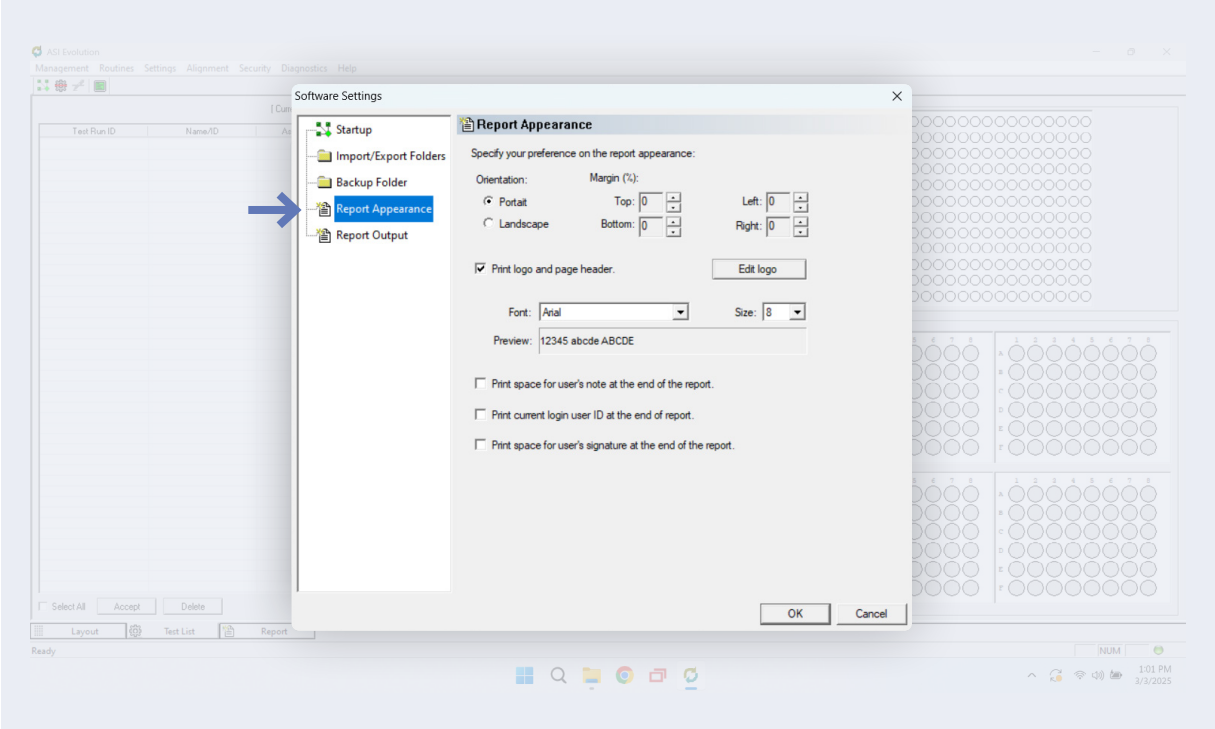
Software searches for the Image in folder “…Root\ImagesTests” folder.

- If not located, the following message box appears:



When you answer, click "Yes", software starts searching all archive folders for the image until it finds it (search is done from the topmost folder to the bottom). If the image is still not found, it is reported to the user.

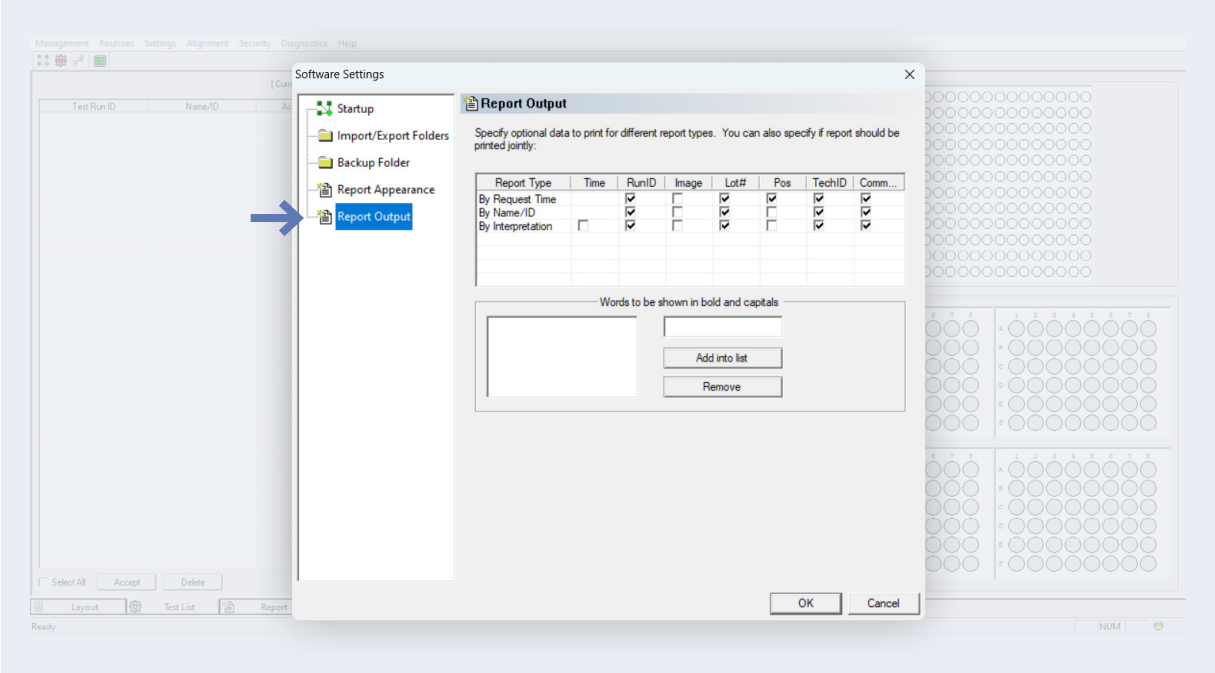
3.3.4 Report Appearance Tab



Software Settings > Report Appearance Tab

If using a custom logo, be sure the “Print logo and page header” is checked.

3.3.5 Report Output Tab



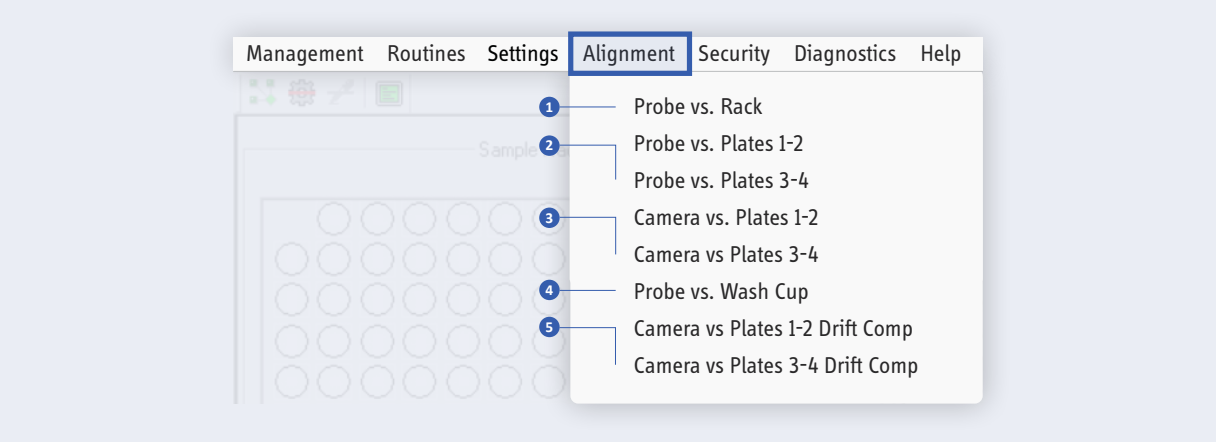
Software Settings > Report Output Tab

The Report Output allows users to designate what information is included in the Report Type.

3.4 ALIGNMENT

As part of the weekly maintenance, the instrument must be aligned and setup. Use the pro-cedures in this section to ensure that the instrument is ready to work properly. If probe is ever replaced, the following steps must performed.

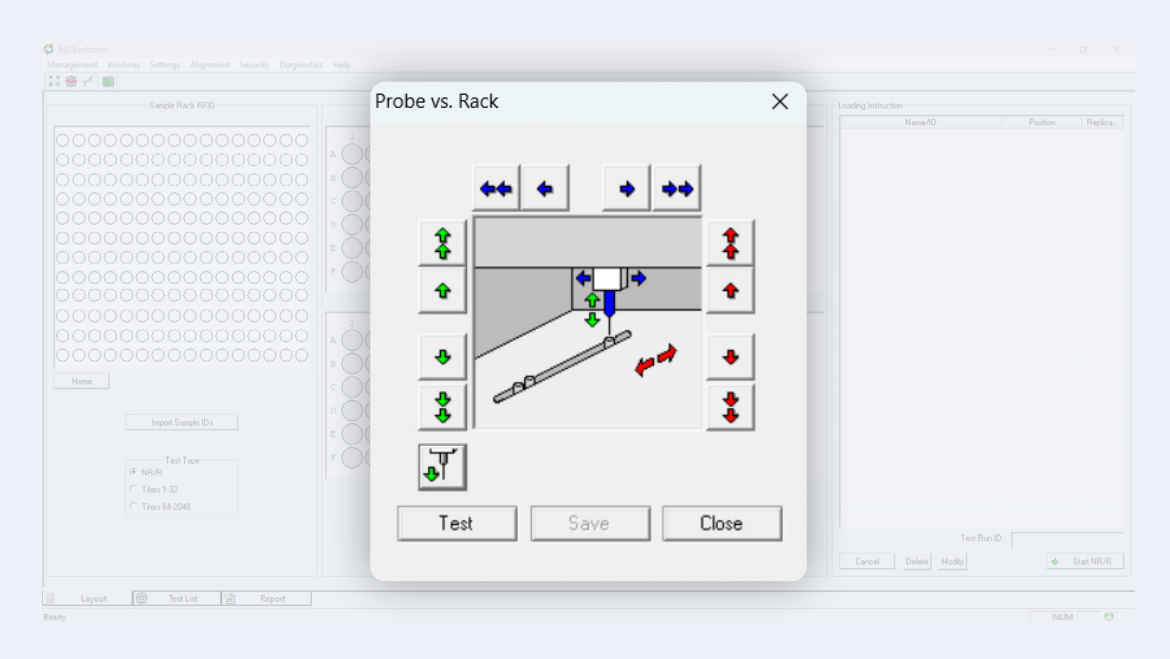
3.4.1 Alignment



Alignment Menu Options

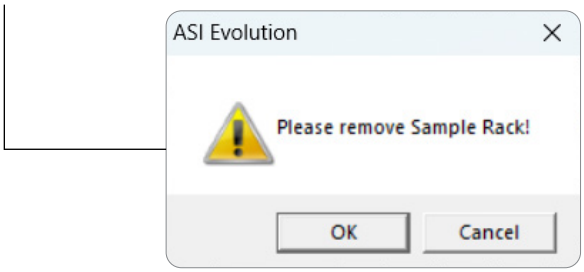
1 Probe vs. Rack

Select "Probe vs. Rack" from the Alignment menu.



Probe vs. Rack Dialog Window to Adust Probe Position

ⓘ *Be sure the Sample Rack is removed from the instrument.*



To check the current alignment, click the  probe button.

If needed, use the arrow buttons to position the probe directly over the rack locating pin.

Select **“Save”.**

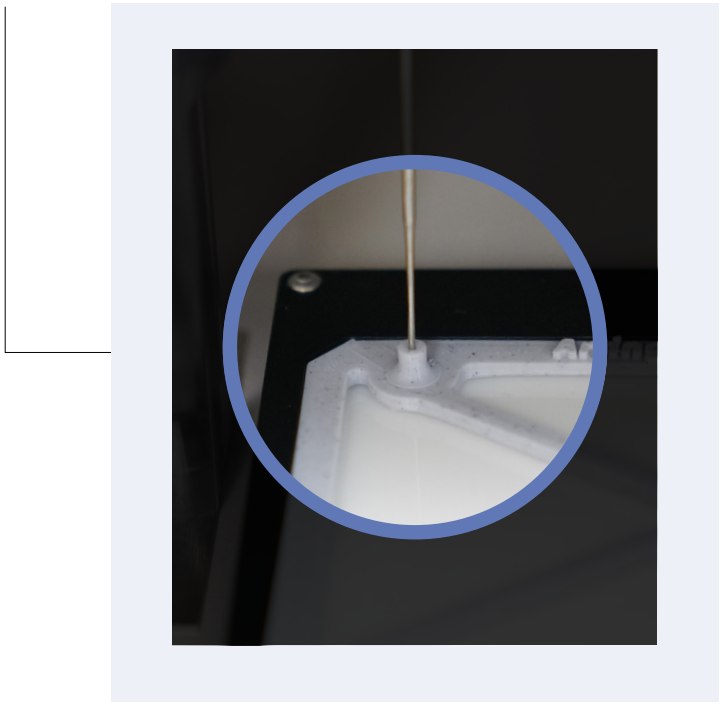
Select **“Test”** to confirm the alignment. Repeat procedure if necessary.

When finished, click **“Save”** and **“Close”.**

2 Probe vs. Plates 1-2*

Select "Probe vs. Plates 1-2" from the Alignment menu.

Insert the alignment jig into position 1 when prompted (left rear plate holder).



To check the current alignment, click the probe button ( ).

If needed, use the arrow buttons to center the probe tip in the jig.

Select **“Save”.**

Press **“Test”** to confirm the alignment.

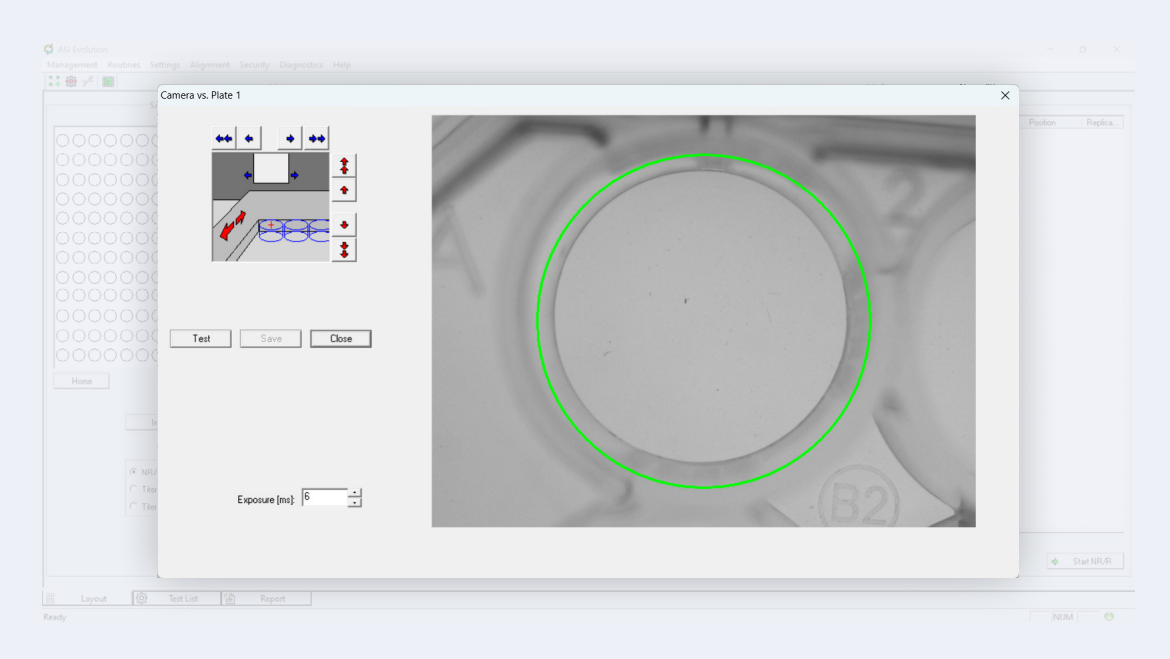
Repeat procedure if necessary.

When finished, click **“Save”** and **“Close”.**

***NOTE:** Be sure to complete these procedures for Plates 3-4.*

3 Camera vs. Plates 1-2*

To check the current alignment, select "Camera vs. Plates 1-2" from the Alignment menu.



Camera vs. Plates Dialog Window

ⓘ *Make sure that you have a well plate in the "Plate 1" position.*

If needed, use the arrow buttons to center the image within the green circle.

Select **"Save".**

Press **"Test"** to confirm the alignment.

Repeat procedure if necessary.

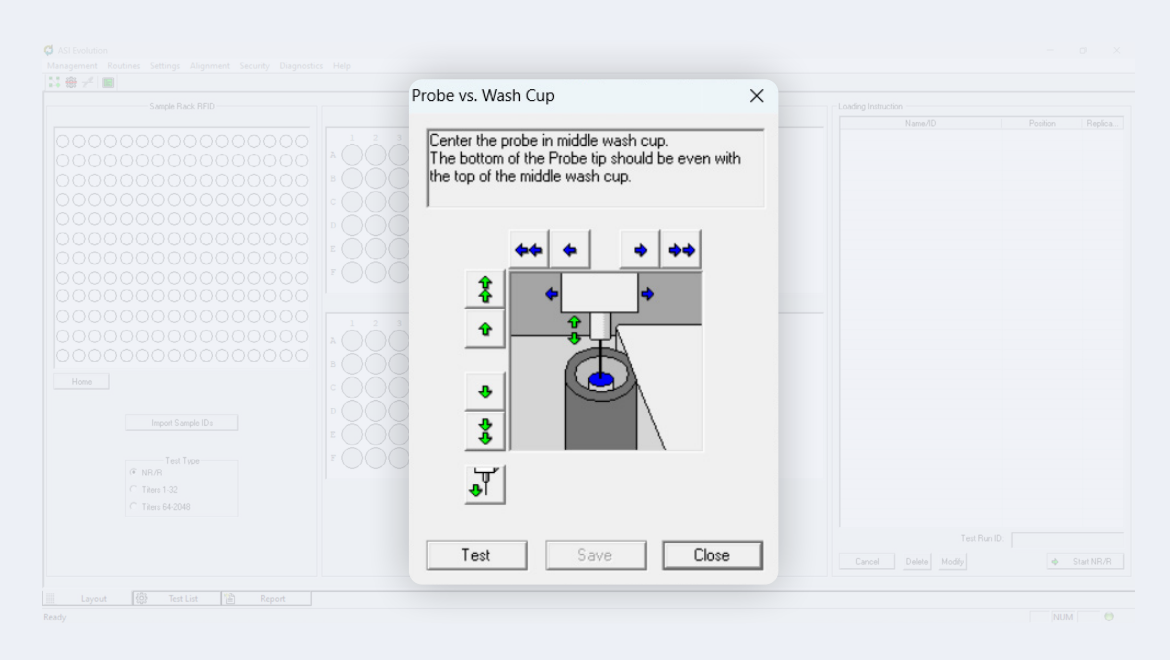
When finished, click **"Save"** and **"Close".**

***NOTE:** Be sure to complete these procedures for Plates 3-4.*

4 Probe vs. Wash Cup

The alignment for Reagent is set by the Wash Cup alignment.

Select "Probe vs. Wash Cup" from the Alignment menu.



Probe vs. Wash Cup Dialog Window

The probe tip should be centered in, and at the rim level of the small, center wash cup. The tip of the probe should be at the top of the wash well.

To check the current alignment, click the probe button ( ).

If needed, use the arrow buttons to center the probe tip.

Select **“Save”.**

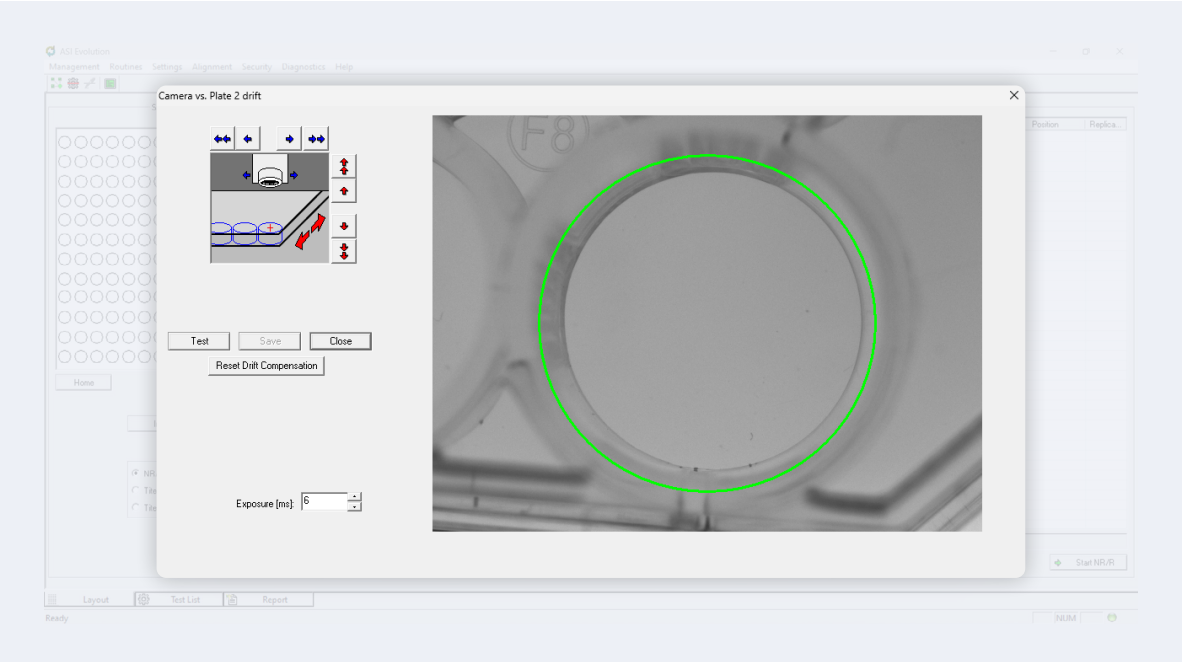
Select **“Test”** to confirm the alignment.

Repeat procedure if necessary.

When finished, click **“Save”** and **“Close”.**

5 Camera vs. Plates 1-2 Drift Comp*

To ensure alignment remains consistent/correct for drift offset, select "Camera vs. Plates 1-2 Drift Comp" from the Alignment menu.



Camera vs. Plates Drift Dialog Window

ⓘ *Make sure that you have a well plate in the "Plate 2" position when adjusting for the left tray and in the "Plate 4" position when adjusting for the right tray.*

Set Drift Compensation:

1. If needed, use the arrow buttons to center the image within the green circle.
2. Select **"Save".**
3. Press **"Test"** to confirm the alignment.
4. Repeat procedure if necessary.
5. When finished, click **"Save"** and **"Close".**

***NOTE:** Be sure to complete these procedures for Plates 3-4.*

3.4.2 Firmware Update

Firmware updates will be conducted by ASI Field Service Engineer.

www.nist.gov/calibrations/recommended-calibration-interval created January 07, 2010, updated August 25, 2016

3.5 SECURITY

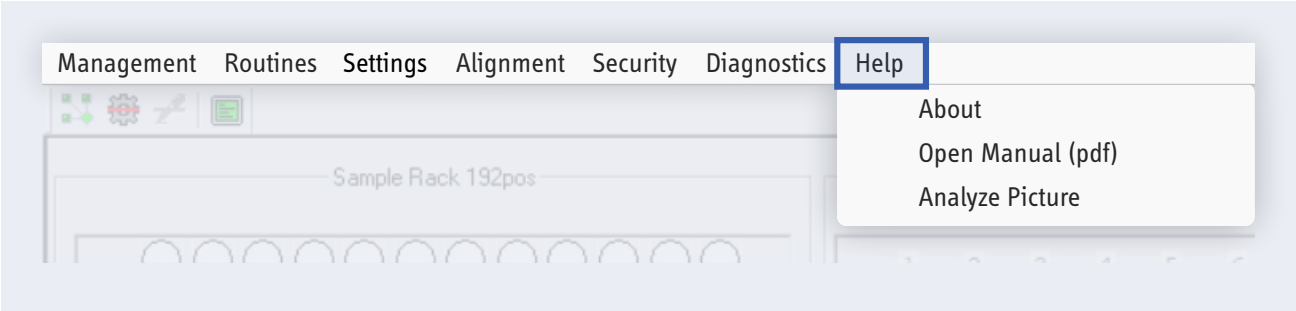
A user-based authentication system is implemented in the software, so only valid users can use the device to generate measurements and results.

1. **Log in as a different user**
   A. Changes user accounts
2. **Create new user**
   A. Add username/password
   B. Repeat for additional users
   C. Operator accounts can only be created by a Manager account. If required to create a Manager account, please contact customer support.
3. **Remover user**
   A. Removes selected user account
4. **Change Password**
   A. Select user for password change
5. **Show all users**
   A. Allows customer to see all accounts created
6. **Who is logged in**
   A. Shows current user account that is operating the ASI Evolution®
7. **View log file**
   A. Shows timestamp of when users log into the system

Function	Manager	Operator
Disable Security - When Disable is checked, the password protection and security restrictions are not being used.	N	N
Enable Security - When Enabled is checked, the password protection and security restrictions are being used.	N	N
Create or Remove a Manager	N	N
Create or Remove a User	Y	N
Change a Password - Any level can use this feature to change their password.	Y	Y
View Log File - Displays a text file of user logins including the date, the time, and anything that has been modified.	Y	Y

Security Levels

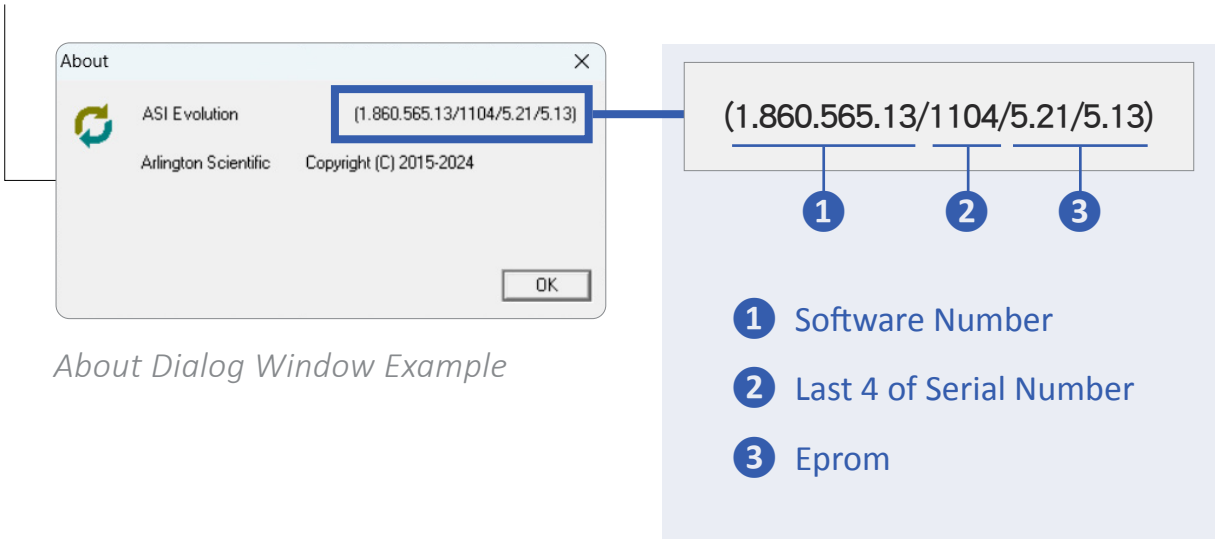
3.6 HELP



Help Tab Options

3.6.1 About

The About selection will open a window and display the version of software and firmware being used with your instrument.



About Dialog Window Example

3.6.2 Open Manual (pdf)

"Open Manual (pdf)" opens a copy of the operator's manual.

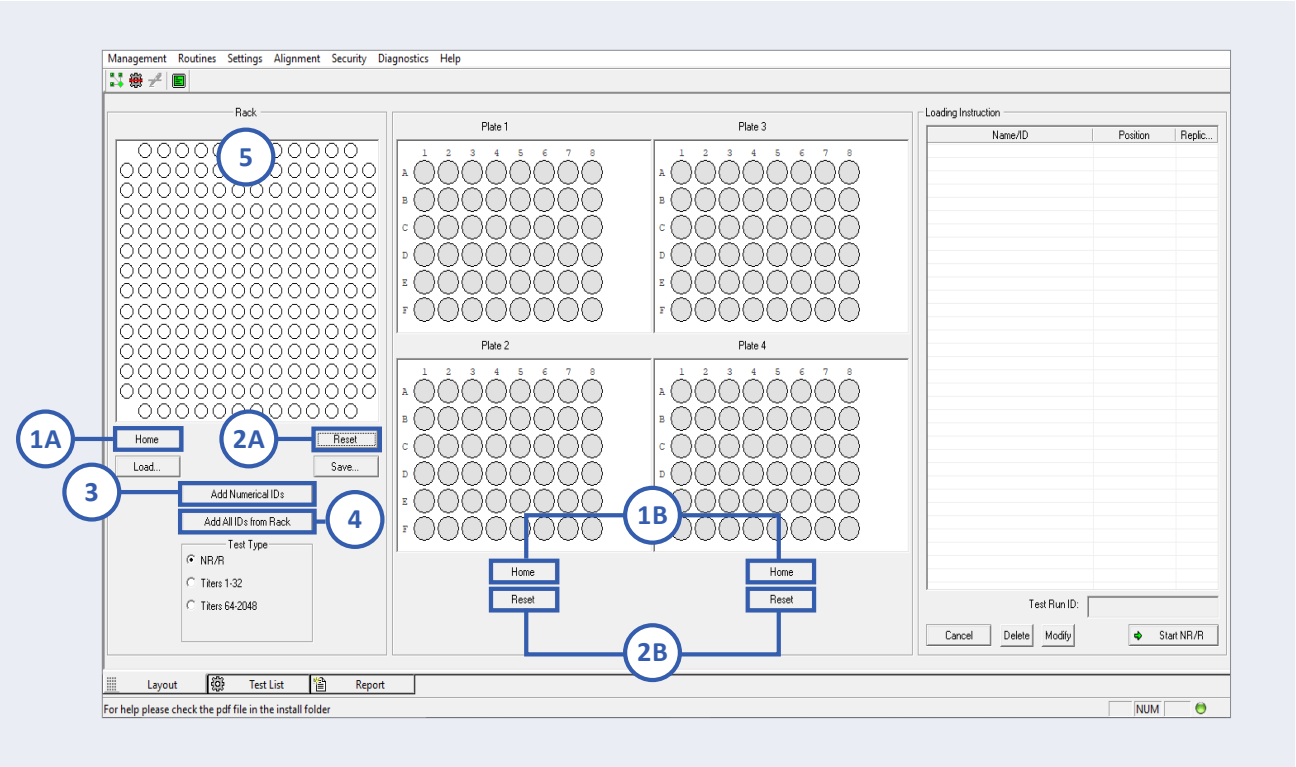
3.6.3 Analyze Picture

"Analyze Picture" is to be used by an ASI Field Service Engineer.

4.0 ASI Evolution® SR Manager

4.1 LAYOUT TAB

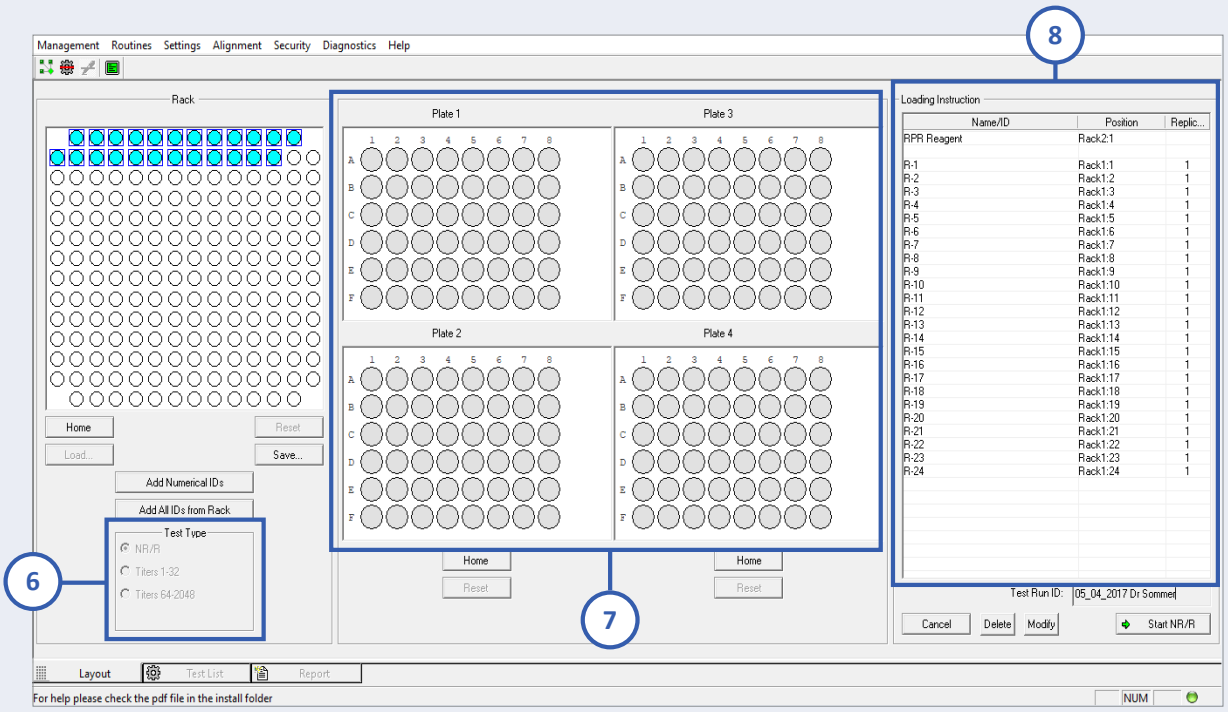
The default window, which is open when the user starts the software, is the **Layout Tab.**



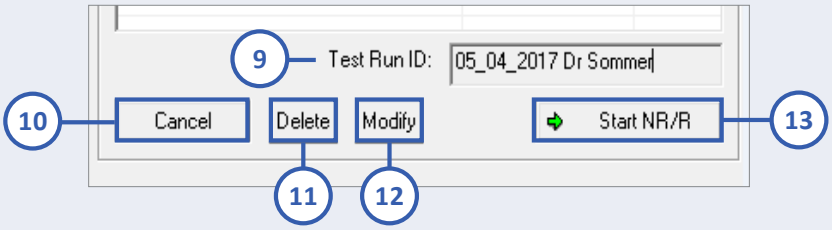
Layout Tab

This window displays the current status of the instrument, including currently loaded rack and plates. The software automatically keeps track of which wells in the reaction plate have been used.

Layout Tab Window Options		
ITEM #	**FEATURE**	**DESCRIPTION**
1A or 1B	Home Rack and Home Plate(s)	Use this button to return the Sample rack or plates to the home positions.
2A or 2B	Reset Rack and Reset Plate(s)	Reset is not accessible when there are items in the Loading Instruction screen. Use the Cancel button to clear any items. Selecting this option will reset the Sample rack and each of the plates as clean. Verify that the positions are clean.
3	Add Numerical IDs	This option is used to manually enter the number of samples to be read.
4	Add All IDs from Rack	The Sample IDs from the Rack are added to the Loading Instructions window with this button.
5	Rack	Be sure to place patient samples in the correct location by referencing the Loading Instructions.



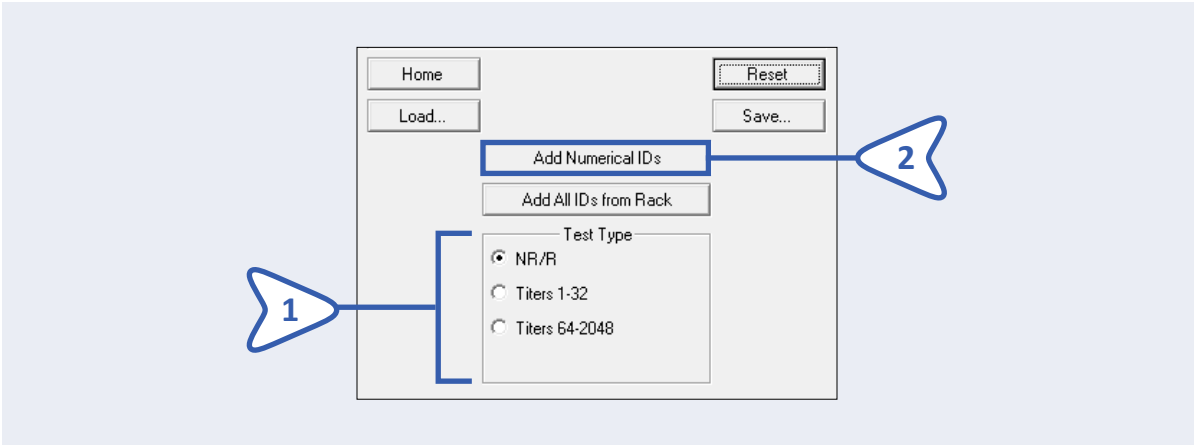
6	Test Type	NR/R – Runs a nonreactive/reactive sample determination.
7	Plates (1, 2, 3, 4)	Plates 1 and 2 and Plates 3 and 4 are to be placed in the designated locations in the instrument.
8	Loading Instructions	Specifies the Test Run ID and locations to load the samples in the rack.



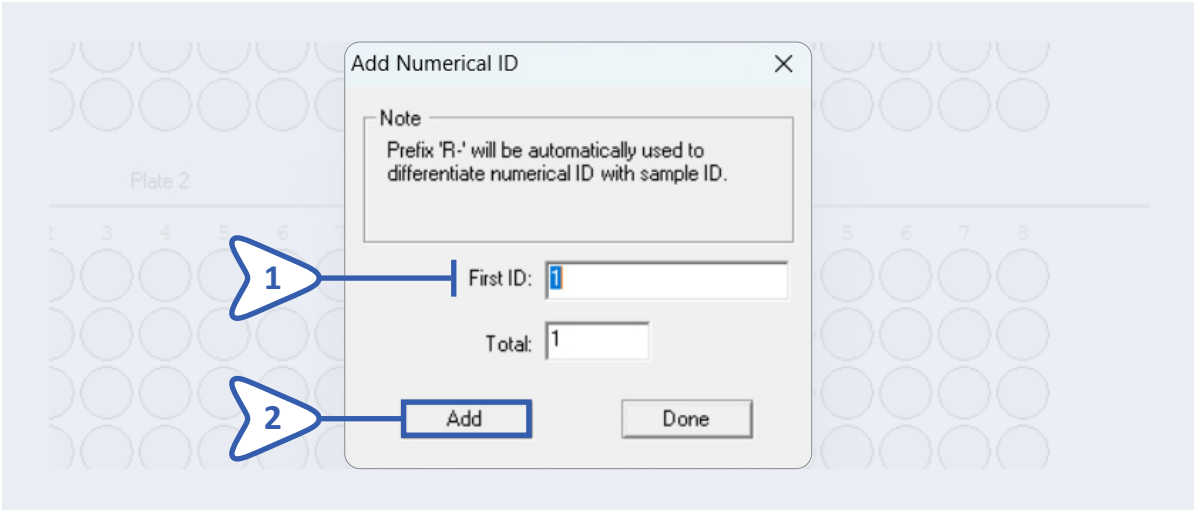
9	Test Run ID	Data can be entered manually; it is loaded automatically when using Import File.
10	Cancel	This will clear all items located in the Loading Instructions screen.
11	Delete	Items can be removed from the Loading Instructions using this button.
12	Modify	Individual patient names/IDs can be manually changed.
13	Start NR/R Start TITERS	Starts the test to run. NOTE: Tests will not run until the software prompt regarding closed status of the shield has been verified

4.2 Test Protocol (Qualitative)

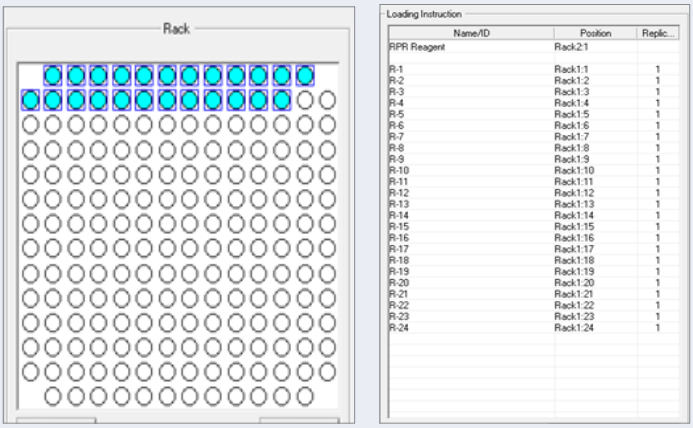
4.2.1 In the Layout tab select your test type by clicking the corresponding radial button (1), then begin to create a worklist by clicking on the “Add Numerical IDs” button (2).



4.2.2 Enter the Sample ID by typing the Sample ID number or scanning a barcode into the “First ID” box (1). If you are manually typing the sample ID’s, press enter or the “Add” button (2) to add the sample to the worklist. If you are scanning barcodes, it will automatically add the sample to the worklist.



4.2.3 – When a Sample ID is entered the position on the sample rack will be highlighted in “blue” to designate the proper position in the rack to place the sample. The position is also listed in the “Loading Instructions” area

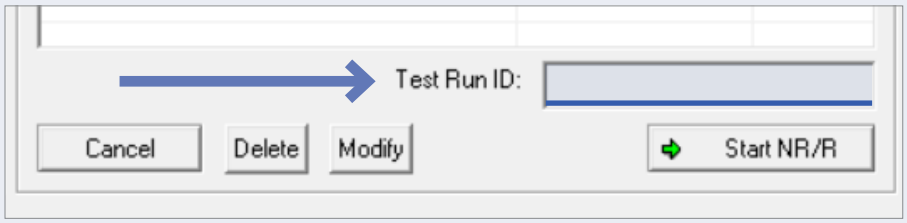


4.2.4 Continue to enter Sample ID numbers until all samples are loaded or a total of 192 samples have been entered into the work list. Once all samples have been added, press the "Done" button to finish creating worklist.

ⓘ ***Note:*** *Do not add more numerical ID/Sample ID's than available wells!*

ⓘ ***Note:*** *If using an ASI Smart Rack System, refer to the ASI Smart Rack Operators Manual for loading instructions.*

4.2.5 Enter a Test Run ID/name in the window at the bottom of the "Loading Instructions" window.



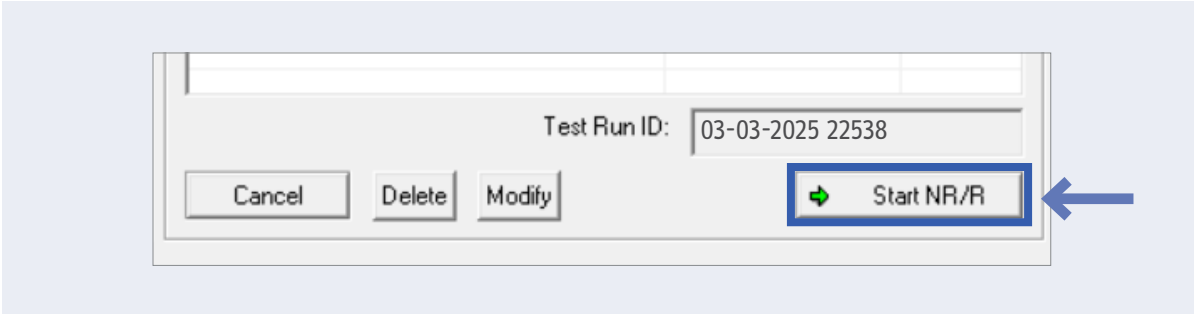
ⓘ ***Note:*** *To import a test list, click "Import" under the "Management" Menu located in the top left corner of the program and select your created .txt or .csv worklist. This will automatically populate the sample positions into the sample rack and the worklist ID (See Section 4.1 Management Menu).*

ⓘ ***Note:*** *When creating worklists outside of the software, remember not to add more samples to the worklist then there are available wells.*

4.2.6 Vigorously agitate (DO NOT VORTEX) the carbon antigen for 20-30 seconds before placing the vial into the reagent rack. Remove cap from bottle.

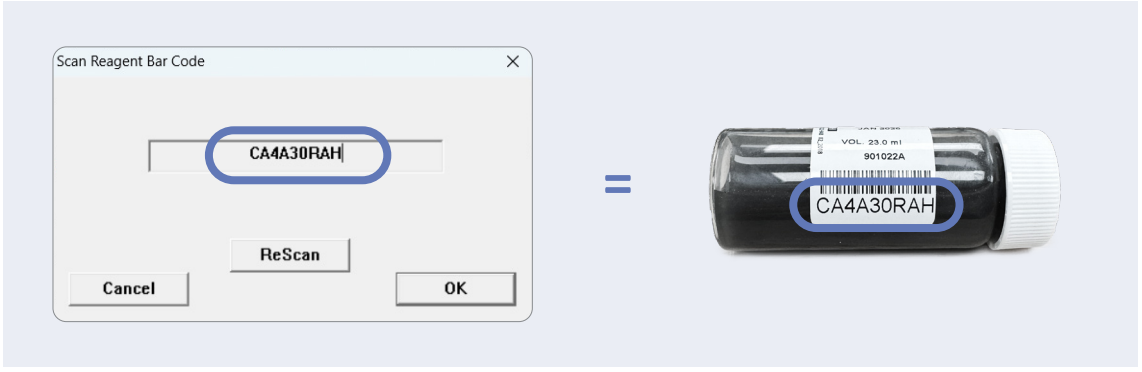
ⓘ ***Note:*** *Ensure that there is a stir bar in the vial. The carbon antigen will mix automatically once the assay starts.*

4.2.7 Press “Start NR/R” (or other selected test type) button located on the bottom of the right column and the instrument will begin tests.

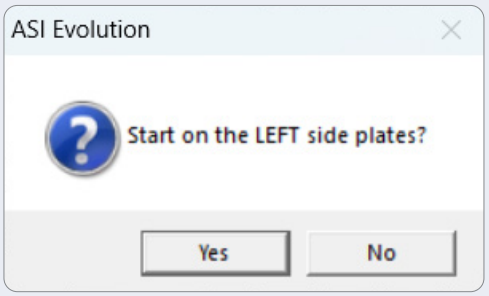


4.2.8 You will need to scan or rescan the barcode of the Carbon Reagent for every run.

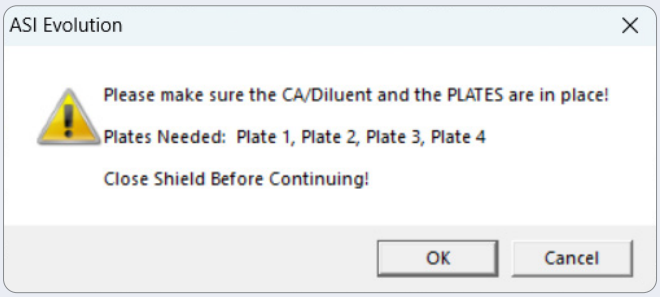
❗ Confirm barcode displayed matches lot number on bottle label.



4.2.9 To start test on Left side plate, Select **Yes**, to start test on Right side plate, Select **No**.

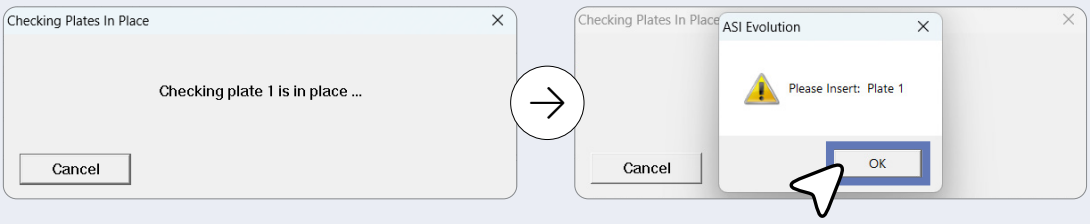


4.2.10 Ensure that the Carbon Antigen and the PLATES are in their correct location for test run. Diaglog box states number of plates needed. Ensure that reagent caps have been removed. Close the "Shield" of the ASI Evolution® SR and select **OK** to continue.



ⓘ ***Note:*** *The "Shield" must be closed during the assay.*

4.2.11 The instrument will scan each plate location to ensure ASI Plates are in place. If no plate is detected, the operator will be prompted to insert ASI Plates into the instrument. Place any missing ASI Plates into the instrument and click **OK.**



Quality control requirements *must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact ASI Technical Support at 800-654-0146 or service@arlingtonscientific.com.*

4.2.12 ASI Evolution Testing Process (192 Samples):

A. The analyzer dispenses 24 samples into the first half of Plate 1. Then Plate 1 will perform a fast rotation to spread the samples evenly in the wells. Next, Carbon Antigen will be dispensed into each of the 24 wells in the first half of Plate 1 followed by a slow incubation rotation of 7 minutes for Plate 1.

B. The analyzer will then begin the same process for the first half of Plate 3. Once the samples and Carbon Antigen are dispensed into the first 24 wells of Plate 3 and the slow incubation rotation begins, Plate 1's incubation will be complete, and the analyzer will begin to read the first 24 wells on Plate 1.

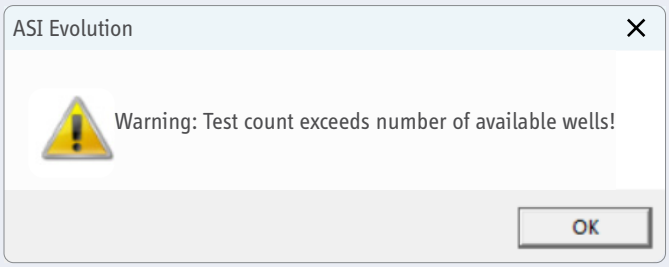
C. Immediately after the analyzer reads the first 24 wells on Plate 1 it will then dispense samples into the last 24 wells of Plate 1. Then analyzer will follow the same process to finish Plate 3 and then move on to Plate 2 and Plate 4. This process optimizes throughput.

4.2.13 On Layout Tab, after the completion of a test run of 192 samples:

A. "Reset" any of the Plates used in the previous Test Run.

B. "Reset" Sample Rack used in the previous Test Run.

C. If the operator does not "Reset" the Plates used in the previous Test Run but does "Reset" the Sample Rack and creates a new Worklist the ASI Evolution Software the following warning message dialog box is displayed:



4.2.14 On Layout Tab, after the completion of a previous sample test run where not all the wells available on the Plates were used and the operator inputs a sample worklist that exceeds the number of available wells that remain on Plates for testing process:

A. The analyzer will test the number of samples in the new worklist to match the number of available wells.

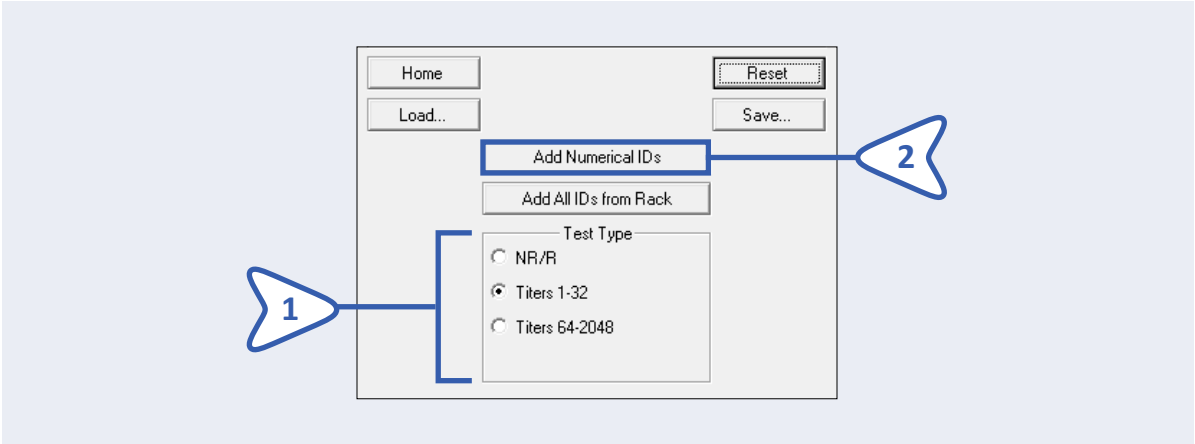
B. The analyzer will display a warning message “Insufficient number of available wells”.

ⓘ ***NOTE:*** *If either the left side (Plate 1 and Plate 2) or right side (Plate 3 and Plate 4) become filled due to subsequent test runs of 24 samples or less while the other side has more than 24 available wells, trying to run a test run of more than 24 samples will not work due to the process of only running 24 samples on each side per incubation cycle. Due to the unavailable wells on the filled side, the analyzer will only be able to run 24 samples on the unfilled side even though there may be more available wells on that side. This will result in any samples after the 24 that are dispensed not being run. These samples will need to be run on a new test run.*

4.3 Test Protocol (Semiquantitative)

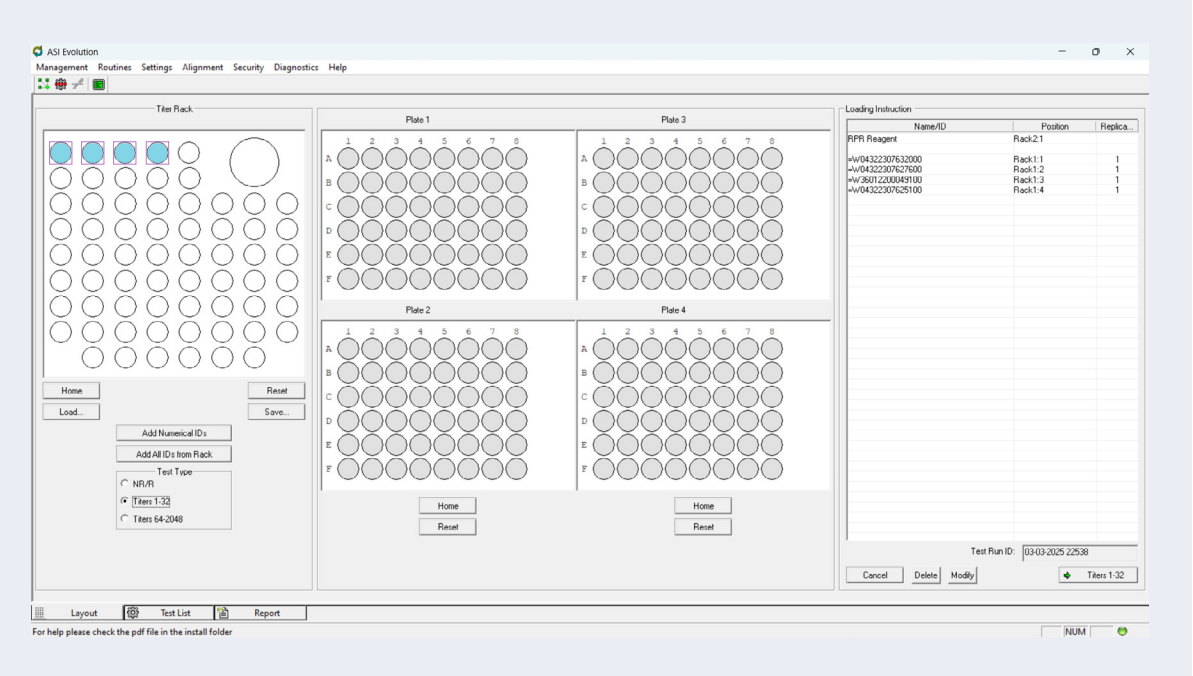
4.3.1 If steps 1 and 2 have already been performed for the day they do not need to be repeated.

4.3.2 In the Layout tab select your test type by clicking the corresponding button (1), then begin to create a worklist by clicking on the “Add Numerical IDs” button (2).



4.3.3 Enter the Sample ID by typing the Sample ID number or scanning a barcode.

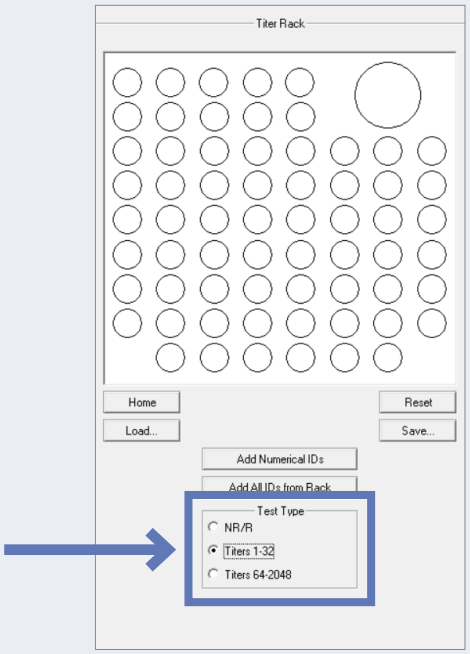
4.3.4 When a Sample ID is entered the position on the sample rack will be highlighted in “blue” to designate the proper position in the rack to place the sample. The position is also listed in the “Loading Instructions” area.



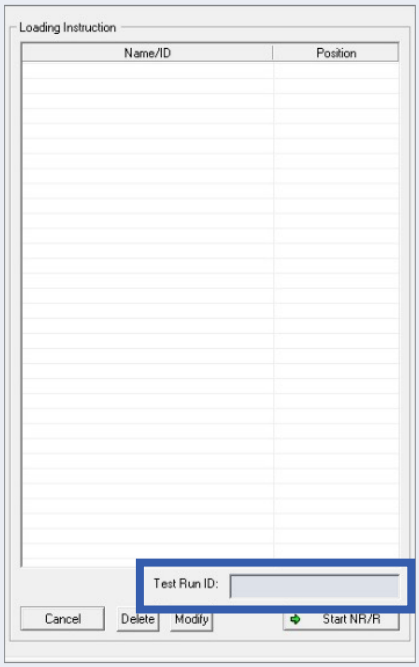
4.3.5 Continue to enter Sample ID numbers until all samples are loaded or a total of 32 samples have been entered into the work list.

ⓘ ***Note:*** *The maximum samples in a work list are 32*

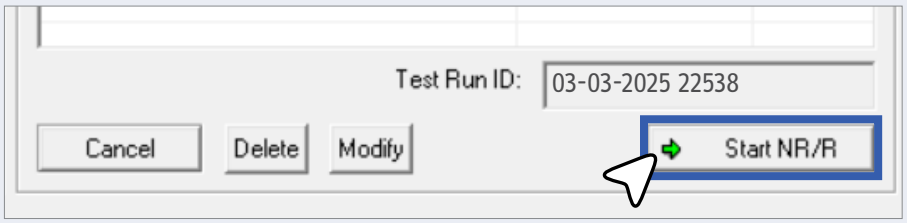
4.3.6 Choose the test type – Titers for semiquantitative testing.



4.3.7 Enter a worklist ID/name in the window at the bottom of the "Loading Instructions" window.



4.3.8 Press **Start NR/R.**



Scan Reagent barcode by using internal barcode scanner or hand scanner.

- Barcode displayed must match barcode on bottle.

Note: *The "Shield" must be closed during the assay.*

4.3.9 Vigorously agitate the carbon antigen for 20-30 seconds before placing the vial into the reagent rack. *(Do Not Vortex)* Remove the bottle cap.

Note: *Ensure that the stir bar is in the vial.*

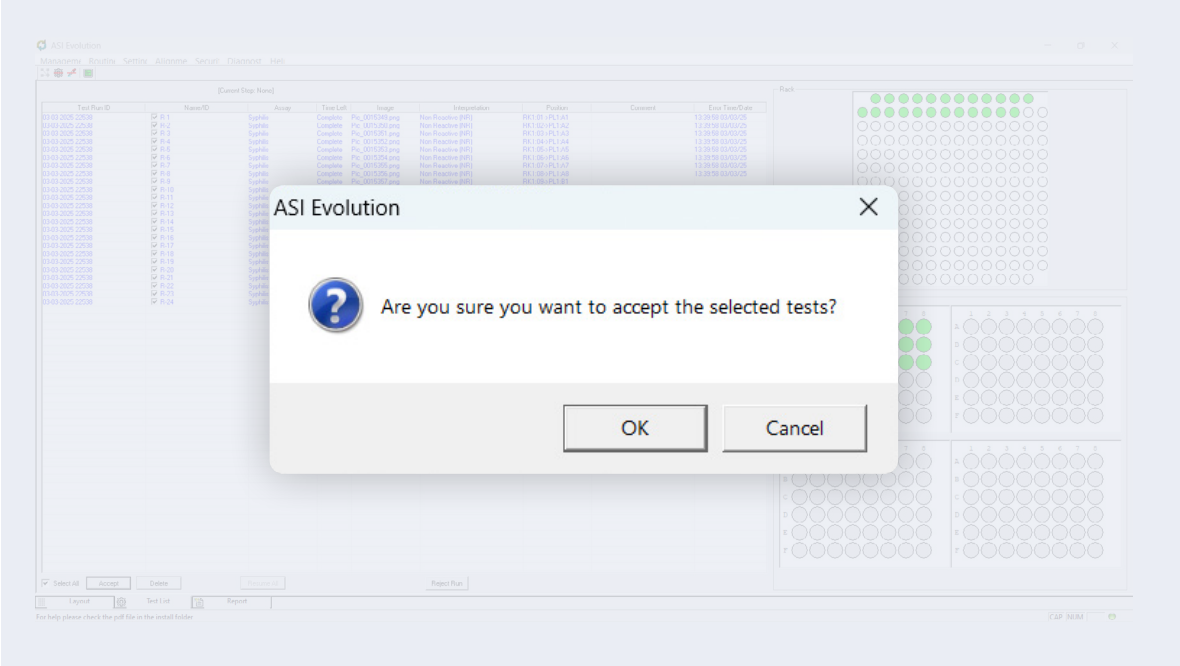
The carbon antigen will mix automatically once the assay starts.

4.3.10 Close the "Shield" of the ASI Evolution® SR.

- The assay will start only after the software prompts regarding status of the "Shield" is closed has been answered in the affirmative.

4.3.11 The instrument will scan each plate location to ensure ASI Plates are in place. If no plate is detected, the operator will be prompted to insert ASI Plates into the instrument. Place any missing ASI Plates into the instrument and click **OK.**

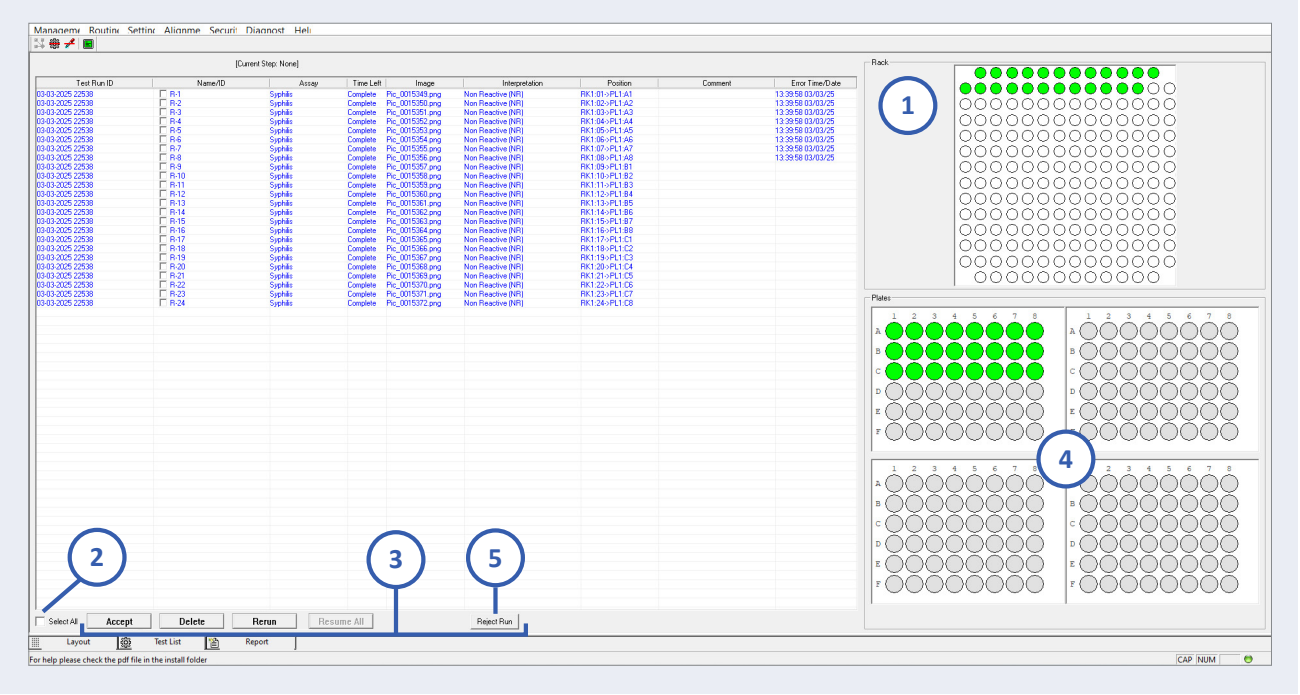
4.3.12 At the completion of the run review and accept or reject the results. Any images deleted cannot be retrieved.



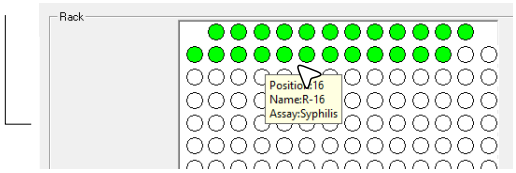
4.3.13 Dispose of used test plates in accordance with federal (40 CFR 261.3), state, local or Good Laboratory Practice requirements.

4.3.14 Interpretation of Results: The endpoint titer (1:1–1:2048) is equivalent to the last well that gave a reactive result.

4.4 Test List Tab

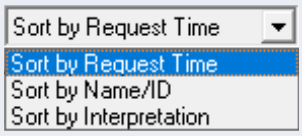


Test List Tab

Test List Tab Options		
ITEM #	**FEATURE**	**DESCRIPTION**
1	Rack	Indicates the location of patient samples. For more information on a substance, highlight it with the mouse cursor. 
2	Select All	Selects all the entries in the list. Items may also be selected individually.
3	Action buttons	Click 'Accept' to accept the results of the selected ID. Use 'Delete' to discard the selected ID Use 'Rerun' to reprocess selected samples from the test list. Choose 'Resume All' to continue the tests. Use 'Reject Run' to reject all tests (see "Reject Run" below) *NOTE: Results must be accepted to allow them to be viewed in the Report Tab.*
4	Plates	Shows positions of the used wells.
5	Reject Run	The "Reject Run" Button only enables the operator to Reject an entire Test Run and not individual Sample ID's. The "Reject Run" process will remove the rejected Test Run from the Test List Matrix and populate the rejected Test Run on the Report Tab with "Reject" in the "Interpretation" column and will be allowed to be printed via standard report layouts. If rejected, no completed results will be available.

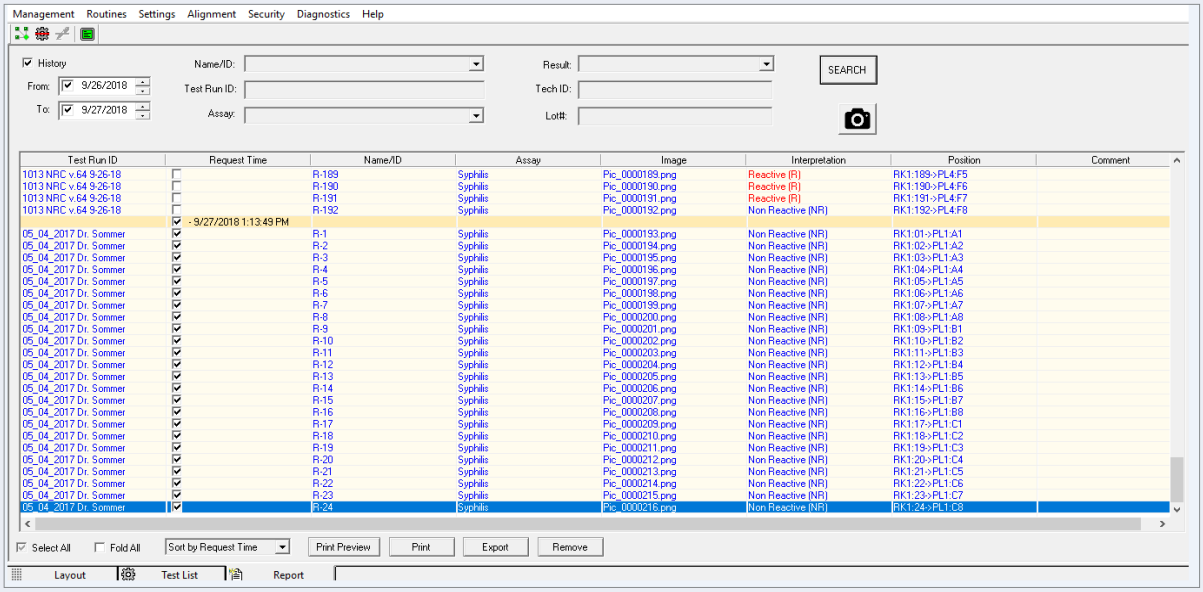
4.5 Report Tab

By default, the Report Tab shows the information from the most recent test run.



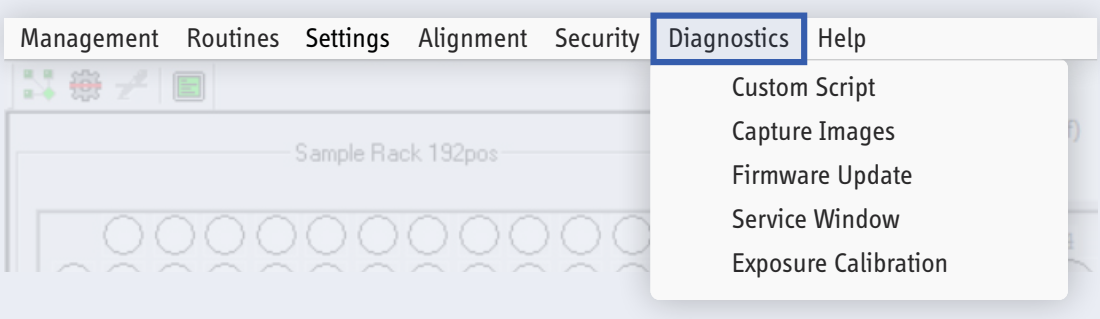
Results may be sorted by Request Time, Name/ID, or Interpretation.

Select the Camera Icon or double click on a result to open Windows Photo Viewer in order to display a captured well image.



5.0 Diagnostics

These selections are password protected. Options are not accessible. Diagnostics are to be conducted by an ASI Field Service Engineer.



6.0 Report Tab

Possible Insufficient Aspiration can be caused by:

❶ Reagent bottles filled past the neck. ❷ Bubbles in the reagent. ❸ Foam on top of the reagent.

⚠ CAUTION! ⚠

Use only the reagent container provided.

Do not over fill.

Do not mix different lots of reagent.

6.1 ERROR MESSAGES

Error messages are displayed when the instrument fails to operate correctly. They are intended to help the operator locate the problem. If error messages appear frequently, a hardware problem is usually indicated.

Error Code	Problem	Solution
001	'Unknown command'	Check command for spelling and validity
002	'Parameter exceeds allowed range'	
003	'Too few or wrong parameter(s)'	
004	'Command has not been implemented'	
005	'Fluid has not been detected in range'	Ensure sample volume is 400 µL or greater.
006	'Probe Z axis is jammed' or 'Probe Z is jammed'; The motor stalled while the instrument was attempting to move the probe in the Z direction.	Check for mechanical obstructions or broken belts. Check motor driver U27 and associated logic. Check the sensors. Make sure the transistor and LED are aligned.
007	'Probe X axis is jammed' or 'Probe X is jammed'; the motor stalled while the instrument was attempting to move the probe in the X direction.	Check for mechanical obstructions or broken belts. Check motor driver U23 and associated logic. Check the sensors. Make sure the transistor and LED are aligned.
010	Diluter not acknowledging	Check the cable that plugs in the back of the diluter
011	CSI/O Inactive	Unable to communicate with coprocessor.

012		'Incorrect length for Move All command'
013	Timeout waiting for coprocessor message	Make sure that the serial cable is firmly connected to both the computer and the Instrument. Use the cable (and adapter, if needed) provided with the instrument.
014	Diluter not responding	Make sure the Instrument is powered up.
015	Timeout waiting for completion of last coprocessor command	See Error Code 013
016	Check reagent/sample level!	Check levels
017		"Probe dip too large!"
018	Probe sensor malfunction	A problem exists with fluid sensing circuitry.
019	Parameter checksum error	See Error Code 013
020	Probe jammed while trying to detect the liquid surface	Make sure you have the proper size bottle (not too small or tapered). Check that the cap has been removed from the bottle. Try adding more reagent. Check the probe depth setting for the rack in Instrument Setup. If "Probe Z jam while detecting" is issued for sample, the test is skipped and is put into interpretation.
022	Large syringe stroke error	A volume greater than syringe capability was attempted. Select the Routines tab from the manager menu and click on the Wash Probe option to reset the syringe position.
023		General message from firmware (direct message)
024		Eeprom chip bad or missing
80	EEPROM Error	EEPROM error. If the error occurs once, the instrument usually fixes it automatically. If the error occurs repeatedly, there might be a hardware issue. Call technical support.
90	I2C Error	I2C error. If the error occurs once, restart the instrument. If the error occurs repeatedly, call technical support.
119	Packet: No Response	This occurs if the main processor cannot communicate with one of the modules. (Most commonly, this error occurs if the sample rack is not present. It will report that there is no response from module S)
120	MC: Abort Timeout	If one of the mover modules is busy for a long time and does not respond, this error is reported. Restart the instrument and check if the error occurs again. If error occurs repeatedly, contact technical support.
121	Plate Mix Left: Speed Out of Range	The error occurs if the measured left plate mix RPM is less than 10 or more than 10 of the target RPM. Eg: If default target RPM of 140 is used, then error occurs if measured RPM < 130 or RPM >150.

122	Plate Mix Right: Speed Out of Range	The error occurs if the measured right plate mix RPM is less than 10 or more than 10 of the target RPM. Eg: If default target RPM of 140 is used, then error occurs if measured RPM < 130 or RPM >150.
302	Plate Side Invalid	Occurs if software sends a bad command with incorrect plate side.
350	Command Parsing Error	Occurs if software sends a bad command with incorrect arguments. Must be fixed in the software
351	Command Argument Error	Occurs if software sends a bad command with incorrect arguments. Must be fixed in the software.
502		'Too few parameters
503		'Command has not been implemented'
507		Unknown coprocessor command'
628	Barcode Not Initialized	Issue with barcode scanner initialization during startup. Check barcode scanner and its connections.

Mover Errors (= MoverId*1000 + Error Code)		
Error Code	**Problem**	**Solution**
900	Mover: Mech Jam Stuck	Mover is jammed and could not move and reach destination. Check mechanical obstructions or broken belts.
901	Mover: Mech Jam, Long Running	Mover maybe jammed and took long time to move before giving up. Destination could not be reached. Check mechanical obstructions or broken belts.
902	Mover: Mech Jam, End Limit	The end sensor was reached. Can occur in probe X, rack or wash.
906	Mover: Command Exceeds Range	Occurs if destination position in the command is greater than the maximum allowed position
907	Mover: Timeout	Occurs if the main processor cannot receive a response from the mover about the result of the move.
910	Mover: Missed Steps At Home	The number of steps it took to move away from home sensor and then back to home sensor was different and was outside the allowed range.
915	Mover: Encoder Based Position Mismatch	After every plate move, the encoder on the plate mover is used to verify the position. If the verification fails, this error is reported. Check the stepper motor mechanism that moves the plate. NOTE: Occasionally, the encoder wheel or the encoder sensor could fail resulting in a false error.

Mover ID	
CAMERA	1
PLATEMIXL	2
PLATEMIXR	3
PLATEYL	4
PLATEYR	5

For Mover errors (>= 900), use "MoverId X 1000 + Error Code" to find the error reported:

Example:

If the PlateY Left has a 'Mech Jam' error, then MoverId = 4 and Error Code = 900.

6.2 FLUID DETECTION UNDER LIGHT TRAY PANELS

ⓘ If Fluid is detected under Light Tray Panels immediately discontinue use the ASI Evolution® SR Analyzer Unit and pull it from Production.

Contact **ASI Technical Support** at **800-654-0146** as soon as possible.

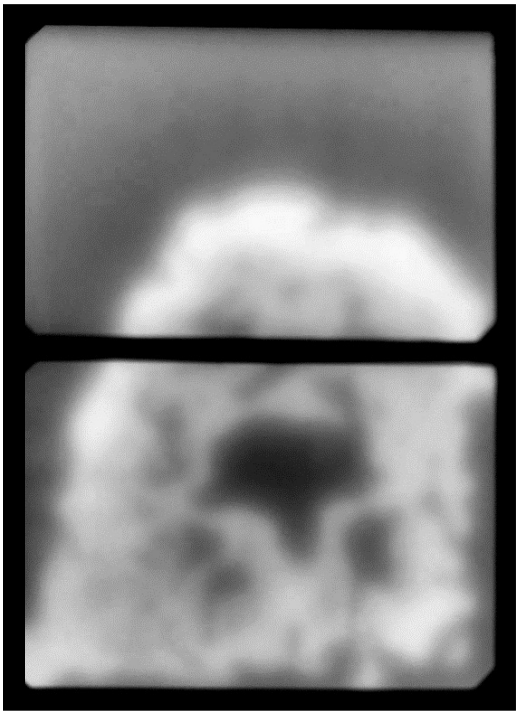


Figure 6.2-1 Example photo of fluid that has been detected under Light Tray Panels.

6.3 BUBBLES IN THE SYRINGE

If large bubbles are present in the Syringe perform the Weekly Alcohol Cleaning procedure that follows (small bubbles are not an issue):

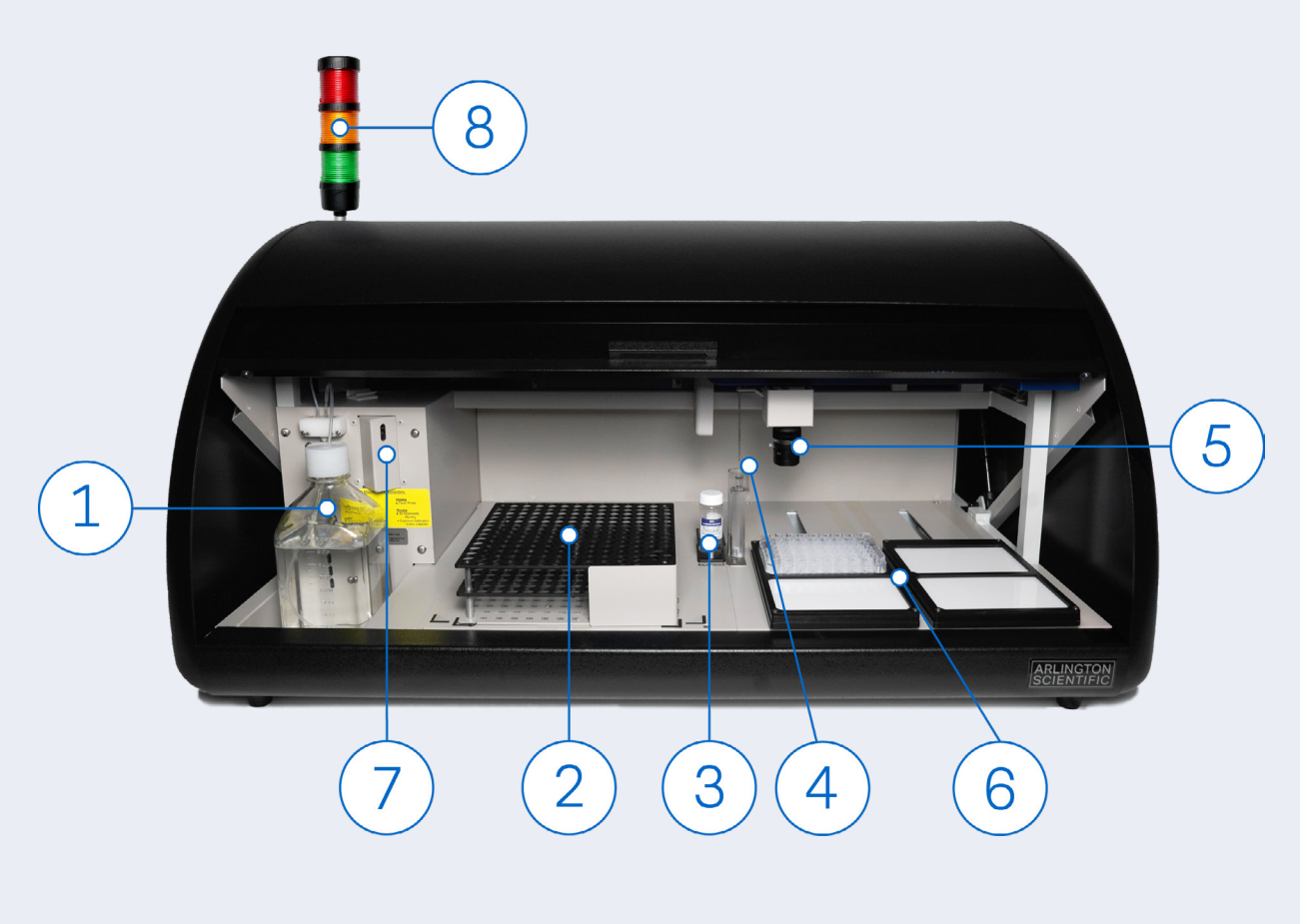
- Replace the prime bottle with a bottle containing 70% Isopropyl Alcohol
- From the Routines Menu, select Prime Syringes
- When the cycle is complete, replace the bottle containing 70% Isopropyl Alcohol with the prime bottle containing fresh deionized water and repeat the “Prime Syringes” procedure at least five (5) times.

NOTE: Do not perform the Weekly Alcohol Cleaning procedure more than once a week. Performing the Weekly Alcohol Cleaning procedure more than once a week may contribute to shortening the lifespan of the Syringe. Performing the Weekly Alcohol Cleaning procedure more than once a week may contribute to shortening the lifespan of the Syringe.

6.4 INITIALIZATION FAILURE

If the Evolution is unable to initialize on startup, verify that the laptop and analyzer have external power and are connected via the USB cable (Section 8.3.3). Reboot the laptop and reseat the USB connection. If problem persists, contact ASI Technical Support at 800-654-0146.

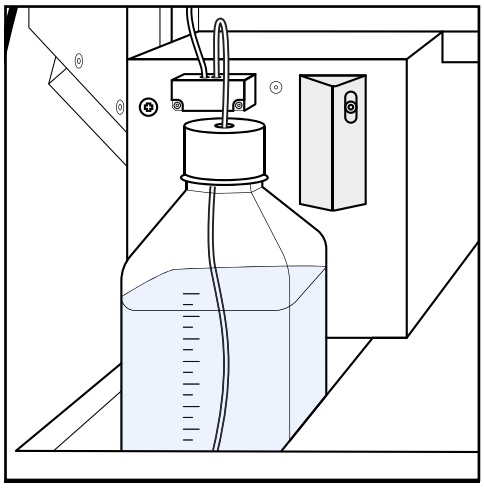
7.0 Instrument Parts



①	Prime Bottle and Syringe
②	Sample Rack
③	Reagent Rack
④	Probe and Wash Cup

⑤	Opteon Camera
⑥	Light Panels + Reaction Trays
⑦	Barcode Scanner
⑧	Status Light

1 Prime Bottle and Syringe

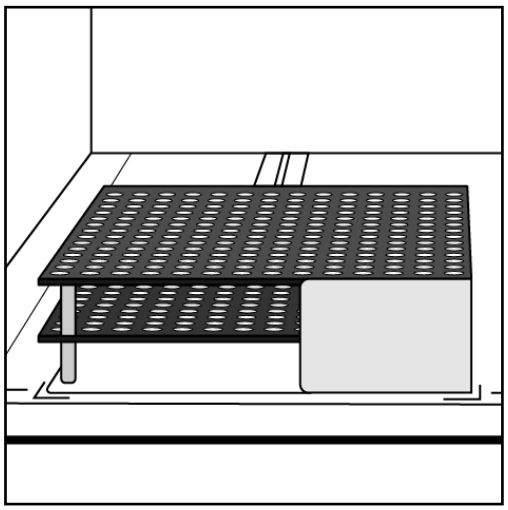


The Prime bottle is to be filled with fresh, clean de-Ionized H2O. This should be done each day.

This water enters the precision calibrated syringe pump and therefore must be very pure to avoid damage & prolong the life of the components.

Syringe comes preassembled and installed.

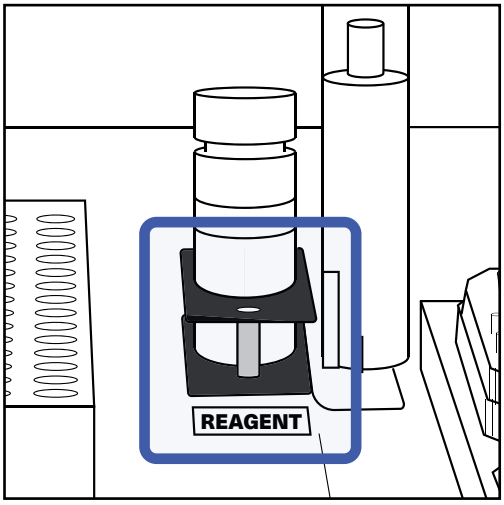
2 Sample Rack



192 positions for 12mm or 13 mm x 75mm tubes.

Contains plate for labeling so rack can be stored and samples read later.

3 Reagent Bottle Rack

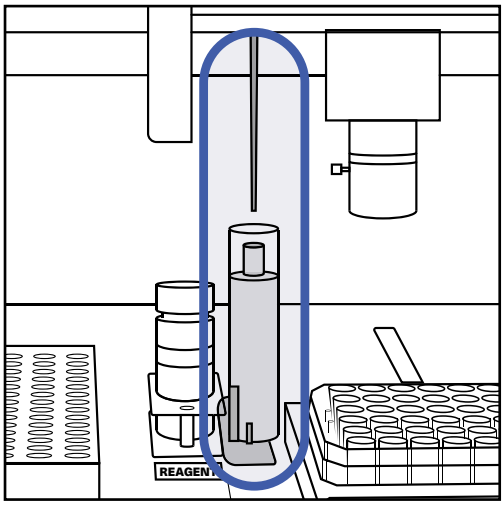


A magnetic stirrer is located under the location labeled REAGENT. It is used to mix reagent.

Do not combine different Lots of Reagent.

Do not fill the reagent bottle past the “neck” of the bottle.

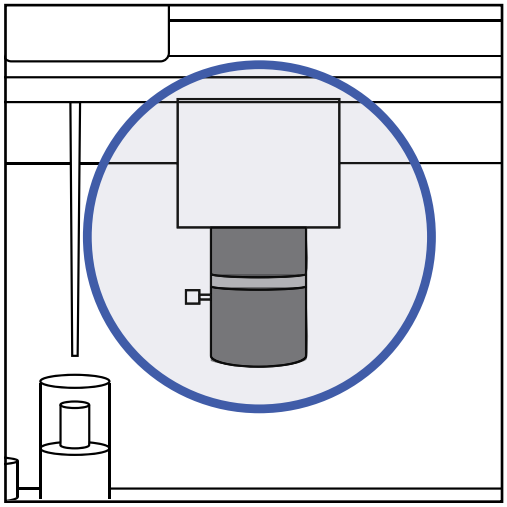
4 Probe and Wash Cup



The probe aspirates, dispenses and washes the probe tip.

The probe empties and flushes in the wash cup. Liquid exits the wash cup through tubing that drains into a waste trough. From there liquid drains to the drain bottle by gravity.

5 Opteon Camera

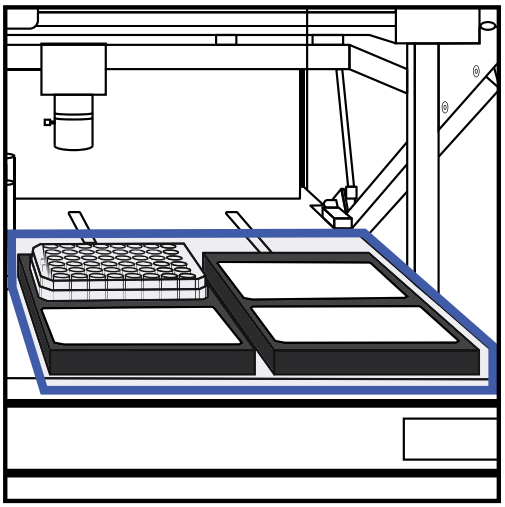


The camera and picture taking are passive. There is no user access to controlling the camera.

When taking a reading, each plate automatically positions itself under the camera which moves to take pictures of each well. Depending on the setup, reports may be displayed or printed to create permanent lab records and physician reports.

ⓘ NOTE: Be sure to remove the lens cover before using the instrument.

6 Light Panels (Plate Carriers)



The four light panels move in sets of 2 [1&2, 3&4].

⊘ Avoid handling the Light Panels.

ⓘ Make sure to wash and dry hands thoroughly to remove any grease or dust. Grease and or moisture will cause light to pool in the plate which will be detrimental to light dispersion.

8.0 Contact Information

If you continue to have problems after consulting your dealer, contact ASI Technical Support at **800-654-0146** during office hours (8am-5pm MST).

Arlington Scientific, Inc.
1840 North Technology Drive
Springville, Utah 84663
800-654-0146
801-489-8911
info@arlingtonscientific.com

> ⓘ *Important: When contacting us, please have the Model and Serial Number of the instrument in question. Have a description of the problem with as much detail as possible. Save any relevant printouts and send or e-mail us the information.*

Model: _____

Serial #: _____

NOTES

_____

_____

_____

_____

_____

_____

_____

_____

9.0 Appendix A

9.1 CLEANING SOLUTIONS

Probe Cleaning Solution (End of Day): 1:10 dilution of chlorine bleach (chlorine bleach = 5.25% sodium hypochlorite)

Alcohol Syringe Cleaning Solution: 70% isopropyl alcohol

Bleach Syringe Cleaning Solution: 1:10 dilution of chlorine bleach

9.2 CLEANING PROCEDURES

Light tray panels: Be sure to keep these clean and dust free, keep the instrument's shield closed whenever possible. Wipe them down with a scratch resistant cloth dampened in DI water. Be careful not to scratch the surfaces. Microtiter plates should also be kept dust free before using.

Camera: The lens cover can be removed during initial installation of the instrument. Be sure to keep the lens cover in the event the instrument needs to be moved.

9.3 ROUTINE MAINTENANCE FOR THE ASI EVOLUTION® SR

The following maintenance steps must be followed to ensure that the ASI Evolution® SR functions properly.

Daily Maintenance

Daily Start Up:

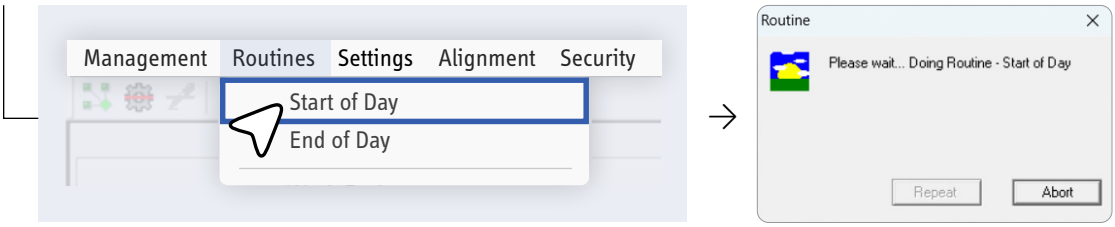
These steps must be done before starting to perform a test *each shift:*

- ☑ Check and fill DI water bottle
- ☑ Gently wipe probe with alcohol. Make sure that you do not bump or bend the probe
- ☑ Check waste drain tube for leaks or blockages. Empty waste container.
- ☑ Perform Start of Day procedure *(if unit has been unused for more than 48 hours it is recommended to run this function twice)*

Start of Day Procedure:

Running *Start of Day* at the beginning of every workday is required. Reference section 9.1- Cleaning Solutions and Procedures.

- ☑ Check the bottle volume levels: empty the Waste bottle if necessary; empty the Prime bottle and refill it with fresh deionized water.
- ☑ From the Routines menu, select Start of Day.



The sample handling system will be primed with deionized water.

NOTE: Observe the fluid handling system and ensure there are no leaks.

- ☑ Visually check lines for air bubbles.

The lines are shown in the image to the left that go from the DI water bottle to the sample probe.

There should be no bubbles in the lines. If after the Start of Day procedure there are still bubbles in the lines, repeat the Start of Day.

Daily Shut Down:

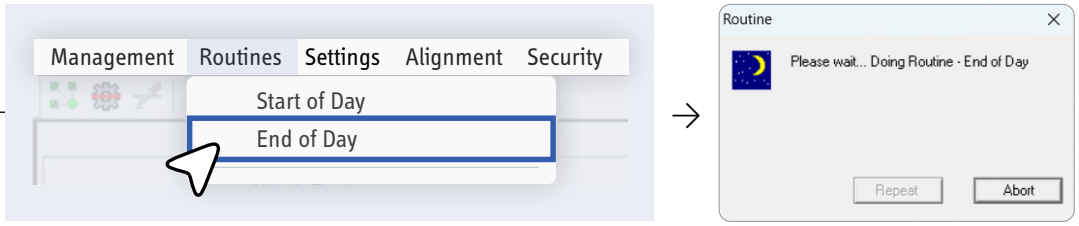
These steps must be done at the end of the day work cycle.

- Unload and store reagents according to the package insert.
- Run *End of Day*.

End of Day Procedure:

Running *End of Day* at the end of every workday is required.

- Place a 12 x 75 tube of approximately 1:10 dilution of chlorine bleach (chlorine bleach = 5.25% Sodium Hypochlorite) in Rack1 Position1.
- From the Routines Menu, select *End of Day* and follow the prompts.



This will completely disinfect the sample handling system.

- Re-prime it with deionized water.
- Turn off computer and analyzer.

Weekly Maintenance

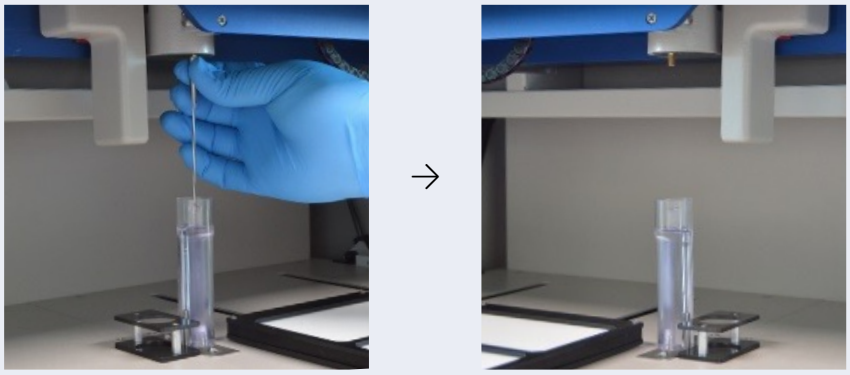
The following maintenance procedures should be done weekly:

- Clean the outside of the syringe with a dampened wipe with 70% Alcohol.
- With the unit off, clean inside of unit with 70% alcohol (Do not spray liquid into analyzer.) Apply alcohol to wipes and wipe internal surfaces.

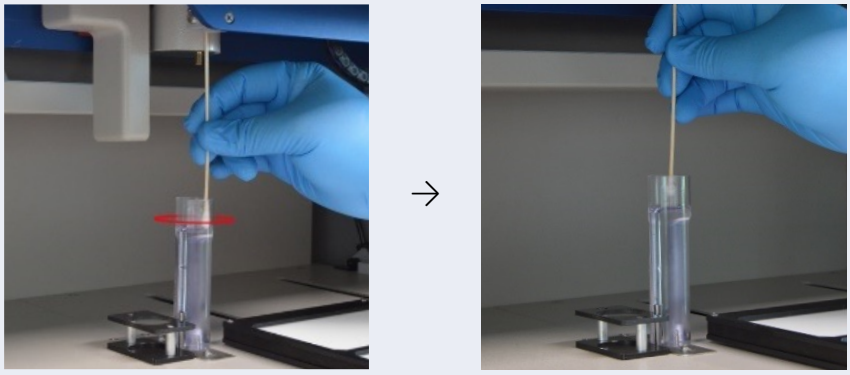
Clean wash cup, using 70% isopropyl alcohol and a cotton tipped applicator. Flush wash cup with isopropyl alcohol after cleaning.

Instructions continued on next page.

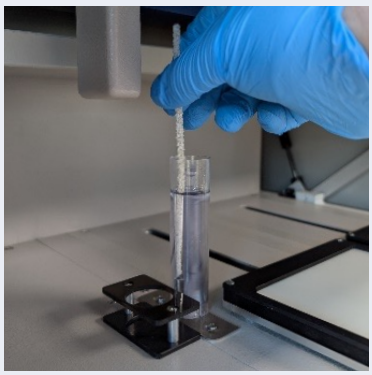
Step 1 – **Remove the sample probe before cleaning** the wash cup by gently twisting in a counter-clockwise direction. Make sure that the probe does not get bent and that the O-ring does not get lost.



Step 2 – Using a cotton tipped applicator dampened with 70% isopropyl alcohol clean the interior of the wash cup. Move the swab around the interior of the wash cup as shown below. Make sure all surfaces are cleaned:

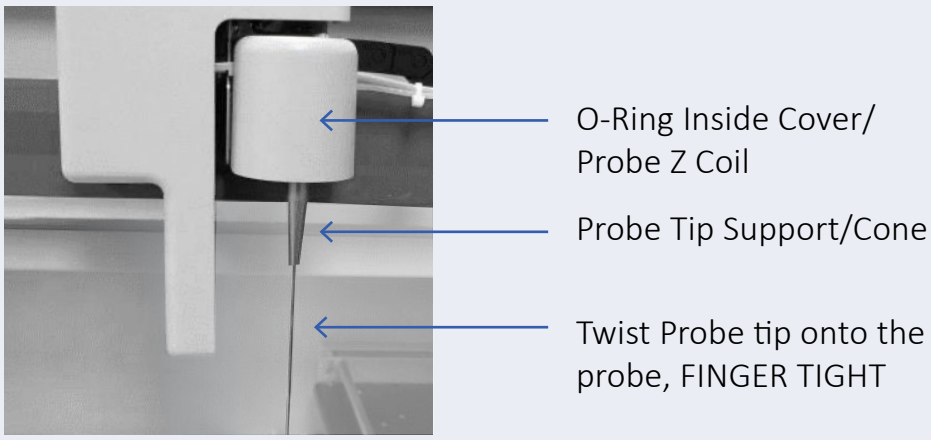


Step 3 – Insert a 6" x ¼" pipe cleaner dampened with 70% isopropyl alcohol clean the drain tube portion of the wash cup by inserting the pipe cleaner into the drain tube as shown below:



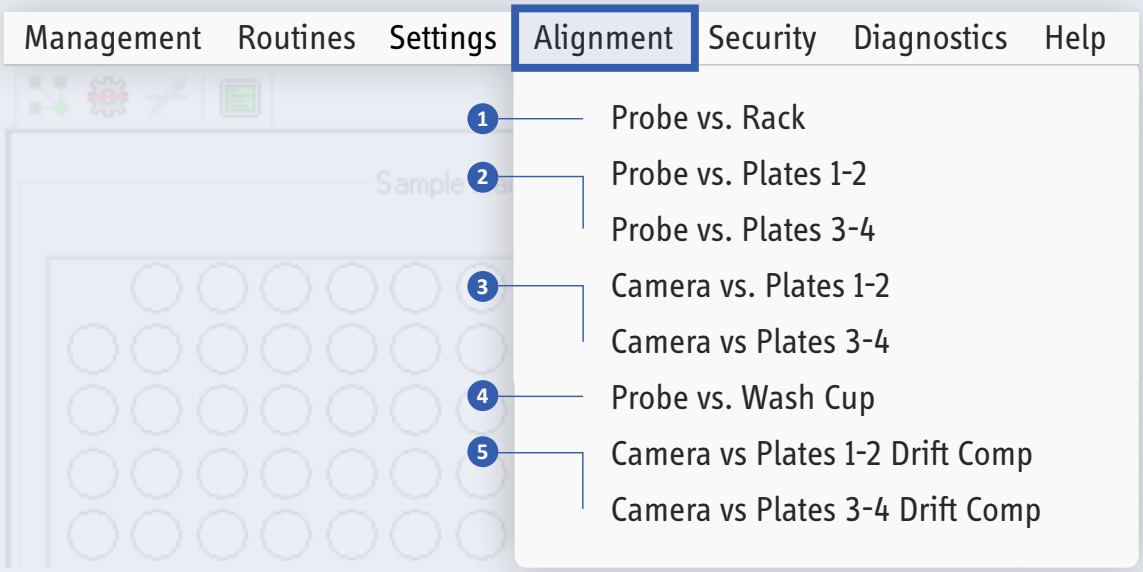
Step 4 – Replace the sample probe into the instrument.

ⓘ Ensure the small orange O-ring remains seated between the tubing flare and the end of the threads on Probe Z coil.



Alignment

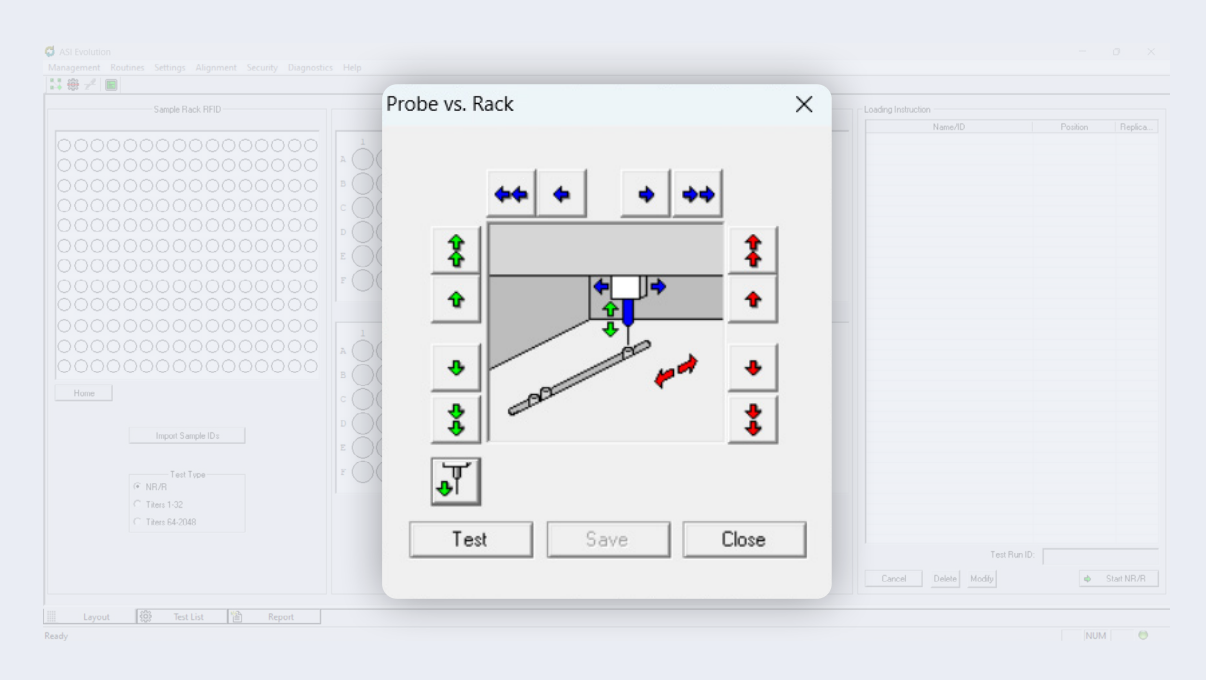
Alignments should be verified weekly. Use the procedures to ensure that the instrument is working properly. Only adjust the alignments if the function is out of specification. If the alignment is within specification do not adjust.



Alignment Menu Options

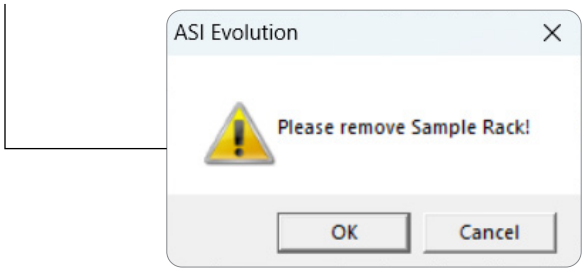
1 Probe vs. Rack

Select "Probe vs. Rack" from the Alignment menu.



Probe vs. Rack Dialog Window to Adust Probe Position

ⓘ *Be sure the Sample Rack is removed from the instrument.*



To check the current alignment, click the  probe button.

If needed, use the arrow buttons to position the probe directly over the rack locating pin.

Select **“Save”.**

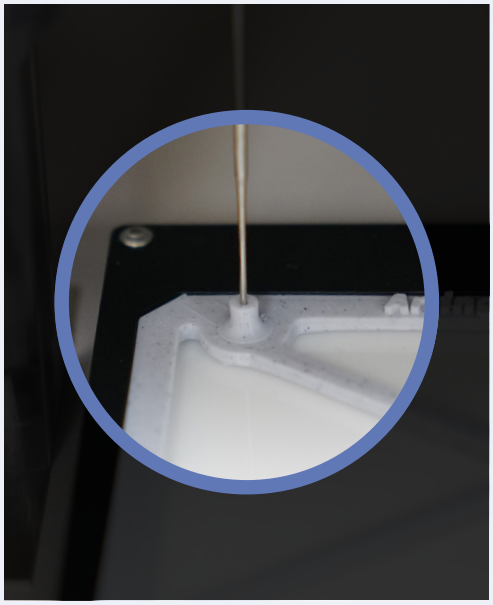
Select **“Test”** to confirm the alignment. Repeat procedure if necessary.

When finished, click **“Save”** and **“Close”.**

2 Probe vs. Plates 1-2*

Select "Probe vs. Plates 1-2" from the Alignment menu.

Insert the alignment jig into position 1 when prompted (left rear plate holder).



To check the current alignment, click the probe button ( ).

If needed, use the arrow buttons to center the probe tip in the jig.

Select **“Save”.**

Press **“Test”** to confirm the alignment.

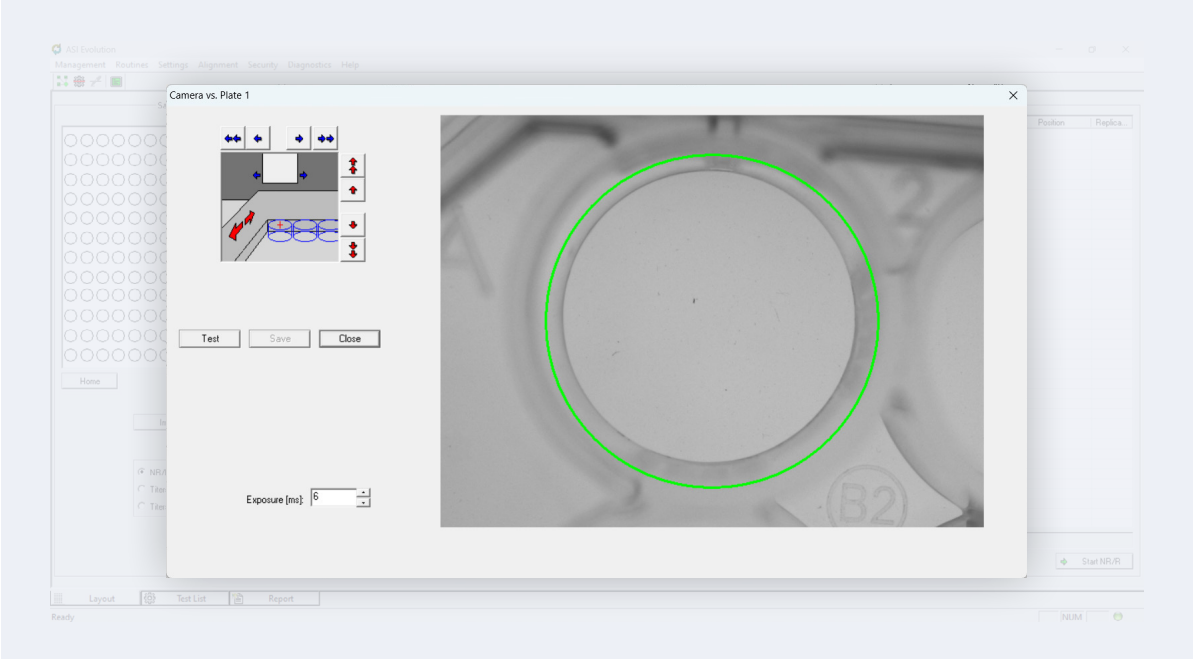
Repeat procedure if necessary.

When finished, click **“Save”** and **“Close”.**

***NOTE:** Be sure to complete these procedures for Plates 3-4.*

3 Camera vs. Plates 1-2*

To check the current alignment, select "Camera vs. Plates 1-2" from the Alignment menu.



Camera vs. Plates Dialog Window

ⓘ *Make sure that you have a well plate in the "Plate 1" position.*

If needed, use the arrow buttons to center the image within the green circle.

Select **"Save".**

Press **"Test"** to confirm the alignment.

Repeat procedure if necessary.

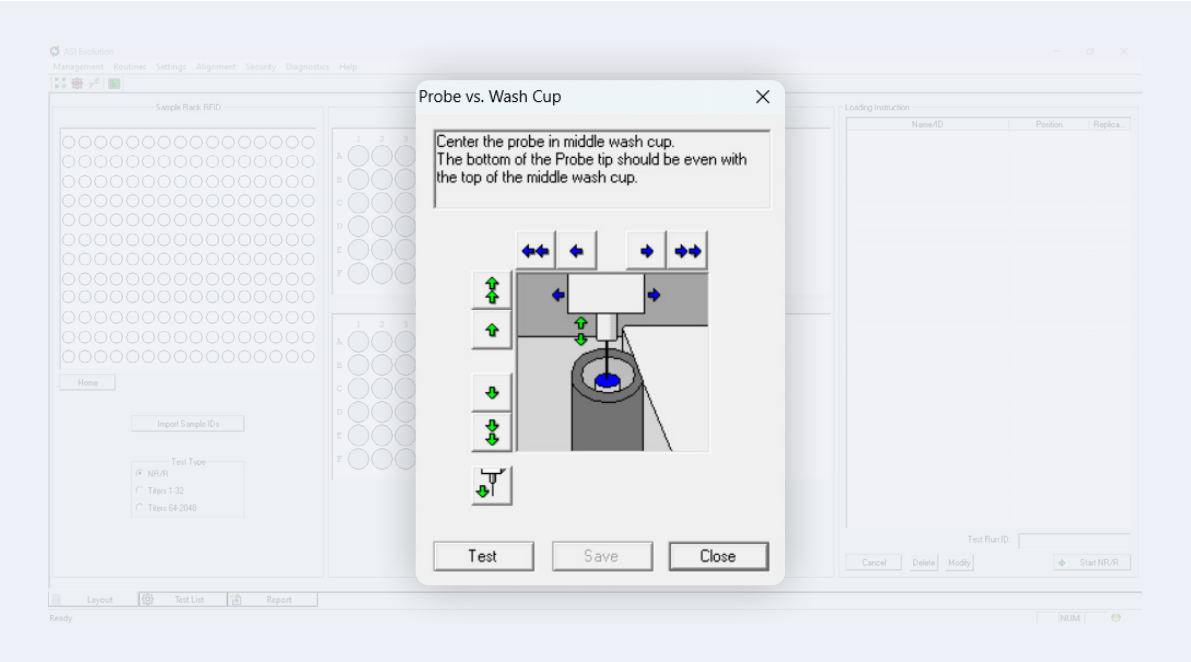
When finished, click **"Save"** and **"Close".**

***NOTE:** Be sure to complete these procedures for Plates 3-4*

4 Probe vs. Wash Cup

The alignment for Reagent is set by the Wash Cup alignment.

Select "Probe vs. Wash Cup" from the Alignment menu.



Probe vs. Wash Cup Dialog Window

The probe tip should be centered in, and at the rim level of the small, center wash cup. The tip of the probe should be at the top of the wash well.

To check the current alignment, click the probe button ( ).

If needed, use the arrow buttons to center the probe tip.

Select **“Save”.**

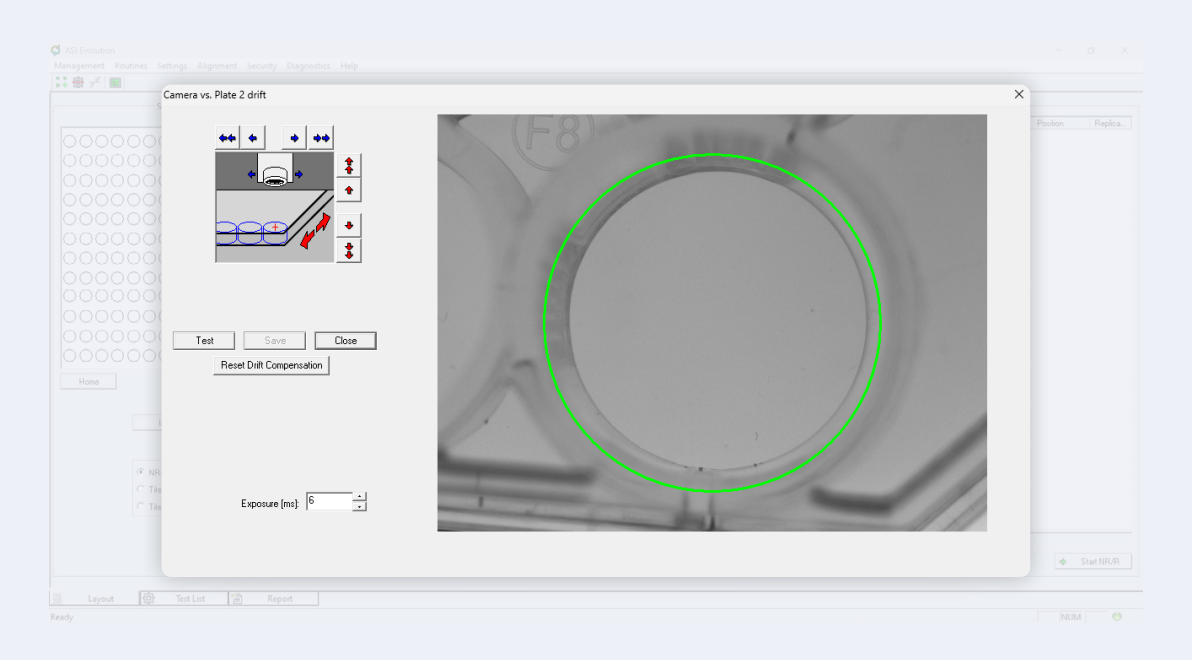
Select **“Test”** to confirm the alignment.

Repeat procedure if necessary.

When finished, click **“Save”** and **“Close”.**

5 Camera vs. Plates 1-2 Drift Comp*

To ensure alignment remains consistent/correct for drift offset, select "Camera vs. Plates 1-2 Drift Comp" from the Alignment menu.



Camera vs. Plates Drift Dialog Window

ⓘ *Make sure that you have a well plate in the "Plate 2" position when adjusting for the left tray and in the "Plate 4" position when adjusting for the right tray.*

Set Drift Compensation:

1. If needed, use the arrow buttons to center the image within the green circle.
2. Select **"Save".**
3. Press **"Test"** to confirm the alignment.
4. Repeat procedure if necessary.
5. When finished, click **"Save"** and **"Close".**

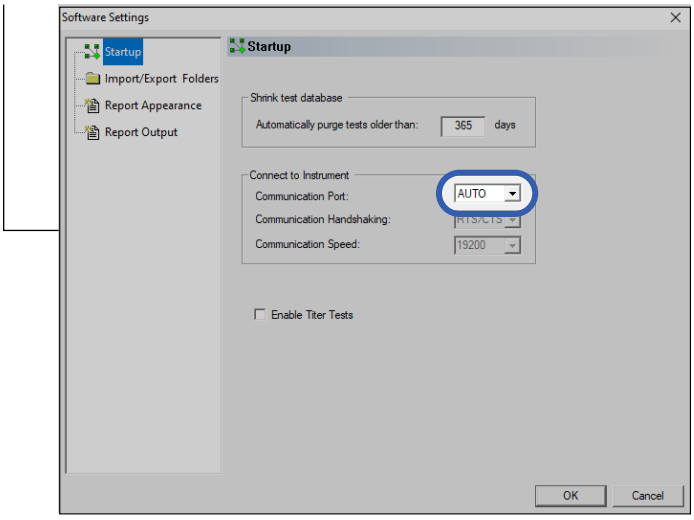
***NOTE:** Be sure to complete these procedures for Plates 3-4.*

Exposure Calibration

Exposure Calibration will be performed at PM by ASI Field Service Engineer. If additional calibration is needed, an ASI Field Service Engineer must assist by remote access to the analyzer.

9.4 COMMUNICATION (COM) PORT SETTING

The program's default communication port setting is AUTO and must remain as such.



NOTES

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