ASI Evolution®

Automated Syphilis Analyzer

OPERATOR'S MANUAL

ARLINGTON SCIENTIFIC

ARLINGTON SCIENTIFIC, INC.®
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1.0 Introduction

The ***ASI Evolution***® 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 non-reactive.

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:

- Load sample tubes into the sample rack
- Load the sample rack into the unit
- Refill the prime bottle with D.I. Water
- Place the reagent in the proper position in the permanent rack
- 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 IN-VITRO DIAGNOSTIC USE

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

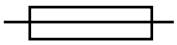
The ASI Evolution is intended to be used as a fully automated analyzer to objectively interpret the results of the ASI Automated RPR Test for Syphilis. The ASI Evolution is designed to provide standardized test interpretation and to provide for storage, retrieval, and transmittal of the test results.

The ASI Automated RPR Test for Syphilis for use on the ASI Evolution is for professional use only. The test is intended to be used for blood donor screening and for screening cadaveric (non-heart beating) donor specimens for tissue donation. This test is not intended for diagnostic use.

1.2 Warning Markings

1.2.1 Safety Symbols / Le Symboles de Sûreté

Safety symbols which may appear on the product / *Les symboles de sûreté peuvent apparaitre sur le produit*:

			
WARNING *AVERTISSEMENT*	**Protective Ground** *La Terre Electrique*	**CAUTION** *L'ATTENTION*	**BIOHAZARD** *BIOHAZARD*
Risk of Shock *Risque de Choc*	**(Earth) Terminal** *Prise de Terre*	**Refer to Manual** *Se Rapportent à Manuel*	**Risk of Infection** *Risque d'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. *FUSIBLE: Pour la protection continue contre le risque du feu, remplacez le fusible seulement par une du type spécifique et des estimations courantes. Démontez l'équipement de l'alimentation d'énergie avant de remplacer le fusible.*		
	**DANGER:** Pinch points, sharp points, and moving parts - mechanisms may operate without warning.		

1.2.2 Safety Terms / Terminologie de Sûreté

These terms may appear on the product: *Les marques sur le produit:* *These terms may appear in this manual:* *Les marques dans l'opérateur manuel:*	
DANGER *DANGER Le "de marque: DANGER"*	Indicates an injury immediately accessible as you read this marking *Indique le risque immédiat de dommages (assessible tandis que vous lisez la marque)*
WARNING *AVERTISSEMENT! Le "de marque: 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. *Ces rapports identifient les conditions ou les pratiques qui pourraient avoir comme conséquence les dommages ou les pertes humaines.*
CAUTION *L'ATTENTION "Le de marque: CAUTION"*	CAUTION statements identify conditions or practices that could result in damage to this product or other property. *Ces rapports identifient les conditions ou les pratiques qui pourraient avoir comme conséquence les dommages a ce produit ou a toute autre propriété.*
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. ***Avertissement****! Lors du fonctionnement, si on renverse des matériaux, coupez immédiatement le courant. Placez le commutateur électrique a AU LOIN(0). Traitez le matériel comme biohazardous, utilisant approprie nettoient et des méthodes de disposition*.

1.2.3 Disposal and Storage

Dispose of according to local regulations.

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. **AVERTISSEMENT** : Utiliser et disposer des matériaux de la même manière que vous utilisé et disposer des matières infectieuses.

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***® 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.

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.

Warning!	
	Warning! To avoid electric shock, the grounding conductor must be connected to earth ground. An optional method is to attach a ground strap from the external grounding terminal on the rear panel of the instrument to a suitable ground such as a grounded pipe or some metal surface to earth ground.

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®*** 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 10% 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 non-reactive 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 smallpox 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 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 4GB.

The ***ASI Evolution***® 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.
- Do not operate the instrument if the probe is damaged.
- Use reagent in the bottle it is supplied in. 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. Reference the drain tube installation instructions in section 8.3.2.

1.5 Expected Values

A comparison of the digital interpretation of the results from the ASI Evolution using the original interpretation algorithm (K173376, BK170114, and K182391) to establish substantial equivalence to the interpretation made by the ASI Evolution using the new interpretation algorithm was conducted.

The ASI Evolution 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

		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

		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%

Sodium Citrate positive agreement is calculated as:
56/(56 + 0) = 100%
95% CI = 93.62% - 100%

EDTA positive agreement is calculated as:
65/(65 + 0) = 100%
95% CI = 94.48% - 100%

Total Plasma negative agreement is calculated as:
771/(711 + 0) = 100%
95% CI = 99.52% - 100%

Sodium Citrate negative agreement is calculated as:
350/(350 + 0) = 100%
95% CI = 98.95% - 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.

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

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	74	0	74
	Nonreactive	0	0	0
	Total	74	0	74

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

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	90	0	90
	Nonreactive	0	0	0
	Total	90	0	90

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.

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

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	0	0	0
	Nonreactive	0	84	84
	Total	0	84	84

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

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	75	0	75
	Nonreactive	0	0	0
	Total	75	0	75

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

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	0	0	0
	Nonreactive	0	51	51
	Total	0	51	51

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

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager- AT Results	Reactive	76	0	76
	Nonreactive	0	0	0
	Total	76	0	76

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** 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** can be calculated:

Using this formula, the negative agreement is calculated as:

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** 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** 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 sample requirement: ……	300 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® 10 Pro
Minimum system: ……	64-bit Windows® 10 Pro, 4 GB RAM, minimum 100MB free drive space, CD drive, USB port
Recommended system: ……	64-bit Windows® 10 Pro, Intel® Core™ i3, i5 or equivalent, 8 GB RAM, CD drive, 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: ……	900480A
4800 test kit: ……..	9004800A
5ml control set: ……	905005A

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 85% 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.*

Environmental shipping conditions

Pressure: ……..	8.3 – 14.7 Psi
Main supply voltage: ……..	30% minimum to 95% maximum
Operating temperature: ……	-20°C minimum to 55°C maximum

Certifications

NRTL Listed, CE Marked, FDA-Cleared for Blood Donor Testing BK170114, FDA-Cleared for in-vitro diagnostic Testing K173376 and K182391

3.0 ASI Evolution® Software

3.1 Management Menu

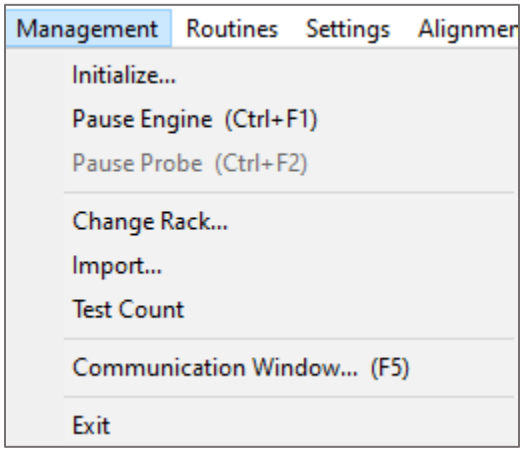
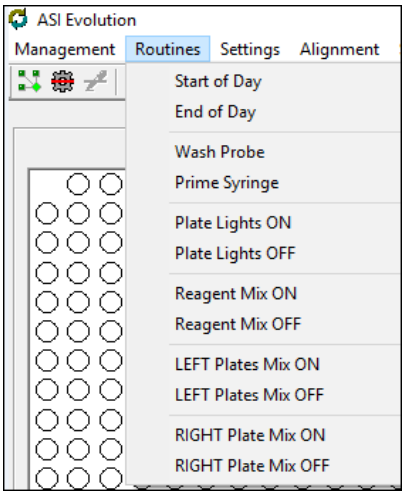


Figure 3.1-1 Management Menu Options

OPTION	DESCRIPTION
Initialize	Establish or re-establish communication between the software and the instrument without restarting the software.
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.
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.
Change Rack	This feature allows the user to switch between the standard 192 sample rack and a custom 100 sample rack.
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.
Test Count	Test count data can be retrieved, printed, and exported, either for a range of dates, or for a specific month.
Communication Window (F5)	Used for Service Purposes ONLY.
Exit	Exit the software.

3.2 Routines



3.2.1 Start of Day

Running **Start of Day** at the beginning of every workday is recommended. 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**.**

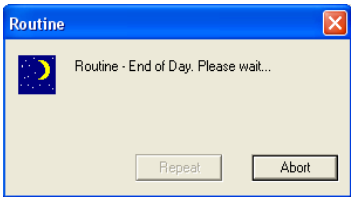
NOTE: Observe the fluid handling system and ensure there are no leaks.

3.2.2 End of Day

At the end of the day, place a 12 x 75 tube of approximately 10% 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. Shut down the unit and laptop at the end of each day.



3.2.3 Wash Probe

Each time a wash probe is performed the air gap is reset. The air gap is required for proper function of the pipetting system.

3.2.4 Prime Syringes

This option ensures the fluid path is full of water. Select prime syringes from the Routines drop down list.

3.2.5 Plate Lights ON/OFF

Manually turns the plate lights on and off.

3.2.6 Reagent Mix ON/OFF

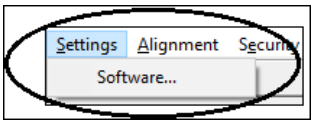
Manually turns the reagent mixing system on and off.

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.



3.3.1 Startup Tab

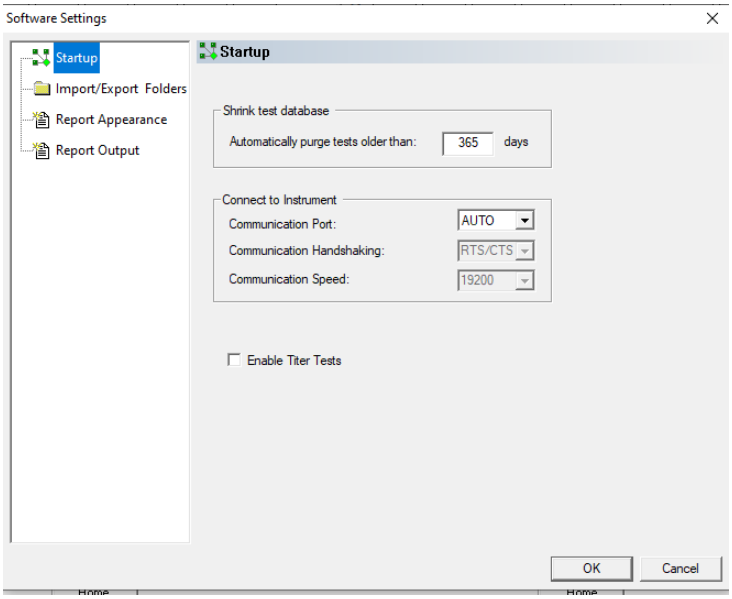


Figure 3.3.1 Software Startup Settings

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. The COM port can be changed if needed. Further information on communication issues can be found in Appendix A, Section 9.3.

3.3.1.3 Enable Titer Tests

For Diagnostic Applications only. Enables the use of end-point titer testing.

3.3.2 Import/Export Folders Tab

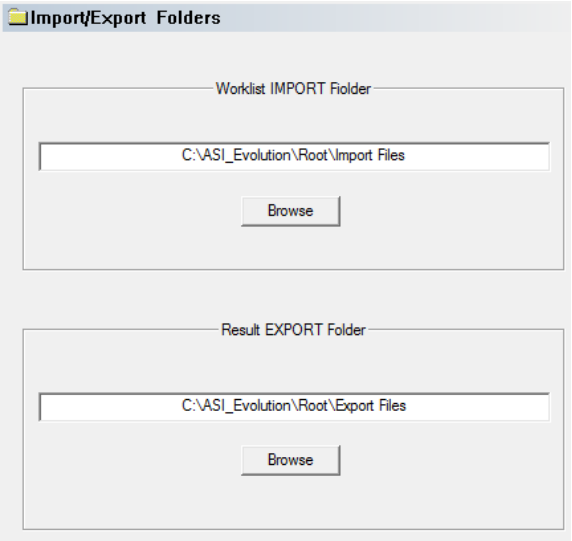


Figure 3.3.2 Import/Export Folders settings

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

3.3.3 Report Appearance Tab

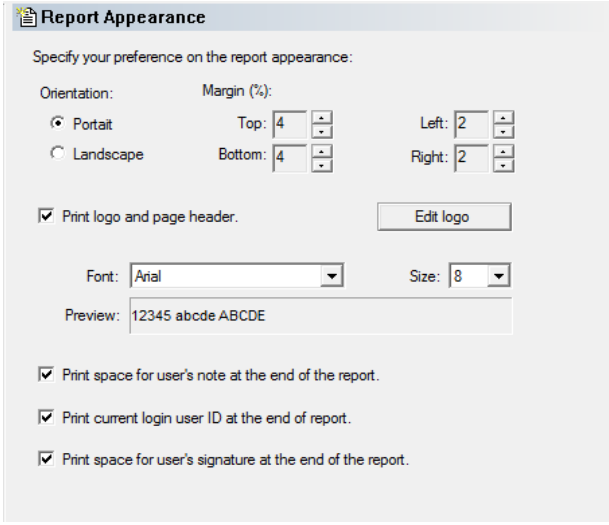


Figure 3.3.3 Report Appearance options

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

3.3.4 Report Output Tab

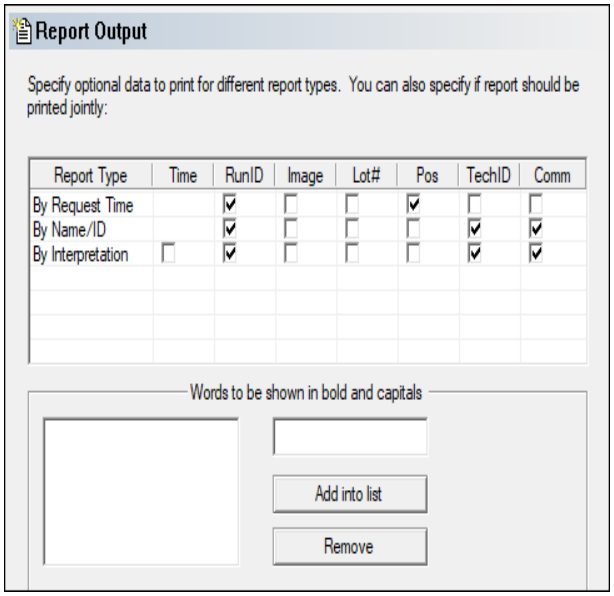


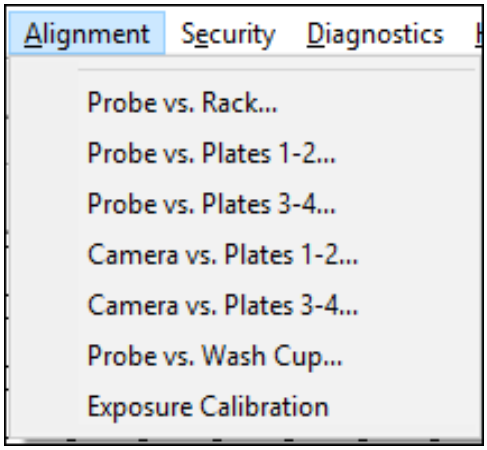
Figure 3.3.4 Report Output options

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

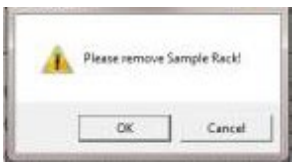
3.4 Alignment

3.4.1 Alignment

Before running any tests or jobs, the instrument must be aligned and setup. Use the procedures in this section to ensure that the instrument is ready to work properly.



Probe vs. Rack



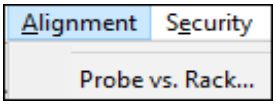
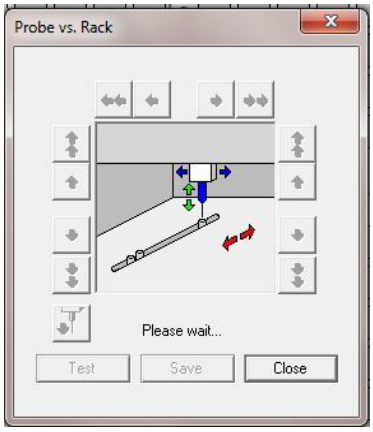
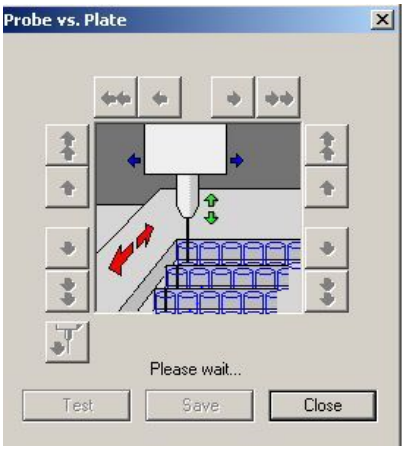


Figure 3.4.1-1 Probe vs. Rack

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".	 ***Figure 3.4.1-2 Adjust Probe Position for Rack***
Select Probe vs. Plates 1-2 from the menu. **NOTE: Be sure to complete these procedures for Plates 3-4!**	 ***Figure 3.4.1-3 Probe vs. Plates***
Insert one of the micro well plates 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 well A01 and almost touching the bottom. Select "**Save**". Press "Test" to confirm the alignment. Repeat procedure if necessary. When finished, click "Save" and "Close".	 ***Figure 3.4.1-4 Adjust Probe Position for Plate***
Camera vs. Plates 1-2 **NOTE:** Be sure to complete these procedures for Plates 3-4!	 ***Figure 3.4.1-5 Camera vs Plates***

Make sure that you have a well plate in the “Plate 1” position.

Use the arrows to center the first well, designated A1, in the reference circle in the alignment window. When centered, click on the test button. The camera and plate mover will return to their home position and back to the current alignment position. Repeat this step until the camera moves back to the center of the reference circle and click on the save button.

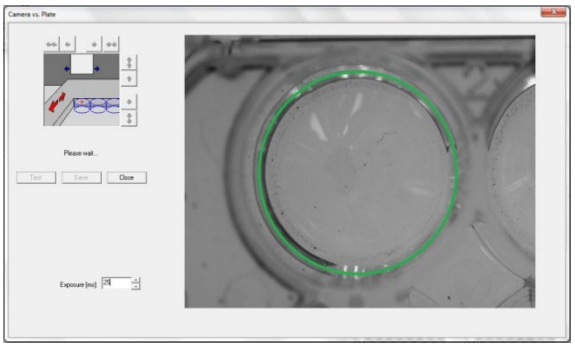


Figure 3.4.1-6 Adjust Camera Position with Plate

Probe vs. Wash Cup

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

Figure 3.4.1-7 Probe vs. Wash Cup

The probe tip should be centered in, and at the surface of the small, center wash cup.

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”.

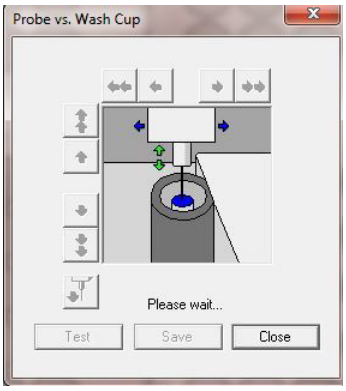


Figure 3.4.1-8 Align Probe to the Wash Cup

3.4.2 Exposure Calibration

1. Choose Exposure Calibration from the menu. (Figure 3.4.1-1)

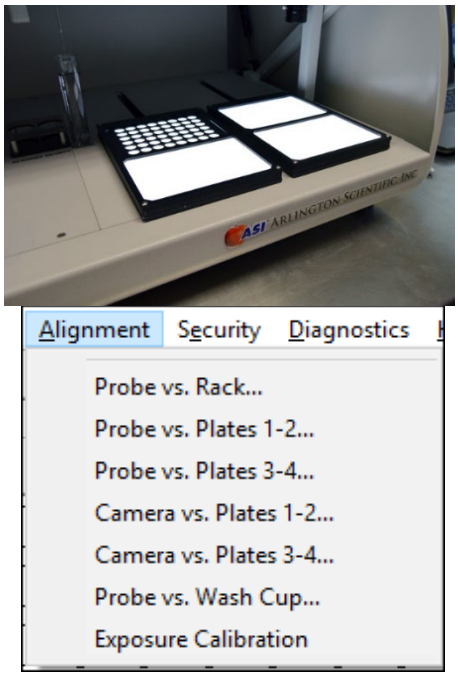


Figure 3.4.2-1

2. Insert black calibration plate into Plate 1 position. (Figure 3.4.2-2) (Black calibration plate included with instrument.)

Figure 3.4.2-2

3. Press “Calibrate” button. (Figure 3.4.2.3)

4. Wait until the system has finished calibrating. (Figure 3.4.2-4)

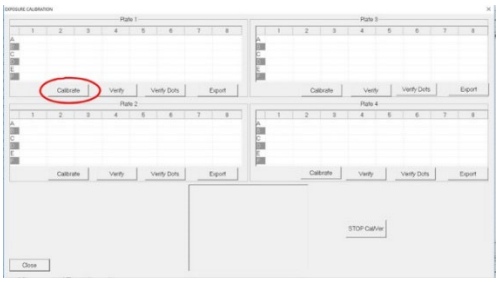


Figure 3.4.2-3

5. Once the system has completed the calibration, Press “Verify” button. (Figure 3.4.2-5)

6. Message will display to indicate if calibration “Passed” or “Failed” (Figure 3.4.3-6)

7. If calibration failed, repeat process for plate 1.

8. If repeat calibration fails, call technical support for assistance. (801-489-8911)

9. If calibration passed, proceed to plate 2 position and repeat steps 3-8.

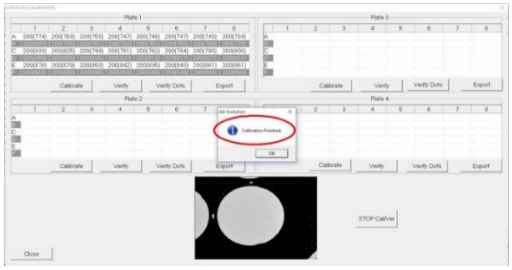
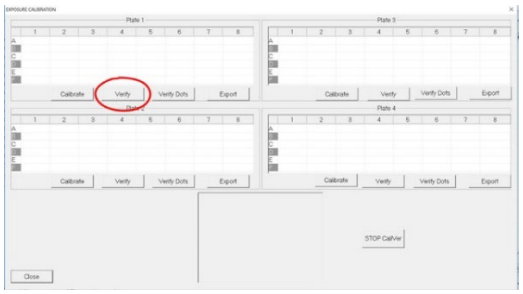
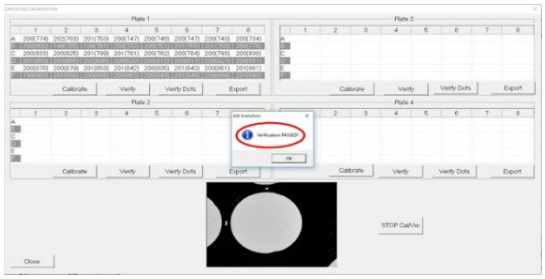


Figure 3.4.2-4

10. Continue until all four plate positions have been calibrated and passed verification. 11. Close window when complete. **<u>Calibration should be performed every 3 months.</u>**	 ***Figure 3.4.2-5***  ***Figure 3.4.2-6***

Arlington Scientific, Inc. (ASI) recommends the calibration procedure be performed every three months (± 2 weeks). The calibration recommendation is based upon the National Institute of Standards and Technology (NIST) stating "in general, NIST does not require or recommend any set recalibration interval for measuring instruments, devices or standards."[1] Specific recalibration intervals depend on several factors including:

1. Accuracy of the device as established by repeated testing of the device
2. Requirements set by regulation or contractual agreement
3. Inherent stability of the device
4. Environmental factors at customer facility that may affect stability[2]

ASI has determined from ***ASI Evolution***® stability testing that the device is stable for three (3) or more months without the need to recalibrate.

3.4.3 Firmware Update

Firmware update feature allows firmware to be updated. Contact your distributor for assistance.

[1,2] www.nist.gov/calibrations/recommended-calibration-interval created January 07, 2010, updated August 25, 2016

3.5 Security

Please refer to Section 8.3.6 Security Settings.

3.6 Help

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

4.0 ASI Evolution® Manager

4.1 Layout Tab

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

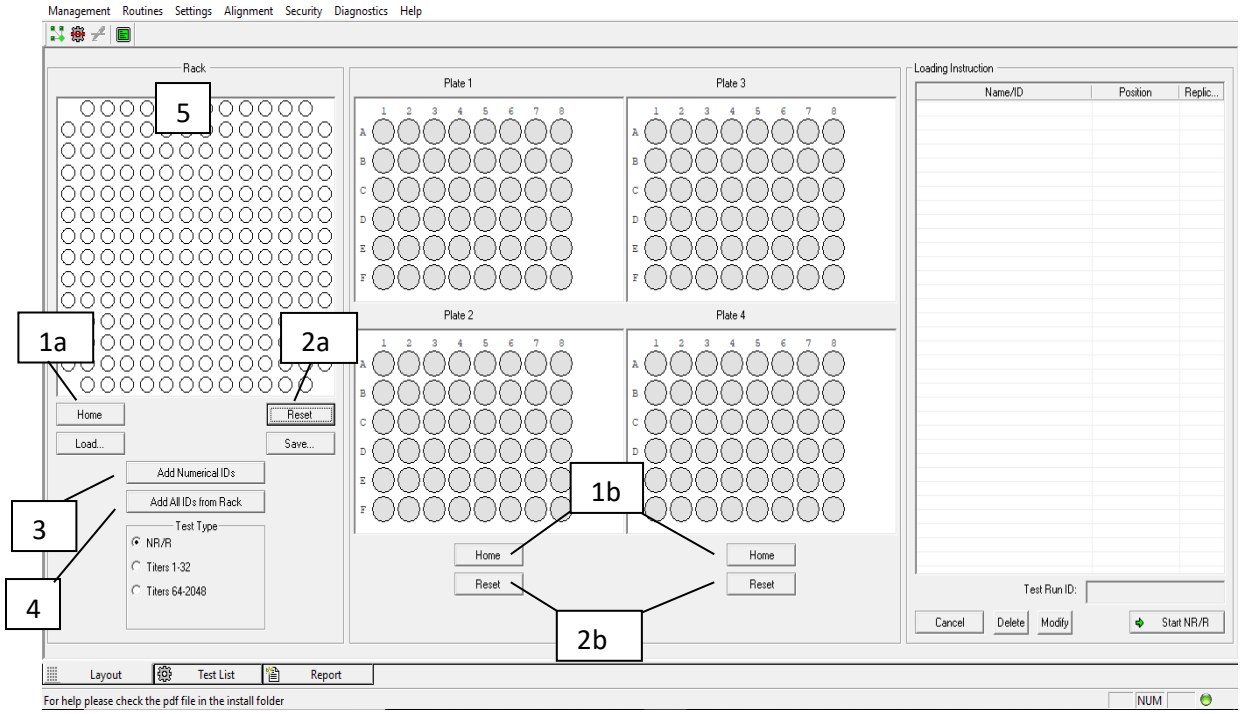
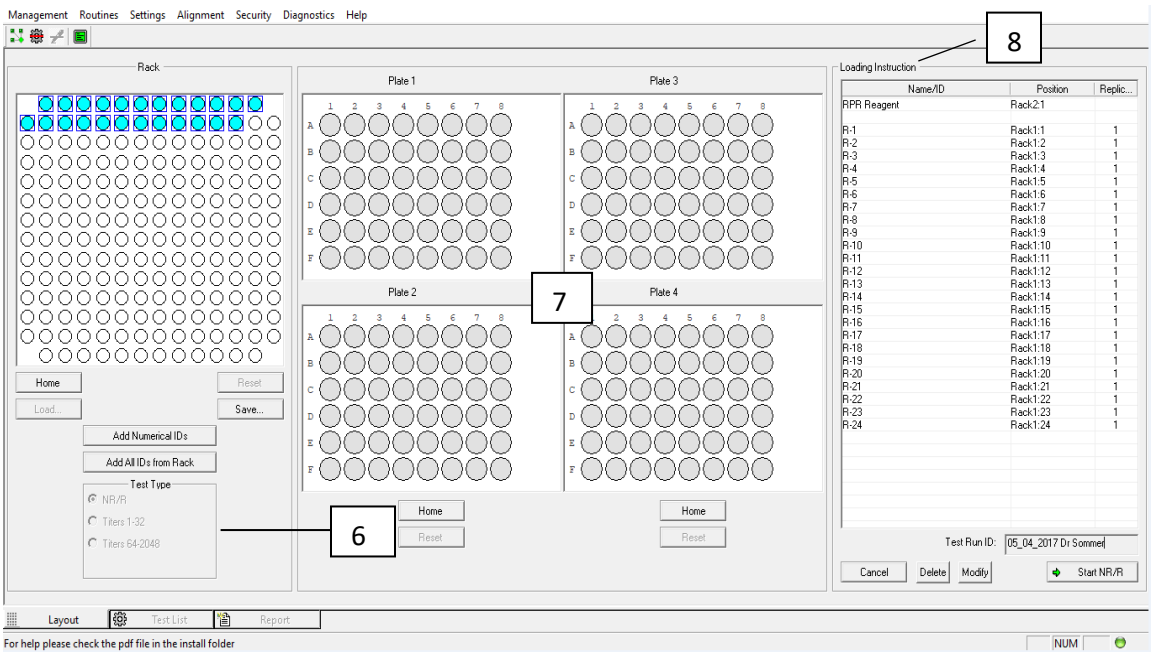


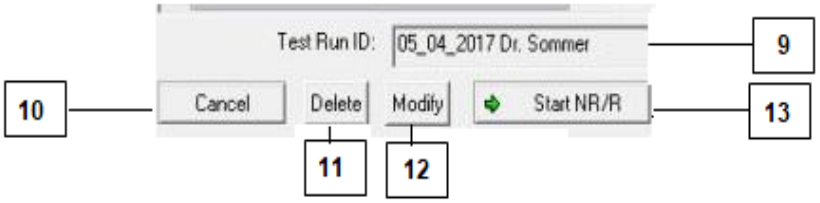
Figure 4.1-1 Layout Tab

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.

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.



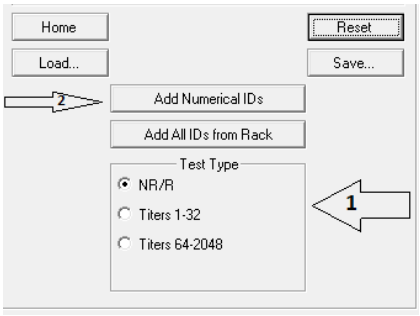
Item #	Feature:	Description:
6	Test Type	NR/R – Runs a non-reactive/reactive sample determination.
7	Plates (1, 2, 3, 4)	Plates 1 and 2 and Plates 3 and 4 are to be placed in the designated locations in the instrument.
8	Loading Instructions	Specifies the Test Run ID and locations to load the samples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



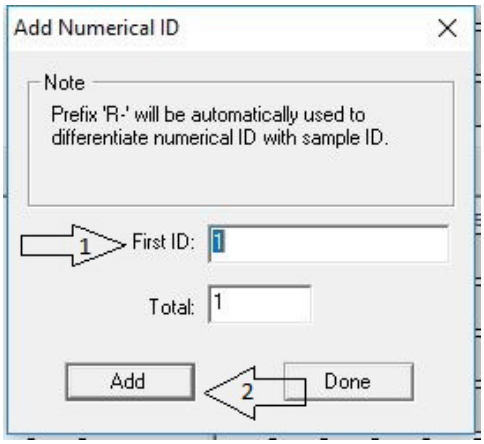
Item #	Feature:	Description:
9	Test Run ID	Data can be entered manually; it is loaded automatically when using Import File.
10	Cancel	This will clear all items located in the Loading Instructions screen.
11	Delete	Items can be removed from the Loading Instructions using this button.
12	Modify	Individual 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)

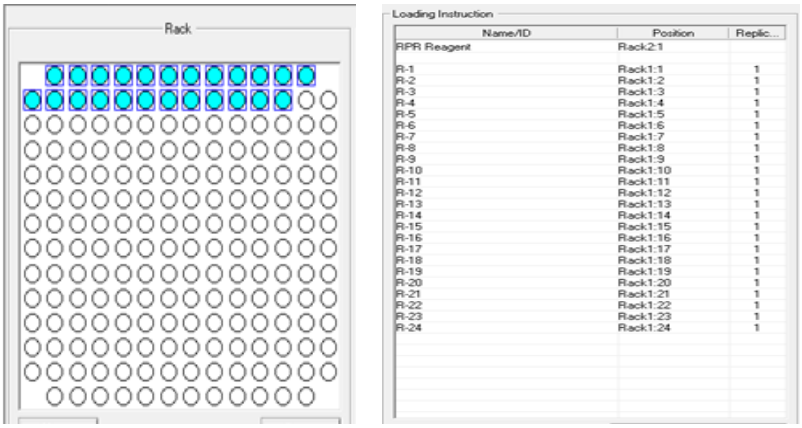
4.2.1 – In the Layout tab select your test type by clicking the corresponding radial button (1), then begin to create a worklist by clicking on the “Add Numerical IDs” button (2).



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.



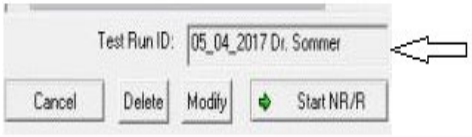
4.2.3 – When a Sample ID is entered the position on the sample rack will be highlighted in “blue” to designate the proper position in the rack to place the sample. The position is also listed in the “Loading Instructions” area.



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!

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).*

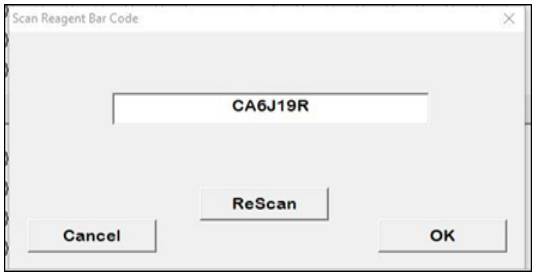
***Note**: When creating worklists outside of the software, remember not to add more samples to the worklist then there are available wells.*

4.2.6 – Vigorously agitate 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.*

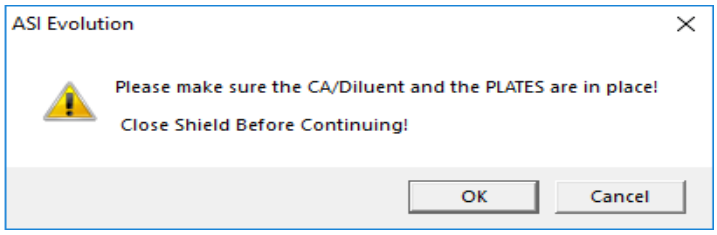
4.2.7 – Press "Start NR/R" (or other selected test type) button located on the bottom of the right column and the instrument will begin tests.

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

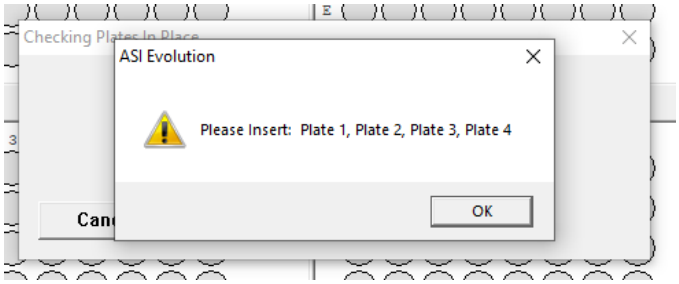


4.2.9 – To start test on Left side plate, Select **Yes**, to start test on Right side plate, Select **No**.

4.2.10 – Ensure that the Carbon Antigen/Diluent and the PLATES are in their correct location for test run. Ensure that reagent caps have been removed. Close the "Shield" of the ASI Evolution® 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.

4.2.12 – ASI Evolution Testing Process (192 Samples):

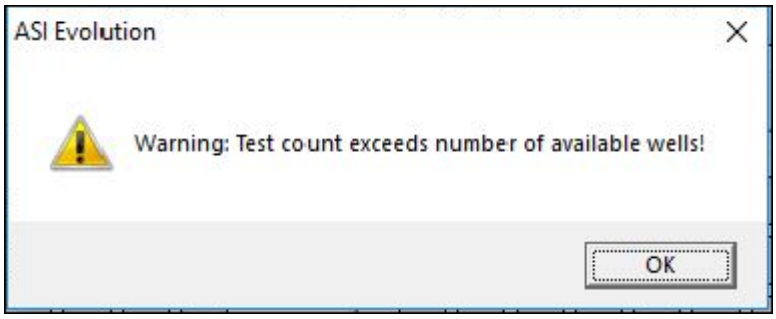
A. The analyzer will dispense 24 samples into the first half of Plate 1. Then Plate 1 will perform a fast rotation to spread the samples evenly in the wells. Next, Carbon Antigen will be dispensed into each of the 24 wells in the first half of Plate 1 followed by a slow incubation rotation of 7 minutes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

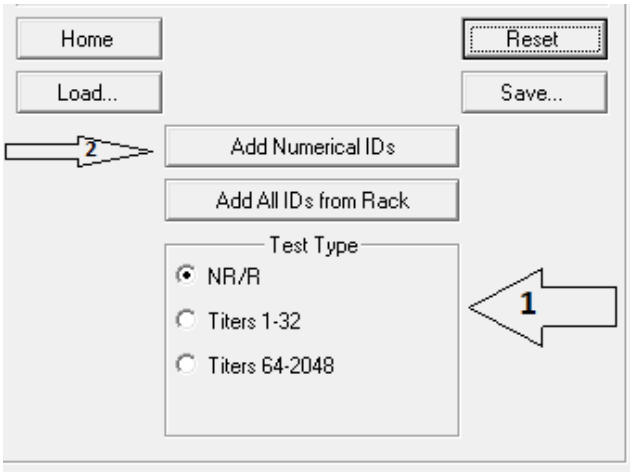
B. The analyzer will display a warning message **"Insufficient number of available wells"**.

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 (Semi-Quantitative)

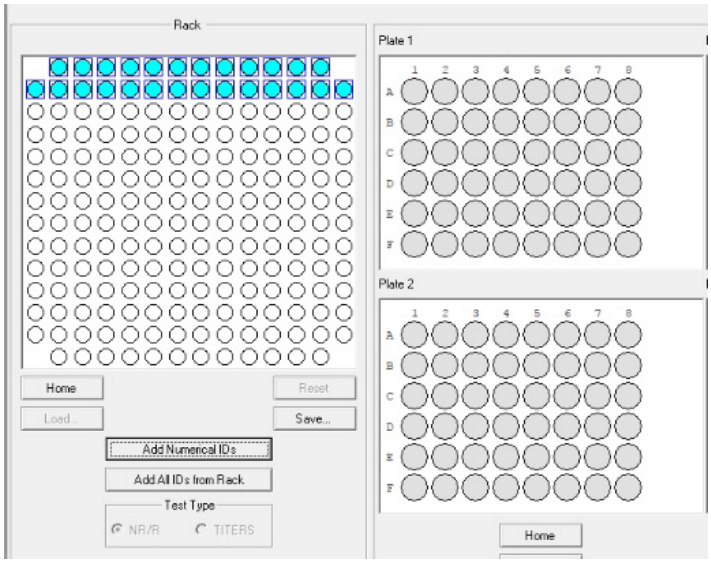
4.3.1 – If steps 1 and 2 have already been performed for the day they do not need to be repeated

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).



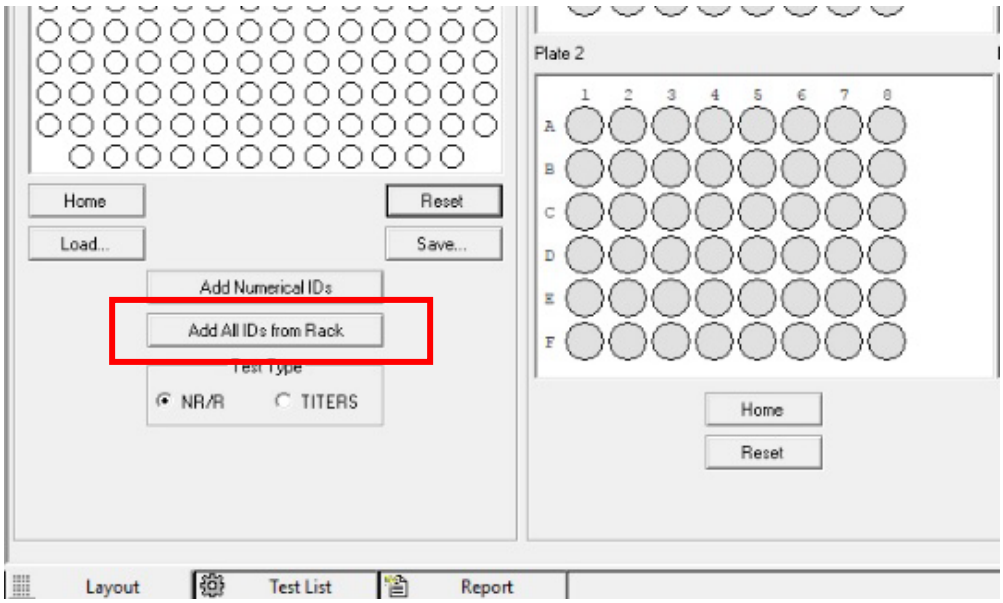
4.3.3 – Enter the Sample ID by typing the Sample ID number or scanning a barcode.

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.

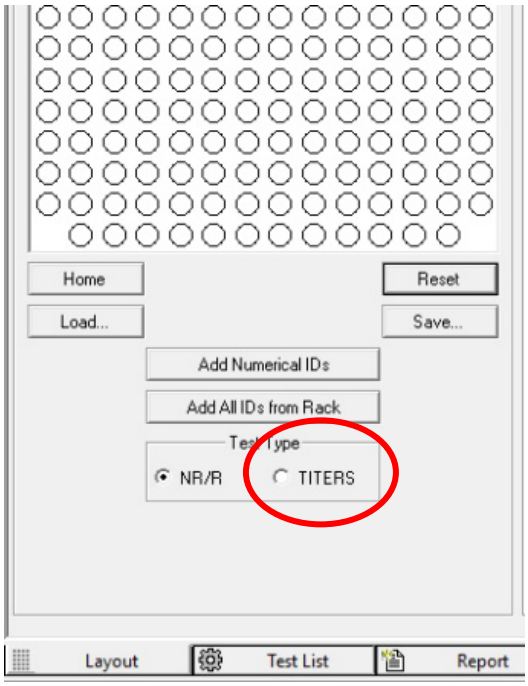


4.3.5 – Continue to enter Sample ID numbers until all samples are loaded or a total of 192 samples have been entered into the work list. **Note**: *The maximum samples in a work list are 192.*

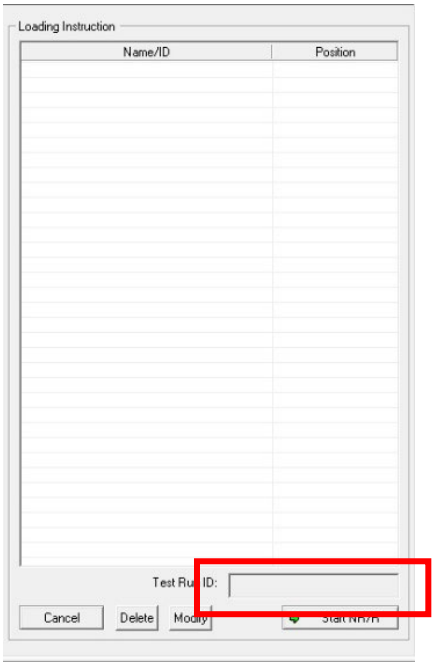
4.3.6 – Click on the "Add All IDs from Rack" button to load the sample IDs from the rack to the "Loading Instruction" window.



4.3.7 – Choose the test type – Titers for semi-quantitative testing.



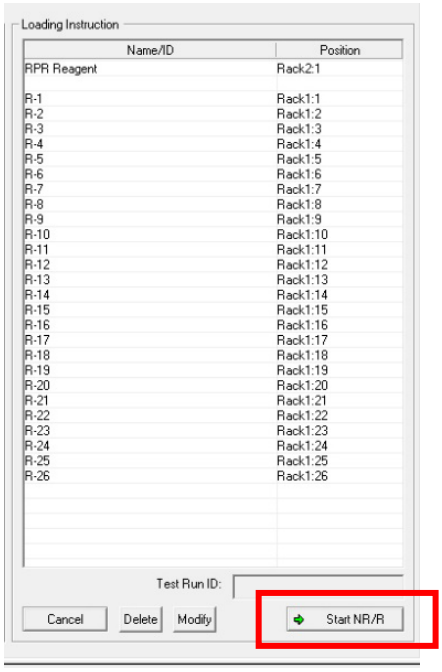
4.3.8 – Enter a worklist ID/name in the window at the bottom of the “Loading Instructions” window



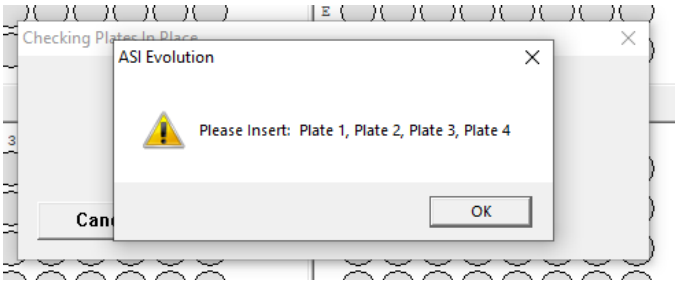
4.3.9 – Vigorously agitate the carbon antigen for 20-30 seconds before placing the vial into the reagent rack. Remove the bottle cap. Note: Ensure that the stir bar is in the vial. The carbon antigen will mix automatically once the assay starts.

4.3.10 – Close the “Shield” of the *ASI Evolution.*

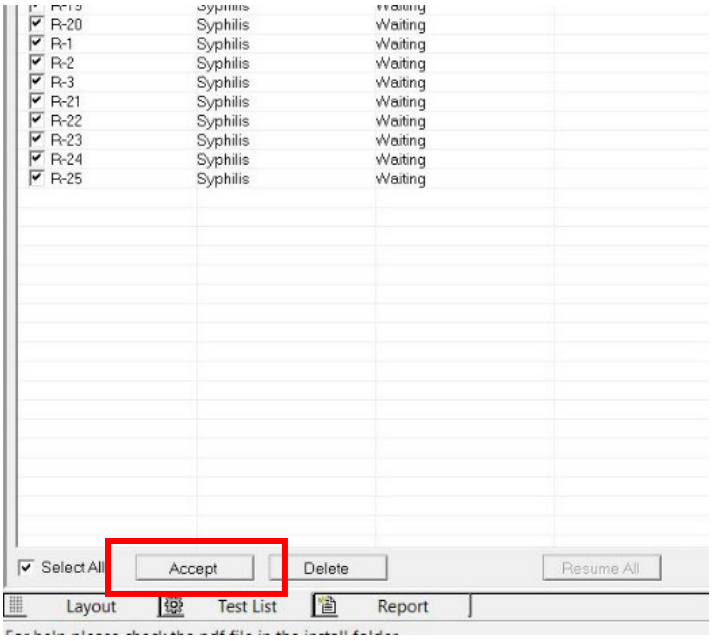
4.3.11 – Press Start NR/R. The assay will start only after the software prompts regarding status of the “Shield” is closed has been answered in the affirmative. Note: The “Shield” must be closed during the assay.



4.3.12 – 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.



4.3.13 – At the completion of the run review and accept or reject the results.



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

4.3.15 – Interpretation of Results: The endpoint titer (e.g. 1:1, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128, 1;256) is equivalent to the last well that gave a reactive result.

4.4 Test List Tab

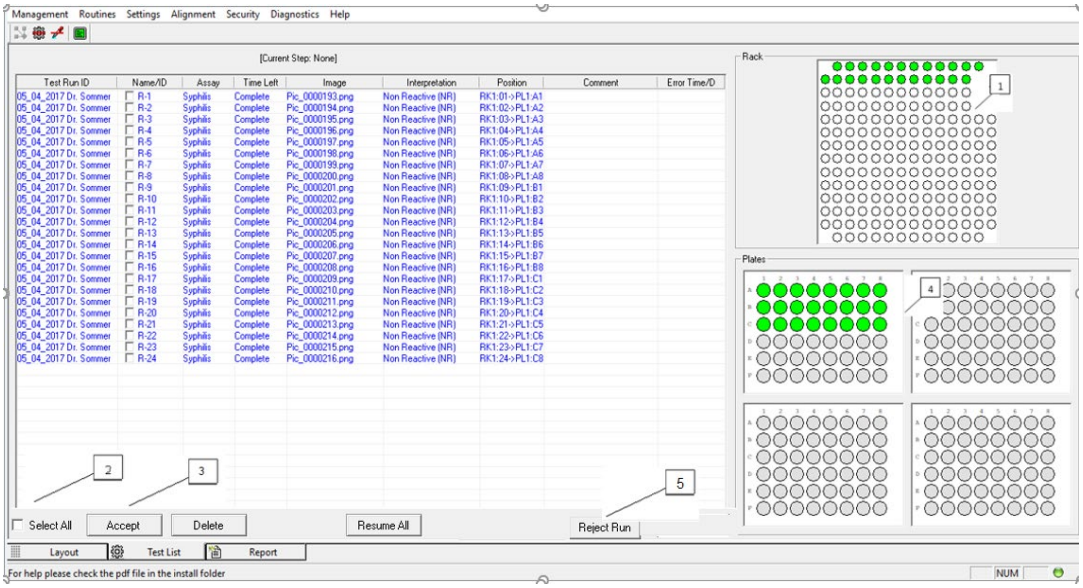
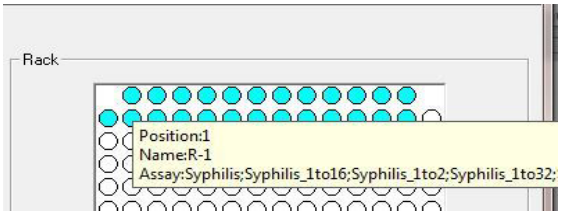


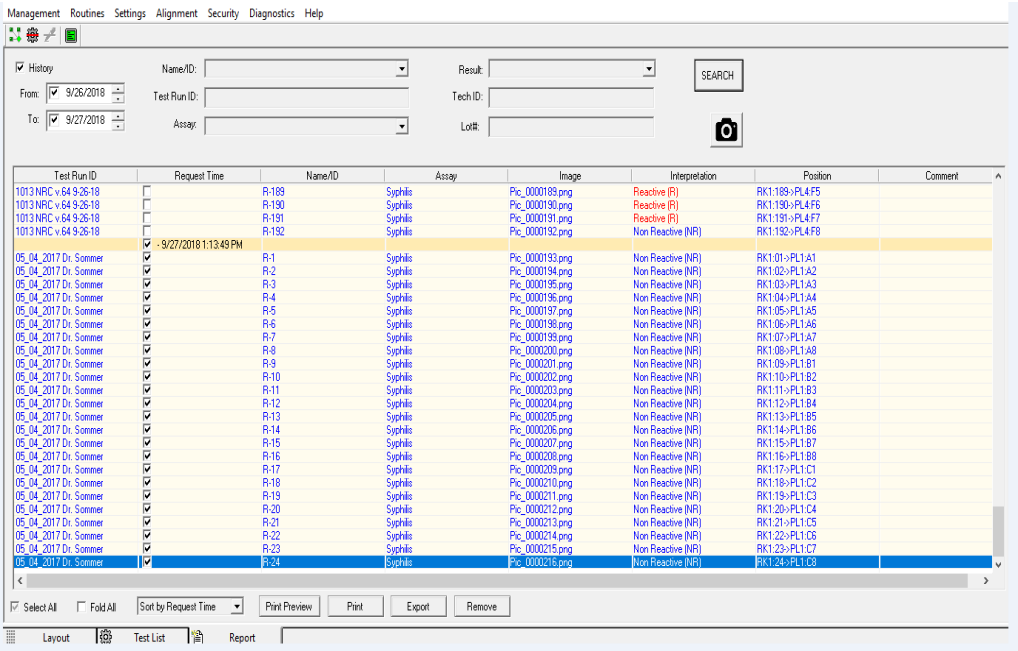
Figure 4.2-1 Test List Tab

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	The 'Select All' button 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 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.

4.5 Report Tab

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

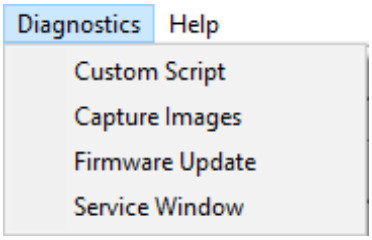
Select the Camera Icon or double click on a result to open Windows Photo Viewer in order to display a captured well image.



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

5.0 Diagnostics

These selections are password protected.



6.0 Report Tab

Possible Insufficient Aspiration can be caused by: Reagent bottles filled past the neck. Bubbles in the reagent. 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'	
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. Make sure the Instrument is powered up.
014	Diluter not responding	See Error Code 010
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 < 100 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:

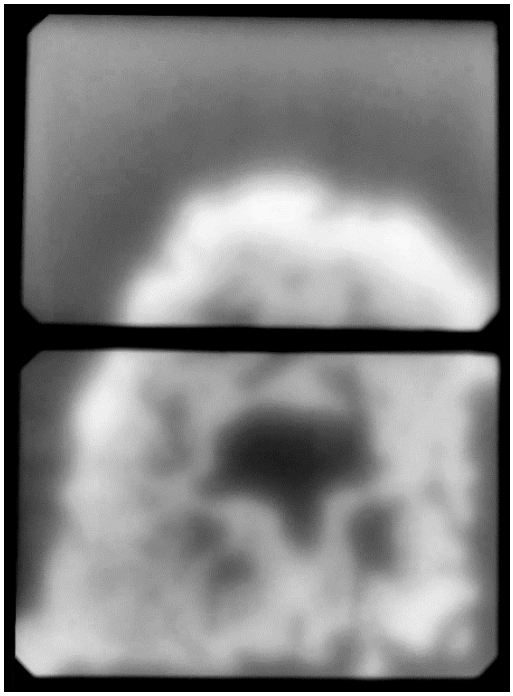
1. If the PlateY Left has a 'Mech Jam' error, then MoverId = 4 and Error Code = 900.

6.2 Fluid Detection Under Light Tray Panels

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

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

Example photo of fluid that has been detected under Light Tray Panels:



6.3 Communication Logs

View communication logs from the Communication Window: Click on any item listed and the log history will open in Notepad.

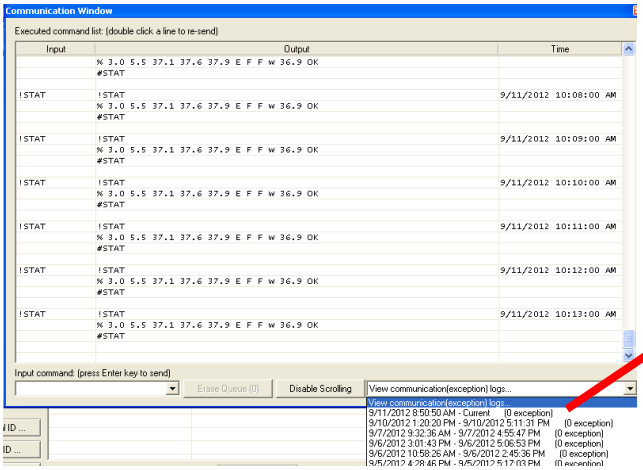


Figure 6.3-1 View communication logs

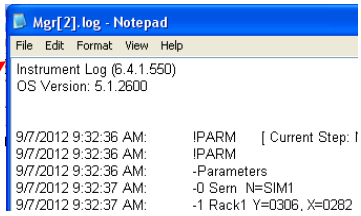


Figure 6.3-2 History Open in Notepad

6.4 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.

6.5 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 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

Model: _____

Serial #_____

NOTES:

8.0 Installation

This instrument is carefully packaged in a custom-made container to assure its safe arrival. If upon receipt the outer packaging is damaged report damage to your freight carrier immediately.

CAUTION!	
	CAUTION! Unpacking this instrument is a 2-person job! Lifting the instrument requires the efforts of two persons. Grasp the instrument at each end of the chassis near the feet of the instrument as shown in the image below and carefully lift the instrument out and onto a stable work surface. 

***NOTE**: Please check the shipping documents for instructions to remove the instrument from the packing carton.*

When shipping, it is important that the instrument be anchored and packaged in the original manner to prevent shipping damage. *Therefore, retain the camera lens cap and packaging in the event the instrument requires future relocation.*

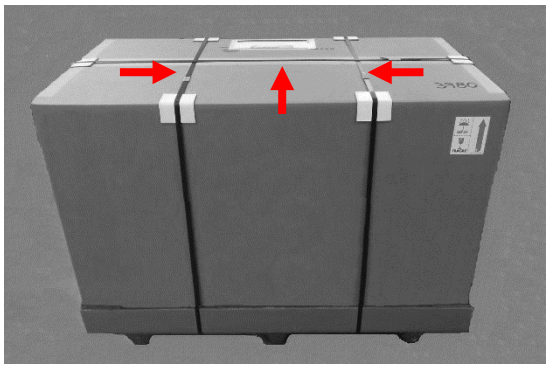
8.1 Packing List

Instrument Kit			**Spare Parts Kit**		
QTY	**PART NO.**	**DESCRIPTION**	**QTY**	**PART NO.**	**DESCRIPTION**
1	2800-000	*ASI Evolution®*	1	2800-020	Exposure Calibration Plate (Black)
1	2800-010	PC Laptop	1	2800-022	Probe Tip
1	X	Operator's Manual (PDF) Installed on Laptop	1	X	Probe Cone
3	2800-021	Sample Racks 192 Positions	1	X	Bottle of Lubricant
1	X	Unpacking Instructions	1	X	Drain Hose
1	X	US or Euro Power Cord	1	X	T-Barbed Connector
1	X	Prime Bottle (Base Only)	1	X	Drain Tubing Clip
1	X	USB Cable	1	X	Drain Tubing Instructions
1	X	Declaration of Conformity			
1	X	Certificate of Quality			

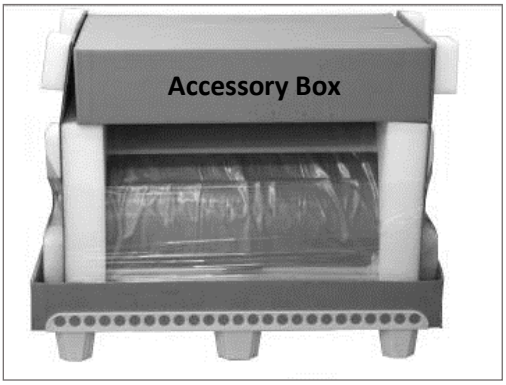
Recommended Spare Parts		
QTY	**PART NO**	**DESCRIPTION**
1	2800-002	Probe Tip
1	2800-017	Syringe
1	2800-019	Waste Container System
1	2800-020	Exposure Calibration Plate
X	2800-021	Sample Racks

8.2 Unpacking Instructions

To open box: Remove (3) banding straps that are securing the box as seen in the illustration below.
Do not cut packaging tape or cardboard cover.



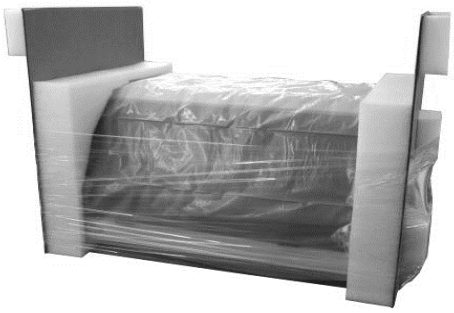
Remove: lift the entire cardboard cover and then the accessory box.



Carefully lift the instrument out. Place the instrument near destination or workstation.

- Do not lift by any components inside housing/casing

Remove the stretch wrap that holds the end caps in place and remove the foam end caps.

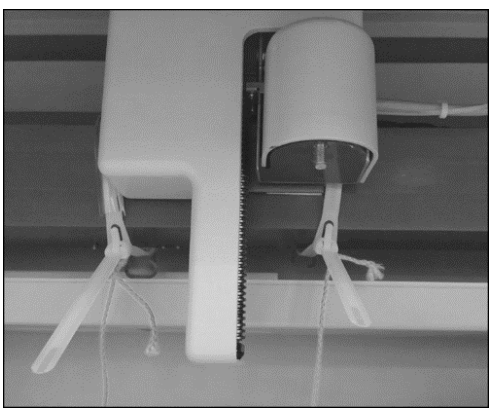


Unpacking Instructions (Continued)

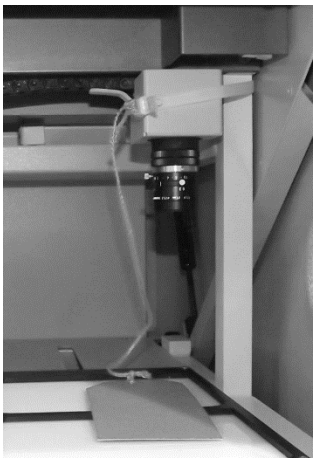
1. Place the instrument on a stable working surface.
2. Remove the protective plastic sheeting from the instrument and save for future use.
3. Cut the twine at the foot of the instrument (at **Red** arrows) that is securing the shield closed, then remove twine as shown below.
4. Once the twine is cut, pull tags away in the opposite direction. (See **Blue** arrows).

5. Remove twin and tag that is securing the Prime Bottle Cap.

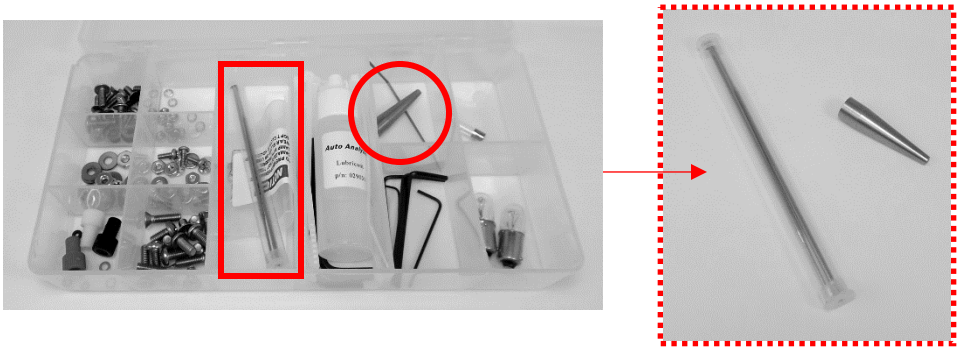
6. Remove the tie wraps that secure the Probe Z for Shipment by pressing the tabs of the tie wraps, then remove with tag. Do not cut the tie wraps.



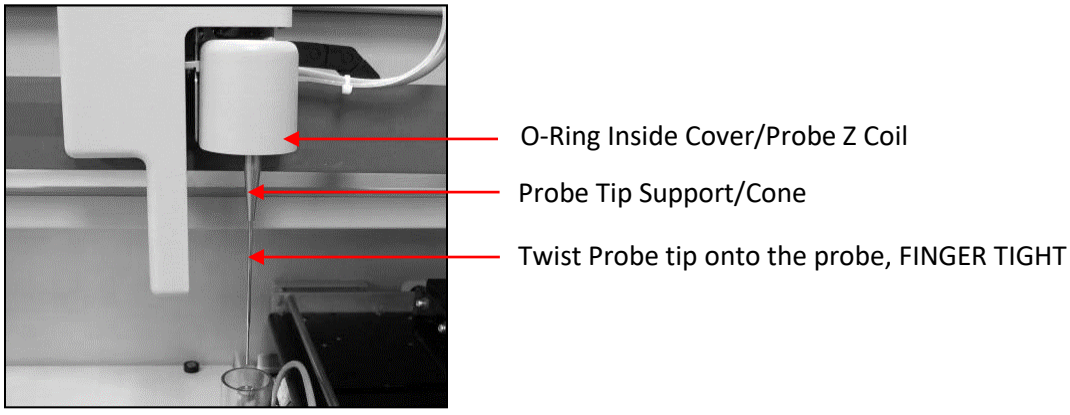
7. Remove the tie wrap that is securing the Camera for shipment, by pressing the tab of the tie wrap and then remove with tag. **<u>Do not cut the tie wrap.</u>**



8. Pull Probe Tip and Probe Cone from the Spare Parts Kit.



9. Remove Probe Tip from holder. Insert the Probe Tip into the Probe Cone with flanged side up.
    - **Ensure the small orange O-ring remains seated between the tubing flare and the end of the threads on Probe Z coil.**



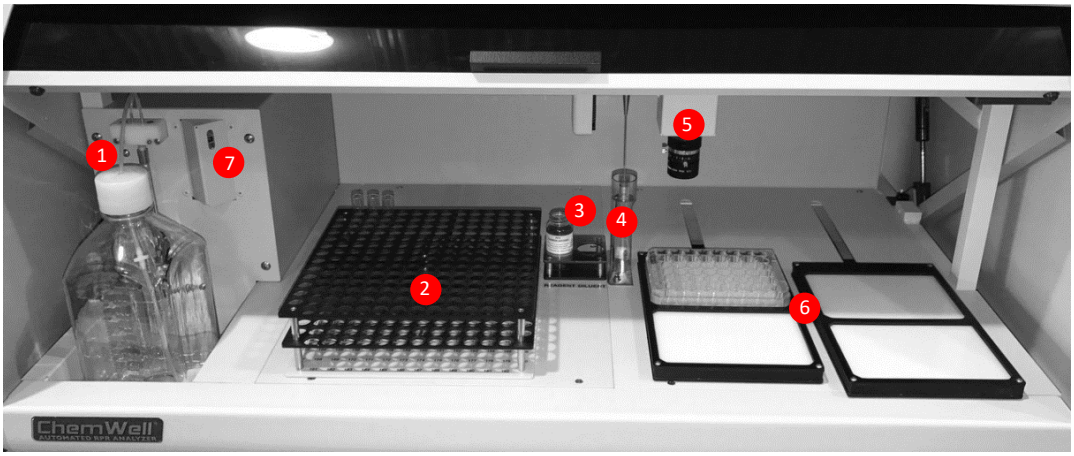
8.3 Instrument Setup

The main power connection is on the back of the instrument. Be sure to leave at least 6 inches (15.2cm) around the instrument to enable access to the power cord.

Position the instrument so that you can easily disconnect main power if required. Please read all Warning and Caution notes.

During first installation, the instrument must be aligned and setup. Use the procedures in this section to ensure that the instrument is ready to work properly. Refer to Section 3.4.1 Alignment.

8.3.1 Instrument Parts



8.3.1-1 Layout of the ASI Evolution®

Item #	Instrument Part
1	Prime bottle and syringe
2	Sample rack
3	Reagent and diluent rack
4	Probe and wash cup
5	Opteon camera
6	Light panels and reaction trays
7	Barcode scanner

8.3.1.1 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 and prolong the life of the components.

Syringe comes preassembled and installed

8.3.1.2 Sample Rack

192 positions for 12mm x 75mm tubes.

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

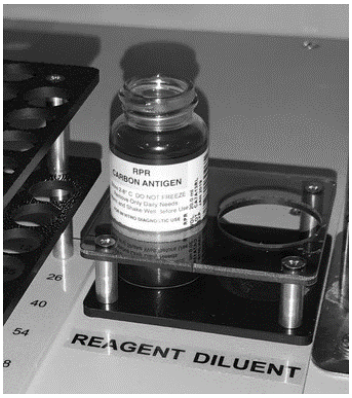
8.3.1.3 Reagent and Diluent Bottle Rack

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

Reagent cannot be placed in the Diluent bottle location.

Do not combine different Lots of Reagent!

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

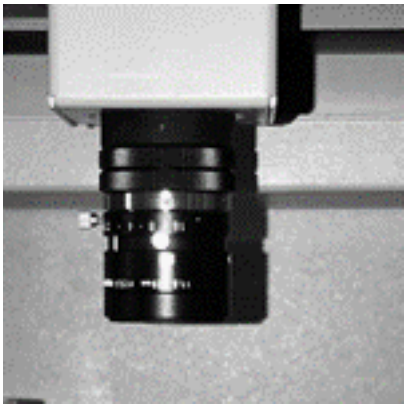


8.3.1.4 Probe and Wash Cup

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.

8.3.1.5 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.**

8.3.1.6 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.

8.3.2 Drain Tube Installation

Read the drain tube installation instructions before cutting the tubing.

CAUTION!	
⚠	CAUTION! To avoid waste fluid backing up into the instrument, ensure that the drain tube is positioned so that the waste fluid can flow and 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.

With the instrument set up in the desired location, connect one end of the drain tubing to the drain outlet located on the bottom of the instrument. Push the tubing over the fitting as far as possible, ideally flush with the plastic nut.

Extend the length of the drain tube over the surface of the lab table (Figure 1) or directly to a drainage port (Figure 2).

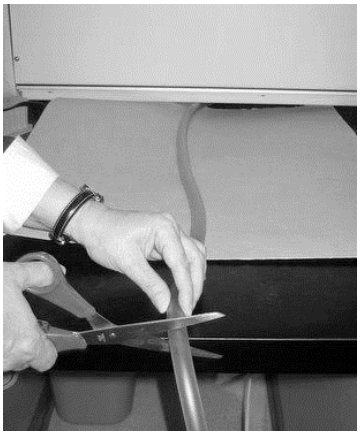


Figure 1

Drainage tube connected to the instrument; measure length of tubing to the edge of lab table.

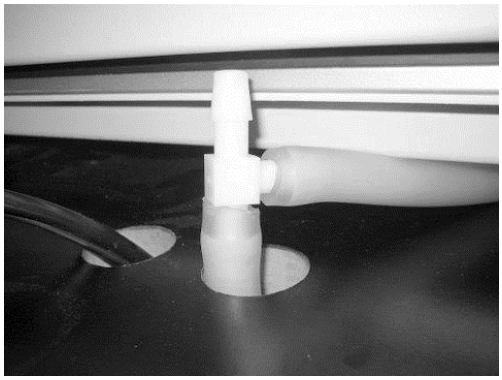


Figure 2

Drainage tube connected with barb tee shown with lab table outlet.

Cut the drain tubing to the desired length (Figure 1).

Drain Tube Installation (Continued)

The upright barb will act as an air gap as shown at A in Figure 3 so that the waste fluid will not develop an air pocket preventing the fluid from flowing into the waste container below.

Push the cut end of the tubing onto the barbed tee as shown at B in Figure 3. This completes the connection from the drain outlet located on the bottom of the instrument to the barbed tee.

Push a piece of tubing onto the barbed tee as shown at C in Figure 3.

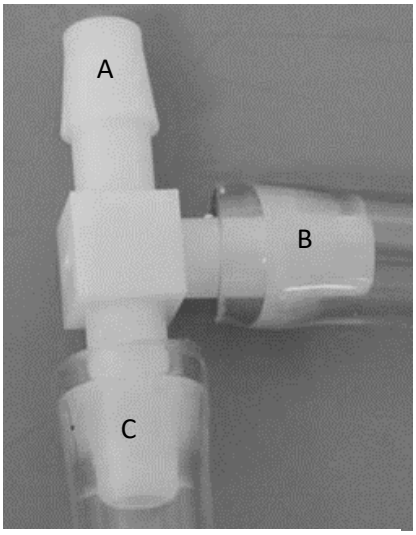


Figure 3

Barbed tee connector with tubing connected.

Connect the drain tubing to the barbed tee as shown.

A. Serves as air gap

B. Tubing attached to the drain outlet on the bottom of the instrument

C. Tubing leading to waste container

Cut the opposite end of the drain tubing on the diagonal (Figure 4) and place it into the waste container. Place the waste drain container at a level lower than the instrument to allow the fluid to flow into the waste drain container. Ensure that the placement of the tubing in the container will allow the waste fluid to flow. The waste drain tubing may be routed through an access hole on the lab bench or routed to the front or back of the instrument as desired to the waste drain container. The drain line may also be connected to an approved permanent drain.

***NOTE**: Cutting the end of the tubing on a diagonal will prevent the tubing from resting on the bottom of the waste container which may cause the waste fluid to back up into the instrument.*

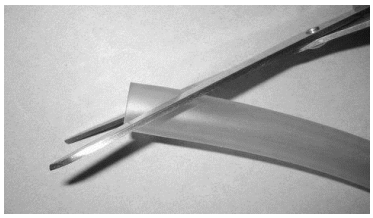


Figure 4 - Cut the drainage tube on a diagonal to prevent tubing from resting on any wall or the bottom of the waste container.

8.3.3 Connect ASI Evolution® to Power Source

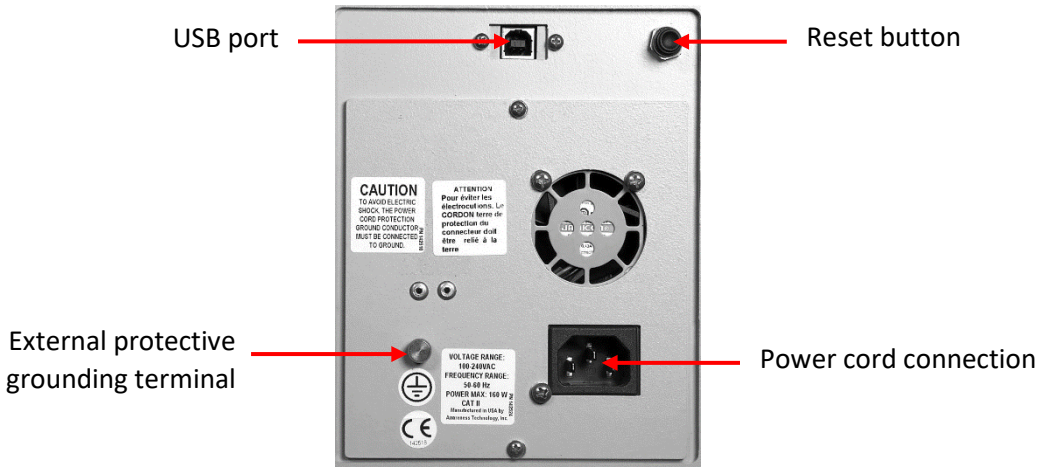
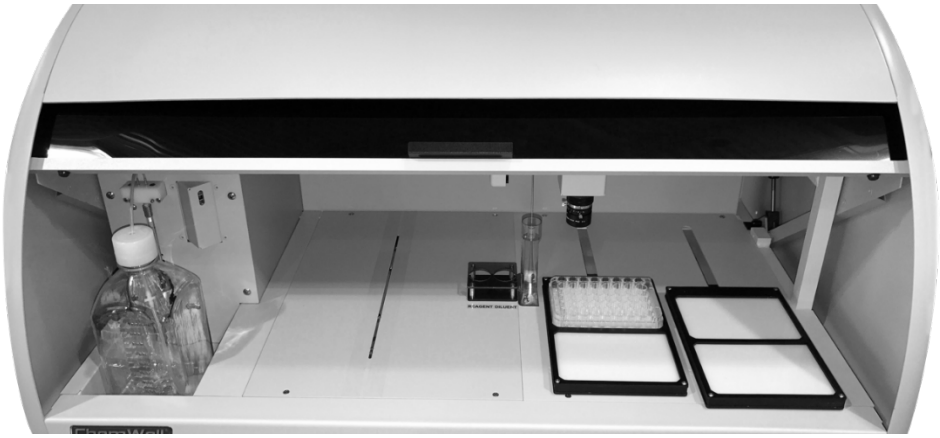


Figure 8.3.3-1 Power and USB connections

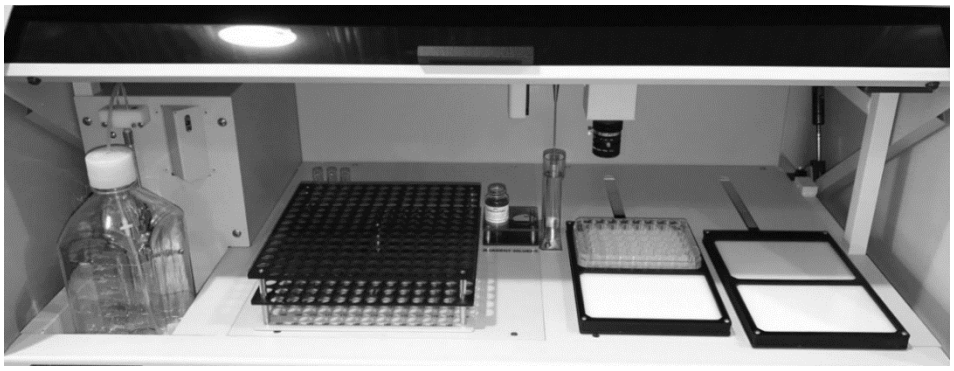
Connect the power cord to the instrument and then to an approved power source. It is strongly advised that an Uninterruptible Power Supply (UPS) be used to avoid power interruptions to the instrument and to the computer.

Warning!	
⏚	WARNING! To avoid electric shock, the grounding conductor must be connected to earth ground. An optional method is to attach a ground strap from the external grounding terminal on the rear panel of the instrument to a suitable ground such as a grounded pipe or some metal surface to earth ground.

8.3.4 Sample Rack and Microwell Plates Placement



8.3.4-1 Location of the Sample Rack Locating Pin



8.3.4-2 Instrument Setup Complete

8.3.5 Power up and Initialization

The program default communication port setting for USB is AUTO for communication with the instrument. If connecting the instrument to a different port, go to the Settings Menu and select Software. Select a communications port and click OK. (For troubleshooting, reference Section 9.3 Comm Port Settings.) Connect the USB cable supplied with the instrument to the USB connection located on the back of the instrument.

Set the power switch, located on the back of the instrument, to ON (I).

The uses ***ASI Evolution***® standard Windows® controls, windows, and dialogs. Refer to your Windows® documentation to become familiar with these controls and how to use them. It is not necessary to turn the instrument off when restarting the software. However, the instrument will make a beeping sound until the software is opened.

The Initialization process establishes communication between the software and the instrument and will occur each time the software program is opened. If Initialization fails at any point, an error message will display.

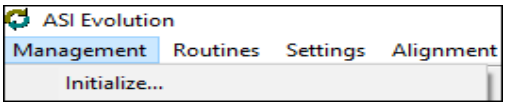
During the first execution of the ***ASI Evolution***® Analyzer software, locate the ***ASI Evolution***® Analyzer icon.

Right click on it and select “Run as Administrator” (See 8.3.6 Security Settings). Communication between the instrument and the software will be automatically established. When the initialization box appears – click “OK”.

The following actions will take place:

- The lights under the light panels (plate carriers) turn on and go off.
- The probe will move to its home position (to the left), and then to the wash cup.
- The syringe pump will prime.
- The light panels will home.
- The camera will move to its home position on the right side of the instrument.

Initialization may also be executed without restarting the software by clicking on Management - Initialize on the software toolbar.



These events are controlled by firmware installed in your instrument; however, the software must be running for proper operation. If the instrument's power comes on, but these actions do not occur, and a beeping sound is heard, there is a problem with the communications setup. Check the cable connections and COM port settings.

> **NOTE**: Before starting any tests, perform the following checklist and correct any problems.
>
> - ✓ Rack setups match the layout on the screen
> - ✓ Bottle caps are removed
> - ✓ The probe pathway is clear of obstacles
> - ✓ There is enough deionized (DiH_20) water in the prime bottle

8.3.6 Security Settings

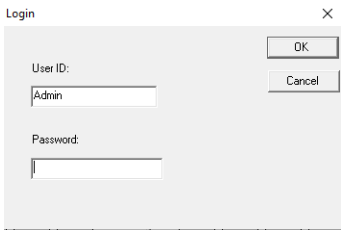
A user-based authentication system is implemented in the software, so only valid users can use the device to generate measurements and results.

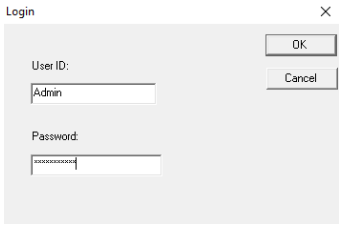
During the first execution of ***ASI Evolution***® Analyzer, the software requires entry of 'Admin' for the password. Once that is entered the 'Admin' will be forced to change the password to something other than 'Admin'.

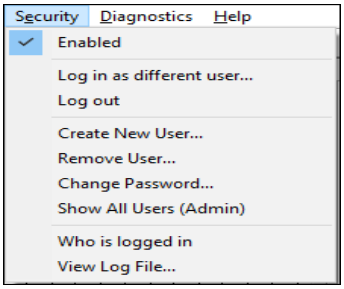
After that, "Admin" will no longer be a valid password option. As 'Admin' be sure to Log Out. This will secure the system.

After the new Admin password has been created the ***ASI Evolution***® Analyzer software can now be launched with Security "Enabled" by simply double clicking on the ***ASI Evolution***® Analyzer icon and Login with the Admin User ID and the Admin Password.

The 'Admin' will select 'Security' from the toolbar in order to establish security access for any other users. There are three security access levels: Administrator, Manager and Operator.







Function	Administrator	Manager	Operator
Disable Security - When Disable is checked, the password protection and security restrictions are not being used.	Y	N	N
Enable Security - When Enabled is checked, the password protection and security restrictions are being used.	Y	N	N
Create or Remove a Manager	Y	N	N
Create or Remove a User	Y	Y	N
Change a Password - Any level can use this feature to change their password.	Y	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	Y

Figure 8.3.6-1 Security Levels

9.0 Appendix A

9.1 Cleaning Solutions

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

Alcohol Syringe Cleaning Solution: 70% isopropyl alcohol

Bleach Syringe Cleaning Solution: 10% chlorine bleach

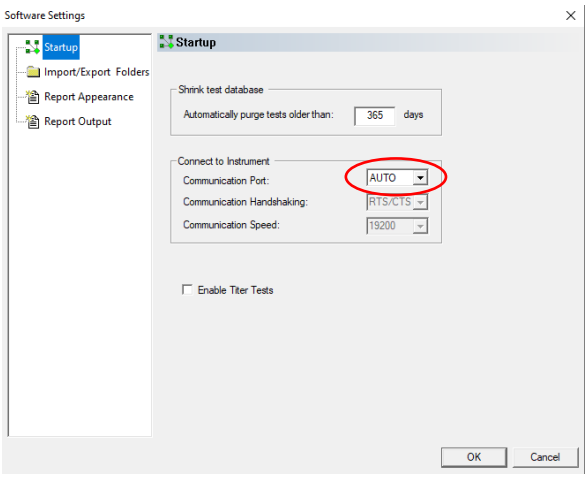
9.2 Cleaning Procedures

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 soft cloth dampened in warm water. Be careful to not 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 Communication (COM) Port Setting

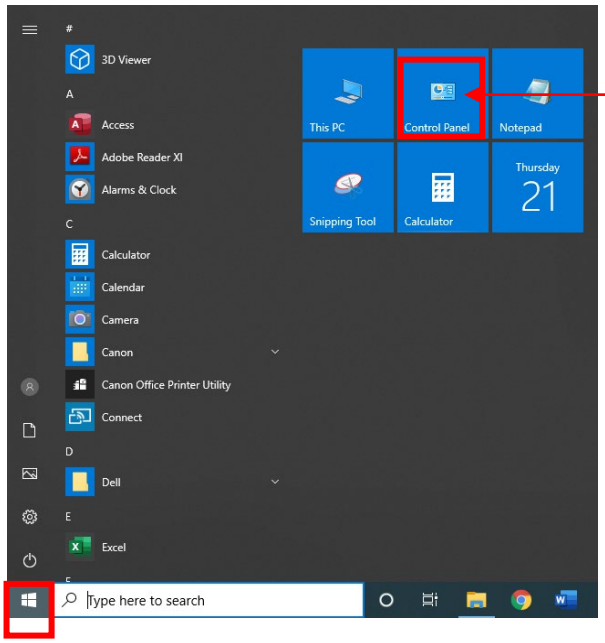
The program's default communication port setting is **AUTO**. To change the communication port, choose Software under the Settings menu. Click on the down arrow to display the optional settings; click to select, click OK to accept.



The following instructions have been included in case they are ever needed. It is rare that the COM Port Setting will need adjustment. If the software has trouble communicating with the instrument, check the COM Port setting on the computer as it may be necessary to make an adjustment to the instrument's software settings. The Windows **Device Manager** needs to be opened in order to know which COM Port your computer system is using for the USB connection to your instrument.

For Windows® 10 follow these steps to access the COM Port Settings:

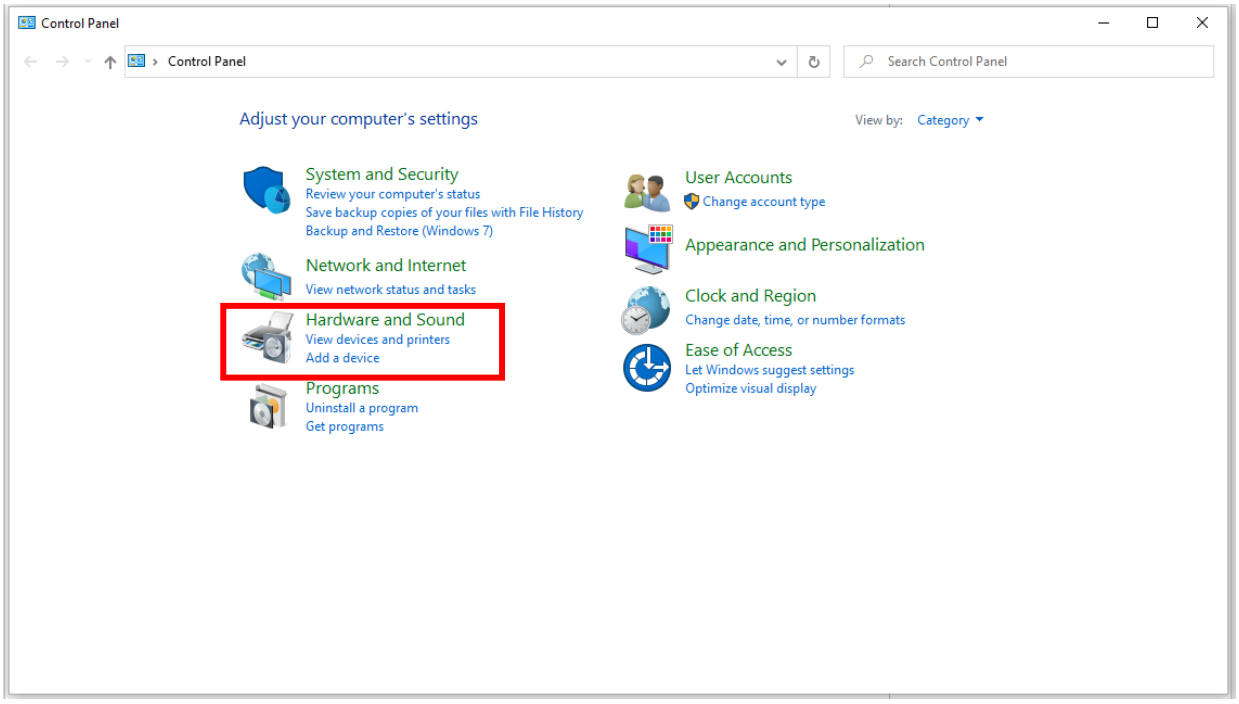
Step 1 – Access the control panel by opening the **Windows ® Start** screen and selecting **Control Panel**.



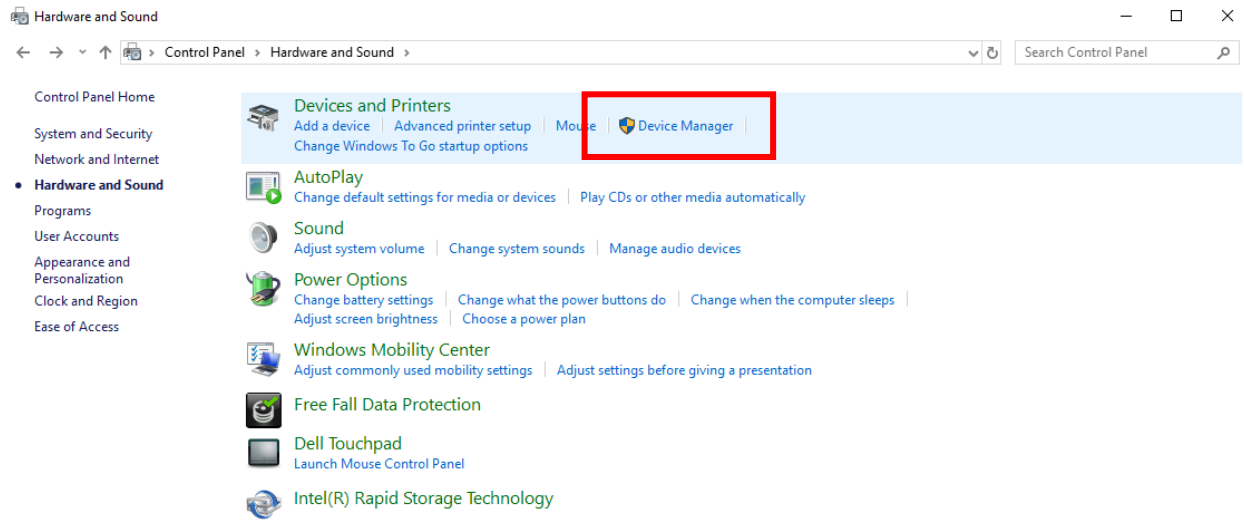
1. Click on the Windows ® Start button.

2. Select the Control Panel from the start menu.

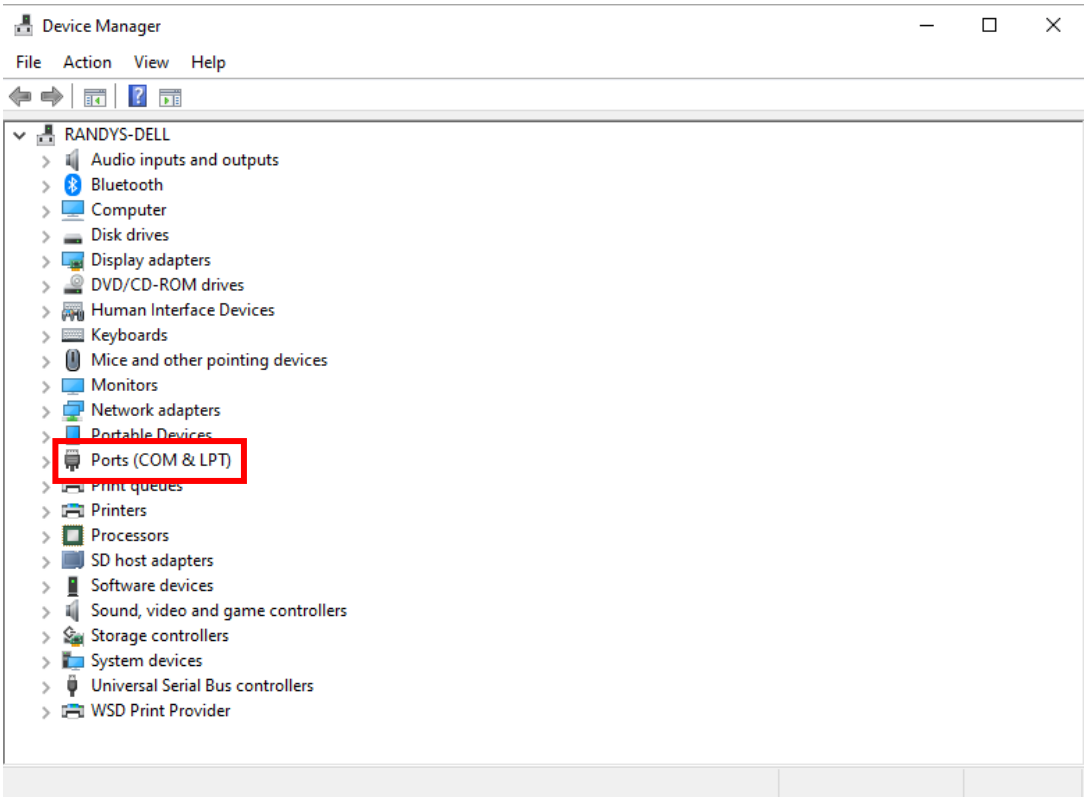
Step 2 – Select **Hardware and Sound** from the **Control Panel**.



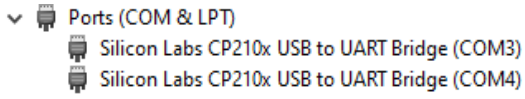
Step 3 – From the **Hardware and Sound** menu select **Device Manager**.



Step 4 – From **Device Manager** select **Ports (COM & LPT)**

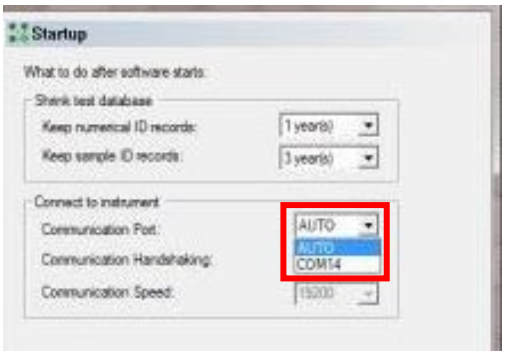


Click on the **Ports (COM & LPT)** folder. You should see a version of Silicon driver.



If Silicon Labs is NOT shown, recheck the connection between the instrument and the PC and be sure the instrument's power switch is set to I (ON).

From here you can see what COM# is connected. If the software is displaying a different communication port, select COM# from the drop down list**.** Be sure to select **OK** to exit at the bottom of the window.



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