

ASiManager-AT™ User Guide



ARLINGTON SCIENTIFIC, INC.

1840 North Technology Drive, Springville, UT 84663 USA

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GENERAL INFORMATION

INTRODUCTION

The ASiManager-AT™ is an integrated digital particle analyzer designed to objectively interpret the Arlington Scientific, Inc. (ASI) RPR Card Test for Syphilis. Qualitative and semiquantitative tests are performed by laboratory professionals who in turn use the ASiManager-AT™ to perform standardized test interpretation using criteria that define reactions.

After performing the ASI RPR Card Test for Syphilis tests (according to the package insert) the test card is inserted into the ASiManager-AT™, the device reads the card, and results are displayed with a predictive titer analysis, and shows if the sample is "REACTIVE," or "NONREACTIVE."

Intended Use

The ASiManager-AT™ is intended to be used as an integrated digital particle analyzer to objectively interpret the ASI RPR Card Test for Syphilis. The ASiManager-AT is designed to provide standardized test interpretation, an initial predictive titer analysis, and provides for storage, retrieval, and transmittal of the test results. It is intended to be acquired, possessed and used only by health care professionals. For *in vitro* Diagnostic Use Only, not intended for screening blood and tissue donors.

Technical Overview

The ASiManager-AT™ employs a CCD (charge-coupled device) camera using light reflectance to create a highly sensitive and high-resolution image of the agglutination immunoassay. This image is then analyzed by ASI's proprietary software algorithm to interpret the degree of agglutination.

Scope Of Use

Only serology tests which have been manufactured and released by ARLINGTON SCIENTIFIC, INC., can be performed on the ASiManager-AT™. The Package Insert for the serology test being conducted must be read, understood and correctly performed prior to being analyzed by the ASiManager-AT™.

User Limitations

- The ASiManager-AT™ should only be used with tests approved for use with the ASiManager-AT™ manufactured by Arlington Scientific, Inc.
- Use the ASiManager-AT™ User Guide in conjunction with the ASI RPR Card Test for Syphilis Package Insert
- The intensity of agglutination patterns will vary with wide fluctuations in room temperature
- In accord with all diagnostic tests, a final diagnosis should not be made from the result of a single test, but should be based on a correlation of test results with other clinical findings

Contents

ASiManager-AT™

- Computer/ Monitor / Imaging Unit
- Wireless Keyboard and Mouse
- Monitor Cables and Power Adaptor
- Bar Code Reader
- ASiManager-AT™ System Check Cards

If you have any questions concerning use of the hardware, please contact ARLINGTON SCIENTIFIC, Inc., by phone, fax or e-mail. (info@arlingtonscientific.com) or contact your distributor.

The ASiManager-AT™ arrives in a single box. If damage is found as a result of inappropriate handling during transport, inform your supplier or forwarding agent immediately.

Quick Start Guide

- Please read the Quick Start Guide entirely for proper setup
- Follow the instructions closely

User Guide

- Please read this User Guide entirely prior to first use
- Follow the instructions closely

Warranty

This product is guaranteed against defects in material or workmanship for one (1) year commencing with receipt by the original end user. If a product fails due to a manufacturing defect, we will repair or authorize repairs to the product without charge, or replace it at ASI's option.

Prior written authorization must be obtained from Arlington Scientific, Inc. in order to return this product. If a product is returned without prior written authorization, the customer shall be responsible for all shipping charges and any applicable duties and/or tax. When a repair is made on site, solely at the request of the customer, the customer is responsible for all travel costs.

Arlington Scientific, Inc. disclaims any implied warranty of merchantability or fitness for a particular purpose and in no event shall Arlington Scientific, Inc. be liable for consequential damages.

Future Software Releases

In the course of the product life cycle, ASI may introduce additional software releases for the following reasons:

- 1) Modify or correct software glitches discovered by ASI or our customers
- 2) Enhancements to either the GUI/APP or algorithm that our customers may elect to install or request
- 3) System upgrades as required

ASI will contact you directly and inform you of the nature of the release and to schedule an update as needed.

Note: Some software release's may be required as part of our ongoing maintenance and preventive maintenance procedure to ensure the overall integrity of the ASiManager-AT™.

Backing up the ASiManager-AT™

ASI recommends that the ASiManager-AT™ be backed-up on a regular basis as required by your facilities procedures. When updating the ASiManager-AT™ software with new software updates, you should back up all data prior to installation.

CONTACT INFORMATION

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(800) 654-0146
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Email

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Customer Service

8 a.m. to 5 p.m. Mountain Time

Web Site

www.arlingtonscientific.com

USER/ADMINISTRATION

PROGRAM START

Start the software by clicking on the ASiManager-AT™ Desktop icon.

Startup Login

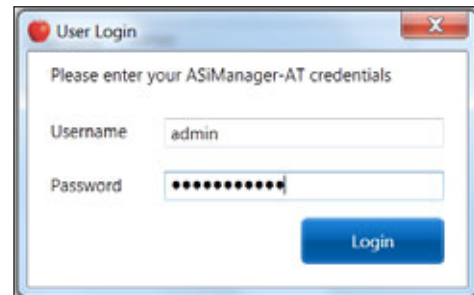
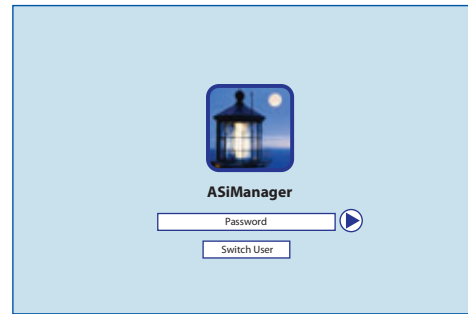
When the program is first started the administrator login password will be automatically assigned. (Please type in "arlington" in lower case letters). Once you have logged in you can change the password.

User Login After Program start:

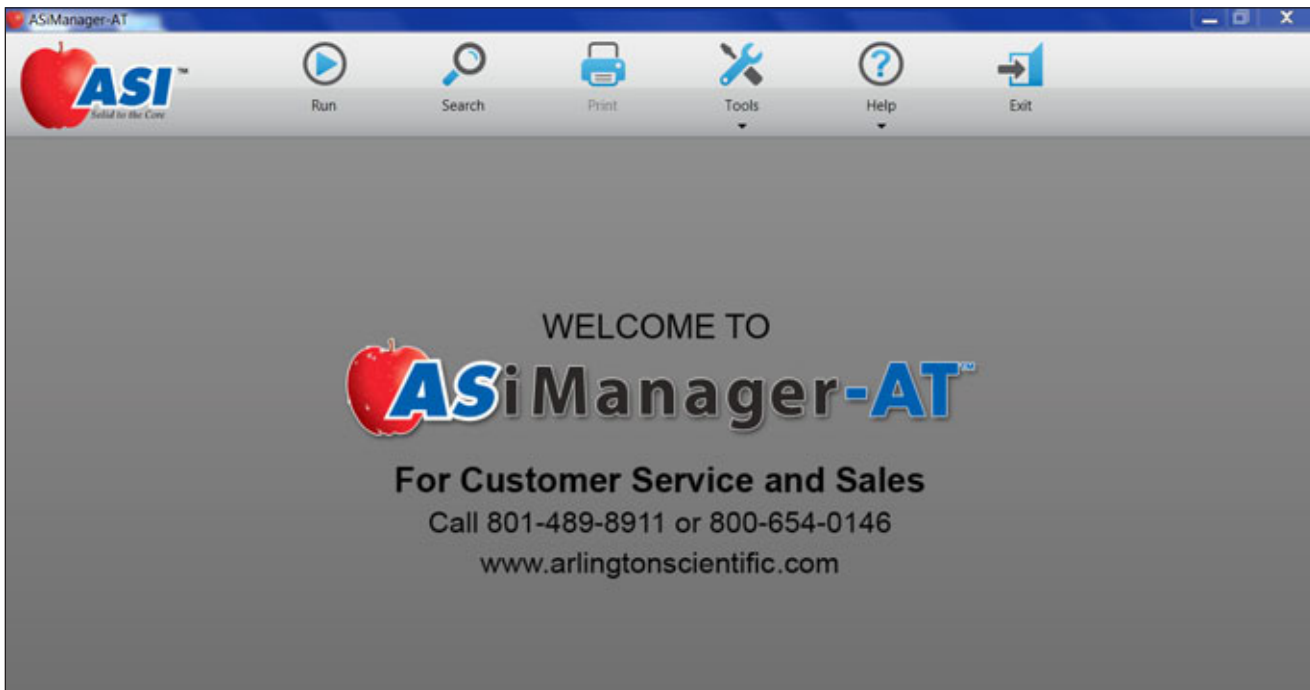
- Type in user name (Temporary default "admin")
- Type in password (Temporary default "arlington")
- Click "Login"

The program starts by using the correct password and the settings that were defined by the administrator for each user. **Passwords are case sensitive.**

Note: If "Caps Lock" is on, you will be notified prior to entering your password.

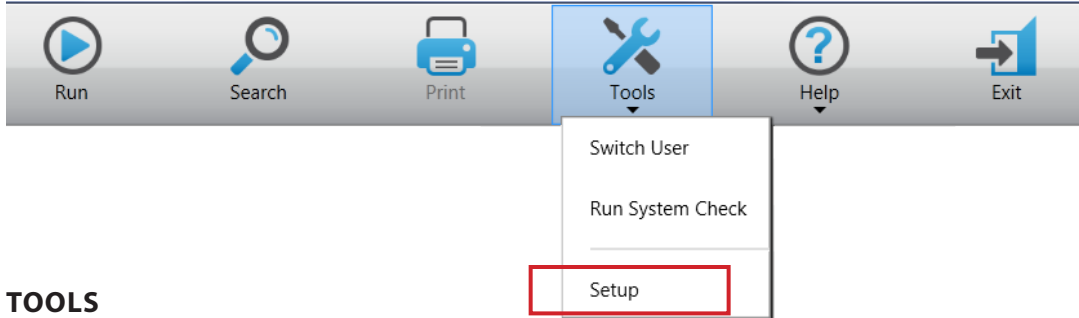


ASiManager-AT™ Welcome Screen



INITIAL SETUP

ASI recommends you establish the following, prior to testing



TOOLS

The Tools icon will allow the user to:

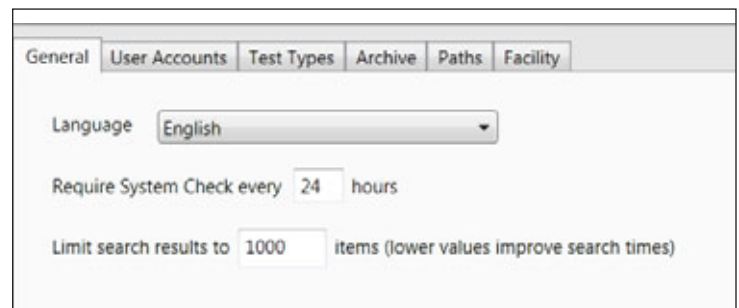
- Switch users
- Run the “System Check” program
- **Go to setup options**

SETUP

The SETUP option allows you to determine several settings.

• General

General Setup includes Language Options (for international users only), Setting your System Check (default is 24 hours) as well as how you would like to limit your search results (default is 1000 samples).



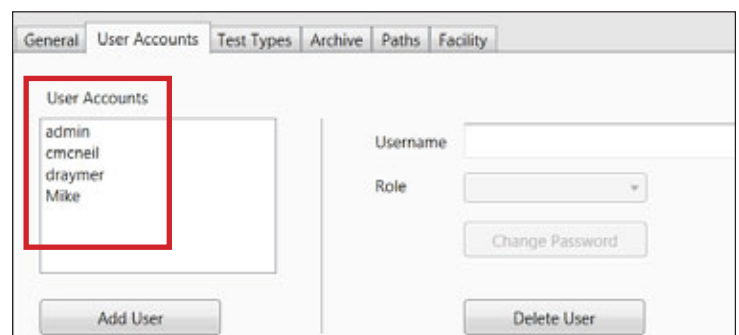
• User Accounts

The ASiManager-AT™ offers the option of a User Administrator.

The administrator can choose to limit program functions for individual user accounts based upon user profiles (see page 21 for profile options).

In the User Accounts module the Administrator can add, modify or delete user accounts (only one user account may be modified or deleted at a time). There are three types of Users –Administrator, Technician and Technologist.

Already established user profiles will be shown on the left. The Administrator creates new user accounts including temporary passwords. Once accounts have been established only the Administrator can add new accounts or delete user accounts. Once a User uses their account, only the User can change their password.



Note: Administrator should track and record all user passwords

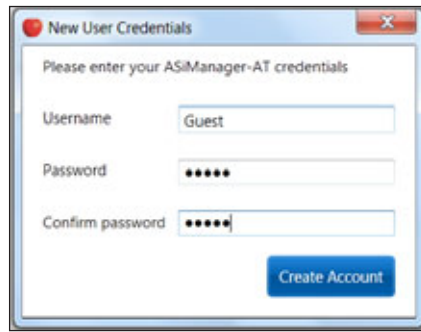
“User-Technician” and “User-Technologist” is only allowed to select “Paths” for “import” and “export” options and “Facility” information.

To add an additional user, click on Add User.



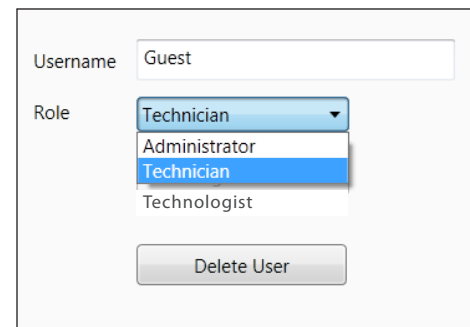
You will be prompted to enter in the New User Credentials.

Enter in the user name and password



Confirm the password.

You will then be able to assign the role of the user as either "Administrator,"



"Technician," or "Technologist."

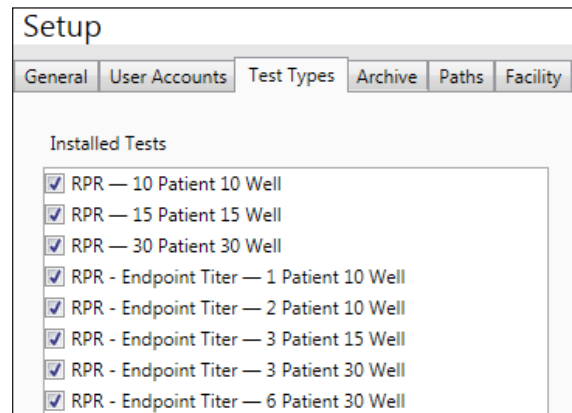
Test Types

This will show the test options that are installed with your ASIManager-AT™.

Select the tests that your facility will be using.


NOTE: This function is set up by the Administrator prior to testing. The system default is set so that all tests are selected.

To change the default, the Administrator must log-in and select tests appropriate for your facility. Clicking on the check box next to each test will select or deselect that item.



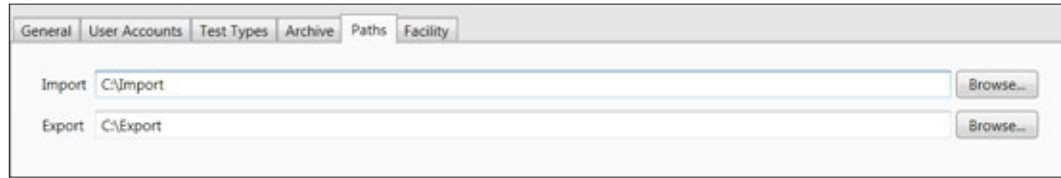
Archive

- Test results can be archived at predetermined quantities. Default setting is 10,000 tests.
- Purge will auto alert user when "X" number of days of results has been received. Default is set at 30 days.
- Purge "All" or "Only nonreactive results" can be set. Default is set to "Purge all results."
- The "Purge Test Results" button will in the above example keep the most recent 10,000 archived test results and purge any archived result older than the most recent results as defined in the above settings. This does not affect results archived in an LIS or external storage device or database system.



Paths

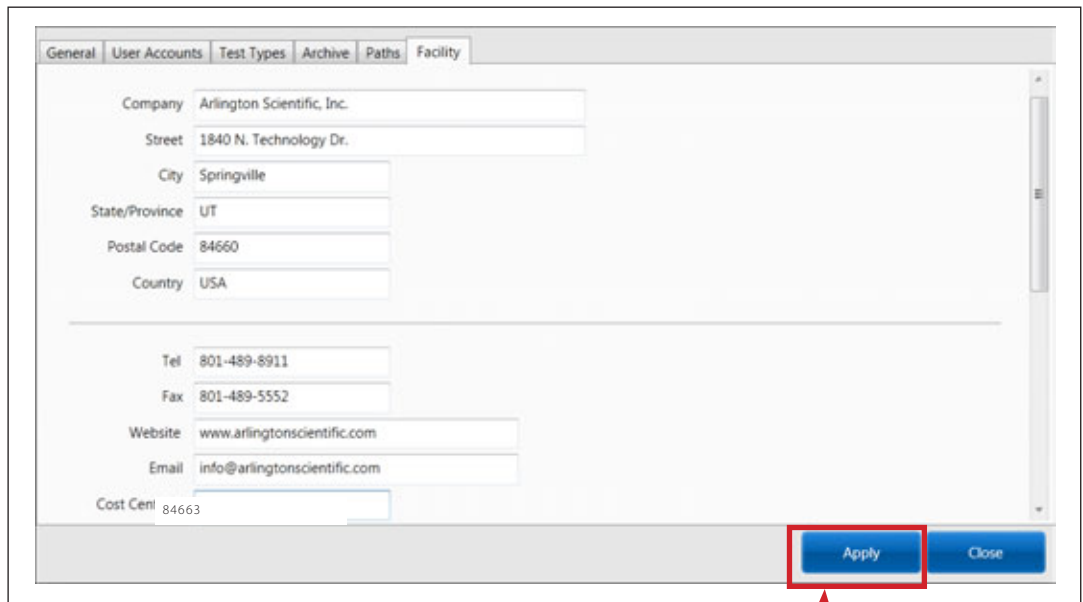
The "Path" option allows data paths to be set for the import or export of data to or from various storage devices or database files.



The screenshot shows the 'Paths' tab of a software window. It contains two text input fields: 'Import' with the value 'C:\Import' and 'Export' with the value 'C:\Export'. Each field has a 'Browse...' button to its right. The window has a tabbed interface with 'General', 'User Accounts', 'Test Types', 'Archive', 'Paths', and 'Facility' tabs.

Facility

The address of the test facility can be entered in this window. This address will appear on the Sample ID report. All data loaded to this work sheet will appear on Report—"Print/or Export Results."

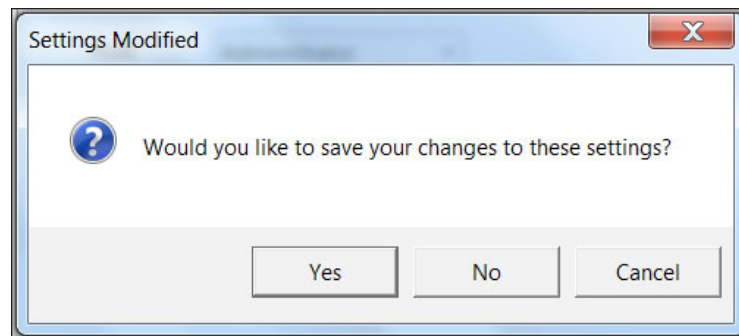


The screenshot shows the 'Facility' tab of a software window. It contains several text input fields for company and contact information: Company (Arlington Scientific, Inc.), Street (1840 N. Technology Dr.), City (Springville), State/Province (UT), Postal Code (84660), Country (USA), Tel (801-489-8911), Fax (801-489-5552), Website (www.arlingtonscientific.com), Email (info@arlingtonscientific.com), and Cost Cent (84663). At the bottom right, there are 'Apply' and 'Close' buttons. A red box highlights the 'Apply' button, with a red arrow pointing to it from the 'Save Changes' section below.

Save Changes

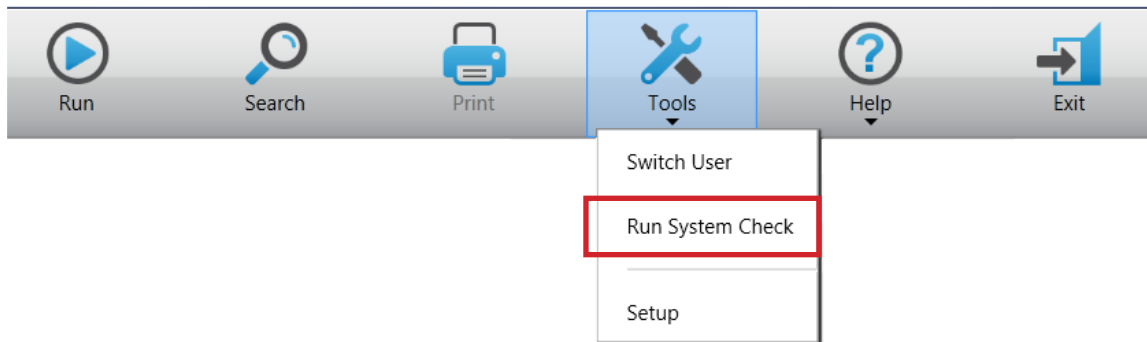
Anytime you make changes to any of the SETUP items, click on the "APPLY" button.

A window will appear asking you to verify your choice.



The screenshot shows a dialog box titled 'Settings Modified' with a question mark icon. The text inside asks, 'Would you like to save your changes to these settings?'. At the bottom, there are three buttons: 'Yes', 'No', and 'Cancel'.

SYSTEM CHECK



ASiManager-AT™ System Check Card (SC)

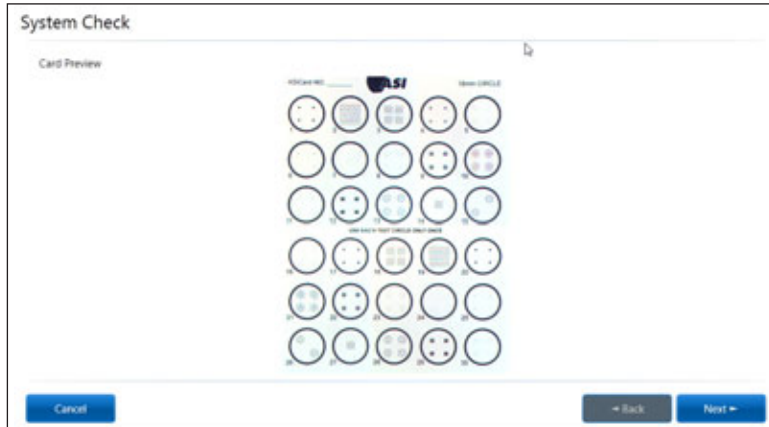
The ASiManager-AT™ System Check Cards are provided with the system and are used to ensure that the instrument is performing as expected.

Under "Tools," "Setup" the ASiManager-AT™ system check default is every 24 hours. This can be changed to accommodate your facilities quality control requirements (See page 5 of this manual).

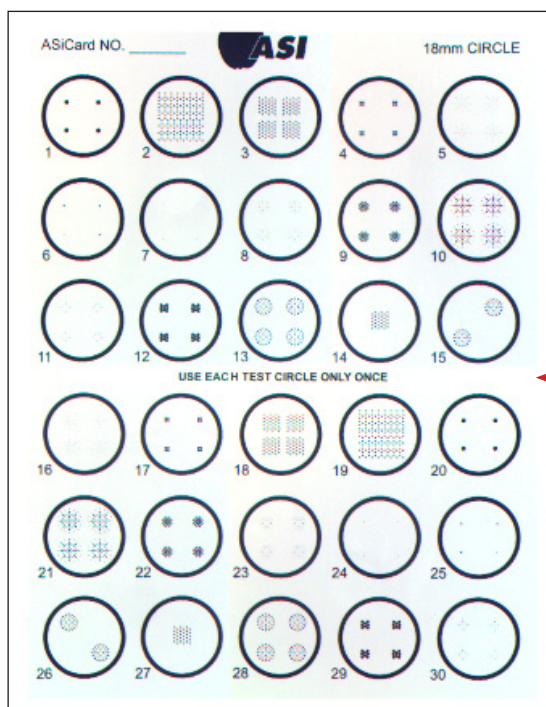
Note: ASI provides a small box to retain and protect the System Check Cards.

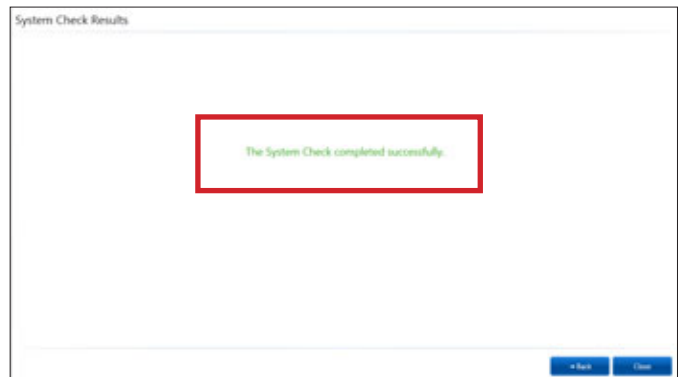
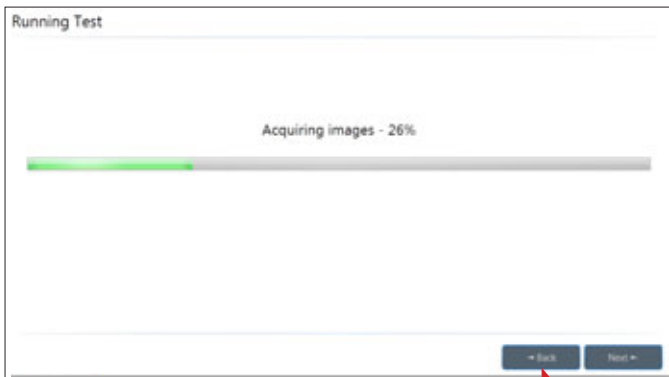
Select Run System Check

- Insert System Check Card into the tray using the 30 well slot. System Check Card will appear in the window.
- 2 (two) System Check Cards are provided with the ASiManager-AT™. Either card can be used.
- Click "Next" to run **System Check function**.
- Results will display as passed or failed.
- When System Check is complete, click "Close."



Sample of what appears in the system check window.





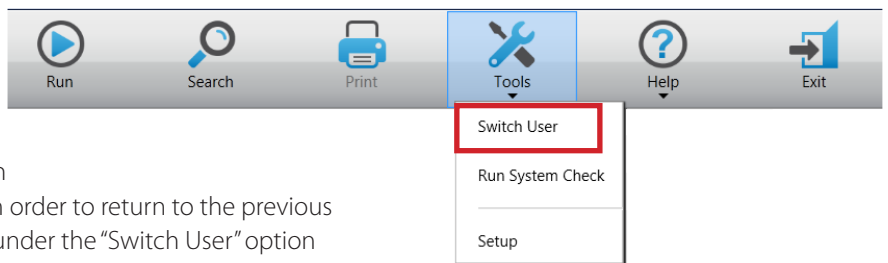
Restart the System Check Card as needed.

– If System Check fails, rerun test and make sure:

- Card is free from debris, not severely warped, or faded and is seated properly in the tray, and that tray is properly closed.
- If System Check test fails again, use System Check backup card and repeat.
- If System Check test fails with backup card, tests should not be run. Call ASI for technical assistance **1-800-654-0146**.

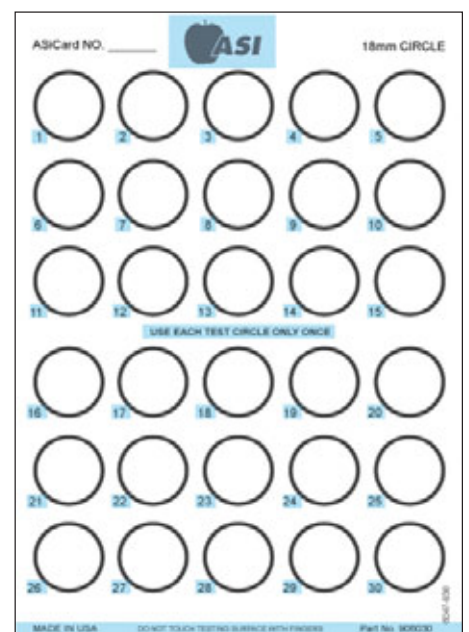
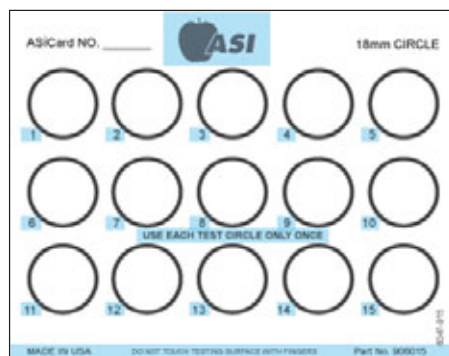
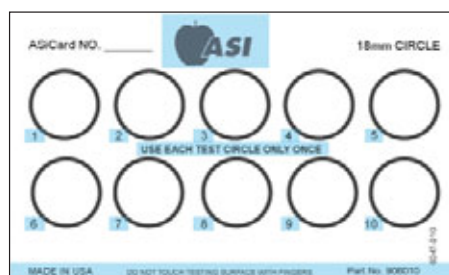
Switch User

When a “User” is logged into the system, an additional user such as an administrator can log in using the “Switch User” option under tools in the toolbar. In order to return to the previous user, the previous user must log back in under the “Switch User” option while on the welcome page.



10, 15, 30 Well Test Card Prepping

When marking test cards with notes, do not mark in the areas shown below in blue (shaded). Marking in those areas obscures information used by the ASiManager-AT™ to run tests, provide well data and traceability.



PERFORMING TESTS



Run

SETTING UP TESTS

- Click **RUN** in the tool bar to start the ASiManager™ program.

Create or Select Worklist

You will be prompted to create a worklist.

Options Available

- Create/Import Worklist
- Select Existing Worklist

Create allows you to enter a unique sample ID by entering it manually through the keyboard or automatically with the barcode reader.

Note: Selecting next will save worklist to Worklist Name file.

Select Existing Worklist allows you to select pre-built worklists that were created manually or with the barcode reader.

Note: Once a worklist is created and saved, they can be run at a later date or time. All worklists that have run every sample in the worklist are removed from existing worklist.

Import allows you to go to the hard drive or external storage device and select prebuilt worklists.

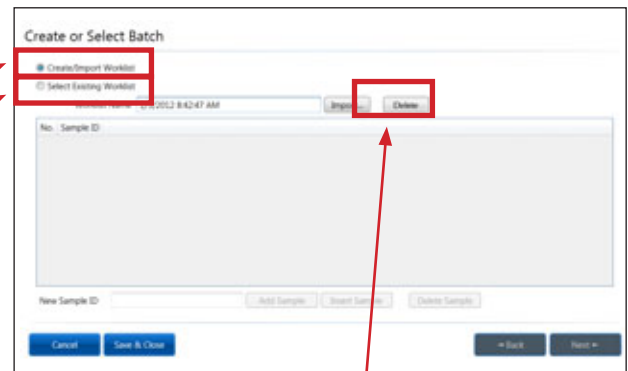
If importing a list, use the "Import" button to recall a previously saved worklist to run.

Naming Worklist

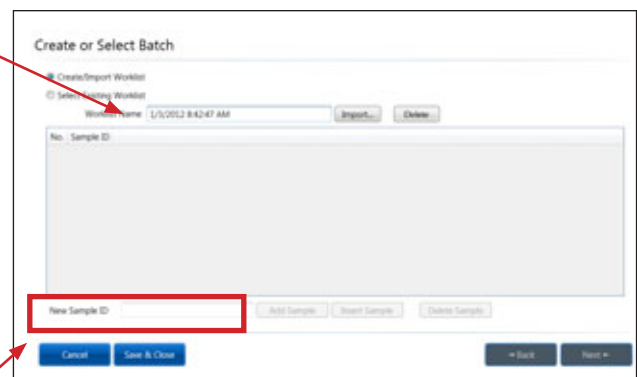
- The system by default will auto enter a date and time stamp for the worklist. The User can create their own unique ID by changing the date and time stamp. To do this, select the date and time and then add the unique worklist ID. Or to retain the date and time stamp as part of the unique ID, insert cursor in front of or behind date and time stamp and enter ID.
- If creating a worklist to use at another time, click "Save & Close" to run at a later time (30 character limit).
- Worklists are saved directly to the "Select Existing Worklist" and stay active until all samples are run.

Create New Sample ID

- Click inside the Sample ID window.
- Enter the sample ID's to be tested by either using the bar code reader, entering manually on the keyboard, or import a list.
- If using a Bar Code Reader, you must click in the New Sample ID Field first.



Note: The "Delete" button can be used to delete individual worklists from the drop down list as necessary. The system will not allow you to delete partially completed or completed worklists.



Note: If you run a test without the date/time stamp filled in, the search folder and report will automatically add date and time stamp.

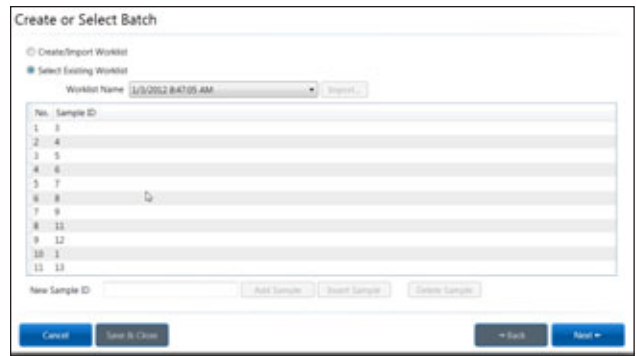
- Press “Next” when finished with worklist (program auto saves when the “Next” button is clicked).

– Barcode reader writes directly into the worklist.

– For a manually entered sample ID, you must hit enter after each sample ID.

– If a duplicate is entered into worklist an error message will appear and ask you if you want to add it “OK” if yes or “Cancel” for no. If you say “OK” duplicate will run through testing.

– If you click into worklist on a sample ID (prior to clicking the “Next” or “Save & Close” button), you can change ID, move its position, insert or delete an ID. If adding an additional ID to list, select “Add Sample” or click return twice. When ready, select “Next.”



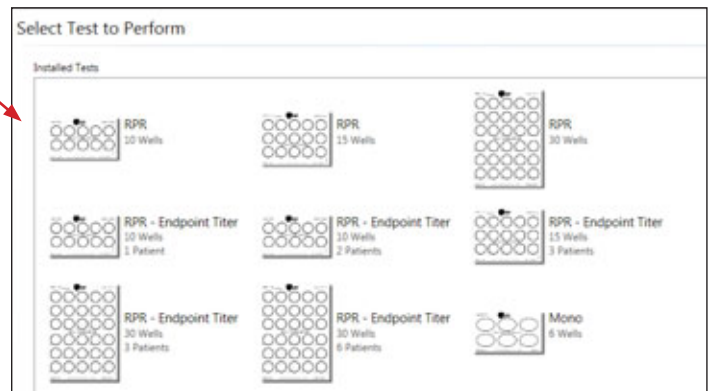
Note: If you select save and close or press next, the worklist can no longer be modified.

Select Test to Perform

Click on the test and card image that is to be performed

Note: When selecting a test card size (10, 15, or 30 Well), the card size you start with is the card size you must finish with. If you are running 64 tests on 30 well cards, you will be required to use a 30 well card to finish the 4 remaining test samples.

Caution: Do not click “Next” until a sample card is ready to insert into the tray.



Prepare The Test Card

Refer to package insert accompanying the test kit for detailed information on the specific tests prior to using the ASiManager-AT™.

- Do not touch the surface of the test card. Ensure card is not warped, clean of dust and is seated correctly.
- After the end of the reaction time (see test package insert) rotate the card by hand 8 times (vigorous rotating motion) to evenly disperse the agglutination/flocculation. Insert the test card face-up into the tray of the ASiManager-AT™ with Well 1 in the upper left corner.

- Push in the tray until it stops. The tray unit has a recessed area that ensures that the card is in its correct position. Ensure that the proper slot is used for the size of test card. Before proceeding, visually inspect card to make sure it is properly seated in tray. Make sure no black bars exist on the right and left sides of the test card when viewed on screen. Black bars indicate the card is not seated properly and will result in an error message during test run.

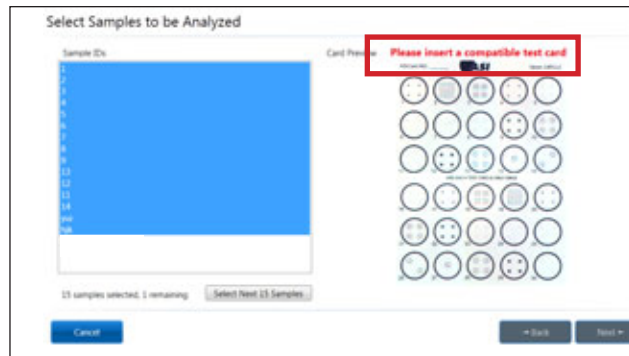
Caution: All card tests should be entered into the ASiManager-AT™ within 3 to 4 minutes or less after removal from rotator and kept under humidity cover. Failure to do so may cause drying, contamination or settling that could discredit test results.



Wrong Test Card Inserted

- If you insert the wrong size test card or it is not seated correctly, the ASiManager-AT™ will alert you. Insert proper card, re-seat card, or return to “Select Test to Perform” and select proper size card for the tests you are running.

Note: Only test cards and reagents from Arlington Scientific, Inc. can be used with the ASiManager-AT™. The software will automatically detect if the card is incorrect.



SELECT SAMPLES TO BE ANALYZED

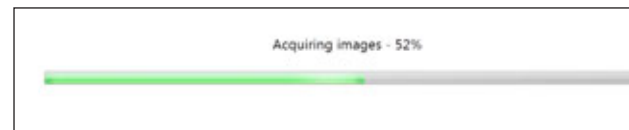
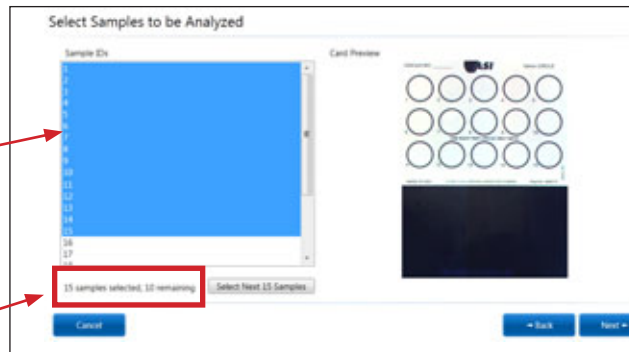
Run The Test

- After inserting card into the reader, the card will appear in the black field on the right side of the screen.
- System will auto select the number of samples based on the card test selected as indicated by the blue field shown in the example. The user can deselect and reselect samples as needed.

Note: Indicates your current status by showing the number of samples to be run and the number of sample that remain to be tested.

- Press “Next” to run or the “Back” button to return to previous screens.

“Running Test” screen will appear.



Test Results

The results will appear on the screen after analysis is completed.

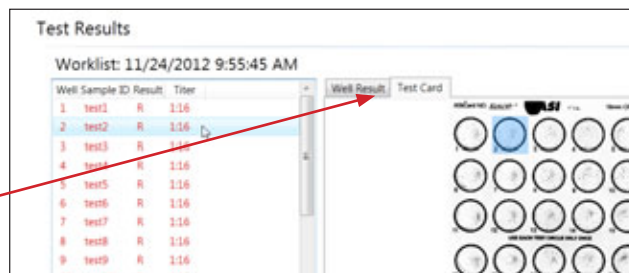
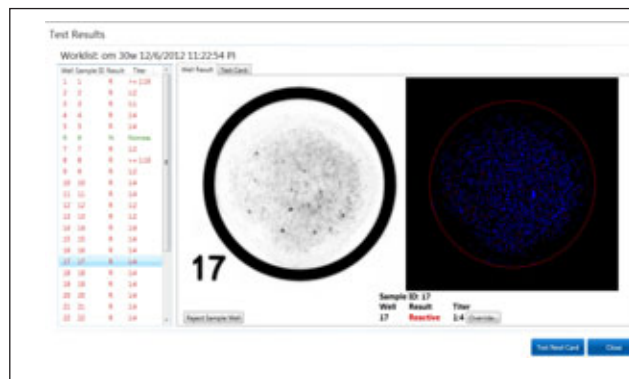
The results can be viewed by clicking on a sample in the columns of tests.

Pressing the down arrow on the keyboard will review each test one at a time.

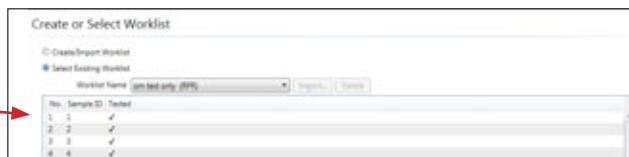
The results include the following information:

- Sample ID
- Pictures of the tested well
- Well number on the card
- Results as either a Nonreactive or Reactive
- Predictive Titer value for reactive RPR samples.

A button is also available to view the entire test card.



Note: If unable to complete or the worklist was only partially completed, the worklist is retained in “Existing Worklist.” Check marks indicate samples completed. Remaining samples can be run at a later time as needed. Completed tests can be reviewed via search.



Show an Individual Result

- From the worklist, click the desired result to view sample.

Well	Sample ID	Result	Titer
1	1	R	>= 1:16
2	2	R	1:2
3	3	R	1:1
4	4	R	1:4
5	5	R	1:4
6	6	N	Nonreactive
7	7	R	1:2
8	8	R	>= 1:16
9	9	R	1:2
10	10	R	1:4
11	11	R	1:4
12	12	R	1:2
13	13	R	1:2
14	14	R	1:4
15	15	R	1:4
16	16	R	1:4
17	17	R	1:4
18	18	R	1:4
19	19	R	1:4
20	20	R	1:4
21	21	R	1:4
22	22	R	1:4

Reject Sample Button

- Use to delete sample results. Sample ID is retained for re-testing and will automatically go to the end of current worklist.

Note: If you are testing a worklist with 30 samples and you reject 1 sample, the "Test Next Card" button will appear for you to run test again with new card/sample, or select "Close" and exit test run.

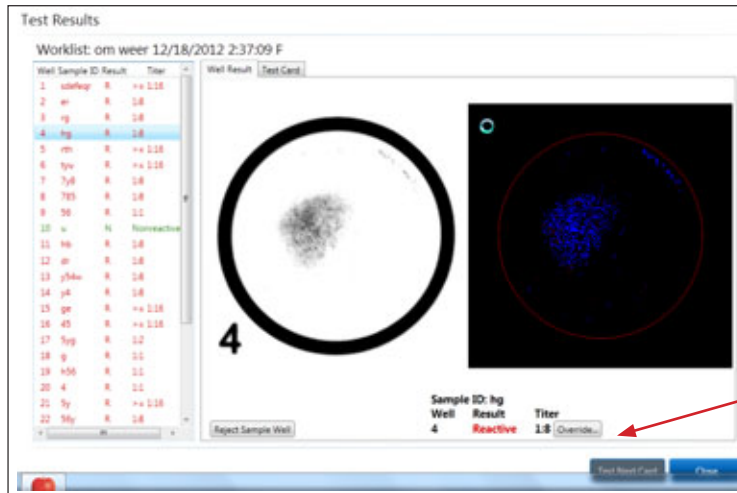
Note: After rejecting a sample, should you choose to re-test the rejected sample, you must first complete the active worklist, remove card, and reprep a new card for the rejected sample (must use same card 10, 15, or 30 well), starting at well one (1) in order of rejected samples.

Note: Samples rejected and then later re-run, will retain well number from retested card.

Well	Sample ID	Result	Titer
10	87	R	>= >= 1:16
11	8758	R	>= >= 1:16
12	k	R	1:1
13	675	R	1:1
14	6h	R	1:2
15	6h54	R	1:1
16	g3	R	1:8
17	gf	R	1:2
18	4	R	1:1
19	d	R	1:1
20	f	N	Nonreactive
21	g	R	>= >= 1:16
22	5	R	>= >= 1:16
23	3	R	1:8
24	fg	N	Nonreactive
25	fgf3	N	Nonreactive
26	fr	R	>= >= 1:16
27	w4t	R	1:1
28	e	R	>= >= 1:16
29	t	R	1:1
30	5e	R	>= >= 1:16

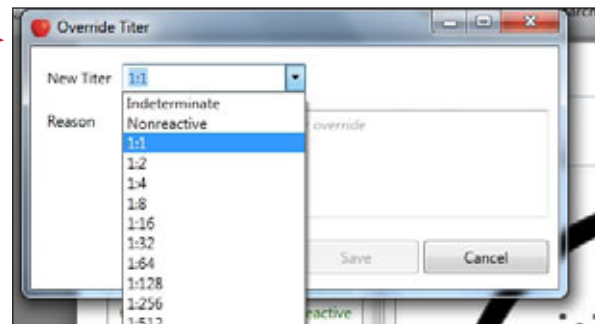
Override Button

- The override button can be used to change results as determined by management when contamination or other event may have discredited results.
- Override allows local control should titer or results require modification (requires management approval). The system is also capable of allowing an indeterminate test result. When entering text into the "Reason" field, text will auto wrap to next line. Do not use "return" key to wrap text to next line. Clicking the "return key" will save your entry as is.

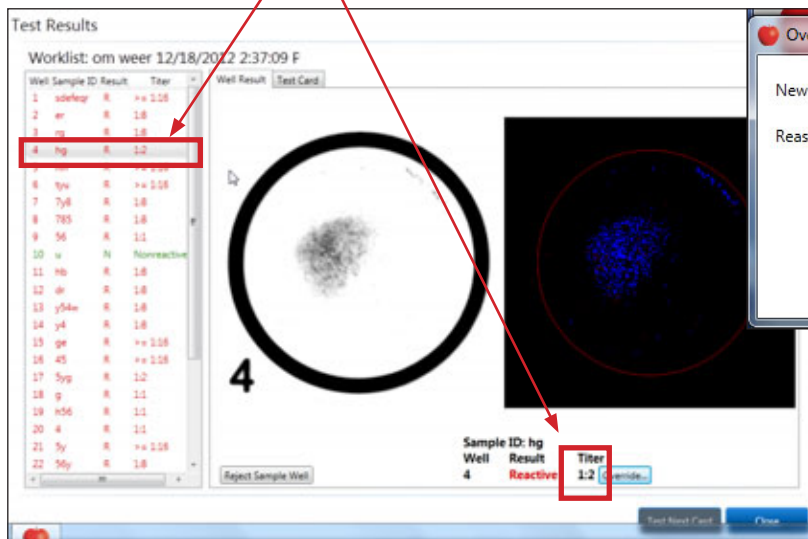


Dialog Box Appears

You can change the titer, classify the sample as Nonreactive, or Indeterminate by clicking on the drop down menu and selecting the required change. Enter the reason for the change and the person who authorized the change. Click Save.



Test results page will immediately reflect your new status.



WARNING:

The presence of foreign particles on the test card can cause erroneous or incorrect results. If foreign particles are present when results appear on the above image, reject and repeat the test.

Should problem persist, you may elect to reject sample and re-run test again or override the results and enter correct results with management approval.

SELECTING ENDPOINT TITERS

Selecting Endpoint Titer Tests (EPT)

Select from the following options:

- 10 Well 1 Patient (1 patient uses entire card)
- 10 Well 2 Patient (each patient uses 5 wells)
- 15 Well 3 Patient (each patient uses 5 wells)
- 30 Well 3 Patient (each patient uses 10 wells)
- 30 Well 6 Patient (each patient uses 5 wells)

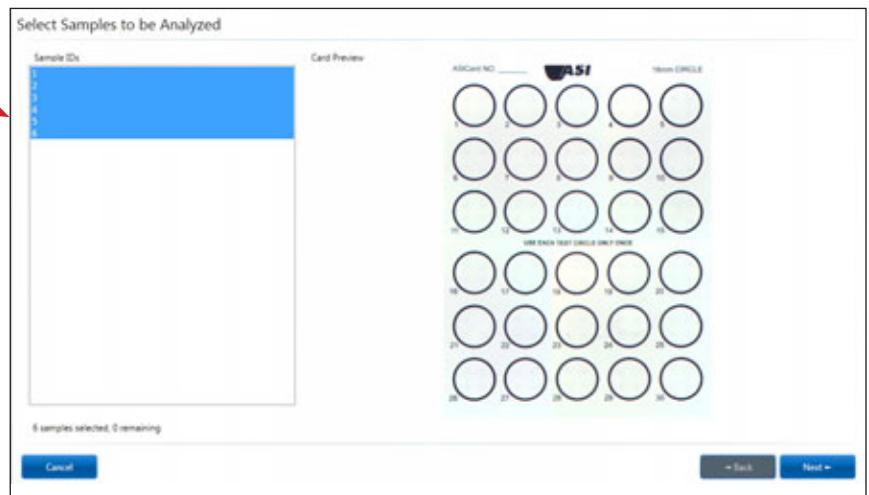
When EPT is selected, system will auto select number of tests to run highlighted by blue field.



Note: On a 30 well 6 patient test, wells 1, 6, 11, 16, 21 and 26 are auto selected for the six unique ID's

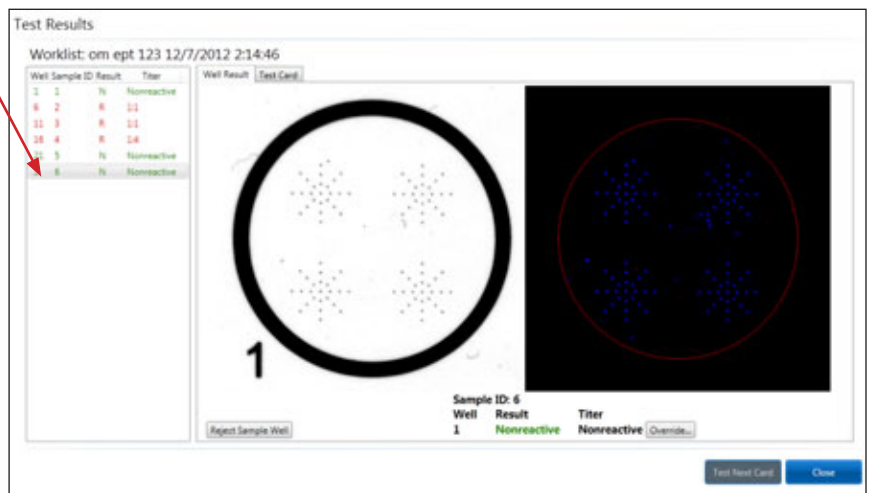
Select "Next" to continue running test

System will auto select number of tests to run for the EPT test selected. This example is how it would appear for 30 well 6 patient test card.



If a sample is rejected, it is automatically moved to the bottom of the sample list.

You will be asked if you want to "Test Next Card" or "Close and Exit" system test.



SEARCH/VIEW TESTS



Search

To begin, click search icon. Search window opens with the following options.

System default is set so that all search fields are selected. At least one search criteria must be selected in order for search to work. User must check box and indicate number of days for search.

Enter "Search Criteria" and "Search Fields" you wish to search.

Only Reactive - searches all tests and filters tests that were only reactive.

Only from last ___ days - filters search by test performed over "X" number of days

Sample - unique Sample ID

Worklist - unique Worklist ID

User - user account name

Test - type test name

Date/Time - auto default Date/Time stamp of worklist

Note: Selecting column heading allows you to change column to ascending or descending order.

Note: Well numbers and Sample ID's are included for data management.

If the "override" option was used a "✓" will appear on the report. Details of why the "override was used will show, when you select sample then print report.

Button options:

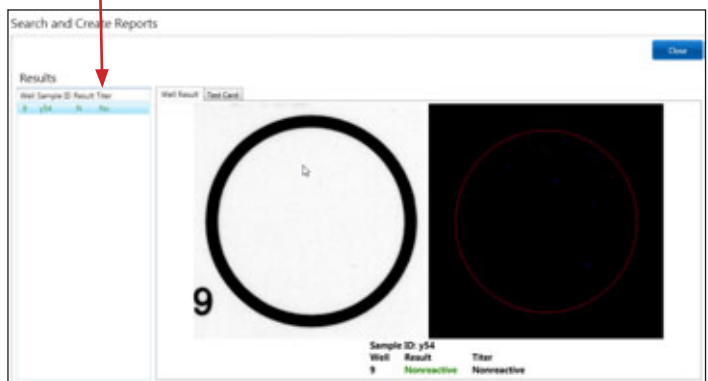
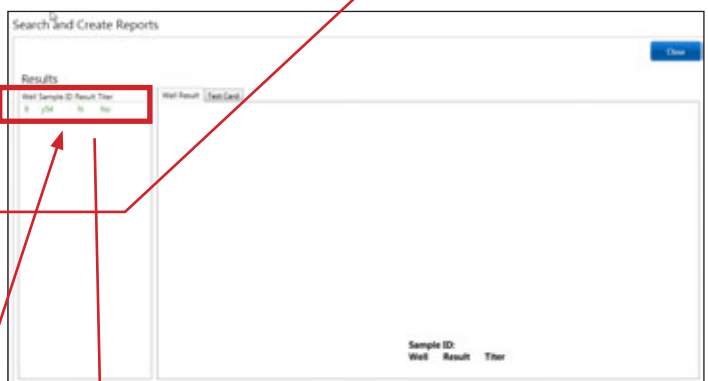
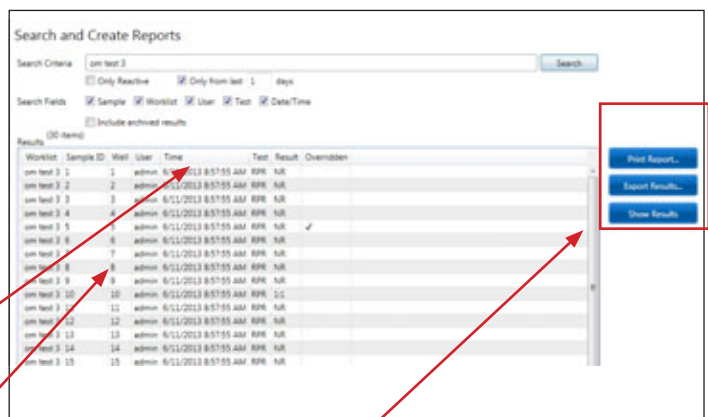
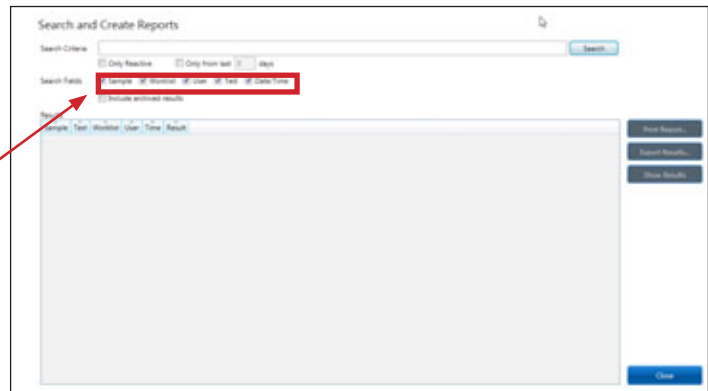
Print Report - a single test or multiple tests as selected.

Export Results - export selected tests to storage, LIS, or database

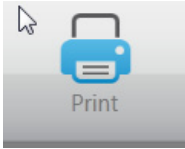
Show Results - show individual results and picture in the "Result" page.

Note: To view "Show Results," you must first select a sample to view. When you select a sample and click on "Show Results," a new window will open that will allow you to view results. To view the card or individual well, you must click on the sample.

Note: It is helpful to establish a naming convention for ID's and Worklist names prior to running tests. Doing so will help eliminate lost or difficult to find results when doing a search for tests.



PRINTING A TEST REPORT



PRINTING REPORTS

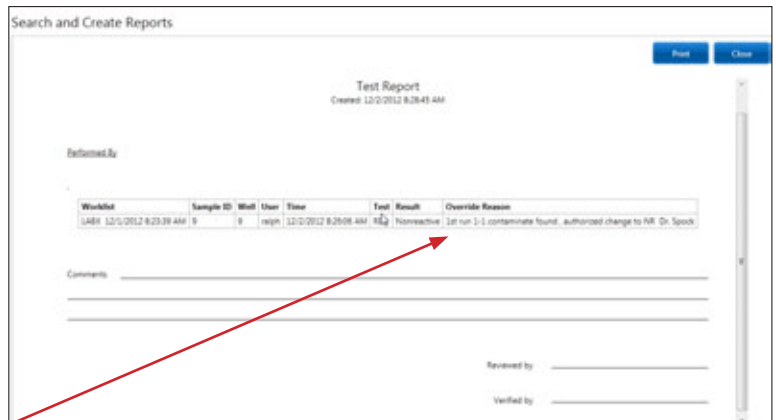
The print button is activated only at the “Search and Create Reports Screen.”

There are several print preview options

- You may activate the preview and printout by using the “PRINT” icon in the tool bar.

The printout includes:

- Address of testing facility
- Date report run
- Sample ID
- Test type
- Worklist ID
- User –run by
- Date & time of test run
- Test results
- Verified by
- Reviewed by
- Override reason
- Well
- Comments



Note: If override was used, it will appear on the print report

Comments _____

Reviewed by _____

Verified by _____

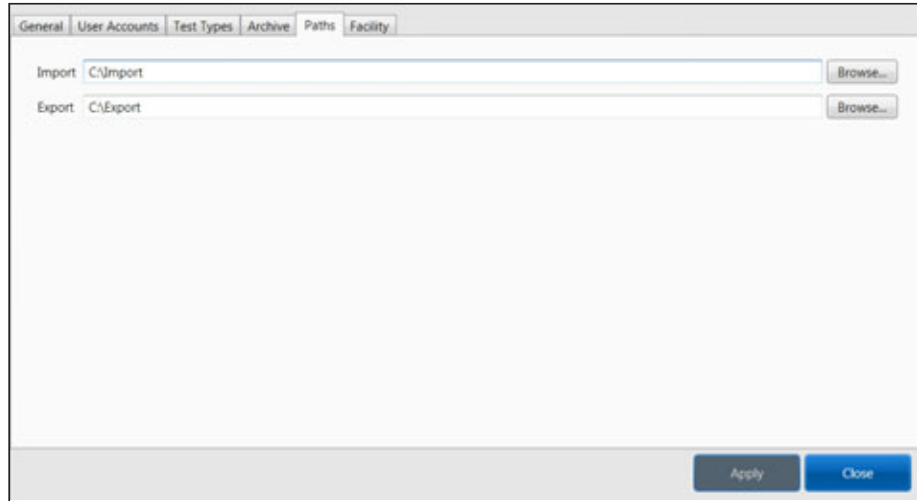
Note: Printout will show data as entered at “Tools/Setup/Facilities”

EXPORT OF DATA

EXPORTING DATA TO FILE

In the menu bar select "Tools – Setup – Paths to access Import Export options.

If you experience difficulties setting up path options, contact ASI for technical support.

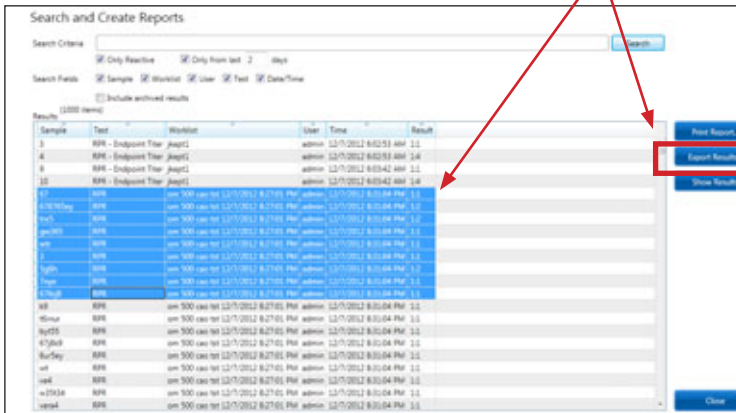
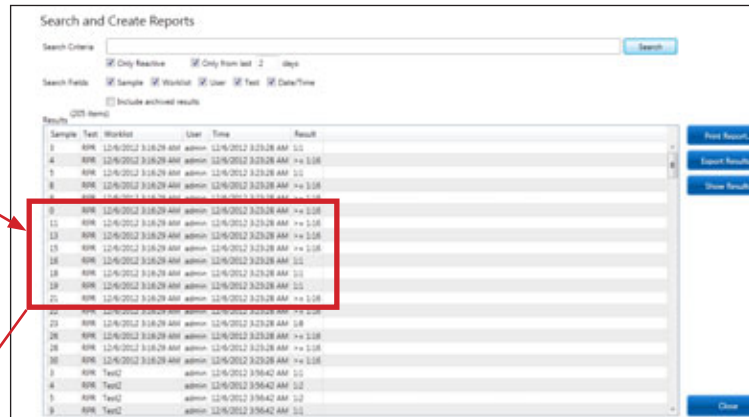


Create an Export folder where you want your data to be collected/stored.

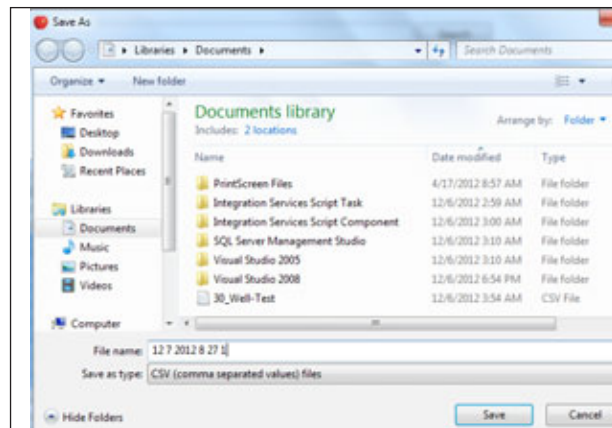
Select sample ID's or Worklist to export. Once selected, ID's will be highlighted.

Click "Export Results" button.

Verify file name, then click "Save"

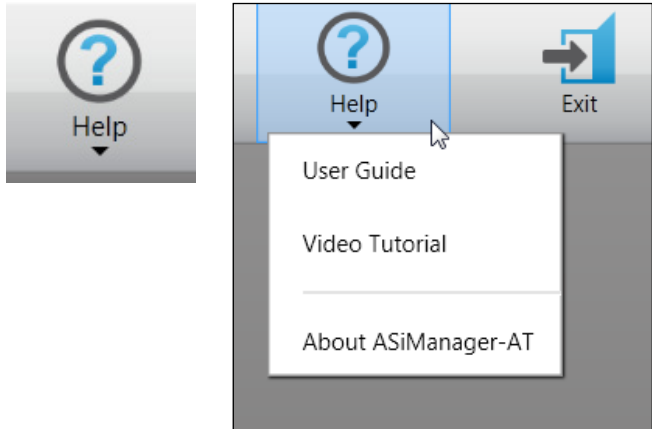


Selected ID's



Verify File Name

HELP AND EXIT

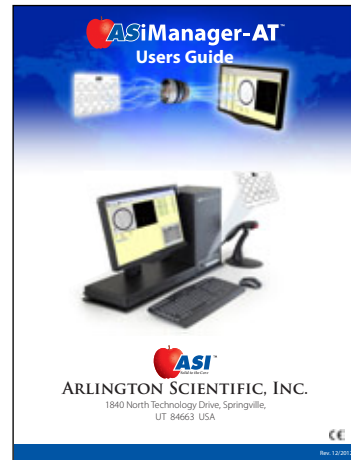


User Guide

Allows you to view and print the ASiManager-AT™ User Guide.

Video Tutorial

Video Tutorial will be available at a future date.



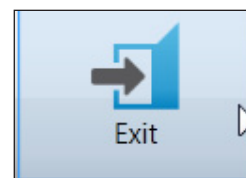
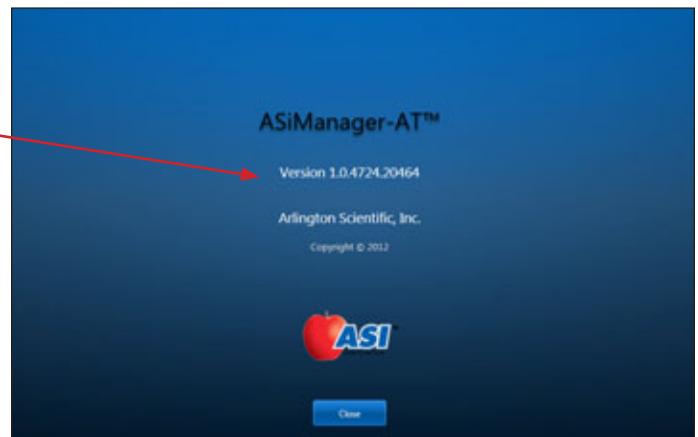
About ASiManager-AT™

Provides software version and date.

Note: When reporting problems, always reference the version number.

Exiting the Program

Closes ASiManager-AT™ program. Close the program first then close PC down using Windows "Shut Down" to safely shut down the computer.



ASIMANAGER SQLSERVER BACKUP

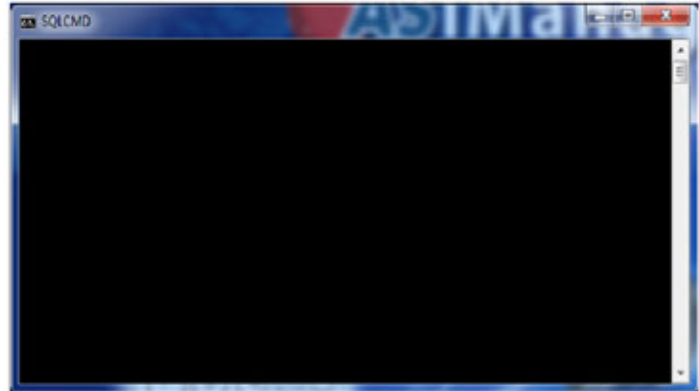
STEP 1

Double click the ASiManager desktop icon for the DB Backup to start.



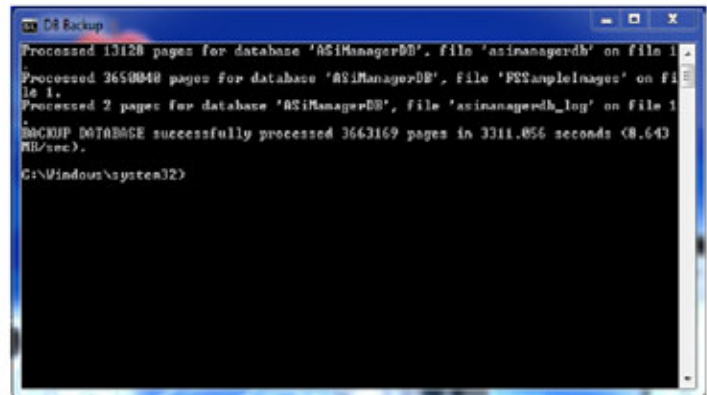
STEP 2

The backup may take up to an hour (depending on size) to backup the data and all images. The SQLCMD screen will be blank until it finishes.



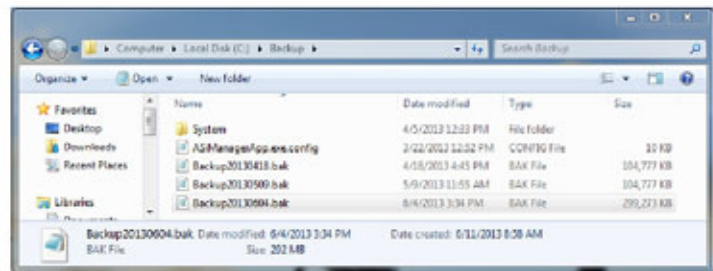
STEP 3

When the backup is completed you will see a screen like the one to the left that shows the number of records processed. The "Backup Database successfully processed" line indicates the backup was complete.



STEP 4

The actual backup file is stored in the C:\Backup folder with the date as part of the backup file ID.



RECOMMENDATION

We recommend that a backup be ran once a week and that the latest copy of C:\Backup be copied to an external source like an external USB hard drive or a LAN mapped file for off-system storage.

RESTORE














Restoring the backup will require technical assistance and should only be done with ASI technical support assisting (call 801-489-8911).

USER PROFILES–USER ACCOUNTS

Options	Descriptions
User	Name of the user Allowed characters: A ... Z, a ... z, 0 ... 9
Password (case sensitive)	Type in password Allowed characters: A ... Z, a ... z, 0 ... 9
Password confirm (case sensitive)	Type in password Allowed characters: A ... Z, a ... z, 0 ... 9
User account	Lists all users with permission to start the program.
Administrator	Only the system Administrator can use all program "Setup" functions (The user profile ADMINISTRATOR cannot be deleted). Administrator may only modify or delete one user account at a time.
Select test	Adds or removes test by checking the box.
Export/Import	Imports or exports single Sample ID or Worklists.
Print	Prints out the measurement results selected.
Search/Open	Allows access to search and open data.

DESCRIPTION OF SYMBOLS

On the packaging, the identification plate of the instrument and in the User Guide you may encounter the following symbols shown here with their meaning:

	For in vitro diagnostic use		Serial number
	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices		Keep the ASiManager-AT™ dry
	Please consult instructions for use		Keep from direct sunlight
	Indication of a warning or a caution concerning operation(s) that may lead to injury or death to persons if not performed correct		Authorized Representative in the European Union
	Manufacturer		<ul style="list-style-type: none"> • Updates to the system's software are prohibited, e.g., service packs • Installation of software on the ASiManager-AT™, apart from printer drivers or connecting the READER, is prohibited
	Content of the packaging	PRECAUTIONS	<ul style="list-style-type: none"> • Correct results are only possible when the test was performed according to its package insert • Intended only for use by suitably qualified personnel • The ASiManager-AT™ is intended for in vitro diagnostic use
REF	Catalogue number	ACTION IN CASE OF SYSTEM FAILURE	In case of system failure, samples can be visually examined by interrupting the routine work and performing the test according to the test kit package insert.
	Store at		
	Fragile handle with care		

TECHNICAL SPECIFICATION · STORAGE · SETTINGS

INTERNATIONAL & EUROPEAN NORM	European Norm: This system can be used according to the conditions of EN 61326: 1997 + A 1:1998 (Class: B) for emission and absorption.
DIMENSIONS	Height: 16.5 inches / 40.64 cm Length: 27.5 inches / 69.85 cm Width: 9 inches / 22.86 cm
WEIGHT	Net weight: 26 lbs / 11.79 kg Gross weight: 29 lbs / 13.15 kg
PHYSICAL DATA	DC 12 V / 8.5 A
POWER CONSUMPTION	Maximum 102 Watt
ENVIRONMENTAL STORAGE/ OPERATING TEMPERATURE WARNINGS	<ul style="list-style-type: none"> • Storage temperature should not be under 59° F (15° C) and not over 122° F (50° C) • The operating environment should be at room temperature • For indoor use only • Do not expose the ASiManager-AT™ to direct sunlight • Keep away from radiators, open windows and air or heat-emitting instruments • Keep away from magnetic fields
TRANSPORT	<ul style="list-style-type: none"> • Use original box for any transport • Use original foam inlay • Handle with care
BASIC SETTINGS	<ul style="list-style-type: none"> • The ASiManager-AT™ software is factory-installed. Do not install other software or programs on the ASiManager-AT™ • Operating system: Windows 7, 64 bit Ultimate / Professional <ul style="list-style-type: none"> - Ultimate (for international use) - Professional (for United States domestic use) • Hard disk space: 500 GB • 8 USB ports available • Imaging Unit USB dual power cable • Power cable and adaptor for 110/220 outlets • Wireless Keyboard and Mouse • Bar Code Reader

POWER SUPPLY AND FEATURES

Power Supply

1. 110-240 v 3 prong wall plug and cord. (110v shown)
2. Receptacle type connector
3. AC Power Adaptor (black box).



Connect Power Supply

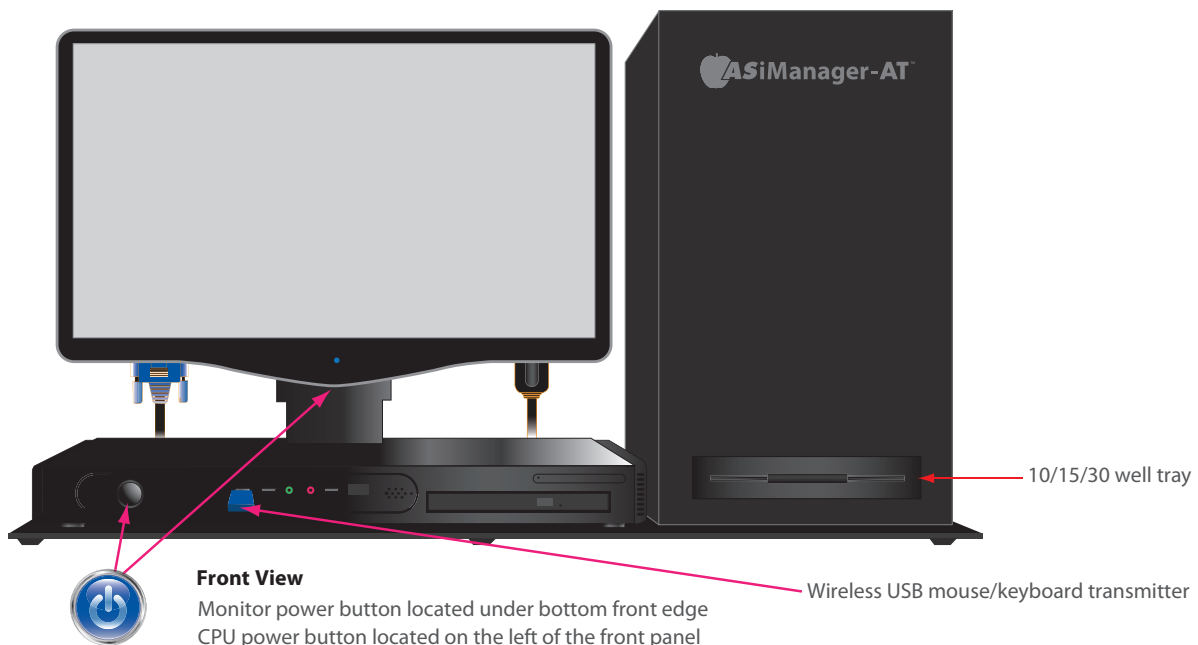
- Ensure the wall receptacle power cord is inserted into the AC power adaptor.
- Connect the receptacle connector to the receptacle located on the back of the CPU/ Monitor.
- Plug in the wall receptacle.
- Turn on the CPU by depressing the round button located on the front left side of the CPU.
- Turn on the monitor by depressing the power button located at the front center of the monitor.

NOTE: To ensure proper and trouble-free functioning of the instrument, the power cable must be connected so that all ends are securely inserted into their receptacle.

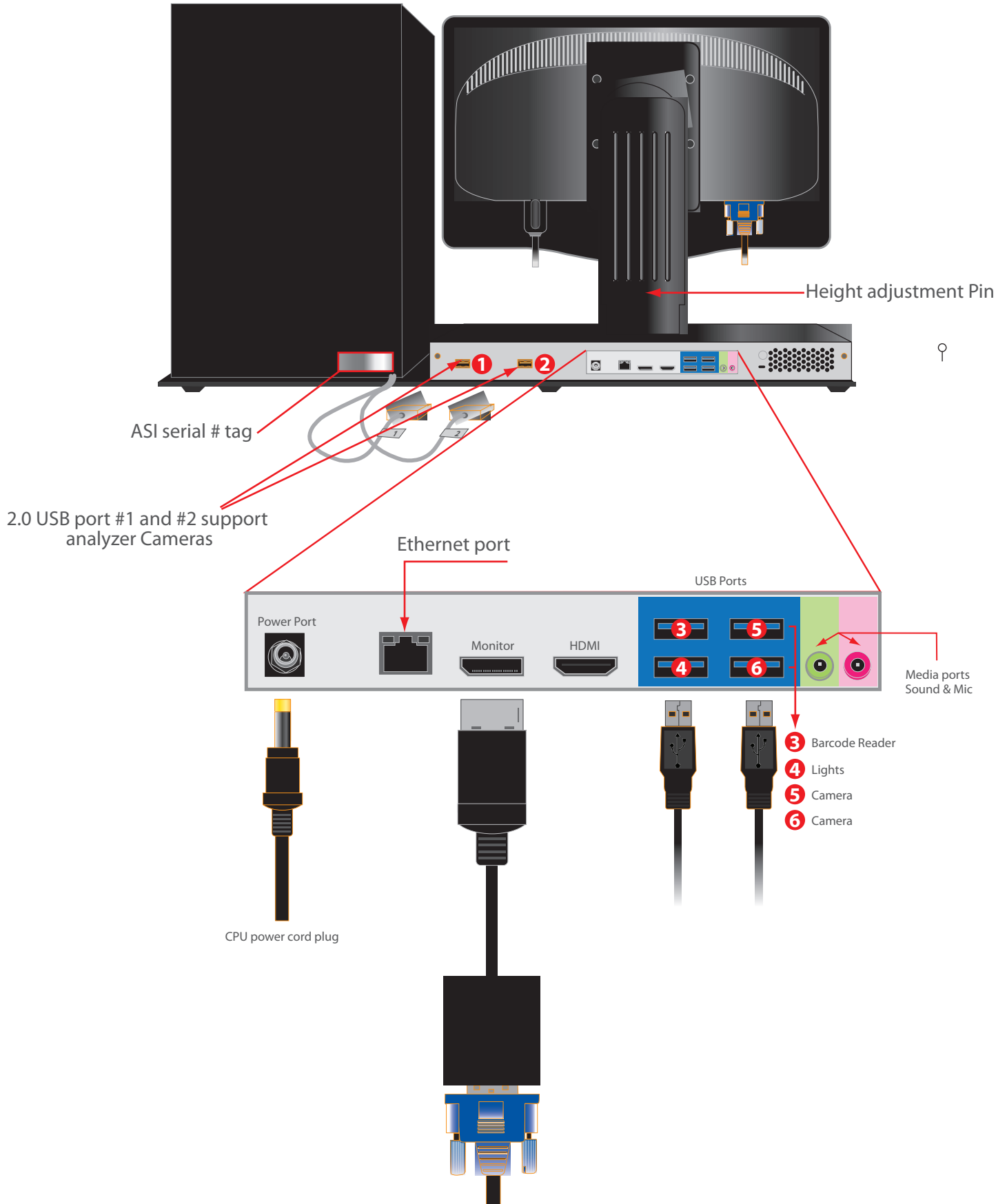
Supplementary Safety Notice

To safely disconnect the ASiManager-AT™ from all power sources, close all applications, shut down the CPU, turn off the monitor, and then disconnect at the wall or receptacle.

ASiManager-AT's CPU Ports & Physical Features



Rear View & Configuration



SAFETY PRECAUTIONS

Please read and take note of the following precautions before using the ASiManager-AT™ components and accessories.

CAUTION

Indicates a caution concerning operations that may lead to injury to persons or equipment if not performed correctly. In order to use the ASiManager-AT™ safely, always pay attention to these cautions.

SETUP AND OPERATING CONDITIONS

CAUTION

- Do not set up in areas where there are excessive fluctuations in temperature. Also do not move the ASiManager-AT™ or any of its components from low temperature areas to high temperature areas. Condensation may cause image errors. Leave the ASiManager-AT™ and its components enough time to gradually adapt to the new conditions before use.
- Do not place the ASiManager-AT™ and components in areas subject to direct sunlight. It may cause damage to the ASiManager-AT™ components or decrease image quality. If you have to place the ASiManager-AT™ components in direct sunlight, make sure to use a thick curtain to block the sunlight.
- Leave enough space (approximately 8 inches or 20 cm) around the ASiManager-AT™ when setting up.

CAUTION

- When Cleaning, **do not use compressed air/gas** to clean tray or spray into open slot. Using compressed air/gas can contaminate internal imaging components and skew readings.
- Do not operate fans or heaters in the vicinity of the ASiManager-AT™. Blowing air or heat can affect card samples and results.

CAUTION

- Do not place the ASiManager-AT™ or any of its components in areas with high humidity, areas subject to direct sunlight, areas with high temperatures and areas near flame sources. Fire or electrical shock may occur.
- Do not place the ASiManager-AT™ or any of its components on shaky stands, unstable surfaces or surfaces subject to frequent vibrations, this may damage internal components. If the ASiManager-AT™ or any of its components fall, it may cause injury.
- Do not place heavy objects on the ASiManager-AT™ or any of its components. Objects may fall and cause injury.
- Do not open imaging compartment, disassemble or replace any components. Doing so will void the warranty. If you are experiencing problems that cannot be corrected with this User Guide, contact Arlington Scientific, Inc. for assistance (See contact information on page 3).

ABOUT THE POWER SUPPLY

CAUTION

- Do not place heavy object on, pull or excessively bend, twist or tie the power and USB cables. Damaged wires may cause fire or electrical shock.
- Always plug all power and USB cables all the way in. If it is not plugged in completely, fire or electrical shock may result.
- Do not use cables other than the ones supplied. Fire or electrical shock may result.
- Always pull on the main body of the plug when unplugging power and USB cables. Pulling the cable may damage the wires and lead to fire or electrical shock.

GENERAL HANDLING PRECAUTIONS

CAUTION

- Do not take apart or modify the ASiManager-AT™ or any of its components. Fire or electrical shock may result in improper modification or handling of components.
- If you hear unusual noises, see smoke, feel excessive heat or smell anything unusual, immediately unplug the power cable and contact ASI. Continued use may result in fires or electrical shock.
- Do not use flammable sprays near the ASiManager-AT™ or any of its components. Also do not spill water, liquids or flammable materials on ASiManager-AT™ or any of its components. If they enter and contact the inner electrical parts, fire or electrical shock may result.
- When cleaning the ASiManager-AT™ and its components, always power the system down. Unplug the power cable. Wipe with a soft cloth. Do not use a flammable liquid such as alcohol, benzene or thinners. If a flammable liquid enters the inner electrical parts, fire or electrical shock may result.
- If anything enters the ASiManager-AT™ or any of its components, immediately power the system down and unplug the power cable and contact ASI.

CAUTION

- Use designated handle when sliding card holder into the Reader. Keep finger tips away from the edges of the sliding card holder. The card holder may cause pinching if finger tips are resting on the edge at the time the user slides card into reader.
- When transporting the ASiManager-AT™ and its components, always unplug all cables. Damaged or crimped cables could cause fire or electrical shock and/or impact the performance of the ASiManager-AT™. Utilize original packing materials when possible.

TROUBLE SHOOTING/MAINTENANCE

Follow all the instructions in this User Guide to ensure error-free operation. If an error occurs, refer to the table below. If, after checking all options, the error persists, contact Arlington Scientific, Inc. or your local distributor.

Only qualified personnel authorized by Arlington Scientific, Inc. may perform repairs or other modifications to the ASiManager-AT™.

Symptom	Problem	Help
Message: Target and source equal when importing	An attempt to import a file that already exists on the CPU	The file is already on the CPU
Image of test card is off center	The test card is not inserted correctly	<ul style="list-style-type: none"> • Ensure the test card properly into the ASiManager-AT™ • Ensure tray is inserted correctly • Retry the reading
Image of test card seems very light or overexposed	<p>The card was not inserted correctly</p> <p>The tray has not been pushed in completely</p>	<ul style="list-style-type: none"> • Re-insert card correctly • Retry the reading • Push in the tray completely • Ensure tray is inserted correctly • Retry the reading
Evaluation of the result is not possible	The wrong test card or the wrong test was selected	<ul style="list-style-type: none"> • Select correct test to be read • Select the correct test card to be read • Retry the reading
There is no visible light inside the ASiManager-AT	Lack of power	<ul style="list-style-type: none"> • Retry the reading • If error is still present: Restart ASiManager-AT™ • Ensure all cables are inserted properly
System Freezes/Locks	PC-Windows based	<ul style="list-style-type: none"> • Press CTRL/ALT/DELETE to access Task Manager to close ASI application • Restart computer • Re-login

MAINTENANCE

- The ASiManager-AT™ is maintenance-free in operation.
- The tray can be cleaned with commercial laboratory cleaners and disinfectants if required (**Note:** *Do not re-insert the tray while it is still wet or if dust has not been cleaned off*).
- Any spills and splatters of human source materials onto the ASiManager-AT™ should be cleaned with 10% bleach solution [Note: Do not autoclave trays].
- Use a lint-free cloth or cotton tipped applicator to clean the corners.
- Wipe the display with scratch-free wipes.
- Do not use acids or solvents.
- Wear gloves when cleaning the instrument.

DISPOSAL OF ASIMANAGER-AT

Contact Arlington Scientific, Inc. or your distributor for pick up. If that is not feasible we recommend you contact a local professional disposal enterprise that specializes in computer / hardware disposal.

It is the responsibility of purchaser (when disposing of ASiManager-AT) to delete or retrieve all sensitive patient data to an external storage device according to local laboratory or clinical procedures.

EU AUTHORIZED REPRESENTATIVE

This user guide has been edited conscientiously and complies with Norm DIN EN 591

EC	REP
----	-----

J B Morphet Ltd

34 Ashdale Road
Kesgrave
Suffolk IP5 2PA, UK

INSTALL DATE: _____

ASiManager SERIAL NUMBER: _____

INSTALLED BY: _____

Sales Rep

Company Name

Location

NOTES: _____

FREQUENTLY ASKED QUESTIONS

Q What should I do if the ASiManager-AT™ arrives with missing parts, components or there is visible damage to the unit?

A Contact ASI immediately for instructions.

Q What should I do if the ASiManager-AT™ shipping box arrives damaged?

A The box should be inspected and received as “damaged upon acceptance” by the shipping company. Contact ASI to determine the extent of possible damage to the unit.

Q What should I do if I encounter an error message while running the ASI program?

A Correct the problem based upon the error message, and select okay to proceed, or exit the test/program and restart the ASiManager-AT program. If error persists or you are unable to correct the error, contact ASI for technical assistance.

Q Can I switch cards during a test?

A Once a card is selected, you cannot switch card sizes (10, 15, or 30 well cards)

Q How do I fix an incorrect worklist ID or sample ID?

A At the create worklist stage and prior to selecting the “Next” button, the worklist and sample IDs can be changed by clicking on them and then correcting the information. Once the “Next” button has been selected modifications cannot be made.

Q How do I delete a worklist from the existing file?

A Deletions can be made as needed by highlighting them and selecting the delete button. Completed or partially completed worklists cannot be deleted.

Q How do I “Override” results?

A Changes to results and titers can be made at the end of the test run. ASI recommends management approval and appropriate documentation before doing so.

Q How do I save a worklist?

A Worklists can be saved two ways. 1. Select the save and close button or 2. Select the “Next” button on the worklist screen.

Q How do I pre-build sequential numerical worklists or re-use a worklist?

A You can pre-build generic worklists (i.e. Select 30 or Select 120) by building them in the database file and saving as a generic worklist, then import and change the worklist ID as needed in the create worklist screen.

Note: Depending on your local procedures, pre-building the next days worklist can be accomplished this same way or saved into the existing worklist name file as needed.

Q How do I “Reject” results?

A Results can be rejected, however the sample ID will remain should you want to re-run the test. If you choose not to re-run the test, just close the test run.

Q How do I print a report?

A From the “Search” program, select sample IDs or worklist, then select print, connect to the desired printer and then push print.

Q I entered a unique worklist ID but forgot to enter the date and time. What do I do and where can I find the date and time stamp?

A Upon test completion, the date and time information is auto assigned to all worklists and will appear on the search and create report section.

Q How do I change the bar code reader from trigger to continuous read?

A The MS9540, VoyagerCG incorporates Honeywell's patented auto-trigger and CodeGate button feature. When a bar code is placed in the scanner's IR range, the auto-trigger activates the laser enabling the user to align the visible laser line over the bar code selected for scanning. The user can then press the CodeGate button, to transmit the data to the host system. When the MS9540 is placed in the stand the CodeGate button feature will automatically deactivate for hands free operation.

Q When does the clock for System Check Card start running?

A The clock for the system check card is always running regardless of when you use it?

Q I keep getting a card insertion error, what do I do?

A The card must be seated correctly into the tray or the test will not operate or capture the results correctly. Upon card insertion, carefully look at the screen. The test card will be displayed. If you see any broad dark lines running around the sides of the card, it is not seated properly. Open the drawer and reset the card. If the problem persists contact ASI.

Q If the system freezes, what do I do?

A The system is a windows based operating system , CTRL/ALT Delete will take you to the task manager screen where applications not responding can be closed. Close, then exit and restart test. If the problem persist contact ASI for technical assistance.

Q I have a hardware error, what do I do?

A Shut the system down and restart , if error persist ensure all cables and USB ports are correctly in place and restart , if problem persist contact ASI.

Q I built a worklist and only partially completed it. How do I find where I left off?

A The Search & Create screen contains all completed test results for worklist that were run and completed as well as partially completed worklists. Samples not run will not appear in this section but can be found in the Create or Select Batch screen using the "Select Existing Worklist" option.

PERFORMANCE CHARACTERISTICS

A comparison of the digital interpretation of the results of testing samples with the ASI RPR Card Test for Syphilis using the **ASiManager-AT™** and visual interpretation by trained laboratory professionals was conducted to show substantial equivalence.

The following data are the results from three testing sites:

Combined Prospective Sample Testing - 375 Samples

ASiManager-AT™ Digital Results			
		Reactive	Nonreactive
Visual Results	Reactive	3	0
	Nonreactive	0	372

These results give a percent agreement positive of 100% with reactive samples and 100% with nonreactive samples.

Combined Prospective Sample Testing - 3131 Samples

ASiManager-AT™ Digital Results			
		Reactive	Nonreactive
Visual Results	Reactive	1799	58
	Nonreactive	29	1245

These results give a 98% concordance with reactive samples and 99.7% with nonreactive samples.

Of the 1849 reactive samples from the qualitative testing 1224 were used to determine the predictive titer. The ASiManager-AT™ is programmed to project or predict the endpoint titer of each qualitative test by reading the undiluted serum (1:1) and determining its corresponding endpoint for reactive serums. This is done using a proprietary algorithm that interprets the reaction in the undiluted sample and projects what the endpoint titer of the sample will be. A one dilution difference is an acceptable range for equivalency because the minimal reactive endpoint titer is subject to interpretation between different observers due to many factors such as lighting, visual acuity, and fatigue, etc. Of the 1224 reactive samples tested 1146 were within the ± 1 titer acceptance criteria, for a concordance of 93.6%

Of the 1849 reactive samples from the qualitative testing 708 were used to determine the endpoint titer. The ASiManager-AT™ is programmed to determine the true endpoint titer of a serial diluted specimen using the RPR endpoint titer function on the instrument. The RPR endpoint titer (semiquantitative) function analyzes the entire card and identifies in which well the serial diluted sample appears nonreactive. The software then calculates the endpoint titer. A one dilution difference is an acceptable range for equivalency because the minimal reactive endpoint titer is subject to interpretation between different observers due to many factors such as lighting, visual acuity, and fatigue, etc. Of the 708 reactive samples tested 700 were within the ± 1 titer acceptance criteria, for a concordance of 98.9%.

