


**GOLD
STANDARD
DIAGNOSTICS**

AIX1000[®] Agglutination Analyzer **(REF 00400) User's Manual**



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1. Introduction

The purpose of this manual is to identify the instrument components and provide instructions for use of the Gold Standard Diagnostics (GSD) AIX1000 Agglutination Analyzer (AIX1000) REF 00400. This manual provides basic safety information, instructions for use and maintenance, as well as general troubleshooting guidance. It is recommended that this manual be kept near the instrument and accessible to the user at all times.

1.1. Intended Use

The AIX1000 is a combination device with a single intended use. The instrument is intended to be used as general purpose laboratory equipment which is labeled or promoted for a specific medical use. The instrument is intended to duplicate manual analytical procedures of a flocculation test by automating all necessary procedural steps. The instrument alone is intended to perform as an 'accessory' which is intended to be used with a device to enable that device to be used in accordance with its intended purpose. The GSD Rapid Plasma Reagin (RPR) reagents are provided as a flocculation test kit intended to be used with the AIX1000. The kit is intended to be a consumable in vitro diagnostic device for the instrument. The GSD AIX1000 RPR Automated Test System (consisting of the GSD RPR reagents REF GSD01-1600 and the GSD AIX1000 Agglutination Analyzer REF 00400) is labeled and promoted by GSD for this specific medical use. The System is a non-treponemal flocculation test that can qualitatively determine the presence of reagin antibodies in human serum. It may be used to aid in the diagnosis of syphilis when used in conjunction with supplemental treponemal laboratory tests and other clinical information. This test may also be used to detect non-treponemal antibodies in samples serially diluted to establish titer information. This test is not intended for screening blood or tissue donors.

WARNING: Please note that, although options to retry a sample (due to insufficient sample volume) is available in the AIX1000 software, these features have not been evaluated and should not be used with the GSD AIX1000 RPR Automated Test System.

1.2. Certifications

The AIX1000 RPR Automated Test System is registered and certified as having met the following regulatory requirements:

ISO 13845:2016

EN ISO 13485:2012

Directive EN 98/79/EC

CMDR SOR/98-282

EN/UL/CSA C22.2 61010-1:2010

EN 61010-2-081 + A1:2003

EN 61010-2-101

EN 62321 (RoHS Compliance)

IEC 61326-1:2013

IEC 61326-2-6: 2021

US and CA national deviations as shown in the test report EN 41983 M0A0

2. Safety Information

The following safety instructions are to be observed at all times during the operation of the AIX1000. It is strongly recommended that all first-time personnel read this manual prior to working with the instrument. The AIX1000 is designed and manufactured in accordance with the safety requirements for electronic and medical systems listed in the certifications section above to ensure that the instrument functions safely, both electrically and mechanically under normal use conditions. The AIX1000 is supplied in a condition that allows for safe and reliable operation.

2.1. General Safety

The AIX1000 must only be operated in accordance with the stated intended use. It is required that the AIX1000 is used only with the consumables and accessories suggested or provided by GSD. The use and maintenance activities defined in this manual are intended to ensure the safety of the operator and the proper functionality of the instrument. All system surfaces must be dry while operating the AIX1000. GSD recommends that all operators be trained in good laboratory practices and observe general laboratory safety guidelines.

The instrument is safe for use at altitudes between 0 and 2000 meters, and ambient temperatures between 5°C and 40°C.

Notice: Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

2.2. Electrical Safety

The AIX1000 must be operated using a power source with an operating voltage compatible with the requirements stated on the device label. The AIX1000 is to be used only with the provided 3-prong grounding type plug to connect the instrument to the main power supply. If a replacement power cord is used, it must have a rating of 110-240VAC with 18 AWG wiring and a 3-prong (grounded) wall plug. It is important to ensure the power switch is in the off position prior to connecting the AIX1000 to the main power supply.

The use of a multi plug is not allowed and it is recommended that the instrument be run from a dedicated socket. Use only extension cables with a protective conductor and grounded contact. The power source (switch/plug) should be easily accessible during operation of the instrument.

The AIX1000 uses two fuses, one AC fuse and one DC fuse with the following specifications:

- AC Fuse (GSD P/N 5015): 5mm x 20mm, Time Delay, Ceramic Tube (T4AH250V)
Voltage Rating: 250VAC
Amperage Rating: 4A
- DC Fuse (GSD P/N 5383): ISO 8820-3 Blade Fuse
Voltage Rating: 32 VDC
Amperage Rating: 5A

Fuses that are non-functioning must be replaced using fuses which match the values (nominal voltage, nominal current, and type) specified for the instrument. A spare AC fuse is included with the instrument.

If at any time the instrument becomes unsafe to use, immediately switch it off and disconnect it from the main power supply.

2.3. Mechanical Safety

Installation and service of the AIX1000 must be completed by a trained technician to ensure a minimized exposure of the operator to mechanical risks. Improper handling of the AIX1000 may cause serious damage to the instrument or result in injury to the user. Avoid touching the probe and other moving parts while the system is in operation. Protective covers should not be removed while the instrument is on due to potential contact with moving parts. Exercise extreme caution when working on or near the peristaltic pump when the cover is not in place. Openings provided for ventilation are not meant as access points into the system.

If the cover must be opened during operation, verify that the movement of the probe has stopped before reaching inside the instrument. This should be done cautiously and only when absolutely necessary.

2.4. Biological Safety

Any parts of the AIX1000 that have come into contact with samples/test reagents are to be treated as being potentially infectious. Some of the general-purpose reagents have the potential to cause irritation of the skin and mucous membranes. It is recommended that the operator use appropriate personal protective equipment (PPE) such as gloves, lab coat, and eye protection while using the instrument. For devices used in conjunction with the AIX1000, it is the responsibility of the user to observe the instructions and warnings provided by the manufacturer for proper use of reagents.

2.5. Safety Labels

The AIX1000 is labeled with universal general warning labels to identify risks which may be encountered by the operator.

3. System Description

The AIX1000 is a fully automated microtiter plate processor that is able to completely perform sample processing steps, including dilutions, dispenses, and aspiration. The AIX1000 is controlled by a custom software program designed to run on the Windows Operating System.

3.1. System

The AIX1000 system consists of a robotic platform that performs the programmed RPR test and a computer with software that enables automated running of assay steps, worklist generation, data management, and data reduction.

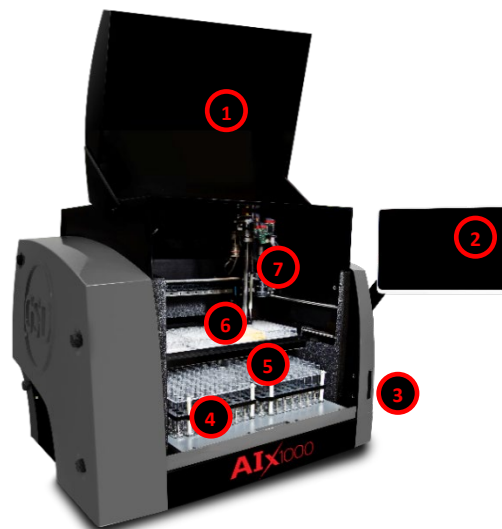
The system components are as follows:

- | | |
|---|--|
| 1 Instrument Cover | 2 Computer |
| 3 Probe (with mounted camera) | 4 Sample racks (intelligent or slide-in) |
| 5 Reagent Rack | 6 Microtiter Plate (MTP) Carrier |
| 7 Barcode scanner or Indicator Light and Camera | |

Slide-in Rack Model



Intelligent Rack Model



The AIX1000 RPR Reagent kits and components are as follows:

1. REF GSD01-1600: Rapid Plasma Reagin (RPR) Test System x 480 tests (Store at 2-8°C)

- REF GSD01-1600-W Pack of 5 uncoated 48- well microtiter plates. 2 units.
- REF GSD01-1600-AS Antigen suspension - 22 mL (ready to use, modified VDRL carbon antigen preserved with sodium azide (1 mg/mL)
- REF GSD01-1600-NC RPR non-reactive control – 0.35mL (ready to use, human serum preserved with sodium azide (1 mg/mL). GREEN CAP
- REF GSD01-1600-PC RPR reactive control – 0.35 mL (ready to use, human serum reactive for syphilis preserved with sodium azide (1 mg/mL). RED CAP

2. REF GSD34-1600-R: Rapid Plasma Reagin (RPR) Test System (Bulk) (Store at 2-8°C)

- REF GSD01-1600-AS Antigen suspension – 34 x of 22 mL (ready to use, modified VDRL carbon antigen preserved with sodium azide (1 mg/mL)
- REF GSD01-1600-NC RPR non-reactive control – 34 x 0.35mL (ready to use, human serum preserved with sodium azide (1 mg/mL). GREEN CAP
- REF GSD01-1600-PC RPR reactive control – 34 x 0.35 mL (ready to use, human serum reactive for syphilis preserved with sodium azide (1 mg/mL). RED CAP

Sold separately:

3. REF GSD01-1600-W-CASE Uncoated 48-well microtiter plates, 85 plates

3.2. System Details

It is recommended that the area for use and storage of the AIX1000 be a space dedicated to the instrument which is able to accommodate the following specifications. For optimum instrument performance, the room temperature should be controlled, the relative humidity should be between 20% and 90% (non-condensing), and the environment should be relatively dust-free and free of excessive vibration.

Instrument Power Specifications

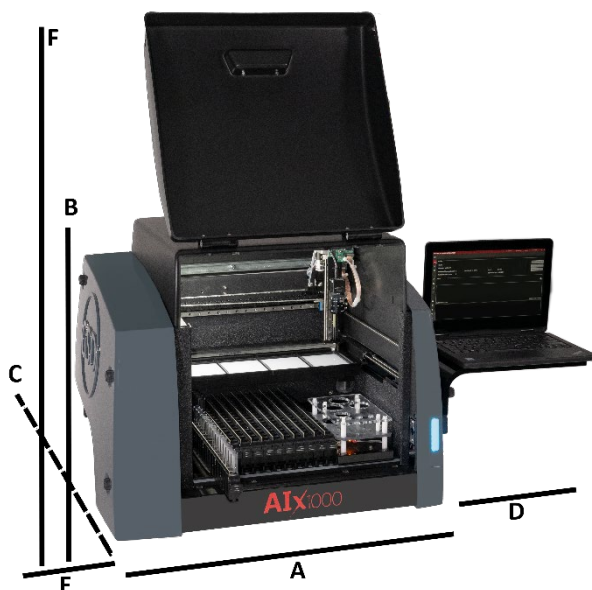
Voltage: 100-265V

Frequency: 50-60 Hz

Power consumption: 120W max

It is recommended that the AIX1000 is be placed near an outlet and connected to a dedicated power source via a surge protector or an uninterruptable power supply (UPS).

Instrument Dimensions and Weight



Dimensions:

A/Width of instrument alone: 66.1 cm (26 in)

B/Height of instrument alone: 55.9 cm (22 in)

C/Depth of instrument alone: 57.2 cm (22.5 in)

D/Width of suspended computer: 33.1 cm (13 in)

E/Width of attached Wash/Waste: 15.3 cm (6 in)

F/Height with door open: 99.1 cm (39 in)

Weight: 50 kg (61.7 lb.)

The total bench space recommended to accommodate the AIX1000 and related equipment is 84.4 cm (33.2 in.) wide x 182.2 cm (71.7 in.) high x 72.2 cm (28.4 in.) deep. The laboratory bench must be sturdy enough to support the full weight of the AIX1000 as well as additional equipment; it is important that the bench does not vibrate during instrument use. Expect the total weight of the AIX1000 and accessory equipment to be approximately 50 kg (110 lbs.).

3.3. Component Details

Note: Certain instrument models may not contain all these components.

Sample Racks

AIX1000 instrument models contain one of two types of sample racks, as explained in detail below.

Slide-In Sample Racks

The Slide-In sample racks use a camera scanning system to detect sample tubes and track sample IDs. Each of the 12 racks can accommodate 16 samples (up to 192 patient samples total). The removable racks are interchangeable and can accommodate 12 to 16 x 75-100 mm tubes. Rack positions are numbered from left to right and sample tube positions are numbered from back to front.

Intelligent Sample Racks

The Intelligent sample racks use automatic sample location management to track sample IDs, regardless of loaded sample positions. The three racks can accommodate up to 192 patient samples. The removable racks are interchangeable (though if racks are moved to different locations, probe alignment should be performed) and can accommodate 12, 13 or 16 x 75 mm tubes. Custom racks are also available. Rack positions are numbered as follows: Front right is rack 1, front left is rack 2, back left is rack 3. Sample tube positions are numbered in each rack beginning in the back left corner and proceeding down each column from top to bottom and continuing across the rack from left to right.

Reagent Rack

The reagent rack contains four reagent positions and accepts 22 to 35mm bottles. Custom reagent adapters are also available. The reagent rack also contains three control positions that accept the control bottles included with the test kit.

Microtiter Plate (MTP) Carrier

The MTP carrier contains four reaction MTP positions (48-well plates). If titrations are run, one position will use a predilution plate (96-well plate), leaving three reaction MTP positions.

Camera

The probe-mounted camera is used to take high resolution images to provide photographic measurement and analysis of agglutination.

Probe Assembly

The AIX1000 utilizes a single probe, dual needle system; no disposable tips are used. This system is capable of precise pickups and dispenses for volumes between 1ul and 300ul. The high-precision

micro-syringe aspirates 1ul with less than 3% CV across an entire reaction plate. Liquid detection is performed via conductivity, with a minimum detection volume of 50ul.

Barcode Camera (applicable only for models with slide-in sample racks)

The fully integrated camera is used in conjunction with the slide-in rack system to detect sample tube location and ID. The camera supports the following barcode types: codabar, code39, interleaved 2 of 5, code 93, code 128, UPC A, UPC E, EAN 13, EAN 8, QR code, Data Matrix.

Barcode Scanner (applicable only for models with intelligent sample racks)

The fully integrated barcode scanner supports the following barcode types: codabar, code39, interleaved 2 of 5, code 93, code 2 of 5, IATA code 2 of 5, matrix 2 of 5, code 11, code 128, telepen, UPC A, UPC E, EAN 13, EAN 8, MSI, Plessey, RSS-14, RSS-14 Limited, RSS-14 Expanded, China Post Code, and PDF417.

Orbital Shaker

The integrated orbital shaker features a no-spill design which closely replicates manual shaking. The AIX1000 can dispense while the shaker is in motion.

Amplitude: 10 mm

Adjustable speed: up to 400 RPMs

Capacity: 4 MTP (4 reaction for screens, 3 reaction and 1 predilution for titers).

Voltage: 24 V

Stirrer

The stirrer is integrated into the reagent rack and is used to stir the Antigen Suspension. The speed is adjustable up to 400 RPMs. A Magnetic Micro, PTFE fluoropolymer covered stir bar is recommended.

Computer

The included instrument computer is attached to the instrument via a USB connection. If the instrument is used in a Central Server Configuration (see **3.1 SOFTWARE PACKAGE CONFIGURATION OPTIONS**), the instrument computer will be connected to the server computer via a TCP/IP connection. The specifications for the instrument computer and the server computer are given below:

Instrument Computer Specifications

The instrument computer (in either a Single Instrument or Multiple Instrument with Central Server configuration) must meet the following minimum specifications:

Processor: Intel Celeron 1.1 GHz

RAM: 4 GB

Hard Disk: 120 GB

Ports: USB 2.0 (RS232, Ethernet ports optional)

Display: DirectX 11 graphics device with WDDM 1.2 driver, 1366x768 resolution

Operating System: Windows 10 Enterprise LTSC

Server Computer Specifications

If running in a multiple instrument environment with a separate server computer, the server computer (with the AIX1000 Server and AIX1000 System Configuration Tool) must meet the following minimum specifications, depending on the number of instruments connected to the server:

# of Instruments	Processor	RAM	Hard Disk	Ports	Display	Operating System
1	Intel Celeron 1.1. GHz	4 GB	120 GB	USB 2.0 Ethernet RS232 (Optional)	Direct X 11 graphics device with WDDM 1.2 driver, 1366x768 resolution	Windows 10 Enterprise LTSC
5	Intel i3 2.0 GHz	8 GB	240 GB			
10	Intel i5 2.4 GHz	8 GB	500 GB			

Software

The pre-installed AIX1000 software suite components run on the Windows based computer included with the instrument. The software provides the ability to create and run Worklists, analyze results from previous Worklist runs, generate reports of Worklist results, and integrates with most LIS systems. The software is highly configurable and includes support for audible alerts for various events that occur during the use of the instrument. Computer speakers should be enabled at all times and additional speakers (provided) are recommended.

4. AIX Software Suite

The AIX1000 system includes a software suite that is required in order for the AIX1000 to operate. The necessary software applications are: AIX1000 Server, AIX1000 Configuration Tool, and AIX1000 Instrument Manager.

The AIX1000 Configuration Tool software is used to configure the AIX1000 Server (these two software components must always be installed together on the same computer). The AIX1000 Server controls the configurations of each Instrument Manager to which it is connected (In the Instrument Manager settings, the user specifies which Server each Instrument Manager is connected to).

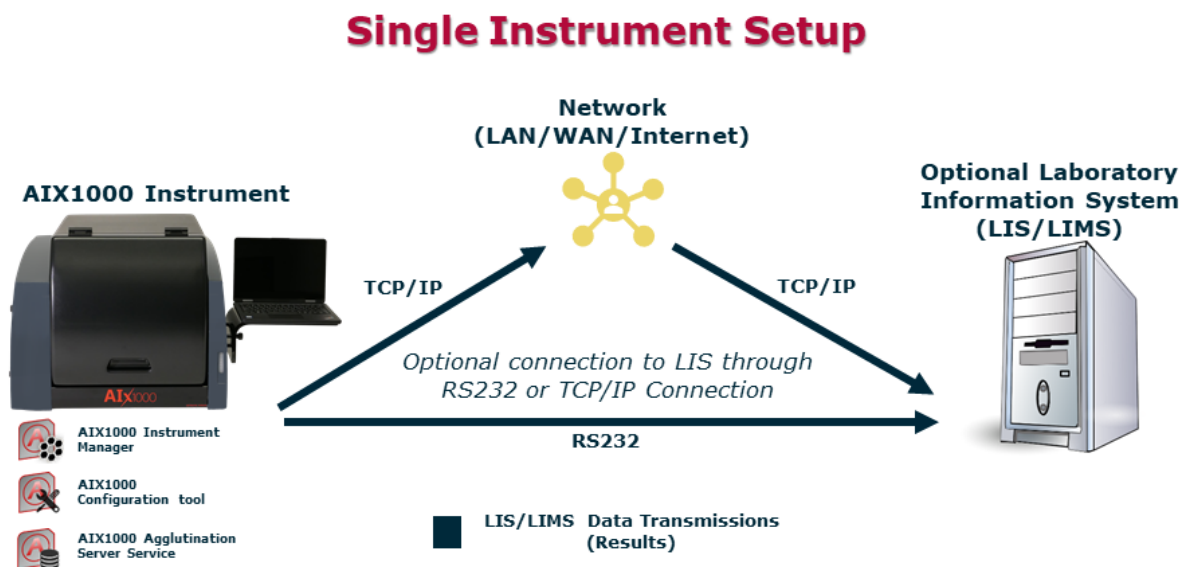
All software components are pre-installed on the computer included with the AIX1000.

4.1. Software Package Configuration Options

There are two ways in which a lab may configure/run the AIX1000 software package:

1. Single Instrument Configuration (default):

The lab may utilize a single computer for the entire software package, as shown in the following topology diagram:



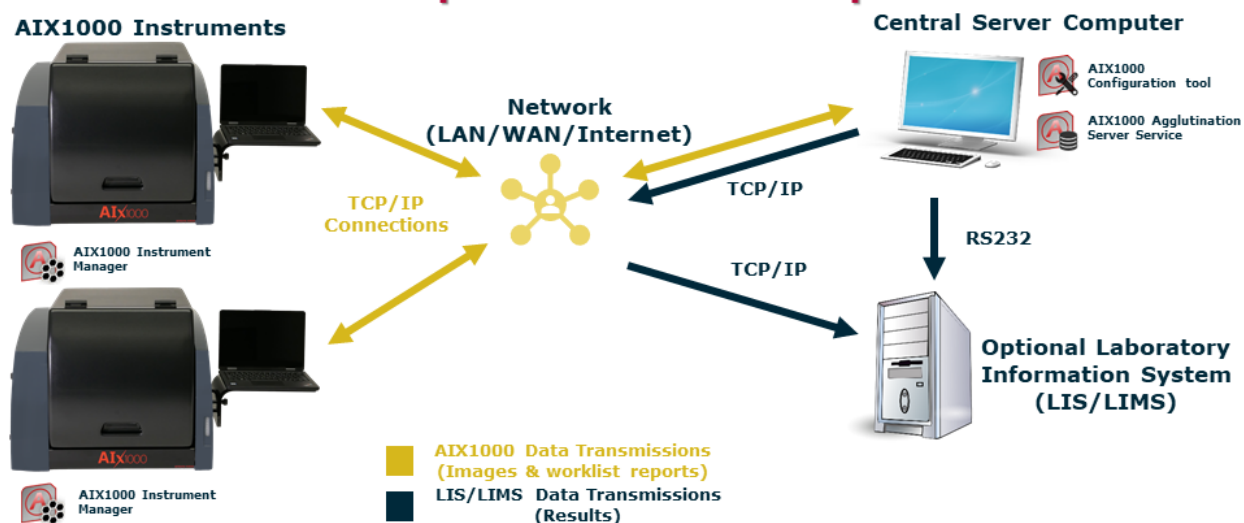
This configuration can be used by labs with a single AIX1000 instrument or for labs with a small number of AIX1000 instruments. The AIX1000 is configured in this way by default at the time of purchase and no additional software installation is necessary to run the system in this format.

Note: This configuration is limited by the amount of computing power and storage space on the instrument computer, which also runs the server.

2. Multiple Instrument Central Server Configuration:

The lab may utilize one central AIX1000 Server for all instruments, which runs on a separate computer as shown in the following topology diagram:

Multiple Instrument Setup



This configuration is ideal for labs with multiple AIX1000 instruments; the central server allows for a common configuration of all Instrument Managers and a single connection to the LIS.

If using the Central Server Configuration, contact your AIX1000 distributor for additional instructions regarding software installation on the central server computer and proper configuration of all software components.

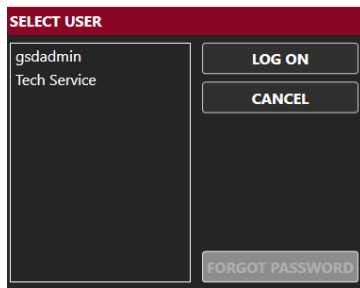
4.2. AIX1000 System Configuration Tool and Agglutination Server Components

The AIX1000 Agglutination Server is a Windows Service that runs in the background of the computer on which it is installed. The Agglutination Server service stores configuration data for the system and processes requests from AIX1000 Instrument Manager instance(s) to store and retrieve data generated from Worklist runs performed on the associated instrument(s).

The AIX1000 System Configuration Tool is used to specify configuration settings for the system. These settings are stored by the Agglutination Server and used by all AIX1000 Instrument Manager instances connected to the server. The AIX1000 System Configuration Tool must be installed on the same computer on which the Agglutination Server service is running. The AIX1000 System Configuration Tool can be utilized as follows:

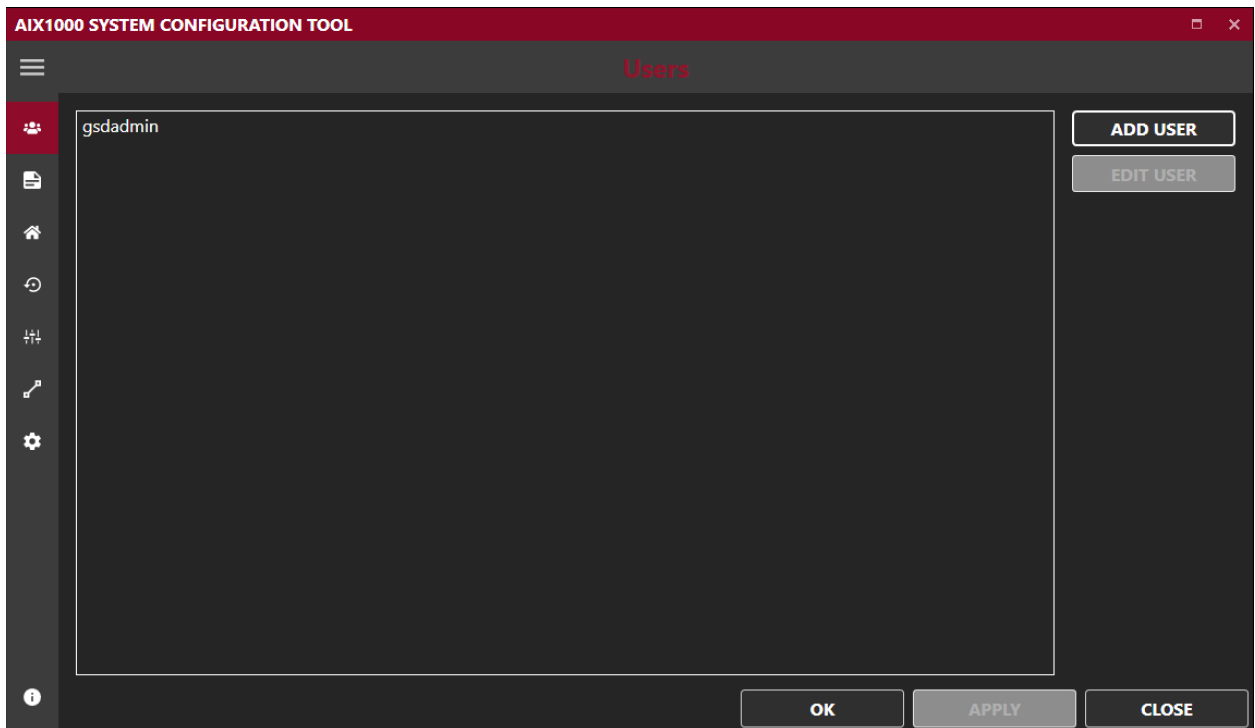
Configuration Tool Access

To access the Configuration Tool software, double click/tap the icon on the desktop. Choose Yes if asked to allow the program to make changes to the computer. If prompted, make sure all Instrument Managers connected to the server being configured are closed prior to using the Configuration Tool. Select desired user (only Administrator and Tech Service users appear in list), enter password on login screen as prompted, and click/tap OK:



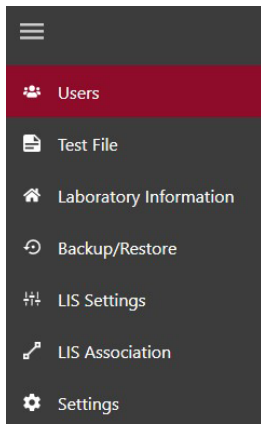
Note: If an Administrator user forgets his/her password, a new password may be set using the Forgot Password button and following the subsequent instructions.

The AIX1000 System Configuration Tool will then open:



AIX1000 System Configuration Tool Configurations

The settings selected in the AIX1000 System Configuration Tool software, as described below, apply to all Instrument Managers that are connected to this Server. The following screens are available in the Configuration Tool software:



Note: Click/tap the three bars at the top of the sidebar to reveal or hide the labels for the sidebar icons.

1. **Users:** Use this screen to add and edit AIX1000 users. These user profiles will be used to log in to the Configuration Tool and to the Instrument Manager(s) connected to this Server.
 - a. To add a user: Click/tap Add User. Enter User Name and Password, Email Address (optional for run notifications), and cell phone number (optional for run notifications) as indicated. Select Basic User, Super User, or Administrator rights for the user by selecting the corresponding user level option. Click/tap OK to save changes.
 - b. To edit a user: Select desired user from the list and click/tap Edit User. Edit user information and settings as desired, then click/tap OK.
 - i. Users cannot be deleted, but their accounts can be inactivated by deselecting the Active User option in the Edit User window.
 - c. User Types: User levels are implemented with different rights/abilities within the AIX1000 software suite:
 - i. **Basic User** accounts are intended for the normal users of the AIX1000 Instrument Manager and its associated instrument. This type of user can perform instrument maintenance and create Worklists and run them on the instrument.
 - ii. **Super User** accounts are intended for users who will review worklists and images and send results to the LIS. This type of user can perform all tasks of Basic Users and can also review worklist reports and send results to the LIS.
 - iii. **Administrator** accounts are intended for users with extra privileges. Users with Administrator accounts can perform all tasks of Basic and Super user accounts, as well as other tasks: Only Administrator users can log in to and change settings in the AIX1000 System Configuration Tool. Also, only Administrator users can access the Settings screen in the AIX1000 Instrument Manager. Certain tools (i.e.: Wash Pump Calibration) are also reserved for Administrator users. At least one Administrator account must always be active.
 - iv. **GSD Tech Service** is an account only for use by GSD personnel.
2. **Test File:** The selected test file will be run by the Instrument Manager(s) connected to this server. This test file determines which actions are available to run in a worklist. The RPR test file comes pre-installed and selected on the instrument computer by GSD at the time of purchase; file cannot be edited by the instrument user.

3. **Lab Info:** Enter the name and address of the lab as it will appear on worklist, sample, and search reports generated by the connected Instrument Manager(s). Upload a logo if desired. Enter the number of instruments connected to the server. Click/tap Apply to save changes.
4. **Backup/Restore:** Use this screen to backup data manually or at scheduled times, purge data or images, or restore a backed-up database.

Note: After beginning a backup, restore, or purge action, wait for the action completion message before proceeding with any other actions on the server computer.

 - a. Backup: Select to backup all data (including images) or only data within a specified date range. Enter name and destination of backup file. Decide to keep or auto-purge the backed up data. Click/tap “Backup” to create the backup file.
 - b. Restore: Click/tap Restore and select path of desired ZIP or TAR file to restore a previously backed up database (including all data and images).
 - c. Scheduled Backup: Set a time for automatic backups to occur, if desired. Select backup frequency and file location. Decide to keep or auto-purge backed up data.
 - d. Purge: Click/tap Purge to purge all images or only images within a specified date range (Data is maintained; only images are removed. This action creates more space on the server computer.).
5. **LIS SETTINGS:** Check to enable Laboratory Information System (LIS) communication, if system is connected to an LIS. Check to enable LIS logging, if desired, and select desired log level. Select which LIS connection type will be used (RS-232 or TCP/IP) and set port or server settings as applicable.

- a. Be sure that all settings match those of the LIS system being connected. Click/tap APPLY to save changes.
 - b. This screen must be completed before LIS communication can be attempted from within the Instrument Manager.
6. **LIS Association:** Map the selected test’s test name to the LIS Name and click/tap Apply.

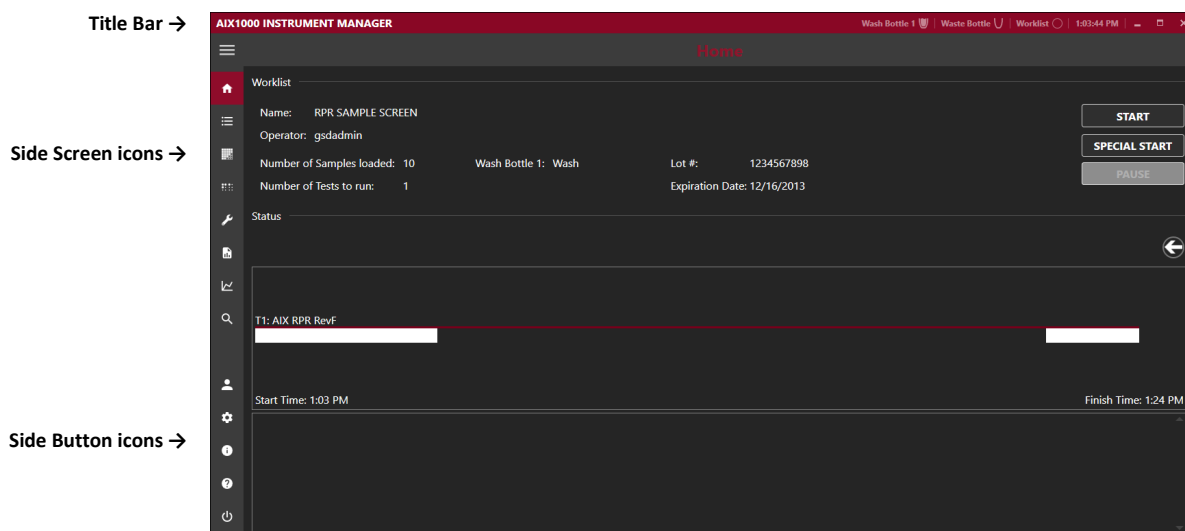
- a. Note: An LIS name is seldom the real test name, but often a shorter one. It could also be a number or code, depending on the laboratory policy.
7. **Settings:** Check the Enable On-Screen Keyboard option if using a touchscreen, to enable on screen keyboard in the Configuration Tool application.

Close the AIX 1000 Configuration Tool window by clicking close in the bottom right-hand corner. If necessary, the Server will automatically be restarted to implement Configuration Tool changes:

Some of the settings changes require the AIX1000 Server to be restarted.
Restarting the server now...

4.3. Instrument Manager

The AIX1000 must be attached to a computer with the Instrument Manager in order to be operational. The interface for the AIX1000 Instrument Manager is designed with a title bar, side screen icons, and side buttons icons (click/tap the  icon to view/collapse the side screen/button names), as shown:



Instrument Manager Modes

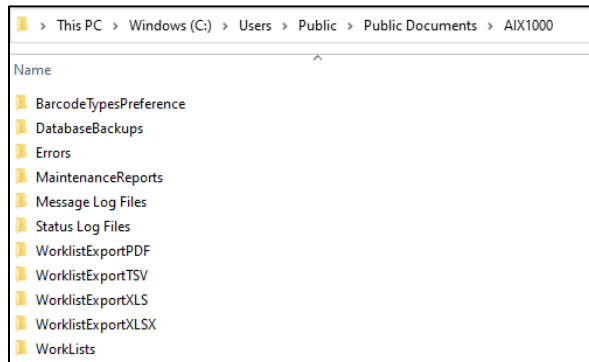
The Instrument Manager can be run in two modes:

1. **Full Functionality Mode:** This Instrument Manager mode enables the running of the RPR test (test file is pre-installed and selected in the Configuration Tool at purchase) and evaluation of test results. When the Instrument Manager is run in this mode, the instrument is powered on when the Instrument Manager is started.
2. **Evaluation Only Mode:** This Instrument Manager mode allows for data evaluation without worklist running functionality. The instrument is not powered on when the Instrument Manager is run in this mode. Only the Evaluation, Analysis, and Search Screens are available in this mode; some items are excluded from title bar and side buttons in this mode as well.

Note: If using the Central Server Configuration, contact the AIX1000 distributor for additional instructions for installation of Instrument Manager software on the central server computer (Evaluation Only mode).

AIX1000 Instrument Manager Documents Folder

All relevant data related to the Instrument Manager is located in the AIX1000 Documents folder on each instrument computer. This folder is accessible via a desktop shortcut or navigation to the following location: C:\Users\Public\Documents\AIX1000.



These folders can be accessed at any time, including when software applications are in use. The Documents folder includes the following sub-folders:

1. **Database Backups:** This is the recommended/default location for any database backups created via the AIX1000 System Configuration tool
2. **Errors:** Errors that are encountered during use of the instrument are automatically named by the date and time at which they occur and stored as text files.
3. **Maintenance Reports:** Records of users' performance of all prompted maintenance actions are stored (one file per month) in the Maintenance Reports subfolder in portable document format (PDF), as shown in the image below:

AIX1000 Software-Recorded Maintenance Action Log																																			
Instrument Serial Number: AIX1000_Fake																Month: July								Year: 2021											
Daily Startup	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31				
Do 10 primes with wash buffer.	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/				
Clean backlights with isopropyl alcohol wipe.	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/				
Daily Shutdown	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31				
Do 50 primes with DI water.	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/				
Shut down instrument and computer.	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	gs	/				
Empty waste bottle.	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	gs	/				
Weekly																																			
	Week 1 Date/Initials:							Week 2 Date/Initials:							Week 3 Date/Initials:							Week 4 Date/Initials:							Week 5 Date/Initials:						
Remove sample racks, inspect for damage and clean with a rag or paper towel dampened with water.	/							/							/							/							2021-07-30 gsdadmin						
Clean intelligent rack deck with isopropyl alcohol.	/							/							/							/							2021-07-30 gsdadmin						
Clean outside of probe with isopropyl alcohol wipe.	/							/							/							/							2021-07-30 gsdadmin						
Perform Instrument Alignment.	/							/							/							/													
Perform Camera Alignment.	/							/							/							/													
Do 20 primes with 1% Liquinox and 50 primes with DI water.	/							/							/							/													
Clean wash bottles.	/							/							/							/													

4. **Message Log Files:** When an error or warning message or software prompt appears to the user during their use of the system, the prompt and the user response are recorded in this folder (one log file for each day).
5. **Status Log Files:** The status (worklist action) logs from each worklist are automatically saved as text files, named with the worklist name and status (completed, stopped, etc.), and organized into folders for each month, in the Status Log Files subfolder. These logs include all the actions

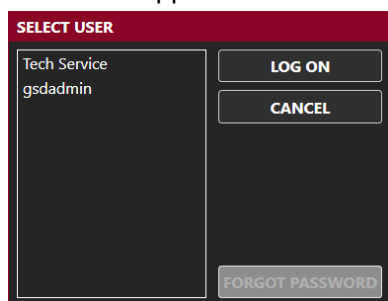
of the instrument for each worklist run, including any anomalies encountered (such as bubble retries).

6. **Worklist Export:** Worklist export folders for the various available file types (pdf, XLS, XLSX, and CSV) are located in the AIX1000 folder after a data report from at least one worklist has been exported to the applicable file type. All exported worklist data (exported from within the Instrument Manager software) can be stored in these export folders, organized by worklist name.
7. **Worklists:** Worklist files, named by the worklist name and organized by month and year of run date, are saved here. These can be loaded from within the Instrument Manager software (files cannot be opened directly).

Instrument Manager Initialization

To initialize the Instrument Manager in Full Functionality Mode on the instrument computer, proceed through the following steps:

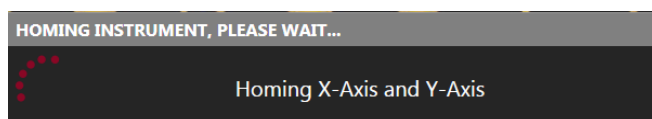
1. Verify that computer with installed Instrument Manager is attached to the AIX1000 instrument, power is connected to instrument and to computer, and instrument power button is in the 'On' position. Turn on computer and double click/tap the Instrument Manager icon (if Instrument Manager does not initialize automatically at computer startup) to initialize the system. Login screen will appear:



2. Select a user (only active users are displayed for selection), click/tap Log On, enter password, and click/tap OK.

Note: If a basic or super user forgets his/her password, a user with an Administrator account can reset the password using the Storm System Configuration Tool. If an Administrator user forgets his/her password, a new password may be set using the Forgot Password button and following the subsequent instructions.

3. After login is complete, the instrument requires approximately 30 seconds to automatically move to its starting, or "home" position. The instrument must always be allowed to complete this "homing" uninterrupted before being used:



After homing, the Instrument Manager opens.

Note: Whenever the Instrument Manager opens, user is prompted to perform daily startup maintenance, as well as weekly maintenance (if scheduled/due). User must address each maintenance prompt before continuing.

AIX1000 Instrument Manager Title Bar

The following are displayed/accessible on the AIX1000 Instrument Manager Title Bar:

1. **Wash and Waste Bottle Status Icons:** Indicate liquid level of wash and waste.
2. **Worklist Status Icon:** Indicates the worklist status as initial (open circle), running (arrow), paused (double lines), stopped (square), or completed (checkmark).
3. **Current Computer time:** Displays the current time as set by the attached computer.
4. **Minimize/Maximize/Restore Down:** Used to minimize/maximize/restore down the AIX1000 Instrument Manager main window.
5. **Close (X icon):** Used to close the software without shutting down the instrument/computer. (Daily shutdown maintenance will be prompted).

AIX1000 Instrument Manager Side Buttons

1. **Current User:** Displays the user ID of the logged in user. Logged in user can be changed by selecting this icon and selecting Switch User. Password of the current user can also be changed by selecting the Change Password option here and entering old and new passwords as indicated.
2. **Settings:** Used to select various software options, described in detail below.
3. **About:** Displays the version of the software/license information.
4. **Help:** Displays a PDF of the system user's manual.
5. **Power:** Used to close the software and shut down the instrument/computer. (Daily shutdown maintenance will be prompted).

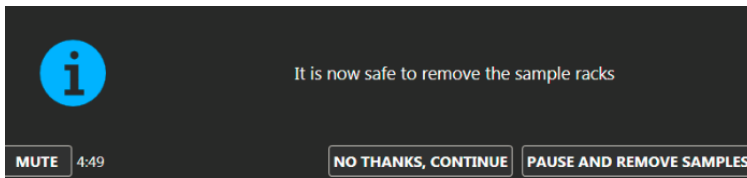
AIX1000 Instrument Manager Settings

Clicking/Tapping the Settings button opens the Settings window, used to adjust various settings for running the AIX1000 Instrument Manager (Instrument Manager Settings can only be accessed by users with Administrator or GSD Tech Service accounts):

1. **Instrument:** Instrument Information section displays instrument details, including serial number, instrument ID, and runtime. Instrument ID can be changed using the Set Instrument ID button. Barcode Scanner section allows user to turn off the integrated scanner and use an attached handheld scanner instead (applicable only for models with intelligent sample racks).
2. **Samples:** Allows user to decide various sample processing options: whether or not to enable an alarm to notify the user when sample pipetting is complete and sample racks can be removed from the instrument and what actions will be taken by the instrument when a sample pickup error occurs during sample pipetting:

Sample Rack Removal: Notify user when it is safe to remove samples:

When this option is enabled, an alarm will sound during the worklist to notify the user when all sample pipetting actions have been completed:

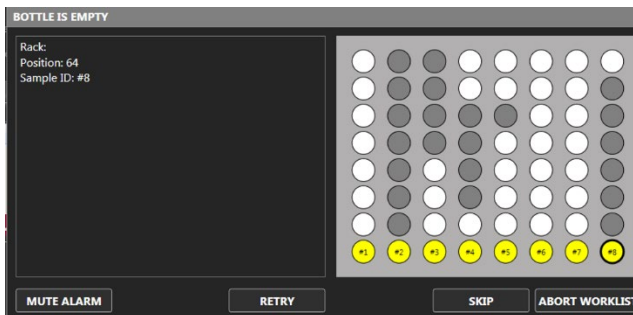


User can mute the alarm and has 5 minutes to either pause the run and remove the samples (instrument cover will unlock) or to choose to continue with the run. If no user action is taken after 5 minutes, the instrument will automatically continue with the worklist.

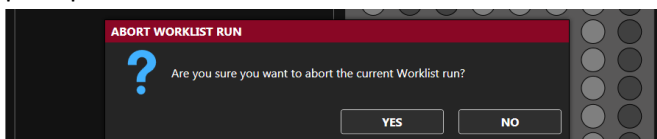
Aspiration Failure: Action when insufficient sample volume detected:

If “automatically continue with next sample” is selected, the sample will automatically be skipped (no alarm to user during the run) and the instrument will continue to the next sample (sample will be noted as skipped on the report and no result will be generated).

If “Ask the Operator” is selected, an alarm window will appear during the run to allow the operator to decide on a case-by-case basis what to do when insufficient sample volume is detected during sample pickup:



User can mute the alarm sound and select **Retry** (instrument will attempt again to perform the pickup), or **Skip** (sample will be noted as skipped on the report and no result will be generated). User can also select **Abort Worklist**; if this option is selected, an additional warning window will prompt the user to confirm the selection:



3. **Racks:** Allows the user to enable/disable intelligent rack and tube detection (for models with intelligent sample racks, depending on laboratory’s preference), and set intelligent racks’ sizes (if tube detection is disabled; rack sizes depend on sample tube sizes used by the laboratory).
4. **Server:** Allows the user to set the server location as the local computer or a remote computer and set IP Address. User also selects the maximum number of worklists to include in the worklist history display on the Evaluation screen (This does not delete worklists from the database).
5. **Sounds:** Allows user to decide which alarms/sounds are enabled and to select which sounds are used. Additional custom sounds (as WAV files) may be added to the computer for selection here.
6. **Languages:** Allows user to select the desired display language.
7. **Touch Screen:** Allows the user to turn on/off the on screen keyboard in the Instrument Manager application for use with touchscreens.
8. **Notifications:**
User can decide if they receive SMS (text messages) or Email notification when alarms or events occur during a run while their operator profile is loaded.

Additional user notification can select more users be notified when specific events occur when *anyone* is running a worklist.

9. **Maintenance:** Allows user to decide which day and time weekly maintenance will be prompted by the software, as well as whether weekly maintenance should be prompted/performed at system startup or system shutdown.

After adjusting Instrument Manager Settings, click/tap OK to save changes.

Note: *Software must be restarted before some Settings selection changes are applied. The Instrument Manager indicates when an applicable setting is changed that requires software restart before taking effect.*

5. Running a Worklist (Instrument Manager)

To run the instrument, initialize the Instrument Manager in Full Functionality Mode as described above and follow the steps below.

5.1. Worklist Preparation

Standard Worklist Preparation:

1. **Perform Maintenance:** Prior to each instrument use, verify that the maintenance log is up to date. Perform daily startup maintenance as described in the maintenance section of this manual (as prompted by the Instrument Manager each time the instrument is turned on/the Instrument Manager is opened) if worklist is the first run of the day/shift. If prompted by the software, perform weekly maintenance.

Note: Always be sure to perform instrument alignment after any of the following: the instrument has been moved, probe-related maintenance has been performed, or if different-sized racks have been placed on the instrument since the previous alignment.

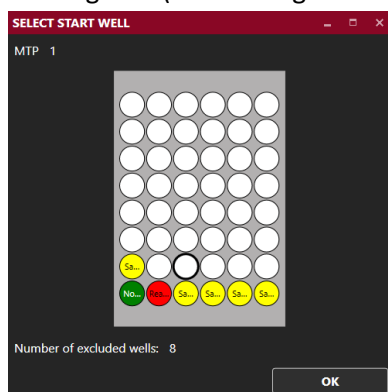
2. **Check Settings:** Be sure to adjust/view the Instrument Manager Settings (described in previous section) as necessary prior to running a worklist (Administrator privileges required).
3. **Prepare Kit:** It is essential that all instructions in the package insert regarding reagent handling and storage are carefully followed for the kit run on the AIX1000. Reagent and sample preparation must be performed according to instructions from technical service, specific to the test.
 - a. Precautions: Do not mix components from different lot numbers. Do not reuse microtiter plate wells that have already been used for testing samples or controls. All reagents must be mixed well before use, and any bubbles formed must be removed from reagent bottles before starting the test. Avoid microbial or other contamination of reagents.
 - b. Reagent Preparation:
 - i. **Temperature/Bubbles:** Equilibrate all reagents and samples to room temperature. Visually verify that there are no bubbles in the bottles or vials of reagents, controls, or samples. Remove any bubbles (a clean transfer pipette or toothpick can be used) before placing vials on the instrument.
 - ii. **Antigen Suspension/Stir Bar:** Shake bottle well. Place a clean stir bar into the Antigen Suspension bottle to be used for testing prior to use (required to maintain

a well-mixed solution). A Magnetic Micro, PTFE fluoropolymer covered stir bar is recommended.

Note: Proper maintenance of the stir bar must be performed to avoid possible contamination and adverse effects on sample results. The stir bar must be removed from the bottle at the end of each testing day or when a new Antigen Suspension bottle is placed in the instrument. Following removal, stir bar must be rinsed with DI water and dried with a clean non-abrasive wipe, prior to its next use.

Additional Preparation Selections (Optional):

1. **Exclude Wells:** If test should start from a position other than the default A1 on the MTP reaction plate(s) or predilution plate (to accommodate partially used plates), navigate to the Microtiter Plates screen. Click/tap the Exclude Wells button below the desired plate(s). Click/tap the desired starting well (a black ring will blink around the well) and click/tap OK:



For example, if the first 10 wells of the predilution plate should not be used, 10 wells should be excluded; predilution wells will be placed beginning in the 11th well (after completing the necessary steps to set up a worklist on the other screens as described in the following sections):



2. **Preload Sample Racks (applicable only for models with intelligent sample racks):** Prior to or during a worklist run, the user can preload racks with sample tubes (outside the instrument) to be used for future worklists. To preload racks:
 - a. On the Worklist screen, click/tap Add Samples; select Preload Sample Rack.
 - b. In the Preload Sample Rack window that appears, specify the Sample Rack ID (scan barcode or manually enter) and Rack Description (Tubes per Sample should be left with the default value of 1), then click/tap Add.
 Note: Rack ID must be in the format X-XXXX. The first digit is the rack type (1 for 12mm rack, 2 for 16mm rack, or 4 for a 13mm rack). The 4 digits after the dash are used to differentiate the racks (the unique number can range from 0000 to 9999).
 - c. Add samples to the rack using one or more of the Sample Entry Methods described in the following section. Click/tap Done when complete.
 - d. Repeat these steps for each preloaded rack. Racks are stored until removed.

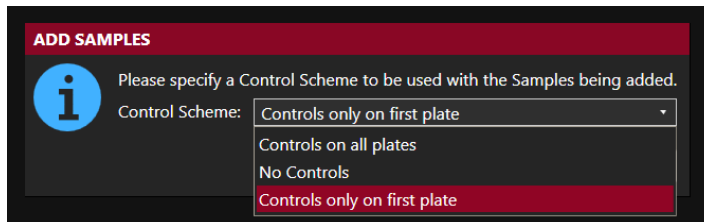
- e. To remove a rack from the stored list: Click/tap Add Samples, select Preload Sample Rack. Click/tap the Delete Preloaded Racks button. Select the rack(s) to remove from the list (selection is highlighted) and click/tap Remove.

Note: Preloading Sample Racks option is only available on models with intelligent sample racks when the intelligent rack detection is disabled.

5.2. Worklist Screen

Navigate to the Worklist screen. This screen is used to select samples and actions for the worklist. The following steps are taken to complete this screen:

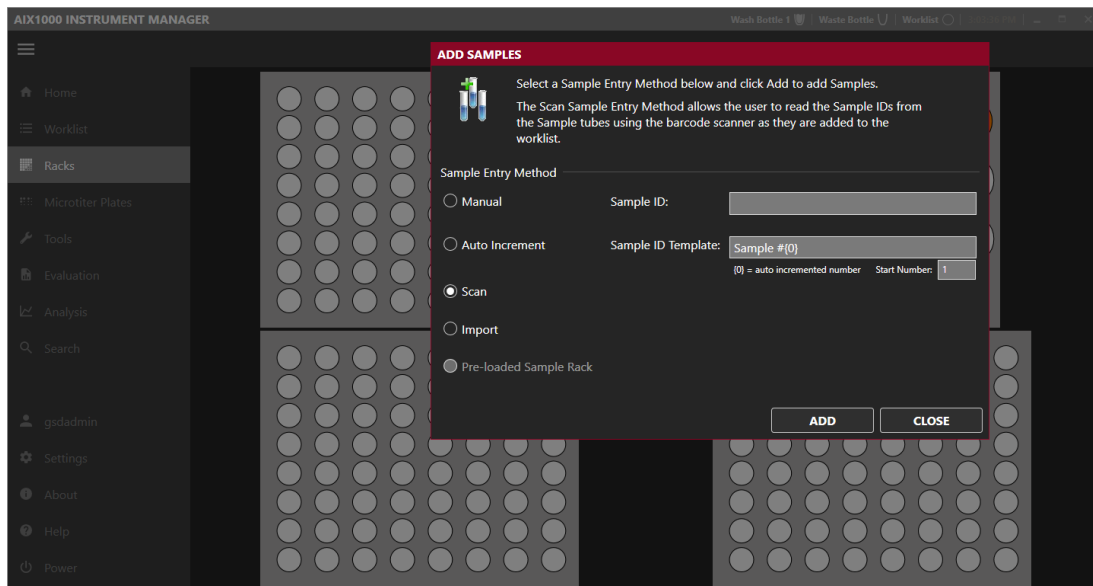
1. **Name:** Enter a worklist name in the Name field. This name will be used to identify all files associated with the worklist.
2. **Select Control Scheme:** Click/tap the Add Samples button and select Add Samples to Worklist. Select a Control Scheme for the worklist as prompted (No controls, controls only on first plate, or Controls on all plates).



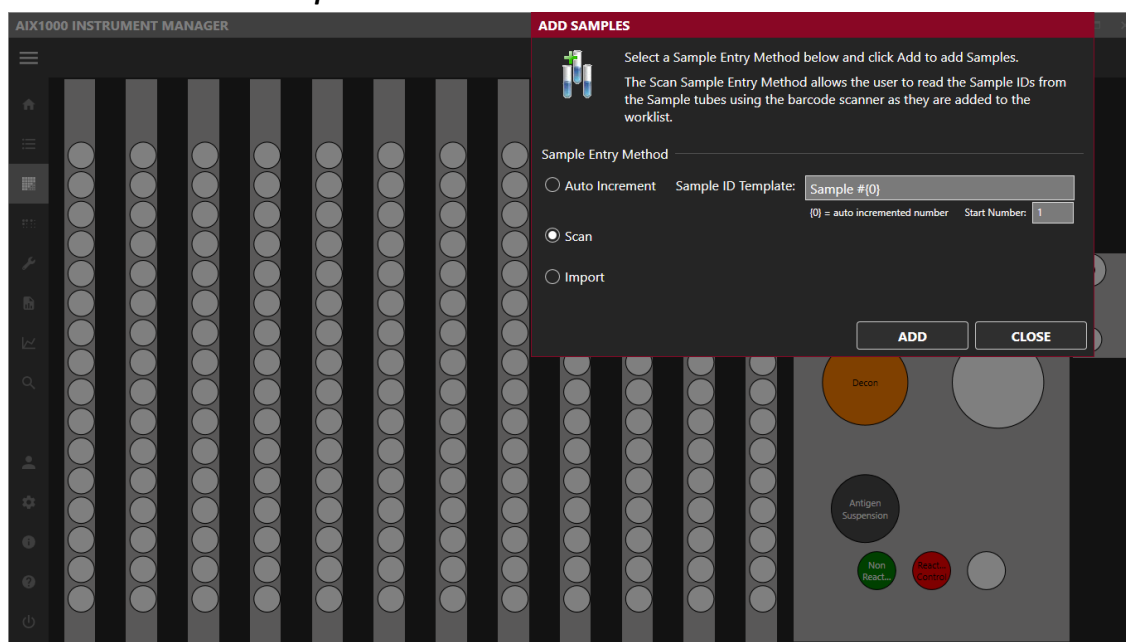
3. **Add Samples:** The Add Samples window will appear in the foreground, and the Racks view will appear in the background to allow for monitoring of sample placement as samples are loaded.

Note: The Racks view in the background will appear differently depending on the model of the AIX1000 instrument being used (Intelligent Sample Rack model versus Slide-in Rack model). These differences are shown below:

Models with Intelligent Sample Racks



Models with Slide-In Sample Racks



Use the radio buttons to select Sample Entry Method. Follow the detailed on-screen instructions for placement of samples using each method; as applicable for instrument models with intelligent sample racks or slide-in sample racks.

Sample Entry Methods:

Use the radio buttons to select the Sample Entry Method. Follow the detailed on-screen instructions for placement of samples using each method, as applicable for instrument models with intelligent sample racks or slide-in sample racks.

- a. **Manual (applicable only for models with intelligent sample racks):** Use for non-barcoded samples with custom IDs. Type the sample ID into the designated field and click/tap Add (or press Enter on the netbook keyboard). Place the sample in the rack as prompted and repeat for all manually labeled samples.

Note: For models with slide-in sample racks the Manual sample entry method is only available as an option when the barcode scanning system detects one or more sample tubes as being present in the rack(s) but is unsuccessful in reading the sample barcode(s).

- b. **Auto Increment:** Use for Auto-numbered samples. Change the Sample ID Template and Start Number if desired and click/tap Add. Place samples in the sample rack, one by one as prompted. Samples will automatically be numbered consecutively, beginning with Sample #1 and continuing with Sample #2, #3, #4 etc. (according to ID Template and Start Number).
- c. **Scan:** Use for barcoded samples
 - i. **For models with intelligent sample racks:** (barcode scanner light will turn on when selected). Click/tap 'Add'. Scan the barcoded sample tube approximately 4 inches (10cm) in front of the built-in barcode scanner (or use a handheld

scanner attached by USB if desired). When the sample is recognized, a beep will be heard, and the scanner light will turn off. Place the sample in the rack as prompted and repeat for all barcoded samples.

Note: A tube must be placed in order for the scanner to reactivate to continue loading additional samples (if intelligent rack tube detection is enabled).

- ii. **For models with slide-in sample racks:** (camera scanner will turn on and move into position when selected). Click/tap 'Add'. Physically place all desired barcoded sample tubes into the slide-in racks with labels facing outward. As prompted, use the rack handle to carefully slide each rack into the indicated position on the slide-in rack deck (as indicated by the green LED). When all tubes of a rack are detected/read, the system will prompt for the next rack to be added, proceeding from left to right until all racks are in place. If any problems with tube/barcode recognition are encountered, the user will be alerted to retry or use another sample entry method.

- d. **Import (applicable only for models with intelligent sample racks):** Use to import sample lists from an Excel spreadsheet. Select the desired XLS or XLXS file as prompted.

Note: This option requires the user to fill in an Excel document template (Inquire with local distributor for guidelines for proper template format) with all sample IDs and rack position locations prior to adding samples to the worklist.

- e. **Preloaded Sample Rack (applicable only for models with intelligent sample racks):** Use to add preloaded racks (prepared as described in Worklist Preparation). Click/tap Add. Select the desired rack from the Preloaded Sample Racks list and click/tap Add. Scan the rack with barcode scanner as prompted and place it into the indicated position inside the instrument (Scanned barcode must match the selected rack in order to add the rack to the worklist). Repeat to add additional preloaded sample racks to the worklist.

f.

Note: This Sample Entry Method is only available for use when intelligent rack tube detection is disabled.

When all samples have been added, click/tap Done and then click/tap Close to exit the Add Samples windows. Display will return to the Worklist Screen where all added samples are listed.

Important Notes for Models with Intelligent Sample Racks:

Tube Detection: If intelligent rack tube detection is enabled, samples can be placed in any desired locations in the sample racks. If intelligent rack tube detection is not enabled, samples must be placed in the designated blinking positions. The Preloaded Sample Rack option can only be used when the intelligent rack tube detection is disabled.

Tube Placement: While placing samples, verify that samples are recognized (spaces with loaded samples display yellow or blue; unoccupied spaces remain white or grey). If sample tubes are removed prior to starting the worklist (and intelligent rack tube detection is enabled), they will be removed from the worklist, and their identification will be lost. To be included in the worklist, they must be added again using one of the Sample Entry Methods described above.

Note: Eppendorf or other conical-shaped tubes are not recommended for use in the AIX1000; only standard-diameter sample tubes are recommended for holding samples.

Sample IDs: Sample IDs cannot be edited after placement. To edit a sample ID, remove the sample from the worklist and add it again with a new ID. Duplicate sample IDs are not permitted; a suffix will be added to the sample ID if a sample with a duplicate ID is added.

Important Notes for Models with Slide-in Sample Racks

Tube Placement: Samples can be placed in any desired locations in the sample racks; empty spaces are permitted in any sample location(s). While placing samples, verify that sample tubes are pushed all the way down into the racks and that all barcode labels are facing outwards.

Note: Eppendorf or other conical-shaped tubes are not recommended for use in the instrument; only standard-diameter sample tubes are recommended for holding samples.

Rack Placement: If a rack is slid into place too quickly, an error will be shown in the software and user will be prompted to try scan again.

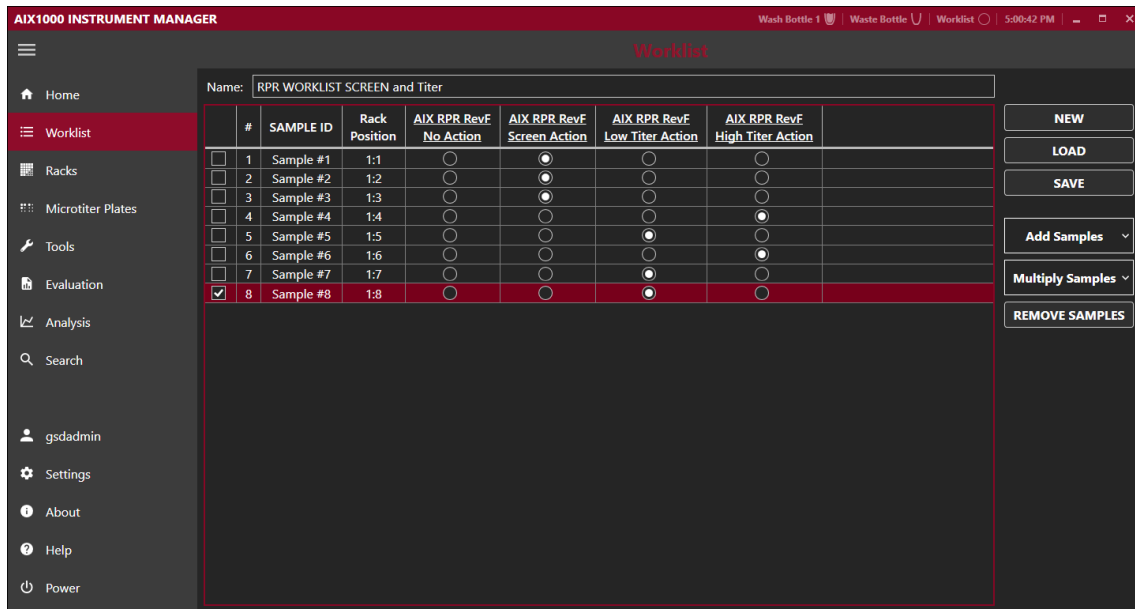
Sample IDs: Duplicate sample IDs are not permitted; user will be prompted to change the sample ID during sample addition if a sample with a duplicate ID is added.

4. **Additional Worklist Screen Options (optional):** Click/tap on the sample ID to select sample(s). Use the CTRL and SHIFT keys to highlight multiple samples.
 - a. **Remove Samples:** Click this button to remove highlighted sample(s).
 - b. **Multiply Samples:** Use this dropdown to change the replicate of highlighted sample(s). Use the preset multiplication factors or enter a custom multiplication factor (use the + and – buttons in the Multiply Samples window) to adjust the indicated sample multiplication (Sample will be pipetted multiple times from the same sample tube.)
 - c. **Processing Order:** Samples will be pipetted in the order listed on the Worklist Screen. Drag and drop individual samples or select multiple samples as a group to adjust processing order as desired. (If using a touchscreen, touch and hold the Sample ID or use the checkboxes to the left of the Sample IDs, then tap the Move button which appears and specify new sample position(s) in the Move Sample window.)
5. **Select Samples/Actions:** Use the radio buttons to select which action to perform on each sample (some samples may already be automatically selected for their next action if they have previously been run). Choices include screen action (qualitative) and titer actions. The titer actions include a low titer (1:2, 1:4, 1:8, and 1:16) and a high titer (1:16, 1:32, 1:64, 1:128 and 1:256). If desired “No Action” can also be selected to exclude sample(s) from a worklist run.

Note: Actions (including reagents, volumes, and instrument movements) are pre-defined by the RPR test file and cannot be edited by the instrument user.

- a. Multiple samples can be selected for an action simultaneously by highlighting multiple samples, then selecting a radio button to select all highlighted samples for an action.
- b. To select all samples in the list for the same action, right click/tap on the desired Action name.

Following is an example of a Samples screen that has been properly prepared for a worklist run:



Note: Rack Position is indicated for each sample (Rack #: Tube position #).

6. Perform Additional Worklist Screen Actions (as needed):

- Use the New button to discard all current worklist information (name, added tests and samples, sample selection) and begin entering information for a new worklist. This button should always be used between runs (when instrument remains on after the first run of the day and user desires to run additional worklist(s)).
- Use the Load button to open and run/rerun a previously saved Worklist. All actions, information, and samples are loaded when a previously run/saved Worklist file is loaded; it is the user's responsibility to ensure that all items are properly placed inside the instrument when running a loaded Worklist.

Note: The intelligent rack is disabled when a Worklist is loaded (even if it was previously enabled when original Worklist was run).

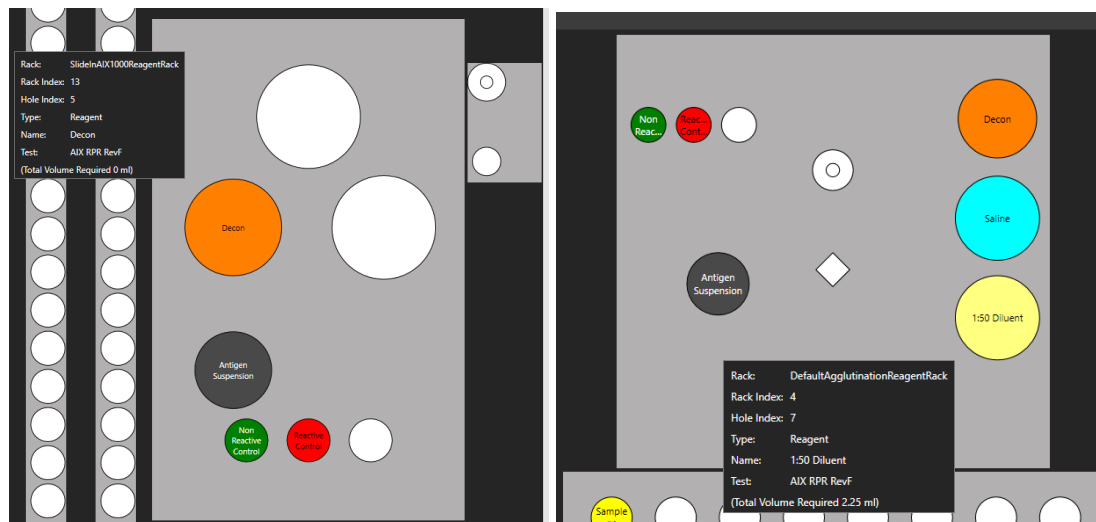
Note: Samples may be deselected or removed from a loaded worklist, if desired.

- Use the Save button to save the current Worklist with a new file name or to overwrite a previously saved Worklist file.

5.3. Racks Screen

Navigate to the Racks screen. This screen displays the reagent rack and sample racks and is used to load reagents and controls, and to verify sample placement. Additional information about each reagent, control, sample, or position can be seen by hovering over/tapping the desired location. The following steps are taken to complete this screen:

- Reagents and Controls:** Load prepared reagents and controls into the AIX1000 reagent rack as indicated by the colors/descriptions on the screen:

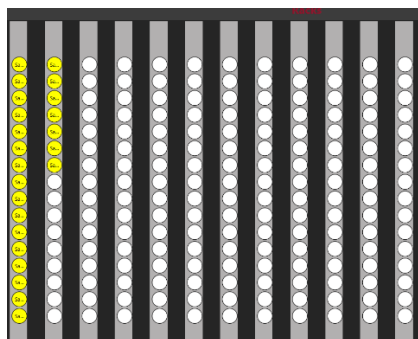


- Use appropriate reagent adapters. Be sure the notched edge of each reagent adapter is facing forward.
- Remove bottle lids prior to starting a worklist.
- Check for/remove any bubbles from reagent/control bottles.
- Be sure that a clean stir bar (as indicated in the Worklist Preparation section above) has been placed in the Antigen Suspension bottle.

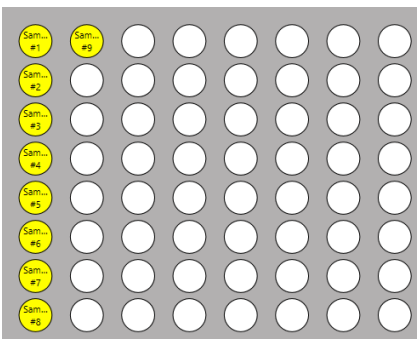
Note: When a Worklist run is started, the Reagent Loading Wizard will also guide the user through the process of adding reagents and calibrators/controls

- Samples:** Verify the placement of all loaded samples in the sample racks, removing any bubbles from the sample tubes:

Slide-in Rack Models

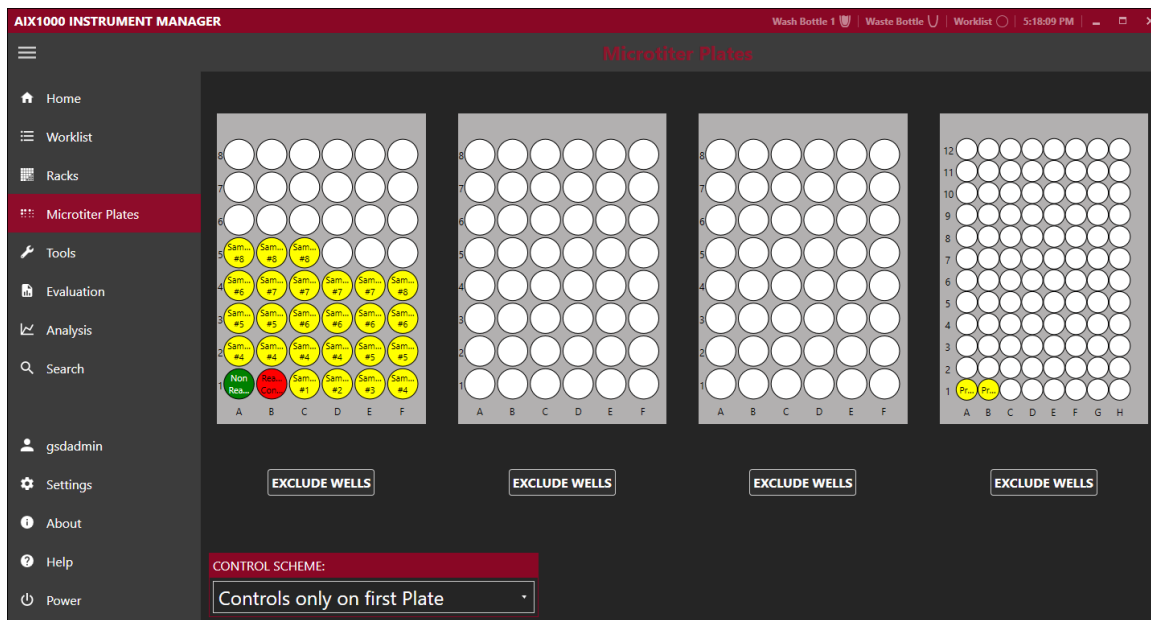


Intelligent Rack Models



5.4. Microtiter Plates Screen

Navigate to the Microtiter Plates Screen. This screen is used to determine the number of plates required for the run by displaying all well locations on the microtiter plates (MTP) and the predilution plate positions. Additional information about each well is displayed on the screen when hovering over/tapping the well. The following steps are taken to complete this screen:



1. **Verification:** Visually verify that all desired samples (and controls, if applicable) appear on the MTP layout in the correct well locations.
Note: Predilution plate will only be used for high titer actions.
2. **Plates:** Obtain the required number/type of plates for the test as indicated by the MTP layout and place them onto the MTP carrier inside the instrument.
3. **Additional Microtiter Plates Screen Options (optional):**
 - a. **Exclude Wells:** If desired, modify the number of excluded wells/starting well location (as described in the Worklist Preparation section above).
 - b. **Control Scheme:** If desired, use the dropdown menu at the bottom left of the screen to modify the selected control scheme.

5.5. Home Screen

Navigate to the Home Screen. This screen displays the system status including details about the currently loaded Worklist, a timing diagram of the worklist run, and the captured image photos (in real time). This screen is used to start, load, save, monitor, pause, stop, and finish a worklist. The following steps are taken to complete this screen :

1. **Lot Information:** Click/tap Lot# to open the Test Properties window:

TEST PROPERTIES
 Test: AIX RPR RevF
 Lot Number:
 Expiration Date: MM/DD

OK
 CANCEL

Enter/change the lot number and expiration date as indicated on the kit package.
 Note: Unless modified, lot number will automatically be saved from worklist to worklist after it is entered the first time.

2. **Verification:** Verify that the test, sample, and kit lot information is accurate.
3. **Wash Bottle:** Verify that the wash bottle is in the indicated location (and instrument is primed).
4. **Start:** Press the Start button to start the worklist.

- a. The start button is to be used only for troubleshooting measures. Use the Special Start button to start the worklist from a stopped/aborted position, from a specific step of the selected action(s), or to recapture well images (images can only be recaptured if worklist has already been run).
5. **Check:** Verify the control scheme as prompted. Check excluded wells, MTP placement and cover removal, and required control and reagent volumes, as prompted.
6. **Run:** Close the cover as prompted and wait for test to run. Worklist actions can be monitored throughout the run using the status log. The bar at the bottom of the screen estimates worklist run time. All captured images will be displayed in the Well Images section in real time.
 Note: If server disk space is low, worklist will be allowed to run, but the user will be notified with a warning.
 - a. It is important to keep cover closed for the entire duration of the worklist, unless a user action is prompted by the software and the cover is unlocked.
 - b. If necessary, use the Pause button to temporarily pause a worklist or the Stop button to completely abort a run (cover will unlock in both cases).
 Note: If worklist is paused for more than 10 minutes, an alarm will alert the user.

Note: Worklist actions can be monitored throughout the run in the 'Status' section of the Home screen. The Status section provides a text description of the current Worklist action, a timing diagram to visually indicate the progress of the run, and the captured well images in real-time.

5.6. Worklist Completion

Standard Worklist Completion:

1. **Finish:** After the worklist is completed, click/tap OK as prompted.
 - a. Stir bar: Remove/clean stir bar as prompted (if run is last of the day or new Antigen Suspension bottle will be used for the next run). Clean stir bar with DI water and dry with a nonabrasive wipe.
 - b. Irregular Samples: Review any skipped an/or invalid samples, if prompted.
2. **Remove Kit Components/Samples:** Remove microtiter plates, reagents, controls, and samples from inside the instrument.
 - a. Samples from each worklist are marked in different colors on the Racks and MTP screens after worklist has completed, for easy identification:
 - i. Red indicates a reactive screen sample.
 - ii. Green indicates a nonreactive screen sample.
 - iii. White indicates an invalid sample.
 - iv. Light Blue indicates a reactive low titer sample.
 - v. Dark Blue indicates a reactive high titer sample.
 - b. Ensure that all instrument surfaces are clean and dry, and close the cover.
3. **Evaluate Results:** Instrument user or other designated laboratory employee can review/display/export/send worklist and/or sample results on the Evaluation screen as described in a following section of this manual (if users have sufficient user level rights).
4. **Perform Maintenance:** After each instrument use, verify that the maintenance log is up to date. If run is the last of the day/shift, click/tap the Power icon and perform daily shutdown maintenance as prompted (described in the maintenance section of this manual).

Additional Completion Selections (optional):

1. **New:** Use this button to clear samples and actions from the completed worklist and allow the setup of a subsequent new worklist.
2. **Load:** Use this button to open and run/rerun a previously saved worklist. All actions, information, and samples are loaded to the Instrument Manager when a previously run/saved worklist file is loaded; it is the user's responsibility to ensure that all items are properly placed inside the instrument.
3. **Save:** Use this button to save the worklist with a new file name.

6. Evaluation and Search Screens (Instrument Manager)

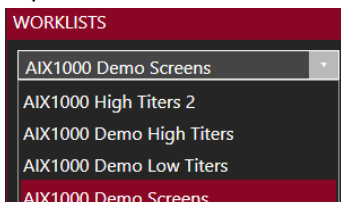
After a worklist is completed, various options are available for evaluation and review of results in the Instrument Manager Evaluation and Search screens. These screens can be accessed at any time from within the Instrument Manager in both the Full Functionality Mode (instrument computer) as well as in the Evaluation Only mode (on instrument computer or another computer).

6.1. Evaluation Screen

This screen is used to review worklist results and images. Users can view and print worklist and individual sample reports, view and export worklist errors, mark a worklist as reviewed, set next actions, and send results to the LIS on this screen (if users have sufficient user level rights for these actions).

Worklist Review:

1. Select a worklist: Select a worklist to view (by worklist name) from the dropdown menu on the top left:



Worklists are listed in order of date with the most recent at the top of the list. Once selected, all controls (if included in run) and samples from the selected worklist are listed on the left in the Controls and Samples list and one of several worklist views is displayed on the right.

2. Select a View: Use the icons in the top right corner to toggle between the different worklist views:



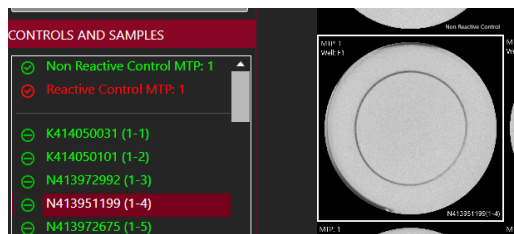
Summary View: Displays a worklist report for the run, including a worklist summary.

Image View: Displays image of individual well highlighted in the Controls and Samples list.

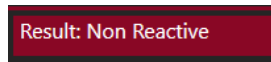
Titer View: Displays images for all wells of titer series highlighted in Controls and Samples list.

Grid View: Displays all captured images for controls and samples (if included in run) for the chosen worklist.

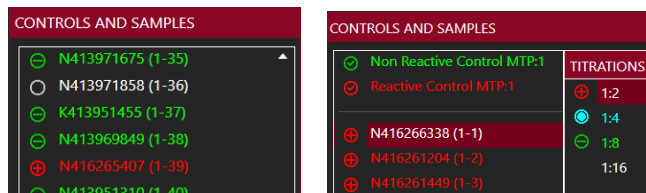
3. Viewing Notes:
 - a. Select a well to view by clicking on its image or ID. Selected well is indicated by a white box around the image (grid view) and highlighted ID in the Controls and Samples list:



- b. The result of the selected well is displayed in the red bar at the top of the screen:

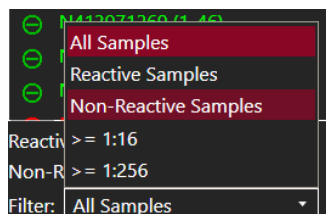


- c. Well result is also indicated by color/symbol in the Controls and Samples list:



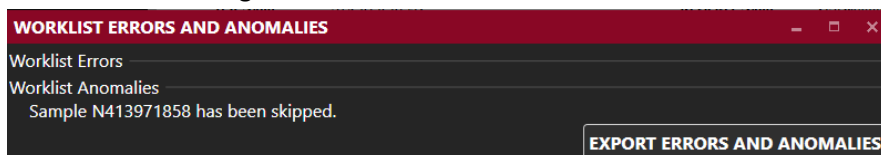
Green indicates non-reactive, red indicates reactive, white indicates skipped or invalid sample well, blue indicates endpoint titer (as seen in images above).

- d. Use the filter on the bottom left to view only selected groups of samples:



Total number of Reactive and Non-reactive samples is listed below the Controls and Samples list.

4. Worklist Errors: Click/tap the Worklist Errors button to view/export a list of errors and anomalies that occurred during the selected worklist run:



This button will not be active if there were no errors or anomalies during the worklist run.

Click/tap Details for additional information about any worklist errors (if applicable). Export errors and anomalies if desired.

Sample Interpretation:

The AIX1000 software automatically interprets captured well images and reports them as Non-reactive, Reactive, Invalid, or Skipped, based on a complex interpretation algorithm.

Note: Since debris or other contaminants could fall into the wells, any suspected results and reported Invalid results should be retested.

Evaluation Screen Actions:

1. Next Action: Click/tap the Next Action button to pre-define the action that should be performed on an individual sample or entire sample group the next time sample(s) is/are loaded in a worklist. Indicated action will be automatically selected on the Samples Screen the next time the selected sample ID(s) is/are included in a worklist. Note: Next Action option is disabled for samples that were added using the auto-increment option.

- a. Set for selected sample: Choose this option to set the next action for samples on an individual basis. Options include: Rerun Screening (if screen was run), Report Endpoint Titer (if titer was run), Run Titration (low/high titration can be specified in dropdown menu), and None. Include a reason for action in the indicated text box if desired:

- b. Auto Set for entire worklist: Choose this option to set the next action for all samples with reactive screen results or $\geq 1:16$ low titer results or for invalid/skipped samples.

Click/tap List Samples to view all samples that the next action will be applied to:

2. Review: Administrator users should check the Worklist Reviewed box to indicate when they have completed review of the worklist results.
3. Change: Click/tap the Change button to mark sample(s) as invalid or to accept the original software interpretation of sample(s) previously marked as invalid. A reason for the result change must be provided.

Note: Users cannot change the result of any sample from reactive to nonreactive (or vice versa) or select a different titer result. The change option can only be used to mark samples as invalid (sample should be rerun) or to accept the sample interpretation already given by the software. In some cases, when no software interpretation is possible (such as skipped samples), the change button is disabled. Any changes to a sample's result are recorded in the sample report (described below).

- a. Change selected sample: Use this option to mark a single sample as invalid:

- b. Change entire worklist: Select this option to mark all samples in a worklist as invalid.
4. Send to LIS: Click/tap the Send to LIS button to send results of the worklist to the LIS.
 Note: The Send to LIS button is disabled until worklist has been marked as reviewed and is only available to users with sufficient user level access.
 - a. A pop-up window will ask the user to confirm the send request.
 - b. Worklist status (sent/send date or not sent) is indicated on the Send to LIS button.

Report Generation:

1. Export Worklist Report: Click/tap the Worklist Report button to export the results of the worklist. Worklist Report can be saved, printed, or exported to a variety of file types. Use radio buttons and dropdown menu in the pop-up window to make desired selection. An example of a portion of a Worklist Report (exported to xlsx format) is shown here:

Worklist Name:	AIX1000 Demo Screens	Operator Name:	GSDadmin		
Test Name:	AIX RPR RevB	Reviewer Name:	GSDadmin		
Lot Number:	RPR	Instrument ID:	428AG		
Expiration Date:	12/16/2013	Room Temperature:	24 °C		
Control Scheme:	Controls only on first plate	Run Date/Time:	3/23/2016 2:55:48 PM		
Control Check:					
	Non Reactive Control MTP:1 - Passed				
	Reactive Control MTP:1 - Passed				
Worklist Anomalies:					
	Sample N413971858 has been skipped.				
Worklist Summary:					
	Number of Samples in Worklist:	80			
	Actions Performed on Samples				
	No Action:	0			
	Screen Action:	80			
	Low Titer Action:	0			
	High Titer Action:	0			
	Results				
	Reactive Samples:	6			
	Non-Reactive Samples:	73			
	Reactivity Rate:	7.5%			
	Invalid Images:	1			
	Status				
	Date Worklist Reviewed:	No Date Available			
	Reviewed by:	GSDadmin			
	Date Result Sent to LIS:	Not Sent			
Worklist Details:					
	Agglutination Screening				
	Number	SampleID	Microtiter Plate Position	Result	Next Action
	1	K414050031	P:1 W:C1	Non Reactive NA	
	2	K414050101	P:1 W:D1	Non Reactive NA	
	3	N413972992	P:1 W:E1	Non Reactive NA	
	4	N413951199	P:1 W:F1	Non Reactive NA	
	5	N413972675	P:1 W:A2	Non Reactive NA	

2. Sample Report: Click/tap the Sample Report button to display a report for an individually selected sample. The Sample Report, which includes the captured well image(s), can then be printed or saved to a variety of file types. An example of a portion of a Sample Report (exported to pdf format) is shown here:



Sample Evaluation Report

Agglutination High Titer Test

Sample ID: GSD-RPR5

Result: Reactive, 1:32

Worklist Name: 190617_1285AG_RPR_1AG

Operator Name: Tech Service

Test Name: AIX RPR RevF

Instrument ID: 1285AG

Lot Number: 902922258

Room Temperature: 27.5 °C

Expiration Date: 2020-04

Run Date: 2019-06-17 11:21:24

Control Scheme: No Controls

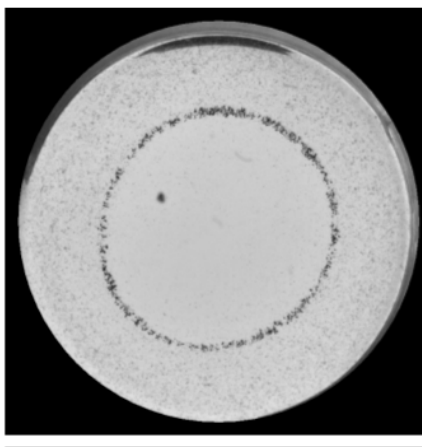
Sample Position

Titer 1:16

Sample Rack: Rack: 2 Position: 14

Microtiter Plate: Plate: 2 Well: A1

Next Action: None



6.2. Analysis Screen

The Analysis screen is used to analyze internal control statistics (for all instruments on the server).

Control Results

Select instruments to analyze as well as lot number and date range to include in analysis. Select which control results and images to show in the report. Click/tap 'Generate Report' to display results. A Control Results Report will be generated, containing information about the internal controls run on the instrument.

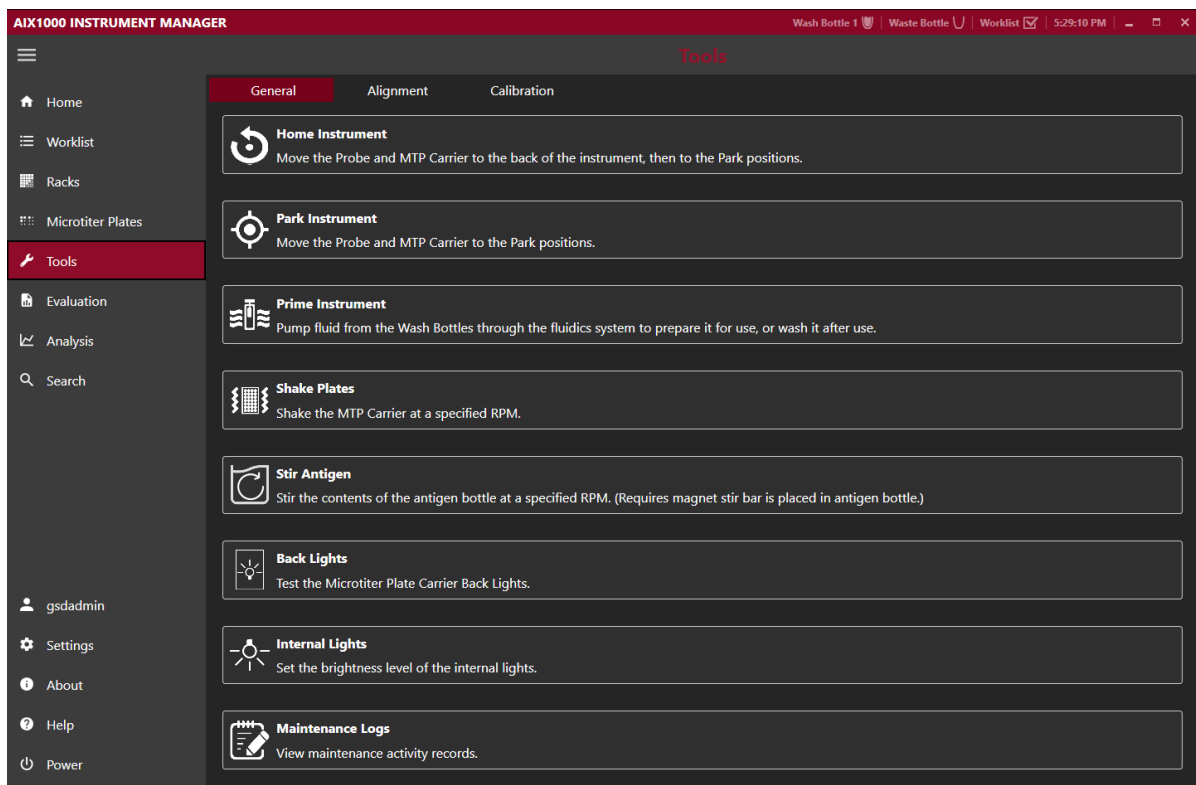
6.3. Search Screen

This screen is used to search for and create reports for previously run samples.

1. Search: Enter all desired search criteria (multiple criteria are allowed) using the checkboxes, text fields, and dropdown menus/date selection tools and click/tap the Search button.
 - a. The results will be displayed under the Search Results section.
 - b. Double click/tap Show to directly view the selected sample on the Evaluation screen.
2. Search Report: Click/tap the Search Report button to display or export the search results. Use radio buttons and dropdown menu in the pop-up window to display or export search results to a variety of file types.
3. Sample Report: Select any sample in the Search Results list and click/tap Sample Report to generate a sample report for that sample.

7. Tools Screen (Instrument Manager)

The Tools screen displays the instrument functions that may be utilized outside of a normal worklist run. These functions are available for use any time that a worklist is not running:



7.1. General

1. **Home Instrument:** Use this button to “home” the instrument, just as is done automatically at Instrument Manager startup.
2. **Park Instrument:** Use this button to reset the AIX1000 back to its starting, or “parked” position (with the probe assembly above the wash cup).
3. **Prime Instrument:** In the pop up window, select desired number of priming cycles and click/tap Start. Liquid from the wash bottle will be pulled through the instrument fluidics system. Priming can be interrupted using the Stop button and then subsequently continued or cancelled using the Continue and Cancel buttons. Priming status and the number of completed priming cycles is indicated in the window. Click/tap Close when priming is completed to exit the Prime Instrument window.

Note: For models with intelligent sample racks: Make sure the Sample tray is pushed back before priming and do not move it during priming, as indicated by the software prompts

4. **Shake Plates:** Use this button to manually shake plate/plates. Choose the desired RPMs by moving the slider bar (maximum value is 400 RPMs). Select the check box next to Shaker On to turn on the shaker; uncheck box to turn it off.
5. **Stir Antigen:** Use this button to manually stir the antigen. Choose the desired RPMs by moving the slider bar (maximum value is 600 RPMs). Select the check box next to Stirrer On, to turn on the stirrer; uncheck to turn it off.

6. **Back Lights:** Use this button to test the back lights. Click/tap the Back lights button. Backlights for each of the four MTP positions will turn on one at a time.
7. **Internal Lights:** Use the slider bar to adjust default light intensity of the ambient interior LED lights. These lights will shut off automatically when appropriate during the test processing and therefore have no effect on final results.
8. **Maintenance Logs:** Click to view dates/times of recent maintenance events (priming, instrument and camera alignment, camera focus, and wash pump calibration). Select a month to add notes to that month's maintenance log or to display a maintenance actionlog with all maintenance actions for that entire month (including any added notes), which can be saved/exported and/or printed

Note: Any days/weeks which the instrument was not used/maintenance was not performed are marked with "/" on the maintenance action log.

7.2. Alignment

These instructions are intended to provide an overview of these functions; detailed step by step instructions are included in pop up windows within the AIX1000 Instrument Manager when each function is performed.

Manually Align Probe/Auto-Align Probe

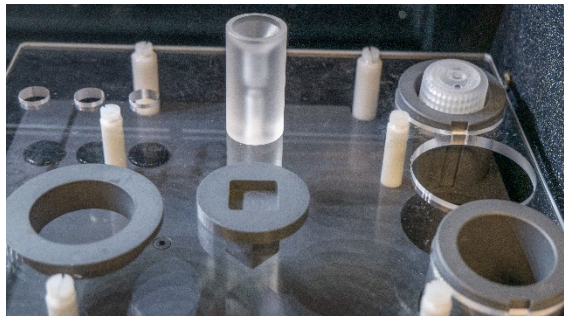
The manual or auto probe alignment processes are performed to align the probe with the reagent and sample racks, the wash cup, and the microtiter plates. Either equivalent process may be used, according to laboratory preference and if available on the instrument model being used.

General Information

1. Perform and record probe manual alignment or auto alignment as part of routine instrument maintenance, when prompted by the AIX1000 instrument manager.
2. If a probe manual alignment/auto-alignment is partially completed and then cancelled, fully complete the procedure prior to the next instrument use.
3. Move the probe throughout the alignment procedures using the on-screen buttons or keyboard keys.
 - a. The left and right arrow keys are used to move the probe to the left and right (X-axis).
 - b. The up and down arrow keys are used to move the probe toward the front and back of the instrument (Y-axis).
 - c. The Page Up and Page Down keys move the probe up and down (Z-axis).
4. Carefully align the probe assembly in the X and Y positions as indicated. The Z-axis position does not need to be manually aligned; it is aligned automatically by the instrument during the instrument alignment/auto-alignment processes.
5. Be sure to wait for the probe assembly to reach each position before clicking/tapping Next Step.
6. It is normal to hear motor humming sounds during the alignment/auto-alignment processes.

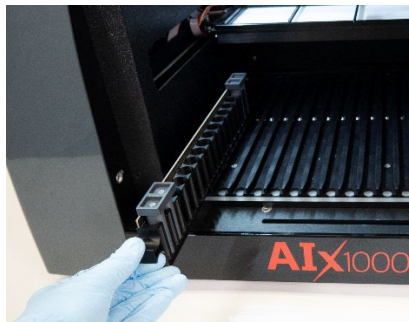
Auto Align Instrument Instructions:

1. Preparation:
 - a. For rack alignment:
 - i. Models with intelligent Sample Racks: Remove the cuvette from the instrument reagent rack (Be sure to remove all reagents and adapters from the reagent rack as well) and place the auto-alignment plug in the square hole with the circular part flush against the rack top:

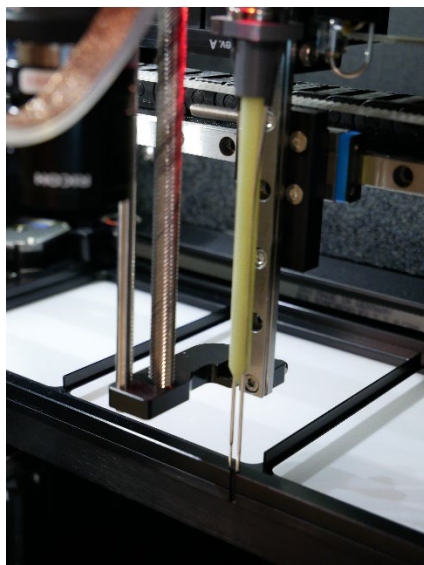


Place empty sample racks in each of the three sample rack positions there should be NO sample tubes in the sample racks

- ii. Models with Slide-In Sample Racks: Remove the racks from the positions indicated by the software. Place the three alignment adapters into the indicated rack positions, as prompted. Be sure that adapters are fully seated:



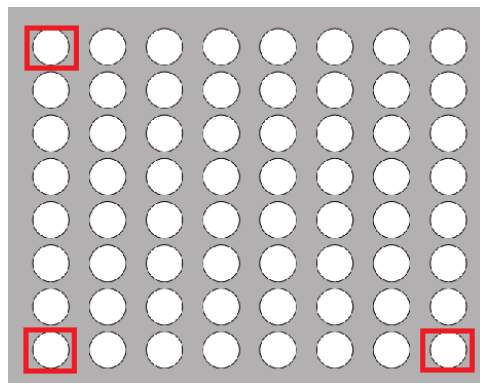
- b. For plate alignment: Place one auto alignment plate in each of the 4 MTP positions on the MTP carrier. Be sure that plates are seated flat/securely.
 - c. Make sure all applicable racks are positioned inside the instrument (with any alignment components fully seated) and click/tap the Auto Align Probe button. A pop up window will appear and provide instructions for each auto alignment step.
2. Alignment:
- a. Use the on-screen buttons to align the probe to the front edge of the MTP carrier as prompted. The probe needles should be directly above the edge of the carrier:



- b. Only the Y axis position is important at this step.
 - c. The correct position has been obtained when the needles can be moved down until the red light turns on, while touching the edge of the carrier.
3. Completion:
- a. After verifying that the auto-alignment plates, plug, and empty sample racks have been properly placed inside the instrument and clicking/tapping Next Step, wait while the instrument proceeds automatically through the remainder of the auto alignment process (this takes approximately 10-15 minutes). DO NOT touch the instrument during this time.
 - b. Click/tap Finish when prompted to complete and save the auto alignment and exit the Auto Align Probe window (instrument will return to its home position).). Remove the auto alignment components, and replace the cuvette (if applicable for the instrument model being used).

Manually Align Probe Instructions (applicable only for models with intelligent racks):

1. Preparation:
- a. Place Empty Sample racks in each of the three sample rack positions.
 - b. Place three properly fitting empty sample tubes into three corners of the sample racks shown below:



Note: If intelligent rack detection is disabled, verify that the proper sample rack sizes have been selected in the Instrument Manager settings before starting the Align Instrument process.

- c. Place a 48 well MTP in each of the first three MTP positions on the MTP carrier. Place a 96 well MTP in the fourth (rightmost) MTP position. Be sure that plates are seated securely.
 - d. Slide the tray in and click/tap the Align Instrument button. A pop up window will appear and provide instructions for each alignment step.
2. Alignment:
- a. Use the on-screen buttons to position the probe needles over the center of each location as prompted, clicking/tapping Next Step after aligning each position. Some example alignment positions are shown below:
Wash cup alignment: Align the probe to the middle of the wash cup, then move it down to verify that the probe can reach the bottom of the wash cup without resistance or touching the side:



After the aligning the wash cup and clicking/tapping Next Step, wait while the instrument automatically aligns the Z-axis position of the probe to the bottom of the wash cup (the spindle will move up and down and the red light will turn on and off).

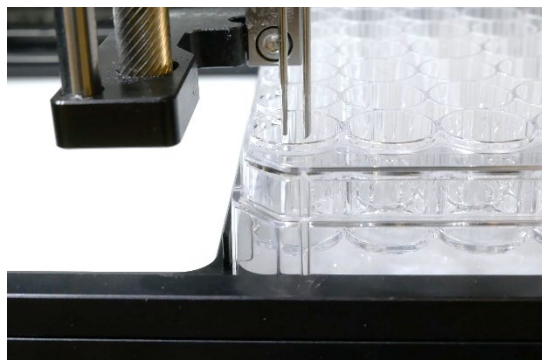
Sample tube alignment: Align the center of the probe needles to the center of the sample tube (X and Y axes):



It is not necessary to move the probe needles to the bottom of the tubes, only far enough to clearly see the needle position in the tubes.

MTP carrier front edge alignment: See instructions/photo in the Auto Align Instrument Instructions above.

MTP well alignment: Align the probe with each 48 well plate and 96 well plate position as prompted. Align all four plates in each of the three MTP carrier positions (MTP carrier will move to its middle, front, and back positions during the well alignment process), as prompted. Align the center of the probe needles to the center of each indicated reaction plate or predilution plate well:



3. Completion:

- a. Click/tap Finish when prompted to complete and save the alignment and exit the Align Instrument window (instrument will return to its home position).

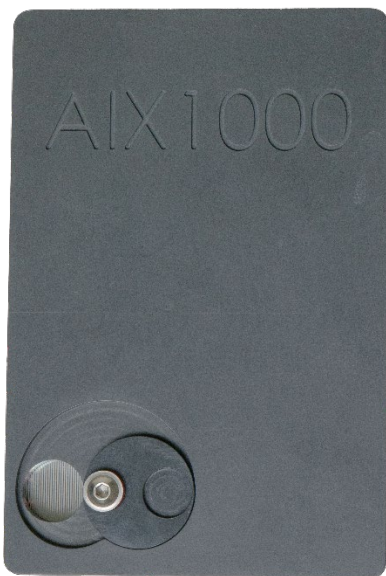
Align Camera

The camera alignment process is performed to ensure that the camera is in the correct position above the wells during image capture and that well images are in focus.

General Information

1. Perform and record camera alignment as a part of routine instrument maintenance, when prompted by the software.
2. Perform probe alignment immediately before camera alignment.
3. Make sure backlights have been cleaned immediately prior to performing camera alignment or focus.
4. If needed, gently clean camera lens with a dry, non-abrasive wipe immediately before aligning the camera.
5. A 48-well MTP and a line pattern plate (Part # 00223) are required to complete camera alignment and focusing.
6. The updated AIX1000 Camera Alignment and Focus Plate (Part # 00225) can be used in place of both plates. The position of the hole on Camera Alignment and Focus plate has been aligned to the A1 well of a 48-well MTP:

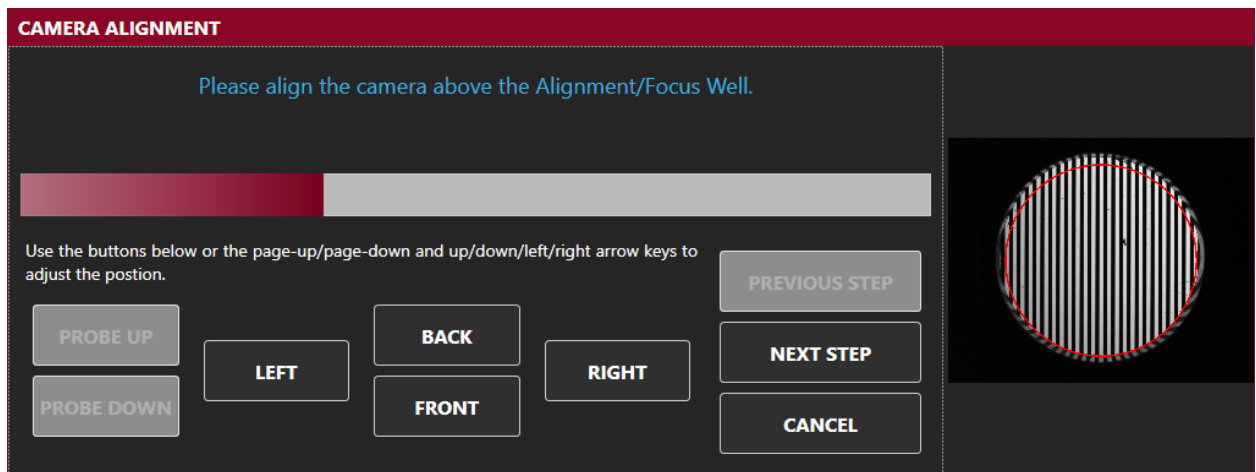
AIX1000 Line Pattern Plate (#00223)



7. The Align Camera process includes both camera alignment and camera focus steps. The Calibration tab on the tools screen contains a Focus Camera option which performs only the camera focus steps (identical to the focus steps in the Align Camera process).
8. Move the camera throughout the alignment procedure using the on-screen buttons; advance between steps using the Next Step button.

Align Camera Instructions:

1. In the Tools screen of the Instrument Manager click/tap the Align Camera button. If instrument alignment has already been completed, click/tap Yes to confirm, and continue.
2. Place the AIX1000 Camera Alignment and Focus Plate or a clean 48 well microtiter plate in the first (leftmost) MTP carrier position with the text facing the front of the instrument.
3. Use the buttons on the screen to adjust the camera position until the camera is aligned above well A1. The image should be in alignment with the red circle superimposed over the well:



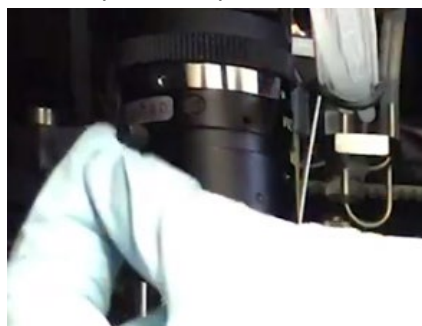
4. Remove the MTP and close the cover, as prompted. Wait while the instrument automatically individually calibrates the integration time for the camera based on the light intensity at each well location.

Note: This process takes approximately 15 minutes; DO NOT touch the instrument during this time

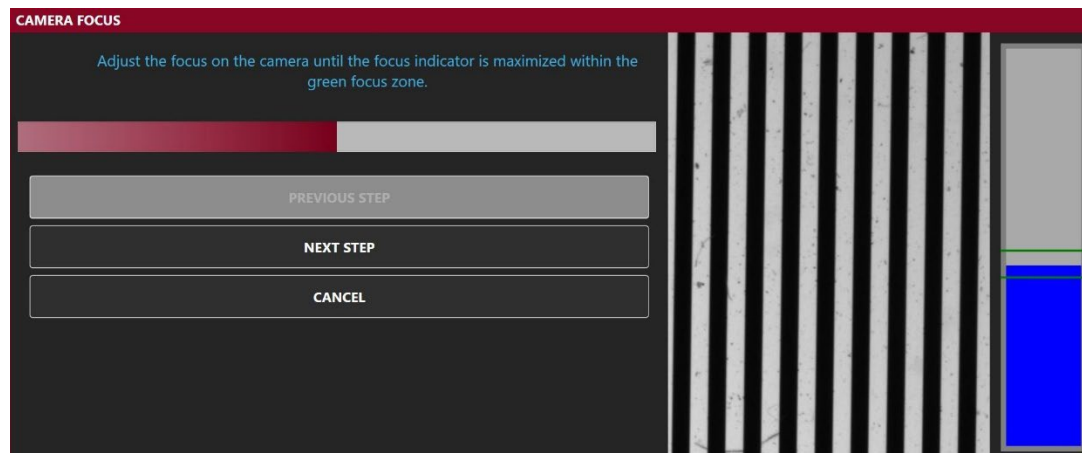
5. Once the camera has finished aligning over all well positions, open the cover as prompted and proceed to focus the camera (as described below).

Focus Camera Instructions:

1. After performing the first steps of camera alignment (described above) or clicking/tapping the Focus Camera button under the Calibration tab, place the line pattern plate in the first (leftmost) MTP position as prompted and click/tap Next Step.
2. If the image appears blurry complete the following to focus the camera. If no adjustment is needed click Next Step to complete and save the alignment/focus and exit the Align Camera/Focus Camera window (instrument will return to its home position).:
 - a. Carefully manually loosen the set screw on the focus ring of the camera:



- b. Adjust the focus ring on the camera until the focus indicator (blue bar) is maximized within the green focus zone on the screen and the image is sharp. Then tighten the focus ring set screw back into place.



- c. Click/tap Next Step and then Finish to complete and save the alignment/focus and exit the Align Camera/Focus Camera window (instrument will return to its home position).

7.3. Calibration

Verify Fluidics

The Verify Fluidics option is used by trained service technicians during instrument installation or service visits to verify the proper function of the instrument's fluidics system (performance qualification). Use of this option requires specific dye and tools; inquire with local distributor for additional information.

Focus Camera

The Focus Camera option is used to perform only the Camera Focus step on the Align Camera process. Perform this function if images appear out of focus, yet the camera is aligned. To complete the Focus Camera option, refer to the instructions above, in the Align Camera Section.

Calibrate Wash Pump

The Wash Pump Calibration option is used by trained service technicians to verify that the wash pump is functioning properly. To use, verify that wash buffer is loaded in the wash bottle position, that a cuvette is in place on the reagent rack, and click/tap the Calibrate Wash Pump button. Follow instructions as prompted to calibrate the wash pump.

8. Maintenance

Maintenance procedures, as prompted by the software, should be followed to ensure proper instrument functionality. It is suggested that maintenance activities be recorded using the provided maintenance log. (Maintenance actions are also automatically recorded by the software and monthly reports accessible from the Tools screen and in the Maintenance Reports folder of the AIX1000 Documents folder.) The information below describes the routine maintenance steps for the AIX1000.

8.1. Daily Maintenance

Daily maintenance includes startup and shutdown steps. Startup steps are prompted/performed prior to the first run of the day/each time the Instrument Manager software is opened, and shutdown steps are prompted/performed following the last run of the day/each time the AIX1000 Instrument

Manager software is closed, or instrument is powered off. It is recommended that the startup and shutdown steps be performed any time the instrument is idle for four or more hours to prevent build up in the fluidics lines.

Startup

1. Ensure the wash bottle is properly connected to the AIX1000 and prime the instrument using the wash buffer that will be used for testing a minimum of 10 priming cycles (as prompted- door will lock during priming).
 - a. Ensure that wash buffer is within its expiration date prior to each use.
2. Clean the backlights of the MTP carrier with an alcohol wipe.
 - a. Debris on the backlights could interfere with sample image interpretation; maintenance of backlights is important for proper system function.

Shutdown

1. Use the Power button within the AIX1000 Instrument Manager software to shut down the instrument and attached computer.
2. Empty waste bottle.
3. Prime the instrument using DI Water a minimum of 50 priming cycles (as prompted- door will lock during priming).
4. Remove any remaining reagents and samples from inside the instrument and close the lid. Ensure all instrument surfaces are clean and dry.

8.2. Weekly Maintenance

Weekly maintenance includes cleaning and alignment steps that are to be performed approximately every seven days, as prompted by the software. It is recommended that the same day of the week be used for consistency. Care should be taken to ensure that no excess liquid comes into contact with the instrument surfaces while cleaning. Cleaning should only be performed with the recommended reagents. Weekly Maintenance steps should be performed as follows:

1. Remove sample racks and inspect each one for cleanliness and damage. Use isopropyl alcohol to gently clean racks.
2. Clean the intelligent rack or slide-in rack deck with isopropyl alcohol.
3. Clean the outside of both probe needles by wiping them down gently with an alcohol wipe.
4. Perform instrument and camera alignments as described in further detail in the Alignment and Calibration section of this manual.
5. Decontaminate the instrument tubing by priming the instrument 20 priming cycles with Liquinox solution (as prompted- door will lock during priming).
 - a. The Liquinox solution is prepared by making a 1:100 dilution of the Liquinox Concentrate supplied with the instrument, using DI water.
 - b. Rinse the tubing by priming the instrument 50 priming cycles with DI Water, following priming with Liquinox solution (as prompted- door will lock during priming).
6. It is recommended that any wash bottles used be cleaned weekly to avoid contamination.

8.3. Periodic Maintenance

Approximately every year (time will vary depending on instrument usage), a professional maintenance procedure should be performed by a trained service engineer. Service agreements are typically

laboratory-dependent and established to meet the specific needs of each client. Contact the local AIX1000 distributor for more information.

8.4. Storage, Transportation, and Disposal

Storage, transportation, and disposal of the AIX1000 must be completed by a trained technician. A complete reinstallation must be performed following any move or storage of the instrument.

To prevent injury during the lifting and carrying of the AIX1000, use the following safety precautions:

1. Disconnect all cables from the instrument and remove the netbook and netbook pedestal.
2. Position two persons on each side of the instrument.
3. Grip the instrument beneath the base plate and lift simultaneously. DO NOT use the front cover handle as a grip.
4. Always use recommended ergonomic guidelines for manual material handling while lifting or moving the instrument.

The recommended storage and transportation conditions for the instrument should be similar to the use conditions. If the instrument is moved from its installed location or removed from service for an extended period of time it is recommended that a minimum of a weekly maintenance (as described above), followed by dry priming cycles to remove liquids from the system, be performed, and that the instrument be returned to the original packaging.

Environmental conditions for extended storage periods should be as follows:

Temperature: 10°C – 60°C (50°F – 140°F)

Relative Humidity: 20 – 90% non-condensing

After shipping, it is recommended that the instrument be stored at room temperature for at least 24 hours before powering on the instrument.

It is recommended that any trained technician disposing of the instrument consult applicable local regulations prior to disposal.

9. Laboratory Information System Integration

The LIS implementation of the AIX1000 completely conforms to the NCCLS LIS2-A2 and NCCLS LIS01-A2 (formerly known as ASTM E1394-91 and ASTM E1381-91) specifications. The AIX1000 can communicate successfully with LIS systems that also conform to these specifications. Please be aware that some LIS companies will need to create special drivers before they will be able to be integrated with the AIX1000.

In addition to the TCP-IP implementation of NCCLS LIS01-A2, the software also supports a “clean” TCP-IP transmission. In this mode the software will send the unmodified NCCLS LIS2-A2 frames including the <CR> at the end of the frame. No checksum or control characters are added.

All LIS Settings for the AIX 1000 are found within the LIS Communication and LIS Mappings screens of the AIX1000 Configuration Tool software. When utilizing the LIS interface, the Send To LIS button on the Evaluation screen is used to send results to the LIS.

9.1. LIS Records

Data is sent to the LIS according to the following:

Header Record: Normal header record identifying the AIX1000 as the sender. All communications begin with the header record. In the "Sender Name or ID" field is the name of the software and the version. Example:

```
H|\^&|||AIX1000^2.0|||||P|LIS2-A2|20150303120000
```

Request Information Record Specifics: For the AIX1000, it is not possible to request information from the LIS. The information from a specific sample is saved in a database. If information (such as the next action on a specified sample) is needed by the AIX1000, the system will search in the database.

Patient Information Record: Identifies the patient for which results are being sent. In the "Laboratory Assigned Patient ID" field the Sample ID is specified. Example:

```
P|1|SampleID
```

Test Order Record: Specifies to the LIS which Test and Action was run on the Sample. The "Universal Test ID" field is used to specify the local test name and the action that was run. The Test name comes from the LIS Mappings in the Configuration Tool software. The action is identified as either a SCREEN or a TITER. Note: it is irrelevant whether a high titer or low titer was run, the indication is only whether a screen or titration was done. Example:

```
O|1|SampleID|^RPR^SCREEN|||||||F
```

or

```
O|1|SampleID|^RPR^LOWTITER|||||||F
```

Or

```
O|1|SampleID|^RPR^HIGHTITER|||||||F
```

Result Record: Used to send the result to the LIS.

In the "Data or Measurement Value" field the test result is specified.

For SCREEN results, the possible values are:

R - screen result was Reactive

NR - screen result was Non-reactive

I - screen result was Invalid (invalid image). Note: when "I" is given, the "Result Status" field is set to 'X' to indicate that result was not valid. Example:

```
R|1|^RPR^SCREEN|R||||F
```

or

```
R|1|^RPR^SCREEN|NR||||F
```

or

```
R|1|^RPR^SCREEN|I||||X
```

For TITER results, the value is the Endpoint titer (the last reactive titer value). For example, if the Sample was titered from 1:16 to 1:256 and the last reactive titer was at 1:64, then 64 would be specified in the data field. If titer images are invalid, then a value of 'I' is sent and the result status is set to 'X'. Example:

```
R|1|^RPR^HIGHTITER|64||||F
```

or

```
R|1|^RPR^HIGHTITER|I||||X
```

Message Terminator Record: Normal message terminator record to specify end of data. Example:

```
L|1|N
```

9.2. LIS Transmission Example

Consider an AIX1000 Worklist run with eight Samples with IDs S001-S008. Assume: the GSD AIX1000 Test file was used, which defines a Screen action, a Low Titer action, and a High Titer action; LIS Mapping for this test is 'RPR'; the first four Samples were screened, and the rest were titered. The output from the sending of result data to LIS would be:

```
H|\^&|||AIX1000^2.0|||||P|LIS2-A2|20150303120000
P|1|S001
O|1|S001|^RPR^SCREEN|||||||||||||F
R|1|^RPR^SCREEN|NR||||F
P|2|S002
O|1|S002|^RPR^SCREEN|||||||||||||F
R|1|^RPR^SCREEN|NR||||F
P|3|S003
O|1|S003|^RPR^SCREEN|||||||||||||F
R|1|^RPR^SCREEN|R||||F
P|4|S004
O|1|S004|^RPR^SCREEN|||||||||||||F
R|1|^RPR^SCREEN|I||||X
P|5|S005
O|1|S005|^RPR^LOWTITER|||||||||||||F
R|1|^RPR^LOWTITER|8||||F
P|6|S006
O|1|S006|^RPR^LOWTITER|||||||||||||F
R|1|^RPR^LOWTITER|16||||F
P|7|S007
O|1|S007|^RPR^HIGHTITER|||||||||||||F
R|1|^RPR^HIGHTITER|I||||X
P|8|S008
O|1|S008|^RPR^HIGHTITER|||||||||||||F
R|1|^RPR^HIGHTITER|256||||F
L|1|N
```

9.3. LIS Configuration

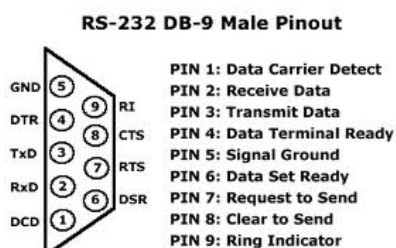
1. Verify that instrument is correctly installed, and all power cords are correctly connected to instrument and attached computer.
2. Ensure that all relevant cords and cables for LIS system are connected to the instrument.
 - a. TCPIP: Ethernet cord; RS232: serial cord
3. Select correct settings within the AIX1000 Configuration Tool LIS Settings section. These must be entered before any communication with LIS is attempted. Select appropriate settings according to LIS being used:

- a. In the **RS-232 Connection** section, set the baud rate, data bits, parity, and stop bits of the port (select instrument or computer serial port). Select Flow Control setting.
 - b. In the **TCP/IP Connection** section, set the Server address and the Server port of the LIS TCP Server. If the “Use LIS01-A2 Encoding” option is used, the software will use a “telnet”- like system (same data as through the RS-232 connection).
 - c. Click Apply to save settings.
4. Assign LIS test IDs to instrument test file names within the AIX1000 System Configuration Tool on the LIS Associations screen. List all LIS names and corresponding test file names, being careful to copy codes exactly as they are used in the LIS system.

Note: An LIS name is seldom the real test name, but often a shorter one. It could also be a number or code, depending on the laboratory policy.

5. Use a worklist to test connectivity:
 - a. On the Evaluation Screen, select a worklist from the dropdown menu.
 - i. Verify in the LIS system that the patient samples in the selected worklist actually have pending orders for the RPR test and that results have not yet been sent to the LIS.
 - ii. Verify that sample images/results are visible on the Evaluation Screen.
 - b. On the Evaluation Screen, click/tap Send to LIS.
 - i. If connectivity is working properly, popup window will appear to confirm send request, and results will be transmitted and appear in the LIS with the corresponding test code.

9.4. RS-232 Pin Layout



10.Troubleshooting Guide

Issue	Details	User Action
AIX1000 Instrument Manager software will not start up	Is a “no connection” error displayed?	Check that power switch on the back of the instrument is turned on. Check that power cord is plugged into the instrument and the outlet. Check that the USB cable from instrument to computer is secure at both ends. Try rebooting. If problem persists, contact technical service.
Run will not start	Does instrument display an MTP plate error?	Check that MTP plate(s) and predilution plate is/are correctly loaded and seated securely.
		Check positions of probe during instrument alignment. If misaligned, realign instrument and restart.
	Does instrument display an insufficient reagent volume error?	Ensure that sufficient volume of the indicated reagent, as calculated by the software, is loaded, in the correct position and standard bottle size.
	Does instrument display a clog error?	Prime 10x, lift probe briefly (1-2sec) to check for steady dispense flow during priming. If dispensing/aspiration appear correct, restart run. If not, carefully use stylet to clean probe.
		Check if blue liquid detection light is functioning properly by placing a small tube of liquid beneath the needles. Blue light should go on when in liquid and turn off when out of liquid. If light is not responding correctly, check for secure connections at the white connector above the probe and at flat cable connection points near the probe. If problem still persists, contact technical service
	Is the blue light constantly on?	Disconnect probe, dry it off from top to bottom. Carefully replace and check all tubing and electrical connections to the probe.
Sample(s) not pipetted during run	Are the samples also missing from the microtiter plates screen?	If missing samples are not selected on the Worklist screen, select them and rerun. If missing samples do not appear on the Worklist or Racks screens, re-add them to Worklist and reselect them.
Samples disappear from sample list (Models with intelligent racks)	Are the samples flickering/beeping?	Check to make sure that samples are being placed all the way to the bottom of the intelligent racks. If the sample rack and sample tubes being used are not matching sizes, place samples in the appropriately sized rack.
Run stops in the middle of a worklist	Is there an IO or read/write error message in the error log file?	Power off computer and instrument, unplug and re-plug power connections and USB connection, and restart. Reload the worklist and special start

Issue	Details	User Action
		worklist from aborted position. If problem persists, contact technical service.
	Is the probe assembly jammed?	Make sure there are no obstructions to probe movement. Make sure probe tubing is zip-tied to flat cable and not being caught anywhere.
	Is there a drop between needles/clog/aspiration error?	Pause the worklist and wipe off any visible drops. If a clot is visible on the needle, clean with an alcohol wipe. Resume worklist. When worklist finishes, carefully clean the probe with the stylet and perform Liquinox decontamination (as indicated for weekly maintenance).
Waste Bottle alarms during run	Are there bubbles or liquid on the waste sensor needles or the white plastic waste connector?	Wipe connector and needles completely dry.
Failed Controls	Were cold reagents or wash used?	Make sure to allow all reagents to come to room temperature before start of worklist and rerun.
	Were reagents from different lot numbers used on the same run?	Rerun with reagents all coming from the same kit lot.
	Was there a pause during the run?	If there was a pause due to insufficient reagent volume, be sure to use appropriate volumes. Rerun worklist.
	Did user fail to prime instrument before the start of the worklist?	Prime instrument 10 cycles with wash buffer and rerun worklist.
	Did user fail to properly prepare controls?	If bubbles were present in the control vials, pop them and rerun worklist.
	Do non-reactive and reactive controls appear switched?	Check if physical positioning of controls in reagent rack matches Racks screen.
	Does it appear that a control was not pipetted?	Check for sufficient volume and bubbles in control vials. Rerun with sufficient volume, bubbles removed. Note: Even if no bubbles are observed at the end of the run, a bubble could have caused the problem and later popped.
Failed controls (cont.)	Has kit been open for too long or is it expired ?	If yes, rerun with new kit.

Issue	Details	User Action
	Is recorded room temperature on report above 25°C?	Rerun worklist once laboratory temperature is within an acceptable range.
	Are bubbles visible in the supply line or syringes?	Prime instrument until bubbles disappear and rerun. If bubbles continue, check tubing for any visible leaks. Contact technical service if problem persists.
		Check pinch valves to ensure that tubing is fully inserted.
	Is there flooding outside the wells on the MTP carrier?	Check that MTPs are correctly loaded and seated securely.
Need to reprint or find past data	Does user know which date the desired data was run?	Retrieve data using the Search screen by entering appropriate search criteria and generating a worklist or sample report as needed.
Invalid image/titer series obtained	Does image show evidence of a camera alignment/focus problem?	Align/focus camera if needed.
	Are there reactive wells following the endpoint well?	Check for artifacts/debris in the abnormal reactive wells. Rerun titer.
Abnormal captured well image obtained	Are there visible bubbles in the well?	Check for bubbles and sufficient volume in sample vials. Rerun with sufficient volume after removing bubbles. If bubbles repeatedly appear in well images, contact technical service.
	Was Antigen Suspension properly mixed during the run?	Check for stir bar in Antigen Suspension vial and proper charcoal mixing and rerun. A Magnetic Micro, PTFE fluoropolymer covered stir bar is recommended. If such mixing problems continue to be encountered, contact technical service.
	Are artifacts visible?	Clean the reaction plate, the backlights, and camera lens. Verify that patient samples are clean. Rerun. If unable to remove artifacts after cleaning, contact technical service.

Issue	Details	User Action
Abnormal captured well image obtained (cont.)	Was sample skipped or not pipetted?	Check for bubbles in the sample, and for sufficient sample volume. Rerun with sufficient volume after removing bubbles. If problem continues or liquid detection errors occur repeatedly during the run, contact technical service.
Dripping Probe Needles/Small amount of fluid in wash cup	Is the dripping/fluid observed after the needles have been sitting for several hours?	Droplets and small amounts of fluid after sitting overnight or following homing are normal. Prime instrument and proceed as usual.
Intelligent Rack is not working properly (models with intelligent racks)	Are racks correctly placed on the sliding tray and appropriate tube sizes being used to correspond to rack sizes?	Check for any liquid damage on bottom of rack. Be sure that any spills are cleaned immediately, and the bottom of the rack is dry. Check the bottom of all sample racks to make sure no metallic objects are stuck on the magnets. Use corresponding tube/rack sizes. Contact technical service if problem persists.
LIS connectivity problems	Are all LIS and LIS Association Settings correct in AIX1000 System Configuration Tool?	Contact IT.
Resistance or Liquid detection lights do not illuminate properly.	Is instrument malfunctioning as a result?	Remove probe and clean and dry thoroughly. Check that probe wires are connected to PCB and that flex cable connections are secure. Replace Z axis flex cable, if available and training has been provided. If problem persists, contact technical service.
X, Y, or Z-axis movements are not smooth	Is instrument malfunctioning or making strange noises?	Contact technical service

11.Revision History

Revision	Date	Change
B	6/10/2022	Spelling correction of regain to reagin. Added Revision History Block. Changed LIS transmissions examples to correctly show titer orders and records. Corrected serial number of line pattern plate. Added safety statement about reporting serious incidents to manufacturer and authority of the member state.

12.Contact Information

12.1. Device Manufacturer



Company Name	Gold Standard Diagnostics Corp.
Company Address	2795 Second Street, Davis, CA 95618
Country	United States
Phone	530-759-8000
Fax	530-759-8012
Website	www.gsdx.us
AIX1000® Agglutination Analyzer	Catalog# 00400
GSD RPR Reagents	Catalog# GSD01-1600

12.2. Authorized Representative

EC	REP
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Company Name	Emergo Europe
Company Address	Prinsessegracht 20 2514 AP The Hague
Country	The Netherlands
Phone	+31 70.345.8570
Website	www.emergogroup.com
email	EmergoEurope@ul.com