AIX1000® Analyzer (REF 00400)

AIX1000 2.1 Software Suite

User's Manual

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Contents

1 Introduction

The purpose of this manual is to identify the components of the AIX1000 system and provide instructions for use of the Gold Standard Diagnostics (GSD) AIX1000 Agglutination Analyzer (AIX1000) REF 00400 with the AIX1000 2.1 software. This manual provides basic safety information, instructions for use and maintenance, as well as general troubleshooting guidance. It is recommended that this manual be always kept near the instrument and accessible to the user.

1.1 Intended Use

The Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin (RPR) Automated Test System is a non-treponemal flocculation test that can qualitatively determine the presence of reagin antibodies in human serum, automated on the AIX1000 Analyzer. 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

For registration and licensing information regarding the AIX1000 RPR Automated Test System, consult official online registration databases such as:

- FDA Device Listing and Establishment Registration Database
- EUDAMED – European Database on Medical Devices
- Health Canada Medical Device Active License Listing (MDALL) Database

2 Safety Information

The following safety instructions are to be always observed 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 necessary.

2.4 Biological Safety

Any parts of the AIX1000 that have encounter 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.

2.6 Electromagnetic Compatibility

The AIX1000 complies with the requirements of IEC 60601-1-2 for a professional healthcare facility environment, including diagnostic laboratories, industrial areas, and hospitals. The instrument's software provides alarms and error notifications to warn users of fault conditions or system errors caused by electromagnetic disturbances, which could otherwise pose unacceptable risks to the user, system functions, or patient sample. (Reference IEC 60601-1-2 clause 5.2.1.1a,b, and 5.2.2.1)

Use only the accessories provided with the instrument. The use of cables, fluidics connectors or any accessories other than those included in the shipment contents may negatively impact the instrument's EMC performance. Refer to the AIX1000 Packing/Receiving List (SOPF-0001-3) shipped with the instrument for list of cables and accessories. (Reference IEC 60601-1-2 clause 5.2.1.1d,e)

The AIX1000 meets the EMC compliance standards and standard levels listed below. The facility in which the unit is being installed should ensure the system is placed in an environment that meets these conditions to maintain the basic safety and essential performance of the device.

Electromagnetic Emissions	EMC Standard	Compliance Level
Radiated Emissions	CISPR 11	Class A
Conducted Emissions	CISPR 11	Class A
Harmonic Current	IEC 61000-3-2	N/A
Voltage Fluctuation & Flicker	IEC 61000-3-3	N/A
Electromagnetic Immunity	**EMC Standard**	**Compliance Level**
Electro-Static Discharge	IEC 61000-4-2	Per IEC60601-1-2 Table 4
Radiated Immunity	IEC 61000-4-3	Per IEC60601-1-2 Table 4 & 9 Professional Healthcare Facility
Electric Fast Transients Immunity	IEC 61000-4-4	Per IEC60601-1-2 Table 5
Surges Immunity	IEC 61000-4-5	Per IEC60601-1-2 Table 5
Conducted Immunity	IEC 61000-4-6	Per IEC60601-1-2 Table 5, Professional Healthcare Facility
Power Frequency Magnetic Field Immunity	IEC 61000-4-8	Per IEC60601-1-2 Table 4
Voltage Dips & Interruptions	IEC 61000-4-11	Per IEC60601-1-2 Table 5
Proximity Magnetic Fields Immunity	IEC 61000-4-39	Per IEC60601-1-2 Table 11

WARNING: *Use of this equipment adjacent to or stacked with other equipment should be avoided to reduce potential for EM disturbances. If such use is necessary, this equipment and other equipment should be observed to verify normal operation. (Reference IEC 60601-1-2 clause 5.2.1.1 c)*

WARNING: *Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AIX1000 System, including cables provided with the instrument. Otherwise, degradation of the performance of this equipment could result. (Reference IEC 60601-1-2 clause 5.2.1.1f)*

NOTE: *The EMISSIONS characteristics of this equipment make it suitable for use in the environments described above, including industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. (Reference IEC 60601-1-2 clause 5.2.1.2)*

3 AIX1000 RPR Test Kit

The AIX1000 RPR Test kit and components are as follows:

1. **REF GSD01-1600, GSD01-1600-5C: Gold Standard Diagnostics Rapid Plasma Reagin (RPR) Test System x 480 tests (Store at 2-8°C)**
    - REF GSD01-1600-W Microplates (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 – 1 x 0.35mL (GSD01-1600), 5 x 0.35mL (GSD01-1600-5C) (ready to use, human serum preserved with sodium azide (1 mg/mL). GREEN CAP
    - REF GSD01-1600-PC RPR reactive control – 1 x 0.35 mL (GSD01-1600), 5 x 0.35mL (GSD01-1600-5C) (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-MW – Microtiterplates (48-well microtiter plates), 5 plates**
4. **REF GSD-1600-W-CASE Microtiterplates (pack of 85 x 48-well microtiter plates), 4 units**
5. **REF GSD05-1600-NC - RPR Non-Reactive Control – 5 x 0.35mL**
6. **REF GSD05-1600-PC - RPR Reactive Control – 5 x 0.35 mL**
7. **REF GSD01-1600-DYE - AIX1000 Performance Check Dye Kit – for routine performance testing of AIX1000 Analyzers**
8. **REF GSD01-1600-DIL – GSD RPR Diluent**
9. **REF SHW-20 – GSD Bleach**

4 AIX1000 Analyzer

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

4.1 Instrument Overview

The AIX1000 instrument is 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 analysis.

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 Sample Rack Model

Classic Sample Rack Model

4.2 Instrument Details

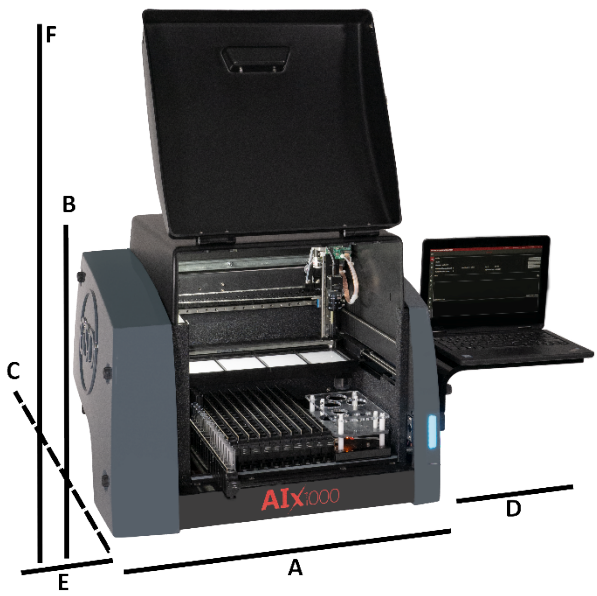
It is recommended that the area for use and storage of the AIX1000 be a space dedicated to the instrument which can accommodate the following specifications. For optimum instrument performance, the room temperature should be controlled, the relative humidity should be between 20% and 90% (non-condensing),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

4.2.1 Instrument Power Specifications

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).

Voltage: 100-265V
Frequency: 50-60 Hz
Power consumption: 120W max

4.2.2 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 instrument 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 instrument as well as additional equipment; it is important that the bench does not vibrate during instrument use. Expect the total weight of the AIX1000 instrument and accessory equipment to be approximately 50 kg (110 lbs.).

NOTICE: Certain instrument models may not contain all components listed below.

4.2.3 Sample Racks

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

4.2.3.1 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 to16 x 75-100 mm tubes. Rack positions are numbered from left to right and sample tube positions are numbered from back to front.

4.2.3.2 Classic Sample Racks

The Classic 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.

4.2.4 Reagent Rack

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

4.2.4.1 Single Stirrer Reagent Rack

AIX1000 instruments with model number 00400-Rev2 include a Reagent Rack which contains four reagent positions and accepts 22mm to 35mm bottles. Custom reagent adapters are also available. The Reagent Rack contains three Control positions that accept the Control bottles included with the RPR test kit.

4.2.4.2 Double Stirrer Reagent Rack

AIX1000 instruments with model number 00400-Rev3 include a Reagent Rack which contains four regent positions and accepts 22mm to 35mm bottles, as well as three Control positions that accept the Control bottles included in the RPR test kit. In addition, the Reagent Rack contains extra Reagent bottle and Control bottle positions to support additional Test kits on the AIX1000 platform in the future. These extra Reagent bottle and Control bottle positions are not used by the AIX1000 2.1 software.

4.2.5 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.

4.2.6 High Resolution Digital Camera

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

4.2.6.1 Camera Specifications

Resolution:	1.3 M 1280x1024 pixels
Sensor:	1/1.8" CMOS Matrix 6.9x5.5mm
Pixel Size:	5.3µm
Dynamic Range:	60 dB
Data Interface:	USB 3.1
Power:	0.9 Watt

4.2.7 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.

4.2.8 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.

4.2.9 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.

4.2.10 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.

4.2.10.1 Shaker Specifications

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
Data Interface:	USB 3.1
Power:	0.9 Watt

4.2.11 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.

4.2.12 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 **5.1 AIX1000 System 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.

4.2.12.1 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 Core i3 12100T 4 Core 2.2 GHz
Memory (RAM):	4 GB
Hard Disk:	120 GB
Ports:	USB 2.0 or greater (RS232, Ethernet ports optional)
Graphics:	Intel(R) UHD Graphics 600, 1.00 GB RAM, 1366x768 resolution
Operating System:	Windows 10 Pro 21H1 19043
.NET Framework:	.NET 4.8

4.2.12.2 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	Graphics	Operating System	.NET Framework
1	Intel Core i3 12100T 4 Core 2.2GHz	4 GB	120 GB	USB 2.0 or greater, Ethernet, RS232 (Optional)	Intel(R) UHD Graphics 600, 1.00 GB RAM, 1366x768 resolution	Win 10 Pro 21H1 19043	.NET 4.8
5	Intel Core i7 1180G7 4 Core 2.2GHz	8 GB	240 GB				
10	Intel Core i9 11900F 8 Core 2.5GHz	16 GB	500 GB				

5 AIX1000 Software Suite

The AIX1000 Software Suite is required to operate the AIX1000 system. The components of the AIX1000 Software Suite are: AIX1000 Server, AIX1000 System Configuration Tool, and AIX1000 Instrument Manager.

The AIX1000 Instrument Manager is used to maintain the AIX1000 Instrument as well as to control it to perform Worklist runs to test Samples. The AIX1000 Instrument Manager must be run on instrument computer connected to the AIX1000 instrument.

The AIX1000 System Configuration Tool is used to specify settings that apply to the overall AIX1000 system. The AIX1000 Server stores and provides access to these system wide settings, as well as the data generated by each of the AIX1000 Instrument Managers to which it is connected. The AIX1000 System Configuration Tool and the AIX1000 Server must always be installed together on the same computer. This computer can be the AIX1000 Instrument computer or a separate dedicated server computer depending on the AIX1000 System Configuration being used. See below for more details.

All software components are pre-installed on the AIX1000 Instrument Computer included with the AIX1000 instrument.

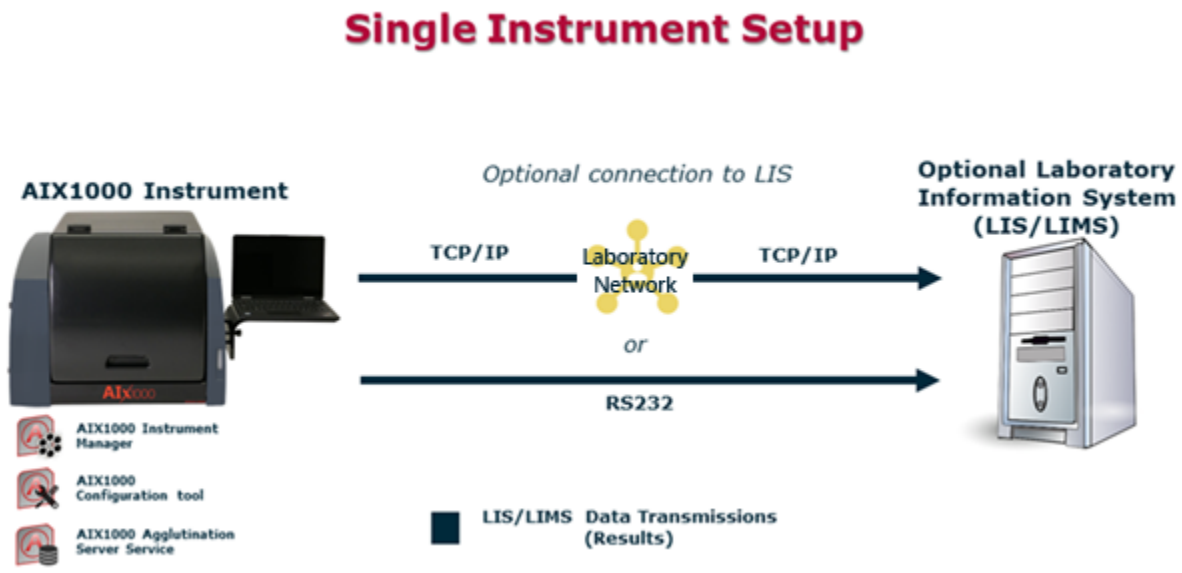
5.1 AIX1000 System Configuration Options

There are two ways in which a laboratory may configure and run the AIX1000 system:

5.1.1 Single Instrument Configuration

The *Single Instrument Configuration* is recommended for laboratories utilizing a single AIX1000 instrument. In this configuration, all components of the AIX1000 Software Suite—including the AIX1000 Server, AIX1000 System Configuration Tool, and AIX1000 Instrument Manager—are installed and executed on the instrument computer itself. This configuration is optimal for single-instrument environments, as it enables centralized management of all system settings directly on the instrument computer, thereby simplifying system administration and operation.

The diagram below provides a graphical representation of the *Single Instrument Configuration*.



If the laboratory requires the AIX1000 system, configured in the *Single Instrument Configuration*, to interface with a Laboratory Information System (LIS), the AIX1000 instrument computer must be connected to the LIS. This connection may be established either over the Laboratory Network or via an RS-232 serial connection, depending on laboratory infrastructure and requirements. A GSD Technical Service Representative or an authorized Distributor Technical Service Representative will collaborate with the laboratory's IT staff during installation to configure and validate LIS communication.

Each AIX1000 system is configured in the Single Instrument Configuration by default at the time of purchase.

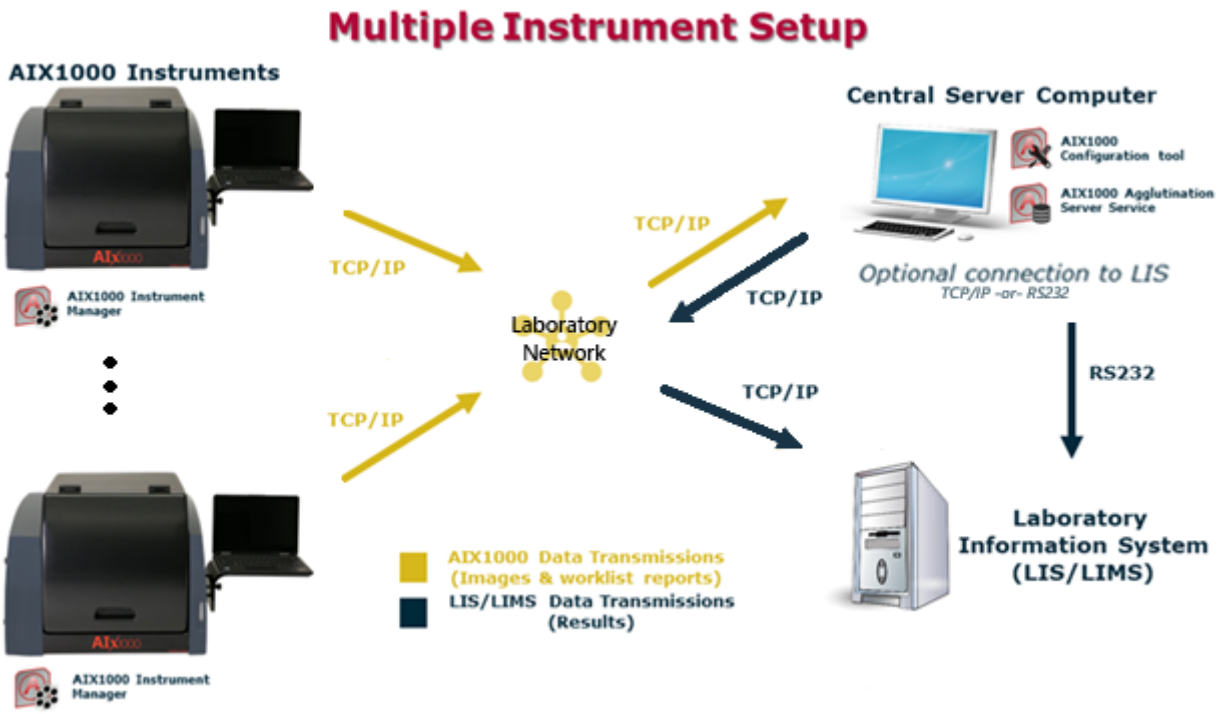
NOTICE: This configuration is limited by the amount of computing power and storage space on the instrument computer, which also runs the AIX1000 Server.

5.1.2 Multiple Instrument Central Server Configuration

The *Multiple Instrument with Central Server Configuration* is recommended for laboratories operating two or more AIX1000 instruments. In this configuration, both the AIX1000 Server and the AIX1000 System Configuration Tool are hosted on a dedicated server computer, while the AIX1000 Instrument Manager is installed on each individual instrument computer. All AIX1000 instrument computers communicate with the AIX1000 server computer via the Laboratory Network.

This configuration is preferred in multi-instrument environments because it enables centralized management of AIX1000 system settings through the AIX1000 System Configuration Tool on the server. These settings can then be distributed to all AIX1000 Instrument Managers across the connected instrument computers. Furthermore, all data generated by each AIX1000 Instrument Manager is securely stored and managed by the AIX1000 Server, ensuring that it can be reviewed either directly from the server computer or from any of the connected AIX1000 Instrument Managers.

The diagram below provides a graphical representation of the *Multiple Instrument with Central Server Configuration.*



If the laboratory requires the AIX1000 system, configured in the *Multiple Instrument with Central Server Configuration*, to interface with a Laboratory Information System (LIS), only a single connection from the AIX1000 server computer to the LIS is necessary. This connection may be established either over the Laboratory Network or via an RS-232 serial connection, depending on the laboratory's infrastructure and operational requirements. A GSD Technical Service Representative or an authorized Distributor Technical Service Representative will coordinate with the laboratory's IT staff during installation to configure and verify LIS communication.

If using the *Multiple Instrument with Central Server Configuration*, contact GSD Technical Service or your AIX1000 distributor for additional instructions regarding software installation on the server computer and proper configuration of all software components.

5.2 AIX1000 Server

The AIX1000 Server is a Windows Service that runs in the background of the computer on which it is installed. The AIX1000 Server service starts automatically when the Windows operating system on the computer boots up. The AIX1000 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).

5.3 AIX1000 System Configuration Tool

The AIX1000 System Configuration Tool is used to specify configuration settings for the system. These settings are stored by the AIX1000 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 AIX1000 Server service is running.

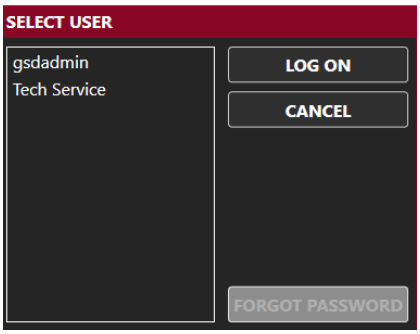
NOTICE: By default, AIX1000 system computers are configured to utilize the local Windows logon mechanism to enforce security best practices, including strong password requirements, account lockout after consecutive failed login attempts, automatic session lock after periods of inactivity, role-based access restrictions, and comprehensive user account management. Each AIX1000 system computer is preconfigured at the factory with a local Windows user account named "GSDTechService", secured with a strong password known only to the GSD Technical Service representative. Upon initial power-up, the Windows operating system will boot and prompt for user authentication. During installation, the GSD Technical Service Representative will log on to the AIX1000 system computer using the "GSDTechService" account and collaborate with designated laboratory personnel—such as the Laboratory Administrator, Laboratory Technicians, and Laboratory IT Staff—to establish secure, individual Windows accounts for all authorized AIX1000 system users. These Windows user credentials are entirely separate from the AIX1000 application user accounts and passwords, which will be described in detail in a subsequent section.

5.3.1 Launching the AIX1000 System Configuration Tool

To launch the AIX1000 System Configuration Tool, double click/tap on the associated icon on the desktop.

NOTICE: All connected Instrument Manager instances must be closed (as prompted) before opening the AIX1000 System Configuration Tool.

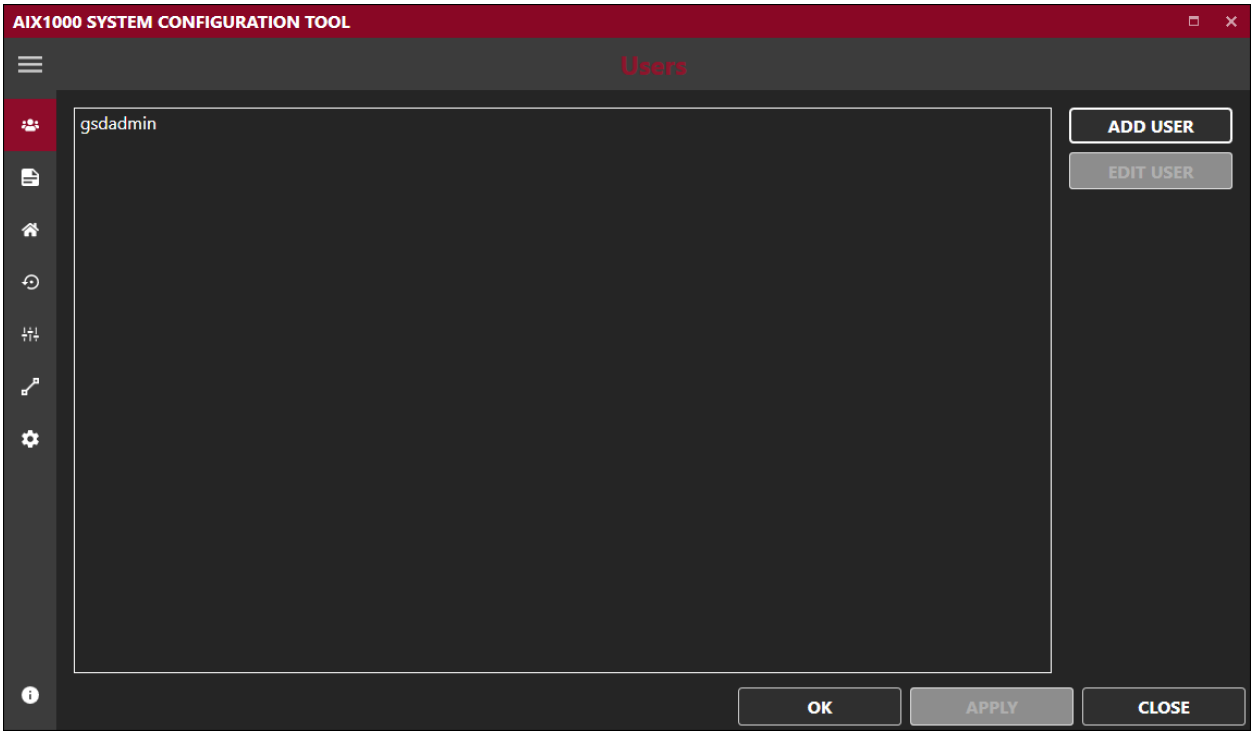
Choose **Yes** if prompted by the Windows operating system to allow the program to make changes to the computer. The AIX1000 System Configuration Tool will prompt the user to choose an AIX1000 System User Account to log on. Only users with Administrator or Tech Service accounts are allowed to access the AIX1000 System Configuration Tool.



Select the desired AIX1000 User Account (only Administrator or Tech Service User Accounts appear in the list), enter the password, and click/tap the **OK** button:

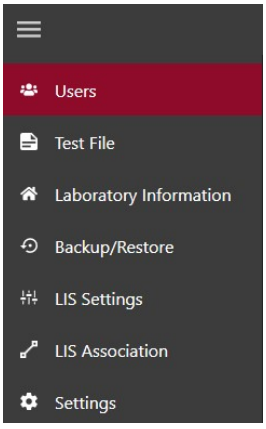
NOTICE: If an Administrator user forgets his/her password, a new password may be set using the Forgot Password button and following the subsequent instructions.

If the user has entered a valid password for the selected Administrator or Tech Service User Account, the AIX1000 System Configuration Tool will then open, as shown in the screen shot below:



The AIX1000 System Configuration Tool provides categories of settings to configure the overall AIX1000 system. These settings apply to the AIX1000 Server and all AIX1000 Instrument Manager instances connected to the server.

Initially, the AIX1000 System Configuration Tool displays icons representing the different setting categories, as shown in the image above. The setting category icons can be expanded to show the category names by clicking the horizontal three lines in the top left corner.



The different AIX1000 System Configuration Tool settings categories are described below.

5.3.2 Users

Use this screen to add and edit AIX1000 user accounts. These user accounts will be used to log on to the AIX1000 System Configuration Tool (Administrator users only) and to the AIX1000 Instrument Manager instances connected to this AIX1000 Server.

5.3.2.1 Add a User

To add a user, Click/tap **Add User**. Enter User Name and Password, Email Address (optional for runtime notifications), and cell phone number (optional for runtime 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.

5.3.2.2 User Levels

The available user levels are:

- **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.
- **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.
- **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.

5.3.2.3 Edit a User

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**.

5.3.2.4 Deactivate a User

User accounts cannot be deleted, but they can be deactivated by deselecting the **Active User** option in the **Edit User** window. Deactivated users do not have access to the AIX1000 system.

5.3.3 Test File

The selected test file will be run by the AIX1000 Instrument Manager instance(s) connected to this AIX1000 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; this file cannot be edited by the instrument user.

5.3.4 Laboratory Information

Enter the name and address of the lab as it will appear on Worklist reports, Sample reports, and Search reports generated by the connected AIX1000 Instrument Manager(s). Upload a logo if desired. Enter the number of instruments connected to the server. Click/tap **Apply** to save changes.

5.3.5 Backup/Restore

Use this screen to backup data manually or at scheduled times, purge data or images, or restore a backed-up database.

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

5.3.5.1 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 images. Click/tap **Backup** to create the backup file.

5.3.5.2 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).

5.3.5.3 Scheduled Backup

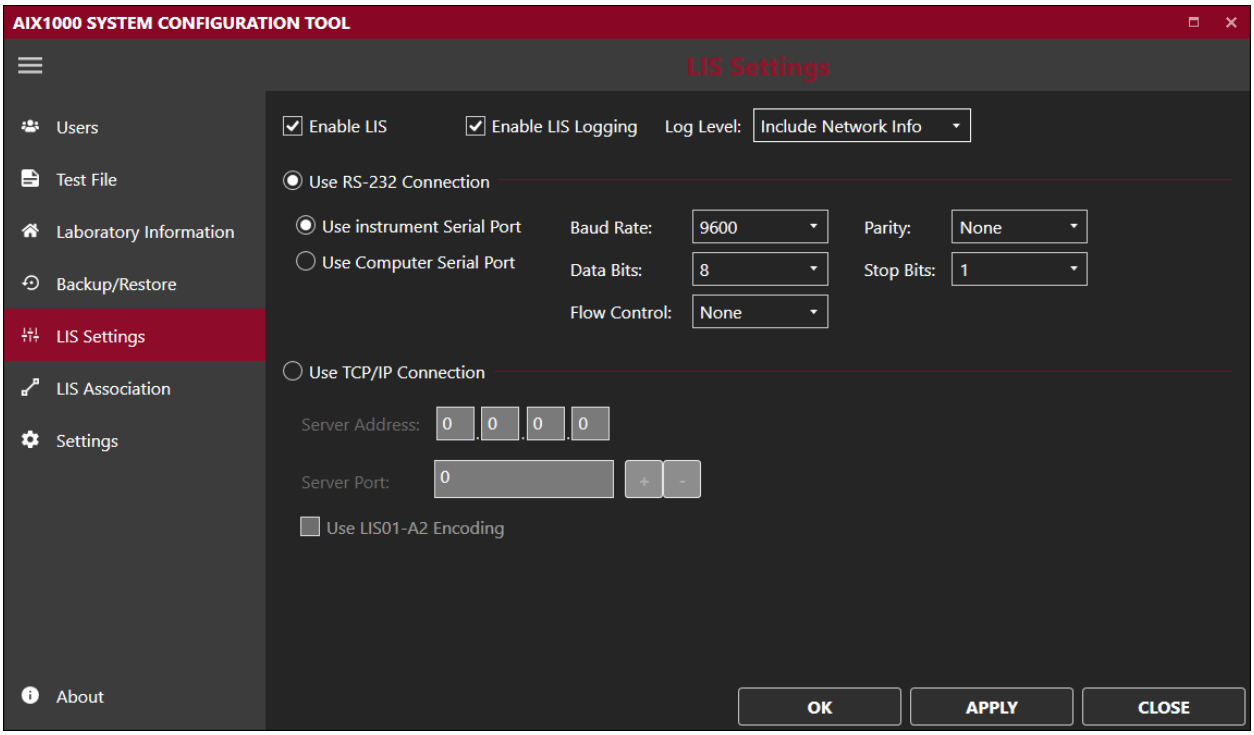
Set a time for automatic backups to occur, if desired. Select backup frequency and file location. Decide to keep or auto-purge backed up images.

5.3.5.4 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.).

5.3.6 LIS Settings

The LIS Settings screen enables the user to configure the AIX1000 system to communicate with a Laboratory Information System (LIS). LIS settings must be configured in the AIX1000 System Configuration Tool before LIS communication can be attempted from any AIX1000 Instrument Manager instance connected to the associated AIX1000 Server.



If the AIX1000 system is required to communicate with an LIS, then the **Enable LIS** checkbox should be checked. It is highly recommended that the **Enable LIS Logging** checkbox is also checked so that the AIX1000 system will generate LIS log data that can be reviewed in case there are communication issues. The LIS log data can be generated with several different levels of detail. Se the **LIS Log Level** as appropriate.

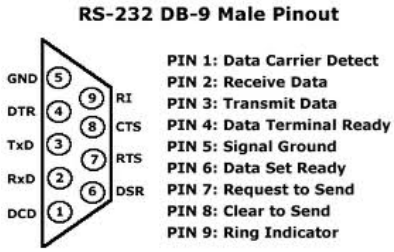
The **LIS Timeout** setting indicates how long the AIX1000 system will wait for a response from the LIS system. The default timeout period is 30 seconds. Some LIS systems may require longer timeout periods. Set the timeout period as appropriate for the Laboratory LIS.

The AIX1000 system can connect to an LIS using two protocols: RS-232 or TCP/IP. Select which LIS connection type will be used (RS-232 or TCP/IP) and set port or server settings as appropriate. Be sure that all settings match those of the LIS system to which the AIX1000 system is connecting.

Click/tap **Apply** to save changes.

5.3.6.1 RS-232 Pin Layout

If connecting to an LIS using an RS-232 connection, it may be necessary to know the pin layout of the physical connection. The pin layout is specified below:



5.3.7 LIS Association

A Laboratory Information System (LIS) will have a unique name or code to represent different Tests/Assays. Recall from section **5.3.3 TEST FILE**, the AIX1000 system uses a Test File to define the RPR Test/Assay protocol it can execute. In order for the AIX1000 system to exchange information with the LIS for a given Test/Assay, the LIS Test name/code must be associated with the corresponding AIX1000 system Test File name. The **LIS Associations** screen provides the Test File name for the RPR Test File loaded into the AIX1000 system. The user must provide the corresponding LIS Test/Assay code name it uses for the RPR Test/Assay. The user must be sure to enter LIS Test/Assay names or codes exactly according to the Laboratory LIS naming convention.

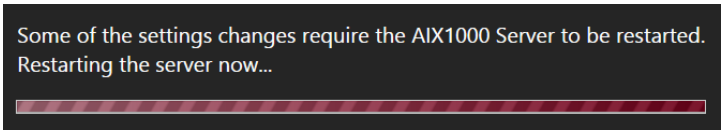
NOTICE: An LIS name is seldom the real test name, but often a shorter one. It could also be a number or code, depending on the laboratory policy. The AIX1000 system will not be able to send or receive information for the RPR Test/Assay if the LIS Association for the Test/Assay is not defined properly.

5.3.8 Settings

Check the **Enable On-Screen Keyboard** option if using a touchscreen, to enable on screen keyboard in the Configuration Tool application.

5.3.9 Exiting the AIX1000 System Configuration Tool

Close the AIX1000 System Configuration Tool window by clicking the **OK** button in the bottom right-hand corner. If necessary, the Server will automatically be restarted to implement changes:



5.4 AIX1000 Instrument Manager

The AIX1000 Instrument Manager enables the user to execute Worklists on an AIX1000 instrument and/or review and evaluate the results of Worklists that have been executed. A Worklist contains a list of Samples and the corresponding RPR Test action(s) to be run on those Samples.

The AIX1000 Instrument Manager can be run in two modes:

1. Full Functionality Mode
   This mode enables the running of Worklists and the review and evaluation of Worklist results. In this mode, an AIX1000 instrument must be connected via a USB connection to the computer on which the AIX1000 Instrument Manager is installed. The instrument is powered on when the AIX1000 Instrument Manager is started.

2. Evaluation Only Mode
   This mode allows for evaluation of Worklist results only. In this mode, an instrument is not required to be connected to the computer on which the AIX1000 Instrument Manager is installed. If an instrument is connected, the instrument will not be powered on when the software is started and the software will not interact with the instrument. This mode is a subset of the Full Functionality Mode -- the AIX1000 Instrument Manager in Evaluation Only Mode provides access to functionality related to reviewing and evaluating results only. This mode is most useful in laboratories with multiple instruments connected to a central server as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**. The AIX1000 Instrument Manager can be run in Evaluation Only Mode on the server computer to allow the review and evaluation of Worklist data from all instruments connected to the central server.

NOTICE: The Evaluation Only Mode is a subset of the Full Functionality Mode. That is, all functionality provided in the Evaluation Only Mode is also available in the Full Functionality Mode. Therefore, only the Full Functionality Mode will be described further in this document.

5.4.1 Launching the AIX1000 Instrument Manager

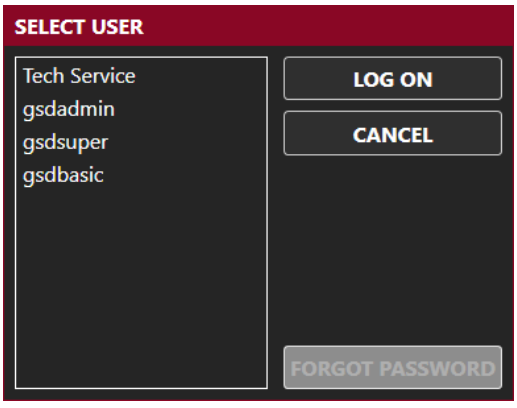
To launch the AIX1000 Instrument Manager, verify that the computer on which the AIX1000 Instrument Manager is installed is connected to the AIX1000 instrument via a USB connection. Power on the computer and allow the Windows operating system to boot up.

NOTICE: By default, AIX1000 system computers are configured to utilize the local Windows logon mechanism to enforce security best practices, including strong password requirements, account lockout after consecutive failed login attempts, automatic session lock after periods of inactivity, role-based access restrictions, and comprehensive user account management. Each AIX1000 system computer is preconfigured at the factory with a local Windows user account named "GSDTechService", secured with a strong password known only to the GSD Technical Service representative. Upon initial power-up, the Windows operating system will boot and prompt for user authentication. During installation, the GSD Technical Service Representative will log on to the AIX1000 system computer using the "GSDTechService" account and collaborate with designated laboratory personnel—such as the Laboratory Administrator, Laboratory Technicians, and Laboratory IT Staff—to establish secure, individual Windows accounts for all authorized AIX1000 system users. These Windows user credentials are entirely separate from the AIX1000 application user accounts and passwords, which will be described in detail in a subsequent section.

If the AIX1000 Instrument Manager was installed with the option to "Launch at Startup", then the AIX1000 Instrument Manager will startup when the Windows operating system boots up and the user logs on. Otherwise, the AIX1000 Instrument Manager will have to be launched by double clicking/tapping the AIX1000 Instrument Manager icon on the desktop.

By default, the AIX1000 Instrument Manager is configured to run in the Single Instrument Configuration (see **5.1.1 SINGLE INSTRUMENT CONFIGURATION** for details). In this configuration the AIX1000 Instrument Manager will communicate with the AIX1000 Server service running on the instrument computer to obtain AIX1000 user account information and prompt the user to logon to the AIX1000 system. When the Multiple Instrument with Central Server Configuration is used (see **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION** for details), the AIX1000 Instrument Manager will communicate with the AIX1000 Server service running on the server computer. If this is the first time the AIX1000 Instrument Manager is being launched, or if there is a network communication issue, the AIX1000 Instrument Manager may prompt for the IP address of the server computer on which the AIX1000 Server service is running. Contact the Laboratory IT for assistance setting the AIX1000 Server IP address if needed.

Once the AIX1000 Instrument Manager is able to communicate with the AIX1000 Server service and obtain AIX1000 user account information, the AIX1000 Instrument Manager log on screen will appear to allow the user to log on to the AIX1000 system:



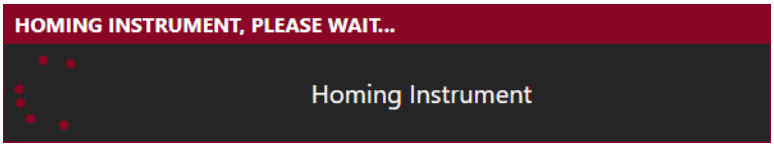
The AIX1000 Instrument Manager log on screen lists all active user accounts defined in the AIX1000 system database. See **5.3.2 USERS** for information on how to define user accounts using the AIX1000 System Configuration Tool.

NOTICE: The Tech Service user account is a special account which is present on all AIX1000 systems. This account is to be used by certified GSD Technical Service representatives when performing service on the instrument, or when troubleshooting issues. This account is to be used by GSD Technical Service representatives only.

To log on to the AIX1000 Instrument Manager, the user selects the appropriate user account name and taps/clicks the **Log On** button. The AIX1000 Instrument Manager will prompt the user for the user account password.

NOTICE: If a user with a Basic User or Super User account forgets his/her password, a user with an Administrator account can reset the password using the AIX1000 System Configuration Tool. If a user with an Administrator account forgets his/her password, a new password may be set using the Forgot Password button and following the subsequent instructions.

Once the user specifies the correct password for the selected user account, the instrument will initialize and move to the starting, or 'home', position. This homing process requires approximately 30 seconds. The instrument must always be allowed to complete this homing procedure uninterrupted before being used.

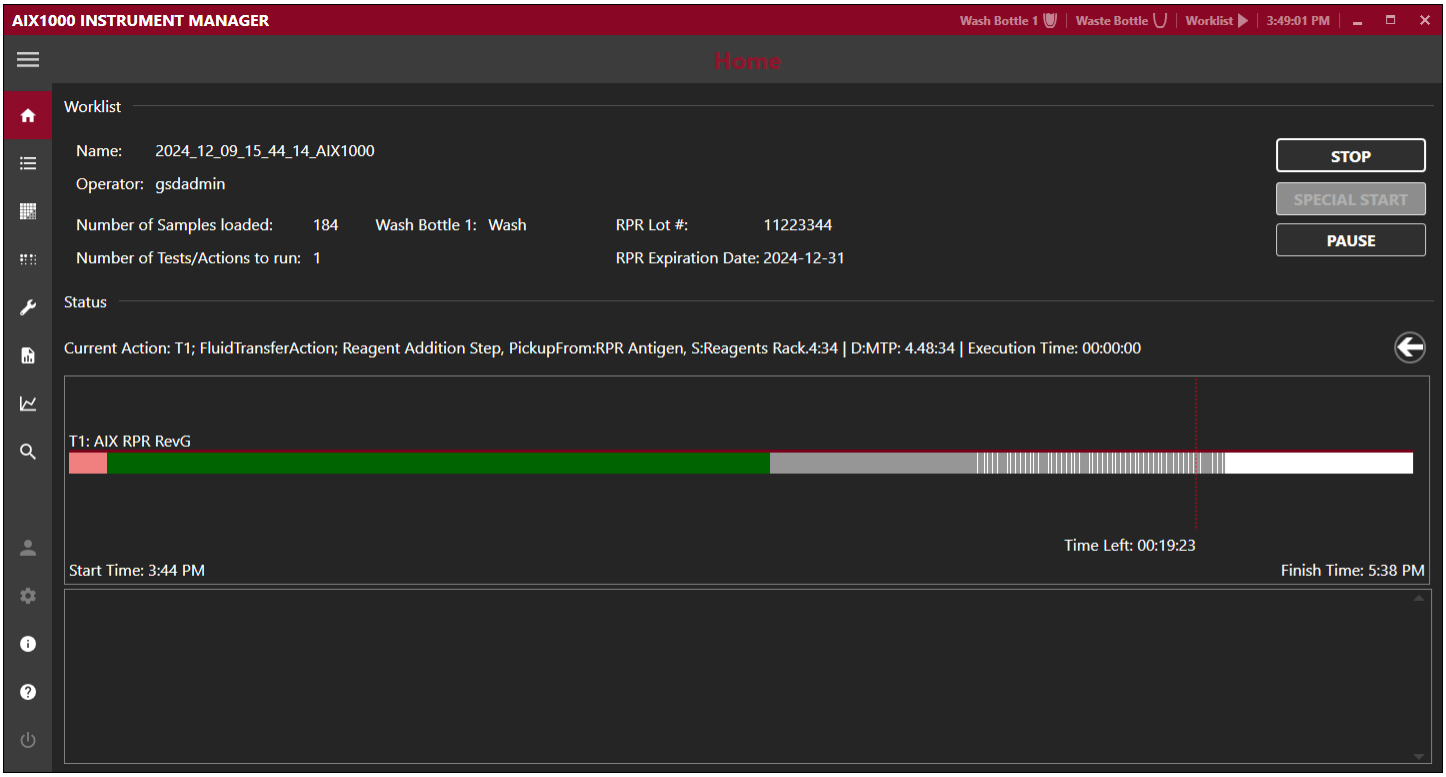


After the homing procedure completes, the AIX1000 Instrument Manager will open.

NOTICE: When the AIX1000 Instrument Manager opens, the user is prompted to perform daily startup maintenance (as well as weekly maintenance, if due and set to be prompted at System Startup). The user must respond to each maintenance prompt before continuing.

5.4.2 The AIX1000 Instrument Manager Interface

The AIX1000 Instrument Manager main window is shown below:



The interface for the AIX1000 Instrument Manager is designed with a title bar, an expandable/collapsible side menu containing items for the different categories of functionality, and a window pane which displays controls and information based on the selected item in the side menu.

The AIX1000 Instrument Manager title bar contains indicators pertaining to the general status of the instrument, as well as some controls to manipulate the AIX1000 Instrument Manager window. The different status indicators and controls in the title bar are described in the table below.

Status Indicator / Control	Description
Wash and Waste Bottle Status Icons	Indicates which wash/waste sensors are enabled and the liquid level of wash and waste (empty or full).
Worklist State Icon	Indicates if a worklist is being created (open circle), running (arrow), paused (double lines), stopped (solid square), or completed (checkmark). *NOTICE: The exterior status indicator light also shows worklist status (on applicable models only).* *Blue: Instrument is idle; ready to load and run worklist.* *Green: Instrument is running a worklist.* *Red: Instrument has an error, alarm, or message stopping the worklist.*
Current Computer Time	Displays the current time as set on the attached computer.
Minimize/Maximize/Restore Down	Used to minimize/maximize/restore down the AIX1000 Instrument Manager main window.
Close (X icon)	Used to close the AIX1000 Instrument Manager window and exit the software without shutting down the instrument/computer. (Daily shutdown maintenance will be prompted).

The different functional categories of the AIX1000 Instrument Manager available in the expandable side menu are described below.

5.4.2.1 Home

The **Home** screen displays the overall status including details about the currently loaded Worklist, a timing diagram of the Worklist run, and the Microtiter Plate Well images captured during the Worklist run. This screen is used to start, monitor, pause, and/or stop a Worklist run.

5.4.2.1.1 Worklist Summary and Actions

The Worklist Summary section of the **Home** screen displays information for the currently loaded Worklist. The name of the Worklist is displayed, the currently logged on user (or operator of the instrument) is displayed, as well as a summary of the Worklist including the number of Samples loaded in the Worklist, the number of Tests included in the Worklist, and the Wash Bottles used by the Worklist.

The buttons in the Worklist Summary section can be used to start, stop, and pause a Worklist run for the currently loaded Worklist.

Start/Stop: The **Start** button will start the Worklist run in full. While a Worklist run is in progress, the **Start** button label will transition to **Stop** and can be used to stop the Worklist run.

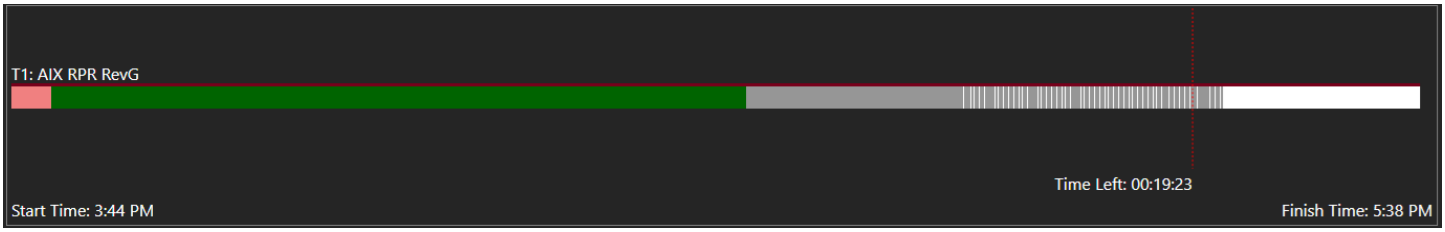
Special Start: The **Special Start** button will start the Worklist in a special or custom manner. For example, the Worklist can be started from a specific step. If the currently loaded Worklist has already been run, the **Special Start** functionality will also allow the user to specify that the Microtiter Plates should be reread.

Pause: The **Pause** button can be used to temporarily suspend a Worklist run. The user can click the **Pause** button to suspend a Worklist run that is in progress to check things such as Reagent Bottles, then continue with the Worklist run from the point at which it was suspended.

5.4.2.1.2 Status

The **Status** section of the **Home** screen displays the current status of the instrument. If a Worklist run is in progress, the first line of the **Status** section shows the current action being executed. The full Status Log showing all actions executed as part of the Worklist run can be seen by clicking the arrow button on the right side of the screen.

Timing Diagram: The timing diagram displays the anticipated run time for the currently loaded Worklist. The RPR Test File in the Worklist is listed with colored bars representing the different actions of the test.

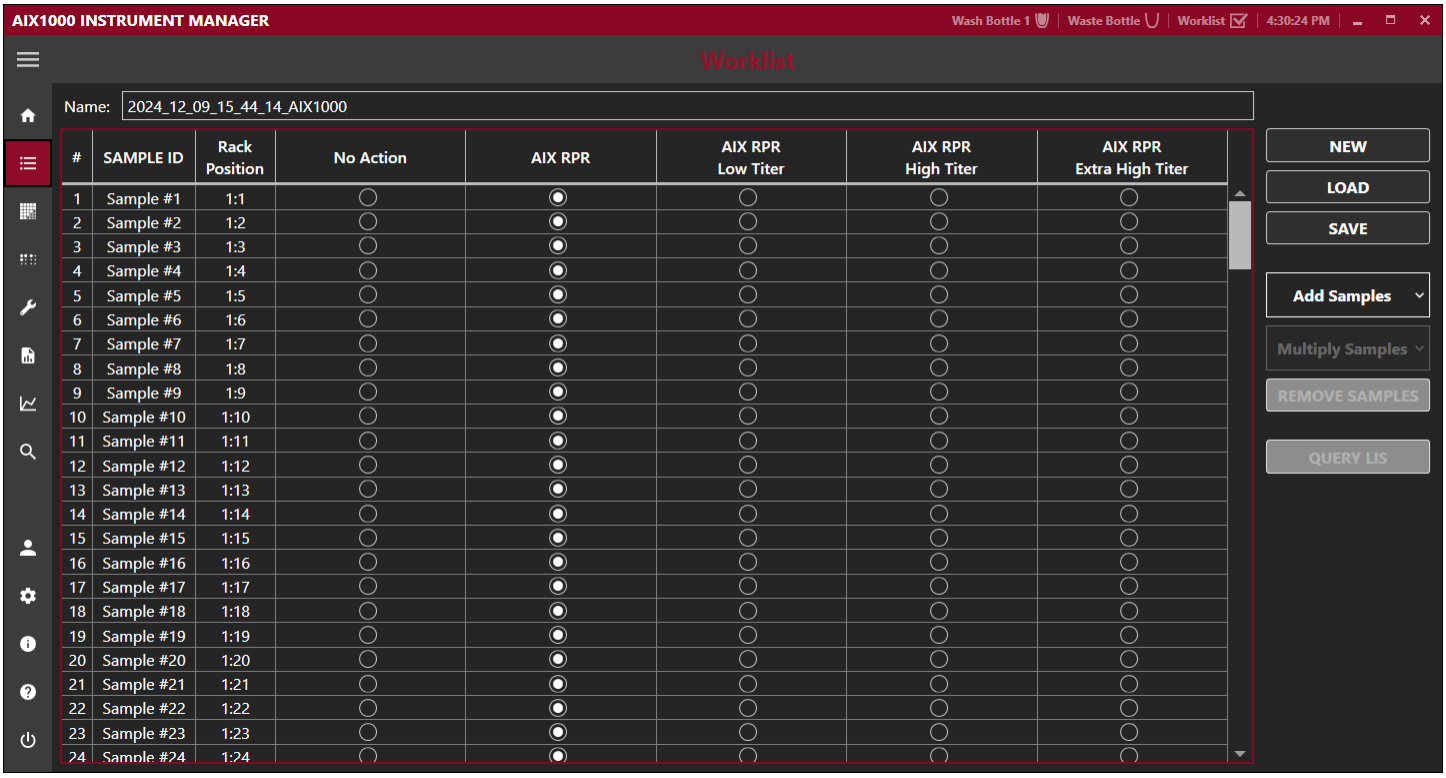


The length of the colored bars corresponds to the amount of time estimated to complete the action. The user can hover the mouse pointer over each colored bar to display additional information about each action. If the Worklist run has not been started, the estimated time to run the Worklist is displayed in the bottom left corner. This estimated run time is based on the actions defined in the RPR Test, as well as the number of Samples added to the Worklist. If the Workist run is in process, the start time is displayed in the bottom left corner, the estimated finish time is displayed in the bottom right corner, and the current position in the Worklist run with the estimated time remaining is displayed with a vertical red line.

Well Image Preview: The Well Image Preview pane displays previews of Microtiter Plate Well images captured by the high-definition digital camera mounted on the probe. These images shown on the **Home** screen during a Worklist run are for informational purposes only. More detailed information about the Well images can be found in the Sample Reports on the Evaluation screen.

5.4.2.2 Worklist

The **Worklist** screen is used to load or create a Worklist to be run on the instrument. A Worklist is a list of Samples, along with the RPR Test actions that are assigned to those Samples, that are scheduled to be processed as part of a Worklist run. The information displayed on the **Worklist** screen is considered the currently loaded and active Worklist.



5.4.2.2.1 Name

The **Name** field on the **Worklist** screen allows the user to enter a name for the Worklist. If no name is entered, the Worklist will be automatically named with a date and time stamp when the Worklist run is started.

5.4.2.2.2 Worklist Grid

The Worklist grid shows the work items in the Worklist. The work items consist of a Sample ID, the Rack Position of the Sample tube in the Samples Rack, and a list of RPR Test actions to be run on the Samples. Samples are added to the Worklist grid using the **Add Samples** feature.

RPR Test Actions: The AIX1000 system supports four RPR test actions: **AIX RPR**, **AIX RPR Low Titer**, **AIX RPR High Titer**, and **AIX RPR Extra-High Titer**. Each RPR Test action is described in more detail below.

- **AIX RPR**
  The AIX RPR Test action (also known as the RPR Screen action) is a qualitative measurement of reagin antibodies that the immune system produces in response to cell damage caused by T. pallidum infection. It is run on the undiluted Sample and is typically used to initially determine if the Sample is Reactive or Non-Reactive.

- **AIX RPR Low Titer**
  The AIX RPR Low Titer action is a semi-quantitative measurement of reagin antibodies that the immune system produces in response to cell damage caused by T. pallidum infection. For the AIX RPR Low Titer action the Sample is serially diluted to 1:2, 1:4, 1:8, and 1:16 dilutions. Each dilution is analyzed and determined to be Reactive or Non-Reactive. The last Reactive dilution in the titer series is reported as the endpoint titer.

- **AIX RPR High Titer**
  The AIX RPR High Titer action is a semi-quantitative measurement of reagin antibodies that the immune system produces in response to cell damage caused by T. pallidum infection. For the AIX RPR High Titer action the Sample is serially diluted to 1:32, 1:64, 1:128, and 1:256 dilutions. Each dilution is analyzed and determined to be Reactive or Non-Reactive. The last Reactive dilution in the titer series is reported as the endpoint titer.

- **AIX RPR Extra-High Titer**
  The AIX RPR Extra-High Titer action is a semi-quantitative measurement of reagin antibodies that the immune system produces in response to cell damage caused by T. pallidum infection. For the AIX RPR Extra-High Titer action the Sample is serially diluted to 1:512, 1:1024, and 1:2048 dilutions. Each dilution is analyzed and determined to be Reactive or Non-Reactive. The last Reactive dilution in the titer series is reported as the endpoint titer.

The Worklist Grid allows the user to assign an RPR Test Action to Samples by clicking on the desired RPR Test Action for each Sample. The user can assign multiple RPR Test Actions to a Sample by Multiplying the Sample (see **5.4.2.2.7 MULTIPLY SAMPLES**) and assigning a different RPR Test Action to each replicate of the Sample. The AIX1000 system will perform the assigned RPR Test Actions on the replicated Sample IDs – the serum will be aspirated from the original Sample ID tube for all replicates. The results of each replicate will be shown on the Worklist Report using the replicate Sample IDs. However, when sending the results to the LIS, all replicated results will be sent under the original Sample ID.

Test Properties: The user can click/tap on the RPR test name/action in the Worklist grid header to open the **Test Properties** window for the RPR Test. The **Test Properties** window allows the user to specify the lot number and expiration date as obtained from the test assay kit (box labels, insert, and vials).

5.4.2.2.3 New

The **New** button allows the user to clear the current Worklist and create a new Worklist. When clicked, the Name field is cleared, Samples and/or assigned RPR Test actions are cleared form the Worklist grid, and any other settings related to the current Worklist are cleared. The user is provided a new, empty Worklist to which he/she can add Samples and assign RPR Test actions to those Samples for a Worklist run.

5.4.2.2.4 Load

The **Load** button allows the user to load a previously saved Worklist. By default, Worklist files of the type *.AIX1000WORKLIST can be loaded. AIX100 also supports loading Worklists saved with the older file name extension of *.TBRPRWORKLIST.

When a previously saved Worklist is loaded, it is the user's responsibility to ensure all Samples, Controls, and Reagents are physically located on the instrument according to the loaded Worklist configuration.

5.4.2.2.5 Save

The **Save** button allows the user to save the current Worklist configuration to a file. The file format is a proprietary format with an *.AIX1000WORKLIST file extension.

Saving a Worklist to a file can be helpful when troubleshooting Worklist run issues. The Worklist can be saved and sent to GSD Tech Support for analysis.

NOTICE: When a Worklist run is started, the Worklist file is automatically saved to the Worklists folder as described in **5.5.8 WORKLISTS***. This saved Worklist file can be used to quickly reload the Worklist in case or errors encountered during the Worklist run. Subsequently, when the Worklist run is completed, the Worklist results are saved to the AIX1000 system database and the Worklist file is automatically saved to the Worklist folder again, overwriting the previously saved Worklist file.*

5.4.2.2.6 Add Samples

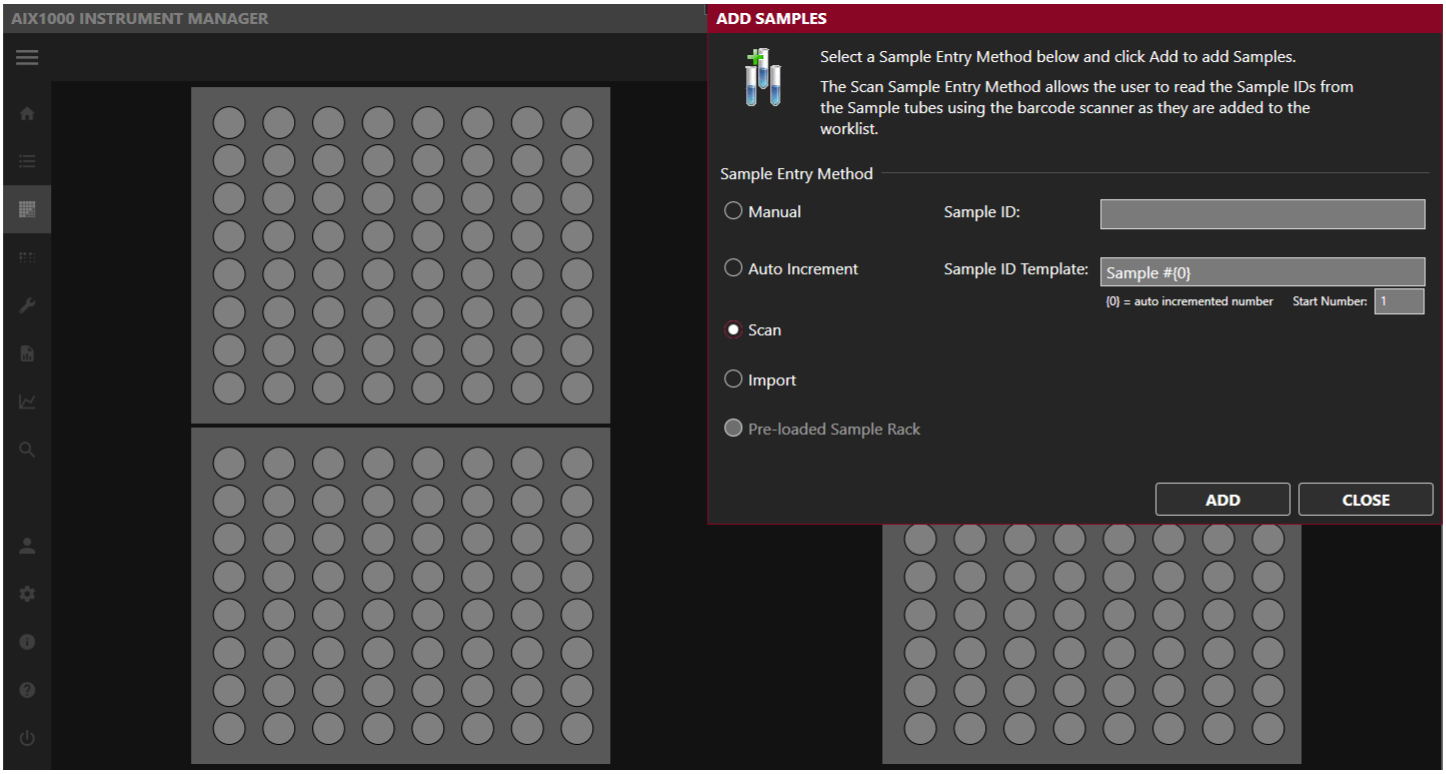
The **Add Samples** button allows the user to add Samples to the Worklist as they are loaded into the Sample Racks on the instrument.

NOTICE: Eppendorf or other conical-shaped tubes are not recommended for use in the instrument. The needles on the instrument probe can be pinched by the conical shape when the probe descends into the tube. This can interfere with the aspiration and/or dispense of fluid from the needles. In addition, when the probe ascends out of the tube, the pinched needles may apply enough force to the sides of the tube to pick up the tube, which often results in spills. Only standard-diameter sample tubes (12mm, 13mm, 16mm) are recommended for use on the instrument.

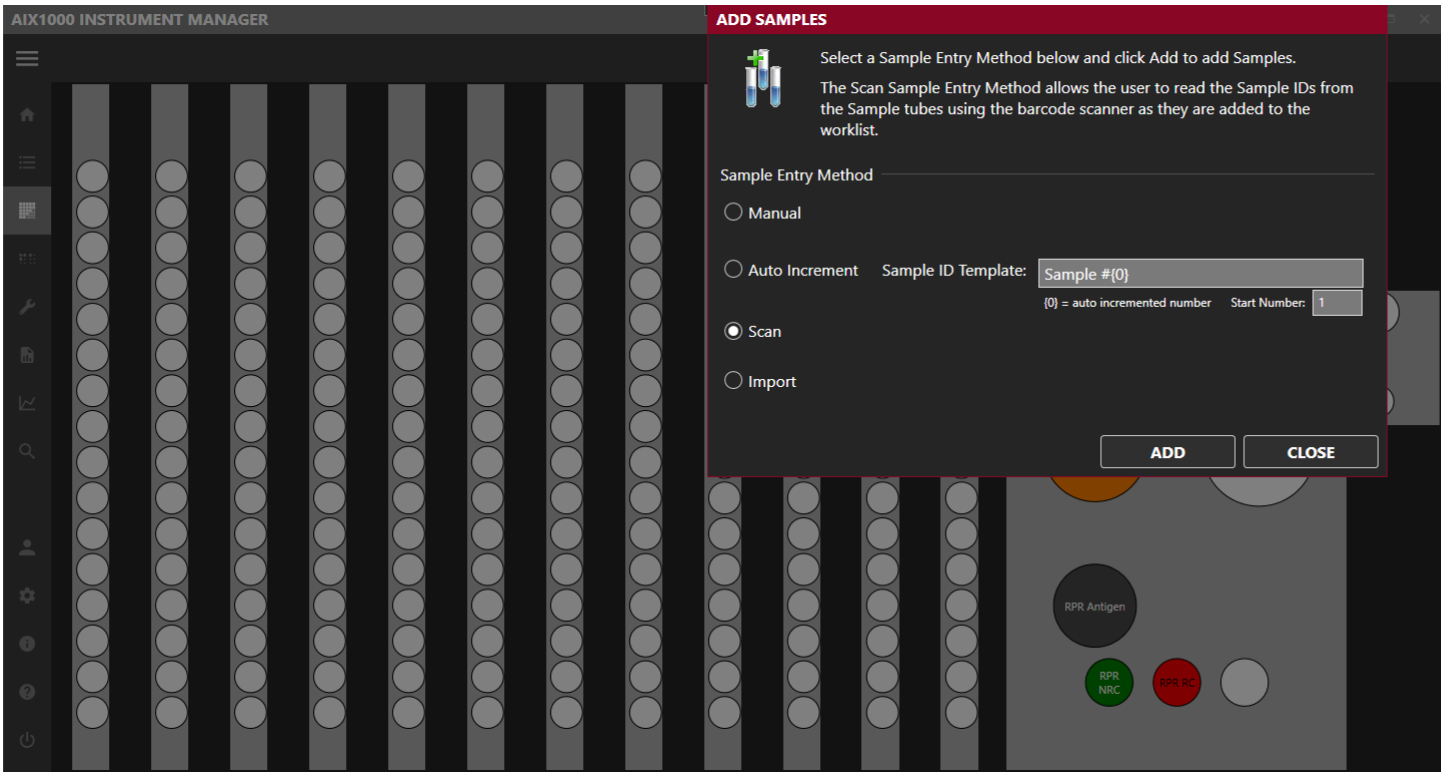
The user can click/tap the **Add Samples** button to open the **Add Samples** window. For AIX1000 instruments with the Classic Sample Rack design, the **Add Samples** button will appear as a dropdown button with two items: **Add Samples to Worklist** and **Preload Sample Rack**. The **Add Samples to Worklist** item will open the **Add Samples** window and allow the

user to add Samples to the Sample Racks on the instrument and to the Worklist. There are several different methods for adding Samples to the instrument and Worklist. These different methods are described in more detail below. The **Preload Sample Rack** item will open the **Preload Sample Rack** window and allow the user to load Samples to a Sample Rack not on the instrument. These Samples are not added to the current Worklist but can be added to the instrument and the Worklist later using the **Preloaded Sample Rack** option from the **Add Samples** window. The **Preloaded Sample Rack** option is described in more detail below.

When the **Add Samples** window is opened, it will appear in the foreground with the **Racks** screen in the background to allow for monitoring of Sample tube placement as Samples are loaded. The Racks screen in the background will appear differently depending on the model of the AIX1000 instrument being used (Classic Sample Rack model versus Slide-in Rack model). These differences are shown below:



Add Samples window for AIX1000 with Classic Sample Racks



Add Samples window for AIX1000 with Slide-in Sample Racks

Sample Entry Methods: The **Add Samples** window provides several methods for loading Samples into the Sample Racks on the instrument and adding them to the Worklist. The user can select the desire Sample Entry Method and click/tap the **Add** button to add the Samples by following the detailed on-screen instructions. The different Sample Entry Methods are described below.

- *Manual:* The **Manual** Sample entry method can be used for non-barcoded Sample tubes which have unique or custom IDs associated with them.

  When adding Samples using this Sample entry method to an AIX1000 instrument with Classic Sample Racks, select the **Manual** Sample entry method and type the sample ID into designated field. Next, click/tap the **Add** button. Place the Sample tube in the rack as prompted. The Sample will be added to the Worklist with the ID that was manually entered. Repeat for all manually labeled samples.

  When adding Samples using this method to an AIX1000 instrument with Slide-in Racks, select the **Manual** Sample entry method and click/tap the **Add** button. Follow the instructions to slide in the Sample Rack with the Sample tubes to be added. The AIX1000 system will detect the presence of the Sample tubes as the Rack is slid in. After the Rack is completely inserted, AIX1000 will prompt the user to manually enter Sample IDs for each Sample tube detected.

- *Auto Increment:* The **Auto Increment** Sample entry method can be used for non-barcoded Sample tubes which have no defined ID associated with them. AIX1000 will automatically assign an ID to the Sample based on the specified Sample ID template. The Sample ID template can contain any sequence of characters, however it must contain the character sequence '{0}'. This character sequence will be replaced with the auto-incremented number. For example, if the Sample ID template is set to 'Sample #{0}' and the start number is set to 1, then the Sample IDs assigned to the Sample tubes as they are added will be 'Sample #1', 'Sample #2', 'Sample #3', etc…

  When adding Samples using this Sample entry method to an AIX1000 with Classic Sample Racks, select the **Auto Increment** Sample entry method and change the **Sample ID Template** and **Start Number** as desired. Next, click/tap the **Add** button. Place Sample tubes in the Sample Rack, one by one, as prompted. Samples will automatically be numbered consecutively, according to the auto-increment Sample ID template.

When adding Samples using this Sample entry method to an AIX1000 instrument with Slide-in Racks, select the **Auto Increment** Sample entry method and change the **Sample ID Template** and **Start Number** as desired. Next, click/tap the **Add** button. Insert the slide-in Sample Racks with the Sample tubes as directed. For each Sample tube detected, AIX1000 will assign the auto-incremented Sample ID according to the Sample ID template.

- *Scan:* The **Scan** Sample entry method can be used for Sample tubes which are labeled with a barcode that contains the Sample ID.

  When adding Samples using this Sample entry method to an AIX1000 instrument Classic Sample Racks, select the **Scan** Sample entry method and click the **Add** button. The barcode scanner light on the built-in barcode scanner on the front of the instrument will turn on. Scan the barcoded sample tube approximately 4 inches (10 cm) in front of the built-in barcode scanner. Alternatively, a handheld barcode scanner attached to the instrument by USB can be used if desired. When the barcode on the Sample tube is read, a beep will be heard, and the scanner light will turn off. The Sample ID will be added to the Worklist and the user will be instructed to place the Sample tube in the Sample Rack. Repeat for all barcoded Sample tubes. See **4.2.9 BARCODE SCANNER (APPLICABLE ONLY FOR MODELS WITH INTELLIGENT SAMPLE RACKS)** for information on the barcode symbologies that are supported.

  *NOTICE: If Intelligent Rack Tube Detection is enabled as described in **5.4.2.10.3 RACKS**, the Sample tube must be placed in the Sample Rack in order for the scanner to reactivate to continue loading additional Sample tubes.*

  When adding Samples using this Sample entry method to an AIX1000 instrument with Slide-in Racks, select the **Scan** Sample entry method and click the **Add** button. The barcode camera scanner will turn on and move into position. Physically place all desired barcoded Sample tubes into a Slide-in Racks with labels facing outward. As prompted, use the Slide-in Rack handle to carefully slide the rack into the indicated position on the Slide-in Rack Deck in the position indicated by the green LED. After the Slide-in Rack has been fully inserted, the user will be alerted if any problems with tube or barcode recognition were detected. If no issues were detected, the system will prompt for the next Slide-in Rack to be, inserted. The system will proceed in this manner from left to right until all Slide-in Racks have been inserted, or until the user clicks/taps the **Done** button. See **4.2.8 BARCODE CAMERA (APPLICABLE ONLY FOR MODELS WITH SLIDE-IN SAMPLE RACKS)** for information on the barcode symbologies that are supported.

- *Import:* The **Import** Sample entry method can be used to import Sample IDs into the Worklist from an Excel spreadsheet. Select the desired XLS or XLSX file as prompted. When this Sample entry method is used, it is the user's responsibility to ensure the Sample tubes have been physically placed in the Sample Racks according to the layout specified in the import file.

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

- *Preloaded Sample Rack (applicable only for models with Classic Sample Racks):* Use to add preloaded racks (prepared as described in Worklist Preparation). Click/tap the **Add** button. Select the desired rack from the **Preloaded Sample Racks** list and click/tap **Add**. Scan the rack 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.

  *NOTICE: This Sample Entry Method is only available for use when Intelligent Rack Tube Detection is enabled as described in **5.4.2.10.3 RACKS**.*

When all Samples have been added, click/tap the **Done** button to exit the **Add Samples** window. The AIX1000 Instrument Manager main window display will return to the Worklist screen, where all added Sample IDs will be listed in the Worklist grid.

Important Notes for Models with Classic Sample Racks

The following items should be kept in mind when adding Samples to an AIX1000 instrument with Classic Sample Racks:

- *Tube Detection:* If Intelligent Rack Tube Detection is enabled as described in **5.4.2.10.3 RACKS**, Sample tubes can be placed in any desired locations in the Sample Racks. When placing Sample tubes in the Sample Racks, verify that Sample tubes are recognized on the **Racks** screen (spaces with loaded Sample tubes display yellow or blue; unoccupied spaces remain white or grey). If Sample tubes are removed prior to starting the Worklist run, the corresponding Sample IDs will be removed from the Worklist. To be included in the Worklist run, they must be added again using one of the Sample Entry Methods described above.

  If **Intelligent Rack Tube Detection** is not enabled as described in **5.4.2.10.3 RACKS**, Sample tubes must be placed in the positions indicated on the **Racks** screen.

- *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; user will be prompted to change the Sample ID during sample addition if a sample with a duplicate ID is added.

Important Notes for Models with Slide-In Sample Racks

The following items should be kept in mind when adding Samples to an AIX1000 instrument with Slide-in Sample Racks:

- *Tube Placement:* Sample tubes can be placed in any desired locations in the Slide-in Sample racks; empty spaces are permitted in any location(s). When placing Sample tubes in a Slide-in Sample Rack, verify that Sample tubes are pushed all the way down into the Rack and that all barcode labels are facing outwards.
- *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 duplicate ID is added.

5.4.2.2.7 Multiply Samples

In some situations, it may be desirable to load a single Sample tube in the Sample Racks, but process the Sample multiple times during the Worklist Run. This can be done using the **Multiply Samples** button. After Samples have been added to the Worklist, the user can select one or more Sample IDs in the Worklist grid and click the **Multiply Samples** button. The user can specify how many multiples of each selected Sample should be added to the Worklist. The selected Sample ID(s) is/are duplicated in the Worklist, but refer to the same Sample tube in the Sample Racks.

5.4.2.2.8 Remove Samples

The **Remove Samples** button can be used to remove Samples from the Worklist. The user can select Sample IDs from the Samples grid and then click/tap the **Remove Samples** button. The selected Samples will be removed from the Worklist. Once the Sample ID is removed from the Worklist, the user may remove the corresponding Sample tube from the Sample Racks. If the Sample tube is left on the Sample Racks during the Worklist run, the Sample tube will simply be ignored – that is, the Sample tube will not be processed during the Worklist run.

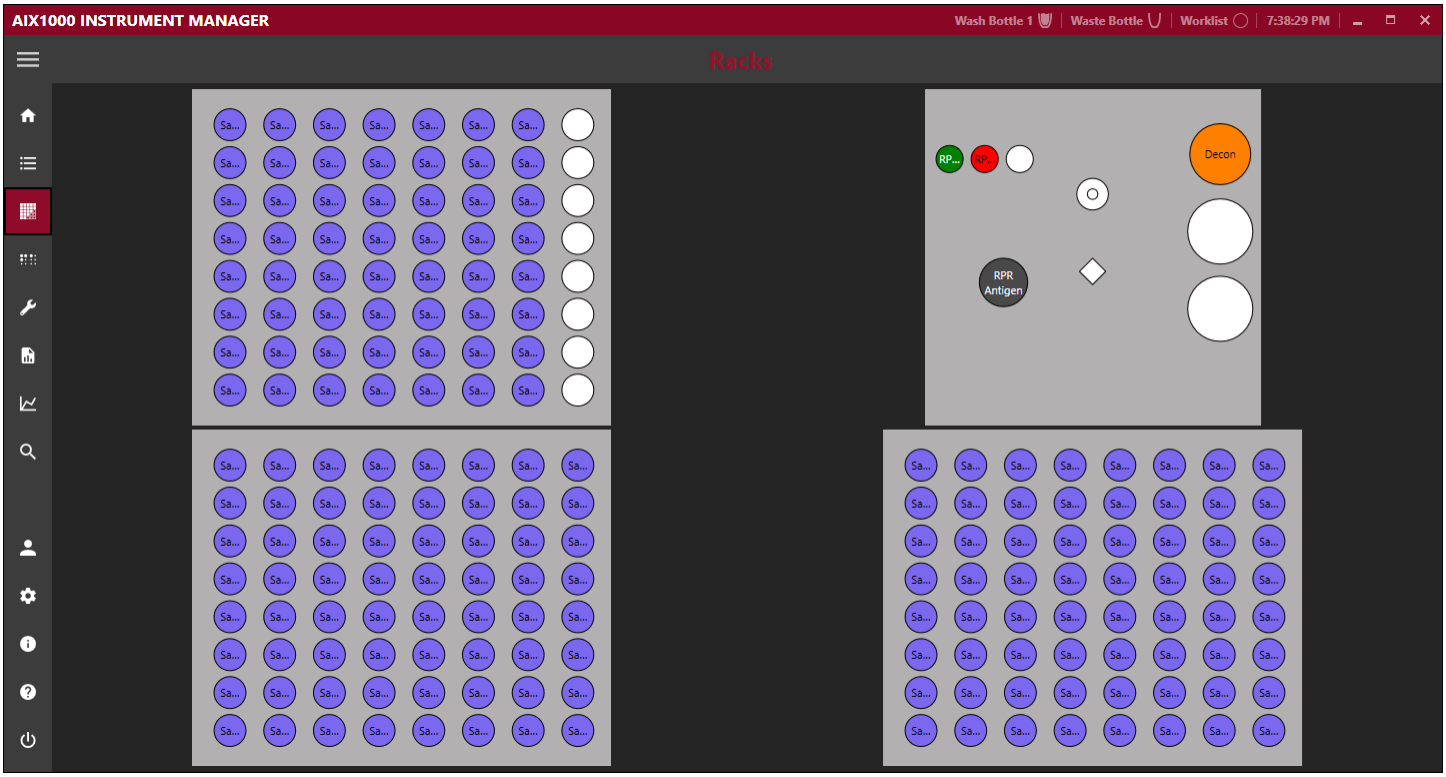
5.4.2.2.9 Query LIS

The Query LIS button allows the user to query the LIS for which RPR Test actions are to be run on the Sample IDs added to the Worklist. The Query LIS button is enabled if the AIX1000 system has been configured for use with an LIS. See **5.3.6 LIS SETTINGS** and **5.3.7 LIS ASSOCIATION** for details on configuring the AIX1000 system for use with an LIS. If the AIX1000 system is not configured for use with an LIS, then the Query LIS button will be disabled.

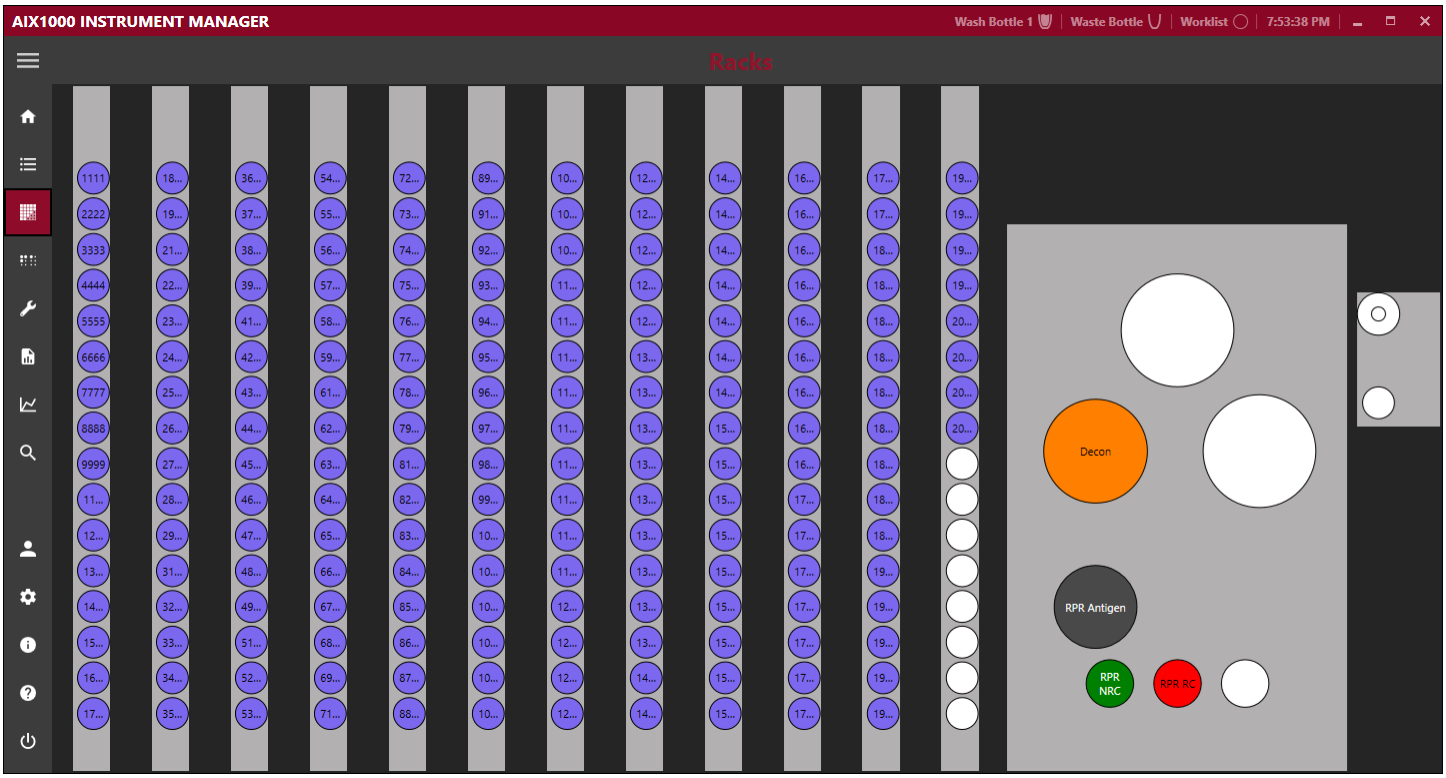
To query the LIS, the user should add Samples to the Worklist, then click/tap the Query LIS button. The AIX1000 system will communicate with the LIS and request which RPR Test actions have been ordered for the Samples in the Worklist. See **7.3.1 EXAMPLE 1: QUERY OF TEST ORDERS FOR SAMPLE IDS** for more details on how AIX1000 queries the LIS.

5.4.2.3 Racks

The **Racks** screen displays the current layout and status of the Sample Racks and Reagent Rack. The user can refer to this screen to verify placement of Samples, Reagents, and Controls on the instrument when configuring a Worklist. The Racks screen will appear differently depending on the model of the AIX1000 instrument being used (Classic Sample Rack model versus Slide-in Sample Rack model). These differences are shown below:



Racks screen for AIX1000 instrument with Classic Sample Racks



Racks screen for AIX1000 instrument with Slide-in Sample Racks

NOTICE: The image above is shown for the AIX1000 2.1 software running with an AIX1000 instrument model number 00400-Rev2. If the AIX1000 2.1 software is run with an AIX1000 instrument model number 00400-Rev3, the Reagent Rack will appear with additional Reagent bottle and Control bottle positions. Refer to ***4.2.4 REAGENT RACK*** *for an explanation of the differences in the Reagent Rack between the 00400-Rev2 and 00400-Rev3 instrument models.*

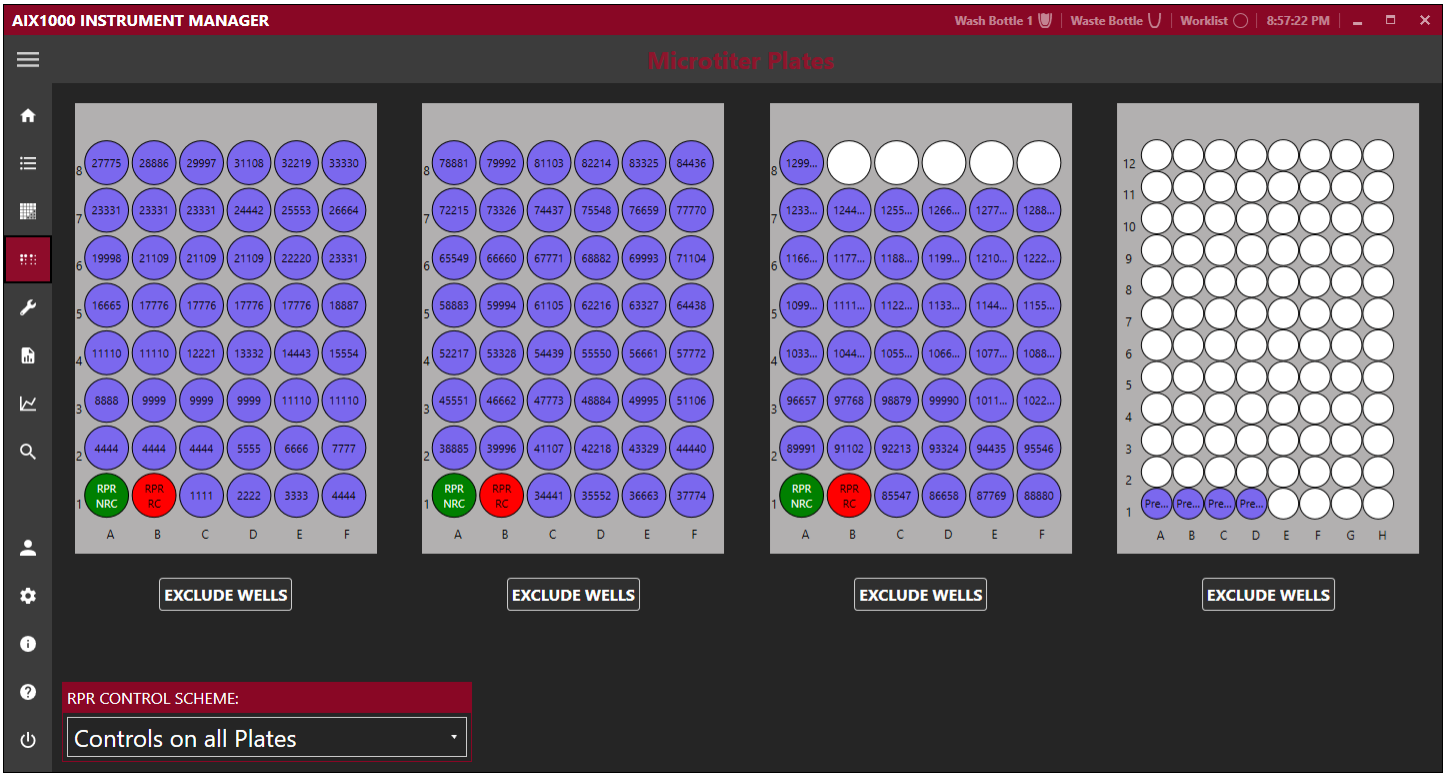
The Sample Racks on the **Racks** screen display the position of the Samples added to the Worklist. See **5.4.2.2.6 ADD SAMPLES** for details on adding Samples to a Worklist. Samples positions are labeled with their Sample ID and colors are used to indicate the status of the Sample position: Blue indicates the presence of a Sample tube; White indicates an empty position; Grey indicates an occupied position that is unused by the Worklist.

NOTICE: When a Worklist run is started, the Worklist Loading Wizard will guide the user through the process of adding reagents and Controls in the require positions.

The Reagent Rack on the **Racks** screen displays the position of the Reagents and Controls for the RPR Test. Reagent locations are automatically assigned according to the instrument model being used. The Reagent bottle and Control bottle positions are labeled and colored according to the Reagent definition in the RPR Test File. When loading Reagents in the instrument Reagent Rack, the user should be sure to follow the layout indicated on the screen.

5.4.2.4 Microtiter Plates

The Microtiter Plates screen is used to indicate the number of Wells, Strips, and Plates required for the Worklist run. All Well locations on the Microtiter Plate (MTP) positions and the Predilution Plate positions that are required to perform the RPR Test actions assigned to the Samples in the Worklist are displayed.



Additional information about each Well can be seen by hovering the mouse cursor over the Well. The **Microtiter Plates** screen should be used to visually confirm that all desired Test Wells and Samples appear on the MTP layout in the correct plate locations.

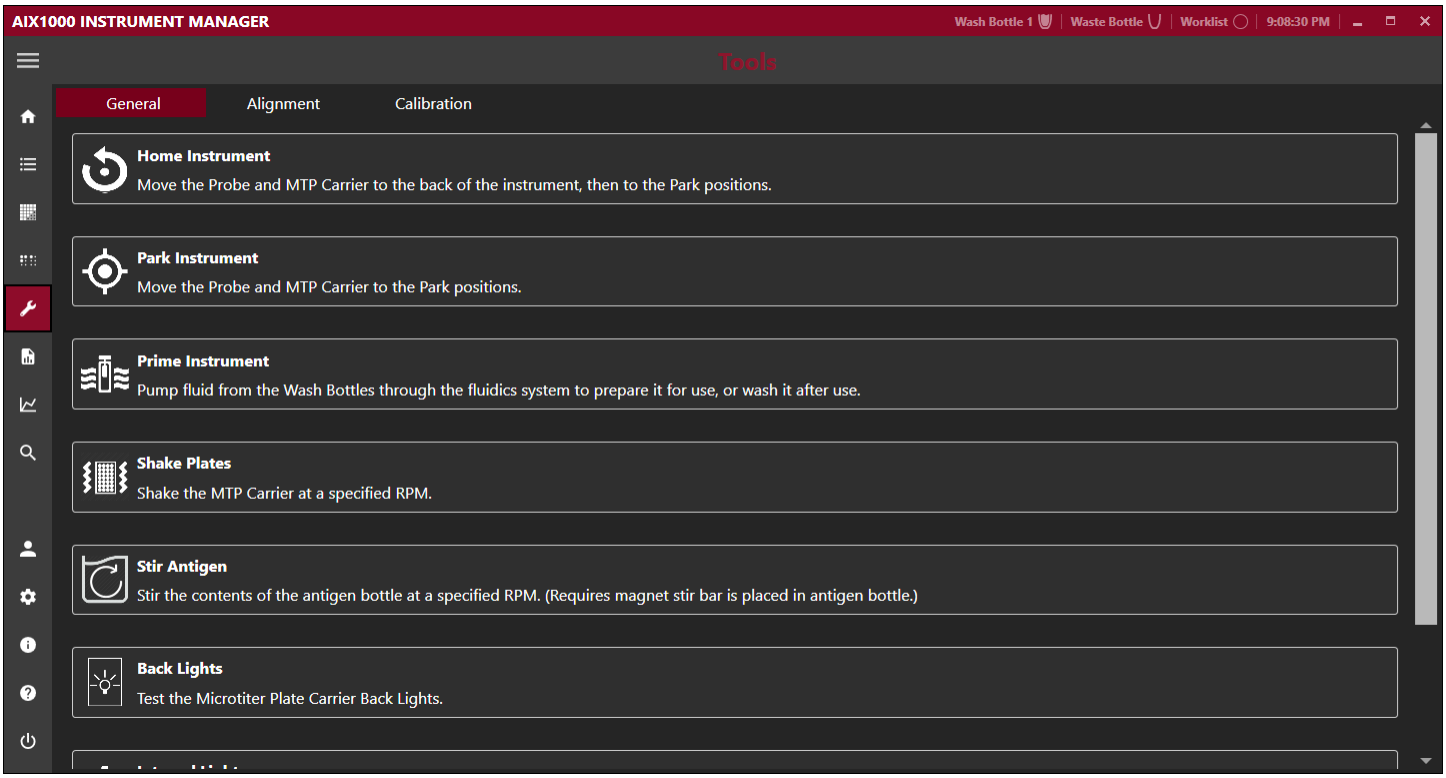
The layout displayed on the **Microtiter Plates** screen can be used to ensure the required number of Wells for the RPR Test actions to be run are secured into place in the appropriate plate frame(s), and that the plate frame(s) are placed in the proper locations in the MTP Carrier.

5.4.2.4.1 Exclude Wells

The **Exclude Wells** buttons allow the user to specify Wells of the Microtiter Plates that should not be used for processing during the Worklist run. This can be helpful if the user wishes to use partially used plates from previous Worklist runs. This user should specify which Microtiter Plate Wells should be excluded during Worklist preparation after Samples have been added to the Worklist.

5.4.2.5 Tools

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 and are organized into the sub-categories **General**, **Alignment**, and **Calibration**.



5.4.2.5.1 General

The **General** category provides access to general instrument functionality.

Home Instrument: Use this button to 'home' the instrument, just as is done automatically at startup. The probe and MTP carrier will move to the back of the instrument and then to their 'parked' positions.

Park Instrument: Use this button to reset the instrument back to its starting, or 'parked' position (with the probe assembly above the wash cup).

Prime Instrument: In the pop up window, select desired Wash Bottle(s) and number of priming cycles and click/tap the **Start** button. If both Wash Bottles are selected, the set number of priming cycles will be performed with Wash Bottle 1 and then immediately subsequently performed with Wash Bottle 2. Liquid from the wash bottle(s) will be pulled through the instrument fluidics system as the progress bar tracks priming cycle progress. Priming can be interrupted using the **Stop** button.

NOTICE: For models with Classic 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.

Shake Plates: Use this button to manually shake one to four plates on the Microtiter Plate Carrier. Select preferred speed using the +/- buttons. Use the **Start** and **Stop** buttons or set timer if desired.

Stir Antigen: Use this button to manually stir the contents of the RPR Antigen bottle in the Reagent Rack. Select the preferred stir speed using the **Speed (RPM)** slider control. Make sure the magnetic stir bar is placed in the RPR Antigen bottle when the bottle is placed in the Reagent Rack. **Stirrer On** check box to start and stop the stirrer.

Back Lights: Use this button to test the Microtiter Plate Carrier back lights.

Internal Lights: Use the slider bar to adjust default light intensity of the interior LED lights.

Maintenance Logs: Click/tap the **Maintenance Logs** button to view dates/times of all recent maintenance events (priming, probe and reader auto alignment, reader calibration, wash pump calibration). Select a month to add notes to that month's maintenance log or to display a maintenance report with all maintenance actions for that entire month (included any added notes), which can be saved/exported and/or printed.

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

5.4.2.5.2 Alignment

The **Alignment** screen provides tools to the user to align different components of the instrument. The instrument components are aligned regularly as part of the daily, weekly, and monthly maintenance procedures. The user should perform alignment as part of routine instrument maintenance as prompted by the AIX1000 Instrument Manager. The alignment tools on this screen can be used to align the instrument components outside of the maintenance procedures, as needed. Each alignment tool provides detailed step by step instructions which should be followed very carefully.

NOTICE: 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.

If an alignment procedure is cancelled and only partially completed, the user should be sure to fully complete the alignment procedure prior to the next instrument use.

NOTICE: The alignment procedures always start from default positions. They do not start from the last aligned position. This is to ensure alignment is as accurate as possible by avoiding alignment 'creep' across multiple alignments.

Manually Align Probe: Manual alignment of the instrument probe is available for legacy reasons with AIX1000 instruments with Classic Sample Racks. The **Manually Align Probe** button does not appear when using an AIX1000 instrument with Slide-in Racks. The user can click/tap the **Manually Align Probe** button to launch the **Manual Probe Alignment** wizard. The user should carefully follow the instructions for each step in the alignment process provided by the wizard.

NOTICE: Manual alignment is subject to variations depending on the user performing the alignment. It is highly recommended that auto-alignment is used instead to ensure the alignment is accurate and consistent.

Auto Align Probe: The user can click/tap the **Auto Align Probe** button to launch the **Auto Probe Alignment** wizard. The user will be required to perform some initial steps such as inserting auto-alignment plates, then the instrument will auto-align itself. The user should carefully follow the instructions for each step in the alignment process provided by the wizard.

If using an AIX1000 instrument with Classic Racks, the AIX1000 Auto-Alignment Kit (Part # 00188) should be used.

If using an AIX1000 instrument with Slide-in Sample Racks, the AIX1000 Auto-Alignment Kit for Slide-in Racks (Part # 00187AGSI) should be used.

Align Camera: The camera alignment process is performed to ensure that the camera is properly aligned for capturing images of Microtiter Plate Wells. The use can click/tap the **Align Camera** button to launch the **Align Camera** wizard. The user should carefully follow the instructions for each step in the alignment process.

The AIX1000 Camera Alignment and Focus Plate (Part # 00225) should be used to align (and focus) the Camera. The position of the hole on Camera Alignment and Focus plate has been aligned to the A1 well of a 48-well MTP:

Verify Alignments: The **Verify Alignments** tool is used to verify the positions of the current alignment. The user can click/tap the **Verify Alignments** button to launch the **Verify Alignment** wizard. The wizard will walk the user through each alignment position to show the user the current alignment offsets. No alignment adjustments can be made when verifying alignment positions.

5.4.2.5.3 Calibration

The **Calibration** screen provides tools to calibrate the different components of the instrument that require adjustment and correlation to a standard reference. Calibration procedures are typically performed by GSD Technical Service representatives or by trained and certified Distributor representatives. The calibration tools are made available on this

screen in case a user needs to perform calibration themselves. The user should only perform calibration procedures under the guidance of a GSD Technical Service representative or a trained and certified Distributor representative.

Verify Fluidics: The **Verify Fluidics** option is used to run a dye test to verify that the fluidics system of the instrument is working properly. The **Verify Fluidics** wizard will guide the user through a series of steps to compare manual dilutions of dye from the AIX1000 Dye Test Kit to dilutions performed by the instrument. Follow instructions as prompted to run the dye test and verify the fluidics.

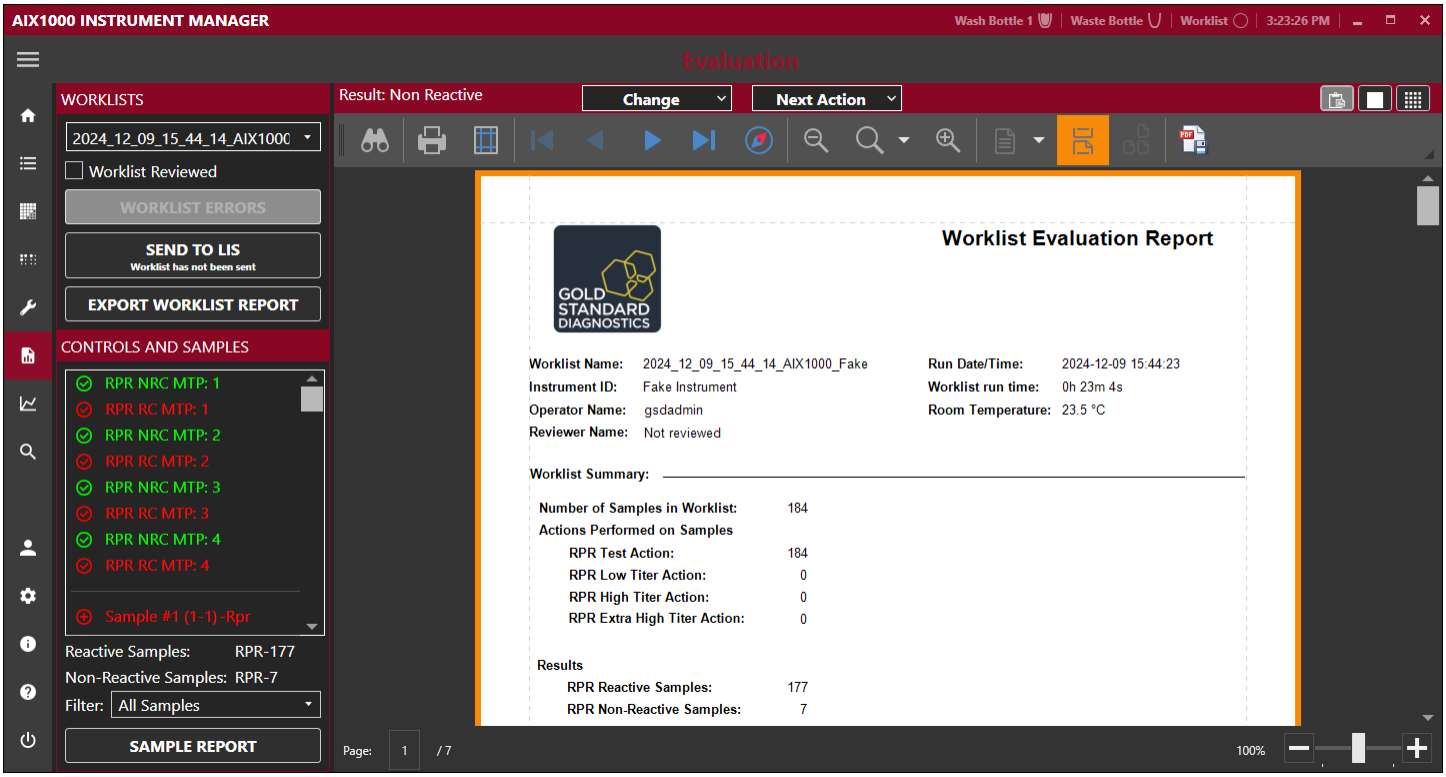
Focus Camera: The **Focus Camera** option is used to focus the high-resolution digital camera used to capture images of Microtiter Plate Wells. The user can click/tap the **Focus Camera** option to launch the **Focus Camera** window. The user should be sure to carefully follow all instructions in the **Focus Camera** window to focus the camera.

The AIX1000 Camera Alignment and Focus Plate (Part # 00225) should be used to focus (and align) the Camera.

Calibrate Wash Pump: The **Calibrate Wash Pump** option is used by service technicians to verify that the wash pump is functioning properly. To use, verify that wash buffer is loaded in the Wash 1 position and that a cuvette is in place in front of or next to the wash cup (as applicable for the instrument model being used), then click/tap the **Calibrate Wash Pump** button. Follow instructions as prompted to calibrate the wash pump.

5.4.2.6 Evaluation

The **Evaluation** screen is used to review Worklist run results. Worklist run results from all instruments connected to the same AIX1000 Server can be reviewed from any of the instrument computers running the AIX1000 Instrument Manager in Full Functionality mode, or from the server computer running the AIX1000 Instrument Manager in Evaluation Only mode. Users can view, export, and print Worklist reports, mark a Worklist run as reviewed, review Worklist run errors, and send results to the LIS on this screen. Users can also view, export, and print Sample Reports for a more detailed presentation of individual Sample results.



5.4.2.6.1 Worklists

The **Worklists** section allows the user to select a Worklist to review by selecting a Worklist name from the Worklists dropdown menu on the top left. The list of Worklists is obtained from the AIX1000 Server. Therefore, if multiple instruments are connected to a central server as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**, any Worklist from any of the instruments can be reviewed. Worklists are listed in order of date with the

most recent at the top of the list. The first Worklist in the list is selected by default when the Evaluation screen is initially opened. When a Worklist name is selected from the dropdown list, the Worklist Report for the selected Worklist is shown on the right.

5.4.2.6.2 Worklist Reviewed

The **Worklist Reviewed** checkbox is used as a flag to indicate if the Worklist has been reviewed or not. The Worklist Reviewed checkbox is enabled only if the logged-on user reviewing the Worklist has a User Account level of Super User or higher. See **5.3.2.2 USER LEVELS** for details about the capabilities of the different User Account levels.

After a user with account type of Super User or higher has reviewed the Worklist Report and determined the results are acceptable, they should check the **Worklist Reviewed** checkbox. The **Evaluation** screen will refresh to display the Worklist Report with the **Worklist Reviewer** field filled in with the reviewer's username. Checking the **Worklist Reviewed** checkbox will also allow other actions to be completed, such as **Send to LIS**, which require the Worklist results to be reviewed and approved before they can be performed.

5.4.2.6.3 Worklist Errors

The user can click/tap the **Worklist Errors** button to view and/or export any errors or anomalies from the Worklist run. This button will be disabled if the Worklist run did not contain any errors or anomalies. Worklist run errors and anomalies are also displayed on the Worklist report. Worklist errors and anomalies included events such as failed clog checks, insufficient Sample or Reagent volume detected, etc…

5.4.2.6.4 Send to LIS

The **Send to LIS** button is used to send the Worklist results to an LIS. The **Send to LIS** button is enabled only if the logged-on user has a User Account level of Super User or higher and LIS communication has been enabled for the AIX1000 system. See **5.3.2.2 USER LEVELS** for details about the capabilities of the different User Account levels. See **5.3.6 LIS SETTINGS** and **5.3.7 LIS ASSOCIATION** for details about enabling LIS communications.

The user can click/tap the **Send to LIS** button to open the **Send Results to LIS** window. The **Send to LIS** button includes a sub-label which indicates the date when the Worklist results were last sent to the LIS. If the Worklist results have never been sent to the LIS, the sub-label will display the text *'Worklist has not been sent'*.

If the Worklist has not yet been marked as reviewed when the user clicks/taps the **Send to LIS** button, a warning message will be displayed informing the user that the Worklist must be marked as reviewed before the results can be sent to the LIS. See **5.4.2.6.2 WORKLIST REVIEWED** for details.

The **Send Results to LIS** window displays a table of Sample results for the Samples in the Worklist. Results for a Test cannot be sent to the LIS if the Test does not have an LIS Test Name associated with it. See **5.3.7 LIS ASSOCIATION** for details about associating LIS Test Names with the AIX1000 RPR Test.

If the Test validation for the Sample result was successful, the Sample result is automatically selected (a checkmark is present in the first column) to be sent to the LIS. Otherwise, the Sample result is not selected. The user can select or unselect Sample results to be sent to the LIS by checking or unchecking the checkbox in the first column of the Send Results to LIS table.

The user can click the **Send** button to send the selected results to the LIS. The user can click the **Cancel** button to dismiss the **Send Results to LIS** window and not any results to the LIS.

5.4.2.6.5 Export Worklist Report

The **Export Worklist Report** button allows the user to export the Worklist Report currently selected. The Worklist Report can be exported to Microsoft Excel format (*.xlsx), PDF (*.pdf), or to Tab Separated Value (*.tsv) format.

5.4.2.6.6 Controls and Samples

The **Controls and Samples** list displays the Controls and Samples run in the selected Worklist. The Controls and Samples items in the list include an icon and are color coded to indicate their result. The tables below list the meaning of the icons and colors used:

Controls

Icon

Control passed

Control failed

Invalid Image

Color

Control Well Image evaluated to be Non-Reactive

Control Well Image evaluated to be Reactive

Samples

Icon

Sample Well Image evaluated to be Non-Reactive

Sample Well Image evaluated to be Reactive

Invalid Image

Color

Sample Well Image evaluated to be Non-Reactive

Sample Well Image evaluated to be Reactive

Selecting a Sample or Control in the list will display the associated result in the top left of the Evaluation view. If the Evaluation view is in **Image View** mode, **Titer View** mode, or **Grid View** mode then the associated image for the Sample or Control will be displayed.

If the selected Sample had a Titer action run on it (Low Titer, High Titer, or Extra-High Titer), a **Titrations** list will appear next to the **Controls and Samples** list showing the titers for the selected Sample. The Samples in the **Titrations** list use the following icon/color scheme to indicate Sample results:

Sample Titrations

Icon

Sample Well Image evaluated to be Non-Reactive

Sample Well Image evaluated to be Reactive

Sample Well Image evaluated to be Endpoint Titer

Invalid Image

Color

Sample Well Image evaluated to be Non-Reactive

Sample Well Image evaluated to be Reactive

Sample Well Image evaluated to be Endpoint Titer

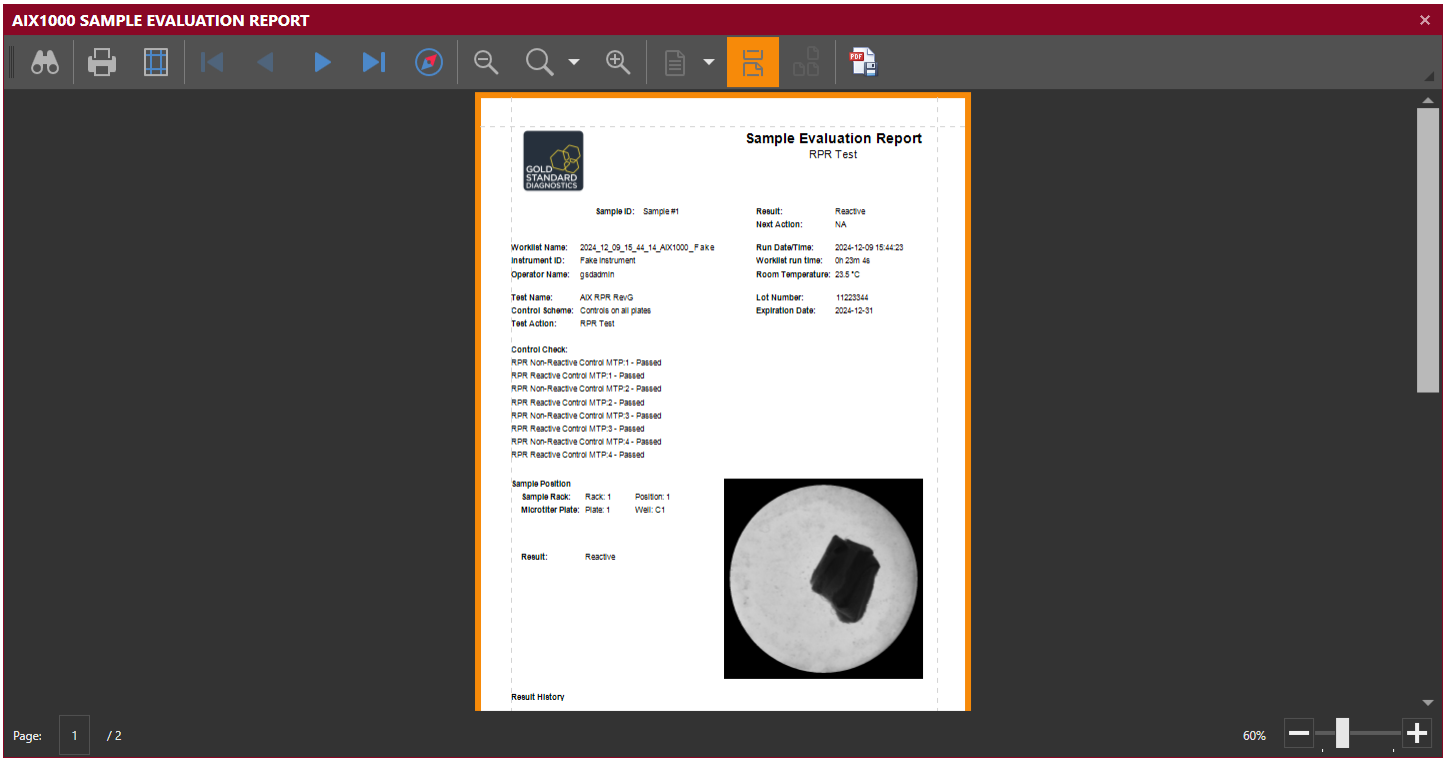
The **Controls and Samples** list includes a summary at the bottom showing how many Samples in the Worklist were evaluated to be Reactive and how many Samples in the Worklist were evaluated to be Non-Reactive.

The **Controls and Samples** list can also be filtered to show different sets of Samples. The choices are: All Samples, All Reactive Samples, All Non-Reactive Samples, RPR Titers >= 1:16, RPR Titers >= 1:256, RPR Titers >= 1:2048.

5.4.2.6.7 Sample Report

Clicking/Tapping the **Sample Report** button will generate a Sample Report for the Sample selected in the **Controls and Samples** list.

The Sample Report is a more detailed report that includes information about the Sample. This includes the result information from the Worklist report as well as the Sample Image and other detailed information about the Sample.



*NOTICE: If a Control is selected in the **Controls and Samples** list, then clicking/tapping the **Sample Report** button will generate a Control Report for the selected Control*

*NOTICE: If the user holds the SHIFT key down and clicks/taps the **Sample Report** button, Sample Reports for all Samples in the Worklist will be generated and combined into one large report.*

5.4.2.6.8 Change

The **Change** dropdown button at the top of the Evaluation view provides the user with options to change the result of all Samples in the Worklist, or change the result of the selected Sample in the **Controls and Samples** list. The user can change the result to Invalid (if the image was determined to contain some sort of artifact that interfered with the result determination), or the user can choose to accept the result determination of the AIX1000.

NOTICE: The user cannot set the result of the Sample to Reactive or Non-Reactive. This violates the Intended Use of the AIX1000 and is not allowed.

5.4.2.6.9 Next Action

The **Next Action** dropdown button at the top of the Evaluation view provides the user with options to set the Next Action for all Samples in the Worklist, or for the selected Sample in the **Controls and Samples** list. As mentioned in **5.4.2.6.11 WORKLIST REPORT VIEW**, the AIX1000 system will automatically suggest Next Actions for Samples based on their results. The **Next Action** button allows the user to override this automatic determination and explicitly set the Next Action for the Sample as desired. The Next Action setting is used the next time the Sample is added to a Worklist to be run. The Test action for the Sample will be set to the Next Action value when the Sample is added to the Worklist.

*NOTICE: The Next Action setting is only a suggestion and offered as a convenience to the user. The user can always explicitly set the Test action to be run on the Samples as described in **5.4.2.2.2 WORKLIST GRID**. The user can also allow the LIS to set the Test actions for the Samples in the Worklist as described in **5.4.2.2.9 QUERY LIS**.*

5.4.2.6.10 Evaluation View Buttons

The Evaluation View can display different information related the Worklist. A set of toggle buttons is provided in the top right corner of the Evaluation Window. These buttons allow the user to select which Worklist information they wish to view. See the next section for a description of the information displayed for each of the toggle buttons.

5.4.2.6.11 Worklist Report View

The **Evaluation** screen displays the Worklist Report information for the selected Worklist to allow the user to view the Test results and other information from the Worklist run. As mentioned in the previous section, the Evaluation View toggle buttons can be used to display different information for the Worklist.

By default, the **Worklist Report View** toggle button will be selected and the Worklist Report will be displayed. The Worklist Report provides information about the Worklist run and results for the RPR Test actions run on each Sample in the Worklist run.

The Worklist Report view contains a toolbar across the top with a set of controls which allow the user to navigate, search, print, and save the Worklist Report. The user can print the Worklist Report using the Print toolbar button. The user can also save the Worklist Report to a PDF file using the Save to PDF toolbar button.

The Worklist Report contains a header section which provides general information about the Worklist run. This includes the name of the Worklist, the date/time the Worklist run was performed, the ID of the AIX1000 instrument the Worklist was run on, and other general Worklist run information.

The Worklist Report contains a Summary section which provides a breakdown of the RPR Test Action run on the Samples in the Worklist. This includes the number of RPR Test (Screen) actions, the number of RPR Low Titer actions, the number of RPR High Titer actions, and the number of RPR Extra-High Titer actions. The Summary section also contains a breakdown of the Sample results: how many Reactive Samples were detected, how many Non-Reactive Samples were detected, what the overall Reactivity Rate for the Worklist run was, and the number of Sample Well Images that were determined to be invalid or were skipped. The Summary section also provides a breakdown of the status of the Worklist. This includes whether the Worklist has been reviewed, who it was reviewed by, and if the results were sent to the LIS.

The Worklist Report contains a Details section which provides more detailed information about the Worklist run. This includes information such as the name of the RPR Test that was run, the Lot Number of the RPR Test Kit used, the Expiration Date of the RPR Test Kit used, and the Control Scheme used for the Worklist run. Also included in the Worklist Details section is the list of RPR Control results run as part of the Worklist.

The Worklist Report contains an RPR Test section which provides a list of the Samples in the Worklist on which the RPR Test (Screen) action was run. The list includes the Sample ID, Microtiter Plate Position of the Well used for the Sample, Result (Reactive, Non-Reactive), and the suggested Next Action for the Sample.

Finally, the Worklist Report contains an RPR Titer section which provides a list of the Samples in the Worklist on which one of the RPR Titer actions (Low Titer, High Titer, Extra-High Titer) was run. The list includes the Sample ID, Microtiter Plate Position of the Wells used to titer the Sample, Result of the titer series (Reactive, Non-Reactive), Endpoint Titer of the titer series, and the suggested Next Action for the Sample.

The Sample results are reported as shown in the table below:

AIX RPR Test	AIX RPR Low Titer				AIX RPR High Titer				AIX RPR Extra-High Titer			Reported Result
	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512	1:1024	1:2048	
NR	-	-	-	-	-	-	-	-	-	-	-	NR
R	-	-	-	-	-	-	-	-	-	-	-	R
R	NR	NR	NR	NR	-	-	-	-	-	-	-	NR
R	R	NR	NR	NR	-	-	-	-	-	-	-	1:2
R	R	R	NR	NR	-	-	-	-	-	-	-	1:4

AIX RPR Test	AIX RPR Low Titer				AIX RPR High Titer				AIX RPR Extra-High Titer			Reported Result
	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512	1:1024	1:2048	
R	R	R	R	NR	-	-	-	-	-	-	-	1:8
R	R	R	R	R	-	-	-	-	-	-	-	>=1:16
R	R	R	R	R	NR	NR	NR	NR	-	-	-	NR
R	R	R	R	R	R	NR	NR	NR	-	-	-	1:32
R	R	R	R	R	R	R	NR	NR	-	-	-	1:64
R	R	R	R	R	R	R	R	NR	-	-	-	1:128
R	R	R	R	R	R	R	R	R	-	-	-	>=1:256
R	R	R	R	R	R	R	R	R	NR	NR	NR	NR
R	R	R	R	R	R	R	R	R	R	NR	NR	1:512
R	R	R	R	R	R	R	R	R	R	R	NR	1:1024
R	R	R	R	R	R	R	R	R	R	R	R	>=1:2048

Next Action: The AIX1000 system will provide a suggested Next Action for a Sample based on results for the Sample from previous Worklist runs. This suggested Next Action is only provided as a convenience to the user. The actual RPR Test Action run on a Sample can always be set by the user in the Worklist screen or overridden by an LIS Query (see **5.4.2.2.2 WORKLIST GRID** and **5.4.2.2.9 QUERY LIS** for details). The suggested Next Actions are shown in the table below:

Sample run in previous Worklist?	RPR Test Action in previous Worklist	Current Result	Next Action
N	N/A	N/A	RPR Screen
Y	AIX RPR (Screen)	Non-Reactive	No Action
Y	AIX RPR (Screen)	Reactive	RPR Low Titer
Y	AIX RPR Low Titer	Endpoint Titer Found - or - All titers Non-Reactive	No Action
Y	AIX RPR Low Titer	No Endpoint Titer Found (All titers Reactive)	RPR High Titer
Y	AIX RPR High Titer	Endpoint Titer Found - or - All titers Non-Reactive	No Action
Y	AIX RPR High Titer	No Endpoint Titer Found (All titers Reactive)	RPR Extra-High Titer
Y	AIX RPR Extra-High Titer	Endpoint Titer Found - or - All titers Non-Reactive	No Action

Sample run in previous Worklist?	RPR Test Action in previous Worklist	Current Result	Next Action
Y	AIX RPR Extra-High Titer	No Endpoint Titer Found (All titers Reactive)	No Action

5.4.2.6.12 Image View

Clicking/Tapping the **Image View** toggle button will cause the Evaluation view to display the Well image of the Control or Sample selected in the **Controls and Samples** list.

The user is encouraged to review the Well images to ensure that no artifact such as hair, dirt, or dust was captured in the Well image and potentially interfered with the result determination provided by the AIX1000 system. If the Well image contains artifact which may be interfering with the AIX1000 automatic result determination, the user can change the Sample result as described in **5.4.2.6.8 CHANGE**.

5.4.2.6.13 Grid View

Clicking/tapping the **Grid View** toggle button will cause the Evaluation view to display a grid of all Control and Sample Well images from the Worklist run. Selecting a Control or Sample in the **Controls and Samples** list will highlight the associated Control or Sample Well image in the grid view.

The user is encouraged to review the Well images to ensure that no artifact such as hair, dirt, or dust was captured in the Well image and potentially interfered with the result determination provided by the AIX1000 system. If the Well image contains artifact which may be interfering with the AIX1000 automatic result determination, the user can change the Sample result as described in **5.4.2.6.8 CHANGE**.

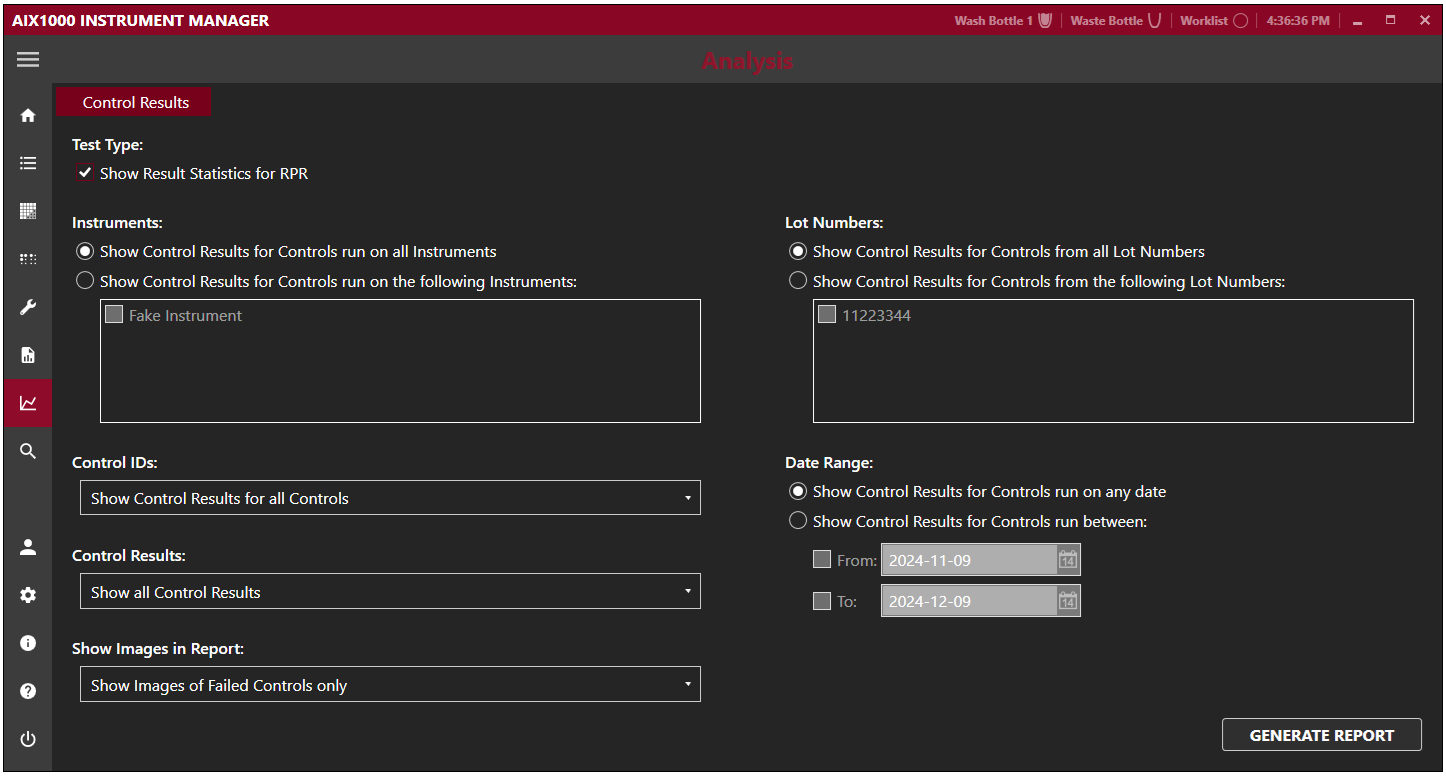
5.4.2.6.14 Titer View

If a Titer Test action (Low Titer, High Titer, Extra-High Titer) was run on the selected Sample in the **Controls and Samples** list, then the **Titer View** toggle button will appear in the top right corner of the Evaluation view. Clicking/tapping the **Titer View** button will cause the Evaluation view to show only the Well images in the Sample titer series.

The user is encouraged to review the Well images to ensure that no artifact such as hair, dirt, or dust was captured in the Well image and potentially interfered with the result determination provided by the AIX1000 system. If the Well image contains artifact which may be interfering with the AIX1000 automatic result determination, the user can change the Sample result as described in **5.4.2.6.8 CHANGE**.

5.4.2.7 Analysis

The **Analysis** screen is used to provide additional information regarding the performance of the AIX1000 system.



5.4.2.7.1 Control Results

The **Control Results** section allows the user to analyze the performance of the AIX1000 RPR Controls for the AIX1000 system. This can be helpful in troubleshooting instrument and/or RPR Test Kit lot issues.

The user can use the **Instruments** setting specify which instruments to include in the analysis. The user can specify all instruments, or specify a subset of instruments. See **5.1.1 Single Instrument Configuration** and **5.1.2 Multiple Instrument Central Server Configuration** for a description of AIX1000 systems with one or multiple instruments.

The user can use the **Control IDs** setting to specify which types of Controls to include in the analysis. The choices are All Controls, Non-Reactive Controls, or Reactive Controls.

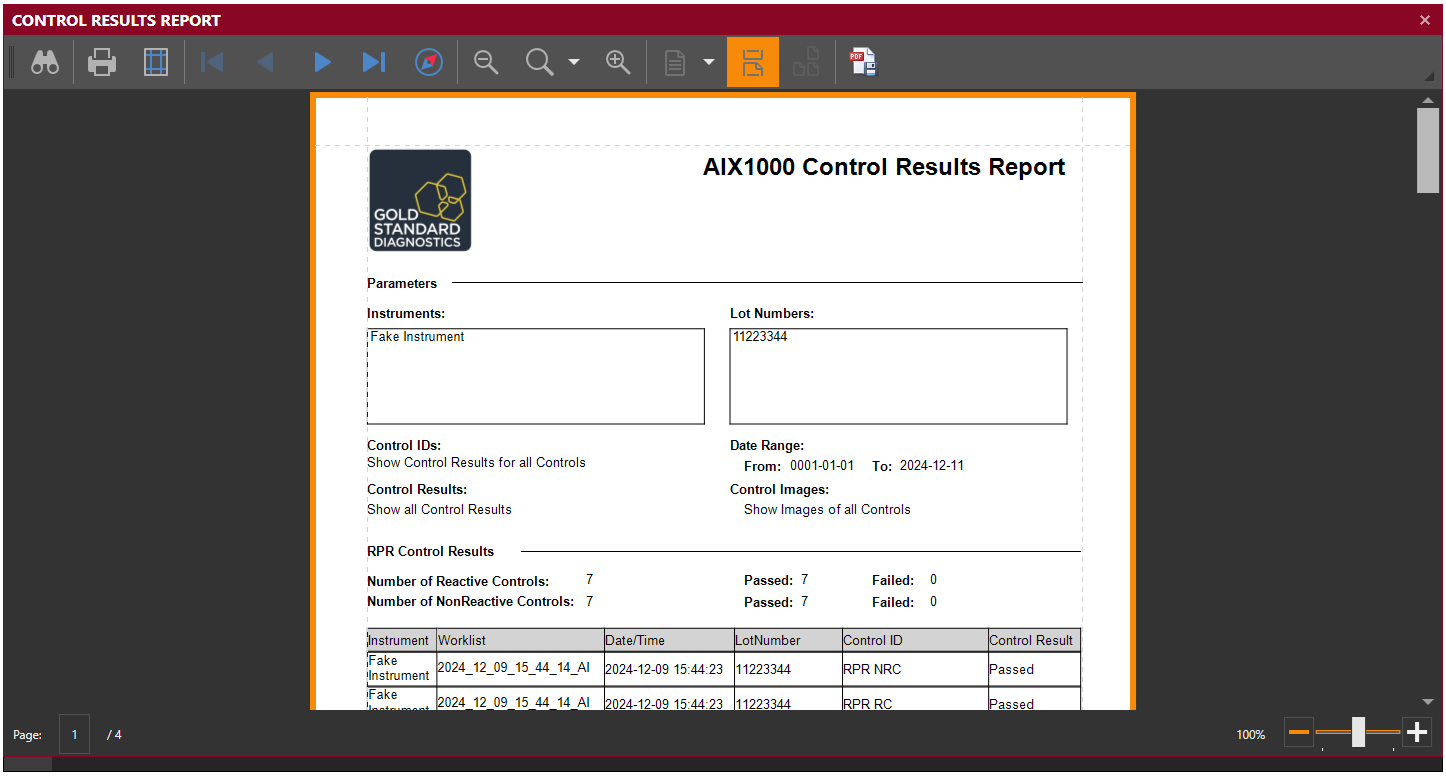
The user can use the **Control Results** setting to specify which Control results to include in the analysis. The choices are All Control Results, Only Controls that Failed, or Only Controls that Passed.

The user can use the **Show Images in Report** setting to specify if the Control Well images should be included in the analysis. The choices are Show Images of All Controls, Show Images of Failed Controls Only, Show No Images.

The user can use the **Lot Numbers** settings to specify which RPR Test Kit lots to include in the analysis. The user can specify to include Control results from all lots, or a subset of lots.

The user can use the **Date Range** settings to specify the dates to be included in the analysis. The user can specify to include Control results run on any date, or the user can specify to include Control results run between a specified date range.

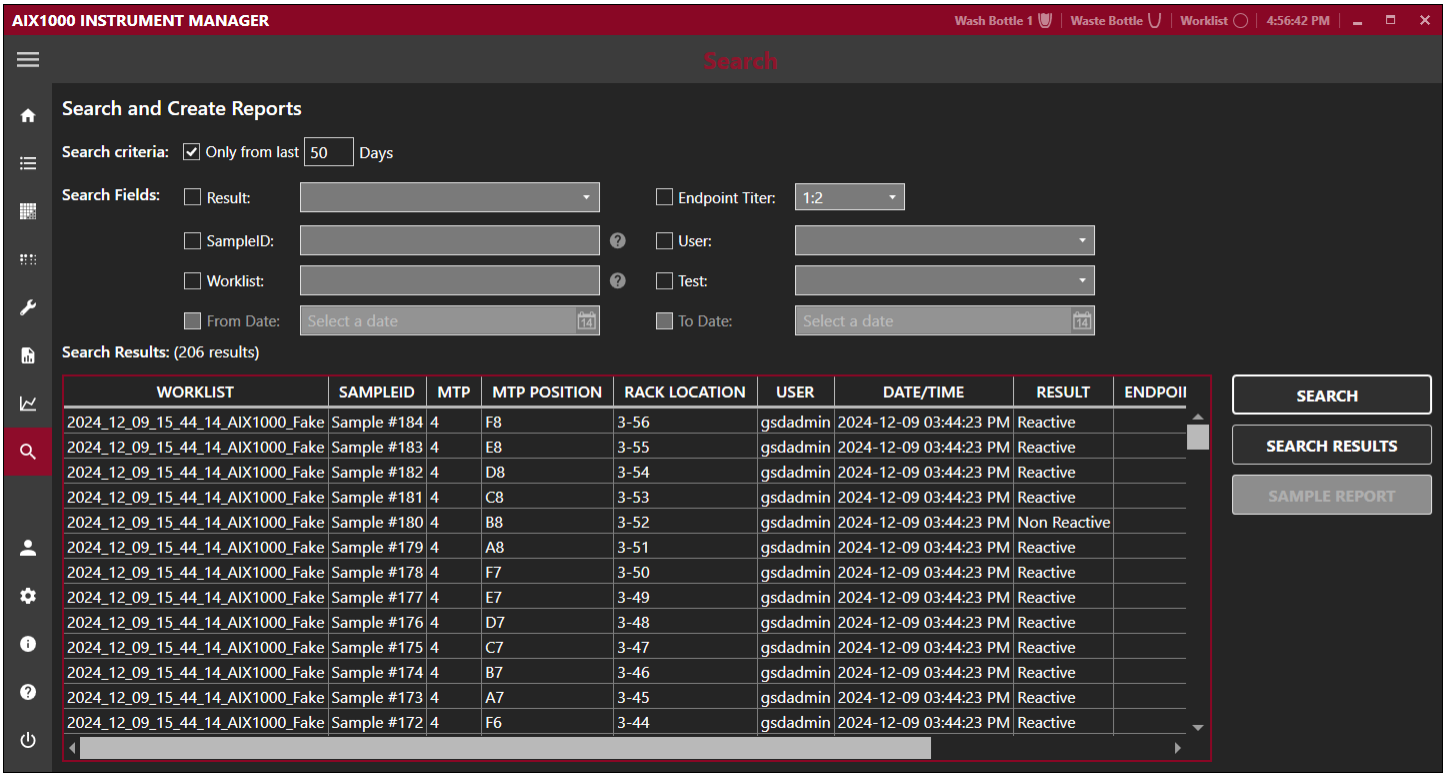
Once the user has configured the Control Results analysis as desired, they can click/tip the **Generate Report** button to display the Control Results report.



This report can be printed or saved to a PDF file as desired.

5.4.2.8 Search

The **Search** screen allows the user to search for results from any Worklist run in the AIX1000 system database.



The user can specify any combination of search criteria using the **Search Fields**. Once the desired search criteria has been set, the user clicks/taps the **Search** button to execute the search. The Search Results table is populated with the items found.

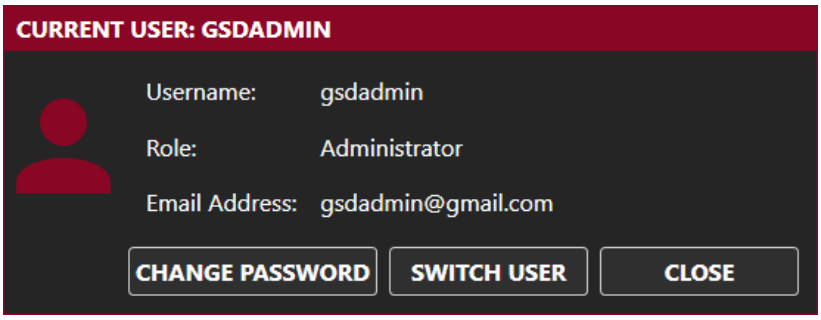
The user can double click/tap on a search item in the **Search Results** table to view the corresponding Worklist Report in the **Evaluation** screen.

The user can click/tap the **Search Results** button to export the search results to an Excel or Tab Separated Value (TSV) file.

The user can select a search result item in the **Search Results** table and click/tap the **Sample Report** button to generate a Sample Report for the selected item.

5.4.2.9 User

The **User** button will display the **Current User** window.



The **Current User** window displays information for the currently logged-on user. The user can change their password using the **Change Password** button.

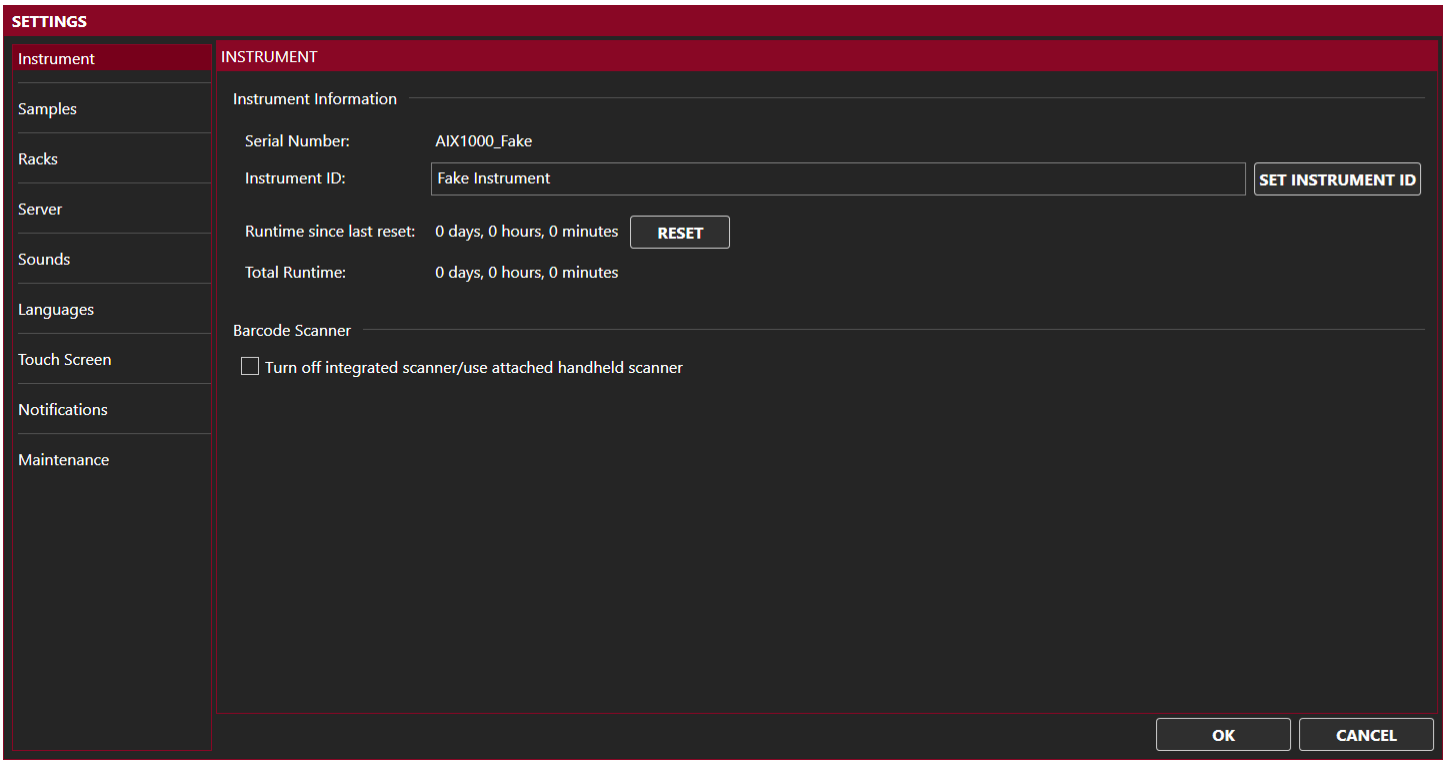
The **Current User** window also allows a different user to log on without the need to exit and restart the AIX1000 Instrument Manager. The user who wishes to log on can click the **Switch User** button and will be prompted with the **Select User** logon window. They can then select the desired user account and log on with the appropriate password to take control of the AIX1000 Instrument Manager session. All access privileges of the AIX1000 Instrument Manager session will be updated based on the User Account level used to log on. See **5.3.2.2 User Levels** for details about the capabilities of the different User Account levels.

5.4.2.10 Settings

The **Settings** button opens the **Settings** window which allows the user to configure settings specific to the AIX1000 Instrument Manager running on the instrument computer (as opposed to **5.3 AIX1000 System Configuration Tool** which allows the user to configure settings for the overall AIX1000 system).

The Settings button is only available if the logged-on user has a User Account level of Administrator or higher. See **5.3.2.2 User Levels** for details about the capabilities of the different User Account levels.

The **Settings** window provides a list of settings categories on the left-hand side. The user can click/tap the different categories to display the settings controls in view on the right-hand side of the window.



Once the user has configured the settings in the different categories as desired, they can click/tap the **OK** button to save the settings changes, or they can click/tap the **Cancel** button to discard the settings changes.

NOTICE: The AIX1000 Instrument Manager may need to be restarted before some settings changes will take effect. The AIX1000 Instrument Manager will notify the user of the need for a restart when appropriate.

5.4.2.10.1 Instrument

The **Instrument** settings view displays information about the instrument connected to the AIX1000 Instrument Manager and allows the user to configure some aspects of the instrument.

Instrument Information: This section of the Instrument settings view includes general information about the instrument.

Serial Number: This field displays the Serial Number of the connected instrument. This value cannot be changed by the user. This value is a unique identifier assigned incrementally or sequentially to the instrument by GSD, to uniquely identify it.

Instrument ID: This field displays the ID given to the instrument. The user can configure this to be any alpha-numeric value they desire to meet the needs of the laboratory. The instrument ID is used to identify the instrument on Worklist Reports.

Runtime since last reset: The **Runtime since last reset** field shows the Days, Hours, Minutes the instrument has been running since this value was last reset. This can be used when troubleshooting instrument issues to help determine how much the instrument has been run over a given time interval. The user can click/tap the **Reset** button to set this value back to zero.

Total Runtime: The **Total Runtime** field displays the total amount of time in Days, Hours, Minutes that the instrument has been run. This value does not reset. It gives and overall indication of how much the instrument has been run over the lifetime of the instrument.

Barcode Scanner: This section of the **Instrument** settings view includes information about the barcode scanner on the instrument.

Turn of integrated scanner/use attached handheld scanner: This setting is only used for AIX1000 instruments with Classic Sample Racks. The user can click/tap the checkbox to enable or disable the use of the built-in barcode scanner on the front of the instrument. If the checkbox is unchecked, the built-in barcode scanner will be used to scan barcodes. If the

checkbox is checked, the built-in barcode scanner will not be used. Instead, the user can plug in a handheld barcode scanner to the back of the instrument using one of the USB ports and scan barcodes with the handheld scanner.

5.4.2.10.2 Samples

The **Samples** settings view is used to configure how events regarding the processing of Samples are handled during Worklist runs.

Sample Rack Removal: This section of the **Samples** settings includes information about the removal of Sample racks.

Notify User When It Is Safe To Remove Samples: When this option is enabled, an alarm will sound during the Worklist run to notify the user when all Sample pipetting actions have been completed. The 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 run.

Aspiration Failure: This section of the Samples settings view includes information and settings related to the handling of aspiration failure events during a Worklist run.

Action when insufficient Sample volume detected: This setting allows the user to specify how the AIX10000 Instrument Manager should proceed during a Worklist run when there is not enough Sample fluid to process the current Sample. There are two options available:

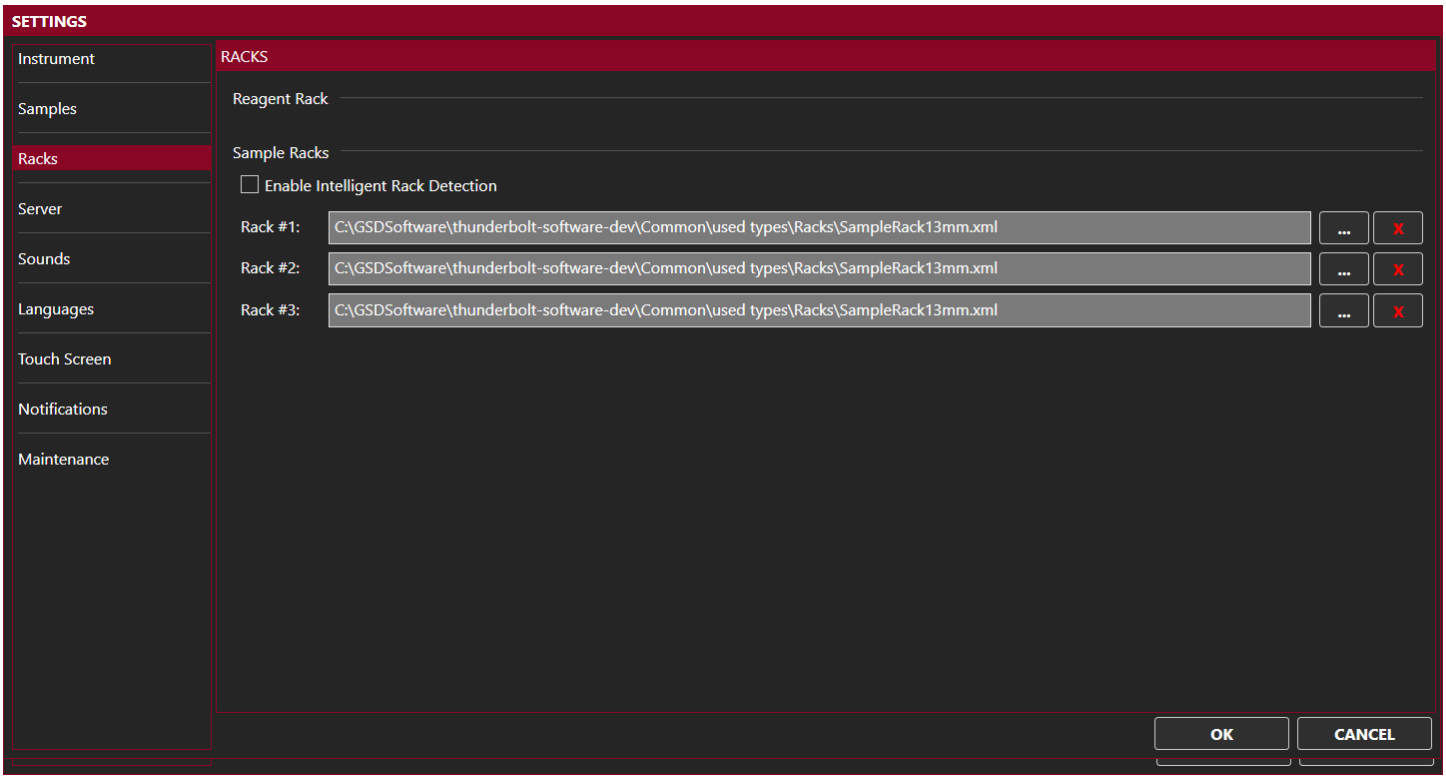
- *Automatically continue with next Sample*
  This option will cause the AIX1000 Instrument Manager to continue with a Worklist run when insufficient Sample volume is detected to process a Sample. The current Sample will not be processed. This event will be noted in the Worklist Status Log and the Error and Anomalies section of the Worklist Report and the skipped Sample will not have a result reported for it.
- *Ask the Operator*
  This option will cause the AIX1000 Instrument Manger to display a Bottle is Empty warning message and prompt the user for information on how to proceed when insufficient Sample volume is detected to process a Sample.

  The prompt that is displayed during a Worklist run when the Ask the Operator option is selected for insufficient Sample volume provides the user with information about the Sample tube that has low volume. The options for proceeding can consist of **Retry**, **Skip**, and **Abort Worklist**.

Number of retries when bubble destroyed: Insufficient volume detection can sometimes be caused by bubbles in the Sample tube. If the probe needles are lowered into a bubble (or pocket of air) in the bottle or tube, this may cause the AIX1000 Instrument Manager to determine there is no fluid present. If the bubble is destroyed, the volume detection may succeed. This option specifies how many times the AIX1000 Instrument Manager should lower the probe needles into the tube before determining there is insufficient volume. Multiple attempts may destroy the bubble and allow the final attempt to successfully detect the fluid.

5.4.2.10.3 Racks

The **Racks** settings view is used to configure the Reagent and Sample Racks used on the instrument. The Racks settings view will appear differently depending on the model of the AIX1000 instrument being used (Classic Sample Rack model versus Slide-in Sample Rack model). These differences are described below.



Racks settings for AIX1000 instrument with Classic Sample Racks

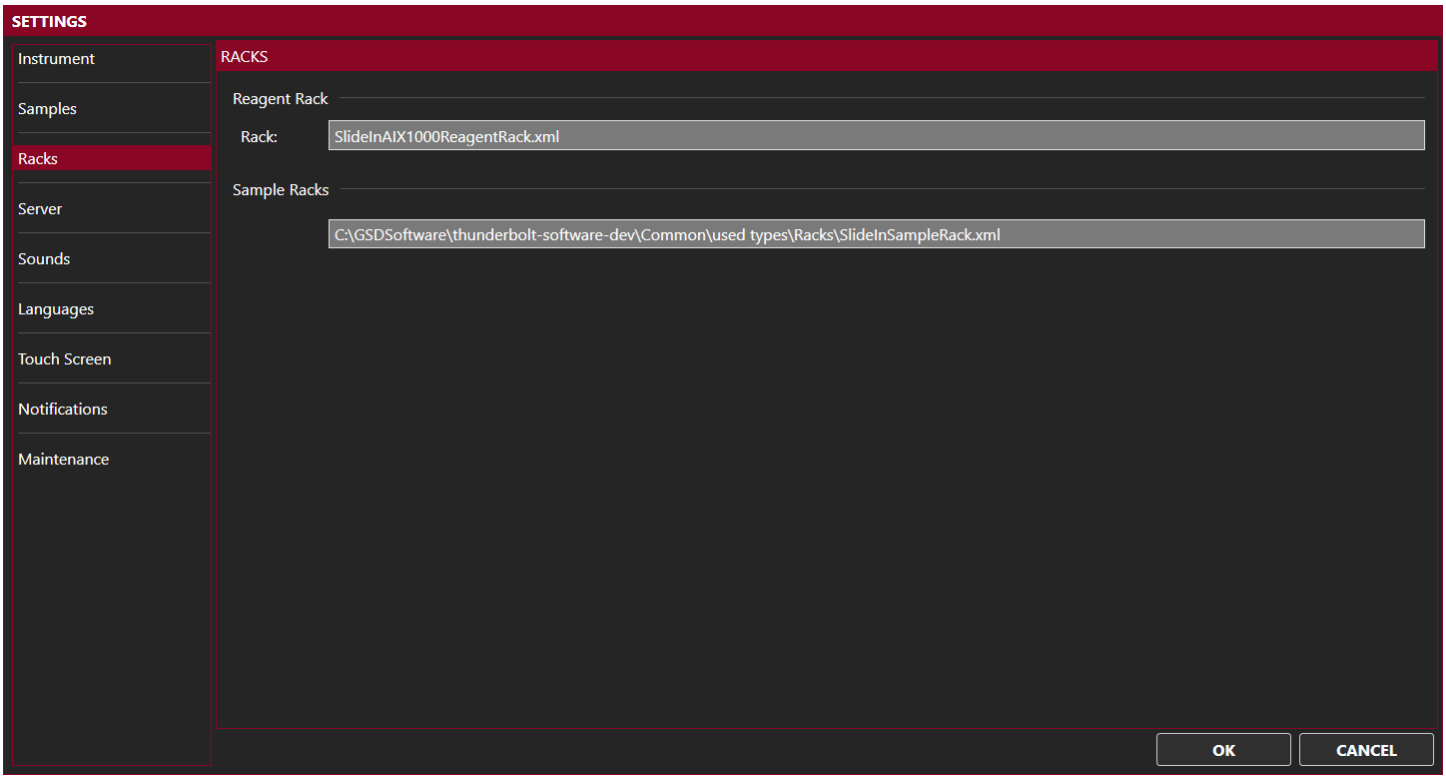
Reagent Rack: This section of the Racks settings view includes information and settings related to the Reagent Rack.

When using an AIX1000 instrument with Classic Sample Racks, the use cannot configure the Reagent Rack. There are no options for specifying a Reagent Rack configuration file. The AIX1000 software is automatically configured to use the Reagent Rack that comes on an AIX1000 instrument with Classic Sample Racks.

Sample Racks: This section of the Racks settings view includes information and settings related to the Sample Racks.

Enable Intelligent Rack Detection: This option enables or disables the Intelligent Rack Detection. The Intelligent Sample Racks contain magnets configured in different combinations which identify them as Sample Racks that support tubes of either 12mm, 13mm, or 16mm diameter. If this option is enabled, the AIX1000 system will detect the type of Sample Rack when it is placed on the instrument by sensing the magnet configuration. If this option is disabled, the Sample Racks are not identified automatically (the magnet configurations are ignored) and the user must specify the Rack configuration file corresponding to the Sample Racks being used for each of the three Sample Rack locationss on this Racks setting screen.

Enable Intelligent Rack Tube Detection: This option is only available if the **Enable Intelligent Rack Detection** option is enabled. The Classic Sample Racks contain a spring magnet at each Sample location. When a Sample tube is placed in a Sample location, this spring magnet is displaced. The AIX1000 system can detect the displacement of the Sample location spring magnet to indicate the presence of a Sample tube. If this option is enabled, the AIX1000 system will detect the presence of individual Sample tubes when they are placed in the Sample Racks. This allows the user to place Sample tubes anywhere on the Sample Racks during the **5.4.2.2.6 ADD SAMPLES** process and the AIX1000 system will automatically know the location. If this option is disabled, the AIX1000 system will not automatically detect the location. The user must place the Sample tube in the Sample Rack at the location specified by the AIX1000 software.



Racks settings for AIX1000 instrument with Slide-in Sample Racks

Reagent Racks: This section of the Racks settings view includes information and settings related to the Reagent Racks.

Rack: This setting specifies the Rack Definition file for the Reagent Racks. The Rack Definition file defines the physical rack dimensions and layout to the AIX1000 Instrument Manager software. By default, these values are set to the Rack Definition file for the Reagent Rack used with the Slide-in Sample racks (the correct Reagent Rack Definition file is automatically selected based on the AIX1000 instrument model 00400-Rev2 or 00400-Rev3). The user cannot change this setting.

Sample Racks: This section of the Racks settings view includes information and settings related to the Sample Racks.

The field in this section identifies the default Sample Rack Definition file used for all slide-in rack positions. This value is not editable. The default Sample Rack can hold 12mm, 13mm, or 16mm Sample tubes and, therefore, it is not necessary to specify different Sample Racks for the slide-in rack positions. The user cannot change this setting.

5.4.2.10.4 Server

The **Server** settings view is used to configure how the AIX1000 Instrument Manager should communicate with the AIX1000 Server.

Server Location: This section of the **Server** settings view includes information and settings related to how where the AIX1000 Sever is located and how the AIX1000 Instrument Manager can connect to it.

Local Computer: This option indicates that the AIX1000 Server is running on the same local computer that the AIX1000 Instrument Manager is running on. This option is used when the AIX1000 system is configured in a Single Instrument Configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION**. If this option is selected, the AIX1000 Instrument Manager will attempt to connect to the AIX1000 Server running on the local computer.

Remote Computer: This option indicates that the AIX1000 Server is running on a separate remote computer. This option is used when the AIX1000 system is configured in a Multiple Instrument configuration as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**. This AIX1000 Server computer must be connected to the instrument computer via a TCP/IP network connection. The IP Address field indicates the IP address of the computer on which the AIX1000 Server is running. If this option is selected, the AIX1000 Instrument Manager will attempt to connect to the AIX1000 Server running on the remote computer located at the IP address specified. Consult with your laboratory IT representative for information regarding IP addresses.

Evaluation: This section of the **Server** settings view includes information and settings related to information the AIX1000 Server will provide for the evaluation of Worklists.

Maximum number of Worklists in Evaluation Tab: The Worklists dropdown on the AIX1000 Instrument Manager Evaluation screen provides a list of Worklists the user can select to evaluate (see **5.4.2.6.1 WORKLISTS** for details). The AIX1000 Server provides this list with Worklist names starting from the newest to oldest. This option specifies how many Worklists the AIX1000 Server will provide to the AIX1000 Instrument Manager for evaluation.

5.4.2.10.5 Sounds

The **Sounds** settings view is used to configure the sounds the AIX1000 Instrument Manager uses for different event notifications.

Enable sound at end of run: This option allows the user to specify if the AIX1000 Instrument Manager should play a sound at the end of a Worklist run. If it is enabled, a sound will be played at the end of a Worklist run. If disabled, no sound will be played.

Enable audio alarm for wash/waste bottles: This option allows the user to specify is an audio alarm will be played to notify the user of Wash bottles being empty or the Waste bottle being full. If this option is enabled, an audio alarm will be played. If this option is disabled, not audio alarm will be played.

Customize sounds: This section of the **Sounds** settings view allows the user to customize the sounds used for different event notifications. The first five event sound notifications **Wash/Waste Bottles**, **End of Run**, **Drop between needles**, **Reagent/Sample tube empty**, and **Incubation Time Exceeded** are set to default sound files. The **Add Sample** and **Remove Sample** event sound notifications are set to *'No Sound'* by default. The user can click the **…** button for any of the event sound notification settings to display a File Open and select a .wav file to be used for the event sound notification. The user can click the **X** button to set the event sound notification value back to the default setting.

5.4.2.10.6 Languages

The **Languages** settings view is used to specify the language/locale in which the AIX1000 Instrument Manager should be displayed.

Select the desired display language: This setting allows the user to select a language/locale in which the AIX1000 Instrument Manager should be displayed. When the Automatic Language Selection item is selected, the AIX1000 Instrument Manager will be displayed in the same language/locale as the Windows operating system. When any other language/locale is selected from the list, the AIX1000 Instrument Manager will be displayed in that language/locale regardless of the Windows operating system language/locale setting.

NOTICE: By default, the list of available languages/locales includes only two choices: Automatic Language Selection and English. An AIX1000 Language Pack must be installed for more choices to be available. If an AIX1000 Language Pack is not installed, the AIX1000 Instrument Manager will always be displayed using its native U.S. English language/locale. In addition, if the Automatic Language Selection setting is selected and the Windows operating system is using a language/locale that is not supported by the AIX1000 Language Pack, then the AIX1000 Instrument Manager will revert to its native U.S. English language/locale. Contact a GSD Technical Service representative or your Distributor for more information regarding AIX1000 Language Packs.

5.4.2.10.7 Touch Screen

The **Touch Screen** settings view is used to specify how the AIX1000 Instrument Manager should provide touch screen interaction.

NOTICE: The AIX1000 Instrument Manager supports all basic touch screen interaction by default. When the AIX1000 Instrument Manager is run on a netbook computer with a touchscreen, the user can use all basic touch screen input methods and gestures when interacting with the software.

5.4.2.10.8 Notifications

The **Notifications** settings view is used to configure SMS and/or Email notification messages to be sent to users of the AIX1000 system for events that occur on the instrument connected to the AIX1000 Instrument Manager.

NOTICE: In order for a AIX1000 system user to receive SMS and/or Email notification messages, the user account must include a mobile phone number and/or email address. If the user account was defined without a mobile phone number,

then the user will not be able to receive SMS notification messages. If the user account was defined without an email address, then the user will not be able to receive Email notification messages. See **5.3.2 USERS** for more details.

NOTICE: The AIX1000 system must be connected to the internet in order to use SMS and/or Email notifications. See your Laboratory IT for information about whether your AIX1000 system has internet access.

Worklist Operator Notifications: This section of the Notifications settings view includes information and settings related to notification messages sent to the user currently logged-on to the AIX1000 Instrument Manager operating the instrument and performing Worklist runs.

Send SMS Text Notification: This option allows the user to specify if SMS notifications should be sent to the currently logged-on user who is operating the instrument and performing Worklist runs. If this option is enabled, the user will receive SMS notifications for events that occur on the instrument. The alarms and events that the user will receive notifications for are: Worklist End, Bottle Refill, Wash Bottle Empty, Waste Bottle Full, Clogged Probe, Fluid Detection Error, and other Miscellaneous Worklist Errors.

Send Email Notification: This option allows the user to specify if Email notifications should be sent to the currently logged-on user who is operating the instrument and performing Worklist runs. If this option is enabled, the user will receive email notifications for events that occur on the instrument. The alarms and events for which the user will receive notifications are: Worklist End, Bottle Refill, Wash Bottle Empty, Waste Bottle Full, Clogged Probe, Fluid Detection Error, and other Miscellaneous Worklist Errors.

Additional User Notifications: This section of the Notifications settings view includes information and settings related to notification messages sent to AIX1000 system users other than the user currently logged-on to the AIX1000 Instrument Manager operating the instrument and performing Worklist runs. These settings can be useful if the user logged-on to the AIX1000 Instrument Manager operating the instrument needs backup to handle alarms or notifications.

Additional User Table: This table provides a list of AIX1000 system users not currently logged-on to the AIX1000 Instrument Manager. The table displays the user name, the user mobile phone number (if defined in the user account), and the user email address (if defined in the user account).

NOTICE: The mobile phone number and email address are partially obscured with asterisk characters (*) to protect the privacy of the user.

The user can select users from the list in the table and configure the alarms and/or events the user should receive notifications before in the Alarms/Events for selected User settings below.

Alarms/Events for selected User: These options allow the user to specify which alarms and/or events the user selected in the Additional User Table should receive notifications for. The user can specify whether the selected user should receive SMS and/or Email notifications for the following alarms and events: Worklist End, Bottle Refill, Wash Bottle Empty, Waste Bottle Full, Clogged Probe, Fluid Detection Error, and other Miscellaneous Worklist Errors.

5.4.2.10.9 Maintenance

The **Maintenance** settings view is used to configure aspects of the maintenance procedures for the instrument.

Weekly Maintenance: This section of the Maintenance settings view includes information and settings related to the execution of the Weekly Maintenance procedures.

Perform Weekly Maintenance on: These settings allow the user to specify the day of the week and time of the day the Weekly Maintenance procedures should be performed. The user can use the Day dropdown to select the desired day of the week and the Time dropdown to select the time of the day.

Perform Weekly Maintenance at: This setting allows the user to specify if the Weekly Maintenance procedures should be run at system startup (when the instrument is powered on) or at system shutdown (when the instrument is powered off).

5.4.2.11 Information

The **Information** button opens the **About** window which displays version and copyright information for the AIX1000 Instrument Manager.

5.4.2.12 Help

The **Help** button opens a copy of this User's Manual on the instrument computer.

5.4.2.13 Power

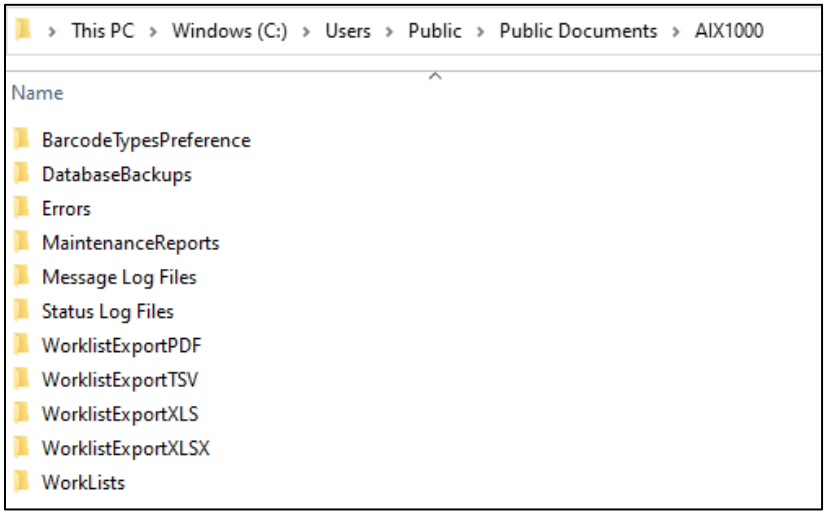
The **Power** button is used to exit the AIX1000 Instrument Manager software and power off the instrument/computer. Daily shutdown maintenance procedures will be prompted.

5.5 AIX1000 Software Folders

The AIX1000 system software (AIX1000 Server, AIX1000 System Configuration Tool, AIX1000 Instrument Manager) stores data and information files in the Windows file system at the location:

```
C:\Users\Public\Public Documents\AIX1000
```

The data and information files are stored in sub-folders based on the type of data and information they contain. Examples of the type of data and information include database backups, Worklist files, error logs, and more.



If the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 Single Instrument Configuration**, all these files will be located in sub-folders under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer.

If the AIX1000 system is being run in the Multiple Instrument Configuration as described in **5.1.2 Multiple Instrument Central Server Configuration**, some of these files will be located on the instrument computer, and some will be located on the server computer. The computer on which the files and sub-folders are stored depends on which AIX1000 system component they are associated with. Files associated with the AIX1000 Instrument Manager will be located in sub-folders under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer. Files associated with the AIX1000 Server or the AIX1000 System Configuration Tool will be located in sub-folders under the C:\Users\Public\Public Documents\AIX1000 folder on the server computer.

The following sub-sections describe each of the folder locations and the files they contain.

5.5.1 DatabaseBackups

This is the recommended/default location for any database backups created via the AIX1000 System Configuration Tool.

If the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 Single Instrument Configuration**, this folder is located under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer.

If the AIX1000 system is being run in the Multiple Instrument Configuration as described in **5.1.2 Multiple Instrument Central Server Configuration**, this folder is located under the C:\Users\Public\Public Documents\AIX1000 folder on the server computer.

*Notice: This folder is only the recommended/default location for database backup files. When a backup of the database is performed, the user has the ability to specify any folder to which the backup should be saved. See **5.3.5.1 BACKUP** and **5.3.5.3 SCHEDULED BACKUP** for details.*

5.5.2 Errors

Errors that are encountered during use of the AIX1000 system are logged in a file named by the date and time at which they occur and stored in the Errors subfolder as text files:

```
AIX1000InstrumentManagerError_2024-12-11T15.43.24.txt
```

If the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION**, this folder is located under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer.

If the AIX1000 system is being run in the Multiple Instrument Configuration as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**, this folder is located under the C:\Users\Public\Public Documents\AIX1000 folder on the server computer.

5.5.3 LISLogging

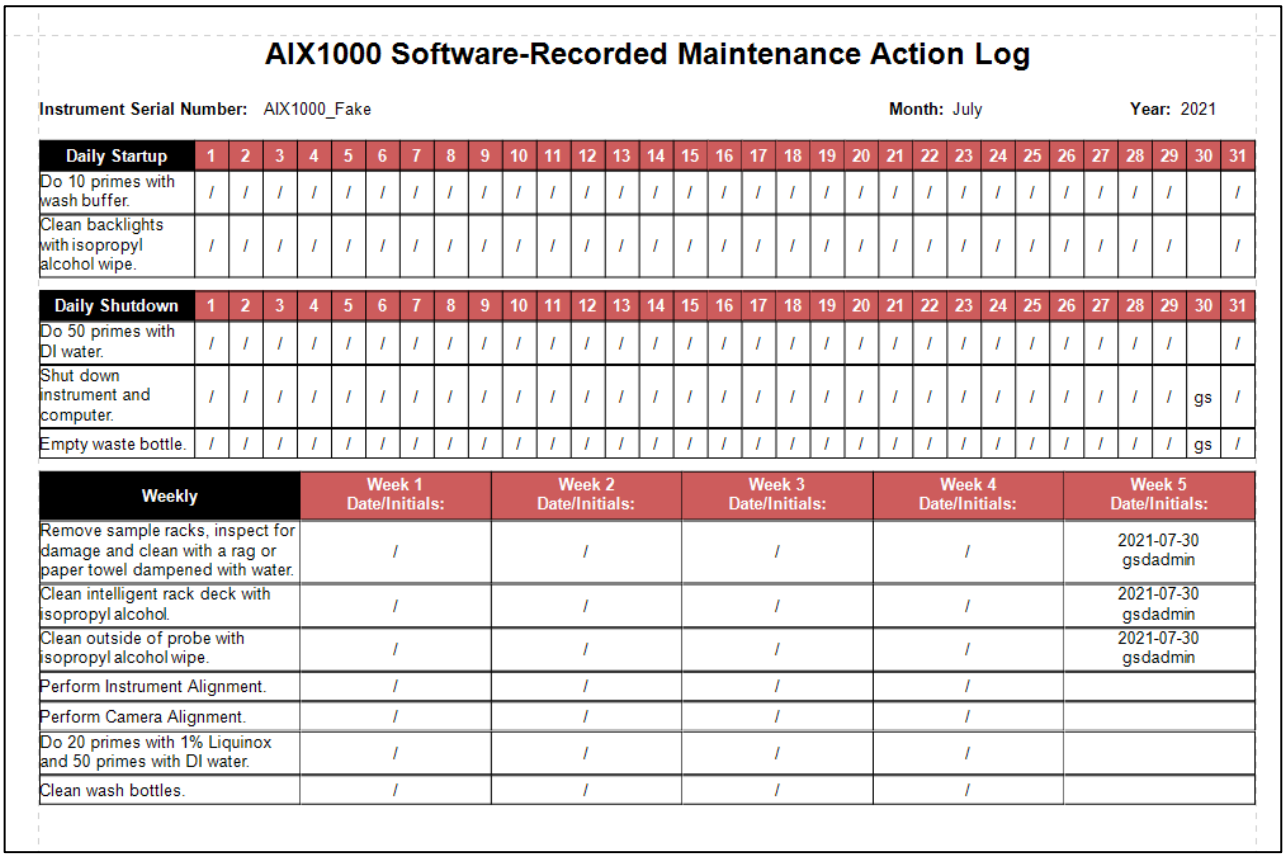
If LIS logging is enabled as described in **5.3.6 LIS SETTINGS**, LIS log files will be stored in this folder.

If the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION**, this folder is located under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer.

If the AIX1000 system is being run in the Multiple Instrument Configuration as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**, this folder is located under the C:\Users\Public\Public Documents\AIX1000 folder on the server computer.

5.5.4 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.	/	/	/	/	

The Maintenance Reports folder is always located under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer, regardless of whether the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION** or in the Multiple Instrument Configuration as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**.

5.5.5 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).

The Message Log Files folder is always located under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer, regardless of whether the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION** or in the Multiple Instrument Configuration as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**.

5.5.6 Status Log Files

The Status Log files record all actions and events from a Worklist run, including any anomalies encountered (such as bubble retries). These Status Log files are automatically saved as text files, named with the Worklist name and status (completed, stopped, etc…), and organized into sub-folders for each month, in the Status Log Folder.

```
worklistRun1122_2024-12-11T15-59-34_Completed.txt
worklistRun3434_2024-12-11T16-15-22_Stopped.txt
```

The Status Log Files folder is always located under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer, regardless of whether the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION** or in the Multiple Instrument Configuration as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**.

5.5.7 Worklist Export

Worklist reports exported from the Evaluation screen of the AIX1000 Instrument Manager as tab separated value (*.tsv) files and Excel (*.xlsx) files are stored by default in the Worklist Export TSV and Worklist Export XLSX subfolders, respectively.

The exported Worklist folders are always located under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer, regardless of whether the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION** or in the Multiple Instrument Configuration as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**.

5.5.8 Worklists

Worklists are automatically saved, named with the worklist name, and organized into folders for each month, in the Worklists subfolder. These can be opened from within the Storm Instrument Manager using the Load button on the Worklist screen. See **5.4.2.2.4 LOAD** for details.

This folder is always located under the C:\Users\Public\Public Documents\AIX1000 folder on the instrument computer, regardless of whether the AIX1000 system is being run in the Single Instrument Configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION** or in the Multiple Instrument Configuration as described in **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**.

6 Maintenance

Maintenance procedures should be followed to ensure proper instrument functionality. Maintenance actions are automatically recorded by the software and monthly Maintenance Reports are accessible as described in **5.4.2.5.1 TOOLS>GENERAL>MAINTENANCE LOGS**. The information below describes the routine maintenance steps for the system.

6.1 Daily Maintenance

Daily maintenance includes startup and shutdown tasks. Startup tasks are prompted and should be performed when the AIX1000 Instrument Manager is opened, prior to the first Worklist run of the day. Shutdown tasks are prompted and should be performed following the last Worklist run of the day, when the AIX1000 Instrument Manager is closed and the instrument is powered off.

6.1.1 Startup Maintenance Tasks

The Startup Maintenance consists of the following tasks:

1. Daily Startup Prime
   The user should ensure the Wash Bottle is properly connected to the instrument and contains the appropriate Wash Buffer. The user should also ensure that the Wash Buffer is within its expiration date prior to each use. The user should also ensure that an empty Waste Bottle is properly connected to the instrument. The Daily Startup Prime consists of 20 priming cycles to ensure the fluidics lines are properly primed prior to the first Worklist run of the day.
2. Clean the Backlights of the MTP Carrier
   The user should clean the Backlights of the MTP Carrier with an alcohol wipe. Debris on the backlights could interfere with sample image interpretation; maintenance of backlights is important for proper system function.

Notice: If the instrument is idle for four or more hours after the Daily Startup Prime is performed, it is recommended that the user prime the instrument again prior to a Worklist run. The user can prime the instrument as described in **5.4.2.5.1 TOOLS>GENERAL>PRIME INSTRUMENT**. *This will help ensure that any potential build-up is cleared from the fluidics lines.*

6.1.2 Shutdown Maintenance Tasks

Use the Power button within the AIX1000 Instrument Manager software to shut down the instrument and attached computer. The Shutdown Maintenance consist of the following tasks:

1. Daily Shutdown Prime
   The user should ensure the Wash Bottle is properly connected to the instrument and contains deionized (DI) water. The user should also ensure that a Waste Bottle is properly connected to the instrument. The Daily Shutdown Prime consists of 50 priming cycles per Wash Bottle to ensure all traces of wash buffer are cleared from the fluidics lines. This will help ensure that no build-up occurs in the fluidics lines while the instrument sits idle after shutdown.
2. Empty Waste Bottle
   The user should empty the Waste bottle by disposing of the contents according to the appropriate laboratory guidelines.
3. Unload Instrument and close the cover
   The user should remove any remaining Reagent bottles and Sample tubes from inside the instrument. Reagent bottles and Sample tubes should be stored in the laboratory according to the appropriate laboratory guidelines. The user should ensure all instrument surfaces are clean and dry. Finally, the user should close the instrument cover.

6.2 Weekly Maintenance

Weekly maintenance includes cleaning and alignment tasks that are to be performed every seven days, as prompted by the software. It is recommended that the same day of the week be used for consistency. The user can specify which day of the week these tasks should be performed as described in **5.4.2.10.9 MAINTENANCE**. Weekly maintenance consists of the following tasks:

1. Sample Rack and Reagent Rack Inspection and Cleaning
   The user should remove Sample Racks and inspect each one for cleanliness and damage. The user should use isopropyl alcohol to gently clean the Samples Racks and Reagent Rack.
2. Rack Deck Inspection and Cleaning
   With all Sample Racks removed, the user should inspect the rack deck for cleanliness and damage. The user should use an alcohol wipe to gently clean the rack deck surface.
3. Probe Cleaning
   The user should inspect the outside of the Probe for cleanliness and damage. The user should clean the outside of the Probe (including both the center probe shaft and both probe needles) by wiping them down gently with an alcohol wipe.
4. Align the Probe and Camera
   The user should perform the probe and camera alignments as described in further detail in the Alignment and Calibration section of this manual.
5. Decontamination Priming
   The user should decontaminate the instrument tubing by priming the instrument for 20 cycles with a Liquinox solution. The Liquinox solution is prepared by making a 1:100 dilution of the Liquinox Concentrate supplied with the instrument and DI water. The user should then flush the instrument tubing by priming the instrument for 50 cycles with DI water.
6. Clean Wash/Waste Bottles
   The user should clean the Wash Bottles by rinsing them with DI Water. The user should clean the Waste Bottle by rinsing it with Wash Buffer. The user should also ensure that the Wash Buffer is within its expiration date prior to each use. The user should then rinse the Waste Bottle with DI water.

Notice: 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 substances and liquids.

6.3 Monthly Maintenance

Monthly maintenance includes cleaning tasks that are to be performed once a month, as prompted by the software. Monthly maintenance consists of the following tasks:

1. Replace Outer Waste Tubing
   If the instrument contains a peristaltic waste pump (older models only), monthly waste pump tubing replacement is also required. Contact local instrument distributor for detailed instructions.

   Notice: Changing the tubing of the waste pump is only applicable only for older instrument models with a peristaltic waste pump. Newer instruments models which contain a membrane/diaphragm waste pump do not require the waste pump tubing to be replaced as part of the monthly maintenance.
7. Bleach Priming
   Bleach priming on a monthly basis helps to avoid the potential for contamination over an extended period of time. This is especially true for AIX1000 systems that run a high percentage of Reactive Samples.

   The AIX1000 system will prompt the user to decontaminate the instrument tubing by priming the instrument with a 1% Sodium Hypochlorite solution (Part # SHW-20). The user must simply follow the instructions provided by the AIX1000 system to perform the Bleach Priming.

6.4 Periodic Maintenance

Approximately every year (frequency will vary depending on instrument usage), a preventative 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 a GSD Technical Service representative or your AIX1000 Distributor for more information.

6.5 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.

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 the maintenance tasks described in **6.2 WEEKLY MAINTENANCE** be performed, followed by dry priming cycles to remove liquids from the system. The instrument should also 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 Technical Service representative disposing of an instrument consult applicable local regulations prior to disposal.

7 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 are found within the **LIS Settings** and **LIS Associations** screens of the AIX1000 System Configuration Tool as described in **5.3.6 LIS SETTINGS** and **5.3.7 LIS ASSOCIATION**, respectively. When creating Worklists, the LIS can be queried from the Worklist screen of the AIX1000 Instrument Manager as described in **5.4.2.2.9 QUERY LIS**. After a Worklist run is complete, Worklist results can be sent to the LIS from the Evaluation screen of the AIX1000 Instrument Manager as described in **5.4.2.6.4 SEND TO LIS**.

7.1 LIS Configuration

To configure an AIX1000 system to communicate with an LIS, follow these steps:

1. Verify that the AIX1000 system is correctly installed and setup in the desired configuration as described in **5.1.1 SINGLE INSTRUMENT CONFIGURATION** and **5.1.2 MULTIPLE INSTRUMENT CENTRAL SERVER CONFIGURATION**.
2. Verify that all physical cords and cables of the AIX1000 system and the LIS system are securely connected. If the AIX1000 system is connecting to the LIS using a TCP/IP connection, then an Ethernet cord must be connected to the system. If the AIX1000 system is connecting to the LIS using an RS-232 connection, then a RS-232 serial cord must be connected to the system.
3. Specify how the AIX1000 system will communicate with the LIS using the AIX1000 System Configuration Tool as described in **5.3.6 LIS SETTINGS**. These settings must be configured properly before any communication with LIS is attempted. Consult with your Laboratory IT representative and/or LIS representative to determine the proper communication settings for the LIS used in your laboratory.
4. Assign LIS Test IDs to the AIX1000 RPR Test File using the AIX1000 System Configuration Tool as described in **5.3.7 LIS ASSOCIATION**. Be careful to enter the LIS Test ID exactly as it is used in the LIS system.

   Notice: An LIS Test ID is seldom the full name of the test, but often a shorter, abbreviated name. The LIS Test ID could also be a number or code, depending on the laboratory policy. Consult with your Laboratory IT representative and/or LIS representative to determine the proper LIS Test IDs for the LIS used in your laboratory.
5. Test the connectivity between the AIX1000 system and the LIS.
   a. Launch the AIX1000 Instrument Manager connected to an instrument in the AIX1000 system.
   b. Log on using a User Account of the type Super User or Administrator.
   c. Create a new Worklist and add Samples using any of the methods described in **5.4.2.2.6 ADD SAMPLES**. Be sure to verify in the LIS that the Samples that were added actually have pending orders for the RPR Test.
   d. Query the LIS by clicking the **Query LIS** button on the Worklist screen as described in **5.4.2.2.9 QUERY LIS**. If connectivity is working properly, RPR Test actions will be assigned to the Samples in the Worklist based on the Order records sent by the LIS.
   e. Run the Worklist by clicking/tapping the **Special Start** button on the **Home** screen to start the Worklist run as described in **5.4.2.1 HOME**. Be sure to specify that the Worklist run starts from the Read step to avoid running the full Worklist which could take hours depending on the Tests in the Worklist. Performing just the Read step should only take a few minutes.

      Notice: If reading is not performed, there will be no results to be transmitted to the LIS.

f. After the Worklist run is complete, navigate to the Evaluation screen and view the Worklist Report. Mark the Worklist as reviewed as described in **5.4.2.6.2 WORKLIST REVIEWED**.

g. On the Evaluation screen, click/tap the **Send to LIS** button to send results to the LIS as described in **5.4.2.6.4 SEND TO LIS**. In the Send to LIS window, select which results to send and click/tap **Send**. If connectivity is working properly, results will be transmitted and appear in the LIS.

7.2 LIS Records

As stated previously, the LIS implementation provided by AIX1000 completely conforms to the NCCLS LIS2-A2 and NCCLS LIS01-A2 (formerly known as ASTM E1394-91 and ASTM E1381-91) specifications. The NCCLS LIS2-A2 specification defines the conventions for the exchange of clinical results and patient data between laboratory instruments and an LIS. This section provides summary information about the records used to exchange information. For full details, refer to the NCCLS LIS2-A2 specification.

7.2.1 Header Record

All communications begin with the Header Record. By default, the "|" character is used to delineate fields in the record.

Example:

```
H|\^&|||AIX1000^2.1.3.0||||||P|LIS2-A2|20241213162157
```

The Header Record starts with H in the first field.

The second field in the Header Record is the "Delimiter Definition" field. This field defines the delimiters to be used throughout the subsequent records of the message. The first character in the second field is the "Repeat Delimiter". The second character in this field is the "Component Delimiter". The third character in the second field is the "Escape Delimiter".

The third and fourth fields in the Header Record are unused by AIX1000 and can be ignored. They are blank in the example above.

The fifth field in the Header Record is the "Sender Name or ID" field. The purpose of this field is to identify the sender of the information. Using Repeat Delimiters and/or Component Delimiters, this field may reflect different attributes to identify the sender. AIX1000 uses the Component Delimiter to divide this field into three components to identify itself as the sender. The first component is the name of the system, in this case "AIX1000". The second component is the version of the AIX1000 software.

The next five fields are unused by AIX1000 and left blank.

The eleventh field in the Header Record is the "Processing ID" field. This field indicates how the message is to be processed. This field is set by AIX1000 to be "P" to indicate that the message is for Production and should be treated as an active message to be completed according to standard processing.

The twelfth field in the Header Record is the "Version Number" field. This is set to "LIS2-A2" to indicate the version of the protocol being used to send the information.

The last field of the Header Record is the "Date and Time" field. This field contains the date and time that the Header Record was sent. The format is YYYYMMDDHHMMSS.

7.2.2 Request Information Record (aka Query Record)

The AIX1000 system will query the LIS using Request Information Records, which are also referred to as Query Records.

Example:

```
Q|1|^S001^||ALL||||||||O
```

The Query Record starts with Q in the first field. The second field is a sequence number.

The third field in the Query Record is the "Starting Range ID" field. Positions within the field are indicated by the ^ delimiters. The first position in this field denotes the "Laboratory Assigned Patient ID", which is unknown by the AIX1000 system at the time of a query and, therefore, left blank. The second position in this field denotes the "Specimen ID" which is filled with the Sample ID from the Worklist.

The fourth field is the "End Range ID" field and is left blank indicating the query is for only the Sample ID specified, not a range of Sample IDs.

The fifth field is the "Universal Test ID" field and is set to 'ALL' to indicate all ordered tests for the Sample ID are being requested.

Several other fields are left blank. There are eight field separators (|). These fields are typically not used by AIX1000. See the NCCLS LIS2-A2 specification for information regarding these fields.

The final field is the Request Information Status Code field. It is set to 'O' to indicate Test Orders are being requested.

7.2.3 Patient Information Record

The LIS system will respond to the software using Patient Information Records.

Example:

```
P|1|1234|5678|*****
```

The Patient Record starts with a P in the first field. The second field is a sequence number.

The third field in the Patient Record is the "Physician Assigned Patient ID" field. This field is ignored by the AIX1000 system for GDPR/HIPPA reasons.

The fourth field in the Patient Record is the "Laboratory Assigned Patient ID" field. This field is read by the AIX1000 system and stored in the AIX1000 database along with the Sample ID.

The ***** in the Patient Record example above represents other fields of the Patient Record which the LIS may provide, but the AIX1000 system does not use. AIX1000 will ignore these fields.

7.2.4 Test Order Record

The LIS system will give specific Patient/Test information using "Test Order Records".

Examples:

```
O|1|S001||^^^RPR|R          -- Order for RPR (screen) test
O|1|S002||^^^RPR^LOWTITER|R -- Order for RPR Low Titer series
O|1|S003||^^^RPR^HIGHTITER|R -- Order for RPR Hight Titer series
O|1|S004||^^^RPR^EXHIGHTITER|R -- Order for RPR Extra-High Titer series
```

The Order Record starts with an O in the first field. The second field is a sequence number.

The third field in the Order Record is the "Specimen ID" field. AIX1000 uses this field to identify the Sample ID in the Worklist which this Order record is associated with. In this example, the Sample ID is "S001".

The fourth field in the Order Record is unused by AIX1000. This field is left blank in the example above.

The fifth field in the Order Record is the "Universal Test ID" field. This field is used to identify the Test being ordered for the Sample ID. This field is divided into four components. AIX1000 does not use the first three components of this field and they are left blank in the example above. The fourth component in this field, the "Manufacturer defined test code" component, identifies the Test ID as defined by the LIS. The AIX1000 supports an extension to the fourth field to identify the different RPR titer actions provided by the AIX1000. The extension is designated by a subsequent Component Delimiter followed by the RPR titer action to be ordered (LOWTITER, HIGHTITER, EXHIGHTITER).

In the first example above, the Test ID is "RPR". The value provided by the LIS in this field component must be associated with the AIX1000 RPR Test File used by the AIX1000 system as described in **5.3.7 LIS ASSOCIATION**. The Test ID is not followed by a subsequent Component Delimiter and titer action, therefore this Order record indicates an RPR Test (also referred to as a Screen).

In the second example above, the Test ID is "RPR" followed by a Component Delimiter and the titer action "LOWTITER". This Order record indicates an RPR Titer action of the Low Titer series (1:2, 1:4, 1:8, 1:16).

In the third example above, the Test ID is "RPR" followed by a Component Delimiter and the titer action "HIGHTITER". This Order record indicates an RPR Titer action of the High Titer series (1:32, 1:64, 1:128, 1:256).

In the fourth example above, the Test ID is "RPR" followed by a Component Delimiter and the titer action "EXHIGHTITER". This Order record indicates an RPR Titer action of the Extra-High Titer series (1:512, 1:1024, 1:2048).

7.2.5 Result Record

The AIX1000 system will send Sample results from Worklist runs back to the LIS using "Result Records".

Examples:

```
R|1|^^^RPR|R|||||F      -- indicates RPR Reactive result
R|1|^^^RPR|NR|||||F     -- indicates RPR Non-Reactive result
R|1|^^^RPR|I|||||X      -- indicates RPR Invalid result

R|1|^^^RPR^LOWTITER|8|||||F       -- low titer with end point titer found at 1:8
R|1|^^^RPR^LOWTITER|NR|||||F      -- low titer with no end point titer found, all images in titer series NR
R|1|^^^RPR^LOWTITER|>16|||||F     -- low titer with no end point titer found, all images in titer series R
R|1|^^^RPR^LOWTITER|I|||||X       -- low titer with invalid image in titer series

R|1|^^^RPR^HIGHTITER|64|||||F     -- high titer with end point titer found at 1:64
R|1|^^^RPR^HIGHTITER|NR|||||F     -- high titer with no end point titer found, all images in titer series NR
R|1|^^^RPR^HIGHTITER|>256|||||F   -- high titer with no end point titer found, all images in titer series R
R|1|^^^RPR^HIGHTITER|I|||||X      -- high titer with invalid image in titer series

R|1|^^^RPR^EXHIGHTITER|1024|||||F     -- extra high titer with end point titer found at 1:1024
R|1|^^^RPR^EXHIGHTITER|NR|||||F       -- extra high titer with no end point titer found, all images in titer series NR
R|1|^^^RPR^EXHIGHTITER|>2048|||||F    -- extra high titer with no end point titer found, all images in titer series R
R|1|^^^RPR^EXHIGHTITER|I|||||X        -- extra high titer with invalid image in titer series
```

The Result Record starts with an R in the first field. The second field is a sequence number.

Notice: Result Records are nested within Patient Records and Order Records to identify which Patient and Sample the Result Record is associated with. See **7.3.3 EXAMPLE 3: TRANSMISSION OF RESULTS** *below.*

The third field in the Result Record is the "Universal Test ID" field. This field is used to identify the Test for which Results are being provided. This field is divided into four components. AIX1000 does not use the first three components of this field and they are left blank in the example above. The fourth component in this field, the "Manufacturer defined test code" component, identifies the Test ID as defined by the LIS. In the examples above, the Test ID is "RPR". The values provided by the LIS in this field component must be associated with AIX1000 RPR Test File as described in **5.3.7 LIS ASSOCIATION**.

According to the LIS2-A2 specification, the "Universal Test ID" field can be divided into further components to provide additional information to indicate the relationship of the result to the test, battery, or batteries ordered. If a test contains multiple results or subtests (e.g. panel based tests), the subtest name is added after the test ID separated by a component delimiter. In the examples above, the Test ID is given as "RPR" and titer results are indicated by the components of "LOWTITER", "HIGHTITER, or "EXHIGHTITER".

The fourth field in the Result Record is the "Data or Measurement Value" field. This field can contain numeric, text, or coded values recorded in ASCII notation. AIX1000 provides the following values in this field for results:

RPR (Screen) Result Values	
Result value	**Description**
R	Reactive
NR	Non-Reactive
I	Invalid (Sample Well image failed to capture, or artifact was found in Sample Well Image)

RPR Low Titer Series Result Values	
Result value	**Description**
NR	No endpoint titer found, all images in Low Titer series Non-Reactive
2	Endpoint titer found at 1:2 titer in Low Titer series
4	Endpoint titer found at 1:4 titer in Low Titer series
8	Endpoint titer found at 1:8 titer in Low Titer series
>16	No Endpoint titer found in Low Titer series, all images in Low Titer series Reactive
I	Low Titer series included one or more Invalid results

RPR High Titer Series Result Values	
Result value	**Description**
NR	No endpoint titer found, all images in High Titer series Non-Reactive
32	Endpoint titer found at 1:32 titer in High Titer series
64	Endpoint titer found at 1:64 titer in High Titer series
128	Endpoint titer found at 1:128 titer in High Titer series
>256	No Endpoint titer found in High Titer series, all images in High Titer series Reactive
I	High Titer series included one or more Invalid results

RPR Extra-High Titer Series	
Result value	**Description**
NR	No endpoint titer found, all images in Extra-High Titer series Non-Reactive
512	Endpoint titer found at 1:512 titer in Extra-High Titer series
1024	Endpoint titer found at 1:64 titer in Extra-High Titer series
>2048	No Endpoint titer found in Extra-High Titer series, all images in Extra-High Titer series Reactive
I	Extra-High Titer series included one or more Invalid results

The next four fields in the Result Record are not used by AIX1000.

The final field in the Result Record is the "Result Status" field. As described in the LIS2-A2 specification, this field contains a one letter code indicating the status of the result information. The possible values for this field are:

Result Status Code	Description
C	Correction of previously transmitted result
P	Preliminary results
F	Final results
X	Order cannot be done

Result Status Code	Description
I	In instrument, results pending
S	Partial results
M	This result is an MIC level
R	This result was previously transmitted
N	This result record contains necessary information to run a new order

Notice: The AIX1000 only uses the "F" and "X" Result Status Codes. If an Invalid result is determined for a Sample, a Result Record is still transmitted for that Sample, but the "Result Status" field is then set to "X" (order cannot be done). If a valid result is determined for a Sample, a Result Record is transmitted with the "Result Status" field is set to "F" (final results).

7.2.6 Message Terminator Record

This is the last record in the message. This record indicates the end of a message containing information encoded as Query Records, Patient Records, and/or Result Records.

Example:

```
L|1|N
```

The Message Terminator Record starts with an L in the first field. The second field is a sequence number. For the Message Terminator Record the sequence number should always be 1.

The final field in the Message Terminator Record is the "Termination Code" This field provides an explanation for the end of the message. The possible values are:

Termination Code	Description
N	Normal termination
T	Sender aborted
R	Receiver requested abort
E	Unknown system error
Q	Error in last request for information
I	No information available from last query
F	Last request for information processed

7.3 LIS Transmission Examples

The following sections provide examples of messages sent between an AIX1000 system and an LIS for common communication scenarios. The examples below assume the user has set the LIS association for the AIX1000 RPR Test File to "RPR" as described in **5.3.7 LIS ASSOCIATION**.

7.3.1 Example 1: Query of Test orders for Sample IDs

AIX1000 → LIS

```
H|\^&|||AIX1000^2.1.3.0||||||P|LIS2-A2|20241213112515
    Q|1|^S001^||ALL||||||O
    Q|2|^S002^||ALL||||||O
    Q|3|^S003^||ALL||||||O
    Q|4|^S004^||ALL||||||O
L|1|N
```

7.3.2 Example 2: Response of Tests ordered for Sample IDs

LIS → AIX1000

```
H|\^&|||LIS|||||||P|LIS2-A2|20241213112517
   P|1|1211|2322|*****
      O|1|S001||^^^RPR|R
   P|2|3433|4544|*****
      O|1|S002||^^^RPR^LOWTITER|R
   P|3|5655|6766|*****
      O|1|S003||^^^RPR^HIGHTITER|R
   P|3|7877|8988|*****
      O|1|S004||^^^RPR^EXHIGHTITER|R
L|1|N
```

*Notice: The "*****" in the Patient Records above indicate fields for the Patient Record that the LIS may provide but the AIX1000 system does not use. AIX1000 will ignore these fields.*

7.3.3 Example 3: Transmission of results

AIX1000 → LIS

```
H|\^&|||AIX1000^2.1.3.0|||||||P|LIS2-A2|20241213141123
   P|1|S001
      O|1|S001||^^^RPR||||||||||||||||||||F
         R|1|^^^RPR|NR|||||F
   P|2|S002
      O|1|S002||^^^RPR||||||||||||||||||||F
         R|1|^^^RPR|R|||||F
         R|2|^^^RPR^LOWTITER|>16|||||F
         R|3|^^^RPR^HIGHTITER|128|||||F
         R|4|^^^RPR^EXHIGHTITER|NR|||||F
   P|3|S003
      O|1|S003||^^^RPR||||||||||||||||||||F
         R|1|^^^RPR^HIGHTITER|64|||||F
   P|4|S004
      O|1|S004||^^^RPR||||||||||||||||||||F
         R|1|^^^RPR^EXHIGHTITER|512|||||F
L|1|N
```

Notice: When sending results to the LIS, the AIX1000 will set the Order record to contain only the Test ID and the Result Records will contain the Test ID and the titer action ordered (if appropriate).

*Notice: In the example above, the user modified the Worklist for Sample "S002" to run all RPR test actions on the Sample as described in **5.4.2.2.2 WORKLIST GRID**. The AIX1000 reports all results for the Sample under a single Order Record as shown above.*

8 Running a Worklist

To run a Worklist on the instrument, follow the steps below.

1. Verify that the AIX1000 system is correctly installed and setup in the desired configuration as described in **5.1.1 Single Instrument Configuration** and **5.1.2 Multiple Instrument Central Server Configuration**.
2. Verify that all physical cords and cables of the AIX1000 system are securely connected. If an LIS is used, make sure all physical cords and cables related to the LIS are securely connected.
3. If an LIS is used, make sure the RPR Test File included with the AIX1000 system has an association to the LIS Test ID as described in **5.3.7 LIS Association**.
4. Launch the AIX1000 Instrument Manager connected to one of the instruments in the AIX1000 system and allow the instrument to initialize and home. Be sure to perform any maintenance tasks as prompted.
5. Navigate to the Worklist screen and add Samples to the Worklist using any of the Sample addition methods described in **5.4.2.2.6 Add Samples**.
6. Assign RPR Test actions to the Samples.
    a. If not using an LIS, assign RPR Test actions to Samples manually as described in **5.4.2.2.2 Worklist Grid**.
    b. If using an LIS, assign RPR Test actions to Samples by clicking the **Query LIS** button as described in **5.4.2.2.9 Query LIS**.
7. Prepare all materials for the Worklist run. It is essential that all package insert instructions for reagent handling and storage are carefully followed. Reagent and sample preparation must be performed according to instructions. Prior to the use of reagents, calibrators, controls, or samples, also visually verify that there are no bubbles in the bottles or vials. Air bubbles must be removed (a clean transfer pipette or toothpick can be used) before placing vials on the instrument.
8. Navigate to the **Racks** screen and verify the layout of the Samples and Reagents. Place the Reagent and Control bottles on the instrument as indicated on the **Racks** screen.
9. Navigate to the **Microtiter Plates** screen and verify the layout of the MTP plates.
10. Navigate to the **Home** screen and start the Worklist run by clicking/tapping the **Start** button. Follow the prompts of the **Worklist Loading Wizard** to ensure the Worklist is properly setup before the run starts.
11. Allow the Worklist run to complete. 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 a live camera feed showing the instrument in action.

    Notice: It is important to keep the cover closed for the entire duration of the Worklist run.

    *Notice: If necessary, use the **Pause** button to temporarily pause a Worklist run, or the **Stop** button to completely abort a Worklist run (instrument movement will stop and door will unlock).*
12. At the completion of a Worklist run the AIX1000 Instrument Manager will notify the user with a prompt that the run has completed. The user can click/tap the **OK** to dismiss the prompt and stop the audio alarm (if end of run sound is enabled). The user can also navigate to the **Evaluation** screen to review the Worklist run results. If using and LIS, the results can also be sent to the LIS from the **Evaluation** screen by clicking/tapping the **Send to LIS button**.
13. The user should remove all RPR Test kit components (Microtiter Plates, Reagents, Controls) and Samples from the instrument. Ensure that all instrument surfaces are clean and dry, and close the cover.

9 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 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 connections, and restart. Reload the worklist and special start 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.

Issue	Details	User Action
	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. NOTICE: Even if no bubbles are observed at the end of the run, a bubble could have caused the problem and later popped.
	Has kit been open for too long or is it expired?	If yes, rerun with new kit.
	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 disappears 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.

Issue	Details	User Action
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.
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

10 Security and Connectivity

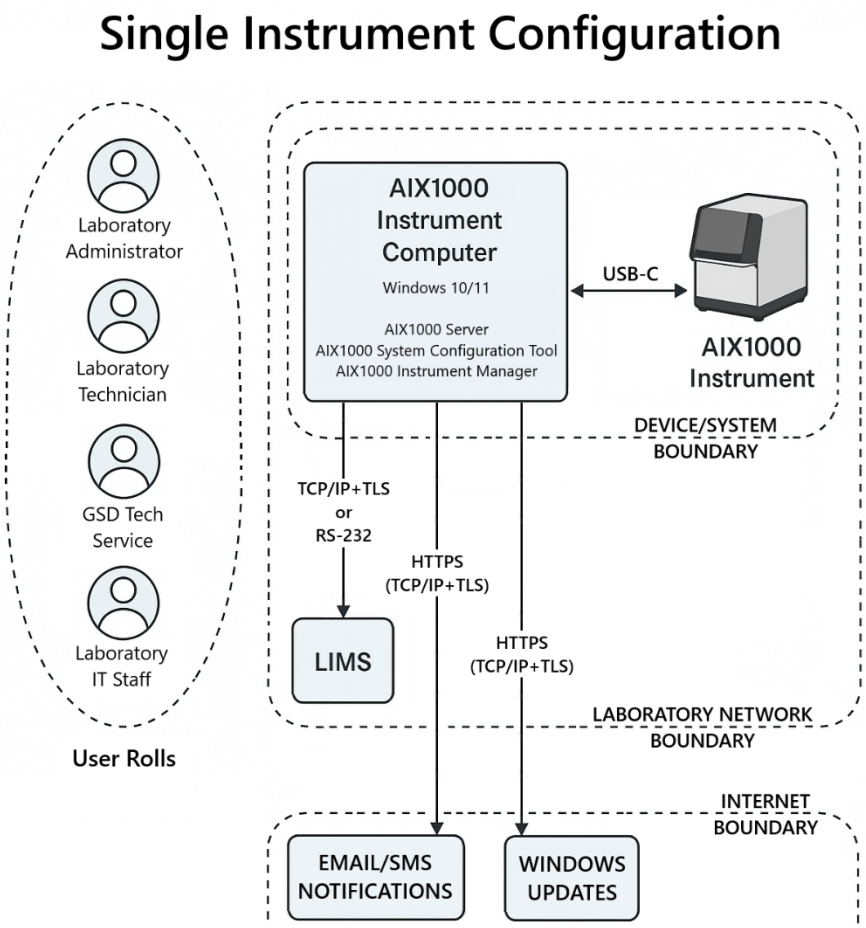
This chapter provides cybersecurity labeling information for the AIX1000 System. The information contained herein is intended to guide end users (Laboratory Administrators, Laboratory Technicians, and Laboratory IT Staff) in the secure deployment, configuration, operation, maintenance, and decommissioning of the AIX1000 Analyzer.

10.1 Network Architecture Diagrams

As described in section **5.1 AIX1000 System Configuration Options**, the AIX1000 system can be run in two configurations: Single Instrument Configuration and Multiple Instrument with Central Server Configuration.

10.1.1 Single Instrument Configuration

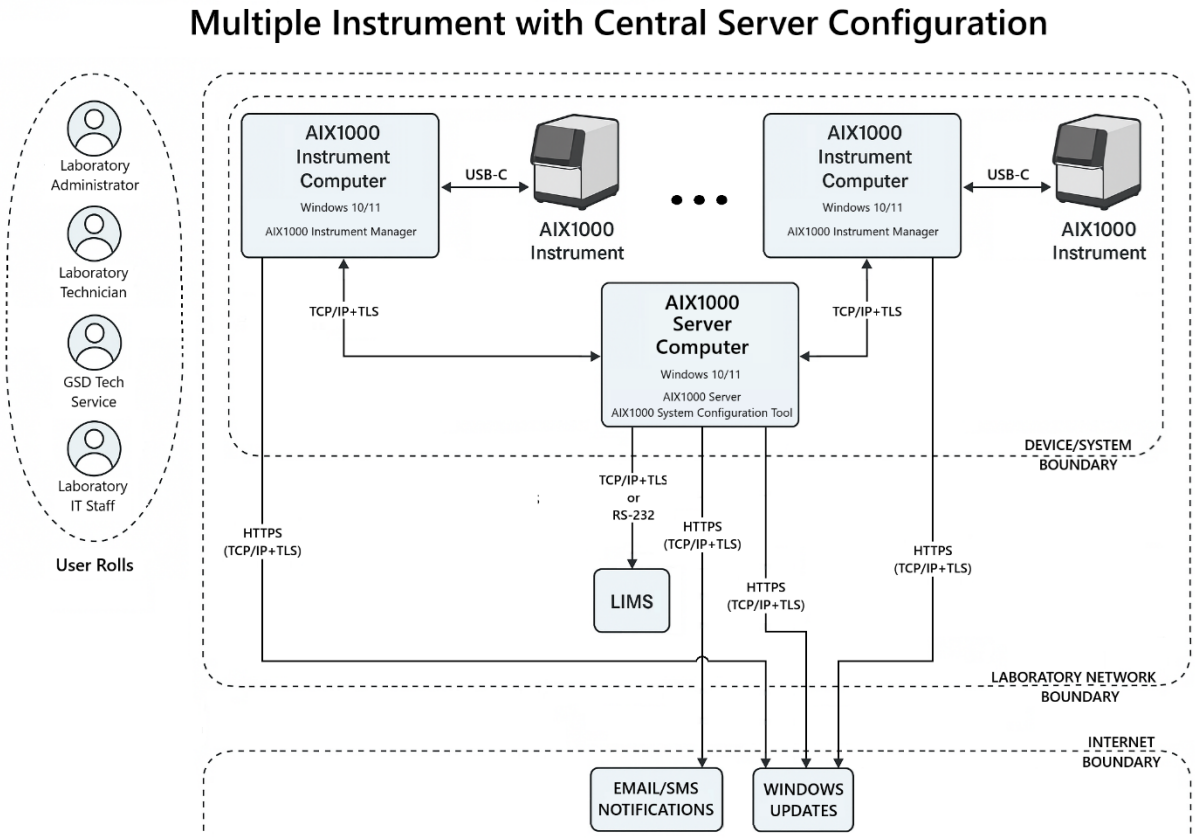
The network architecture diagrams for the Single Instrument Configuration is provided below.



In the Single Instrument Configuration, the AIX1000 Instrument Manager, AIX1000 System Configuration Tool, and AIX1000 Server are run on the instrument computer. In this configuration, if a connection to a Laboratory Information Management System (LIMS/LIS) is required, the instrument computer must be connected to the LIMS/LIS.

10.1.2 Multiple Instrument with Central Server Configuration

The network architecture diagram for the Multiple Instrument with Central Server Configuration is provided below.



In the Multiple Instrument with Central Server Configuration, the AIX1000 Instrument Manager is run on the instrument computers. The AIX1000 System Configuration Tool, and AIX1000 Server are run on the AIX1000 server computer. In this configuration, if a connection to a Laboratory Information Management System (LIMS/LIS) is required, the server computer must be connected to the LIMS/LIS.

10.2 Port and Interface Specifications

10.2.1 Single Instrument Configuration

Port / Interface	Protocol	Direction	Endpoints	Security Considerations
USB-C	USB 3.1	Bi-directional	AIX1000 Instrument ↔ AIX1000 Instrument Computer Physical USB Link	Local, physical connection only; no network exposure
Loopback	TCP/IP TLS 1.3	Bi-directional	AIX1000 Instrument Computer ↔ AIX1000 Instrument Computer IP Address: Localhost (127.0.0.1) AIX1000 Instrument Manager ↔ AIX1000 Server TCP Port: 8099 AIX1000 System Configuration Tool ↔ AIX1000 Server TCP Port: 8099	Restricted to AIX1000 Server computer; no external exposure
Ethernet 10/100/1000 GigE (IEEE 802.3ab)	HTTPS	Outbound only	AIX1000 Instrument Computer ↔ Windows Update Service IP Address: Configurable ↔ windowsupdate.microsoft.com Windows OS ↔ Windows Update Service TCP Port: 443	Outbound firewall exceptions for Windows Update Service

Port / Interface	Protocol	Direction	Endpoints	Security Considerations
Ethernet 10/100/1000 GigE (IEEE 802.3ab)	HTTPS	Outbound only	AIX1000 Instrument Computer ↔ Twilio/SendGrid Service IP Address: Configurable ↔ api.sendgrid.com AIX1000 Server ↔ Twilio/SendGrid Service TCP Port: 443	Outbound firewall exceptions for AIX1000 Server to Twilio/SendGrid Service
Ethernet 10/100/1000 GigE (IEEE 802.3ab)	TCP/IP TLS 1.3 LIS01-A2 LIS2-A2	Bi-directional	AIX1000 Instrument Computer ↔ LIS Computer IP Address: Configurable ↔ IP Address: Configurable AIX1000 Server ↔ LIS TCP Port: Configurable	TLS 1.3 for secure encrypted, authenticated communication Firewall exceptions for AIX1000 Server and LIS
RS-232 Serial Port	RS-232 LIS01-A2 LIS2-A2	Bi-directional	AIX1000 Instrument Computer ↔ LIS Computer RS-232 Serial Port ↔ RS-232 Serial Port	Inherently insecure. For legacy purposes only. Not recommended. Requires secure physical access such as cable control, tamper evident seals and locks, shielded cabling/conduit, and external hardware serial-to-serial encryptors (if possible).

10.2.2 Multiple Instrument Configuration with Central Server

Port / Interface	Protocol	Direction	Endpoints	Security Considerations
USB-C	USB 3.1	Bi-directional	AIX1000 Instrument ↔ AIX1000 Instrument Computer Physical USB Link	Local, physical connection only; no network exposure
Ethernet 10/100/1000 GigE (IEEE 802.3ab)	TCP/IP TLS 1.3	Bi-directional	AIX1000 Instrument Computer ↔ AIX100 Server Computer IP Address: Configurable ↔ IP Address: Configurable AIX100 Instrument Manager ↔ AIX1000 Server TCP Port: Configurable	TLS 1.3 for secure encrypted, authenticated communication Firewall exceptions for AIX1000 Instrument Manager and AIX1000 Servers
Ethernet 10/100/1000 GigE (IEEE 802.3ab)	HTTPS	Outbound only	AIX1000 Instrument Computer ↔ Windows Update Service IP Address: Configurable ↔ windowsupdate.microsoft.com Windows OS ↔ Windows Update Service TCP Port: 443	Outbound firewall exceptions for Windows Update Service
Loopback	TCP/IP TLS 1.3	Bi-directional	AIX1000 Server Computer ↔ AIX1000 Server Computer IP Address: Localhost (127.0.0.1) AIX1000 System Configuration Tool ↔ AIX1000 Server TCP Port: 8099	Restricted to AIX1000 Server computer; no external exposure
Ethernet 10/100/1000 GigE (IEEE 802.3ab)	HTTPS	Outbound only	AIX1000 Server Computer ↔ Windows Update Service IP Address: Configurable ↔ windowsupdate.microsoft.com Windows OS ↔ Windows Update Service TCP Port: 443	Outbound firewall exceptions for Windows Update Service
Ethernet 10/100/1000 GigE (IEEE 802.3ab)	HTTPS	Outbound only	AIX1000 Server Computer ↔ Twilio/SendGrid Service IP Address: Configurable ↔ api.sendgrid.com AIX1000 Server ↔ Twilio/SendGrid Service TCP Port: 443	Outbound firewall exceptions for AIX1000 Server to Twilio/SendGrid Service
Ethernet 10/100/1000 GigE (IEEE 802.3ab)	TCP/IP TLS 1.3 LIS01-A2 LIS2-A2	Bi-directional	AIX1000 Server Computer ↔ LIS Computer IP Address: Configurable ↔ IP Address: Configurable AIX1000 Server ↔ LIS TCP Port: Configurable	TLS 1.3 for secure encrypted, authenticated communication Firewall exceptions for AIX1000 Server and LIS
RS-232 Serial Port	RS-232 LIS01-A2 LIS2-A2	Bi-directional	AIX1000 Server Computer ↔ LIS Computer RS-232 Serial Port ↔ RS-232 Serial Port	Inherently insecure. For legacy purposes only. Not recommended. Requires secure physical access such as cable control, tamper evident seals and locks, shielded cabling/conduit, and external hardware serial-to-serial encryptors (if possible).

10.3 System Hardening Requirements

All AIX1000 system computers are configured by the manufacturer with essential security measures enabled by default to safeguard system integrity, confidentiality, and availability. These measures comply with industry best practices and applicable regulatory guidance for medical device cybersecurity. The following security controls are pre-configured and operational upon system deployment:

- **Secure Boot**: Secure Boot is enabled by default to ensure that the system firmware permits only trusted, digitally signed bootloaders and operating system files to be executed. This prevents unauthorized or malicious software from compromising the system during the startup process.
- **Windows Authentication**: All user access to the AIX1000 system computers is governed by Windows Authentication. This enforces strong password requirements, account lockout after repeated failed login attempts, and role-based access restrictions to ensure that only authorized personnel can access system functions.
- **Windows Firewall**: The Windows Firewall is enabled by default and configured to block all inbound connections unless explicitly required for system functionality (e.g., LIS communication, Windows Updates). Outbound connections are restricted to approved endpoints as documented in Section 13.2.
- **Microsoft Defender Antivirus**: Real-time antivirus protection is enabled using Microsoft Defender. This includes automatic signature updates, continuous threat monitoring, and daily scheduled scans to mitigate malware risks.
- **Windows Updates**: The system is configured to receive and install critical Windows operating system updates, including security patches, from trusted Microsoft Update endpoints. Updates are scheduled to occur during periods of system inactivity to minimize operational disruption.

These default security configurations provide a foundational layer of protection. End users and laboratory IT administrators are responsible for maintaining these configurations and ensuring that any site-specific security requirements are applied in a manner that does not compromise the device's intended functionality or regulatory compliance.

10.4 AIX1000 Software Updates and SBOM Access

All software and firmware updates for the AIX1000 system are developed, validated, and released in accordance with the manufacturer's quality management system and regulatory requirements. To ensure both operational reliability and cybersecurity integrity, the following procedures govern update deployment and Software Bill of Materials (SBOM) access:

- **Technical Service Bulletins**: All updates, including security patches, feature enhancements, and firmware revisions, are formally announced through Technical Service Bulletins (TSBs) issued by GSD. Each TSB includes a detailed description of the update, applicability, prerequisites, installation instructions, and verification procedures.
- **Authorized Installation**: Software and firmware updates are installed exclusively by GSD Technical Service representatives or certified GSD Distributors. End users shall not attempt to install updates independently.
- **Update Integrity and Security**: All update packages are digitally signed and validated prior to installation to ensure authenticity, integrity, and protection against unauthorized modification.
- **Notification and Scheduling**: Laboratory IT administrators and system operators are notified in advance regarding planned updates. Installation is scheduled to minimize operational disruption and maintain laboratory workflow continuity.
- **Software Bill of Materials (SBOM) Access**: A complete, machine-readable SBOM (e.g., JSON or SPDX format) for each software version is maintained by the manufacturer. The SBOM includes component-level details to facilitate vulnerability assessment, asset management, and cybersecurity risk mitigation. Laboratory IT departments and regulatory authorities may request the SBOM through GSD Technical Support for integration into their cybersecurity risk management programs.

This controlled update and SBOM management process ensures that the AIX1000 System remains secure, compliant, and operational throughout its service life while providing transparency and traceability for all software components.

10.5 Event Logging and Incident Response

Comprehensive event logging and a structured incident response process are integral to maintaining the cybersecurity posture of the AIX1000 System. The following logging mechanisms and incident response protocols are implemented to ensure accountability, traceability, and rapid containment of potential security incidents:

- **Windows Event Logging**: All authorized and unauthorized access attempts to AIX1000 system computers are recorded using the native Windows Event Logging framework. This includes user logins, account lockouts, privilege escalations, and security policy changes, thereby providing a complete audit trail of system access activities.
- **Windows Firewall Logging**: The Windows Firewall on all AIX1000 system computers is configured to log both successful connection attempts and blocked (dropped) packets. This enables laboratory IT administrators to review inbound and outbound network traffic for indications of unauthorized access or anomalous communication patterns.
- **Microsoft Defender Antivirus Logging**: Microsoft Defender Antivirus integrates with the Windows Event Logging framework to record all detected threats, actions taken (e.g., quarantine, removal), scan activities, and other relevant security events. These logs support proactive threat management and forensic analysis during incident response.
- **Laboratory Information System (LIS) Communication Logs**: The AIX1000 software suite maintains detailed logs of all LIS communication events, including message transmission, acknowledgments, errors, and time-stamped transaction identifiers. These logs facilitate both routine operational troubleshooting and forensic investigation in the event of a cybersecurity or data integrity incident.
- **Centralized Log Storage**: All logs, including Windows Event Logs, Windows Firewall logs, Microsoft Defender Antivirus logs, and LIS communication logs, are stored in designated system directories with access restricted to authorized personnel only. Retention policies align with laboratory IT governance and applicable regulatory requirements.
- **Incident Detection and Response Protocol**:
    1. **Detection**: Security events such as repeated failed login attempts, unexpected firewall blocks, antivirus threat alerts, or LIS communication anomalies trigger immediate review by laboratory IT staff.
    2. **Containment**: The affected AIX1000 system computer shall be isolated from the network to prevent potential compromise propagation.
    3. **Notification**: Laboratory IT administration and GSD Technical Support shall be notified without delay to coordinate diagnostic assessment and corrective actions.
    4. **Investigation and Recovery**: Authorized personnel shall analyze all relevant logs to determine root cause, implement containment measures, apply corrective updates or patches, and document findings for regulatory compliance.

This integrated approach to event logging and incident response ensures system transparency, supports regulatory reporting obligations, and provides a robust framework for maintaining the cybersecurity integrity of the AIX1000 System.

10.6 Backup, Restore Operations

The AIX1000 System incorporates comprehensive backup and restore capabilities to ensure operational continuity, data integrity, and rapid system recovery in the event of a cybersecurity incident, system malfunction, or environmental disruption. These functions are designed in accordance with applicable regulatory requirements, information security best practices, and laboratory operational needs.

- **Backup Operations**:

  - **Automated Scheduling**: Backups of critical system configuration data, application settings, and laboratory test results are automatically scheduled through the AIX1000 Configuration Tool at user-defined intervals, typically on a daily basis or as required by laboratory policy.
  - **Backup Integrity Verification**: Each backup archive undergoes automated integrity verification using cryptographic hash validation to ensure the completeness and accuracy of the data prior to storage.
  - **Secure Storage**: Backup files are encrypted, preserving both security and integrity of the AIX1000 system configuration and data.
- **Restore Operations**:
  - **Authorized Access**: System restoration activities may be performed exclusively by GSD Technical Service representatives, certified GSD Distributors, or authorized laboratory IT administrators.
  - **Controlled Recovery Process**: Backup archives may be restored only from verified, signed, and trusted sources to prevent introduction of compromised or corrupted data into the AIX1000 System environment.
  - **Validation after Recovery**: Following a restore operation, system functionality and data integrity are verified prior to the resumption of normal laboratory operations.

This structured approach to backup and restore of AIX1000 database ensures that the AIX1000 System maintains high availability, resilience, and security throughout its operational lifecycle, while supporting laboratory compliance with applicable regulatory and data protection standards.

10.7 Device Decommissioning and Data Sanitization

Device decommissioning and data sanitization activities for the AIX1000 System shall be performed in a controlled and secure manner to ensure the confidentiality, integrity, and protection of all laboratory data, system configuration information, and intellectual property. The following requirements govern the decommissioning process:

- **Absence of Sensitive Patient Information**:
  The AIX1000 System does not store any sensitive patient information such as names, dates of birth, or personal identifiers. All samples processed by the AIX1000 System are tracked and managed exclusively by Sample ID or Accession Number. These identifiers do not contain personally identifiable information, thereby reducing privacy risk and regulatory exposure during system operation and decommissioning.
- **End-of-Support Timelines**:
  GSD will publish official end-of-support timelines for each AIX1000 software version through formal Technical Service Bulletins (TSBs). These TSBs will specify the final dates for security patching, technical assistance, and software updates, thereby enabling laboratories to plan system upgrades, migrations, or decommissioning activities in a timely and compliant manner.
- **Pre-Decommissioning Requirements**:
  Prior to device retirement or repurposing, the following steps shall be performed:
  1. **Final Data Backup**: A final backup of all required AIX1000 data shall be performed in accordance with laboratory policy and regulatory requirements.
  2. **Data Review**: Laboratory IT administrators shall verify that no residual laboratory or configuration data remains outside designated backup archives.
- **Data Sanitization Procedures**:
  To prevent unauthorized access to any residual system or laboratory information following decommissioning, the AIX1000 System provides the following secure data sanitization methods:
  - **Erasure Tools**: Windows-based `diskpart clean all` utility shall be used to overwrites every sector on the AIX1000 system computers hard-disks with zeros, rendering data irretrievable. This command is destructive and will erase the entire disk without a chance for recovery.

- **Audit Verification**: Sanitization activities shall be documented and verified by laboratory IT administrators or GSD Technical Service representatives to ensure compliance with applicable data protection regulations (e.g., HIPAA, GDPR).

- **Device Retirement and Physical Disposal**:
  Upon successful data sanitization, hardware components shall be retired or disposed of in accordance with local, regional, and national regulations governing the handling of electronic medical devices and environmentally controlled waste streams. Certificates of destruction shall be obtained when required by regulatory authorities.

This structured decommissioning and data sanitization process ensures that the AIX1000 System is retired securely, with full traceability and compliance with regulatory, cybersecurity, and data protection standards.

11 Symbols Glossary

Symbol	Title	Explanation	Reference	Reference number
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union	ISO 15223-1	5.1.2
	Catalogue number	Indicates the manufacturer's catalogue number so that a specific medical device can be identified	ISO 15223-1	5.1.6
	Serial number	Indicates the manufacturer's serial number so that the medical device can be identified	ISO 15223-1	5.1.7
	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1	5.1.8
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	ISO 15223-1	5.5.1
	UKCA (UK Conformity Assessed) marking	Indicates UKCA marking of conformity	UK MDR 2002	-
	Symbol for marking of EEE (electrical and electronic equipment)	Indicates separate collection for EEE	Directive 2012/19/EU, Annex IX	-

12 Revision History

Revision	Date	Description of 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.
C	02/03/2023	Changed AIX1000 Agglutination Analyzer to AIX1000 Analyzer (cover and 13.1); corrected address format (13.1); added Symbols Glossary (11); removed Authorized Representative and added UK Responsible Person (13.2)
D	03/10/2023	Edit to the LIS Records description, Section 9.1 page 46, to read the accurate Test Order Record description, as depicted in the image example following it.
E	09/03/2025	Complete updated of Users Manual for AIX1000 2.1 release.

13 Contact Information

13.1 Device Manufacturer

Company Name	Gold Standard Diagnostics, LLC
Company Address	2795 2nd Street Suite 300, Davis, CA 95618
Country	USA
Phone	530-759-8000
Fax	530-759-8012
Website	www.gsdx.us
AIX1000® Analyzer	Catalog# 00400
GSD RPR Reagents	Catalog# GSD01-1600

13.2 UK Responsible Person

Company Name	LAUNCH DIAGNOSTICS LIMITED
Company Address	Ash House, Ash Road New Ash Green, Longfield Kent, DA3 8JD
Country	England

13.3 Document History Changes

Version	Date	Changes
0	10/21/2025	New User's Manual for the AIX1000 2.1 release.