Operator's Manual

CAAS Automated Analysis System

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1. Introduction

CAAS is an automated, “hands off”, microtiter plate format analyzer for quantitative determination of anatoxin-a, cylindrospermopsin, microcystins,Saxitoxins, glyphosate, atrazine and others. The analyzer is computer controlled and capable of automating all the steps of both ELISA and RBA assays including fluid handling, plate mixing, incubation/timing, optical reading, calculations and reports.

Assay automation with CAAS is easy, reliable, and consistent; moreover, multiple analyte assays can be run simultaneously (multiplexing).

- Fluid Handling - aspirates and dispenses from 2 µL to 1.95 mL
- Incubating - heating temperatures - coil heats to 37°C, plate heats to 25°C or 37°C or at ambient temperature. Reagent cooling available with optional Reagent Cooling Accessory® (RCA)
- Mixing - reaction plate only
- Timing - from 1 second to 24 hours
- Optical Reading - UV/visible range
- Calculating - uses numerous preprogrammed equations
- Data Storage - unlimited capacity
- Data Reporting - many options and customizations to choose from

The system allows one to define and program an unlimited number of customized protocols by selecting displayed menu options from a Microsoft Windows® software program (see Operating Precautions, Section 1.4).

It has many possible applications in clinical and veterinary testing; environmental testing; analysis of food and water; and life science research.

This instrument may also be used in production processes involving micro volume dispensing, diluting, incubating, and reading.

Reactions occur in standard plastic microwells instead of sample cups or a carousel. Microwell strips are commercially available from many sources. Reagent bottles and sample tubes are placed into the removable instrument racks. The instrument is programmed to pick up from one place, dispense to another, wash the probe, read the wells, incubate, mix, etc. When doing chemistry reactions, groups of four wells may be timed simultaneously to improve throughput.

This instrument is not dedicated for use with any particular chemical reaction, method, or manufacturer. This provides many advantages, including great flexibility in how it is used. Each lab decides how to set up the racks and plates, which reagents to use, how many controls to run, number of applications to be used, and so on. To assure the quality of clinical information, each new setup must be validated before reporting specimen results. In some cases the programming, optimization, and validation may have already been done.

It is advised to run specimens having known concentrations to verify the instrument setup parameters. After that, programs can easily be recalled for review, use, change, or deletion. The user can decide everything, including how much is manual and how much is automatic.

1.1 Intended Use

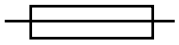
IVD **FOR IN-VITRO DIAGNOSTIC USE**

This instrument is designed for use in processing general chemistry and ELISA tests. It is a general purpose instrument intended to be used by trained laboratory professionals who are capable of selecting the appropriate features and options for each specific clinical application. Contact your company's instrument service provider to arrange for training.

1.2 Warning Markings

1.2.1 Safety Symbols Le Symboles de Sûreté

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

			
WARNING ***AVERTISSEMENT***	**Protective Ground** ***La Terre Electrique***	**CAUTION** ***L'ATTENTION***	**BIOHAZARD** ***BIOHAZARD***
Risk of Shock ***Risque de Choc***	**(Earth) Terminal** ***Prise de Terre***	**Refer to Manual** ***Se Rapportent a Manuel***	**Risk of Infection** ***Risque d'infection***
	**FUSE:** For continued protection against risk of fire, replace only with fuse of the specified type and current ratings. Disconnect equipment from supply before replacing fuse. *FUSIBLE: Pour la protection continue contre le risque du feu, remplacez le fusible seulement par une du type spécifique et des estimations courantes. Démontez l'équipement de l'alimentation d'énergie avant de remplacer le fusible.*		
	**DANGER:** Pinch points, sharp points, and moving parts - mechanisms may operate without warning.		

1.2.2 Safety Terms Terminologie de Sûreté

These terms may appear on the product : Les marques sur le produit *These terms may appear in this manual: Les marques dans l'opérateur manuel*	
DANGER *DANGER Le "de marque: DANGER"*	Indicates an injury immediately accessible as you read this marking *Indique le risque immédiat de dommages (assessible tandis que vous lisez la marque)*
WARNING *AVERTISSEMENT! Le "de marque: WARNING"*	WARNING statements identify conditions or practices that could result in injury or loss of life. WARNING indicates an injury hazard not immediately accessible as you read this marking. *Ces rapports identifient les conditions ou les pratiques qui pourraient avoir comme conséquence les dommages ou les pertes humaines.*
CAUTION *L'ATTENTION "Le de marque: CAUTION"*	CAUTION statements identify conditions or practices that could result in damage to this product or other property. *Ces rapports identifient les conditions ou les pratiques qui pourraient avoir comme conséquence les dommages a ce produit ou a toute autre propriété.*
BIOHAZARD	BIOHAZARDS are biological agents that can cause disease in humans. Lab workers handling potentially infectious materials must use universal precautions to reduce the risk of exposure to these agents.

 **CAUTION! *L'ATTENTION*!** 	
	**BIOHAZARD**: If any materials are overturned during operation, immediately set the power switch to OFF (0). This material should be treated as potentially biohazardous. Appropriate cleanup and disposal of biohazardous waste should be used. ***Biohazard****! Lors du fonctionnement, si on renverse des matériaux, coupez immédiatement le courant. Placez le commutateur électrique a AU LOIN(0). Traitez le matériel comme biohazardous, utilisant approprie nettoient et des méthodes de disposition*.

1.2.3 Disposal and Storage

Dispose of according to local regulations. Before the instrument is removed from the laboratory for storage, disposal, transporting, or servicing, it must be decontaminated.

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

 BIOHAZARD! 	
	**WARNING**: Treat all components during use and disposal as you would any biohazardous material. **AVERTISSEMENT** : Utiliser et disposer des matériaux de la même manière que vous utilisé et disposer des matières infectieuses..

1.3 Safety Precautions

To assure operator safety and prolong the life of your instrument, carefully follow all instructions outlined below.	
Read Instructions	Take time to read this manual carefully before using this instrument. Review the following safety precautions to avoid injury and prevent damage to this instrument or any products connected to it. To avoid potential hazards, use this instrument only as specified. For best results, familiarize yourself with the instrument and its capabilities before attempting any clinical diagnostic tests. Refer any questions to your instrument service provider.
Servicing	There are no user-serviceable parts inside the instrument. Refer servicing to qualified service personnel. Use only factory-authorized parts. Failure to do so may void the warranty.
Wear Protective Apparel	Many diagnostic assays utilize materials that are potential biohazards. **WARNING:** Always wear protective apparel and eye protection while using this instrument.
Follow Operating Instructions	**WARNING:** Do not use this instrument in a manner not specified by the manual, or the protection provided by the instrument may be impaired.
Use Proper Power Cord	**WARNING:** Use only the power cord specified for this product and certified for the country of use.
Observe All Terminal Ratings	**WARNING:** To avoid fire or shock hazard, observe all ratings and markings on the instrument. Consult this manual for further ratings information before making connections to the instrument.
Install as Directed	Install the instrument on a sturdy, level surface capable of safely supporting the instrument's weight 90lbs (45 kg). The mounting surface should be free of vibrations. The instrument does not require fastening to the bench top.
Provide Proper Ventilation	Refer to the installation instructions for details on installing the product so it has proper ventilation. The instrument should be surrounded by the following clearances: 46cm on each side, 117cm on top, 15cm in front, and 18cm in back.
Do Not Operate Without Protective Covers	**WARNING:** Do not operate this instrument with covers and panels removed.
Do Not Operate without Probe Shield	Do not operate this instrument with shield removed. Doing so risks the operator to biohazard injury from the probe
Avoid Exposed Circuitry	**WARNING:** Do not touch exposed connections and components when power is present.
Probe Tip	**WARNING:** Do not touch exposed probe tip when power is on to the instrument. Disconnect the power cord before any maintenance.

Safety Precautions (Continued)

Keep Instrument Surfaces Clean and Dry	**CAUTION:** Solvents such as acetone or paint thinner will damage the instrument. • Do not use solvents to clean the unit. Avoid abrasive cleaners; the aerosol shield is liquid-resistant, but easily scratched. • Clean the exterior of the instrument with a soft cloth using plain water. If needed, a mild all-purpose or nonabrasive cleaner may be used. • Use as a 10% solution of chlorine bleach (5.25% Sodium Hypochlorite) or 70% isopropyl alcohol. • Take special care not to spill liquid inside the instrument **NOTE**: The manufacturer or his agent is to be consulted if there is any doubt about the compatibility of decontamination or cleaning agents.
Transporting	CAUTION! Treat instrument and components as you would any biohazardous material. See Section 1.2.3 Disposal and Storage for decontamination recommendations. When shipping the instrument, it is important that the instrument be anchored using the original shipping screws and packaging. Pack the instrument in the original manner to prevent shipping damage.

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

Do Not Operate In An Explosive Atmosphere	**WARNING**: Do not operate instrument in an explosive atmosphere.
Do Not Operate With Suspected Failures	**WARNING**: If you suspect there is damage to this instrument, have it inspected by a qualified service person.
Do Not Operate in Wet/Damp Conditions	**WARNING:** Do not operate instrument in wet/damp conditions.
Avoid Excessive Dust	Do not operate in an area with excessive dust.

1.4 Operating Precautions

WARNING: Insufficient RAM will adversely affect the performance of your instrument. The minimum RAM required is 1GB.

This general purpose instrument is intended to be used by laboratory professionals who are capable of selecting the appropriate features and options for each specific clinical application.

- Some diagnostic assays utilize materials which are potentially biohazardous.
- Always wear protective apparel and eye protection while using this instrument.
- Always operate the instrument with the aerosol shield lowered.
- Do not use the instrument in a manner not specified by the manual, or the protection provided by the instrument may be impaired.

- Probe tips are sharp and may cause bodily injury. Do not place hands or fingers under the probe or wash head probes while instrument is in operation. Always set the power switch to OFF (O) before working on the probe or wash head. Never touch the probe or wash head while the instrument is operating.

 CAUTION	The probe performs a self-clean periodically while the probe is idle. Keep hands away from the probe at all times when the instrument is ON (I).

- Watch the instrument during "Start of Day" operation to ensure that the probe and wash head dispense functions are operating properly.
- Visually check the sample handling tubing and the syringes for the presence of any bubbles.
- Be sure to run a sufficient number of controls in each assay. If controls are not within their acceptable limits; or if incomplete, or non-uniform washing is suspected, disregard test results.
- Since the ambient light may interfere with the optical sensors used to monitor mechanical movements, always operate the instrument with the top cover down.
- Do not operate the instrument if the probe is damaged or the pressure is unstable.
- If the Waste bottle is overturned during operation, set it upright. When the run has finished, check that the filter has not become wet, and replace it if necessary. If the hydrophobic filter becomes wet due to an overturned Waste bottle, it will be blocked. ***Continued use of the instrument with a blocked filter will impair washer effectiveness and may result in damage to the instrument.***

 **CAUTION! *L'ATTENTION*!** 	
	CAUTION! To avoid waste fluid backing up into the instrument, ensure that the drain tube is positioned such that the waste fluid is allowed to flow and to drain directly into the waste container. The end of the drain tube should not rest in the waste fluid nor should it rest against any wall or the bottom of the waste container. Reference the drain tube installation instructions in Section 2.3.2.

- Do not fill reagent bottles past the neck. Doing so may cause the system to inadvertently aspirate air.
- Do not fill Wash or Rinse bottles into the neck to prevent fluid from entering the pressure tube.
- The Wash and Rinse bottles are pressurized during normal operation, and the Waste bottle is under vacuum.
    - Do not remove bottle caps or tubing connections while the bottles are pressurized.
    - Turn the instrument off or click the Pause Engine in the Management menu before adding more solution, changing bottles, or connecting tubing.
- The quality of washing often affects the validity of test results. To assure adequate washing follow these precautions:
    - Perform "End of Day" to clean probe with bleach and flush wash head with H_2O
    - Handle and store the wash head carefully to prevent damage.
    - Use the prime cycle before each wash.

2. Installation

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

	CAUTION! *L'ATTENTION!*
	CAUTION! Unpacking this instrument is a 2-person job! Lifting the instrument requires the efforts of two persons. Grasp the instrument at each end of the chassis near the feet of the instrument and carefully lift the instrument out and onto a stable work surface.

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

When shipping, it is important that the instrument be anchored and packaged in the original manner to prevent shipping damage. *Therefore, retain all* packing material, such as: plastic sheeting, splints, orange shipping bracket, hardware & bubble wrap,in the event the instrument requires future relocation.

2.1 Packing List

		2925			*SPARE PARTS BOX
QTY	**PART #**	**Description**	**QTY**	**Part #**	**Description**
1	2925	CASS ChemWell	1	990113	Plate Cover
1	994317	Reagent Rack (in Box)	1	997425	8-Way Wash Head
1	994316	Sample Rack (in Box)	1	029019	Performance Check Kit
1	188171	Carrier Insert (in box)	1	952905	Complimentary Card
1	188483	Probe Shield	1	183827	Mouse Pad
1	104455	USB Cable	1	137140	Exhaust Filter
1	137521 or 137222	US or Euro Power Cord	1	029017	Wash Solution
1	994008	Bottle Set	24	157202	Microwell Strips
1	994040	Prime Bottle	1	157201	Microwell Strip Tray
1	994073	3 Bottle Stand	1	188656	Probe Cone
1	950509	Unpacking Instructions	2	102220	Probe Tip
1	004301	USB Flash Drive - includes Software and Operator's Manual	1	XXXXXX	Hardware/Accessories Box
1	029010	*Spare Parts Box		**** DRAIN TUBING KIT**	
1	XXXXXX	**Drain Tubing Kit	1	135237	6" Drain Hose
1		Certificate of Quality	1	137154	T-Barb
			1	137059	Drain Tubing Clip

2.2 Instrument Setup

2.2.1 Parts of the Instrument

- The main power connection is on the back of the instrument. Position the instrument so that you can easily disconnect main power if required. Be sure to leave at least 6 inches (15.2cm)around the instrument to enable access to the power cord.
- Read all Warning and Caution notes.
- Refer to the Unpacking Instructions and the Packing List to ensure correct setup of the instrument.
- During first installation, the instrument must be aligned and setup. Use the procedures in this section to ensure that the instrument is ready to work. Refer to Section 4.2.1 and 7.1 for help with Alignment.

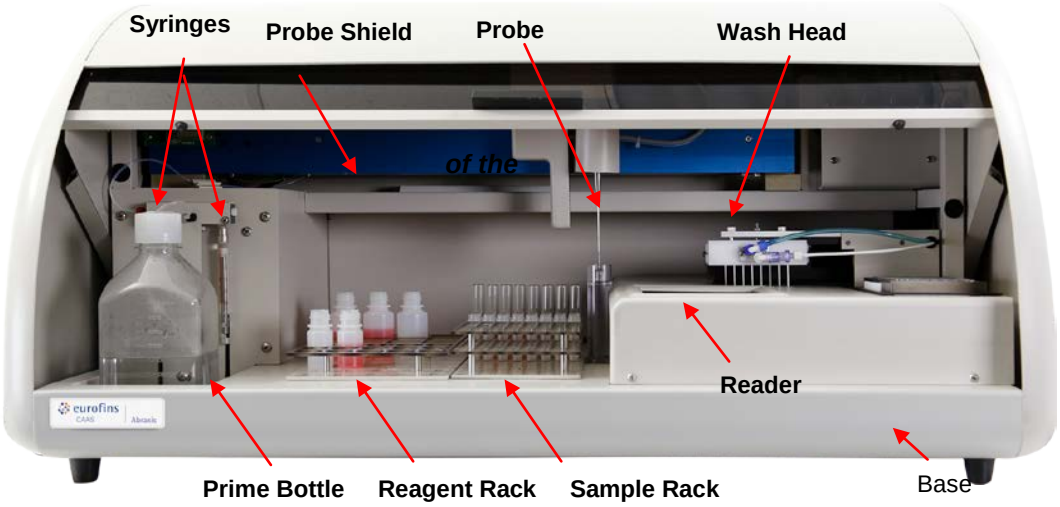


Figure 2.2.1-1 Parts of the instrument

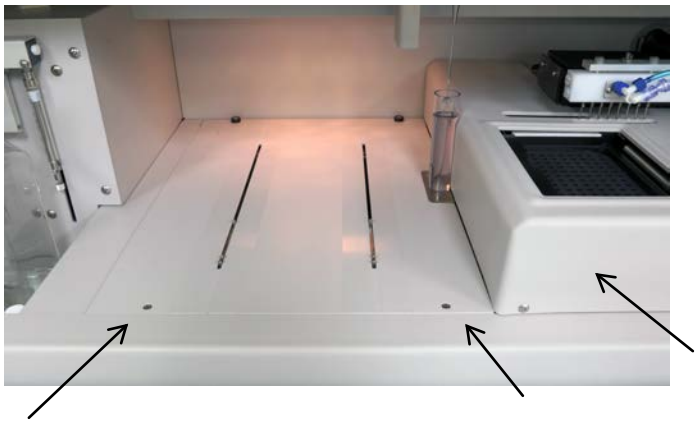


Figure 2.2.1-2 Rack Holder locations

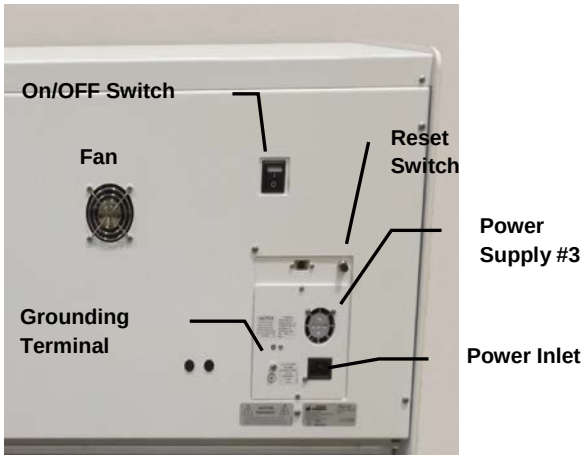


Figure 2.2.1-3 Back Panel

2.2.2 Drain Tube Installation

Read the drain tube installation instructions before cutting the tubing.

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

To ensure that waste fluid does not back up into the instrument, position the drain tube such that the waste fluid is allowed to flow and drain directly into the waste container.

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

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

Figure 1 - Drainage tube connected to the instrument; measure length of tubing to the edge of lab table.

Figure 2 - Drainage tube connected with barb tee shown with lab table outlet.

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

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

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

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

Connect the drain tubing to the barbed tee as shown.

A serves as air vent

B tubing attached to the drain outlet on the bottom of the instrument

C tubing leading to waste container

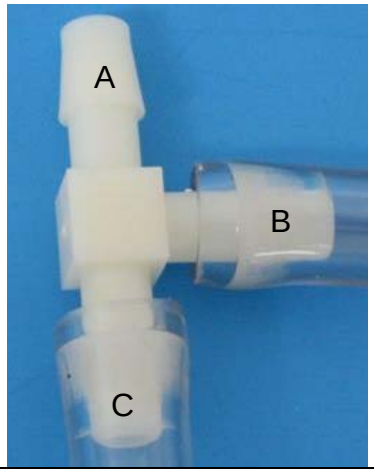


Figure 3 - Barbed tee connector with tubing connected.

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

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

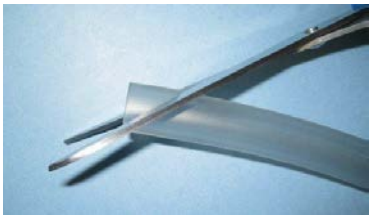


Figure 4 - Cut the drainage tube on a diagonal to prevent tubing from resting on the bottom of the waste container.

2.2.3 Bottle Assemblies and Connectors

NOTE: DISREGARD *FIGURE 2.2.3-1 CONNECTORS,* IF YOUR INSTRUMENT DOES NOT HAVE A WASHER

CAUTION! *L'ATTENTION!*	
	CAUTION! The hydrophobic filter on the waste bottle is designed to protect the pump from liquid and may become clogged when wet. Arrange the tubing so that the filter hangs down below the connecter on the side of the instrument to prevent clogging.

Match the color-coded connectors on the three bottle cap assemblies to the colored connectors on the right side of the instrument. Turn each connector about 1/4 turn clockwise to lock it in place. Insert the sensor cable jacks, matching the colored tie wrap with the color-coded connectors.

Figure 2.2.3-1 Connectors

Put de-ionized water into the bottle marked Rinse. Put wash buffer provided into the bottles marked Wash. Leave the Waste bottle empty. Check that each bottle cap is securely fastened and that no sensor wires are crossed. Note that the *Waste* bottle has short sensor leads in order to detect when waste is nearly full. *Rinse* and *Wash* bottles have long leads in order to sense when bottles are nearly empty.

Fill the *Prime* bottle with fresh, clean de-Ionized H_2O. *This should be done each day* - this water enters the precision calibrated syringe pumps and therefore must be very pure to avoid damage and prolong the life of these components.

This instrument has the ability to use two different plate washing solutions. One is placed in the bottle labeled *Wash*, and the other can be placed in the bottle labeled *Rinse*. If only a single assay washing solution is needed, one should put de-ionized water in the bottle labeled Rinse. This rinse solution can then be used to flush out the plate wash head after running assays. A wash concentrate Tween-20 solution is included with your instrument. This solution can be used as a plate wash solution after performing the instrument Self Test Procedure (Section 4.2.6). Leave the *Waste* bottle empty.

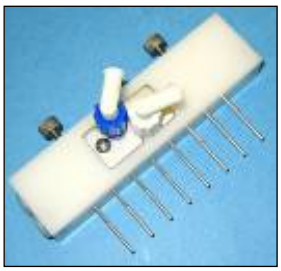
Check that each bottle cap is securely fastened and that no sensor wires are crossed. Note that the *Waste* bottle has short sensor leads in order to detect when waste is nearly full. *Rinse* and *Wash* bottles have long leads in order to sense when bottles are nearly empty.

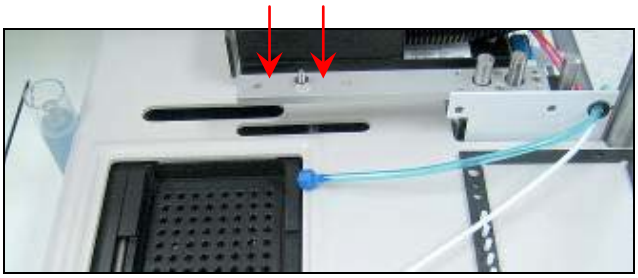
Figure 2.2.3-2 Install Prime Bottle

2.2.4 Wash Head Installation

When the instrument power is turned on, the probe arm will be raised up in order to allow installation of the wash head. More detailed and troubleshooting information are in Section 7.1.2 Alignments.

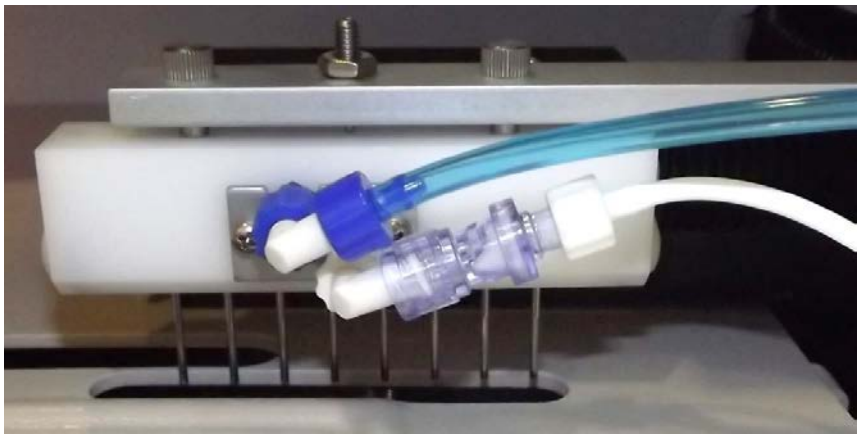
Wash head installation location





Install the 8 way wash head (found in the accessories carton) to the wash arm using the two attached thumbscrews (**A**). The center screw (**B**) is factory set – do not adjust.

A B A



CAUTION! *L'ATTENTION!*	
	CAUTION! Do not adjust the center screw (reference close up view in Figure 2.2.4-2). It has been set at the factory. Too much pressure on the top of the wash head will cause the aspiration needles to shift out of alignment with the washer opening in the X-Y cover. Contact Technical Support for guidance if you experience aspiration problems.

The probe performs a self-clean periodically while the probe is idle. Keep hands away from the probe at all times when the instrument is ON (I).

The luer fittings must face outward (toward the user), and the color-coded fittings on the tubing should be fastened finger-tight to the wash head.

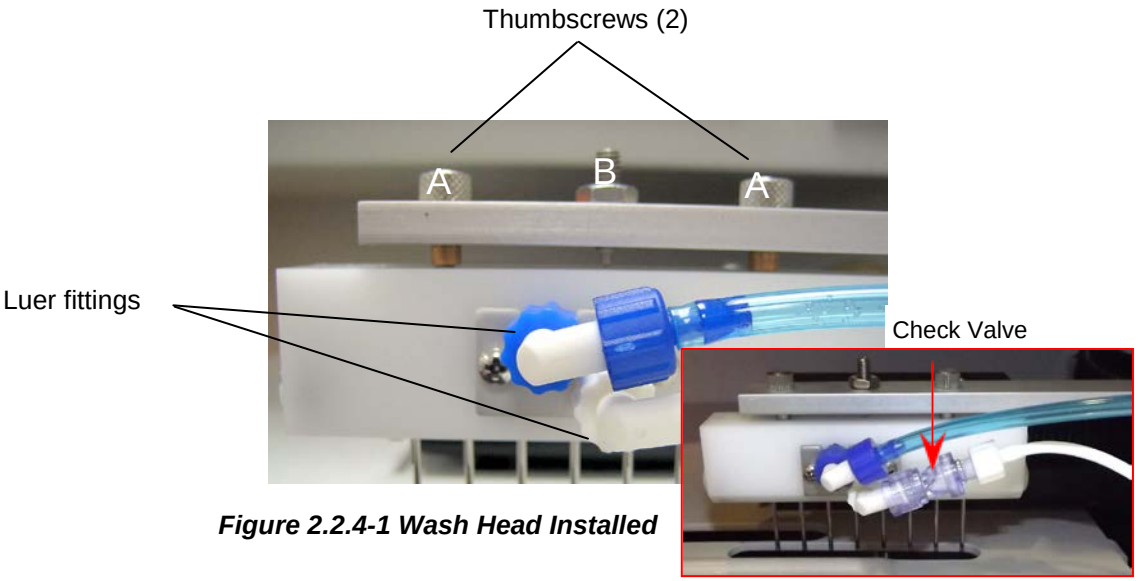


Figure 2.2.4-1 Wash Head Installed

The center screw (B) is set at the factory; it has been adjusted such that the spring-loaded pin (C) exerts constant downward pressure on the top of the wash head.

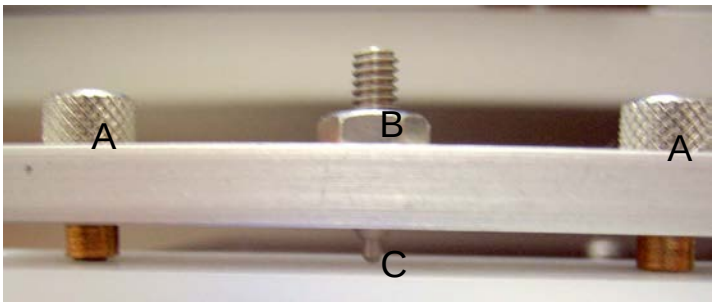


Figure 2.2.4-2 - Close up view of thumbscrews (A),center screw (B), and spring-loaded pin (C)

Before running the instrument for the first time, perform Self Test, Section 4.2.6.

2.2.5 Software Installation and Computer Connectivity

> ***IMPORTANT NOTE!*** As with many USB devices, it is critical that you do not connect the USB cable to the instrument until the software has been installed. Doing so may affect the installation of the applicable drivers needed to run the ***CAAS*** Manager Software.

Follow the steps below to install the software and connect to a computer.

Turn on the computer and insert the installation CD or USB drive. The installer should start automatically.

If not, or if the software is on a USB flash drive, locate the software by searching from the Windows start button. Double click to open the ***CAAS*** folder.

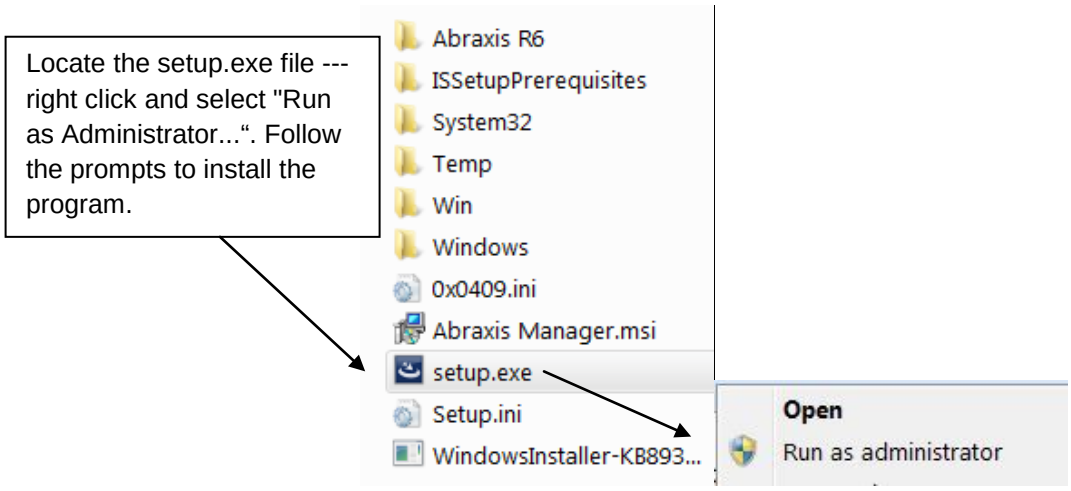


Figure 2.2.5-1 Install the software

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

Software Installation and Computer Connectivity (Continued)

There are 2 important steps to take when installing, and then using, the Manager software on Windows 8 or 10 computer systems. You must install and run this program as Administrator for all the software features to be installed correctly. When installing the software make sure you right click on the setup file and select "Run As Administrator" as shown in ***Figure 1***. After installing the software for the first time, open the icons for **both** Manager and Assay Editor as administrator.

1. To install Manager program (setup.exe) – right click on "Run as Administrator".

2. To open the Manager and Assay Editor icons – right click on each one and select "Run as Administrator".

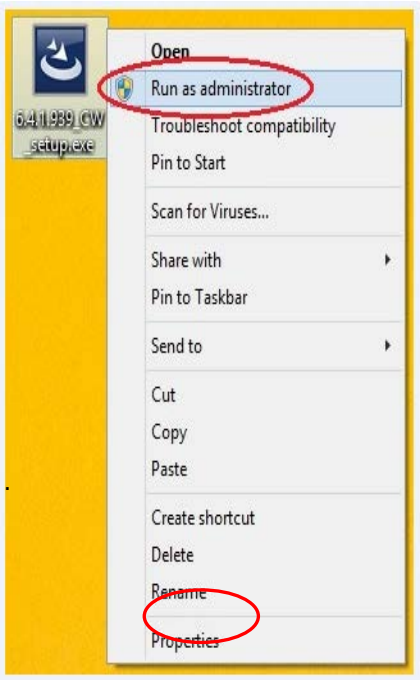


Figure 1

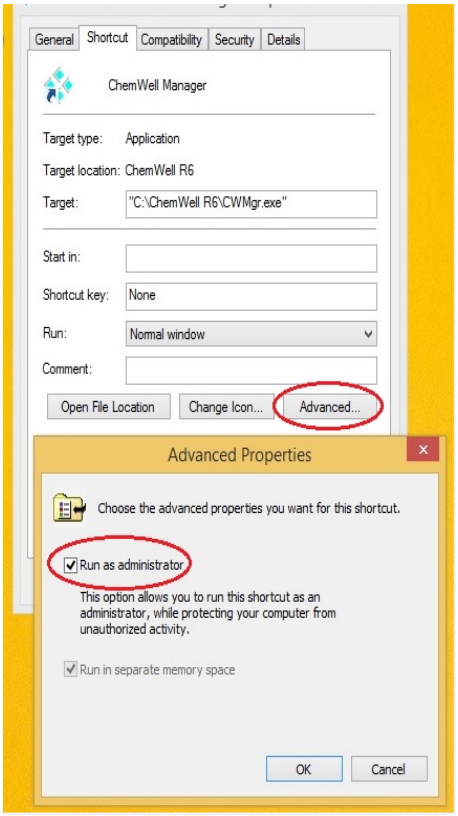
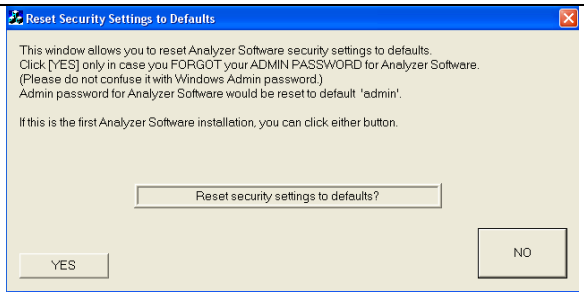
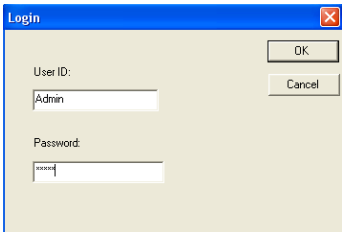
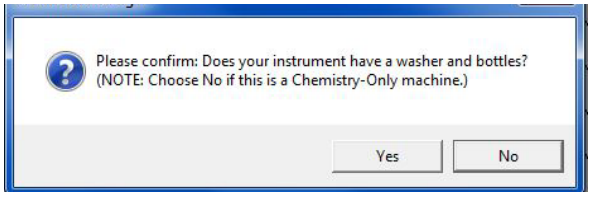


Figure 2

NOTE: Sometimes, running the software for the first time as administrator is all that is needed. However, on some computers, you need to always run as Administrator. You can set the "Advanced" properties of the software icons to always Run as Administrator without having to remember to right click each time. To set Icons to ALWAYS run as administrator, click on Properties (***Figure 1***). A new window will open. Click Advanced and then click the box next to Run as Administrator (***Figure 2***).

The program default communication port setting for USB is AUTO for communication with the instrument. If connecting the instrument to a different port, go to the Settings Menu and select Software. Select a communications port and click OK. Reference Section 7.4 for further information on communication port settings.

Steps	Prompts/Screen Display
Reset Security Settings Defaults: This window will open when the software is installed for the first time. It allows the user to reset the software security settings to the default settings "Admin", or to set new User ID and Password. (If this is the first ***CAAS*** software installation, clicking either button will reset the default password "Admin".)	 ***Figure 2.2.5-2 Reset Security Settings to Defaults***
Right click on the ***CAAS*** **icon** and "Run as Administrator" to run the program. At the Login prompt, enter **Admin** in the User ID: field, and the Password field, Select OK. Using the USB cable provided, connect the computer's USB port to the instrument's USB port.	 ***Figure 2.2.5-3 At Login prompt enter Admin***
NOTE: When starting the software for the first time the software prompt will ask if there is a washer. Answering "No" when an instrument does have a washer will result in a 511 error code (Wash Movement Error) when a wash command is called.	 ***Figure 2.2.5-4 Washer Questions***

2.3 Instrument Check Out

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

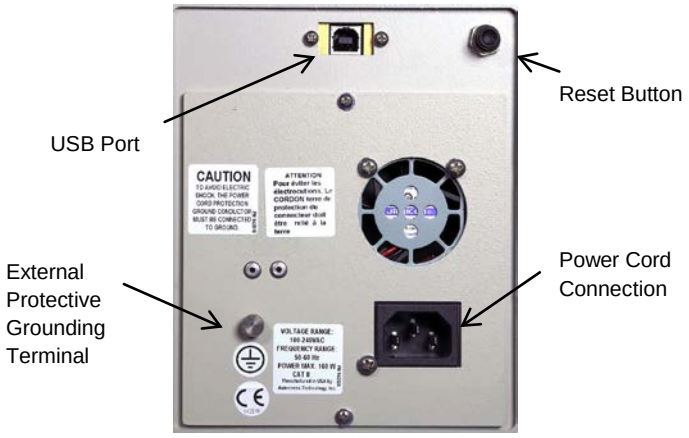


Figure 2.3-1 Back of Instrument

With the instrument connected to a computer, start the *CAAS Analyzer* software, and switch on the instrument. When the instrument powers up, note the following actions:

- The probe moves to its home position (to the left), over the plate, and then to the wash cup
- All racks move to the front (home) positions
- The syringe pumps prime
- The instrument optical system lights come on

These events are controlled by firmware installed in your instrument; however, the software must be running for proper operation.

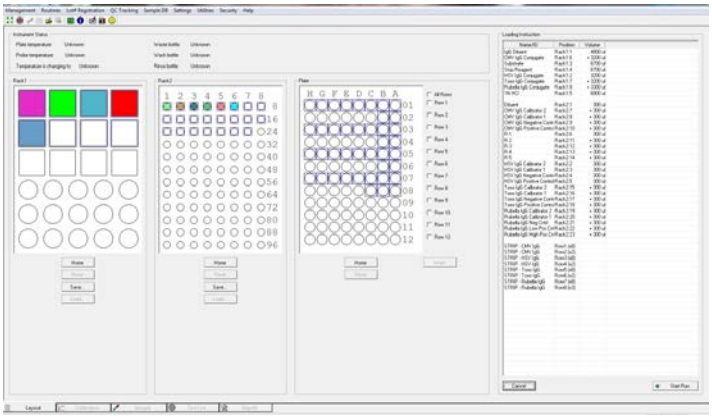
If the instrument's power comes on, but these actions do not occur and the beep sound continues, there is a problem with the communications setup. Check the serial cable connections and refer to Section 7.4 PC Communication Port Settings.

Notes:

3. Principles and Specifications

Two syringe pumps are used to make precise dilutions. Based on the volume required, selection of the appropriate size syringe is made automatically made by the instrument. The smaller syringe measures volumes of 230µL or less. All dispenses are performed by the large syringe. The single probe moves left and right as well as vertically. It is equipped with a liquid surface detection mechanism that stops the probe automatically when the tip is sufficiently submerged. Probe washing uses de-ionized H_2O from the prime bottle and drains to the waste bottle below the instrument.

The plate and two racks move independently toward the front and back of the instrument. Commonly referred to as a “Reagent rack”, a “Sample rack”, and a “Reaction plate“. However, reagents can be placed in the Sample rack, or two racks can be used to perform pre-dilutions. Each rack has an arrangement of holes or grooves configured to hold different types of tubes, bottles, micro tubes, microwells, and other containers. Racks are identified in the software in order to tell the instrument which configuration is to be used.



Graphic display of Reagent Rack1, Rack2 and Plate from Layout screen

The incubator plate/well can be set to heat to 25°C, 37°C, or remain at ambient room temperature. The plate/well will heat to 25°C providing the ambient room temperature is below 25°C. (It should be noted that the option of heating the plate/well to 25°C should only be used when the ambient room temperature is consistently below 20°C.)

When the probe carries a reagent to an incubated reaction plate, the temperature-controlled coil can be set to pre-warm the liquid before dispensing.

Reagent racks can be loaded and unloaded with bottles from run to run. The location of each reagent is indicated using a color-coded computer screen. Alternately, preferred reagent rack setups can be stored in panels. For convenience, multiple pre-loaded racks can be stored in the refrigerator ready to load and use.

When taking an optical reading, the reaction plate automatically positions itself under the 4-channel optical system. Four lamps are aligned to simultaneously shine down through four wells. A filter wheel with eight filters rotates constantly below the plate. The filter wheel is designed so that four filters align with the four lit wells for absorbance readings.

Depending on the setup, reports may be displayed or printed to create permanent lab records and physician reports.

3.1 Continuous Loading

Continuous loading allows the addition of tests and samples "on the fly" (while other tests are currently running) instead of collecting a batch of specimens for a run. Calibrators and Controls can be loaded at any time, allowing updating of stored curves or validation of tests when needed. If tests associated with the newly loaded Calibrators are already running, the Sample concentrations for those tests would be automatically adjusted for the new curves without any user intervention. Results for individual Samples can be accepted or re-run for verification, simply by clicking a button - it is no longer necessary to setup another job to re-run your samples.

3.2 Technical Specifications

Overall:

Maximum throughput	Up to 200 endpoint reactions per hour or 170 kinetic reactions per hour, kit dependent
Typical reaction	Volume 250 uL or less
Dimensions and Weight	36.25" (92.1cm) width,18.75"(47.6cm) height, 21.5"(54.6cm) depth; Weight = 78lbs (35kg)

- ***Reagent and Sample Dispensing:***

Capabilities:	Dilutions, predilutions, dispensing single or multiple reagents
Pumps:	Two syringe pumps, sized: 250µL and 2.5mL
Probe:	316 stainless steel for maximum reagent compatibility, level sensing
Minimum and Maximum Volume:	5µl – 1.95ml
Maximum number of specimens:	96 (including calibrators and controls)
Maximum number of reagents:	Typically 27 or 44 o Assorted replaceable racks and custom designed racks are available for various bottle sizes. o Reagents can also be programmed to go to the Sample rack.
Reaction vessel:	Standard microwells, strips
Instrument bottles:	1L Priming bottle

NOTE: If microplate washer is present included are: a) 2L Wash bottle w/ low volume warning sensor, b) 1L Rinse bottle (or 2nd wash) w/ low volume warning sensor, and c) 2L Waste bottle w/ full warning sensor.

Technical Specifications (Continued)

- ***Incubation, timing and temperature control:***

Chemistries:	Each group of four wells is timed separately
Thermal control:	Plate/Well 25°C, 37°C, or ambient temperature o Temperature controlled to 25°C providing the ambient room temperature is below 25°C o Refrigerated Reagent Rack (optional) cools 12° to 15°C below ambient through Peltier thermoelectric modules connected to an external controller o Sample Rack is not temperature controlled

- ***Washing (if microplate washer is included):***

Wash Head:	8-probe, automatic prime and rinse
Programs:	Create and run user programmable protocols (aspirate, dispense, and soak). Can wash wells for re-use as applicable

- ***Reading:***

Optical design:	Reads absorbance in four simultaneous channels; NIST traceable calibration; user selects monochromatic or bichromatic results
Light Source:	Tungsten-Xenon lamp
8 position filter wheel:	340, 405, 450, 505, 545, 600, 630, 700 or custom
Interference filters:	Long life, hard coat, ion-assisted deposition, +/- 2nm, 10nm typical half band pass
Linear range:	-0.2 to 3.0A
Photometric Accuracy:	± (1% of the reading +0.01A from 0 to 1.5A) ± (2% of the reading +0.01A from 1.5 to 3.0A)

Software:

Format:	USB and Internet upgrades
Operating Systems:	Windows® 7, 8.1 or 10
Minimum System:	MS Windows® 7, 8.1 and 10 (32 bit), Internet Explorer 11, 1GHz processor, 1GB Ram; CD or DVD rom, USB 2.0 port, Ethernet port or Wi-Fi card
Recommended System:	MS Windows® 7, 8.1 and 10 (64 bit), 2GHz processor, 4GB Ram; DVD R/W, USB 2.0 port, Ethernet port or Wi-Fi card

Technical Specifications (Continued)

Secondary menu options:	Create/edit protocols, import/export data, etc., Control, Run, and Setup
Calculation modes:	Single standard, factor, fixed time kinetics, kinetics by standard or factor, multi-calibrator point-to-point, linear regressions, log-logit, cubic spline, and nonlinear regressions (curve fit), cutoffs, %Absorbance
Self monitoring modes:	Lamp, bottle volume, filters, pressure, vacuum, mechanical function, and more
QC options:	Store control data, print Levey-Jennings or QC range plots, calculate SDs
USB port:	USB cable provided

Power:

Voltage Range:	100-240VAC
Frequency Range:	50-60Hz
Power Maximum:	160W
Installation Category:	CAT II

- ***Recommended Environmental Condition:***

Indoor Use

Mains supply voltage:	Fluctuations not to exceed ±10% of the nominal voltage
Operating Temperature:	18-35°C recommended
Operating Humidity:	Less than 80% recommended

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

Certifications: NRTL Listed

4. *CAAS* Software and Features

4.1 Opening the Software and Security

CAAS uses the standard Windows® controls, windows, and dialogs. Refer to Windows® documentation to become familiar with these controls and how to use them.

4.1.1 Opening the CAAS Manager Program

Power on the instrument.

Right click on the ***CAAS* Manager** icon  and Run as Administrator to open the software.

NOTE: It is not necessary to turn the instrument off when restarting the software.

4.1.2 Initialization

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

NOTE: Initialization may also be executed without restarting the software by clicking on the Initialization icon (see Main Menu Selections and Features section for more information).

After all functions have been checked, press OK to continue.

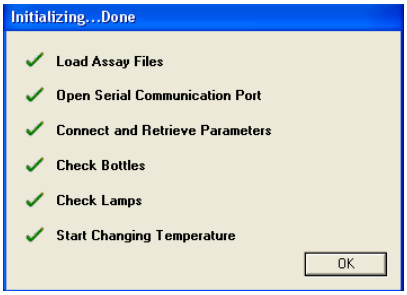


Figure 4.1.2-1 Initialization Screen

4.1.3 Password Security and Logging In

There are three security access levels: Administrator, Manager and Operator.

Security Level	Administrator	Manager	Operator
Disable Security	Y	N	N
Enable Security	Y	N	N
Create Manager	Y	N	N
Create Operator	Y	Y	N
Remove Manager	Y	N	N
Remove Operator	Y	Y	N
Change Password	Y	Y	Y
View Log File	Y	N	N

Figure 4.1.3-1 Security Levels

4.1.4 Security Menu Options

Enabled When Enabled is checked, the password protection and security restrictions are being used.

The instrument can be set up with or without a password security system.

- To remove the password security system so that a login is no longer required, go to the “Security” menu and uncheck “Enabled”.
- With “Enabled” checked, the security system is on. Only Administrators have access to this option.

Figure 4.1.4-1 Security Menu Options

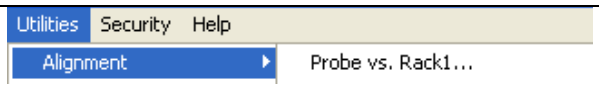
- **Login as Different User** displays the Login screen and allows you to login with a different name and password.
- **Logout** logs current user out of the system.
- **Create New User** creates a new user with ID, password, and security level. The manager can create users, but will only be able to give them operator level security.
- **Remove User** Administrators can remove any user, Managers can only remove operators.
- **Change Password** Any security level can use this feature. Enter the old password followed by the new password.
- **Who is logged in** Security access window appears to show who is logged in and their access level .
- **View Log File** opens a log of every user name that has logged on, including a time and date stamp and a running count of entries.

4.2 Utilities Menu

Before running any tests or jobs, the instrument must be aligned and setup. Use the procedures in this section to ensure that the instrument is ready to work properly. Also refer to Section 7.1 for tips on alignment troubleshooting.

4.2.1 Alignment

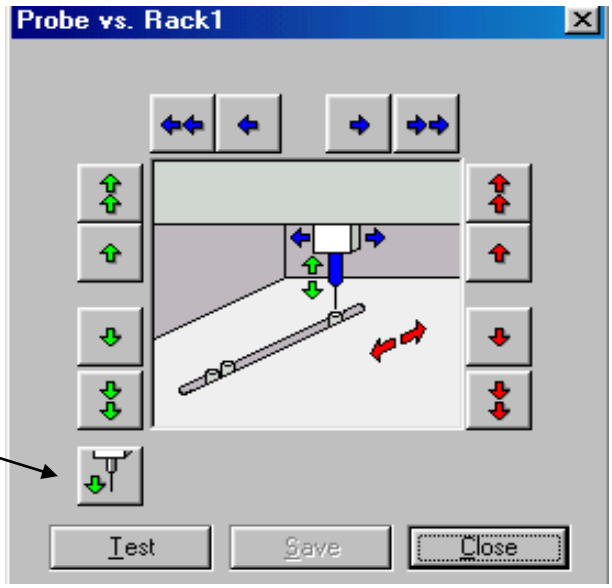
Probe vs. Rack1



Blue arrows move the probe Side-to-Side

Green arrows move the probe Up and Down

To check the current alignment, click the probe button.



Red Arrows move the rack backward and forward

Figure 4.2.1-1 Probe vs Rack1

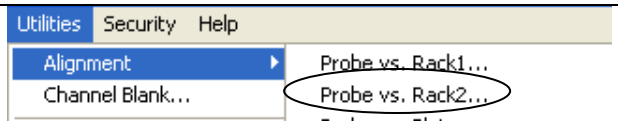
Use the arrow buttons to position the probe correctly.

The probe tip should be centered about 3mm above the rear pin, as shown.

To check new alignment, select “Test”. When finished click “Save”, then click “Close”.

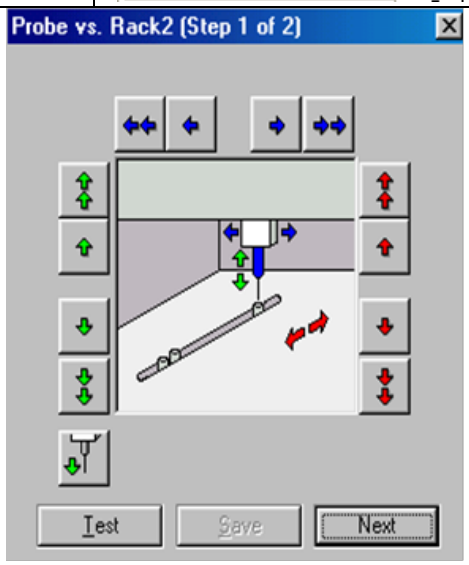
Alignment (Continued)

Probe vs. Rack 2 – Step 1 of 2



Blue arrows move the probe Side-to-Side

Green arrows move the probe Up and Down



Red Arrows move the rack backward and forward

Figure 4.2.1-2 Probe vs. Rack 2

To check the current alignment, click the probe button.

Use the arrow buttons to position the probe correctly. The probe tip should be centered about 3mm above the rear pin, as shown. To check new alignment, select “Test”. When finished click “Save”, then click “Close”.

Probe vs Rack 2 - Step 2 of 2

This step prompts to replace Rack 2 and place a sample cup in position number 96 in the back of the sample rack (view *Figure 4.2.1-3*).

NOTE*:* Select “Close” to pass the option to set an alternate depth. Otherwise, select the probe button.

Use the green arrow keys to move the probe until it almost reaches the bottom of the sample cup. When the correct depth has been reached click Save and then the Close button.

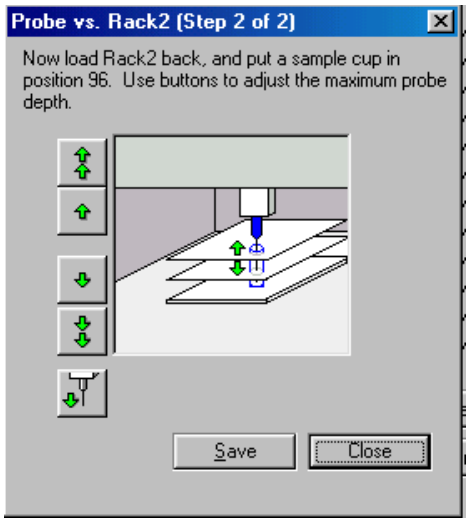
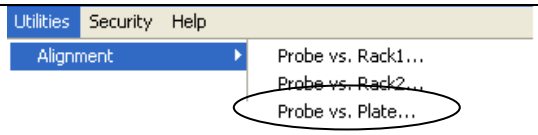


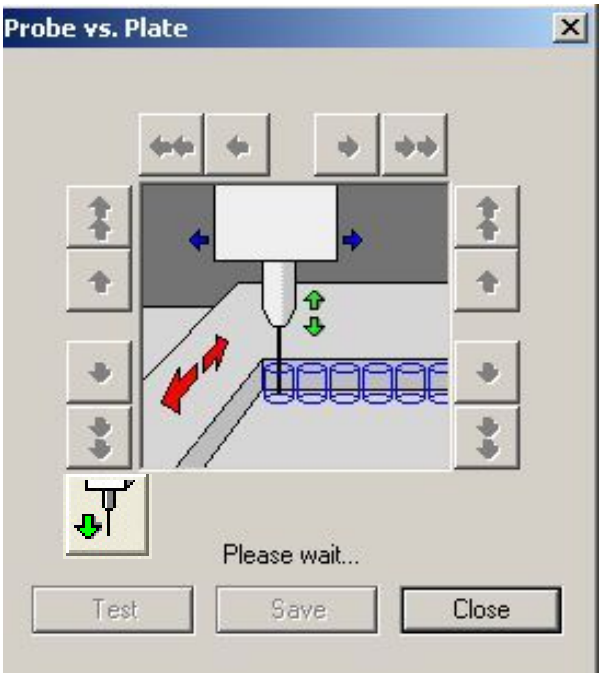
Figure 4.2.1-3 Step 2 Adjust Probe Depth for Rack2

Alignment (Continued)

Probe vs. Plate	

Blue arrows move the probe Side-to-Side

Red Arrows move the plate backward and forward



Green arrows move the probe Up and Down

Figure 4.2.1-4 Adjust Probe Position for Plate

Insert a plate or strip tray into position when prompted.

To check the current alignment, click the probe button:

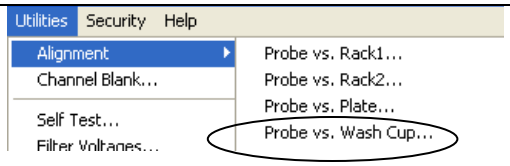
Use the arrows to move the probe into the correct position.

The probe tip should be centered in well H01 and almost touching the bottom.

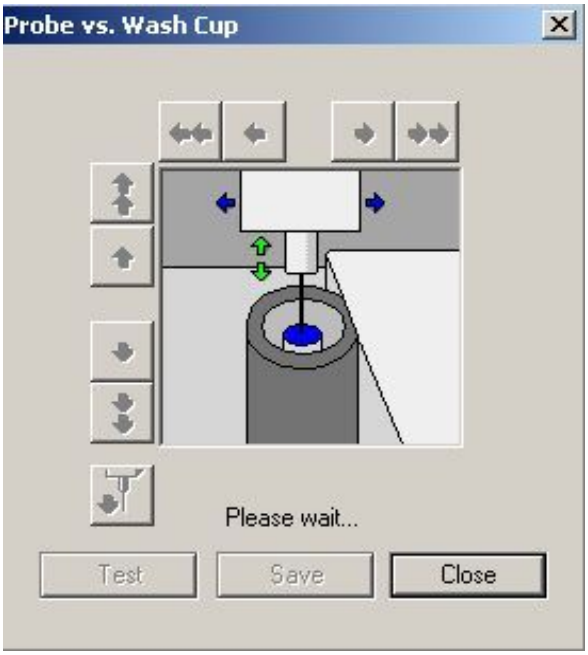
Press “Test” to confirm.

When finished, click Save and then the Close button.

Alignment (Continued)

Probe vs. Wash Cup	

Blue arrows move the probe Side-to-Side



Green arrows move the probe Up and Down

Figure 4.2.1-5 Probe vs. Wash Cup

Press the probe button. 

The probe will move to the center wash position and lower into the cup.

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

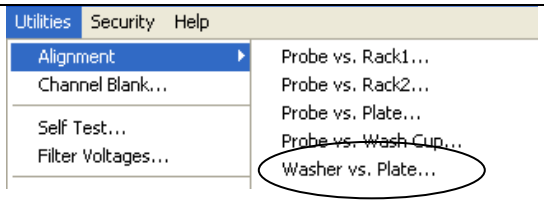
If it is not in position, use the arrow keys to move the probe into position.

When finished, click Test to check new alignment.

When aligned, click Save, then Close.

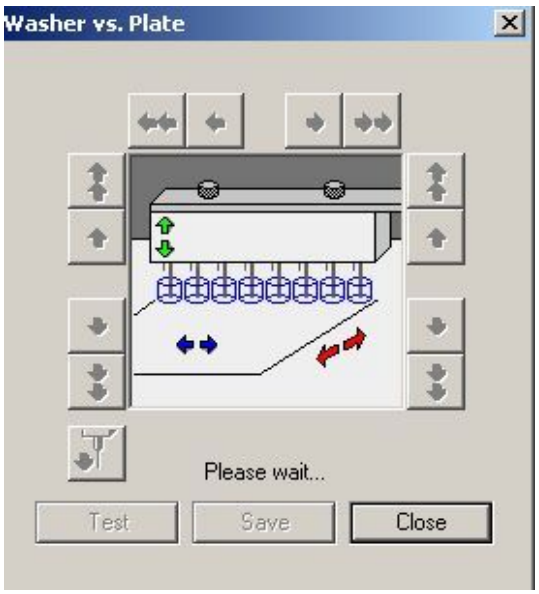
Alignment (Continued)

Washer vs. Plate



Blue arrows move the plate Side-to-Side

Red Arrows move the plate backward and forward



Green arrows move the wash head up and down.

Figure 4.2.1-6 Washer vs. Plate

Insert a plate or strip tray when prompted. Click the probe button. 

The plate will move under the wash head and the wash head will lower into the wells.

The plate and wash head should be positioned so that the aspiration needles are centered left to right, toward the back of the wells; touching but not pressing on the bottoms of the wells.

Use the arrows to position the wash head correctly.

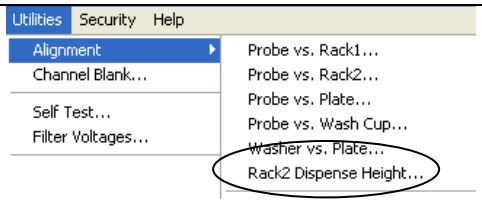
When finished, click Test to check new alignment.

If aligned, click Save, then Close.

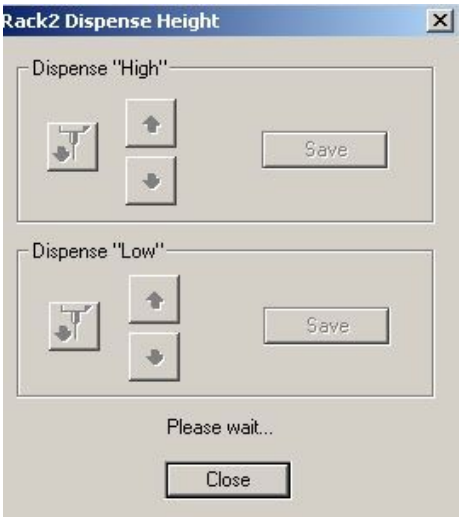
Alignment (Continued)

Rack2 Dispense Height

NOTE: This adjustment is used to select the dispense height when dispensing to a sample rack for pre-dilution purposes.



Dispense "High" is normally used for dispensing a large volume of diluent. (These settings are specified when programming the assay in Assay Editor.)



Dispense "Low" is normally used for dispensing small volumes such as serum to a predilution.

Figure 4.2.1-7 Rack2 Dispense Height

Use the top set of three buttons to select the "High" dispense height, and the bottom set of three buttons to select the "Low" dispense height - the up and down arrows will adjust the probe up and down.

Low should be set inside the tube to eliminate splashing and loss of sample.

High should be set as high as possible to thoroughly mix the sample/diluent, but not high enough to cause reagent foaming.

Test with your particular reagents for appropriate dispense heights.

Click on Save to save new settings, then Close.

4.2.2 Display Instrument Parameters

Choose Display Instrument Parameters from the Utilities>Alignment menu. Notepad opens and the following text displays:

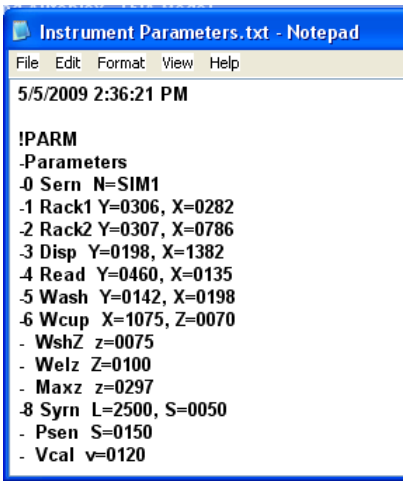
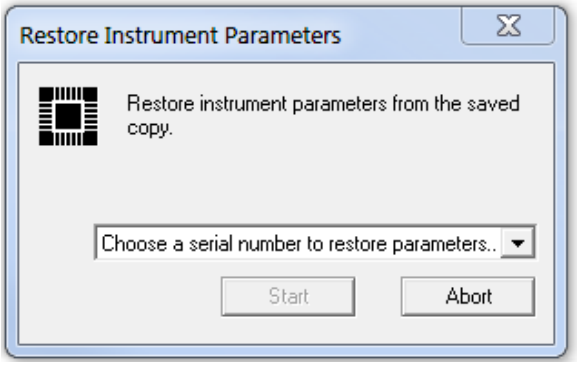


Figure 4.2.2-1 Example of Instrument Parameters.txt Notepad file

This file can be saved and/or printed or filed for future reference.

4.2.3 Restore Instrument Parameters

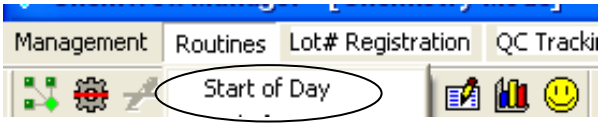
Select restore instrument parameters to restore parameters from the copy saved at the last initialization.



4.2.4 Start of Day

Running **Start of Day** at the beginning of every workday is recommended. Reference Section 10, Appendix B - Solution Compositions.

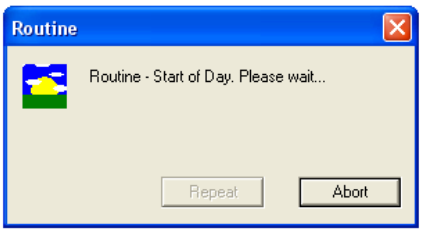
Check the bottle volume levels: empty the Waste bottle if necessary; empty the Prime bottle and refill it with fresh deionized water.
From the Routines Menu, select Start of Day



The sample handling system will be primed with deionized water. The washer (if applicable) will be primed with wash solution and the lamps will turn on.

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

Start of Day window will display



After running the Start of Day program, visually check the sample handling tubing and the syringes for the presence of any bubbles.

If bubbles are present, repeat the Start of Day program, tapping the tubing where the bubbles are present.

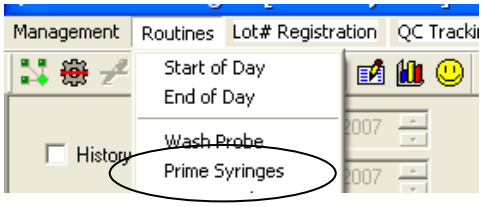
If this does not eliminate trapped bubbles, perform the **Weekly Alcohol Cleaning** procedure.

4.2.4.1 Weekly Alcohol Cleaning

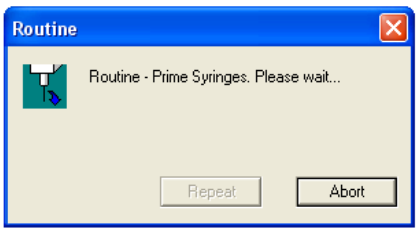
Perform this procedure to purge the tubing of trapped air bubbles.

Replace the prime bottle with a bottle containing 70% Isopropyl Alcohol.

From the Routines Menu, select Prime Syringes



When the cycle is complete, replace the bottle containing 70% Isopropyl Alcohol with the prime bottle containing fresh deionized water and repeat the “Prime Syringes” procedure.



4.2.5 Channel Blank

Tips and troubleshooting information can be found in Section 7.1.3.

CAUTION	**Run Start of Day before performing Channel Blanks!**

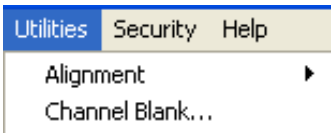


Figure 4.2.5-1 Select Channel Blank

This will allow the user to blank the four photometer channels on a wetted optically-clear solution (example blanking solution included, 0.1N NaOH with 100µL Triton X-100/L). The software will display which wells it will be using for channel blanks (preferably, use a new set of wells), and then prompt to put Blanking Solution in position 1 of Rack 1.

Never use plain water!

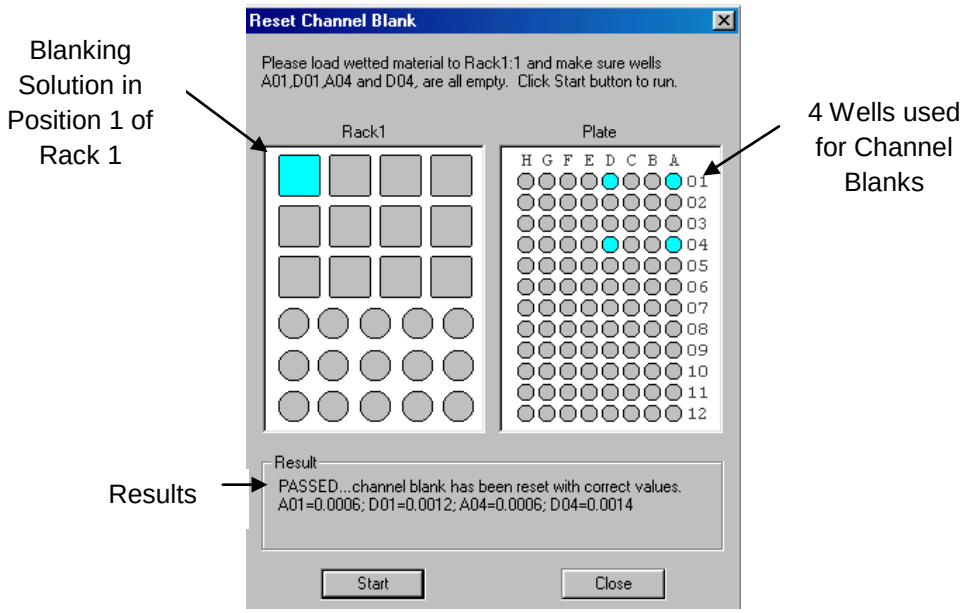


Figure 4.2.5-2 Reset Channel Blank

The instrument will then pipette the four blank wells, read, and store them, then do a reading to confirm the results. The absorbance values of the readings will be displayed and should be 0 ± 0.0050A. These blanks will be automatically subtracted from absorbance readings. The result of the reading will be displayed in the bottom of the window.

If one of the values is not between 0 ± 0.0050, follow the instructions and try doing channel blanks again. Do make sure there are clean wells in the positions indicated to run channel blanks again. If the user continues to obtain incorrect channel blanks, notify the instrument service provider.

NOTE: Be sure to replace the caps on the Performance Kit bottles after running Channel Blanks.

4.2.6 Self Test

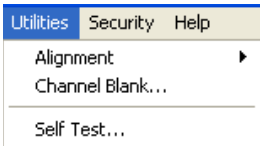
IMPORTANT! Only clean, preferably unused, wells should be used for the self test.Any residue or smudges on the bottom of the wells will cause the self test to fail.

Tips and troubleshooting information can be found in Section 7.1.4.

Self Test presents the user with the status of the instrument and records the data into the Self Test log in Notepad.

From the ***CAAS*** Manager main screen, select Utilities, followed by the Self Test option. Load “NaOH Diluent” in Rack 1, position 1. Place “PNP” in Rack 2, position 1.

Be sure to use an empty plate!



Press Start to execute Self Test.

Self Test will pipette and read repeats of three volume levels of a dye spanning the linear range of the photometer. The report will print out the results. Use the Performance Kit included with the instrument. (Refer to Section 10.2 Reading Solutions.)

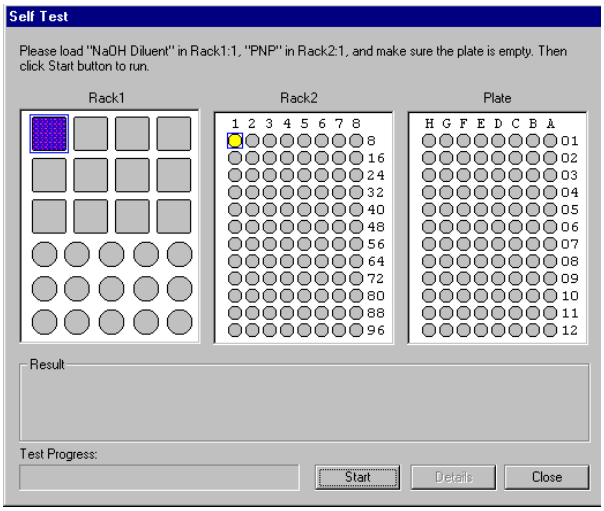


Figure 4.2.6-1 Self Test

Check the %CV. All results should be less than 2%CV, except the 5µl (small) sample should be less than 3%CV. If you encounter a higher %CV, or increasing %CV over time, it may indicate that cleaning is necessary.

Self Test (Continued)

Self Test creates a log in Notepad that can be printed out. Self Test performs an instrument test and provides a reading on the status of Blank, Pipetting, Photometer/Plate Positioning, Temperature, Blank Abs, Filter Volts, etc. NOTE: If standard filters are not installed, the instrument will select the most appropriate of the available filters. The screen will track the progress of the test.

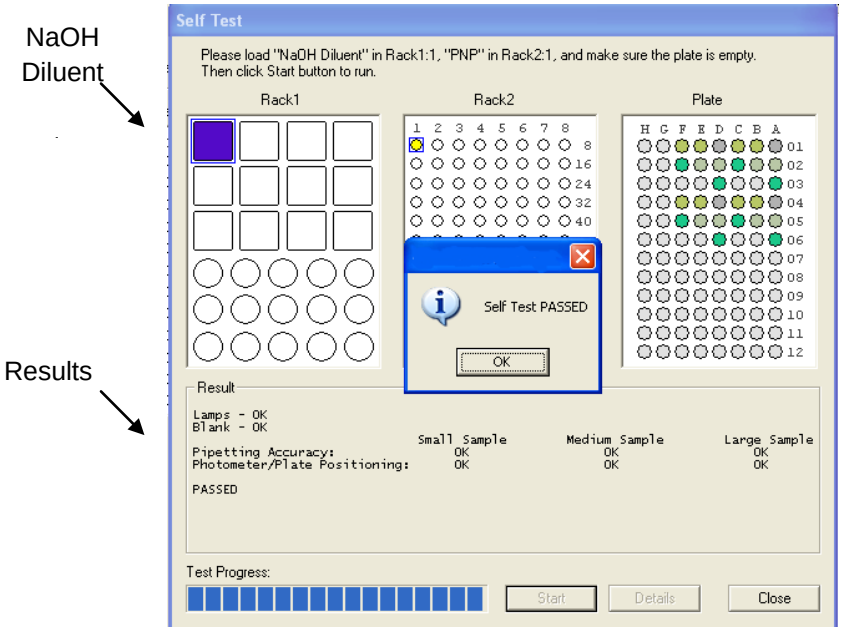
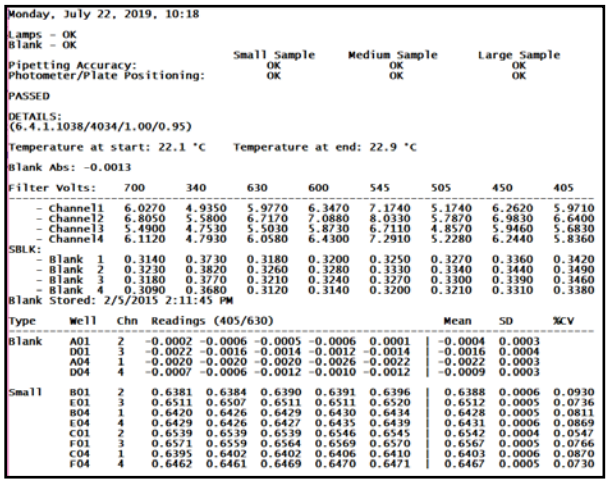


Figure 4.2.6-2 Self Test Finished

Once the Self Test is completed, press the Details button to open the Self Test log in Notepad. The Self Test log displays the date, time, status of Lamps, Blank, Pipetting



```
Monday, July 22, 2019, 10:18

Lamps - OK
Blank - OK
                                    Small Sample    Medium Sample    Large Sample
Pipetting Accuracy:                      OK              OK              OK
Photometer/Plate Positioning:            OK              OK              OK

PASSED

DETAILS:
(6.4.1.1038/4034/1.00/0.95)

Temperature at start: 22.1 °C    Temperature at end: 22.9 °C

Blank Abs: -0.0013

Filter Volts:      700      340      630      600      545      505      450      405
-------------------------------------------------------------------------------------
    - Channel1   6.0270   4.9350   5.9770   6.3470   7.1740   5.1740   6.2620   5.9710
    - Channel2   6.8050   5.5800   6.7170   7.0880   8.0330   5.7870   6.9830   6.6400
    - Channel3   5.4900   4.7530   5.5030   5.8730   6.7110   4.8570   5.9460   5.6830
    - Channel4   6.1120   4.7930   6.0580   6.4300   7.2910   5.2280   6.2440   5.8360
SBLK:
    - Blank  1   0.3140   0.3730   0.3180   0.3200   0.3250   0.3270   0.3360   0.3420
    - Blank  2   0.3230   0.3820   0.3260   0.3280   0.3330   0.3340   0.3440   0.3490
    - Blank  3   0.3180   0.3770   0.3210   0.3240   0.3270   0.3300   0.3390   0.3460
    - Blank  4   0.3090   0.3680   0.3120   0.3140   0.3200   0.3210   0.3310   0.3380
Blank Stored: 2/5/2015 2:11:45 PM

Type     Well   Chn  Readings (405/630)                                  Mean     SD      %CV
-------------------------------------------------------------------------------------------
Blank    A01    2    -0.0002 -0.0006 -0.0005 -0.0006  0.0001  | -0.0004  0.0003
         D01    3    -0.0022 -0.0016 -0.0014 -0.0012 -0.0014  | -0.0016  0.0004
         A04    1    -0.0020 -0.0020 -0.0020 -0.0026 -0.0022  | -0.0022  0.0003
         D04    4    -0.0007 -0.0006 -0.0012 -0.0010 -0.0012  | -0.0009  0.0003

Small    B01    2     0.6381  0.6384  0.6390  0.6391  0.6396  |  0.6388  0.0006  0.0930
         E01    3     0.6511  0.6507  0.6511  0.6511  0.6520  |  0.6512  0.0005  0.0736
         B04    1     0.6420  0.6426  0.6429  0.6430  0.6434  |  0.6428  0.0005  0.0811
         E04    4     0.6429  0.6426  0.6427  0.6435  0.6439  |  0.6431  0.0006  0.0869
         C01    2     0.6539  0.6539  0.6539  0.6546  0.6545  |  0.6542  0.0004  0.0547
         F01    3     0.6571  0.6559  0.6564  0.6569  0.6570  |  0.6567  0.0005  0.0766
         C04    1     0.6395  0.6402  0.6402  0.6406  0.6410  |  0.6403  0.0006  0.0870
         F04    4     0.6462  0.6461  0.6469  0.6470  0.6471  |  0.6467  0.0005  0.0730
```

Accuracy, Photometer/Plate Positioning, Temperature, Blank Abs, Filter Volts, etc.

Figure 4.2.6-3 Example of Self Test Log in Notepad

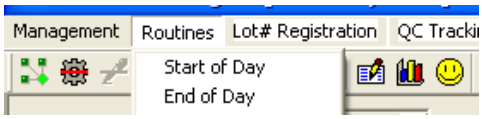
IMPORTANT: Make sure to put the PNP solution back in the plastic container!

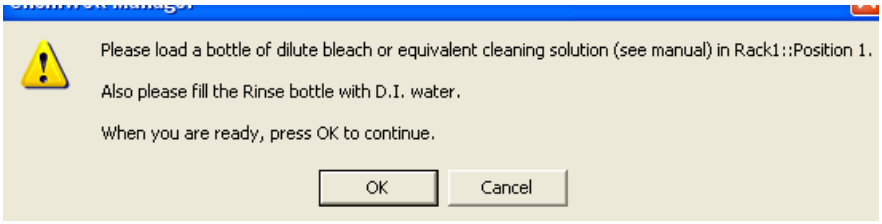
4.2.7 End of Day

NOTE: It is important that you place deionized water in the Rinse bottle prior to running End of Day

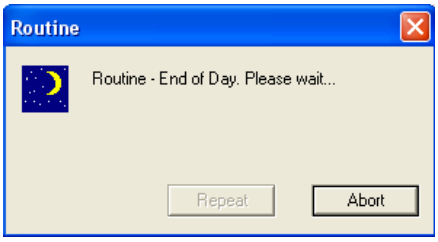
Place a bottle of 1N HCl in Rack1 Position1.

From the Routines Menu, select **End of Day** and follow the prompts





This will completely clean the sample handling system, re-prime it with deionized water, and rinse the wash head (if applicable) with deionized water. It is optional whether you turn the unit off or not.



4.2.8 Filter Voltages

Select Filter Voltages from the Utilities **menu.**

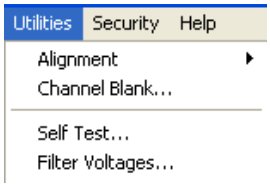


Figure 4.2.8-1 Select Filter Voltages

Press the Test Current Voltages button to view the filter voltage readings for all four channels at each of the eight wavelengths. (If nothing happens, wait for the automatic lamp warm-up time.)

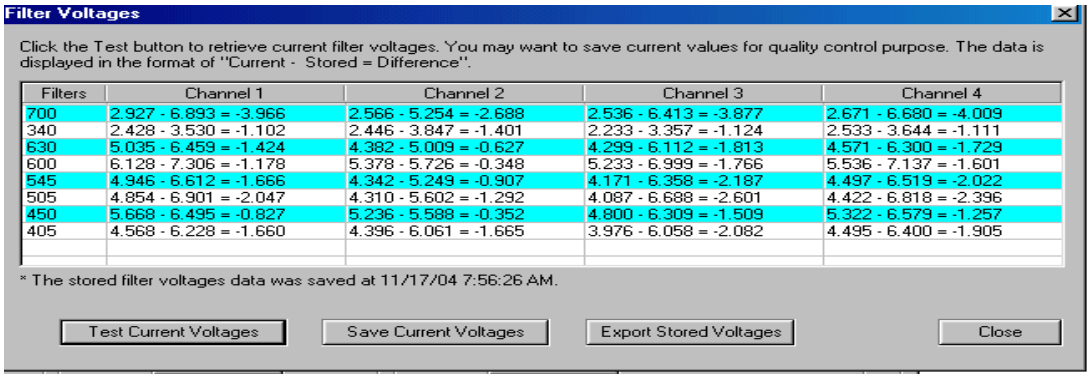


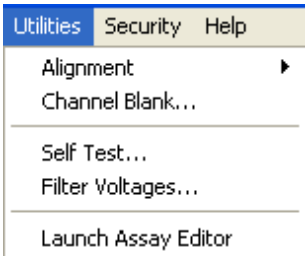
Figure 4.2.8-2 Current Voltages Test Results

All filter voltages should be between 2.00 and 10.00. Lower readings might indicate that a lamp is misaligned or partially blocked. Consult your Trouble Shooter Guide or contact your instrument service provider if correct voltages cannot be achieved. The data storage buttons on this window are for troubleshooting and are only used when instructed to do so by service engineers. Click Close to exit.

If abnormally low voltage is detected, the user will be prompted to mark the wells read by that lamp as “unavailable”. If not able to immediately replace the lamp at that time, allow the software to mark the wells as unavailable until it can be replaced.

4.2.9 Launch Assay Editor

Launch Assay Editor will open the Assay Editor when the option is selected from the Utilities Menu.



4.2.10 Launch Pack

The Pack application is used by technical support to troubleshoot problems. From the Utilities Menu select Launch Pack.

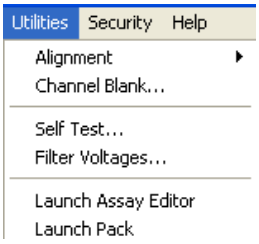


Figure 4.2.10-1

The default setting is Pack LOG files.

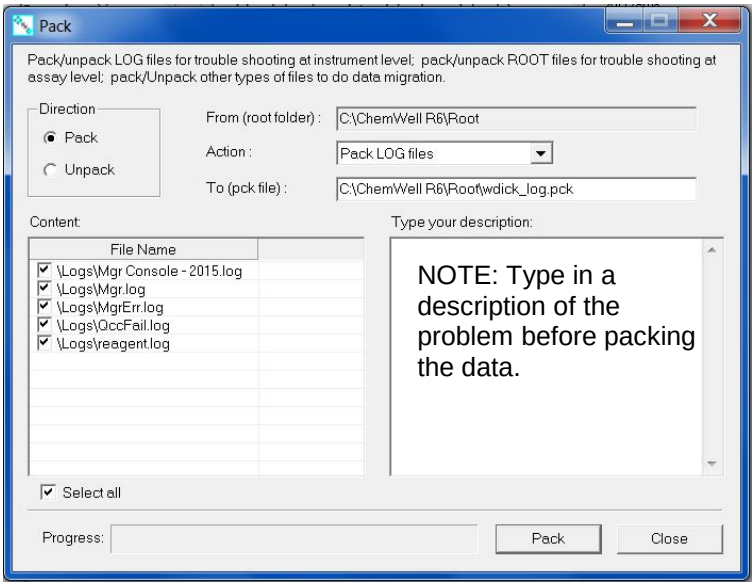


Figure 4.2.10-2 Pack Log files window

Options include packing root files, log files, assay files, lot# files, and rack files.

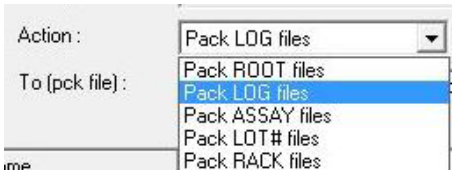
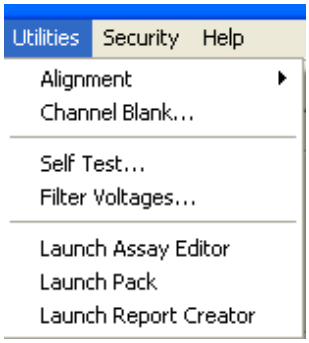


Figure 4.2.10-3 Pack Files

An individual file may be selected by clicking in the check box next to the file name, or all files may be selected by clicking on the Select all checkbox.

The packed file will be located in the directory with the filename shown in the “To” display box on the screen.The screen will display a message when the pack file operation has completed.

4.2.11 Launch Report Creator



The Report Creator application allows users the opportunity to create unique formats for their reports. Reference Section 6 for an overview and instructions on how to get started.

4.2.12 Toolbar Icons

Figure 4.2.12-1 Toolbar Icons

Feature:	Description:	Item No:
Initialize	Press the Initialize icon to establish or re-establish communication between the software and the instrument without restarting the software.	1
Pause or Resume Engine	Utilize the Pause/Resume Engine feature before adding more solution, changing bottles, or connecting tubing.	2
Pause or Resume Probe	Press Pause Probe and the probe will finish pipetting and wash the probe before pausing. The probe will be paused until Pause Probe is selected again; in the meanwhile, other tasks will continue.	3
Auto Wash Plate	Automatically washes plate after completion of tests. Available only in biochemistry mode.Refer to Appendix D	4
Reload Assay Files	Use this feature after editing or creating new assays with Assay Editor. The new or edited assays are then added to the list of available assays.	5
Switch Mode	Press the Switch Mode icon to switch between EIA and Chemistry modes. Refer to Appendix D for information regarding Chemistry modes.	6
Communication Window	Used for Service Purposes ONLY	7
Calibration Event	See Section 5.2.1 Calibration Event	8
Lot # Registration	See Section 4.4.3	9
QC Tracking	See Section 4.4.4	10
Sample Database	See Section 4.4.5	11

4.3 Manager Tabs

4.3.1 Layout Tab

This is the default window that opens when the user starts the software. It displays the current status of the instrument including the temperature. Also shown are the currently loaded racks and plate. The software automatically keeps track of which wells in the reaction plate have been used.

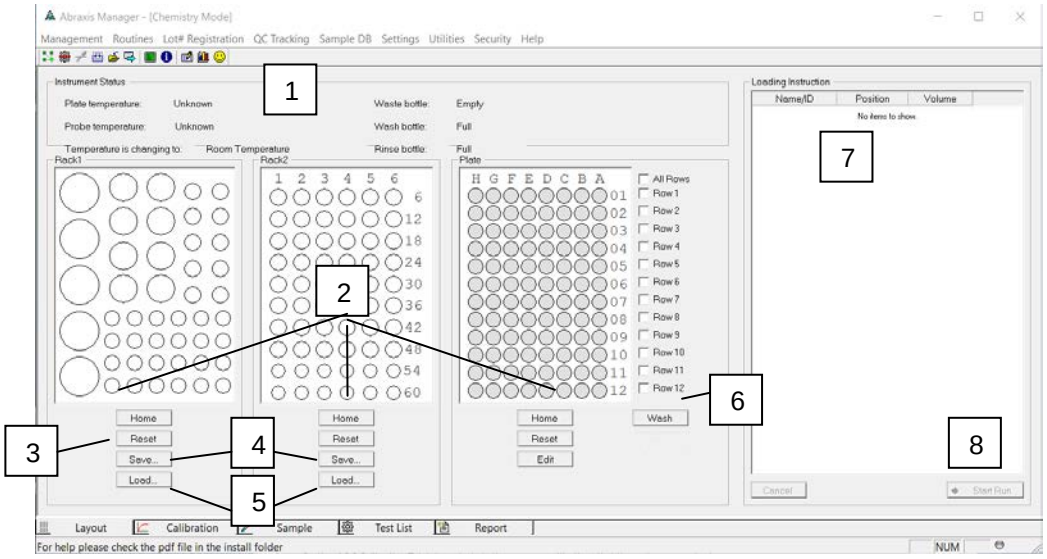
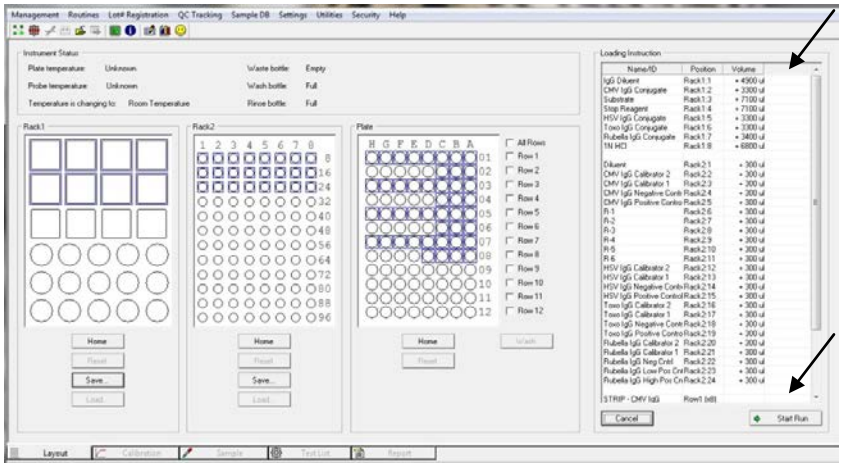


Figure 4.3.1-1 Layout Tab

Feature:	Description:	Item #
Status Window	The temperatures of the probe/coil and reaction plate are continually displayed in the instrument's **Status Window**. The temperature reading of the probe coil and plate are only accurate near 37°C. At normal ambient temperatures, the reported temperatures are not accurate and often the displayed temperature of the probe coil and plate do not agree and may report higher than the actual temperature. When plate heating is turned off under *Routines*, so is probe coil heating. When running room temperature assays, disregard the displayed temperature values.	1
Go Home buttons	Use these buttons to return to the home positions.	2
Reset buttons	Press the Reset buttons in Rack 1 and Rack 2 to reset rack as clean. Press Reset under Plate to reset wells as clean. If using this button, make sure that the positions are clean. Any tests running that are waiting for clean well positions will continue.	3

Layout Tab (Continued)

Feature:	Description:	Item #
Save	Press the Save button to save the rack layout.	4
Load	Press the Load button to load a previously saved rack layout.	5
Wash	Press to wash the wells.	6
Loading Instructions	Verify names, locations and minimum volume requirements of reagents, controls and samples as indicated.	7
 Verify the location of all samples. Press the 'Start Run' button when finished loading the racks. The tests will now begin.		
Start Run	Select this button when ready to run tests.	8

4.3.1.1 Drag and Drop feature

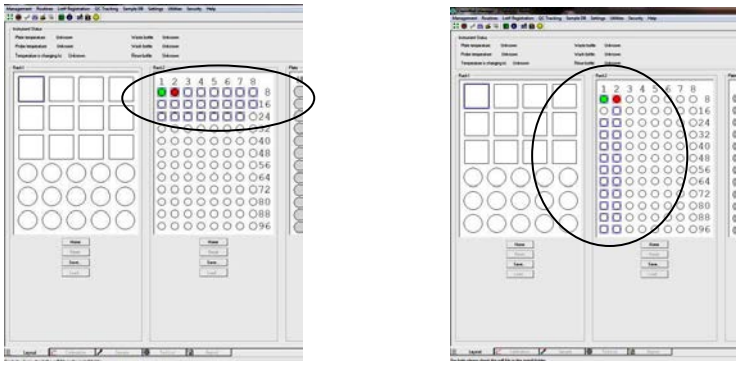


Figure 4.3.1.1-1 Locations before and after

To use 'drag and drop' feature, place the cursor over the well to be moved. Reagent and Sample locations can be changed using standard Windows® 'drag and drop' both within their rack location and between racks. The Worklist, on the right side of the screen, will identify the sample and reagent location changes that have been made.

4.3.1.2 Reagent Rack Assignments

Two reagent rack positions may be assigned in case one reagent bottle runs empty during running assays, the instrument will automatically locate and use the second reagent bottle. See the example below. Note, two assignments are the recommended limit.

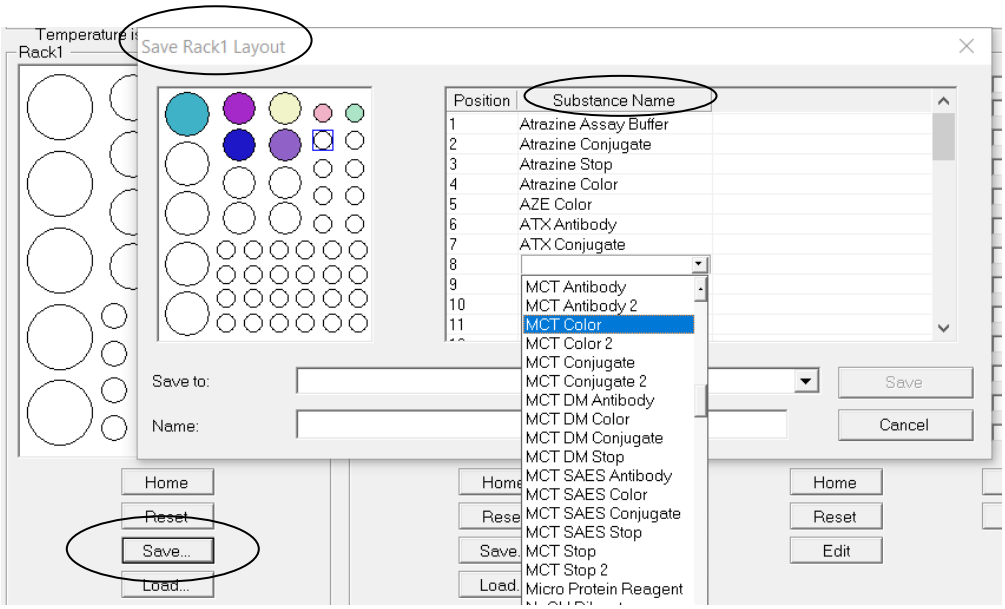


Figure 4.3.1.2-1

From the Layout Tab Click on the ‘Save’ button.

When the Save Rack1 Layout screen opens, click in the ‘Substance Name’ field to view the drop down menu options.

Click on the desired reagent assignment for position 1, repeat for an additional assignment for position 2.

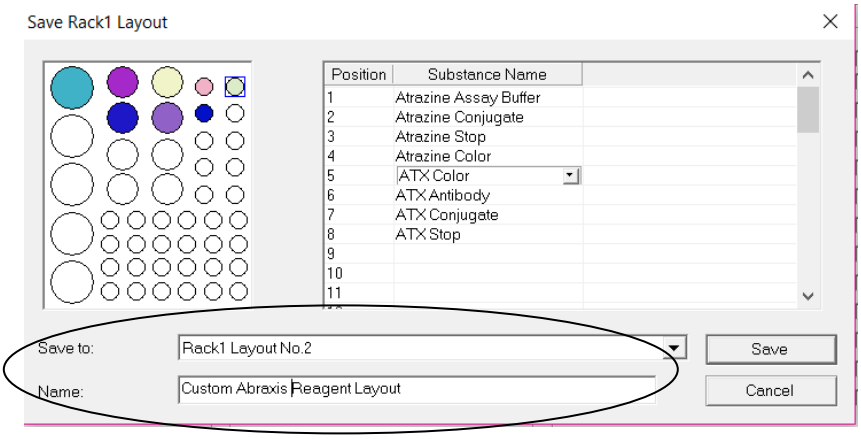


Figure 4.3.1.2-2

The Rack1 layout may be saved and given a unique file name for future use. Press ‘Save’ on the Save Rack1 Layout screen when finished.

4.3.2 Calibration Tab

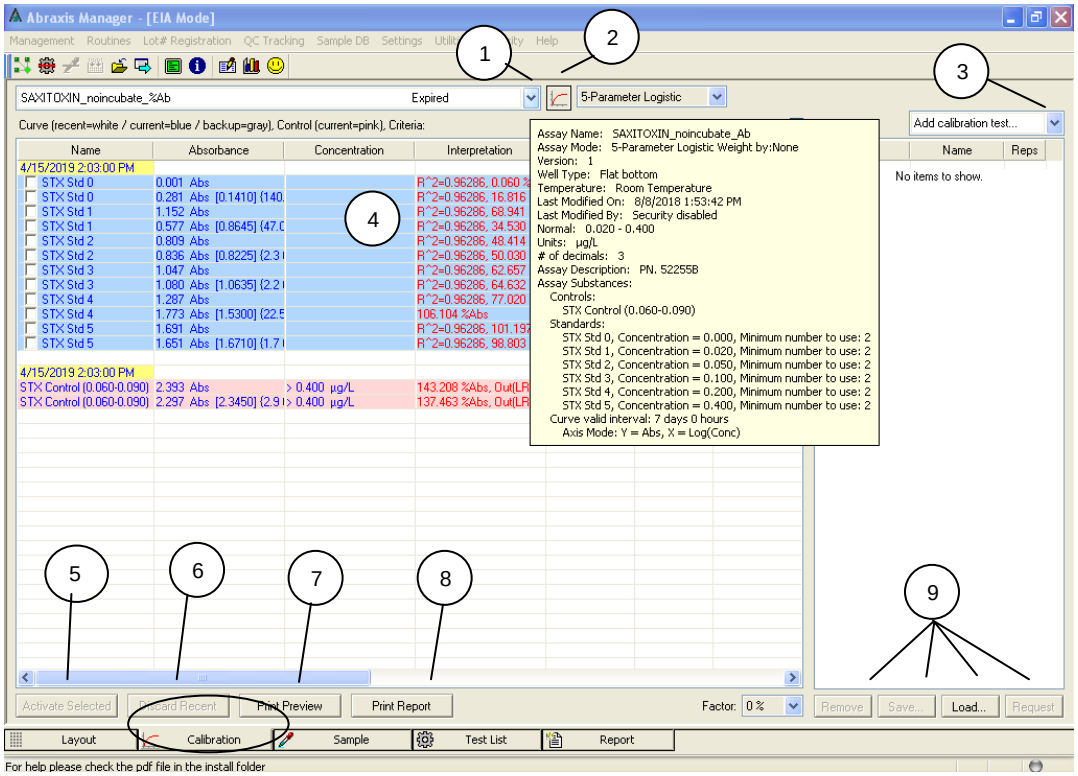


Figure 4.3.2-1 Calibration Tab

Feature:	Description:	Item #
Choose Assay	Use the drop-down menu to choose one of the assays from the list.	1
Curve Button	Toggles between substances selected (calibrators, controls) and calibration curves. • *Curve Based on Selected records* - The curve based upon the calibrators selected in the "Curve" box. Select calibrators by clicking on the box to the left of the calibrator name. • *Current Curve* - When the desired calibrators have been selected (as shown above), click on the Activate Selected button to accept. The curve is displayed in the screen. The current curve will then be used for sample calculations.	2

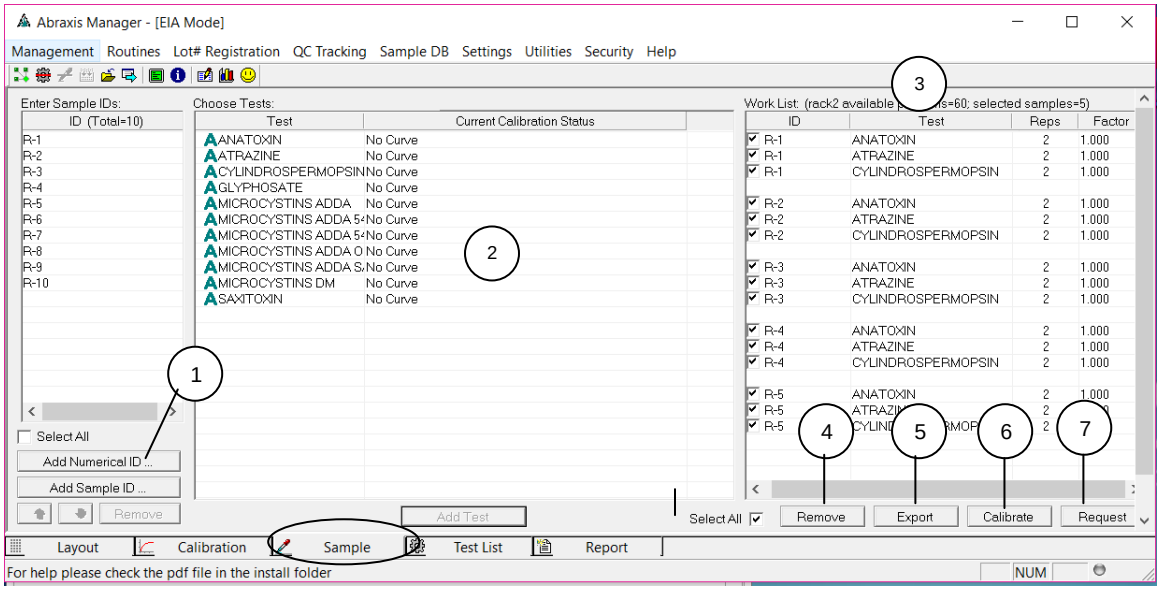
Calibration Tab (Continued)

Feature:	Description:	Item #
Add Calibration Test Information	Lists the calibrators and controls by name, copies required, and whether or not they are valid. **Selections –** • Select the ***Curve*** option to insert a blank and a calibrator for the assay into the work list. Select multiple times to add more copies of each. This button is not active if the user is running an assay that does not require calibrators. • Select the ***Control*** option to add all of the Controls specified in the assay. Press the button multiple times to add multiple copies of the controls. • NOTE: The user may also select calibrators, controls, and blanks individually.	3
View Results	View the calibration and control results in this area.	4
Activate Selected Button	To edit the curve, check the curve records (choose part of curve records which look good to user), then click the **Activate Selected** button. This button will be enabled once the software calculates (based on time, logic, math, etc.) a valid curve. After activating new curve records, the current curve is changed. The software will look at the test list to recalculate all finished tests of this assay.	5
Discard Recent	Upon accepting the new adjusted curve with the settings in Strategy Settings set to Auto, the option to 'discard recent' is no longer available. However, if Strategy Settings remain defaulted to 'manual', the user has the option to 'discard recent' and return to the previous curve. With Strategy Settings set to Manual, the new concentration values will display, however, the original values remain, allowing the user to 'discard recent'.	6

Calibration Tab (Continued)

Feature:	Description:	Item #
Print Preview	Preview calibration and control results before printing statistics such as %CV, %Dif; mean values are also shown.	7
Print Report	Allows the user to print the selected assay.	8
Worklist Buttons	Worklist items can be deleted, the worklist can be saved for future use, the worklist can be selected to run, and the entire worklist can be discarded. Click 'Save' to store the current work list. Press the 'Load' button to retrieve a previously saved work list. Choose any or all of the items in the work list and click the 'Remove' button to delete them from your work list. Press the 'Request' button to go to the Layout Tab to load and verify the locations of the reagents, calibrators, etc.	9

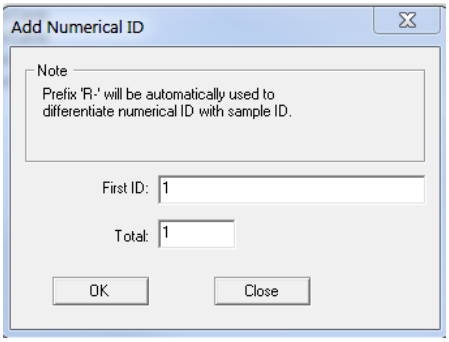
4.3.3 Sample Tab



4.3.3-1 Sample Tab

This tab can be used to set up a quick and easy work list.

Sample Tab (Continued)

Feature:	Description:	Item #
Enter Sample IDs	Press the 'Add Numerical ID' button to enter samples by number.  Press the 'Add Sample ID' to choose a patient from the Sample Database Setup (refer to Section 4.4.5).	1
Choose Tests	Click on one or more of the numeric/sample ID's on the left to highlight, choose a test to run with the chosen IDs. Click on the test and press 'Add Test'.	2
Work List	The Work List area of the screen lists the IDs and assays assigned to each, the number of requested copies (Reps), and a column labeled 'Urgent'. To add more copies to a test, highlight that row and use the hidden pull down to change the number. If it is important to run a certain Patient ID's sample first, check the 'Urgent' checkbox that corresponds with that Patient ID.	3
Remove	To remove a Patient, click the row and press the 'Remove' button.	4
Export	Press the Export button to send the Work List to a text file in Notepad. Print the file from Notepad.	5
Calibrate	Prepares calibration tests.	6
Request	Press the Request button to open the Layout Tab. Verify the location of all samples, and press the 'Start Run" button when finished loading the racks. The tests will now begin.	7

4.3.4 Test List Tab

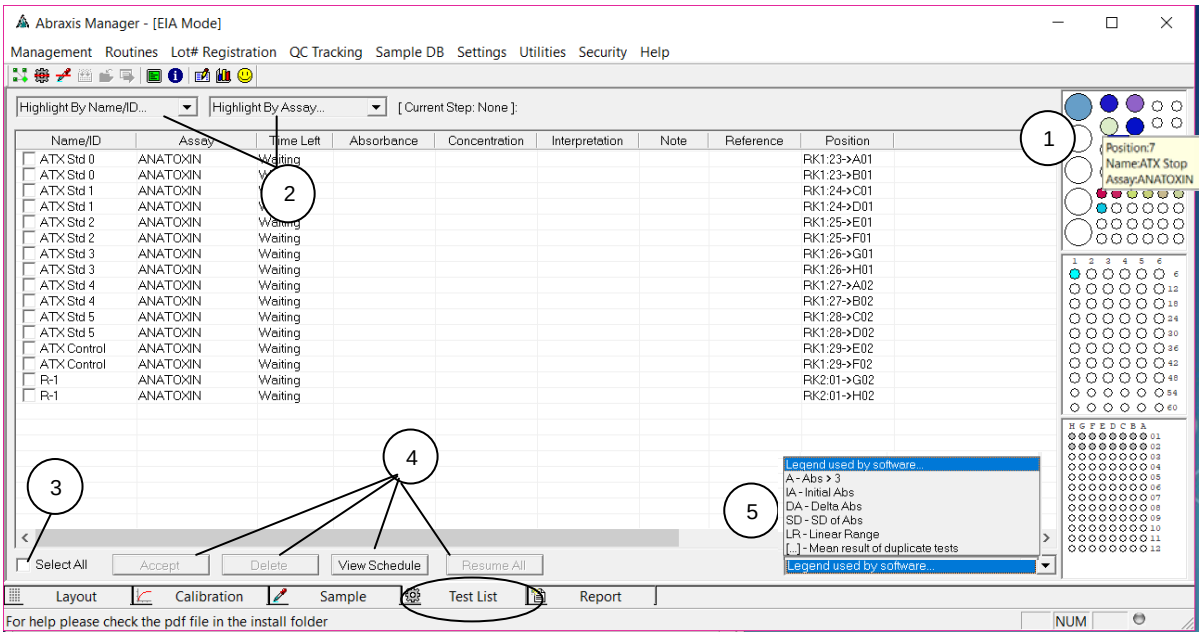


Figure 4.3.4-1 Test List Tab

Feature:	Description:	Item #
Layout Area	Indicates the location of patient samples, reagents, and pertinent assays. For more information on a particular substance, highlight it with the mouse cursor.	1
List	Use the 'Highlight by Name/ID' drop down menu to highlight a patient, or use 'Highlight by Assay' drop down menu to highlight by type of assay. A list of all of the assays will display. The Current Step that is running displays to the right of the drop down menus.	2
Select All	The 'Select All' button selects all of the entries in the list. Items may also be selected individually.	3
Action buttons	Click 'Accept' to accept the results of the selected ID. Select 'Rerun' to run the selected ID again. Use 'Delete' to discard the selected ID Check the Assay processing status by clicking on View Schedule button. Choose 'Resume All' to continue the tests. NOTE: Results must be accepted to allow them to be viewed in the Report Tab.	4
Legend Used by Software	Used to identify the processes and results used by the software.	5

4.3.5 Report Tab

By default, the Report Tab shows the information from the most recent test run. However, by clicking on the History checkbox it is possible to search by date, Name/ID ,test name or Lot#, and to display those test results.

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

Select the Magnifying Glass Icon to view Kinetic Trend Data.

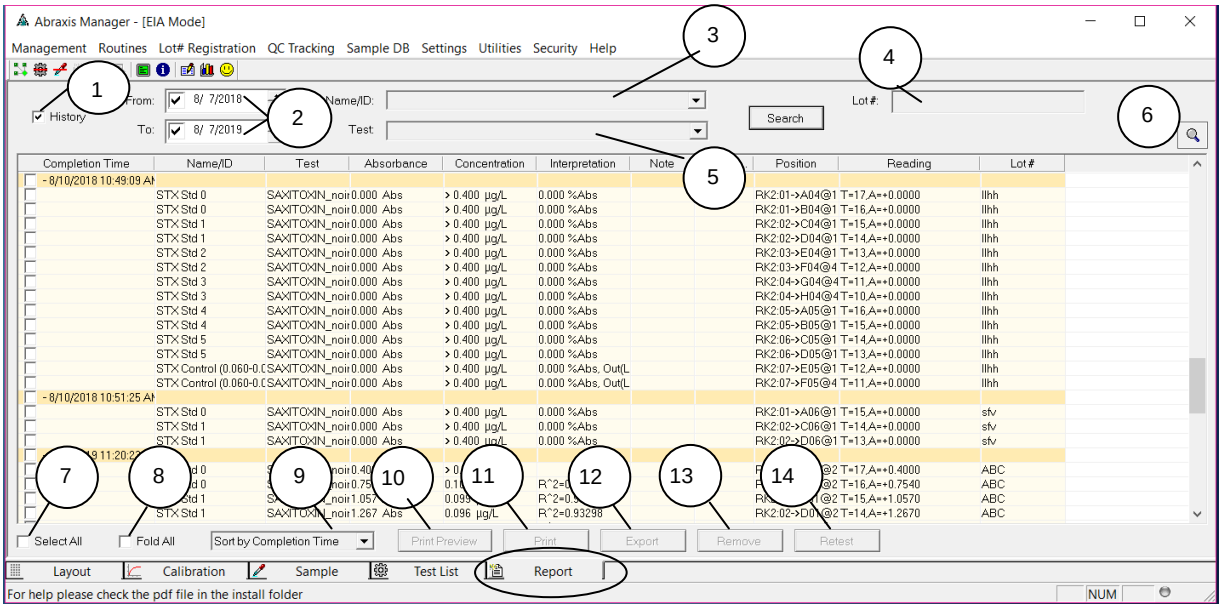
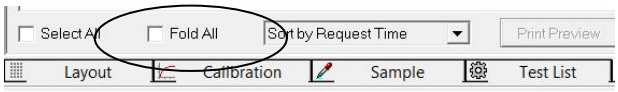


Figure 4.3.5-1 – Report Tab features

Feature:	Description:	Item #
History Checkbox	Select the History checkbox to begin searching for results by From/To, by Name/ID, by Test or by Lot#.	1
Search by Date	This allows a search for test results between a start date and an end date.	2
By Name/ID	Searches can be done for specific name or ID.	3
Search by Lot#	Allows user to find all tests for a specific kit lot number	4
By Test	Use this menu to search for results from a specific test.	5
Magnifying Glass Icon	Select the Magnifying Glass Icon to view Kinetic Trend Data (See Figure 4.3.5-2 below)	6

Report Tab (Continued)

Feature:	Description:	Item #
Select All	Check this box to select all of the results. Only the selected results will appear in printouts.	7
Fold All	Fold All narrows the display down to the selection made in the Sorting Options. For example, after sorting by Name/ID, click on the Fold All checkbox. The screen displays only the Name/ID column: 	8
Sorting Option	Select the Sorting Option from the drop down menu to change the way the results are displayed.	9
Print Preview	Select the Print Preview button, the report will display providing an advanced glance of what the output will look like.	10
Print	Selecting the Print button will print the selected Results in report format.	11
Export	Exports selected results to a text file (*.txt), MS Excel file (*.xls), or XML file (*.xml). Save for future reference.	12
Remove	Selecting the Remove button will remove all selected items from the results display.	13
Retest (add to Sample Tab)	Adds the selected items to the Sample Tab to be re-tested.	14

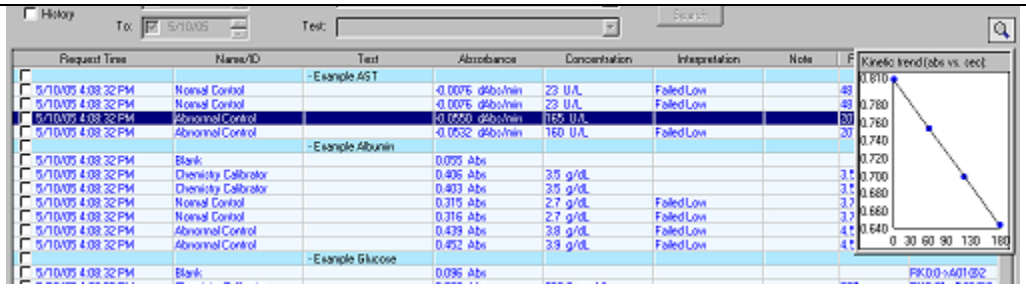


Figure 4.3.5-2 Kinetic Trend Data

4.4 Toolbar Selections and Features

Management Routines Lot# Registration QC Tracking Sample DB Settings Security Help

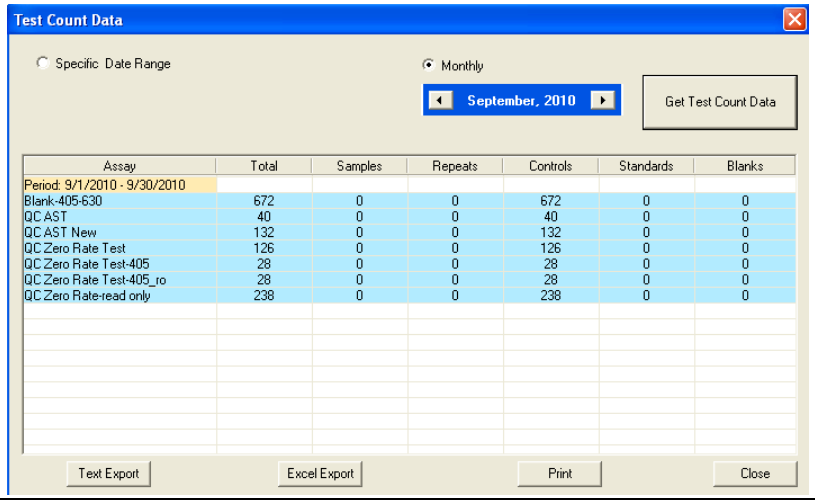
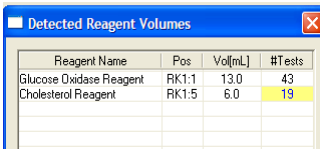
This section will introduce you to the items located in the software manager's main menu.

4.4.1 Management Menu

Figure 4.4.1-1 Management Menu Options

OPTION	DESCRIPTION
Initialize	Establish or re-establish communication between the software and the instrument without restarting the software.
Pause Engine	Press Pause Engine and all tasks pause; press again and the instrument will resume the task from the point it was paused.
Pause Probe	Press Pause Probe and the probe with finish pipetting and wash the probe before pausing. Probe will be paused until Pause Probe is selected again; in the meanwhile, other tasks will continue.
Auto Wash Plate	Refer to Appendix D
Reload Assay Files	This is used to add new or edited assays to the list of available assays. .
Switch Mode	Serves as a toggle switch between Chemistry and EIA Mode
Change Temperature	Change the temperature for specific tests. For instance, when running the Performance Check, change to "Room Temperature".

Management Menu (Continued)

OPTION	DESCRIPTION
Change Rack1	Change the rack style (if available)
Change Rack2	Change the rack style
LIS Import	Read the information that follows this table explaining the LIS Import Option and examples of import and export files.
Multi-Plate Test	Used when running a plate that contains long incubation times. Other tests, including entirely different modes, can be run by loading a different plate. There is a reminder to reload the plates when time is almost expired.
Test Count	Displays the test count for each assay by month or by date range. This data can be printed or exported to a text or Excel file. 
Communication Window (F5)	Used for Service Purposes ONLY
Calibration Event (F8)	When the instrument is finished reading, the "**Calibration Event**" window opens. This window shows whether the new curves and controls were accepted. If the curve is not accepted, this procedure must be repeated
Reagent Volume (F7)	This window shows: reagent positions, volumes and number of tests left for each assay. If the number of tests left is less than 30, the number background becomes yellow; if less than 10, the number background becomes red. 
Exit	Exit the software.

4.4.1.1 Laboratory Information System (LIS)

The Laboratory Information System (LIS) provides a method, or protocol, to allow for ease of information exchange between two systems. The patient information from external sources can be easily uploaded into our patient database. This database will contain patient information and tests requested. Upon job completion the patient information and assay results can be downloaded into a text file following the same protocol. The protocol for data exchange is listed below.

- **Import Process**:
  - Select Management > **LIS Import**
  - Choose a file containing LIS requests.
  - Requested tests are added automatically to request list in the Sample tab.
- **Export Process**:
  - In the Report tab, user will select records and press Export button.
  - In the Save-As Type drop down list, the user will select LIS files (*.lis).
  - User types in a filename, and a folder, for the file and presses Save button.
- **Record Definitions and Specifications**

Record Type Definitions	
H|	Indicates a Header Record, primarily for informational purposes.
P|	Indicates a Patient Record and is patient specific information.
OBR|	Indicates a Requested Assay to be run for the preceding patient.
OBX|	Results from the Requested Assay preceding.
L|	Indicates the End of the file.
A|	Append this information to the preceding record; may be used on any record.

Figure 4.4.1-2 Record Type Definitions

A Carriage return is used to indicate the end of the line (220 is the maximum).

Laboratory Information System (LIS) (Continued)

- Record Layout Specifications Minimum Requirements

Message Header													
H|												
Append to the Previous Record													
A|												
Patient Segment													
P|	Transmission Seq#|	Patient-ID |	|	|	Patient Name |	|	|	Sex|	|	Address|	|	|	Doctor
Observation Order Segment													
OBR|	Sequence Number|	|	|	Assay Name								
Result Observation Segment													
OBX|	Sequence Number|	Value Type|	|	Observation Value |	Units |	Reference Range |	Abnormal Flags |	|	Nature of abnormal checking			
Message Terminator													
L|	Sequence Number|	|	Patient Count |	Line Count |	Batch Number								

NOTE: A solid bar (|) indicates the field is for future use. The bar delimiter is necessary for correct formatting within the record.

File Examples:

```
H|^~\&||||||||||P|A.2|200502231044
P|1|123783479|||Doe^John
OBR|1|||Example Albumin
OBR|2|||Example Cholesterol
OBR|3|||Example Glucose
P|2|239393850|||Smith^Betty
OBR|1|||Example Albumin
OBR|2|||Example Cholesterol
OBR|3|||Example Glucose
P|3|450862376|||Jones^David
OBR|1|||Example Albumin
OBR|2|||Example Cholesterol
OBR|3|||Example Glucose
L|||3|14
```

Figure 4.4.1-3 Import File Example

(.LIS file extension)

```
H|^~\&||||||||||P|A.2|200504121156
P|1|123783479|||Doe^John^||||||||
OBR|1|||Example Albumin
OBX|1|ST||4.0|g/dL|3.5 - 5.2||
OBR|2|||Example Cholesterol
OBX|2|ST||137.2|mg/dL|< 200.0||
OBR|3|||Example Glucose
OBX|3|ST||95.3|mg/dL|70.0 - 110.0||
P|2|239393850|||Smith^Betty^||||||||
OBR|1|||Example Albumin
OBX|1|ST||3.3|g/dL|3.5 - 5.2|Low|
OBR|2|||Example Cholesterol
OBX|2|ST||119.3|mg/dL|< 200.0||
OBR|3|||Example Glucose
OBX|3|ST||75.2|mg/dL|70.0 - 110.0||
P|3|450862376|||Jones^David^||||||||
OBR|1|||Example Albumin
OBX|1|ST||3.9|g/dL|3.5 - 5.2||
OBR|2|||Example Cholesterol
OBX|2|ST||130.9|mg/dL|< 200.0||
OBR|3|||Example Glucose
OBX|3|ST||126.8|mg/dL|70.0 - 110.0|High|
L|||3|23
```

Figure 4.4.1-4 Export File Example

(.LIS file extension)

4.4.2 Routines Menu

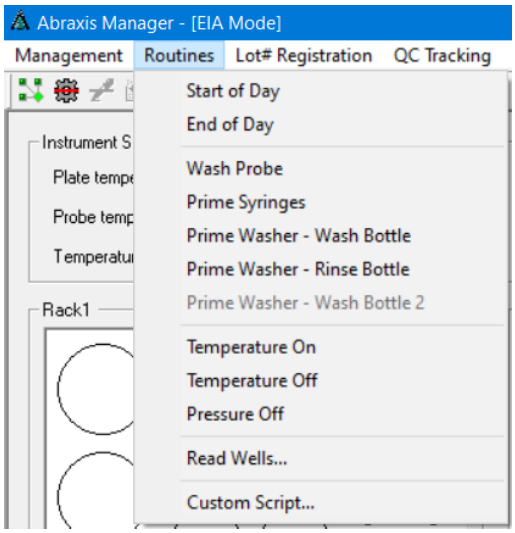
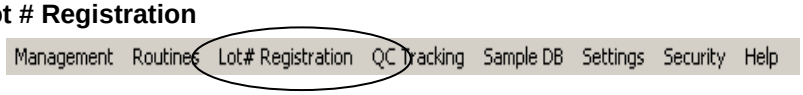


Figure 4.4.2-1 Routines Menu

OPTION	DESCRIPTION
Start of Day	Refer to Section 4.2.4 *Run Start of Day* for more information.
End of Day	Refer to Section 4.2.7 *End of Day* for more information.
Wash Probe	Select 'Wash Probe' and reset syringe positions.
Prime Syringes	Primes the fluid handling system with the liquid in the Prime bottle.
Prime Washer (if applicable)	Primes the wash system with the solution in the Wash bottle.
Prime Rinse (if applicable)	Primes the wash system with the solution in the Rinse bottle.
Temperature On / Temperature Off	Enable and disable temperature control.
Pressure Off	Releases pressure from the wash system
Read Wells	Enables selection of wells to be read; selection of filters (primary and differential); number of reads; and to use, or not use, a stored blank. Select the 'Clear' button to remove all of the results. Select 'Export' to send the results to a text (.txt) file.
Custom Script	Allows scripts to be run consisting of a series of commands. Recommended for advanced users.

4.4.3 Lot # Registration



The Abraxis CAAS has preprogrammed assays. When any of these are selected, a window will pop up, which replaces the need to access this feature.

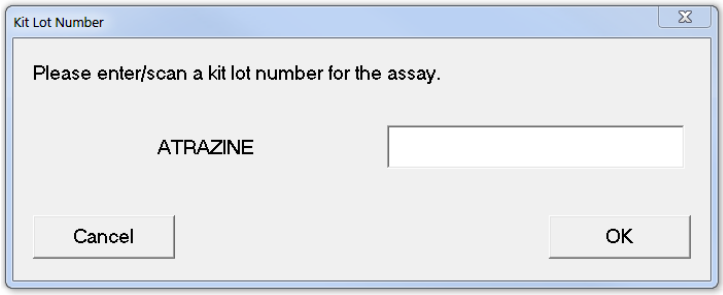


Figure 4.4.3-1 Kit Lot Entry

In Chemistry mode, Calibrators must be registered and read. Open the Calibration Tab and choose a substance from the drop down menu. This is done before Samples are read.

Select Register and enter the Lot # and a description (optional). Click OK to Save.Specify standard's concentration for curve calculation; specify range to monitor the quality (optional). Highlight the field to change, type in new value.

Press the Close button to save. Once you close the tab you cannot make a change to the concentration value.

4.4.4 QC Tracking

QC tracking enables Controls and Calibrators to be tracked using a Levey-Jennings chart. This feature is accessed by selecting **QC Tracking** from the main menu. First choose between Assay or name, then select specific control or calibrator and lastly, choose the lot number in order to edit QC points. A checkbox in the software settings allows deleted (by saving unchecked) QC data points to be restored and made visable.

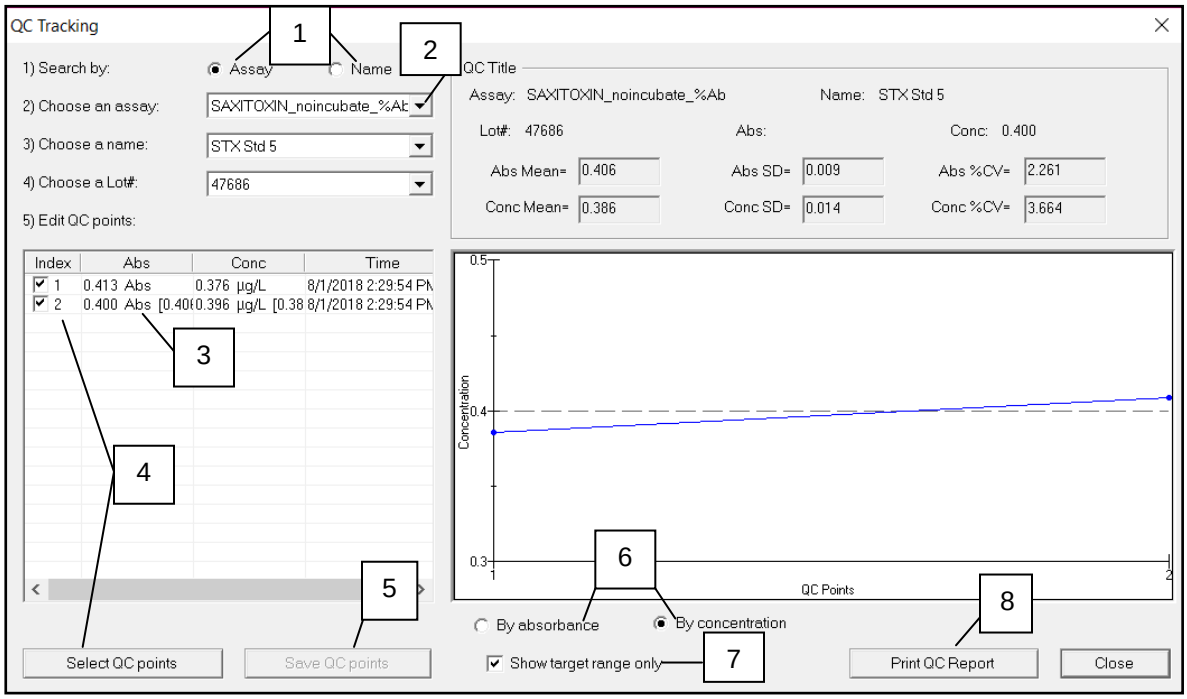


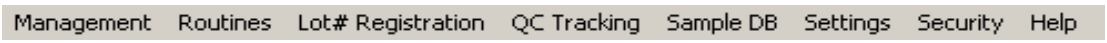
Figure 4.4.4-1 QC Tracking Example

Feature / Description:	#
Search by Assay or Name.	1
Choose an assay from the drop down list.	2
Edit QC points by clicking on an item in the list and highlighting it.	3
Use the Select QC Points button or un-check the checkbox for specific QC points to remove points.	4
Select the Save QC Points button to save the QC points displayed.	5
The curve may be viewed by Absorbance or Concentration results.	6
The software allows showing the graph without the calculated mean and SD ranges, only the Target and Target Range are shown. If the Target is not set in the Lot Number Registration, the calculated mean is used instead. Selection of this option (checkbox "Show target range only") is remembered for the next time the window opens.	7
Data can be printed from this screen by pressing the Print QC Report button. NOTE: Lot numbers are entered in the tab labeled Lot # Registration.	8

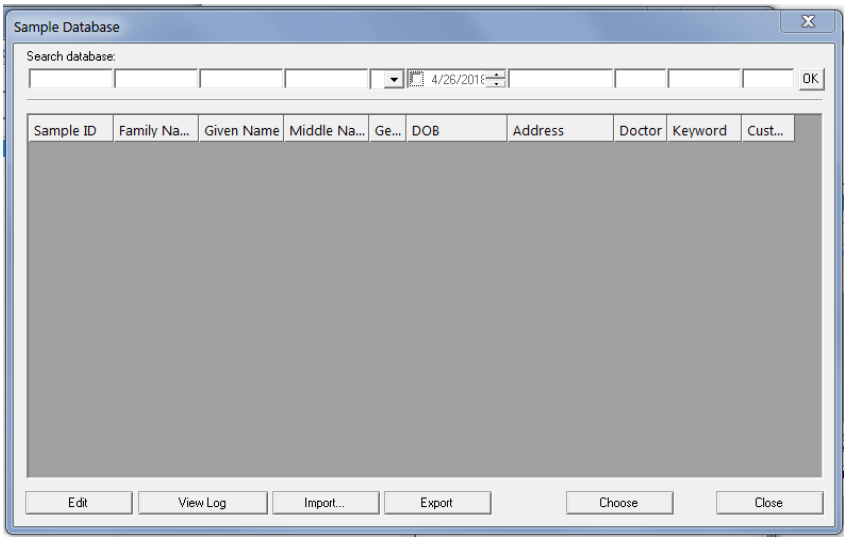
4.4.5 Sample Database

4.4.5.1 Add Sample ID

Select Sample DB from the toolbar.



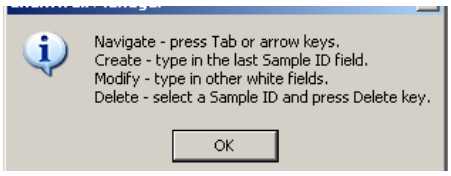
When first opened, the Sample Database window will not have any records to display.



Select the Edit button to enter Sample ID, Family Name, Given Name, etc. This will be helpful as search criteria when searching the database. Press the Done button when finished. NOTE: The Edit button toggles to Done.

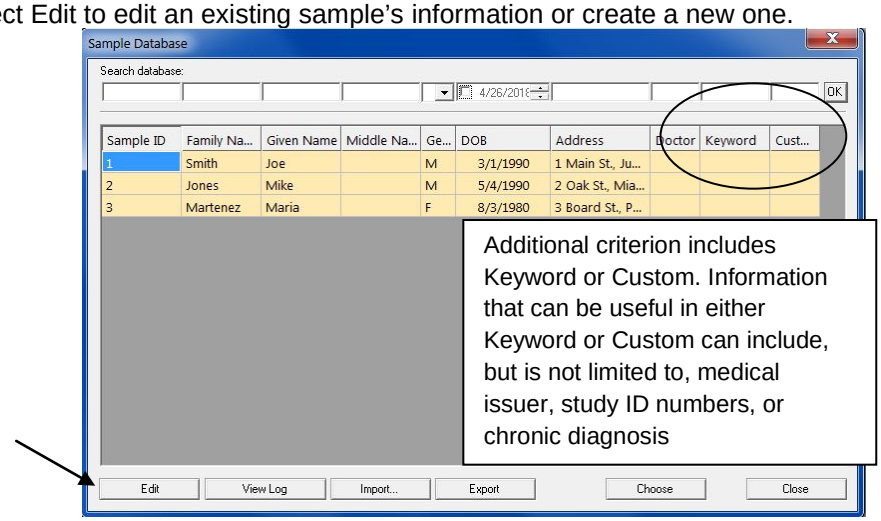
An instructional dialog box will open.

- Navigate through the fields on the screen by using the Tab or arrow keys on the keyboard.
- Create a Sample ID by typing in the Sample ID field.
- Modify a Sample ID record by clicking on the field to edit and typing.
- Delete a Sample ID by highlighting the record to delete and press the Delete key on the keyboard.



4.4.5.2 Modify Sample ID

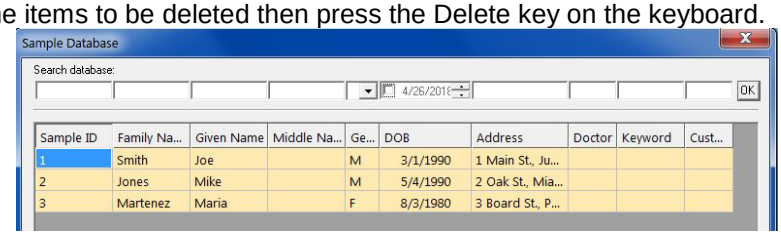
1) Select Edit to edit an existing sample's information or create a new one.



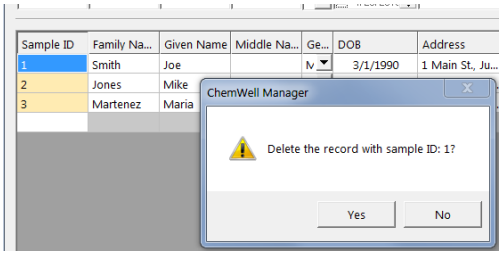
2) Modify the information and then press the Done button to save the changes.

4.4.5.3 Delete Sample ID

Highlight the items to be deleted then press the Delete key on the keyboard.



A dialog box will open prompting the user to confirm the deletion of the record. Press Yes to delete, press No to cancel the deletion process.



4.4.5.4 View Log

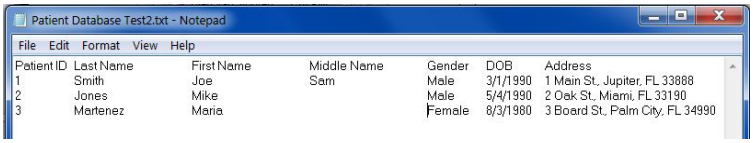
The ‘View Log button . will display any additions or modificationa made to a Sample.

```
//Modify @ 3/6/2012 9:49:32 AM
Sample ID:                      123 => 123
Family Name:                    Smythe => Smythe
Given Name:                     John => John
Middle Name:                    Alexander => Alexander
Gender:                 M => M
DOB:                    3/6/1973 => 1/6/1973
Address:                456 Elm St => 456 Elm St
Doctor:                 Burke => Burke
Keyword:                Smoker => Smoker
Custom:                  =>
```

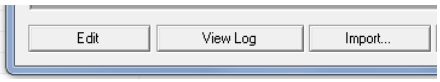
4.4.5.5 Import Patient Record

To import Sample Records, export data from MS Excel, MS Access, MS SQL Server, or similar into a text file. Data must be separated by the use of the Tab key, or ‘Tab as delimiter’.

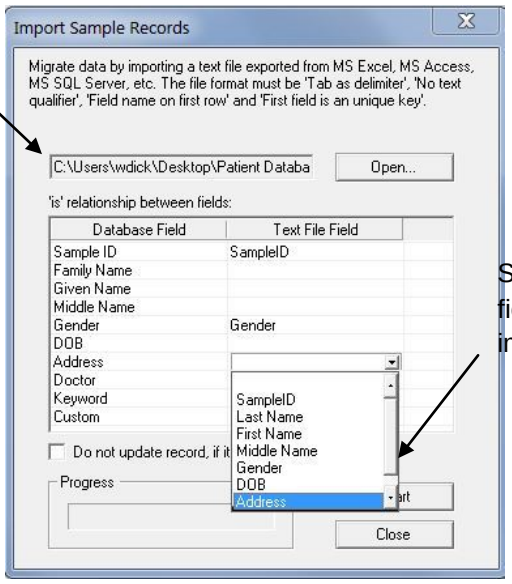
The first line of the file to be imported must contain the data fields, with the first field containing ‘ Patient ID’. Sample (patient) data begins on the second line of the text file.



Select the ‘Import’ button at the bottom of the Sample Database window.



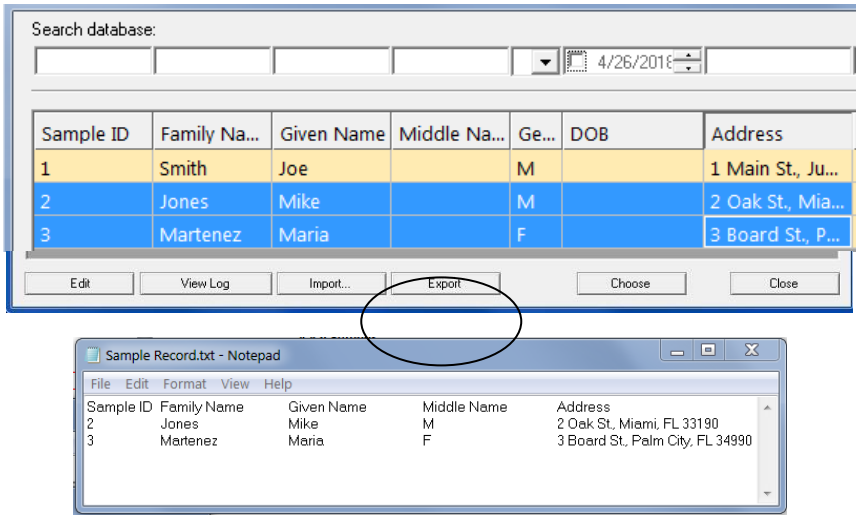
Select ‘Open’ to locate the text file to be imported.



Select the data fields to be imported.

4.4.5.6 Export Patient Record

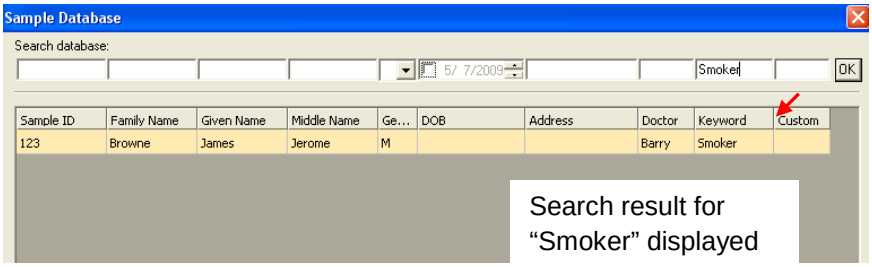
Click to highlight the Sample ID to export. Select the Export button to send the selected record to the Sample Record text file in Notepad.



Save the file and close the window when finished.

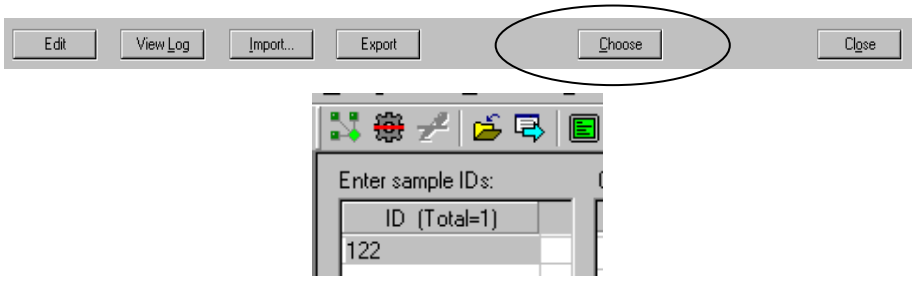
4.4.5.7 Search Patient Record

Enter criteria into Search Database area, press OK. All records containing the specified criteria will display. All records in the Patient Database can be displayed by pressing OK and leaving all search fields blank.



4.4.5.8 Choose Patient Record

Select the ‘Choose’ button to add a selected patient to the Sample ID list on the Sample tab.



4.4.6 SoftwareSettings

4.4.6.1 Startup

Choose Software under the Settings menu.

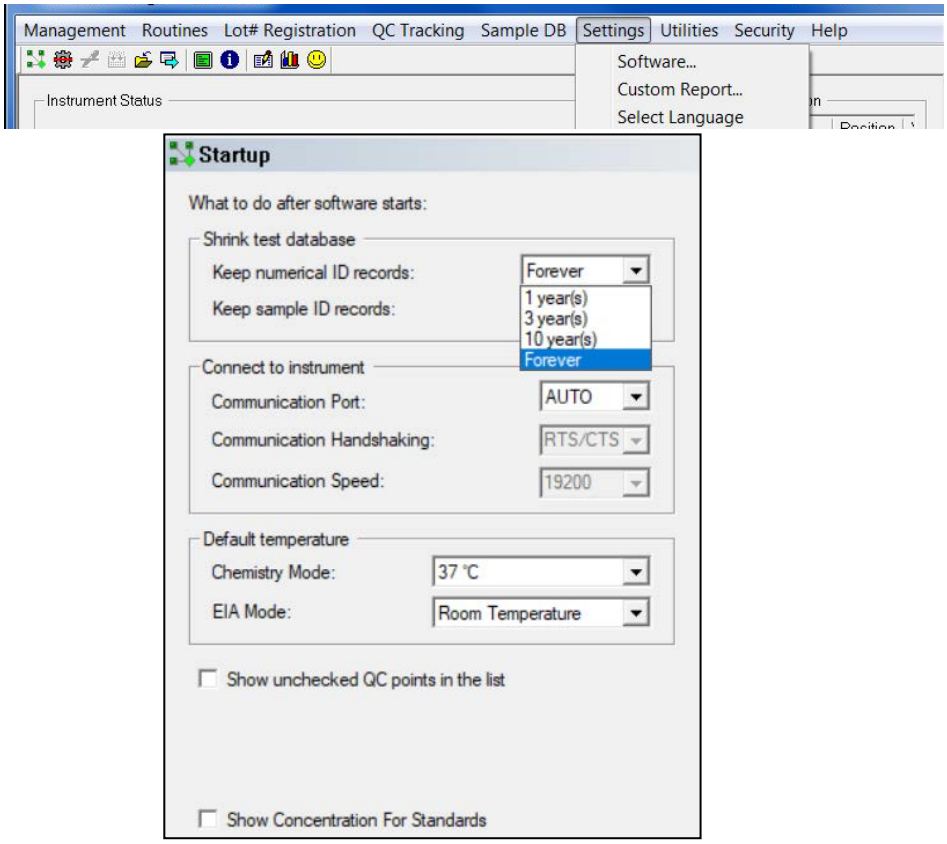


Figure 4.4.6.1-1 Software Startup Settings

You may choose to keep numerical ID and sample ID records for 1 year, 3 years, 10 years or forever. However, whatever preferences you choose, all sample test records are backed up monthly to an archive database.

To change the communication port, click on the down arrow to display the optional settings; click to select, click OK to accept.

The default temperatures are displayed for chemistry mode and EIA mode. Setting choices are: room temperature, 25 deg C, and 37 deg C.

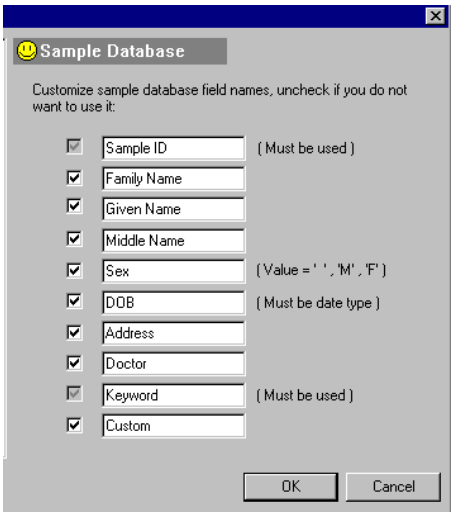
‘Show unchecked QC’ points refers to the QC Tracking Section 4.4.4. This checkbox makes unchecked QC points visable (so they can be checked again) and allows deleted points to be restored.

‘Show Concentration for Standards’ refers to calibration and results Section 5.2. This checkbox will display the concentration for calibrators and standards when checked.

Press OK when finished.

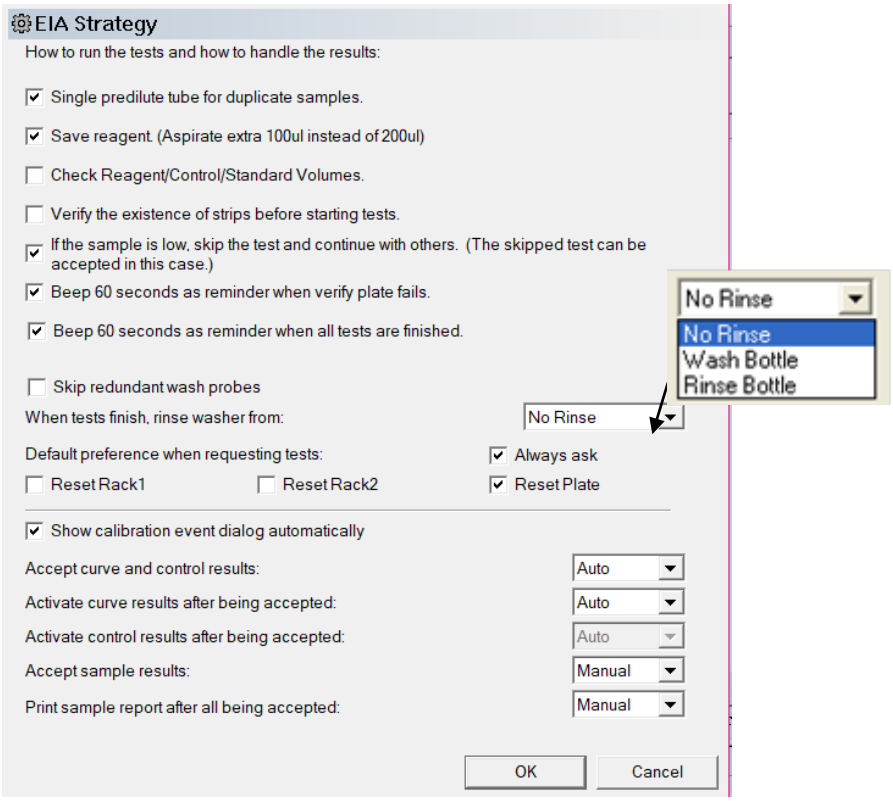
4.4.6.2 Sample Database

NOTE: The Sample ID field and the Keyword field must be used.Customize sample database field names, uncheck field name from the list displayed if you do not want to use it.



4.4.6.3 EIA Strategy

EIA Strategy features allow control over how tests are run and how the results are to be handled.



Single predilute tube for duplicate samples – When running assays with a predilution in the sample rack the software has the option to make a single predilution and run this multiple times in the assay or make a separate predilution for each assay replicate. This check box controls this option. NOTE: If the probe senses that the volume of predilute is insufficient, more predilution will be automatically added to the tube.

Save Reagent – This option is checked by default. When reagents are aspirated as a group of 8 an extra reagent volume is aspirated to prevent dilution of the dispensed reagent by the water used in the pipetting system. The volume of extra reagent aspirated is 20% more than the requested dispensed volume.

Skip redundant wash probes- If selected, the probe will skip washes in between same samples When this box is checked the maximum extra reagent volume aspirated is set to 100µl. When the box is un-checked the maximum extra reagent volume aspirated is set to 200µl. For most assays the Save Reagent feature should be used, but for some assays which are sensitive to reagent dilution this box can be unchecked.

When tests finish, rinse washer from - choice of rinse source include the wash bottle, the rinse bottle or no rinse. Rinsing the washer with water after running EIAs helps keep the wash head from getting clogged with crystallized EIA wash solution.

Default preference when requesting tests – check the appropriate box – to always ask, reset the plate, reset specific racks.

Auto Accept Curve (default) – The curve generated is automatically accepted.

Manual Accept Curve – When tests are complete, they remain in the test list. The user can review the step log to see if there are timing errors, etc. The user should check the curve set and click the accept button. Curve records will be written into the database and displayed in the Calibration tab.

Manual Activate Curve – After accepting curve, curve records go to the Calibration tab. They are available for the user to activate. After user activates a curve, Sample Results are calculated. This setting is helpful when a user chooses Auto Accept Sample and Auto Print Report.

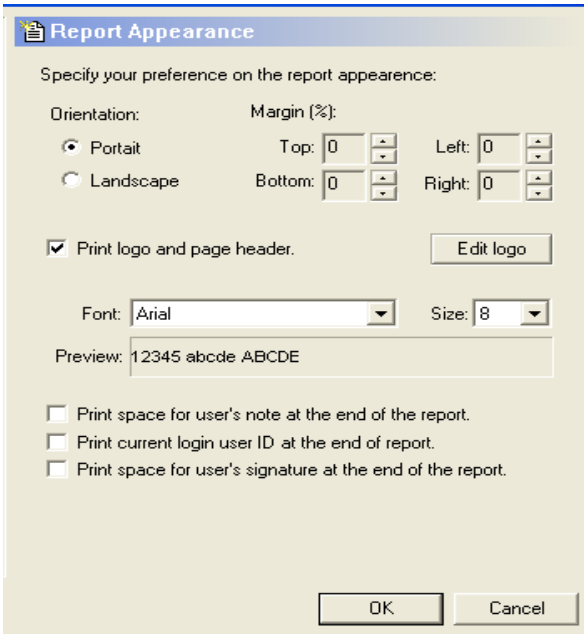
4.4.6.4 Report Appearance

Specify your preferences on the report appearance

Preferences can be set as to paper orientation and margin settings.

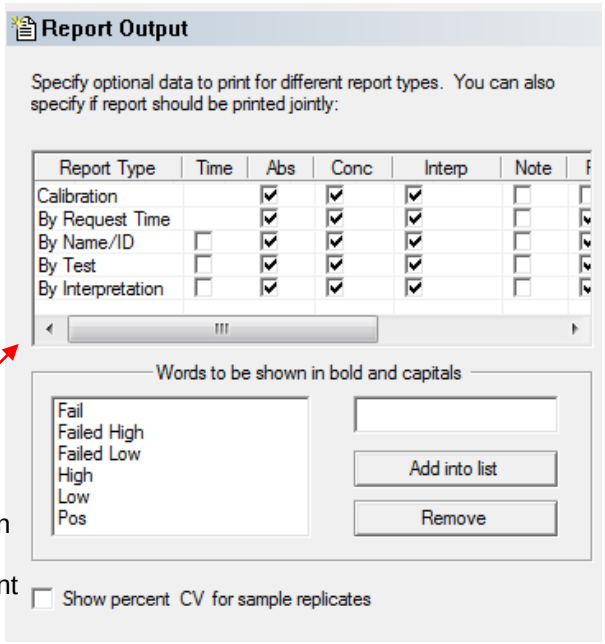
Print logo and page header must be checked to have to include these features on reports. Logo and font size can be edited.

A printed space can be added for notes and signatures.

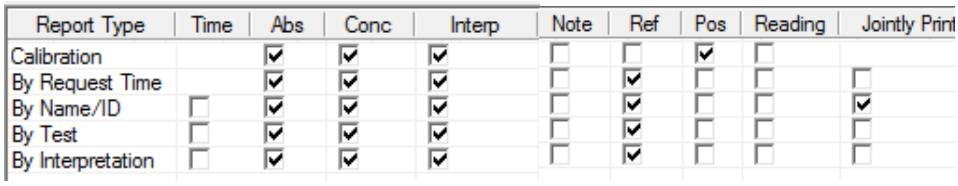


4.4.6.5 Report Output

The data to be included in a report is selected by clicking in the appropriate box in Report Output.



By using the scroll bar, the data shown below can be selected for different report types.



When an assay has had a concentration correlation factor added, the formula used can be displayed by selecting the **Note** column when defining report output.

The **Ref**(reference) column is used to report the Normal range for results.

Pos (Position) indicates where each Calibrator, Control or Sample was located in the cuvette carrier.

The **Reading** column, when activated for output, reports the actual absorbance read by the instrument.

The "**Printed Jointly**" allows less paper to be used. Instead of one test or patient per page, multiple results will print on the allowable paper space

Words to be shown in bold and capitals

To select a word from the list or add a word to appear in bold and capitalized on the output of the report, click on the word, Select OK. To attach a new Word to the list, type the word in the space provided, and press the 'Add to list' button.

4.4.6.6 Custom Report Settings

Choose Custom Report under the Settings menu.

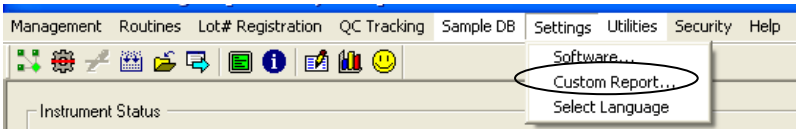


Figure 4.4.6.6-1 Select Custom Report Option

The Custom Report Template screen allows users to choose a report template for each type of report they desire to run. Choose the type of report to run and click on the Set Template button. The report will be formatted according to the chosen template until the Custom Report template has been cleared by clicking on the Clear button.

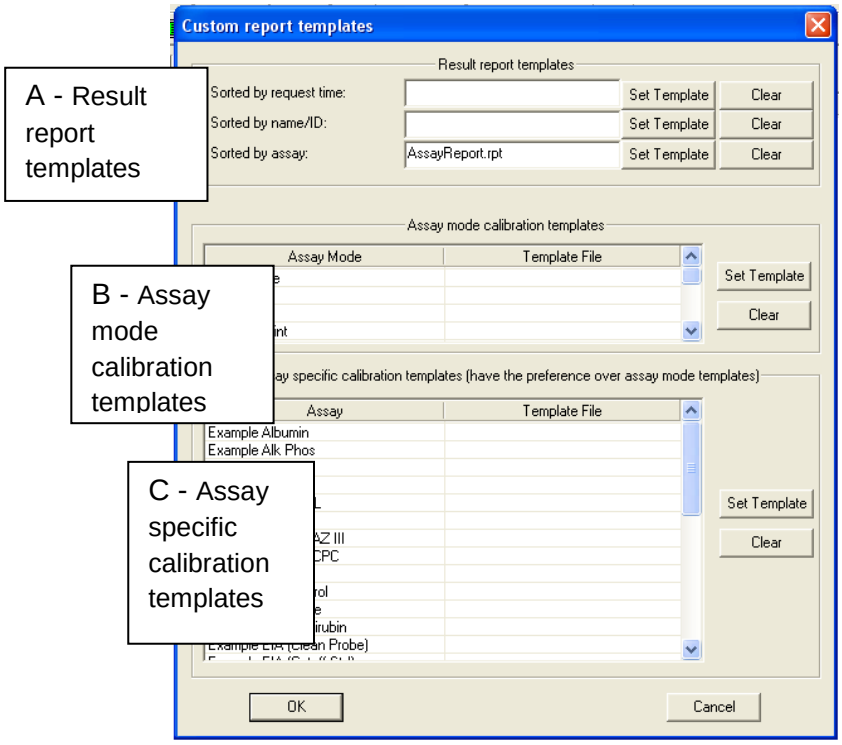


Figure 4.4.6.6-2 Custom Report Templates

	Feature / Description:
A	Result Report Template are for custom reports that have been sorted by request time, sorted by name/ID, or sorted by assay.
B	Assay Mode Calibration Templates are for custom reports that contain calibration data. NOTE: Only Calibration objects can be used in these reports such as curve.
C	Assay Specific Calibration Templates - Choose a specific Assay to produce a report from this data. NOTE: Assay Specific Calibration Templates override the Assay Mode Calibration Templates.

Several example Custom Report templates are provided for the user. Reference the custom report samples in the Report Creator section of this manual to help determine which template to use for the desired report.

Click on the Set Template button to select a Custom Report template. Preview calibration reports via the Calibration Tab and preview button; preview sample reports via the Report Tab and preview button. Modify the example Custom Report and save it to a new file name; or create a report by following the instructions found in the Report Creator section of this manual.

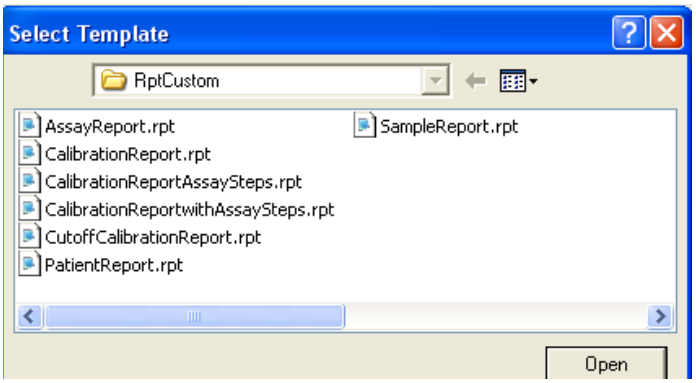


Figure 4.4.7-3 Set Template Result

4.4.6.7 Select Language

To change the language setting from the default, choose Select Language under the Settings menu.

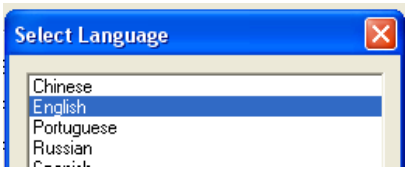


Figure 4.4.8-1 Example of available languages

A list of the available language choices will display. After selecting a language, it will be necessary to close the Manager and restart the software to initialize the selected language.

The selected language will remain in effect until another language is selected and the software is restarted as in the step above.

4.4.7 Security

Refer to Section 4.1.3 Password Security and Logging In for more information.

4.4.8 About

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

Notes:

5. Running CAAS Manager Software

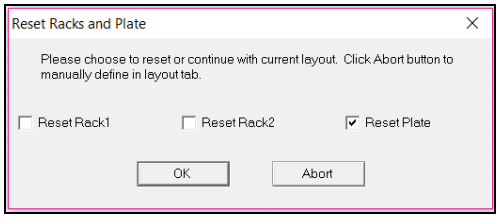
5.1 Running Assays

1. Before running an EIA make sure to perform the following:
   - Check for full strips of wells
   - Check that the wells are flush with the plate frame
   - Prime syringe and check for any air bubbles
   - Prime the washer and check for 8 steady streams

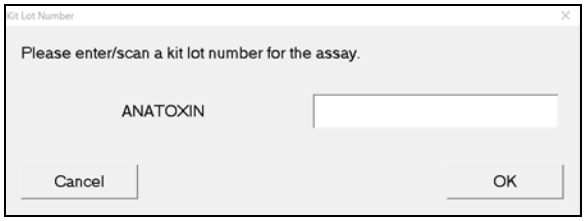
2. Open the Calibration Tab to add the curve(s) necessary for the Assay(s) being run. Controls should also be selected at this point. Next go to the Sample Tab to enter the patient samples to be run. Clicking Request will then process the standards, control and samples together as a batch.

3. Click on the Sample Tab in order to enter the patient samples.

4. Click on the Request button. You will be asked to confirm addition of the calibration standards and asked whether to reset or continue with current layout. Select OK to continue with tests or Abort to go back to worklist.



5. Next, a window will open for entry of Kit lot number(s). Each test will have a separate entry window. These lot numbers can be searched and tracked through the Report tab when tests are complete.



6. If defined Special Interpretation Groups are in the Assay(s) being run, the Interpretation Group window (***Figure 5.1-1 Interpretation Group***) is displayed, otherwise the Work Schedule (***Figure 5.1-2 Work Scheduler***) is displayed. Using Special Groups Interpretation, unique normal ranges are used for different "group" definitions.

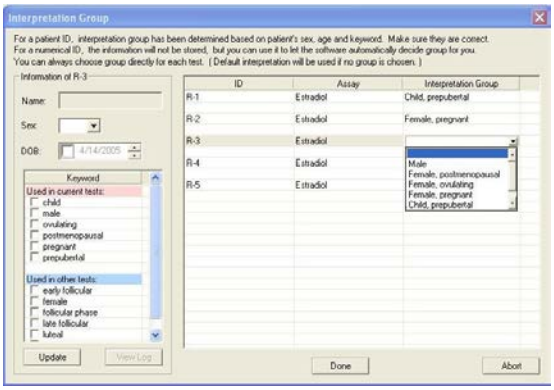


Figure 5.1-1 Interpretation Group

When multiple Assays are run simultaneously, the software will automatically generate the best run order based on the shortest total completion time. The desired run order can be changed by selecting an alternate schedule. The software will delay the start of certain assays so that conflicts do not occur.

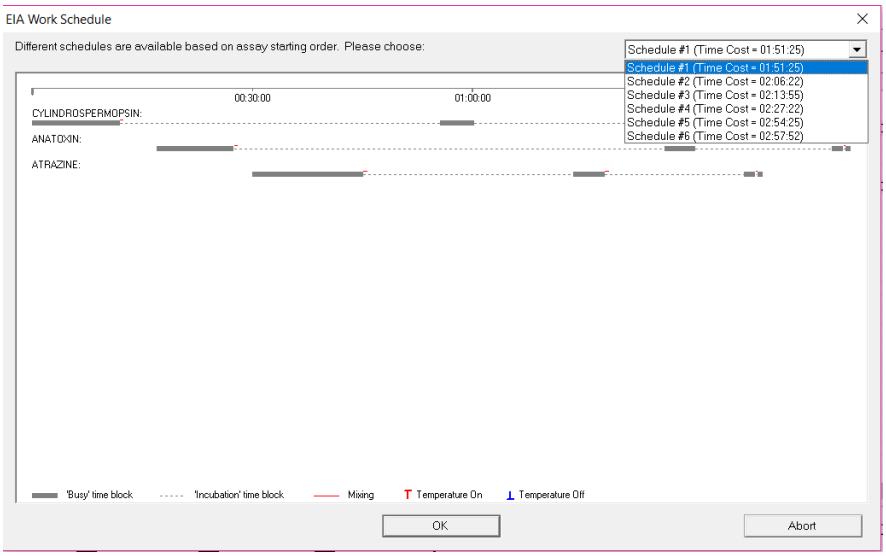
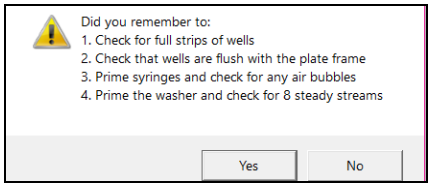


Figure 5.1-2 Work Scheduler

Running Assays (Continued)

7. After reviewing the work schedule, click on “OK”.

8. Place all the needed reagents and samples into the correct rack locations, place the proper-coated EIA strips into a plastic strip tray, and select ”Start Run”. A dialog box will open for important reminders. Select “yes” and assay will begin.



9. The Assay processing will begin. The time remaining for completion of each Calibrator/Standard, Control and Sample is displayed on the screen ***Figure 6.1-3 Test List***).

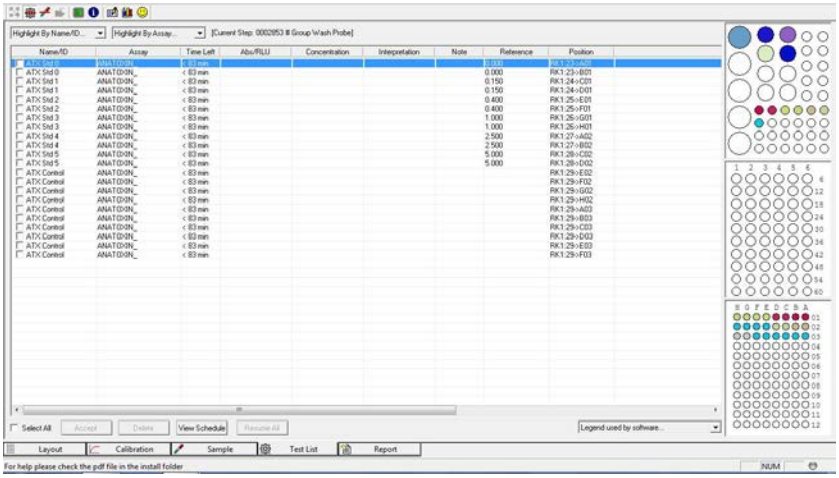


Figure 5.1-3 Test List

Running Assays (Continued)

Double clicking on any of the Sample rows will display the **Step Log** (***Figure 5.1-4***) for that Sample.This can be helpful for verifying that all the Assay events have occurred reasonably on time. For example: if a reagent runs out during a test and has to be refilled, the timing in this window can help determine whether to accept or delete a result.

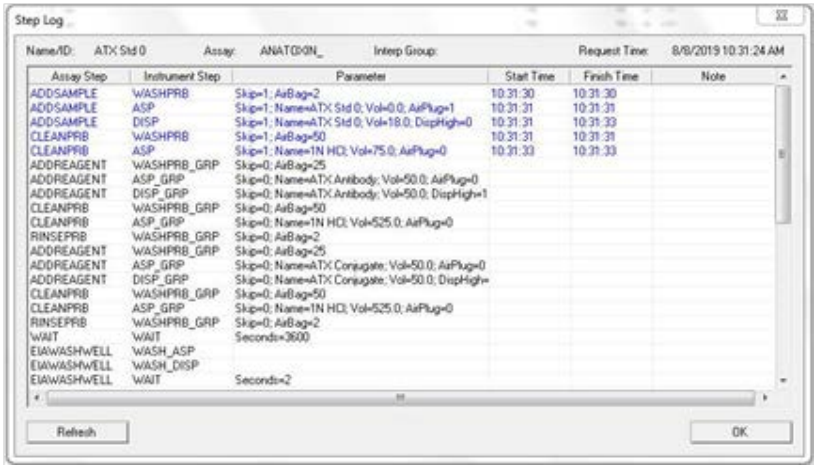


Figure 5.1-4 Step Log

Check the Assay processing status by clicking on View Schedule button. This will display an approximated time line of the Assay processing (***Figure 5.1-5***).

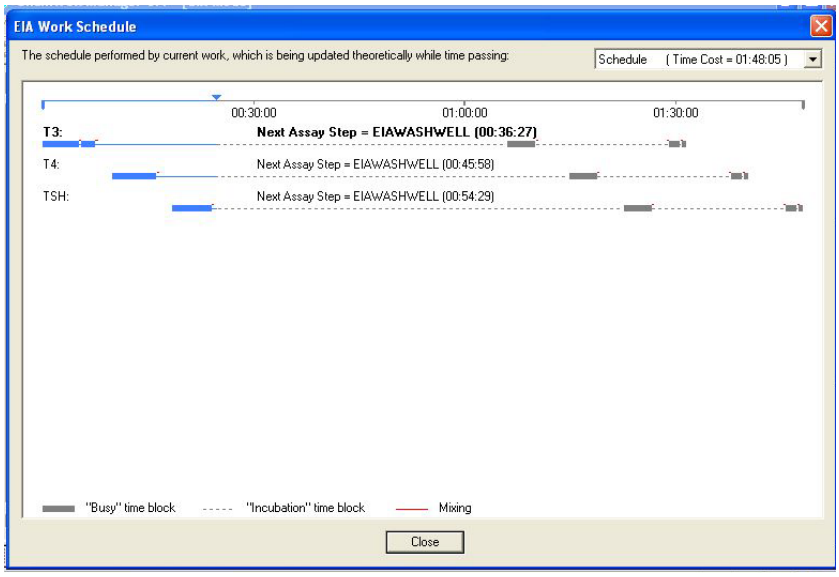


Figure 5.1-5 EIA Work Schedule

When Assays are complete the curve can be accepted. Patient concentrations will be calculated. If controls are run in an Assay, the Statistics can be displayed. Select the Controls with the left mouse button and hold down the “Ctrl” key. (***Figure 5.1-6***)

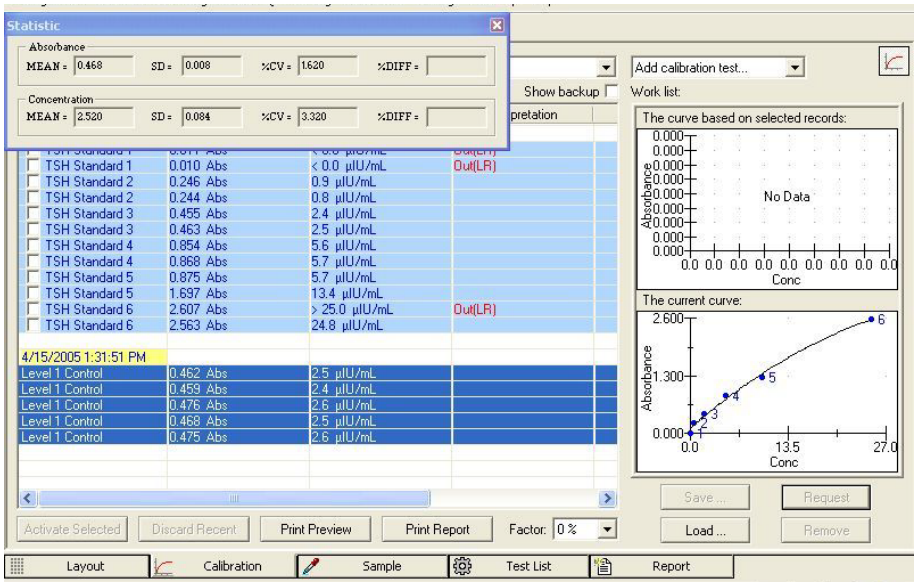


Figure 5.1-6 Statistics

5.2 Accepting and Activating Calibration Results

Calibrators must first be “Accepted” and then “Activated” before they are used to calculate sample concentrations. Click on the Accept button to accept results.

Accepting calibrators moves them from the Test List tab to the Calibration Tab.

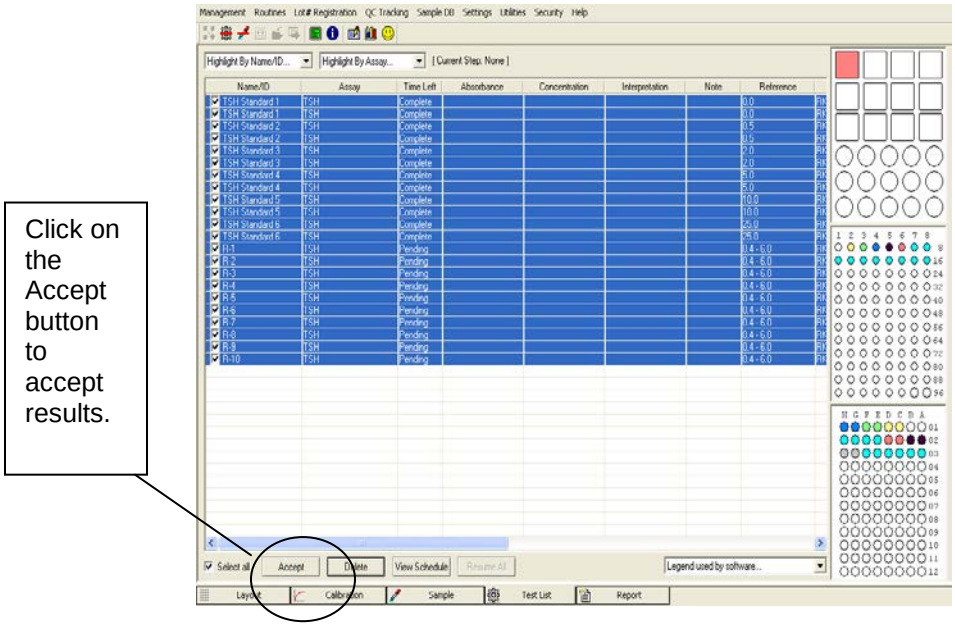


Figure 5.2-1 Accepting Calibrators

NOTE: Calibrators must be accepted and activated before samples can be accepted.

Once the calibrators have been moved into the Calibration Tab they need to be activated. However, selecting the calibration does not make the calibration graph visible. Select the assay from the dropdown list and then click on the graph icon (***Figure 5.2-2***) and the calibration curve will display on the right hand side of the screen (***Figure 5.2-3***).

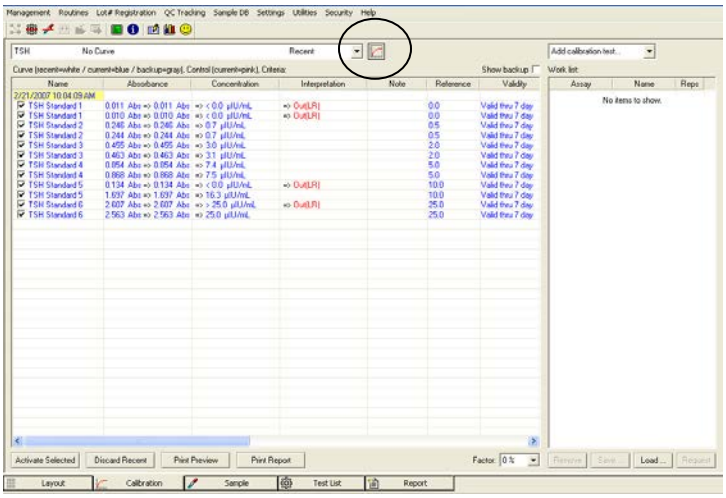


Figure 5.2-2 Select assay, click on graph icon to display curve

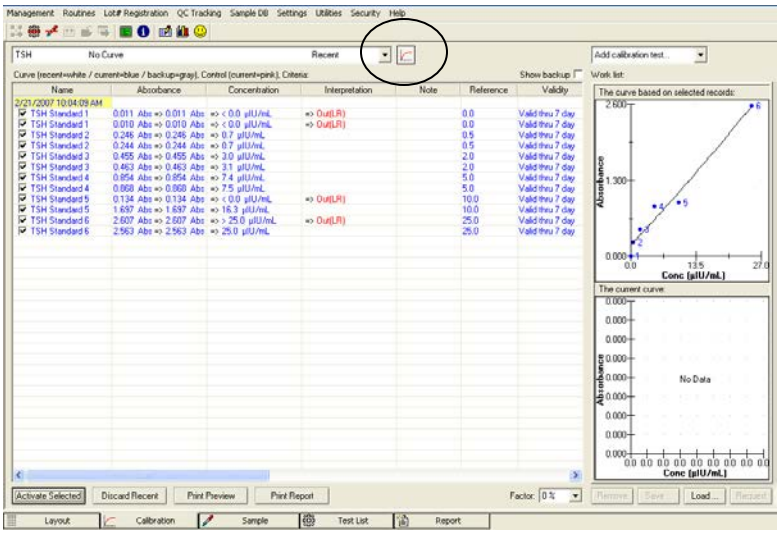


Figure 5.2-3 Select assay, click on graph icon to display curve

The curve which is active is displayed on the bottom of the screen. This may be the previously stored curve or a newly activated curve. Before the curve is activated it can be reviewed for any adverse outlying calibrators. If outlier values are seen for any of the calibrators, these may be removed by unchecking the check box next to this calibrator.

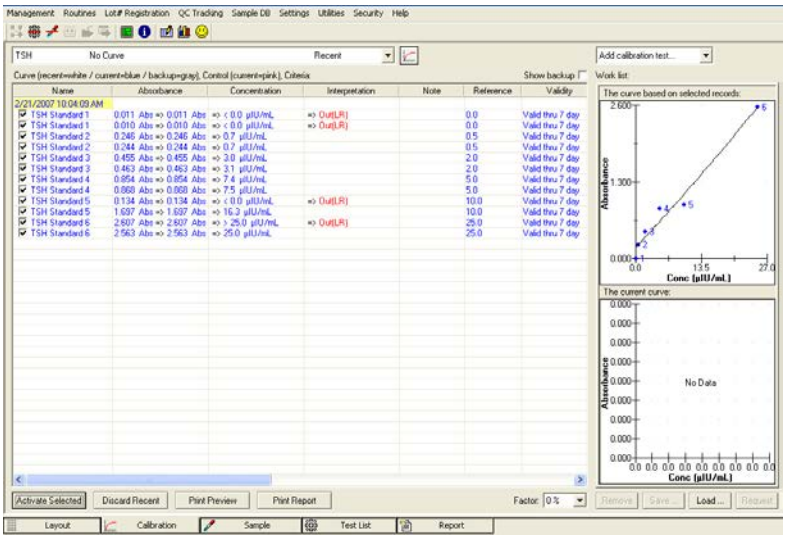


Figure 5.2-4 Calibration curve displayed based on selected records

The resulting calibration curve is shown in the upper graph (***Figure 6.2-4***). Once you are satisfied with the calibration curve in the upper graph, click the Activate Selected button and this will move the curve from the upper graph to the lower current graph

(***Figure 5.2-5***).

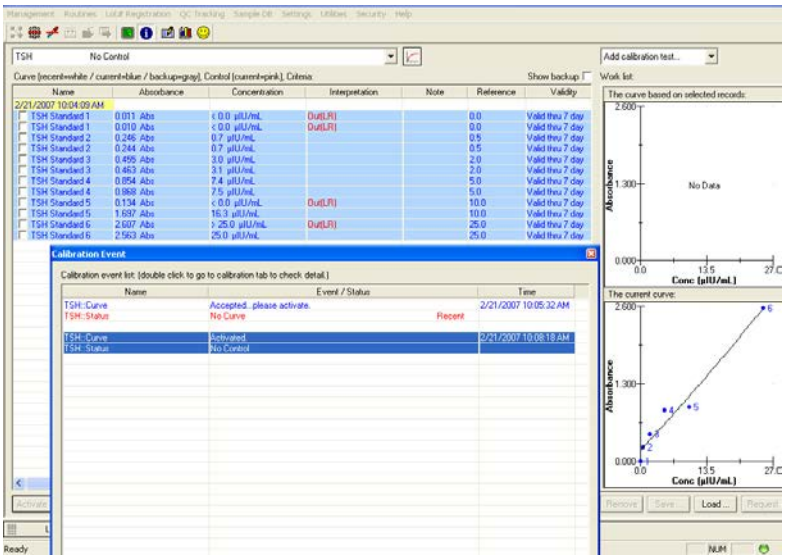


Figure 5.2-5 Curve displayed in lower graph display area

At this point concentration values will be calculated for the samples and displayed in the Test List Tab.

The samples can now be accepted by clicking on the Accept button (***Figure 5.2-6***). The sample results will be moved from the Test List Tab to the Report Tab where they are automatically stored in the Instrument database and may be printed in reports.

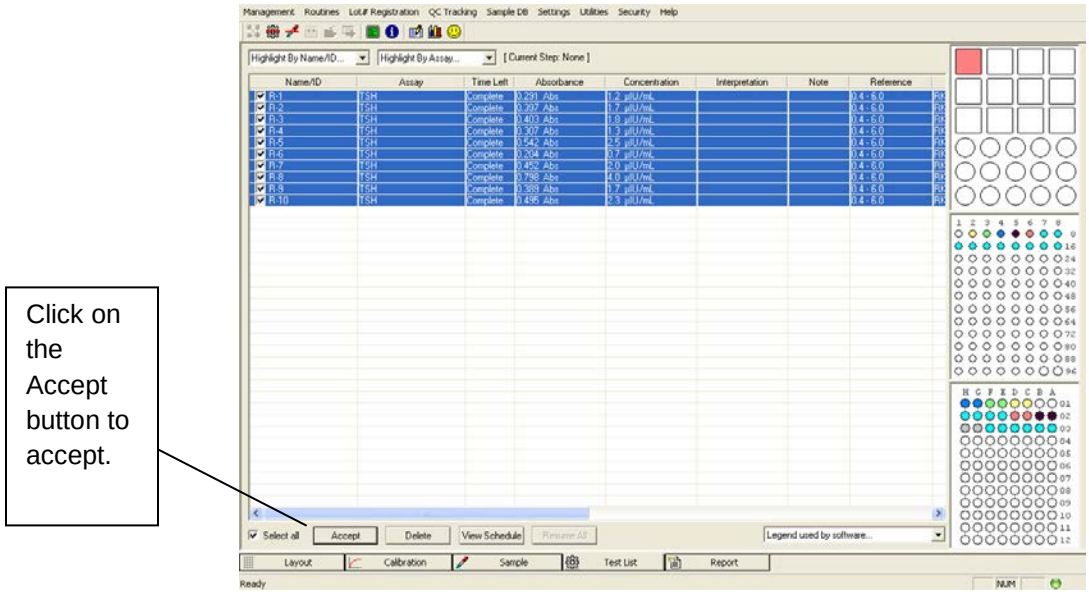


Figure 5.2-6 Click on the Accept button to accept the sample results

Your preference for accepting and activating curve and sample results can be set to occur manually or automatically in the EIA Strategy settings (reference Section 4.4.6.3).

Manually accepting results has the advantage that you can look at the Step Log for any individual calibrator or sample to verify that all assay steps were performed on time in the event of a low reagent or instrument error. Once the samples are moved from the Test List this Step Log is lost.

Manually activating the calibration curve has the advantage that the curve can be reviewed for calibrator outliers and edited before it is used to calculate sample concentrations.

5.3 Adjusting Standard Curves

5.3.1 Deleting Calibrators

In the picture below, a standard curve is displayed. This data shows that standard 5 is incorrect. By checking the boxes to the left of each of each standard, a valid curve can be generated.

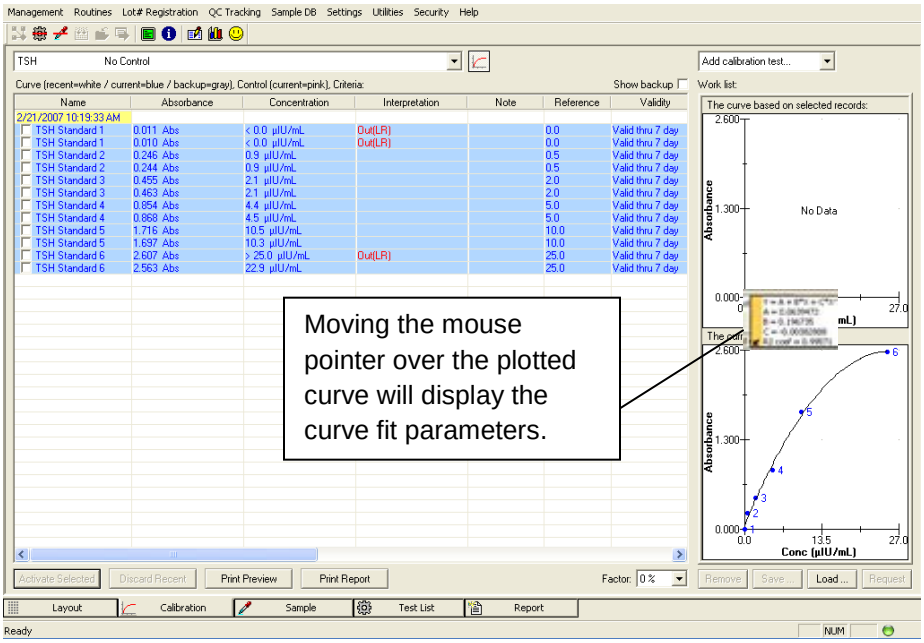


Figure 5.3.1-1 Unedited Curve

Clicking on the Test List tab will display the patient results (sample shown below.)

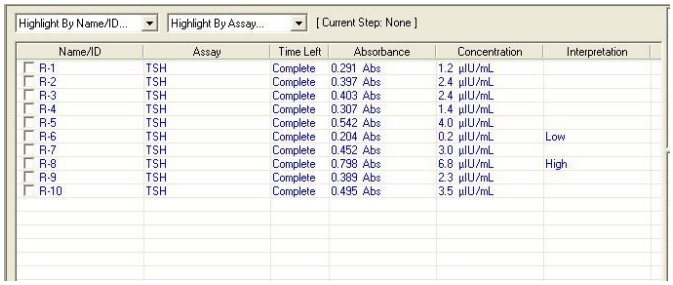


Figure 5.3.1-2 Unedited results

Once a satisfactory curve is generated, clicking on the “Activate Selected” button will cause this curve to be the current standard curve in use and will update the concentration values of the samples in the Sample Tab. The corrected curve is shown below in ***Figure 5.3.1-3 Curve Edited***.

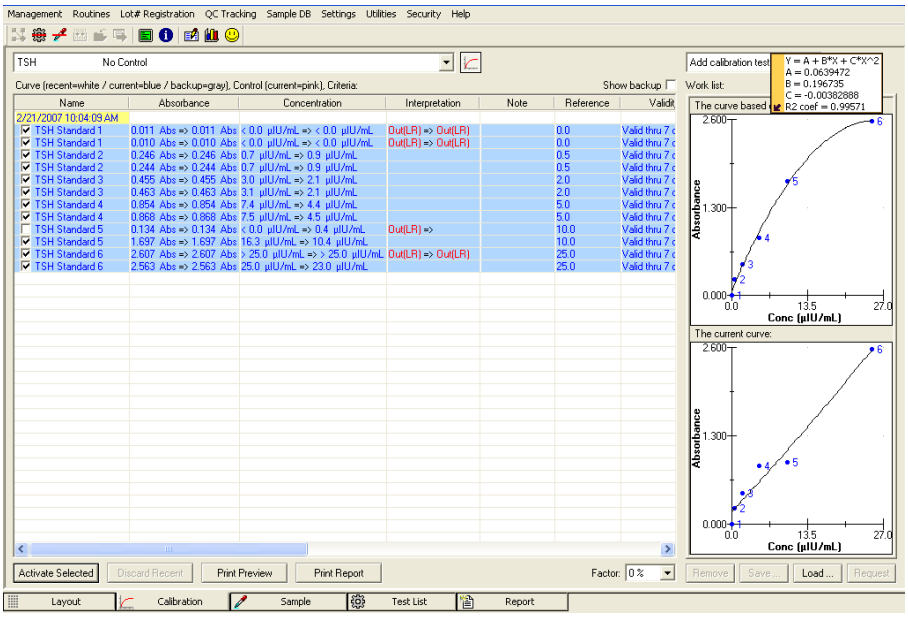


Figure 5.3.1-3 Curve Edited

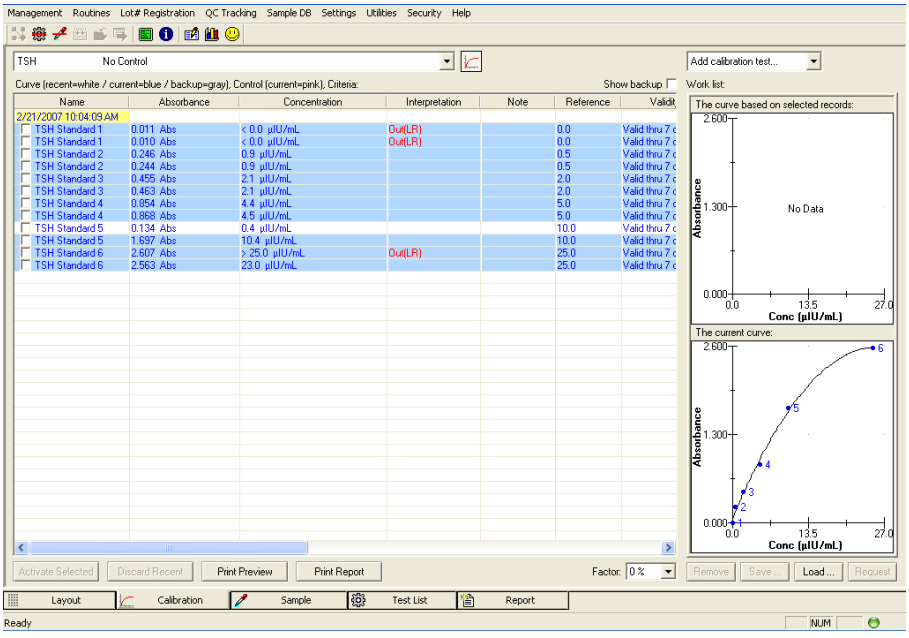


Figure 5.3.1-4 New Curve Activated

The patient sample results are now updated, which you can see by clicking on the “Test List” tab.You can now choose to accept or delete any of the sample results by clicking on the buttons.

In Figure 5.3.1-5 Accepted Results, all Samples are selected.

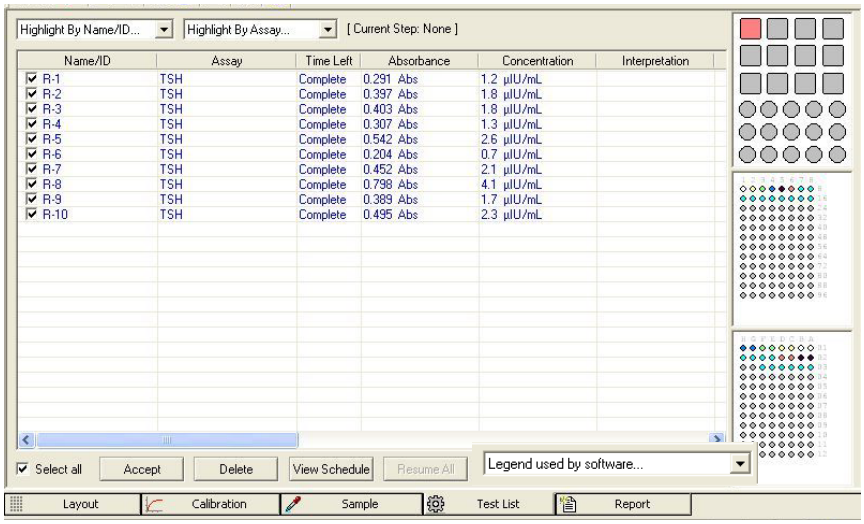


Figure 5.3.1-5 Accepted Results

5.3.2 Adjusting Curves by a Percentage Factor

Curves can also be adjusted by a percentage factor. This is set by the factor setting in the calibration tab. Normally this value is set to 0%, and the actual standard curve absorbance values are used with no adjustment.

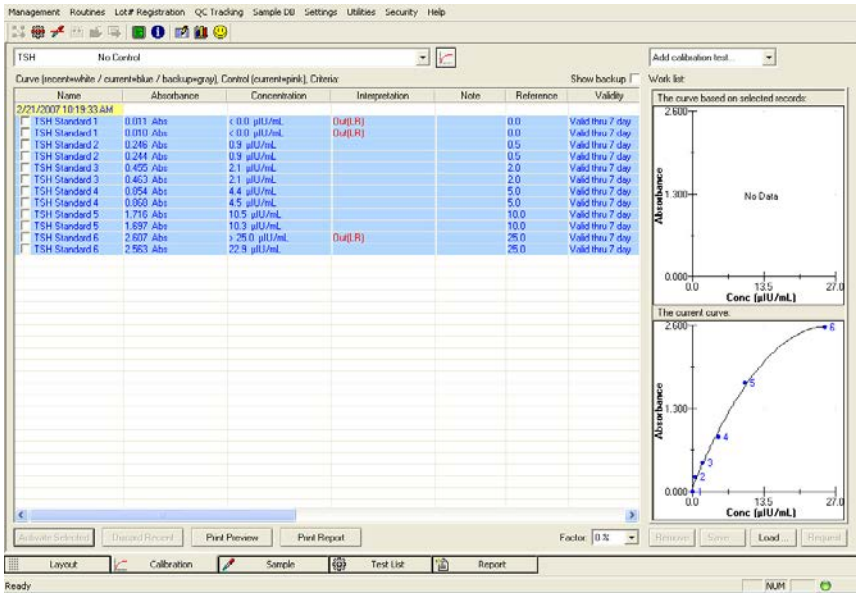


Figure 5.3.2-1 Curve Adjusted with 0% Factor (default, no adjustment)

Resulting concentration values for the samples run are shown below in ***Figure 5.3.2-2 Results***.

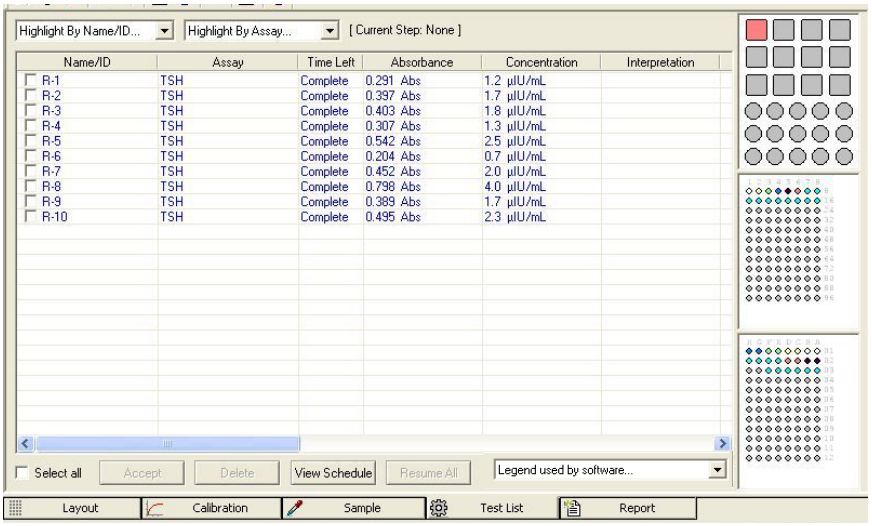


Figure 5.3.2-2 Results

In ***Figure 5.3.2-3 Curve with -10% Factor*** below the calibration curve is adjusted by -10%. Factor adjustments occur immediately and do not require clicking on the Activate Selected button.

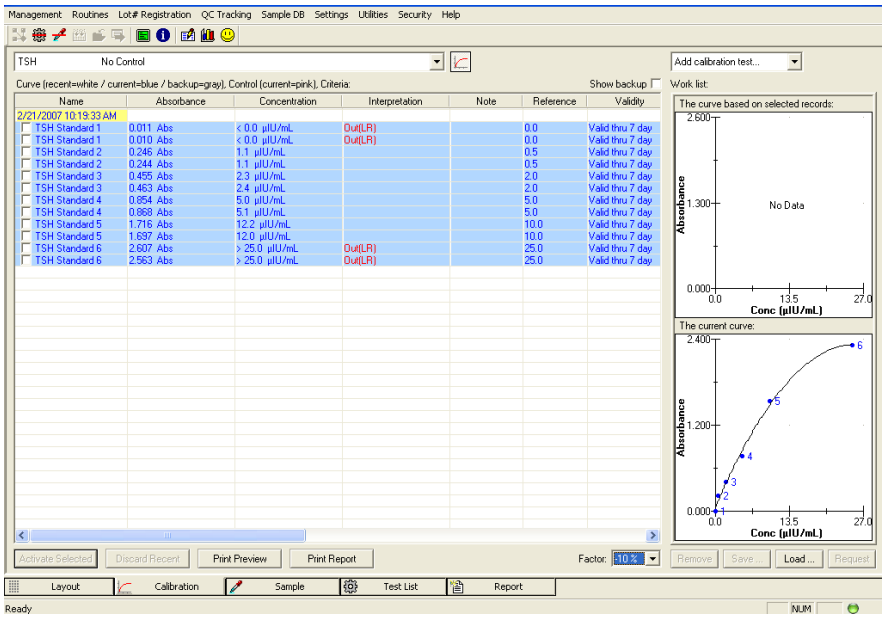


Figure 5.3.2-3 Curve Adjusted with -10% Factor

The new concentration values are displayed in the Sample Tab as shown below in ***Figure 5.3.2-4*** *Results*:

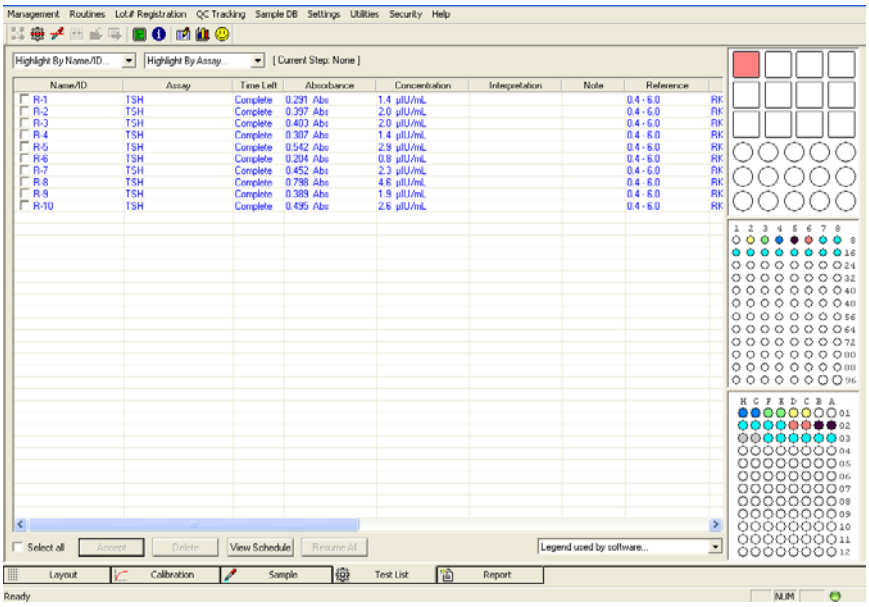


Figure 5.3.2-4 Results

The percent adjust feature can be used when stored curves are used and there is evidence that the current run has resulted in increased or decreased absorbance levels than what is expected.

NOTE: Decreasing the standard curve by a percentage will result in increasing the sample concentration values.

5.3.3 Adjusting Curves by Running Less than All the Calibrator Values

Less than all the calibrators used in an assay can be run and the stored curve can be adjusted accordingly. The adjustment factor will be calculated based on the average percent change of all the new calibrators run compared to their stored absorbance values. The new curve will be generated from the new calibrator(s) absorbance values which are currently run and the adjusted absorbance values of the remaining calibrators from the stored curve. This feature can be used to control for changes in reagent activity when using stored curves.

In the ***Figure 5.3.3-1,*** Standard 5 is used to adjust the stored curve. Instead of requesting an entire new curve, Standard 5 is requested individually.

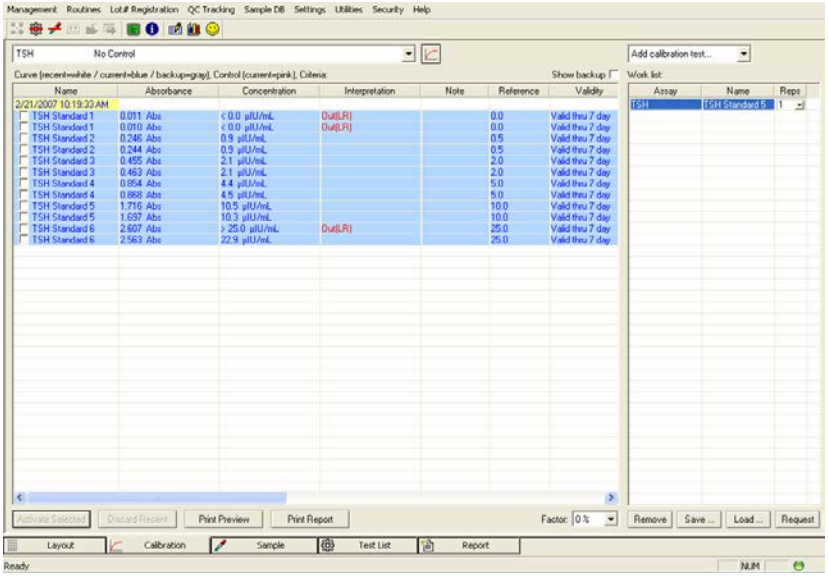


Figure 5.3.3-1 Curve Adjusted With Standard 5

In this example, Standard 5 yielded an absorbance value of 1.366. This is an absorbance drop compared to the Standard 5 absorbance values of the stored curve.

By selecting this standard and all the stored standards the new adjusted curve can be activated.

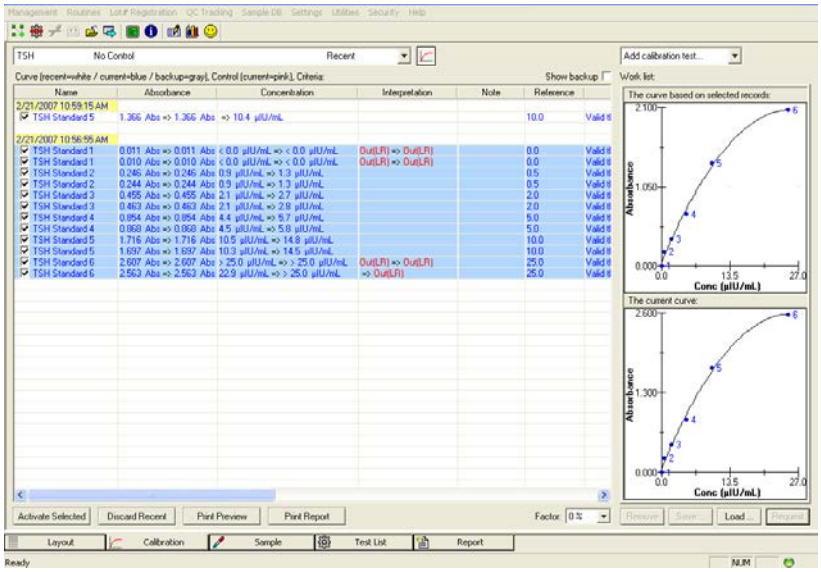


Figure 5.3-3-2 Adjusted Curve

Once activated the original absorbance values remain, but the new calculated concentration values of the standards are displayed.

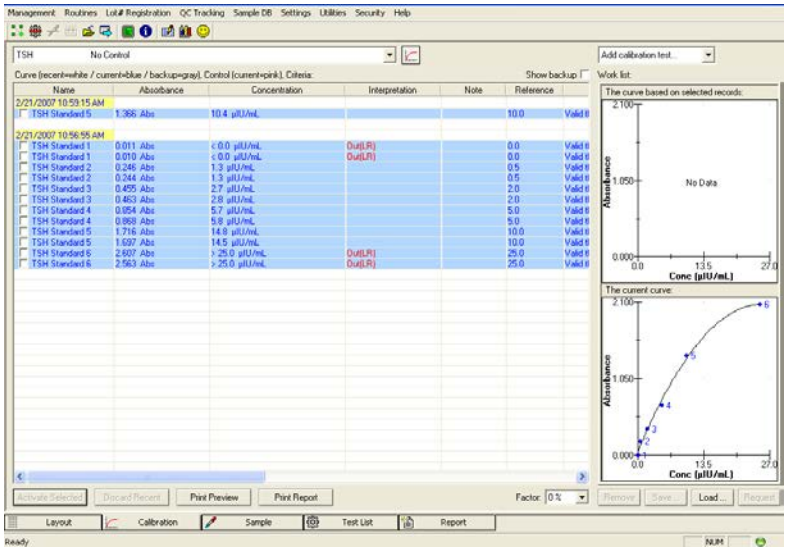
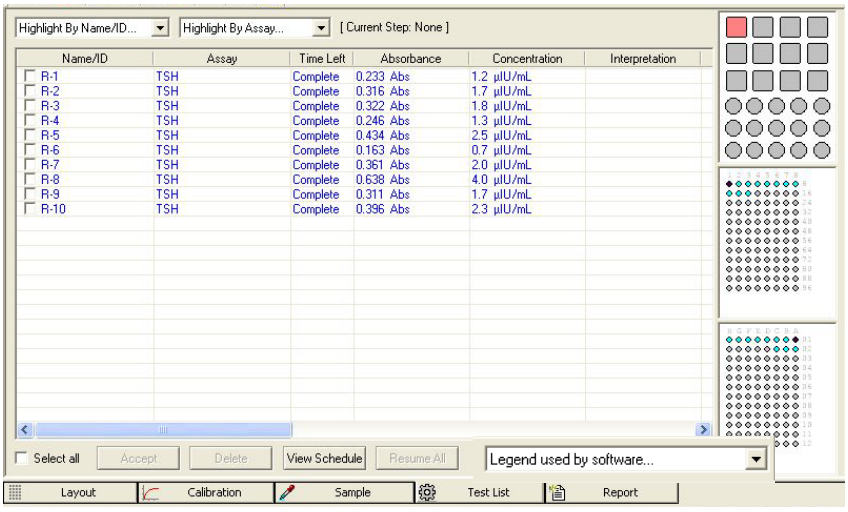


Figure 5.3.3-3 Activated Adjusted Curve

Even though the samples show decreased absorbance values similar to the one adjustment standard run, the resulting concentration values for the samples are the same as when they were run with the original complete standard curve (***Figure 5.3.3-4***).



Name/ID	Assay	Time Left	Absorbance	Concentration	Interpretation
R-1	TSH	Complete	0.233 Abs	1.2 µIU/mL	
R-2	TSH	Complete	0.316 Abs	1.7 µIU/mL	
R-3	TSH	Complete	0.322 Abs	1.8 µIU/mL	
R-4	TSH	Complete	0.246 Abs	1.3 µIU/mL	
R-5	TSH	Complete	0.434 Abs	2.5 µIU/mL	
R-6	TSH	Complete	0.163 Abs	0.7 µIU/mL	
R-7	TSH	Complete	0.361 Abs	2.0 µIU/mL	
R-8	TSH	Complete	0.638 Abs	4.0 µIU/mL	
R-9	TSH	Complete	0.311 Abs	1.7 µIU/mL	
R-10	TSH	Complete	0.396 Abs	2.3 µIU/mL	

Figure 5.3.3-4 Standard 5 Results

5.3.4 Changing Curve Fit Type

The assay curve fit type can be changed at run time provided the patient results have not been accepted and are still remaining in the Test List tab.

To change the curve fit type (***Figure 5.3.4-1***), go to the Calibration Tab (**A**), check all the standards you wish to use (**B**). Select the desired curve fit type from the drop down menu (**C**) located to the right of the graph icon. Clicking on the graph icon (**D**) will display the standard curves if they are not visible. The new curve fit graph will be displayed in the upper graph (**E**).

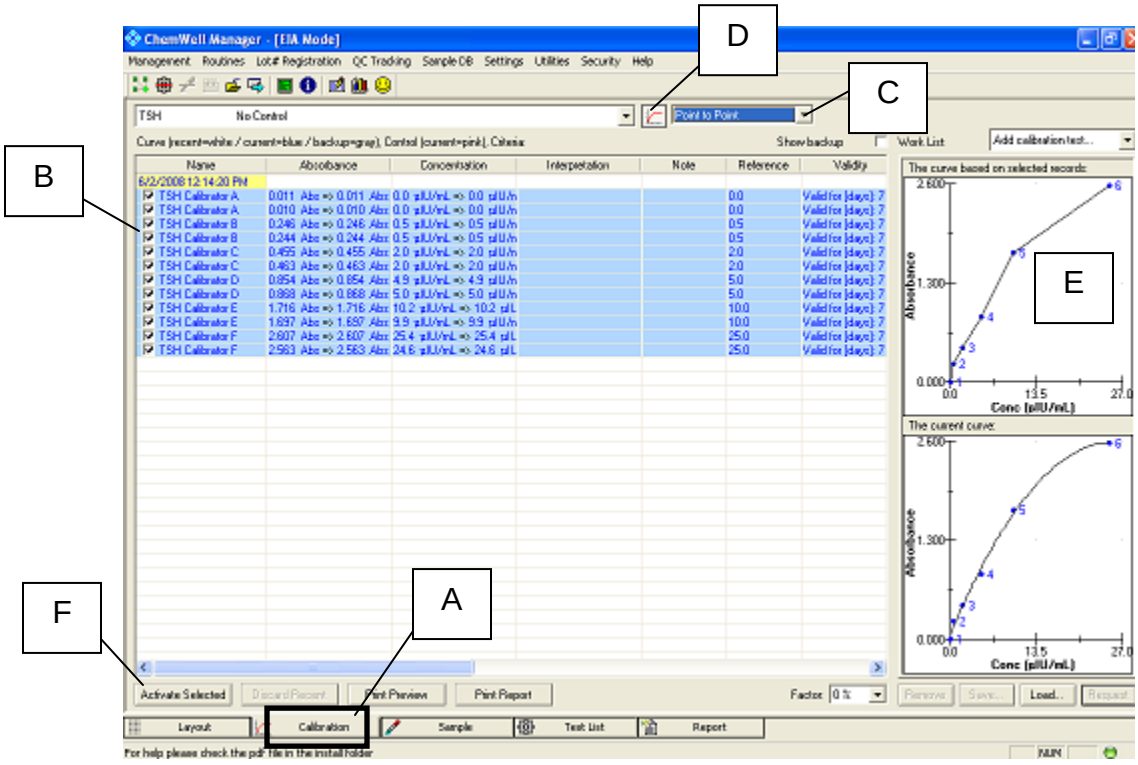


Figure 5.3.4-1 –Changing the Curve Fit Type

Once the desired curve fit type is selected, click on the Activate Selected button (**F**) and the graph will be activated. The patient results will be recalculated using this curve (***Figure 5.3.4-2*** Item **A**).

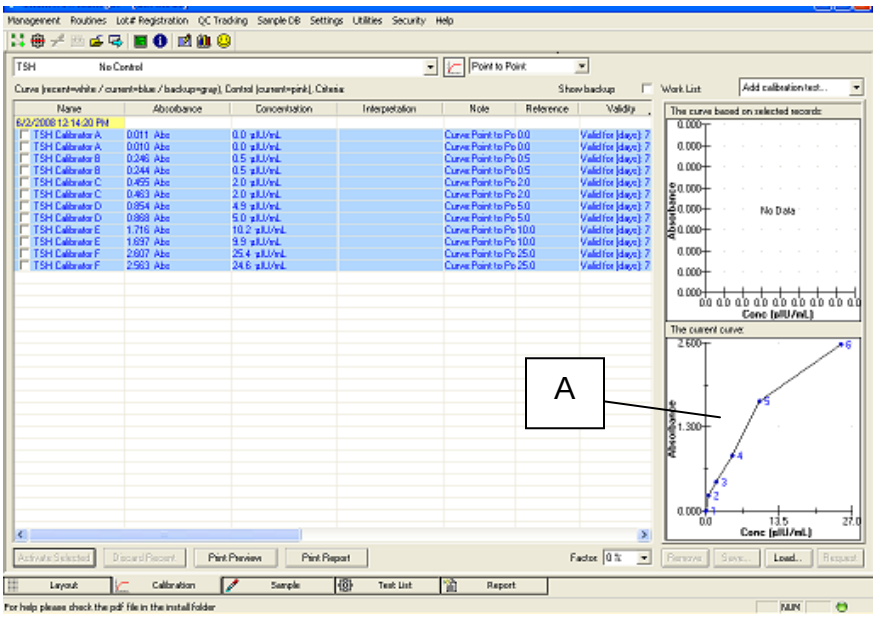


Figure 5.3.4-2 –New Curve Fit Activated

You can review the patient results in the Test List tab where they can be accepted into the database by checking the boxes followed by clicking on the Accept button (***Figure 5.3.4-3*** Item ***A***).

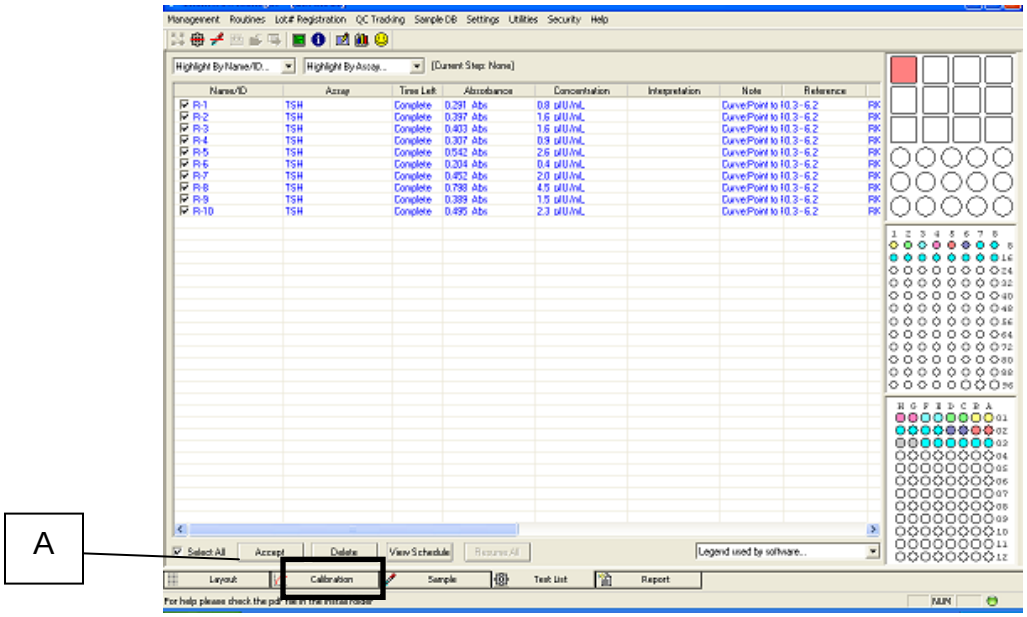


Figure 5.3.4-3 – Patient Results

Changing the curve fit in this way affects only the assay used in the Manager at this time and will not alter the original curve fit type programmed within the assay.

The newly selected curve fit type will remain in effect until the assays are reloaded or the Manager software is restarted; then the curve fit type programmed in the assay will be used.

When the assay's curve fit type is changed, the Note field will display the change next to each patient's sample result in the database.

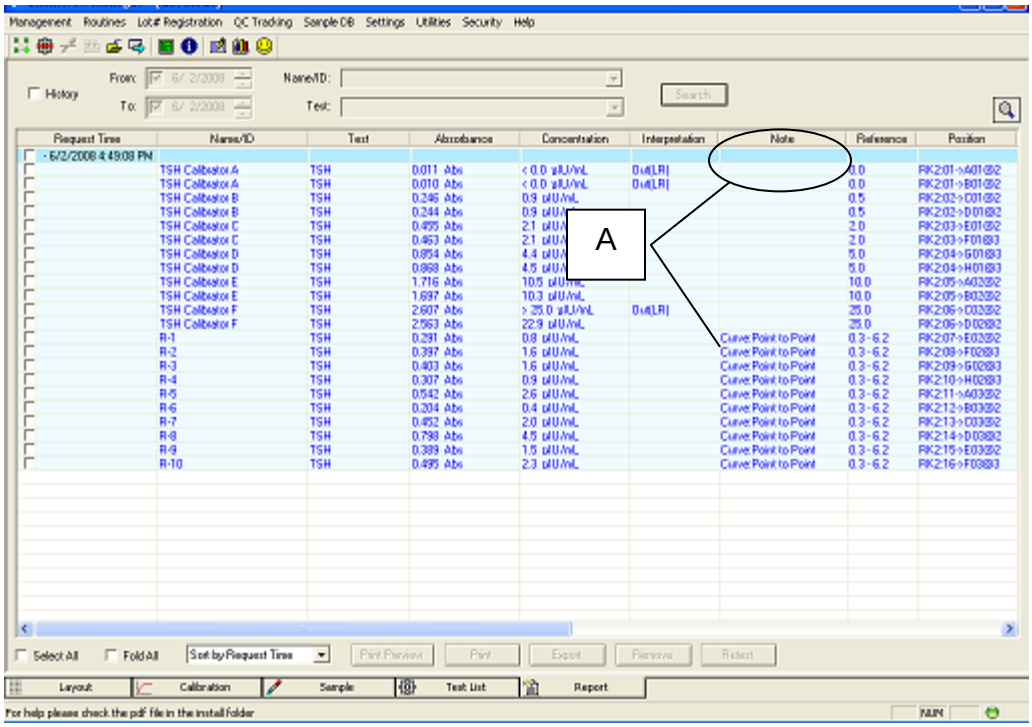
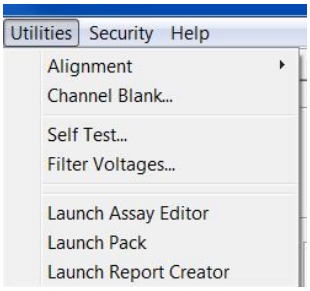


Figure 5.3.4-4 – Note field annotated when curve fit type is changed

Notes:

6. Report Creator



The Report Creator application allows users the opportunity to create unique formats for their reports. The ***Overview*** section that follows provides a short description of the options available. The ***Getting Started*** section explains each feature in greater detail.

The ***Custom Report Settings*** section provides information on using pre-defined report templates if creating a unique report is not desired.

6.1 Overview

Use *Report Creator* to create/format reports.

Execute the application from the ***m***anager menu by clicking on Utilities, and then select Launch Report Creator from the drop down menu . A blank report will display.

- To open an old file:

  Select *File Open filename*

- To create a new file:

  Select *File New*

Toolbar selections include:

- General Objects. General objects provide the ability to create elements and place them anywhere in the report. These general objects have properties that can be formatted. For example, text can be a particular color; lines can have a specific thickness. The body of the report can expand as needed and the objects outside the outline hold their positions. General objects that can be added to the report are:
  - box
  - ellipse
  - line
  - label
  - pictures

- Calibration Objects. Calibration objects can only be used on Calibration Reports. Assay data is from the Assay Editor. Create objects to display the assay data and place them anywhere in the report. Calibration objects have properties that can be formatted. For example, text can be a particular color; lines can have a specific thickness. The body of the report can expand as needed and the objects outside the outline hold their positions. Calibration objects that can be added to the report are:

    - Assay information
    - Assay substances
    - Standard curve
    - Curve formula
    - Table
    - Table statistics
    - Assay steps
    - Assay QCC

- Report Objects. Report objects can be used on any report. Report objects provide sorted data that can be placed anywhere in the report. Note that the default is sorted data for multiple assays. Also, Patient Data must exist in the Sample Database in order for patient data to appear in the report. Report objects have properties that can be formatted, such as alignment, border, etc. Report objects that can be added to the report are:

    - Grid sorted
    - Patient data

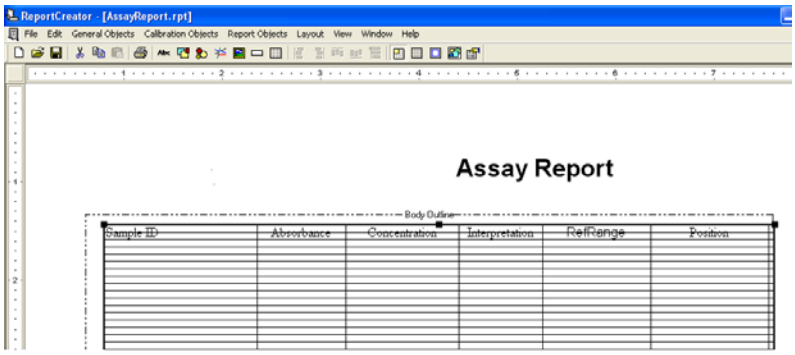
- Layout. Layout provides the ability to align data as desired in the report. Layout can be used with any report. Use the zoom to fit feature to place an object. The snap to grid feature provides ease of placement of general objects. Modify settings from pixels to inches, margins, width of objects etc. Layout features that can be used for the report are:

    - Align
    - Zoom to fit
    - Snap to grid
    - Settings

- View. View features the ability to display the toolbar, status bar, set grid lines on or off, display the setting for the margins for ease of placing the objects onto the report grid.

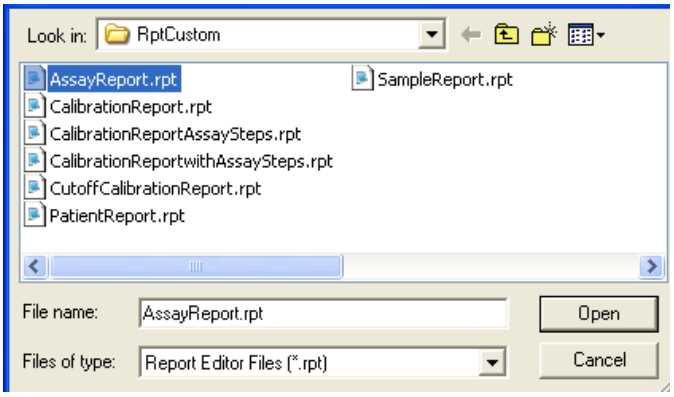
- Report Samples. A variety of reports have been supplied at the end of the section as examples of how reports can be formatted.

  The Assay Report sample below displays the default column headings and body outline.



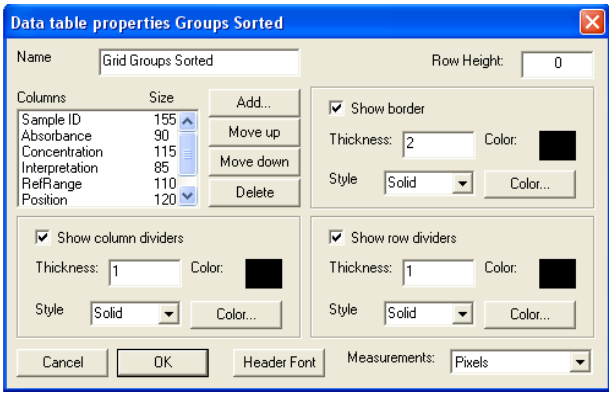
To view the Assay Report as shown, go to Utilities, click on Launch Report Creator.

Click on File Close to close the white screen. Click on File Open, select Assay Report.rpt, and click on the Open button.



- Maximize the report screen, mouse click on the report, use the scroll wheel on the mouse to zoom in, or click on Layout, Align, Zoom In.
- Right mouse click on the report, the Properties window will display.

The data properties dialog box shows the default column headings, width sizes, thickness of the column dividers, border thickness, solid line style etc. Select settings on the properties window to affect the report format.



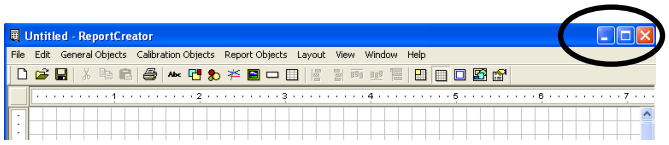
To save the file, click on File Save As, type in a file name, press the Save button. Note that the default report location is RptCustom and .rpt is the default file extension.

6.1.1 Launch Report Creator

Select Utilities from the manager menu, a drop down menu will appear, select Launch Report Creator.

A blank report will appear. An untitled report will open. Assign a report name by using File Save As.

Click on maximize to enlarge the view of the work area of the report screen.



File New

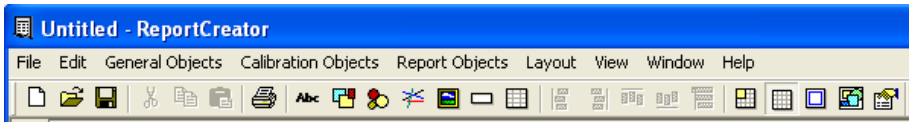
Click on File to reveal the drop down menu with the following options: New, Open, Print Setup, Exit.

6.1.2 Report Creator Toolbar

TheToolbar centralizes the following list of tools necessary for the user to create unique reports:

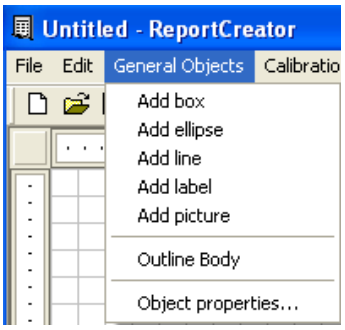
- General objects
- Calibration objects
- Report objects
- Layout

Sample reports are provided at the end of this section to give the user ideas for creating their own unique reports.



The following tables identify the menu options and describe each feature found on the drop down menus.

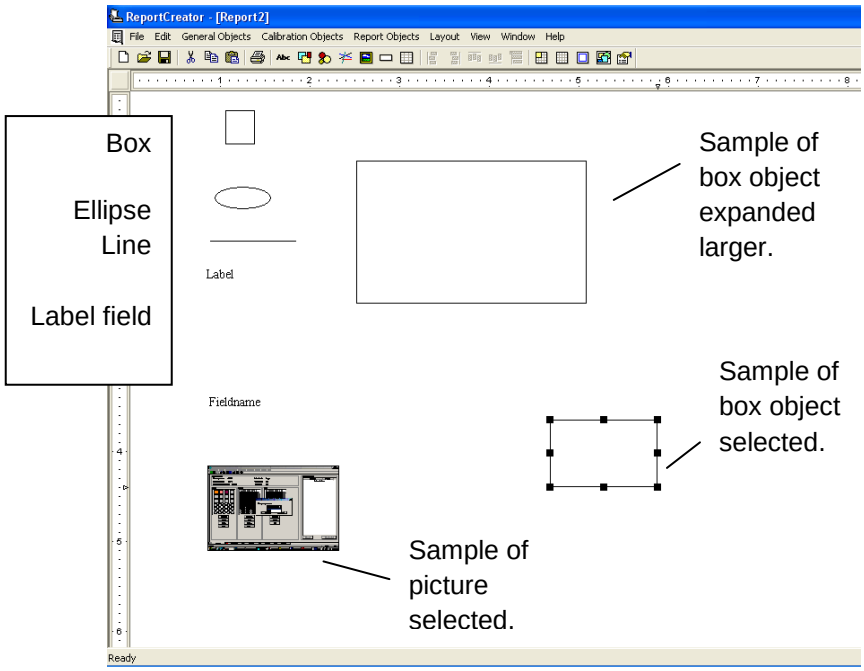
6.1.3 General Objects



Feature	Description	Output
Add box	Draws a box; enables user to click and drag a box	
Add ellipse	Draws an oval; enables user to click and drag an oval	
Add line	Draws a line; enables user to click and drag a line	
Add label	Draws a text box; enables user to click and drag a text box	text
Add field	Draws a box labeled field name	**Fieldname**
Add picture	Draws a box; allows user to insert an image from browser	Image
Outline Body	Defines the body of the report; adds structure to the report. Tables placed within the body outline will be automatically sized based on the reported dataset.	Structured output
Object properties	Select object properties after selecting the object; allows user to designate alignment, color of line, fill, font, border, etc. See specific object properties.	User designated properties

Placing an object

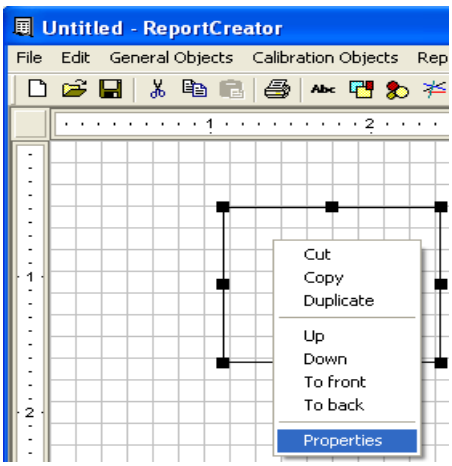
When a feature from the drop down menu is selected, the mouse pointer will change to crosshairs. Click to where you want to begin an object, and drag the mouse pointer to where the object should end. Release the mouse pointer and the object appears. To move the object, click on the center of the object, crosshair arrows will appear and highlight the edges of the object with small squares. Use the up, down, left, right arrows on the keyboard to nudge the object to the position desired.



Sample General Objects

6.1.3.1 Properties

To change the properties of an object, right click on the object, and select Properties from the drop down menu. An alternative to right clicking on the object to arrive at the object properties window is to left click on the object, click on the General Objects, and then click on Object properties from the drop down menu.



Box and Ellipse Properties

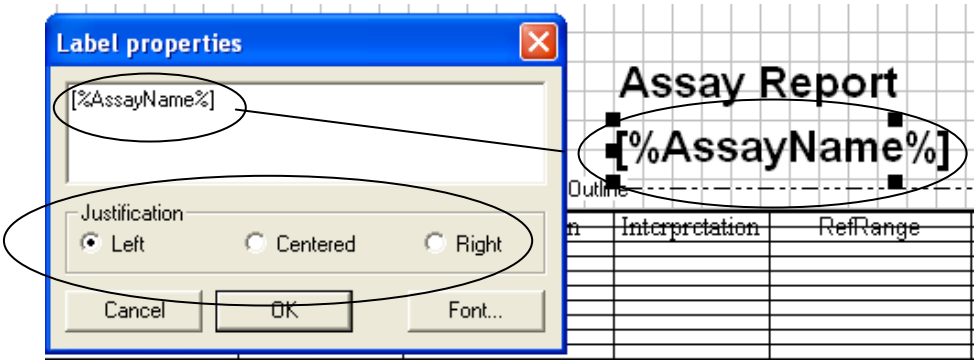
Feature	Description
Show border	Draws a border around the box object. This is the default setting. Click on Show border to remove the border from the box; the border will be invisible.
Thickness	Allows the user to set the thickness of the lines of the border
Style	Border styles include dashed, dotted, solid. Solid is the default.
Color	Border color defaults to black. Click on Color, select a color, and click OK.
Fill object	Default setting unfilled object. Click on Fill object to fill object with color. Click on Color, select color, click OK. Object displays filled with color selected.
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

Line Properties

Feature	Description
Thickness	Allows the user to set the thickness of the line
Style	Line styles include dashed, dotted, and solid. Solid is the default.
Color	Line color defaults to black. Click on Color, select a color, and click OK.
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

Label Variables

To manage data on your reports, consider using the label variables found under label properties.

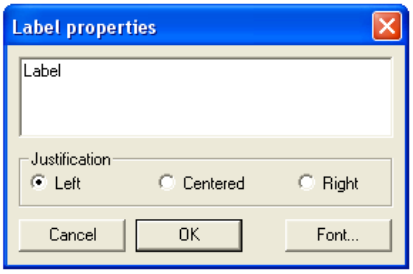


Place the label object at the desired location in your report. Click on the label object, click on Object Properties. Type the label variable in the Label properties window. Note that you may adjust the placement by left or right justification or centering.

Label Variables

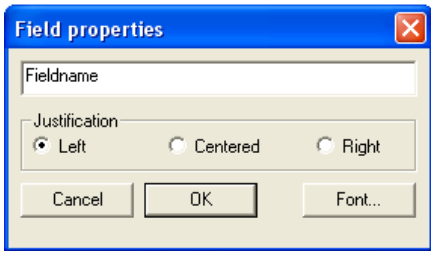
Variable:	Output:
[%page%]	Prints page number
[%date%]	Prints current date
[%time%]	Prints current time
[%AssayName%]	Prints assay name (intended for use in calibration reports only)
[%AssayUnits%]	Prints assay units (can be used in a grid object)
[%RunDate%]	Prints the date the test was run
[%RunTime%]	Prints the time the test was run
[%AssayVersion%]	Prints assay version number
[%SWVersion%]	Prints instrument's software version number

Label Properties



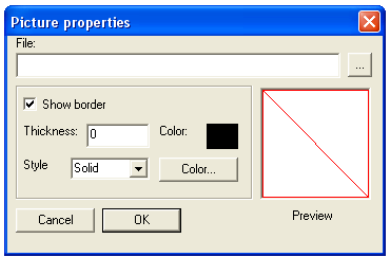
Feature	Description
Label	Assign a name to the label by typing over the word label in display
Justification	Align text; left justification is the default setting. Choose to center or right align.
Font	Select the font style, effect, color and size
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

Field Properties



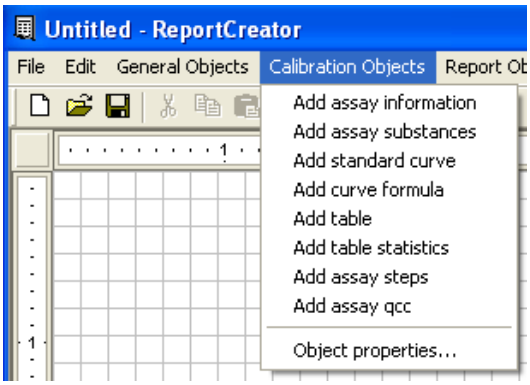
Feature	Description
Fieldname	Assign a name to the field by typing over the word fieldname in display
Justification	Align fieldname; left justification is the default setting. Choose to center or right align.
Font	Select the font style, effect, color and size
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

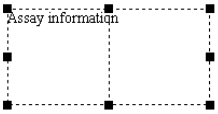
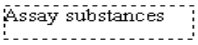
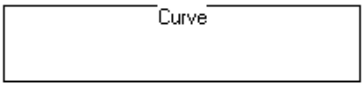
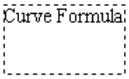
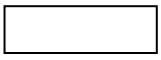
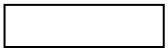
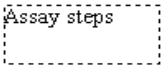
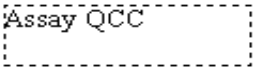
Picture Properties



Feature	Description
File	Click on browse box to open browser; allows a picture to be selected and placed in the picture box (graphs, logos etc.); image will display in Preview window.
Show border	Draws a border around the box object. This is the default setting. Click on Show border to remove the border from the box; the border will be invisible.
Thickness	Allows the user to set the thickness of the lines of the border
Style	Border styles include dashed, dotted, and solid. Solid is the default.
Color	Border color defaults to black. Click on Color, select a color, and click OK.
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

6.1.4 Calibration Objects

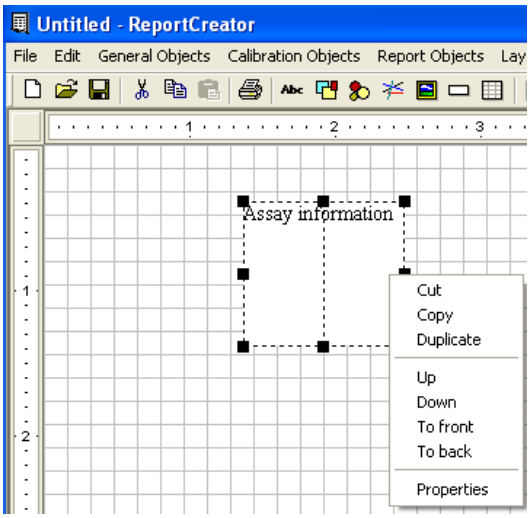


Feature	Description	Output
Add assay information	Draws a box labeled Assay Information	
Add assay substances	Draws a box labeled Assay Substances	
Add standard curve	Draws a box labeled Curve	
Add curve formula	Draws a box labeled Curve Formula	
Add table	Draws an unlabeled box used for data table	
Add table statistics	Draws an unlabeled box used for statistical data table	
Add assay steps	Draws a box labeled Assay steps	
Add assay qcc	Draws a box labeled Assay QCC	
Object properties	Select object properties after selecting the object; allows user to designate alignment, color of line, fill, font, border, etc. See specific object properties.	User designated properties

Calibration Objects (Continued)

6.1.4.1 Properties

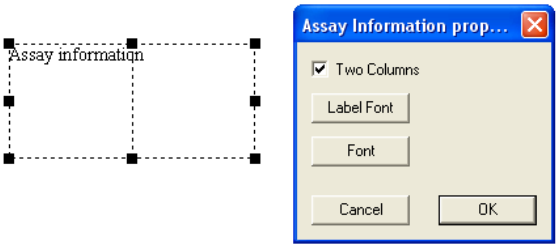
To change the properties of an object, right click on the object, and select Properties from the drop down menu.



Example of add Assay Information

An alternative to right clicking on the object to arrive at the object properties window is to left click on the object, click on the Calibration Objects, and click on Object properties from the drop down menu.

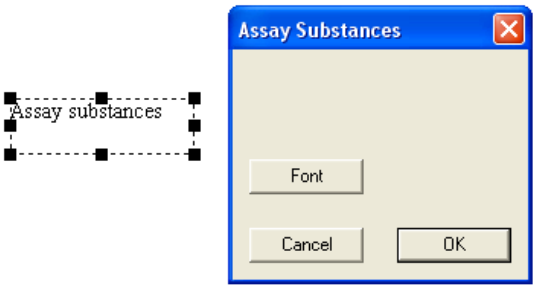
Assay Information



Feature	Description
Two Columns	Allows the user to set the number of columns to one or two. Two columns is the default.
Label Font	Select the font style, effect, color and size
Font	Select the font style, effect, color and size
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

Calibration Objects (Continued)

Assay Substances



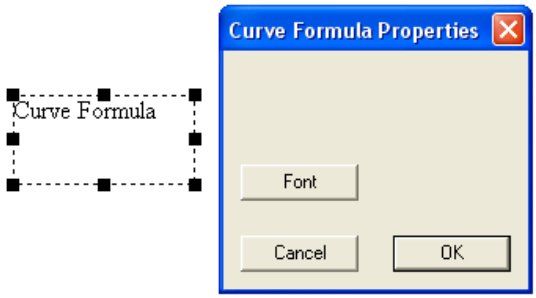
Feature	Description
Font	Select the font style, effect, color and size
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

Curve Properties

Feature	Description
Show border	Draws a border around the box object. This is the default setting. Click on Show border to remove the border from the box; the border will be invisible.
Thickness	Allows the user to set the thickness of the lines of the border
Style	Border styles include dashed, dotted, and solid. Solid is the default.
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

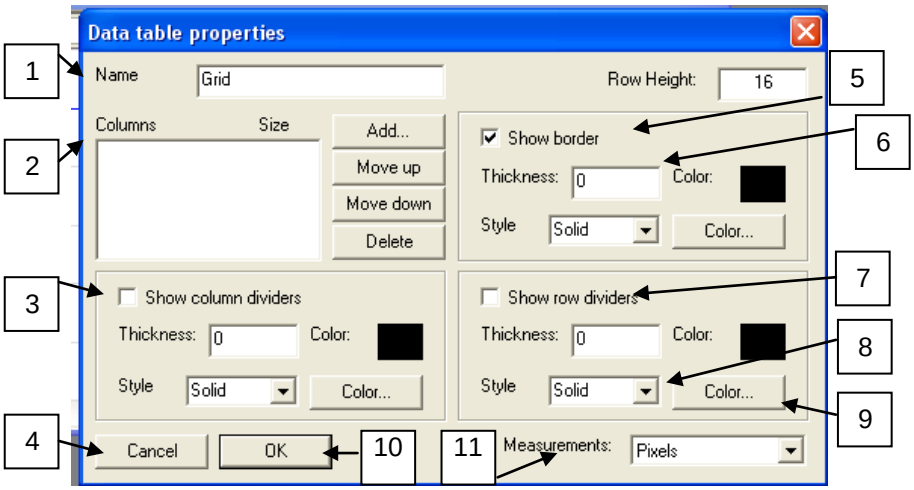
Calibration Objects (Continued)

Curve Formula



Feature	Description
Font	Select the font style, effect, color and size
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

Data table

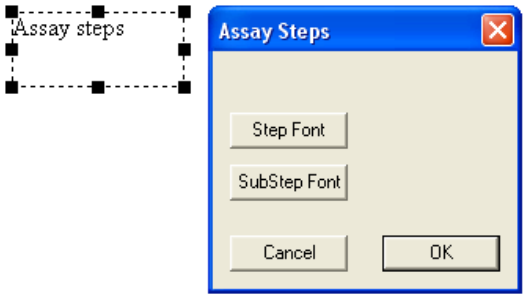


Feature	Description	
Name	Allows user to assign a name to the grid	1
Columns	Add or edit column by choosing a heading from the list provided	2
Show column divider	Draws dividers between the columns. This is the default setting. Click on Show column dividers to display on report.	3
Cancel	Cancels selection; closes properties window	4

Calibration Objects (Continued)

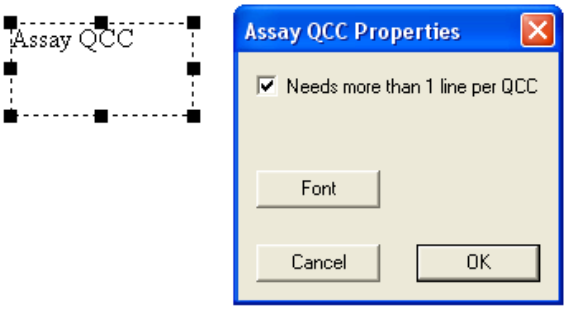
Show border	Draws a border around the box object. This is the default setting. Click on Show border to remove the border from the box; the border will be invisible.	5
Thickness	Allows the user to set the thickness of the lines of the border	6
Show row divider	Draws dividers between the rows. This is the default setting. Click on Show row dividers to display on report.	7
Style	Border styles include dashed, dotted, and solid. Solid is the defult.	8
Color	Border color defaults to black. Click on Color, select a color, and click OK.	9
OK	Accepts and applies selection; closes properties window.	10
Measurement	Pixels, inches or centimeters	11

Assay Steps Properties



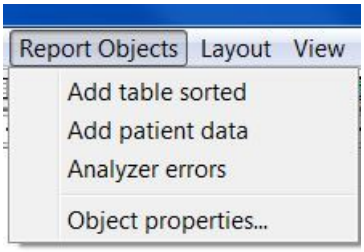
Feature	Description
Step Font	Select the font style, effect, color and size
SubStep Font	Select the font style, effect, color and size
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

Assay QCC Properties



Feature	Description
Needs more than 1 line per QCC	Default setting is more than 1 line per QC Criteria; based on the length of the formula
Font	Select the font style, effect, color and size
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

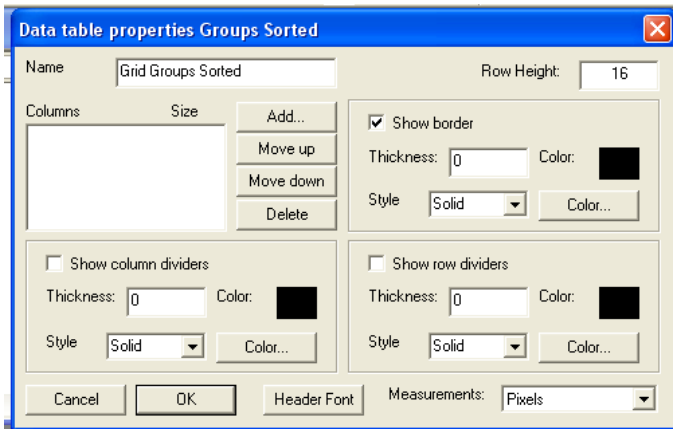
6.1.5 Report Objects



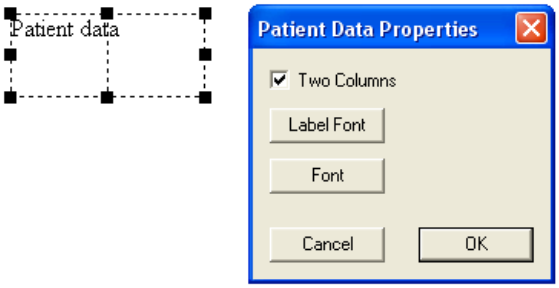
Feature	Description
Add table sorted	Default is sorted data for multiple assays
Add patient data	Data will be displayed if it exists in the Sample Database
Analyzer errors	This is a text box in which any instrument errors encountered can be included in the report
Object properties	Allows user to edit the Data Table properties, including alignment, color of line, fill, font, border, etc. See specific object properties.

Add Table Sorted

Once the Table is placed in the create report field, clicking on Properties will open this window.

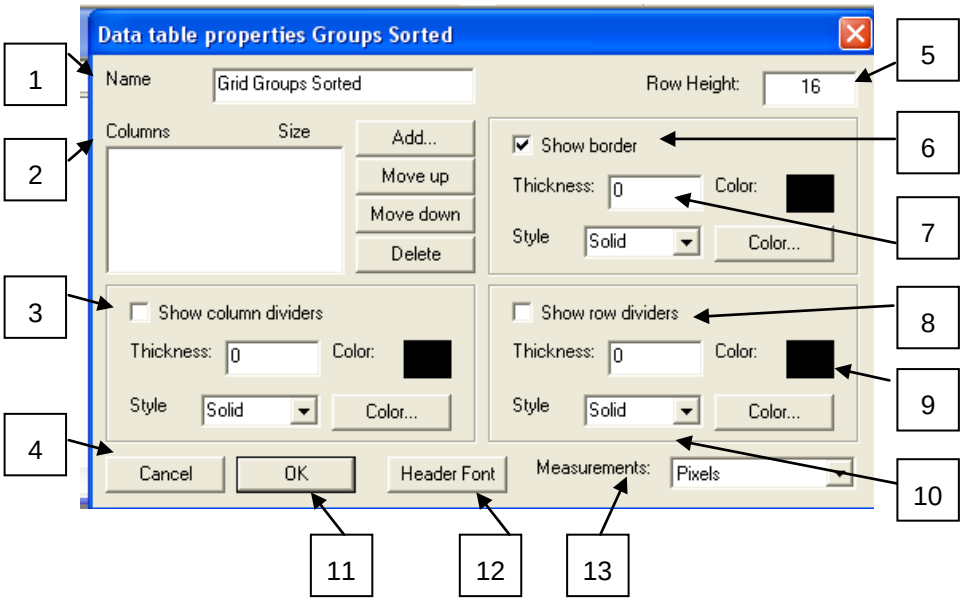


Add Patient Data



Feature	Description
Two Columns	Default setting is two columns; uncheck box to format as one column
Label Font	Select the font style, effect, color and size
Font	Select the font style, effect, color and size
Cancel	Cancels selection; closes properties window
OK	Accepts and applies selection; closes properties window.

Data Table Properties

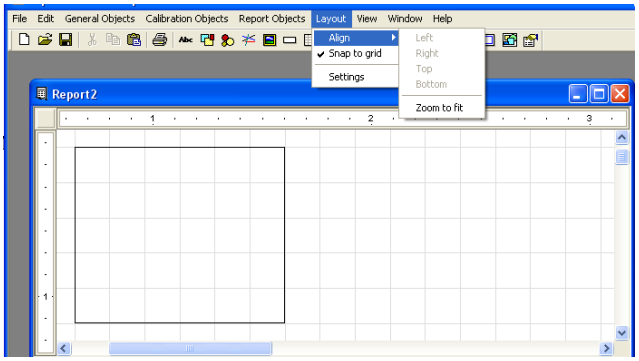


Feature	Description	
Name	Allows user to assign a name to the groups	1
Columns	Add or edit column by choosing a heading from the drop down list provided	2
Show column divider	Draws dividers between the columns. This is the default setting. Click on Show column dividers to display on report.	3
Cancel	Cancels selection; closes properties window	4
Row Height	User may set desired row height	5
Show border	Draws a border around the box object. This is the default setting. Click on Show border to remove the border from the box; the border will be invisible.	6
Thickness	Allows the user to set the thickness of the lines of the border	7
Show row divider	Draws dividers between the rows. This is the default setting. Click on Show row dividers to display on report.	8
Color	Border color defaults to black. Click on Color, select a color, and click OK.	9
Style	Border styles include dashed, dotted, and solid. Solid is the default.	10
OK	Accepts and applies selection; closes properties window.	11
Header Font	Select the font style, effect, color and size	12
Measurement	Pixels, inches or centimeters	13

6.1.6 Layout

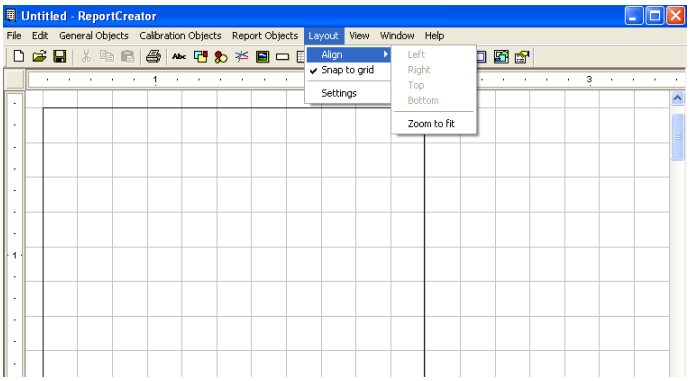
Align - Zoom to fit

This option allows user a closer view of the grid to align data as desired.



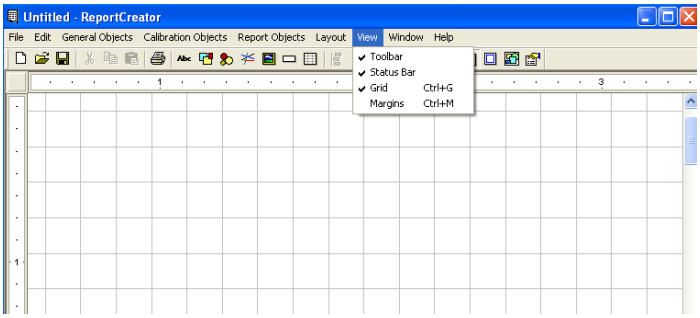
Snap to Grid

This option allows user ease of placement of general objects.



6.1.7 View

View allows user to display the Toolbar, the Status Bar, set grid lines on or off, and set margins. Example shows grid lines on.



6.2 Sample Reports

Assay

Assay Report

Sample	Absorbance	Concentration	Interpret.	Normal Range	Position
8/29/2006 4:18:49 PM					
TSH Standard 1	0.018 Abs	0.0 µIU/mL		0.0	RK2:14->A01@2
TSH Standard 1	0.013 Abs	0.0 µIU/mL		0.0	RK2:14->B01@2
TSH Standard 2	0.108 Abs	0.5 µIU/mL		0.5	RK2:15->C01@2
TSH Standard 2	0.098 Abs	0.5 µIU/mL		0.5	RK2:15->D01@2
TSH Standard 3	0.298 Abs	2.0 µIU/mL		2.0	RK2:16->E01@2
TSH Standard 3	0.310 Abs	2.1 µIU/mL		2.0	RK2:16->F01@3
TSH Standard 4	0.638 Abs	5.1 µIU/mL		5.0	RK2:17->G01@3
TSH Standard 4	0.610 Abs	4.9 µIU/mL		5.0	RK2:17->H01@3
TSH Standard 5	1.190 Abs	9.9 µIU/mL		10.0	RK2:18->A02@2
TSH Standard 5	1.215 Abs	10.1 µIU/mL		10.0	RK2:18->B02@2
TSH Standard 6	2.607 Abs	25.2 µIU/mL		25.0	RK2:19->C02@2
TSH Standard 6	2.563 Abs	24.8 µIU/mL		25.0	RK2:19->D02@2
R-1	0.323 Abs	2.2 µIU/mL		0.4 - 6.0	RK2:04->E02@2
R-2	0.397 Abs	2.9 µIU/mL		0.4 - 6.0	RK2:05->F02@3
R-3	0.403 Abs	2.9 µIU/mL		0.4 - 6.0	RK2:06->G02@3
R-4	0.307 Abs	2.0 µIU/mL		0.4 - 6.0	RK2:07->H02@3
R-5	0.081 Abs	0.4 µIU/mL		0.4 - 6.0	RK2:08->A03@2
R-6	0.204 Abs	1.3 µIU/mL		0.4 - 6.0	RK2:09->B03@2
R-7	0.452 Abs	3.4 µIU/mL		0.4 - 6.0	RK2:10->C03@2
R-8	0.798 Abs	6.5 µIU/mL	High	0.4 - 6.0	RK2:11->D03@2
R-9	0.389 Abs	2.8 µIU/mL		0.4 - 6.0	RK2:12->E03@2
R-10	0.495 Abs	3.8 µIU/mL		0.4 - 6.0	RK2:13->F03@3

Cut Off Calibration

Cut-off Calibration Report
HIV

COV = 0.328

(Run Time: August 29, 2006 10:13:57)

Control Data:

Sample	Abs.	Mean	Abs/COV	Mean	S.D.	% C.V.
Blank	0.032	0.032				
HIV Negative Control	0.076 0.080	0.078	0.232 0.244	0.238	0.008	3.57
HIV Positive Control	1.581	1.581	4.820	4.820		

QC Control Criteria:

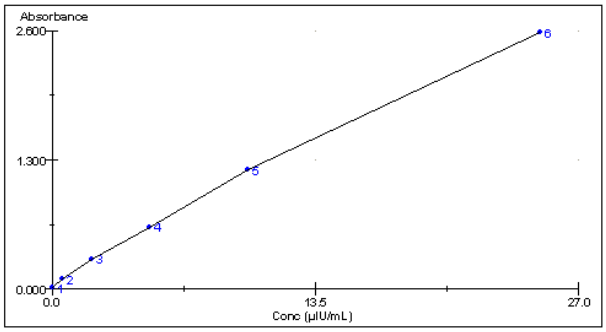
'ABS(Blank)' < 0.100 Pass
'MeanA(HIV Negative Control)' <= 0.180 Pass

Calibration Report

Calibration Report
TSH

Standard Curve:

Run Time: August 29, 2006 16:18:49



Points 1 - 2 : Slope = 0.17600, Intercept = 0.015000
Points 2 - 3 : Slope = 0.13400, Intercept = 0.036000
Points 3 - 4 : Slope = 0.10667, Intercept = 0.090667
Points 4 - 5 : Slope = 0.11580, Intercept = 0.045000
Points 5 - 6 : Slope = 0.092133, Intercept = 0.28167

Data:

Sample	Value	Abs.	Mean	µIU/mL	Mean	S.D.	% C.V.
TSH Standard 1	0.0	0.018 0.013	0.015	0.000 0.000	0.000	0.000	0.00
TSH Standard 2	0.5	0.108 0.098	0.103	0.500 0.500	0.500	0.000	0.00
TSH Standard 3	2.0	0.298 0.310	0.304	2.000 2.100	2.050	0.071	3.45
TSH Standard 4	5.0	0.638 0.610	0.624	5.100 4.900	5.000	0.141	2.83
TSH Standard 5	10.0	1.190 1.215	1.203	9.900 10.100	10.000	0.141	1.41
TSH Standard 6	25.0	2.607	2.585	25.200	25.000	0.283	1.13

Patient Report

Patient Report

Patient Data:

Family Name:	Jacobson	Doctor:	Smith
Given Name:	Jeff	Address:	102 SW 1st Street, Miami, FL 33130
Middle Name:	B.		
Sex:	M	Keyword:	
DOB:	4/18/1972	Custom:	

Test Results:

Assay	Concentration	Interpretation	Normal Range
	001546		
Albumin	4.0 g/dL		3.1 - 4.3
Alkaline Phoshatase	56 U/L		30 - 115
ALT	34 U/L		7 - 55
AST	24 U/L		4 - 36
BUN	28.8 mg/dL	High	8.0 - 25.0
Calcium	9.2 mg/dL		8.5 - 10.5
Creatinine	1.2 mg/dL		0.6 - 1.5
Glucose	96.0 mg/dL		70.0 - 110.0
Total Bilirubin	0.1 mg/dL		< 1.0
Total Protein	7.2 g/dL		6.0 - 8.0

Sample Report

Sample Report

Assay	Concentration	Interpretation	Normal Range
001546			
Albumin	4.0 g/dL		3.1 - 4.3
Alkaline Phoshatase	56 U/L		30 - 115
ALT	34 U/L		7 - 55
AST	24 U/L		4 - 36
BUN	28.8 mg/dL	High	8.0 - 25.0
Calcium	9.2 mg/dL		8.5 - 10.5
Creatinine	1.2 mg/dL		0.6 - 1.5
Glucose	96.0 mg/dL		70.0 - 110.0
Total Bilirubin	0.1 mg/dL		< 1.0
Total Protein	7.2 g/dL		6.0 - 8.0

Calibration Report with Assay Steps

Calibration Report
FSH

Assay Steps:

Add Sample, Volume [50.0 µL]
Aspiration Speed=2, Air Gap=11µL, Dispense Speed=2, Dispense Height=Low
Add Reagent [FSH Enzyme Conjugate], Volume [100.0 µL]
Aspiration Speed=0, Air Gap=25µL, Prewarm Time=0sec, Dispense Speed=2, Dispense Height=High
Clean Probe with [1N HCl], Volume [500 µL]
Aspiration Speed=2, Air Gap=50µL
Rinse Probe, Volume [2000 µL], 1 time(s)

Incubate 01:00:00 [1h 0min 0sec]

Wash 3x, Volume [400 µL], Soak Time [30 sec]
Substep 1: Aspirate Dispense Volume [400 MicroLiter] SoakTime [30 Sec]
Substep 2: Aspirate Dispense Volume [400 MicroLiter] SoakTime [30 Sec]
Substep 3: Aspirate Dispense Volume [400 MicroLiter] SoakTime [30 Sec]
Substep 4: DoubleAspirate

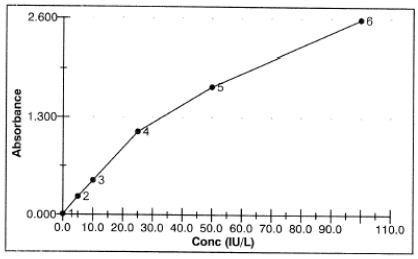
Add Reagent [Substrate Solution], Volume [100.0 µL]
Aspiration Speed=2, Air Gap=25µL, Prewarm Time=0sec, Dispense Speed=2, Dispense Height=High
Incubate 00:15:00 [0h 15min 0sec]

Add Reagent [Stop Solution], Volume [50.0 µL]
Aspiration Speed=2, Air Gap=25µL, Prewarm Time=0sec, Dispense Speed=2, Dispense Height=High
Incubate 00:00:10 [0h 0min 10sec]

Read with Primary Filter[450], Differential Filter[630]

Standard Curve:

Run Time: September 20, 2006 12:23:42



Points 1 - 2 : Slope = 0.047000, Intercept = 0.0100000

Page: 1

Calibration Report
FSH

Points 2 - 3 : Slope = 0.042800, Intercept = 0.031000
Points 3 - 4 : Slope = 0.043400, Intercept = 0.025000
Points 4 - 5 : Slope = 0.023880, Intercept = 0.51300
Points 5 - 6 : Slope = 0.017560, Intercept = 0.82900

Data:

Sample	Value	Abs.	Mean	IU/L	Mean	S.D.	% C.V.
FSH Calibrator A	0.0	0.011 0.010	0.010	0.000 0.000	0.000	0.000	0.00
FSH Calibrator B	5.0	0.246 0.244	0.245	5.000 5.000	5.000	0.000	0.00
FSH Calibrator C	10.0	0.455 0.463	0.459	9.900 10.100	10.000	0.141	1.41
FSH Calibrator D	25.0	1.108 1.112	1.110	25.000 25.100	25.050	0.071	0.28
FSH Calibrator E	50.0	1.716 1.697	1.707	50.500 49.600	50.050	0.636	1.27
FSH Calibrator F	100.0	2.607 2.563	2.585	101.300 98.700	100.000	1.838	1.84

7. Troubleshooting

7.1 Tips for Running CAAS

7.1.1 Avoiding Bubbles

Prime syringes with 70% isopropyl alcohol (standard drugstore rubbing alcohol). Place the tubing that sits in the priming bottle into a bottle of alcohol, then go to “Routines” and choose “Prime Syringes.”

Pay attention to the larger syringe and be sure to repeat the priming step until there are no air bubbles at the very top of the syringe.

NOTE: during regular use, there may be a few “stationary” bubbles at the top of the syringe that will wobble/move while the syringe is working—these types of bubbles are common and usually do not affect performance. Once you are confident the syringes are bubble-free (usually 1-3 prime cycles), place the tubing back into the priming bottle (prime bottle must always be filled with deionized or distilled water), and repeat “Prime Syringes” for double the amount of times that alcohol was cycled (ex. 2 alcohol primes = 4 water primes).

Additionally, pinching the tubing (see figure below) from the prime bottle to the diluter, while the larger syringe is mid-stroke, can quickly remove air bubbles, but be sure to prime the syringes thoroughly after applying this technique.

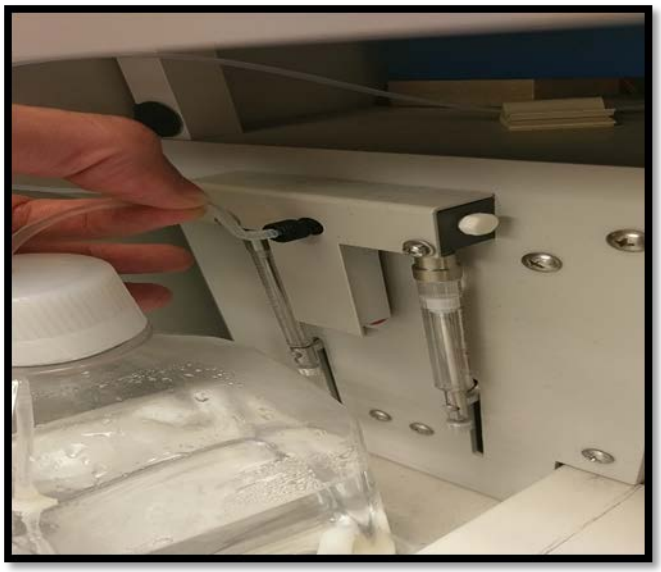


Figure 7.1.1-1 Tubing from Prime Bottle to the Diluter

7.1.2 Alignments

Check all alignments. Most alignments do not need to be adjusted on a routine basis—unless there are clear issues, or errors being produced. However, double-checking the alignments could prevent a failed run in the future. If CAAS results are producing high %CV values, the wash-head alignment should be checked.

If adjustments are made to the main probe (used to pipette all reagents and samples into the plate wells), a quick check of the MAXZ and MXZ2 settings should be conducted. Press the “F5” key on your keyboard.

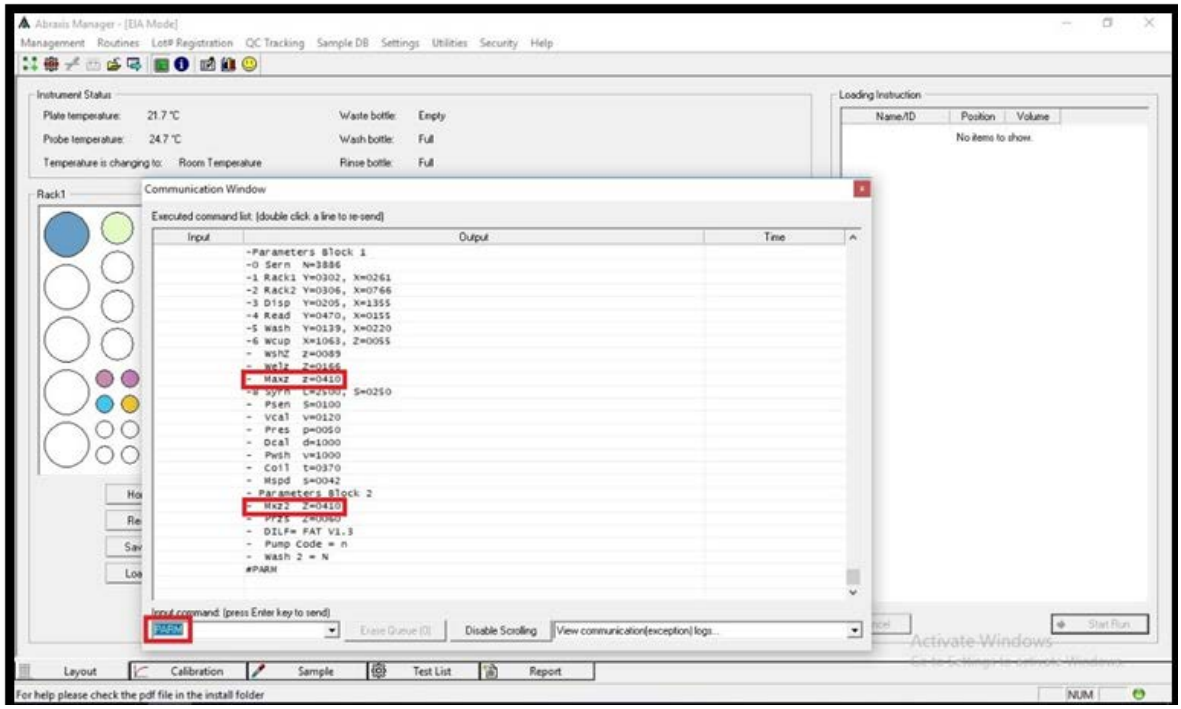


FIGURE 7.1.2-1 MAXZ and MXZ2 Settings

A communication window will appear. In the bottom-left corner, type “PARM” into the input command, then press “Enter” key. A list will be generated as shown below.

Abraxis prefers that MAXZ and MXZ2 have Z values of 0410. If Z does not equal 0410, type “MAXZ0410” into the input command, then press “Enter.”

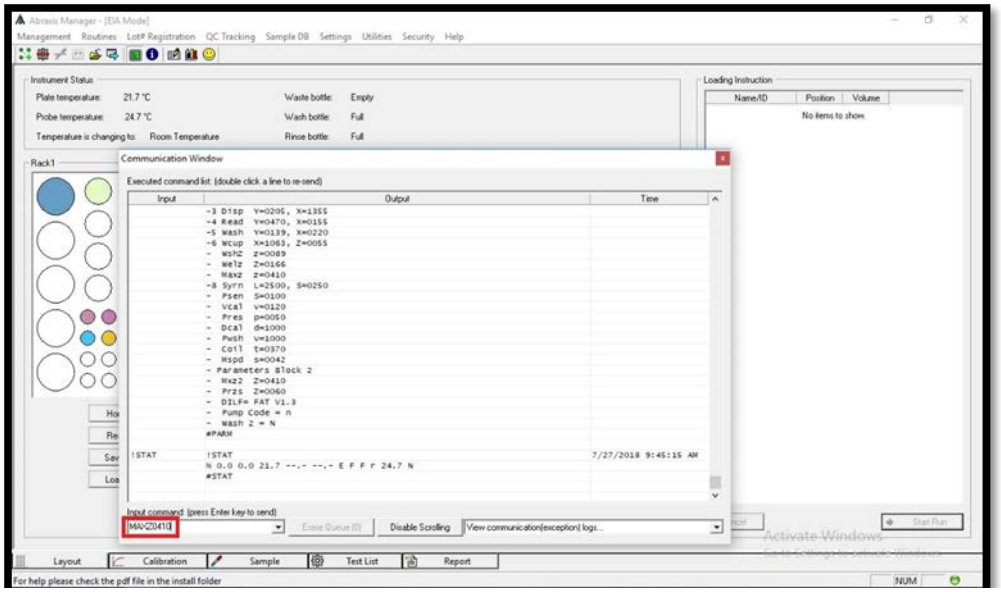


Figure 7.1.2-2

The picture below is confirmation that the software has accepted the new parameters.

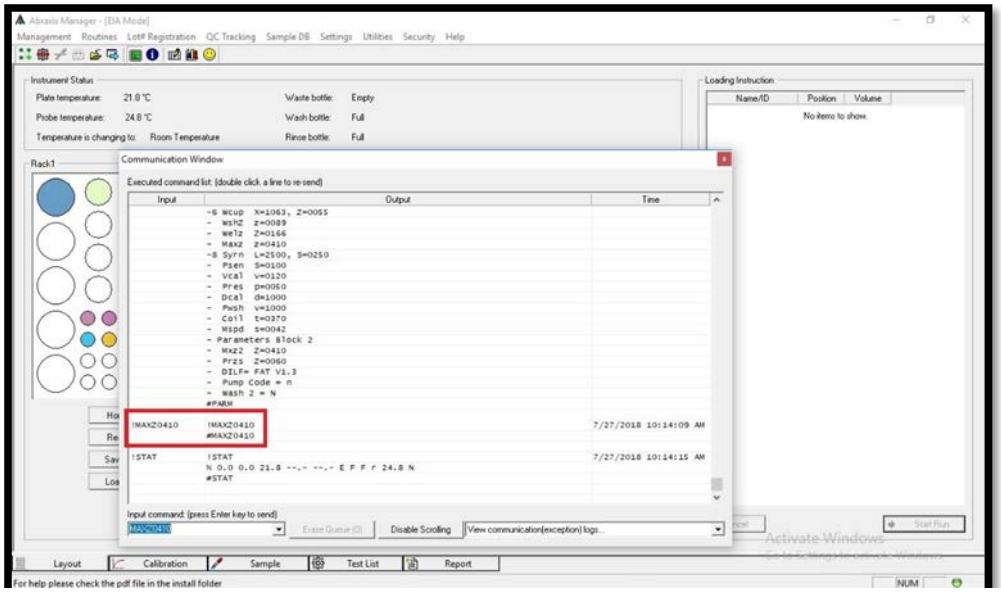


Figure 7.1.2-3

Perform the same steps for MXZ2 so the Z value is also 0410, and then type “PARM” into the input command once more to confirm the changes have officially been made.

To confirm that the wash-head is properly aligned, place an uncoated plate (preferably an Abraxis plate—plate(s) can be provided/shipped with any order at no additional cost) into the plate tray (**see FIGURES 7.1.2-5 and 7.1.2-6**), then goto the “Layout” tab at the bottom-left of the screen. Be sure to check off ~6 rows:

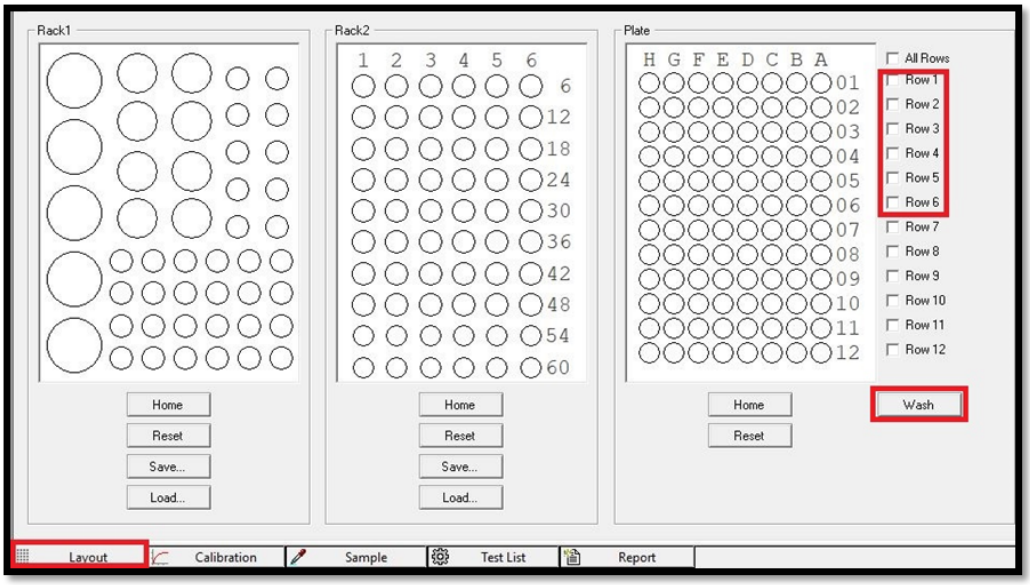


Figure 7.1.2-4 Layout Tab

Before placing the microtiter plate into the plate tray, place the plate flat on the benchtop, face down (the top of the wells), and gently press the plate against the benchtop to insure the strips become flush against the plate frame—if the strips are not flush, this could lead to uneven washing of the wells during the washing steps of the assay.

Figure 7.1.2-5

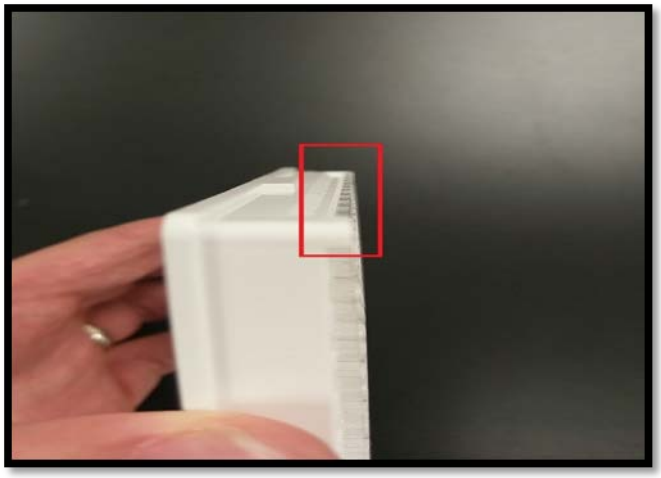


Figure 7.1.2-6

Take notice during the filling/dispensing that all wells are being filled uniformly. See picture below.

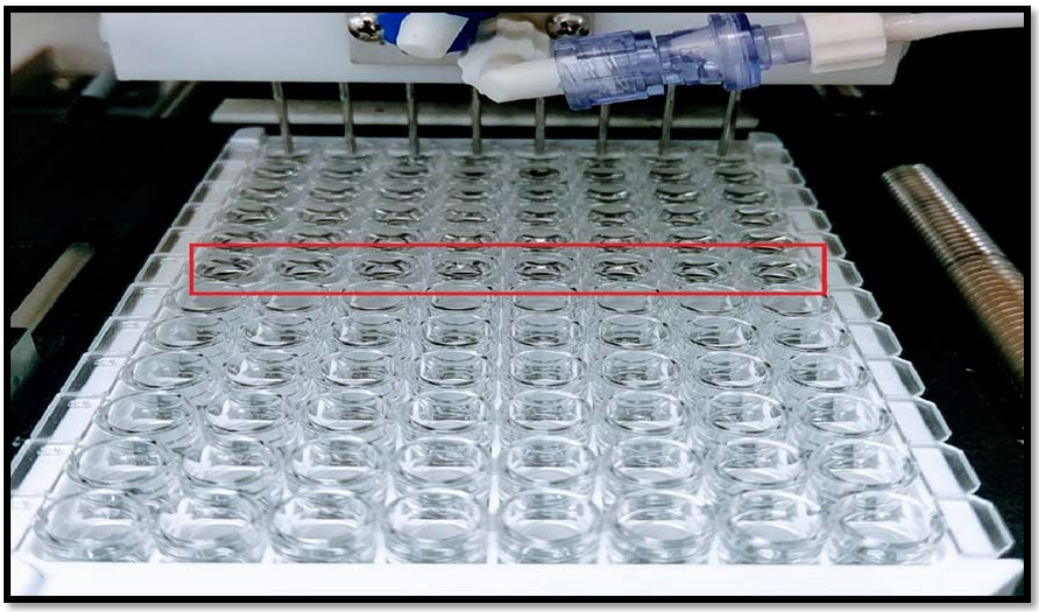


Figure 7.1.2-7

Once this process is complete, remove the plate from the tray, lift and hold the plate up to the light, and check for liquid remnants still inside the wells:

This is acceptable:

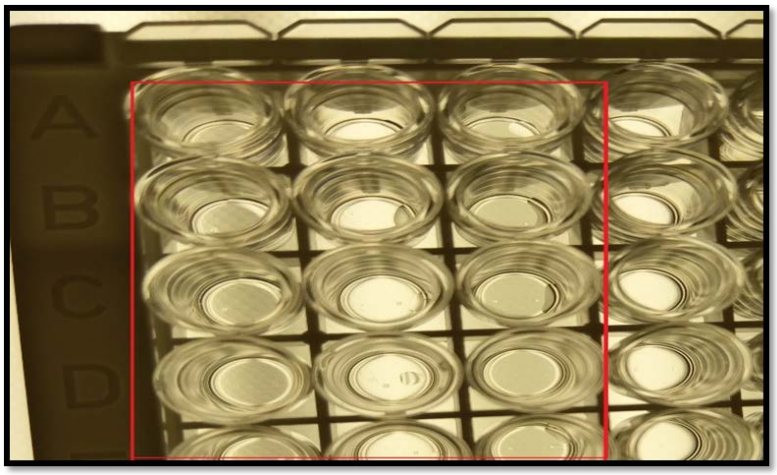


Figure 7.1.2-8

The figure below would be unacceptable, and further wash-head alignment is required.
NOTE: *notice the "half-moon" liquid remnants that are left at the bottom of the wells.*

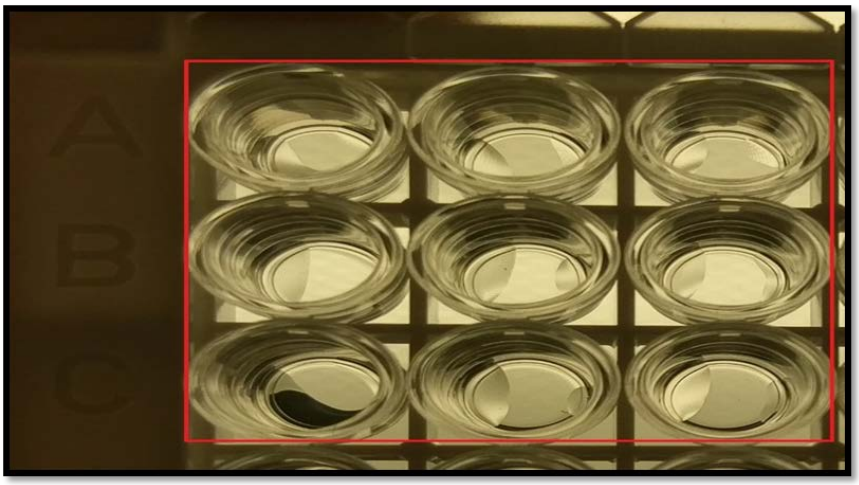


Figure 7.1.2-9

Continue to wash and check the wells after any new adjustments are made to the wash-head alignment. Abraxis can send a replacement 5X wash bottle with any new order/shipment.

7.1.3 Channel Blank

Perform a channel blank by clicking on “Utilities” then choose “Channel Blank.”

Be sure to clean the wells before performing the Channel Blank or Self-test. The channel blank procedure will require the NaOH Blanking Solution that comes with the self-test solution pack—Abraxis provides 30 mL bottles (same bottle type that 1N HCL is held—usually placed in Rack 1-Position 1) with each self-test pack to hold the blanking solution from the large white bottle.

****BE SURE THE NaOH SOLUTION HAS NOT EXPIRED****

If the channel blank FAILS, please repeat the action until the result is “PASS.” Once the channel blank has passed, before sure to clean the wells again.

7.1.4 Self Test

Perform a self-test by clicking on “Utilities” then choose “Self Test.” The self-test will require the same blanking solution as with the channel blank, but also PNP (yellow) solution.

****BE SURE THE SELF-TEST SOLUTIONS HAVE NOT EXPIRED****

Pour off some PNP solution (~2 mL) into a 4 mL glass vial and place into Rack 2-Position 1. The self-test will take ~8-10 minutes to complete. Once complete, the dialogue box will display if the test “PASSED” or “FAILED.”

Either way, click the “Details” button and print the report. An Abraxis or Awaretech technician may ask to see these details. If the self-test does “FAIL,” an Abraxis (or Awaretech) technician will decide if cause is insignificant, or further diagnostics are necessary.

****TRANSFER THE PNP (YELLOW) SOLUTION BACK TO ORIGINAL BOTTLE AFTER USE, AS IT CAN NOT REMAIN IN GLASS****

7.1.5 Timing

Remove all racks/plates/etc. from the CAAS, press F5 to bring up the communication window, Type the following commands, and ensure that the elapsed times that the CAAS displays are within the associated ranges:

1.1 **XTIM:** 18 – 23 seconds
1.2 **ZTIM:** 11 – 13 seconds
1.3 **PLXT:** 17 – 22 seconds
1.4 **PLYT:** 45 – 55 seconds
1.5 **R1TM:** 41 – 48 seconds
1.6 **R2TM:** 41 – 48 seconds
1.7 **FSPD:** 0.280 – 0.320 seconds

If any of the above commands produce elapsed times that are outside of the acceptable range, please contact Abraxis for instructions on how to adjust.

7.1.6 Before Running an ELISA

At this point, if everything checks out, the CAAS should be ready to go, but before running an ELISA, always remember to:

- Perform “Start of Day” before each analysis, and also after opening any of the bottles located on the side of the instrument (waste, wash, rinse)—this will insure all the lines and pressures are adequate.

- Prime the wash-head 2-3 times before starting the run. Click on “Routines” then “Prime Washer – Wash Bottle.” During these primes, take notice if all 8 wash-head probes are delivering consistent, uniform streams of wash buffer. If they are not, there must be a clog in the wash-head. Seek an Abraxis or Awaretech technician for assistance removing the clog.

- Prime the syringes. Click on “Routine” then “Prime Syringes.” During these priming, be sure there are no air bubbles in either syringe—particularly the larger syringe.

- Before placing the microtiter plate into the plate tray, place the plate flat on the benchtop, face down (the top of the wells), and gently press the plate against the benchtop to insure the strips become flush against the plate frame—if the strips are not flush, this could lead to uneven washing of the wells during the washing steps of the assay.

7.2 Flags and Error Messages

Flags are warning messages to the user of a possible problem condition that will need to be corrected. The instrument will continue to operate under these conditions. An example of a Flag is “Wash Bottle is Low”.

Error Messages indicate a condition that causes the instrument to be unable to proceed, and must be corrected before the instrument is used further. An example of an Error Message is “Probe Z axis is jammed.”

7.2.1 Flags

7.2.1.1 Possible Insufficient Aspiration:

This flag may appear:

- If incorrect bottle sizes are used in the reagent rack.
- If reagent bottles are filled past the neck.

Volume Calculation

Instrument automatically detects liquid surfaces and makes approximate volume calculations based upon the diameters of the rack cutouts and the distance between the detected surface and the bottom of the rack. Hanging containers that do not rest on the bottom of the rack will introduce error to the volume approximation if the container bottom level is not set to a new value. These types of containers can only be used provided the new container bottom level is properly set using Rack 2 setup (refer to Section 2.2 Instrument Setup).

 CAUTION**:** Conical containers and containers narrower than the rack openings will always result in volume calculation errors.

Probe Insertion Depth

For reagents, it is important to choose straight-walled bottles that snugly fit the rack hole cut-outs. (Refer to Figure 7.2.1.1-1 Probe Insertion Depth Illustration.)

Sample volumes are usually so small that the vessel configuration is not a factor. Reagent handling, however, can be adversely affected by significantly tapered or under-sized vessels.

This is why: the probe detects the liquid surface at the start then Instrument calculates the proper insertion depth for the probe so that the probe tip will remain just below the liquid surface when the aspiration is finished.

This calculation is based on the diameter of the rack hole cut-out, and it assumes a straight-walled bottle. If a much smaller diameter bottle or a conical vessel is used, the liquid surface will descend faster and could result in the aspiration of some air and less than the desired reagent volume.

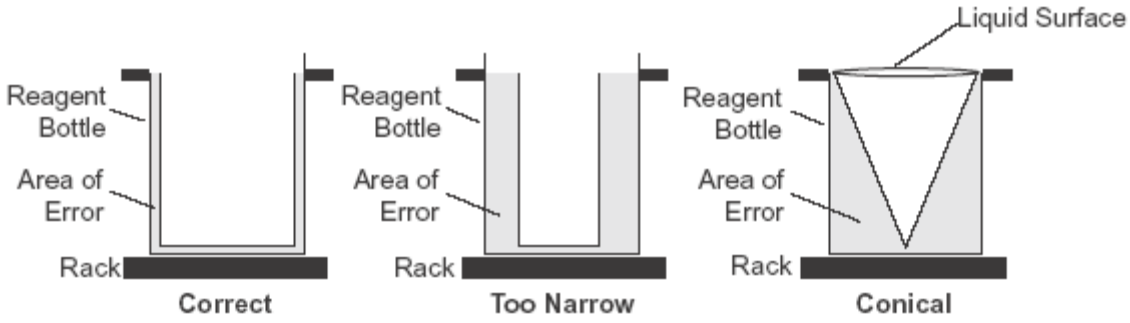


Figure 7.2.1.1-1 Probe Insertion Depth Illustration

Flags (Continued)

⚠ CAUTION: Pipette errors may occur if reagent bottles are used which have a smaller diameter than that for which the rack was designed. This can result in inaccurate volumes or no reagent being dispensed to some reaction wells..

7.2.1.2 Wash/Rinse Bottle Low:

When the wash or rinse bottle is low, you will be warned as appropriate.
The software will automatically check the status of the bottles when preparing to run assays.
Refill the bottle(s) before starting the assays.

- If one of the bottles becomes low during the run, the Error Status Board will display a message “Wash bottle empty” or “Rinse bottle empty” and will continue to perform the wash with the remaining solution.
- To refill the wash bottle, select Pause Engine from the Management Menu. Refill the wash bottle. Select Resume Engine from the Management Menu.

7.2.1.3 Waste Bottle Full:

- When the waste bottle becomes full during a run the software will prompt “Waste Bottle Full”.
- If the message appears to be in error, wipe out the inside of the bottle cap with a dry cloth. It is very important not to run the instrument when the Waste bottle is full to avoid damage. The software does not check the drain waste container.

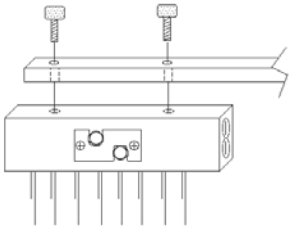
NOTE: Although the software only checks the Wash, Rinse, and Waste bottles when necessary for assays, the instrument checks itself periodically. If the instrument is beeping periodically during periods of inactivity, check the bottle volume levels.

⚠ CAUTION: Do not open the WASTE bottle until the pressure is released.

7.2.2 Error Messages

Error Code(s)/Problem:	Solution:
001 Unknown Command	Check command for spelling and validity.
002 Parameter exceeds allowed range	Verify correct number of numbers and placeholders
003 Too few or wrong parameters	Check command has valid number of argument(s) or parameters
004 Command has not been implemented	
005 Fluid not detected in range. Not enough Sample or Reagent	Add more fluid to the container and press "Resume All". When setting up a run, be sure to have about 100 uL of extra volume in each serum vial. It is also important to place more reagent volume in the reagent bottles than is actually necessary in the assay. If the reagent volume is limited, the reagent bottle position should be assigned in the assay or in the run to use one of the smaller rack positions.
006 Probe Z axis is jammed 007 Probe X axis is jammed	Make sure the probe is properly seated with the retention hook over the collar. When a jam message appears, look for a physical obstruction to remove, and verify correct instrument set-up (alignments).
008 Rack 1 is jammed 009 Rack 2 is jammed	Possible causes are bottles that are too tall or have too small of a diameter for the rack cut-out. Make sure bottle caps have been removed, correct rack files are being used, and the setup alignment parameters including probe depth and wash head depth are correct. If normal operation does not resume after clearing the obstruction, select Initialize from the Management tab on the manager menu. If the problem is not solved by re-initializing, turn the instrument off and restart it. If the jam has not cleared, contact Technical Support.

Error Code(s)/Problem:	Solution:
010 Diluter not acknowledging	Check the cable that plugs in the back of the diluter
011 CSI/O Inactive	Unable to communicate with coprocessor.
013 Timeout waiting for coprocessor message	Make sure that the serial cable is firmly connected to both the computer and the Instrument. Use the cable (and adapter, if needed) provided with the instrument. Make sure the Instrument is powered up.
014 Diluter not responding	See Error Code 010
015 Timeout waiting for completion of last coprocessor command	See Error Code 013
016 Check reagent/sample level!	Check levels
018 Probe sensor malfunction	A problem exists with fluid sensing circuitry.
019 Parameter checksum error	See Error Code 013
020 Probe jammed while trying to detect the liquid surface	Make sure you have the proper size bottle (not too small or tapered). Check that the cap has been removed from the bottle. Try adding more reagent. Check the probe depth setting for the rack in Instrument Setup.
021 Small syringe stroke error 022 Large syringe stroke error	Check the assay programs to make that the maximum (2.5 mL max large syringe; 50 uL max small syringe) has not been exceeded. Select the Routines tab from the manager menu, and click on the Wash Probe option to reset the syringe position.
504 Plate X axis is jammed	Check for physical obstructions blocking the path of the plate in the X direction.
505 Plate Y axis is jammed	Check for physical obstructions blocking the path of the plate in the Y direction.

Error Code(s)/Problem:	Solution:
506 Wash axis is jammed	Select Initialize from the Management tab on the **manager** menu. If the wash head does not lift free, loosen the two thumbscrews that connect the wash head to the wash arm (Figure 9.1.2-1).  ***Figure 7.2.2-1*** Possible causes include setting the washer depth too low or setting it such that the wash head tubes hit the edge of the reaction plate wells. (See Instrument Set Up). The Set Up should be re-checked so that the long tubes of the wash head just lightly touch the microwells and are set toward the back of the center of the wells. Make sure that the wash head appears level after installation and that the screws are snug.
511 Wash movement error. Wash aborted.	Check for physical jams blocking the path of the wash head.
512 Waste bottle is full	Pause the Engine by clicking on the Pause Engine icon  Pause/Resume Engine. (Click on icon again when finished to Resume Engine.) Carefully unscrew the cap and empty the waste bottle. ⚠ CAUTION: Protect yourself from contact with hazardous waste. Make sure the aerosol filter does not get wet in the process (replace if this happens). If the Waste bottle is already empty when the error message is observed, check that the sensors are not shorted by foam, or touching each other. Clean the inside of the cap with a paper towel. Close the cap tightly and assure that the colored luer locks and sensor are plugged in before resuming operation.

Error Code(s)/Problem:	Solution:
513 Wash bottle is empty	Wash/Rinse bottles are low. The instrument detected an empty condition on the wash or rinse bottle. If the bottle is full, check that the sensor's lead is securely connected to the bottle cap and plugged in properly. Check the sensor leads for continuity.
514 Rinse bottle is empty	The instrument detected an empty condition on the wash or rinse bottle. If the bottle is full, check that the sensor's lead is securely connected to the bottle cap and plugged in properly. Wrong cap has been used. Make sure the cap with the long wires is inserted into the bottle and closed snug. The black plastic separator should be at the bottom of the wires and the wires should not be crossed or touching each other. Check that the sensors are submerged in the liquid. Pause/resume the engine by clicking on  icon. Unscrew and refill the bottle. Close the caps tightly and assure that the colored luer locks and sensors remain plugged in before resuming operation.
515 Filter Wheel Error Wheel is not rotating	Check filter wheel pulleys for freedom of movement.
516 Pressure System Error 517 Vacuum System Error Pressure not building rapidly enough	Select the option Pause Engine from the Management Tab on the menu. (Select Resume Engine when finished.) Open and re-close each bottle cap to flatten and reset each gasket. Check all of the bottle caps and connections for tightness. Make sure there are no cracks in the caps, tubing, or connections. Check the operation of the pinch valves. If the valve opens but the tubing remains pinched, move the tubing so that a different area gets pinched. Open the tubing by stretching it and rolling it between your fingers. If the aerosol filter on the waste bottle gets wet it will no longer function; try changing this filter assembly.

Error Code(s)/Problem:	Solution:
518 Possible aspiration failure	To prevent accidental flooding of the plate during washing, the Instrument automatically verifies adequate aspiration before beginning a wash cycle by moving down and blocking the aspiration probes against a foam test strip. If the foam is worn away or if the wash head is not level, air may leak into the system and cause this message. Check that the wash head is properly installed. Check the wash head alignment, setting the wash head height to a lower setting usually solves this problem (see Section 4.2 Instrument Setup). Check that all tubing is connected and not pinched. If this does not solve the problem, replace the foam strip.
519 Vacuum over range	Check for obstruction in the head or tubing. A clogged aerosol filter may also be the cause; try replacing this assembly.
520 Y slot not detected	Y Slot flag not properly situated. Physical obstructions in path of Plate Y. Malfunctioning Y slot sensor.
521 X slot not detected	X Slot flag not properly situated. Physical obstructions in path of Plate X. Malfunctioning X slot sensor.
522 Lamp X failure	Look for all four lights and replace any burned out bulbs. Always contact your Instrument Service Provider first. If all the lamps are lit, check for fluid spillage. Spillage or an obstructed or damaged optical filter may also cause this message due to decreased detection of light. Clean spills immediately and wipe chemical residue away with repeat cleanings using fresh water.
523 Channel blanks are not valid!!	Under Settings, select Alignment, click on Channel Blanks option. Run Channel Blanks using the blanking material provided with Instrument and new clean and clear-flat bottom microwells. Follow the instructions as prompted.

7.3 Log Files

Log files are available for service and troubleshooting issues and are located in C:\Abraxis CAAS \Root\Logs.

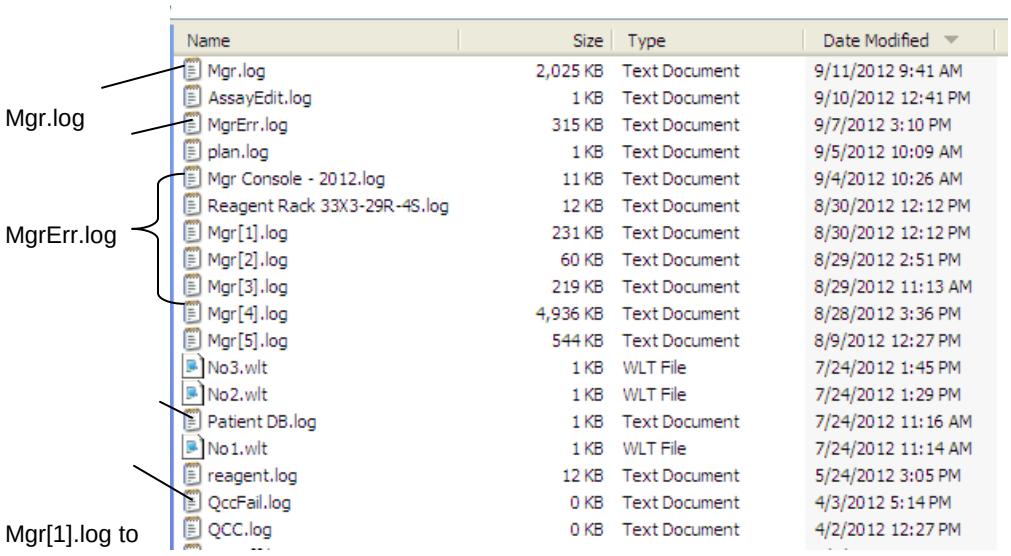


Figure 7.3-1 Example Log Files

Log Name	Description
Mgr.log	Mgr.log stands for Manager log
Mgr[1] through Mgr[5].log	Five backups of the Mgr.log
MgrErr.log	Lists errors
QccFail.log	Lists failed QC
AssayEdit.log	Records assay changes
PatientDB.log	Records patient database changes

7.3.1 View Communication Logs

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

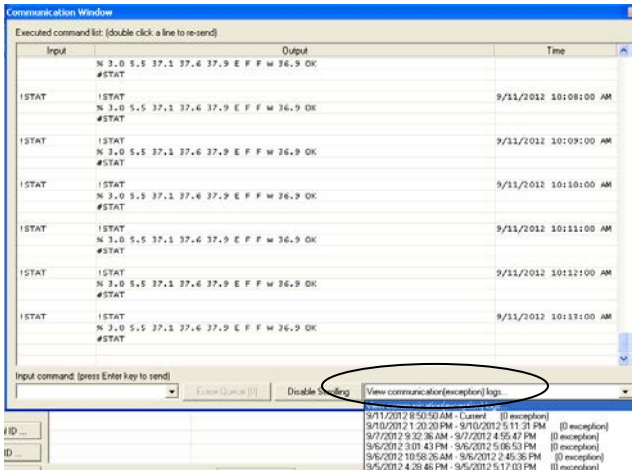


Figure 7.3.1-1 View communication logs

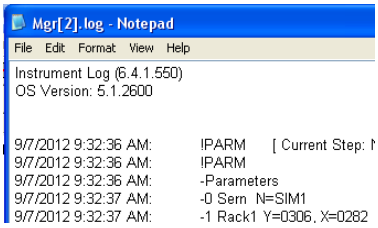


Figure 7.3.1-2 Log Displayed

7.4 PC Communication (COM) Port Setting

The program's default communication port setting is **AUTO**.

To change the communication port, choose Software under the Settings menu.

Click on the down arrow to display the optional settings; click to select, click OK to accept.

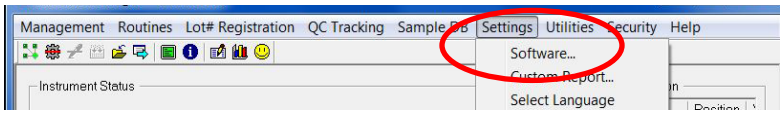


Figure 7.4-1 Software Settings

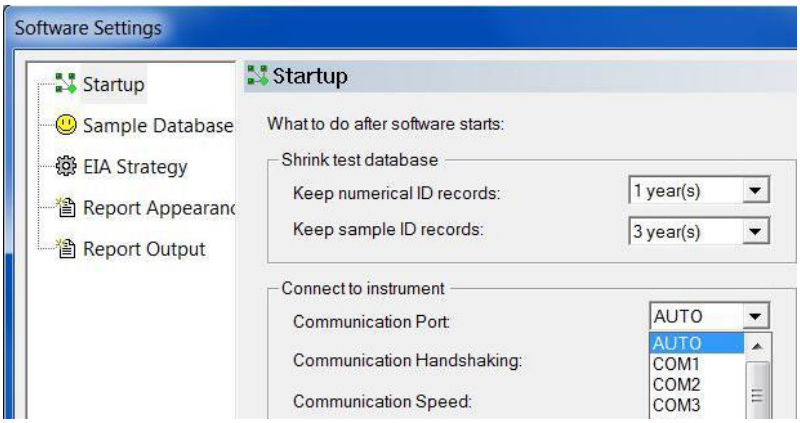
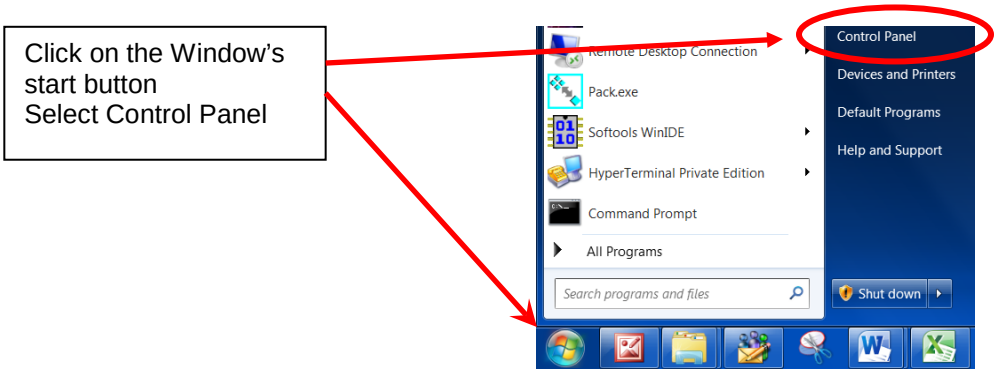


Figure 7.4-2 COM Port options

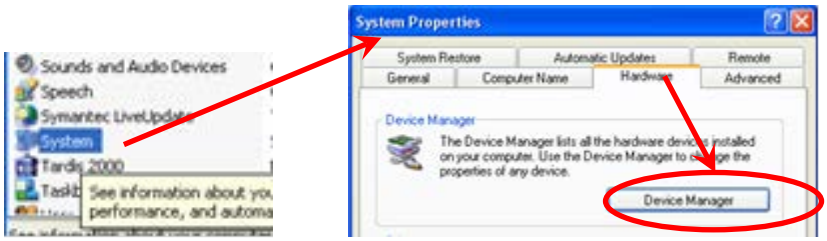
The following instructions have been included in case they are ever needed. It is rare that the COM Port Setting will need adjustment. If the software has trouble communicating with the instrument check the COM Port setting on the computer as it may be necessary to make an adjustment to the instrument's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



PC Communication (COM) Port Setting

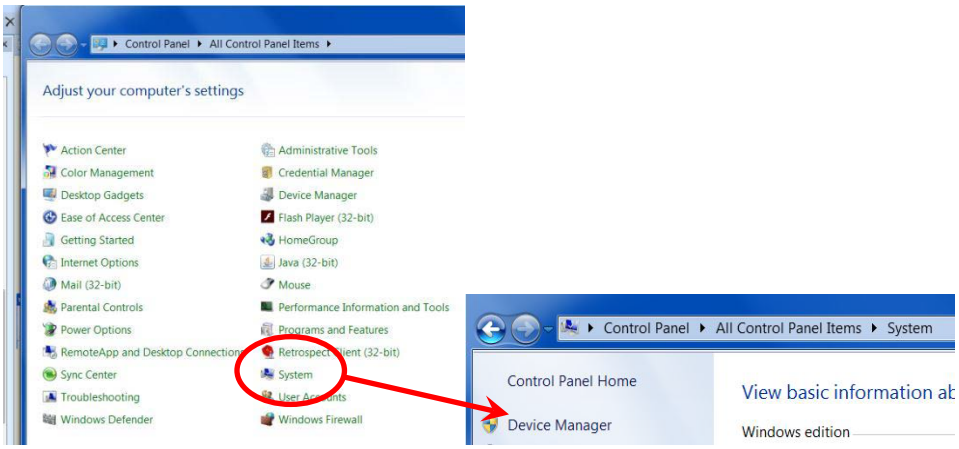
Depending upon the version of Windows® being used, you may see one of the following paths to access the COM Port Settings..

Example 1 – From the Control Panel, select System. The System Properties window will open. Select the tab Hardware. You can then open the Device Manager.

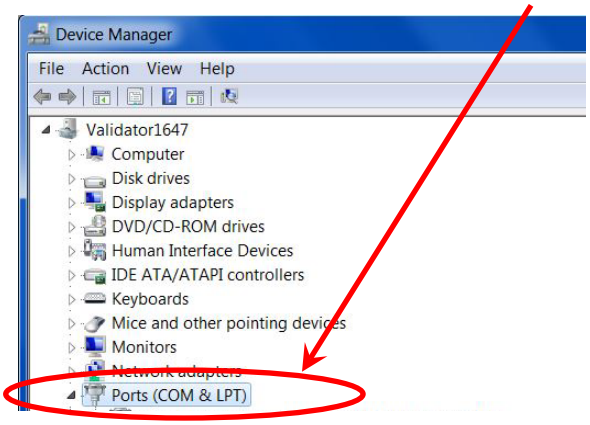


Example 1 - Control Panel to System to Device Manager

Example 2 – From the Control Panel, select System. In the next window that opens, select Device Manager.



The Device Manager window will have a folder named **Ports (COM &LPT).**



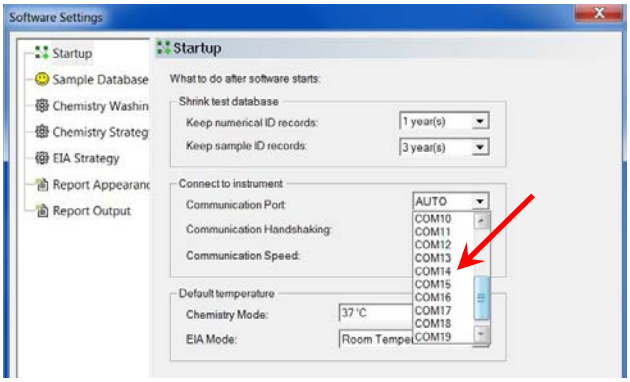
Example 2 - Control Panel to System to Device Manager

PC Communication (COM) Port Settings (Continued)

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

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

In Example 2 above, Windows® is reporting that the COM port is #14. If the software is displaying a different communication port, select COM14 from the drop down list.



Be sure to select **OK** to exit at the bottom of the window

Notes:

8. Contact Information

eurofins Abraxis Inc.

124 Railroad Drive

Warminster, PA 18974

Phone: (215) 357-3911

Fax: (215) 357-5232

www.abraxiskits.com

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

Model:_____

Serial #:_____

	BIOHAZARD: Instruments to be returned must be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing center or from any authority's intervention.

Notes:

9. Appendix A – Reagent Cooling Accessory® (RCA) - Optional

The Reagent Cooling Accessory (RCA) is an optional accessory.

The RCA protects reagents from high ambient temperatures.

Technical Specifications

- Peltier thermoelectric modules cool the reagent rack via cold plates placed internally in the instrument and connected to an external controller.
- Allows complete freedom of rack movement during all functions of assay operations, testing and sampling.

Overall

- Dimensions: 14” (36 cm) L x 6” (15cm) W x 8” (20cm) H
- Weight: 8 lbs (3.6 kg)
- Cooling Capability: 12° C to 15° C below ambient
- Insulated Reagent Racks: Standard 27 or 44 positions
- Control: Automatic Thermal Control

Requirements

- Input Voltage to RCA: 115 or 230 VAC

Notes:

10. Appendix B – Solution Compositions

10.1 Plate Washer Solutions

Wash Solution (for chemistry assays): 0.01% Tween® 20 (100µl Tween® 20 to 1L Deionized H_2O). An 80X concentrate is available for purchase, order Plate Washing Kit P/N 029017.

Rinse Solution: Deionized H_2O.

10.2 Reading Solutions

Blanking Solutions and Performance Check Diluent: 0.1 N NaOH with 0.01% Triton® X-100 (4.0g NaOH + 100µl Triton® X-100 to 1 L Deionized H_2O).

Performance/Dye Check Solution: Dilute aqueous solution of p-nitrophenol (PNP). A ready to use calibrated solution is available for purchase, order Performance Check Kit P/N 029019.

10.3 Cleaning Solutions

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

Alcohol Syringe Cleaning Solution: 70% isopropyl alcohol

Bleach Syringe Cleaning Solution: 10% chlorine bleach

Wash Head Tubing Cleaning Solution: 30% chlorine bleach

Notes:

11. Appendix C – Maintenance Log

Daily: CAAS Maintenance Log Month: _____ Year: _____

	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	28	30	31
Start of day																															
Wash probe																															
Prime syringes																															
Prime: wash bottle																															
Prime: Rinse bottle																															
Check/Fill H_2O prime bottle																															
Check large waste bottle																															
Check wash/rinse bottles																															
Check wash & rinse bottles																															
End of day																															
Mark (X) when not in use																															

Biweekly:

Rinse H_2O bottle w/ 70% IPA																															

Every 6 Months: (Initial and date each item)

- ☐ Exercise, lubricate & inspect each mechanism axis
  - ☐ Probe X _____
  - ☐ Probe Z _____
  - ☐ Plate X _____
  - ☐ Plate Y _____
  - ☐ Wash Head Z _____
  - ☐ Rack 1 _____
  - ☐ Rack 2 _____
- ☐ Check filter voltages _____
- ☐ Filter wheel speed check _____
- ☐ Inspect Plate X/Y- _____
- ☐ Check photometer alignment _____
- ☐ Check system for leaks _____
- ☐ Wash System _____
- ☐ Pressure Check _____
- ☐ Wash-head clean/system checks _____
- ☐ Cleaning
  - ☐ Clean Syringes _____
  - ☐ Clean Wash Head _____
  - ☐ Check for air in syringes _____
- ☐ Performance verification _____