INFINITI® PLUS Analyzer
Operator's Manual

For *In Vitro* Diagnostic Use

Manufactured by AutoGenomics, Inc., 1600 Faraday Avenue, CA USA 92008

CE   Authorized EU Agent: Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41, 30175 Hannover, Germany

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US: The INFINITI PLUS Analyzer is cleared when used with FDA cleared assays.

EU: The INFINITI PLUS Analyzer is CE-marked.

CAUTION AND SAFETY WARNINGS

Danger

Before opening the INFINITI® PLUS Analyzer, turn the main power switch **OFF** and remove the power cable from the power outlet.

Do not replace components or attempt any repair with the INFINITI PLUS Analyzer switched ON.

Do not operate the INFINITI PLUS Analyzer in an atmosphere containing explosive gases; components of the INFINITI PLUS Analyzer could possibly generate sparks.

Caution

Read the INFINITI PLUS Analyzer Operator's Manual.   Failure to follow directions for use could result in erroneous and/or misdiagnosis.

If the INFINITI PLUS Analyzer is used in a manner not described in this manual, the protection provided by the equipment may be impaired.

The INFINITI PLUS Analyzer is ONLY for use with AutoGenomics assays.

Follow the package Insert for the specific assay for operations/steps outside of the INFINITI PLUS Analyzer.

Avoid spilling fluid on or into the INFINITI PLUS Analyzer at any time. Spills should be wiped up promptly.

When working with biological samples, all accessible parts of the INFINITI PLUS Analyzer must be considered bio-hazardous. The pipette tip trays, sample tray and the waste drawer should be routinely disinfected.

Follow Universal Precautions when handling all samples. Wear safety equipment or clothing such as gloves, safety glasses, and lab coats when working with biological samples in and around the equipment.

SAFETY LABELS

 The front cover of the INFINITI PLUS Analyzer as well as other mechanisms inside the analyzer operates under motor control.

PLEASE KEEP HANDS AWAY FROM THE FRONT COVER WHILE IT OR ANY OTHER MECHANISMS ARE MOVING.

 When the INFINITI PLUS Analyzer is analyzing samples, the front cover is closed. During this time the WP-24 bottom block will heat up and cool down.

DURING LOADING AND UNLOADING OF THE VARIOUS TRAYS, THE INCUBATOR AND SAMPLE TRAY PARTS MAY STILL BE WARM.

EQUIPMENT MAINTENANCE

Routine operator maintenance is provided in Section 7. Please read this section before using the INFINITI PLUS Analyzer.

Servicing and repair should be done by AutoGenomics service personnel. In general, any covered assembly which is accessible only by use of a tool, should be serviced by AutoGenomics service personnel only.

Fuses and Main Power Switch - The main AC power switch for the INFINITI PLUS Analyzer also serves as an electrical circuit breaker protecting the instrument from electrical overloads. If any emergency arises, turning off this switch will remove all power to the analyzer. There are three fuses in the system which are located in the AC Input Box. These fuses are inaccessible by the operator. If any fuse should fail, they should only be replaced by AutoGenomics service personnel.

Batteries
The INFINITI PLUS Analyzer has one battery which is located on the computer motherboard located in the Electronics Tub. The battery type is: Lithium Battery. A failed battery should only be replaced by AutoGenomics service personnel.

WARRANTY AND ASSISTANCE

Warranty

AutoGenomics warrants that the INFINITI PLUS Analyzer shall meet the required performance specifications to perform the assays as described in the operator's manual for a time period of twelve (12) months from the unit installation date. The extent of AutoGenomics' liability under this warranty is limited to repairing or at the discretion of AutoGenomics, replacing a defective INFINITI PLUS Analyzer. The foregoing warranty shall not apply:

(a) if the INFINITI PLUS Analyzer is not used and/or maintained in accordance with the guidelines and procedures set forth in this operator's manual;

(b) if the INFINITI PLUS Analyzer is used with reagents and supplies not expressly authorized by AutoGenomics;

(c) if the INFINITI PLUS Analyzer is repaired or altered by a party other than AutoGenomics without AutoGenomics prior written approval;

(d) if the operator has installed commercial or non-AutoGenomics software on the analyzer; or

(e) if the INFINITI PLUS Analyzer has been subject to misuse, negligence, or accident.

THE FOREGOING WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT AND THOSE ARISING FROM COURSE OF DEALING OR USAGE OR TRADE.

To request for service or for technical assistance, call AutoGenomics Tech Support:

Toll Free Number: 1-866-STAT MDx   (1-866-782-8639)
Or 760-477-2248 between 8:00 am to 5:00 pm Pacific Standard Time
Website: www.AutoGenomics.com

TRAINING

Training in the use of the INFINITI PLUS Analyzer is provided by AutoGenomics Technical Support at its Carlsbad, CA facility. Training may also be provided by individuals trained and authorized by AutoGenomics, and may be provided at the customer's facility as authorized by AutoGenomics.

The AutoGenomics Training Program is typically a 3-day program which provides the trainee at a minimum:

- Background knowledge of the INFINITI® platform
- Operation and function of the INFINITI® PLUS Analyzer
- Hands-on training on sample preparation followed by running the assay on the INFINITI® PLUS Analyzer
- Interpretation of assay report and results
- Maintenance and troubleshooting

1   Introduction

1.1   Intended Use

The INFINITI PLUS Analyzer is an upgraded version of the INFINITI PLUS Analyzer. The intended use remains unchanged. The INFINITI PLUS Analyzer is instrumentation used for clinical multiplex systems intended to measure and sort multiple signals from samples. The INFINITI PLUS Analyzer is designed to measure fluorescent signals of labeled DNA target hybridized to BioFilmChip® microarrays. The INFINITI PLUS Analyzer automates the assay and integrates all the discrete processes of sample (PCR amplicon) handling, reagent management, hybridization, detection, and results analysis. The assays are processed automatically and read by the built-in confocal microscope. Results are analyzed and presented as genotype calls.

1.2   INFINITI® PLUS Analyzer

The INFINITI PLUS Analyzer is an upgraded version of the INFINITI PLUS Analyzer. The INFINITI PLUS Analyzer was modified to increase throughput to meet the demands of high-volume laboratories.

This section of the operator's manual provides a full description of the INFINITI PLUS Analyzer and is very similar to the section in the INFINITI PLUS Analyzer Operator's Manual. The INFINITI PLUS Software Manual can be found from the Qmatic screen (INFINITI screen) under HELP by clicking Qmatic Help.

The bench top INFINITI PLUS Analyzer is completely self-contained and automates all processes for genomic analysis or detection of viral or bacterial nucleic acid following sample preparation. The INFINITI PLUS Analyzer generates fluorescent labeled DNA which hybridizes to oligonucleotides arrayed on BioFilmChip® microarrays. The INFINITI PLUS Analyzer automates and integrates all the discrete steps of the chosen assay including sample (PCR amplicon) handling, reagent management, hybridization, detection, and results analysis. Results are analyzed and presented as genotype calls.

The INFINITI PLUS Analyzer has two main components: reagent management and optics modules. A variety of electronic components inside the instrument are used for its operation. These include multiple stepper motors, heating and cooling devices, a barcode reader, and a camera--all connected to USB ports.

Reagent Management Module
The reagent management module performs all the operations related to the dispensing and aspiration of reagent and the processing of the amplified sample to be dispensed on the microarray. When the sample has been processed and hybridized to the microarray, it is transferred to the optics module for scanning and reading.

Optics Module
The optics module is comprised of a 3-axis stage and a camera. It is the enclosed casement into which the microarray is transported automatically after being processed on the stringency station. The optics' stage follows X-Y-Z motions that are stepped at a very precise rate. Using excitation wavelengths of 760nm, the camera takes a picture for each registration spot of a fluorescent dye. Analysis of these pictures allows the determination of the location of three registration spots. With respect to the position of the three registration spots, coordinates of all the bio-spots can be calculated. While scanning, the stage moves along the Z-axis to focus the chip and the X and Y-axes to locate the individual spots on the microarray.

QMATIC® Operating Software

The INFINITI PLUS Analyzer hardware is controlled by the Qmatic® operating software, which is installed within the on-board computer and utilizes a LCD screen display. The INFINITI PLUS Analyzer modules are controlled by multitasking real time software. The operator specifies the sample locations and clicks "Run." Results are available for review via the LCD screen. The operator can also print the displayed results (printer is not included with INFINITI® PLUS Analyzer).

The Qmatic® operating software has a schedule manager that is capable of controlling all operations of the INFINITI PLUS Analyzer such as assay protocol, fluid handling, robotics, optical detection and result analysis.

The INFINITI PLUS Software Manual can be found on the INFINITI Plus in the Qmatic screen (INFINITI screen) under HELP by clicking Qmatic Help.

Consumables
The following are INFINITI PLUS Analyzer consumables which can be replenished when required.

- 48 well plates (48WP), cat# 11-0100-00: 10 plates /pack used for processing and storing of up to 48 different samples. Get 5 packs/case.
- 24 well plates (24WP) silicone lids (need 2 ea. for 48WP), cat#11-0030-00: 10 lids /pack used for thermocycling processing and storing of up to 24 different samples. Get 5 packs/case.
- Reusable Silicone Lid, cat# 11-0110-00, 48WP Lids, 1 each, used to cover samples during INFINITI PLUS use.
- Disposable tips, cat # 11-0010-00: Six trays containing 126 tips each/pack. Get 6 packs per case.
- Buffer, cat # 12-0330-00: Stored in four bottles of 125 ml each. Some assays may call for other specific buffers.
- Waste tray liners, cat# 11-0020-00: Twenty five plastic liner that collects all used tips and microarrays.
- Tip Barrel Plugs, cat # 110070-00, prevent liquid from entering the nozzle. 12 each in a pack.
- Stir Bars, cat # 11-0060-00, 5 ea./pack.
- BioFilmChips: These are assay specific.
- Intellipac Reagent Modules: These are assay specific.

1.3   BioFilmChip® Magazine with 12 Microarrays

The BioFilmChip® microarray consists of a polyester film coated with proprietary multi-layer components designed for DNA analysis. The layers have been designed to provide a versatile surface to enhance test performance. There can be up to 240 spots per microarray with each spot representing a different allele. The microarrays are designed to be assay specific and to accept the probes specific for the assay. Multiple assays can be developed using the same microarray.
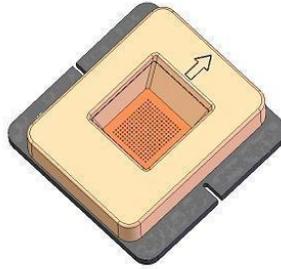
Fig. 1-1 BioFilmChip® Microarray

1.4   Intellipac® Reagent Module

The Intellipac® reagent module contains up to four reservoirs and has an integrated memory chip. The Intellipac reagent module comes pre-filled with the test reagents and is assay specific. Information on the test reagent such as lot number, expiration date and volume usage is archived in the memory chip and appears on the worklist (run report). The memory chip is updated immediately after a volume is aspirated.
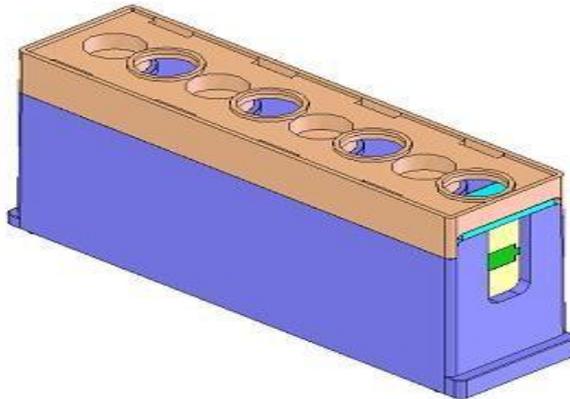
Fig. 1-4 Intellipac® Reagent Module

2   INFINITI® ANALYZER SPECIFICATIONS

2.1   Reagent Management Module (Pipetting System)

Equipment Type: Automated genomic system in continuous-flow.
Modes of Operation: Simultaneous random and continuous access processing of genomic samples.
Incubation temperature: 39°C (±0.5°)
Stringency temperature: 40°C (±1.5°)
Throughput: 48 tests/run
Waste drawer capacity: Sufficient for waste materials for processing 48 samples
Reagent tray capacity: Four modules with four wells each
Maximum storage capacity of reagent well: 2.7 ml
Sample tray capacity: A 48WP and two bottles of buffer
Maximum storage capacity of each sample well: 0.35 ml
Maximum storage capacity of each buffer bottle: 30 ml
Disposable tip tray capacity: 4 boxes
Reagent volume requirement: > 200 μl dead volume required by assay
Automatic pipettor: 15 μl to 100 μl

2.2   Processor: Minimum Specification

Mac OS-X operating system/ computer with the following minimum requirements:

1 GHz CPU
1 GB RAM
160 GB HDD
Bluetooth keyboard and mouse
3 USB ports
Ethernet port

Other Information:

15" LCD screen (1024 x 768)
Recommended Printer (not supplied with INFINITI PLUS Analyzer):
    HP LaserJet 1022 - USB connection.

2.3   Optical System

Main detector: Camera
Red LED, 632.8nm
Emission Filter: 590nm and 700nm
Image size: 1200μm×1200μm

3   Installation Requirements

Upon receiving the INFINITI PLUS Analyzer, inspect the exterior of the shipping container for any damages. If there is obvious exterior damage to the container, notify your shipping department and contact AutoGenomics customer service immediately.

An authorized representative from AutoGenomics must install the INFINITI PLUS Analyzer. Prior to the representative's arrival, ensure the following requirements are met.

3.1   Environmental Requirements

Relative Humidity: Between 35% and 85% RH
Operating Temperature: 15°C - 30°C (59°F -86°F)
Storage Temperature: 0°C - 60°C (32°F -140°F)

3.2   Space Requirement

The INFINITI PLUS Analyzer should be installed on a flat, non-flexing table top.
The instrument dimensions are:
Length: 44 in (111.76 cm)
Depth: 25 in (63.5 cm)
Height: 25 in (63.5 cm)
Weight: 275 lb. (124.74 kg) approximately
Allow at least 24 inches (61cm) of clearance on all sides and top of the INFINITI PLUS Analyzer. Also allow at least 4 inches (10.2 cm) clearance in back of the INFINITI PLUS Analyzer to ensure proper cooling.

> **Note:**
> Reserve a level and solid bench-top space with a minimum of 24 inches clearance on the sides and top and 4 inches at the back of the instrument. All six of the supporting feet of the INFINITI PLUS Analyzer must be resting on the bench top.

3.3   Electrical Requirements

The INFINITI PLUS Analyzer must be operated with the following power specifications:
Input Voltage: 100-240 VAC
Dedicated line   15A minimum
Circuit Breaker: 12 amp (on/off switch)
Frequency: 47-63 Hz
Input Power: 1000 VA
EMI: Complies with FCC Part 15 Class A requirements

The INFINITI PLUS Analyzer can be used with a (main) power voltage of 100-240 VAC (47-63 Hz). Check the voltage and current requirements shown on the S/N label located at the rear of the instrument. Verify that the power outlet has sufficient current and will not be overloaded when the INFINITI PLUS Analyzer is connected. It is recommended, but not mandatory, that the INFINITI PLUS Analyzer be plugged into a wall outlet having its own separate circuit breaker that is not shared with other equipment.

Always plug the INFINITI PLUS Analyzer into a grounded outlet.

> **Warning:** Only an authorized representative of AutoGenomics is authorized to install the INFINITI PLUS Analyzer. The warranty agreement may be declared void if the instrument is installed by an unauthorized person.

4 Operation Flow

The INFINITI PLUS Analyzer is a fully automated system offering genotyping and / or viral or bacterial nucleic acid detection. The PCR amplicons are automatically processed to generate probes which are pipetted onto the appropriate BioFilmChip microarray. After hybridization of probes to oligonucleotides on the microarray, the BioFilmChip is washed and scanned. The microarray information is then processed by software that displays easy to interpret results.

4.1 INFINITI PLUS Analyzer Operation

To operate the INFINITI PLUS Analyzer, the operator loads pipette tips, the sample plate containing the amplified DNA or cDNA samples, reagent packs, buffer, and magazines, containing the BioFilmChip® microarrays as directed on the INFINITI PLUS Analyzer dropdown menus. Following a series of reagent and volume checks performed by the INFINITI PLUS Analyzer, the operator is directed to the worklist where the sample name is entered. A unique identification, comprised of operator-entered information plus date and time, is attached to each worklist sample identifier (ID) in order to distinguish one run from another. For simplified sample ID entry, a bar-code reader may be used to enter sample IDs.

Once the worklist is submitted, all pipetting, detection primer extension, hybridization, washing, drying, scanning, and result display are completed without manual intervention.

The INFINITI PLUS Analyzer run begins by pushing the required number of microarrays from the magazine into the incubator. This is followed by pipetting of Analyte Specific reagent mix that contains primers and fluorescent nucleotide into the sample wells using an individual tip for each sample. Then the samples are subjected to 40 thermocycling steps which allow for detection primer extension. Following thermocycling:

- The pipettor moves to pick up a new pipette tip, and dispenses hybridization buffer into the extended and labeled primer reaction.
- The pipettor moves to pick up a new pipette tip, and dispenses reaction mixture onto the microarray.
- The microarrays are incubated allowing extended labeled primer to anneal to oligonucleotide spots on the microarray.
- The microarrays are washed to remove unbound primer and unincorporated label.
- The pipettor adds and removes wash buffer from the microarray.
- The microarray is transferred to the stringency station to undergo a drying phase.
- The microarray is then transferred to the optics station.
- The optics stage moves such that the individual fluorescent spots can be located and scanned.
- The pusher arm then retrieves the microarray and places it on the stringency station and causes the microarray to fall down the chute and into the waste compartment.

Results are analyzed by Qmatic® Software, and are displayed showing the sample's genotype. Alternatively, in diagnostic tests, the results page displays viral or bacterial genetic material that has been detected.

4.2   Optical Measurement

From the stringency station, the microarray is pushed through the open optics door for registration on the 3-axis stage. There are three registration spots at different positions on the microarray. The coordinates of the three registration spots are calculated from the camera's images. The time required for registration of all three spots is less than 20 seconds. Using the registration spot coordinates as map-points, the coordinates of all 240 spots are computed.

4.3   Continuous Access

The continuous access feature allows the operator to access specific features on the INFINITI PLUS Analyzer at virtually all times. Even while assays are in progress, the operator can access results. The INFINITI PLUS Analyzer is designed to operate in a random access manner. Random access permits the ability to run 48 microarrays simultaneously to accommodate 48 different patient samples.

5   Operating Software

The INFINITI® operating software is a multitasking application that runs under the Mac OS-X operating system software and uses a graphical user interface (GUI).

The operating software identifies samples, queries which assays are to be run, and integrates all discrete processes of sample handling, reagent management, hybridization, and identification of the genotype(s). During sample processing, the INFINITI PLUS Analyzer can deliver results of already scanned microarrays.

6   DIRECTION FOR USE

Definitions:

Cover: Opens and closes the instrument cover for adding or removing consumables to the instrument.

Inventory: Accesses the inventory menu for editing the amount and type of reagents, tips, buffers and microarray magazines loaded on the instrument.

Worklist: Accesses the "worklist" menu to select and submit assays and samples to the INFINITI PLUS Analyzer.

Status Screen: Displays the progress of assays, as well as temperatures, in various sections of the instrument. The status of disposables in the INFINITI PLUS Analyzer can also be viewed.

Results: Displays a chronological storage of various sample results along with sample ID, assay and the reagents used.

Error: Displays errors for rejection or abnormal shutdown of the instrument.

Help: Provides help on all operating software topics.

Exit: Allows the operator to exit the main screen menu and the operating software.

6.1   INFINITI PLUS Analyzer Shutdown

The system power should not be exited or turned off, as salts would crystallize in the nozzle. If the power is required to turn off during a run, then it should immediately be turned back on and the INFINITI PLUS Analyzer system should be started following the instructions. In the Idle state, the system primes automatically every 36 hours. It uses 500 µL of wash buffer every time it primes.

Note:
- A message will be shown if the operator tries to shut down the machine while the microarray is still in process, or in the optics station.
- Click "OK" to shut down the system anyway or "Cancel" to continue operation.
- Do not shutdown the system during microarray processing. May sure that the button is green [IDLE] and not red [BUSY].

To Shutdown:

If there is a need for the INFINITI PLUS Analyzer to be shutdown, then exit the INFINITI PLUS Analyzer software and then shutdown the computer. Turn the power off to the instrument by switching off the power switch on the right side of the instrument.

6.2   Start Up

Press the power button on the auxiliary power unit located on the right side of the instrument. Locate the main power switch, situated on the right hand panel of the instrument, and select the "on" position by pressing the top of the switch so that the line on the button becomes recessed and the circle on the button protrudes. Press the power button situated in the bottom right-hand of the front panel to power up the unit.
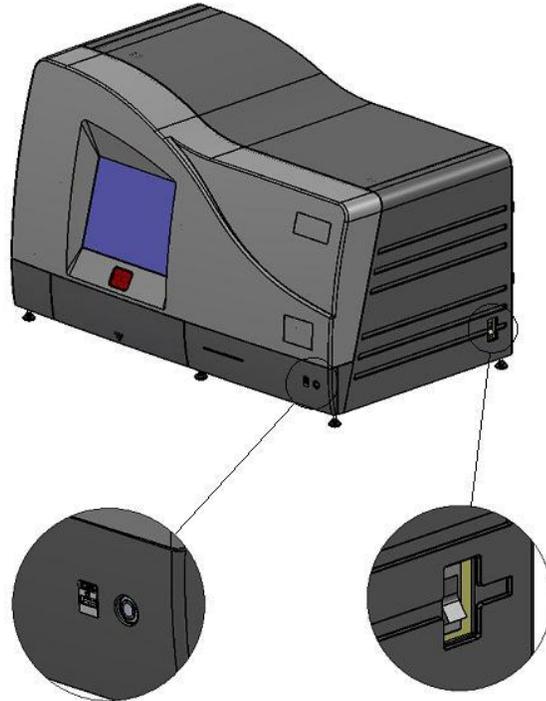
Run Qmatic by clicking icon available in the Dock.

6.3   INFINITI PLUS Analyzer Initialization

Qmatic will be ready to accept operator input in less than a minute, if the INFINITI PLUS Analyzer has already been ON and one of the applications has already been executed. If the INFINITI PLUS Analyzer has to be powered up, it will be ready in about 5-7 minutes.

6.4   Main Screen Menu Description

After initialization is complete, the system launches the "Results" application and minimizes it to the dock. The "Start" button is enabled. At the bottom left hand corner "System ready" message is displayed and the indicator at the bottom right hand corner turns green and shows status Idle.

The light button (located next to the Start button).can be clicked to turn on or off the light. The light will stay on for approximately 15 minutes before it will automatically turn off. This light will also automatically turn off when the cover closes.

To begin a run, click the "Start" button at the top left corner of the screen. This displays the worklist screen.
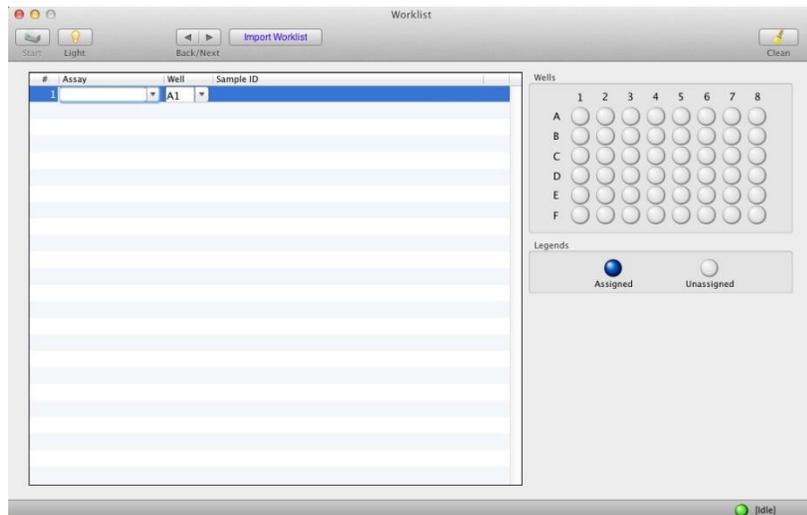
6.5 WORKLIST

Select the assay you want to run with the "Assay" drop down list. Multi sample assays (Duplex/ Quad/ Hex) require items to be submitted in multiple of number of samples per micro-array without skipping wells. (e.g. for QUAD assays, number of worklist items is to be in multiple of 4).
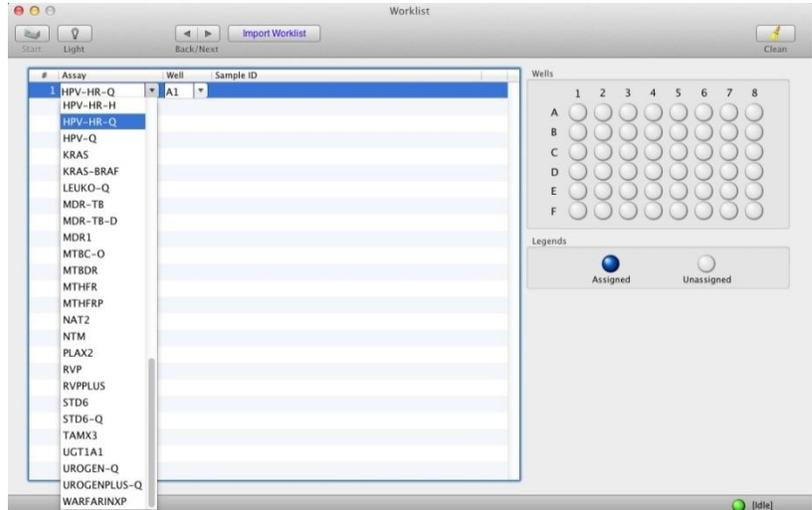
Select well number from well dropdown list. Select consecutive wells for multi sample assay.
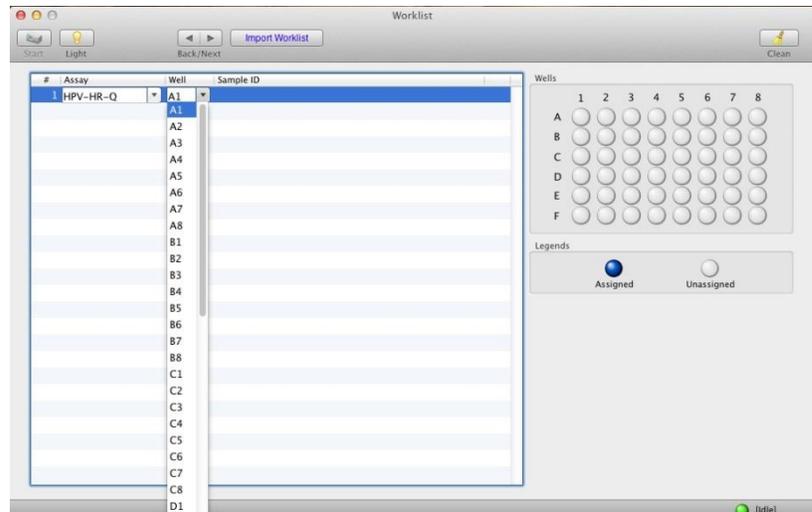
Enter your Sample ID in the field provided for each sample. Maximum of 31 characters are allowed in the Sample ID.

The Handheld Barcode Scanner can also be used to enter Sample ID. Point the scanner on the item barcode and click trigger button. This saves the entry and opens a new item for the next entry.
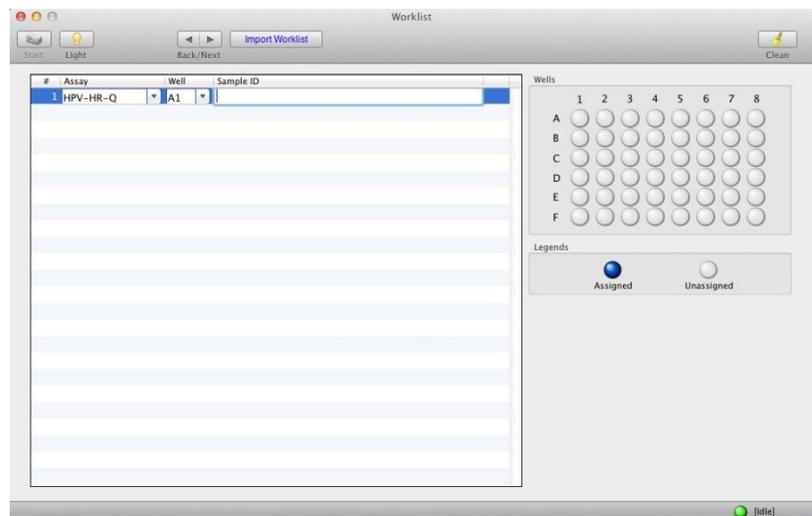
Click "Enter"/"Tab" to save the item. This also opens new item for entry. Last saved item is shown with

❌ in last column. Clicking this deletes the item from worklist.

To correct errors, click on the error, enter the correction, and click "Enter". This will save your correction.

Worklist from LIS can also be submitted. Place the 'Worklist.txt' from LIS system on desktop and click "Import Worklist" button. This populates the worklist in view.
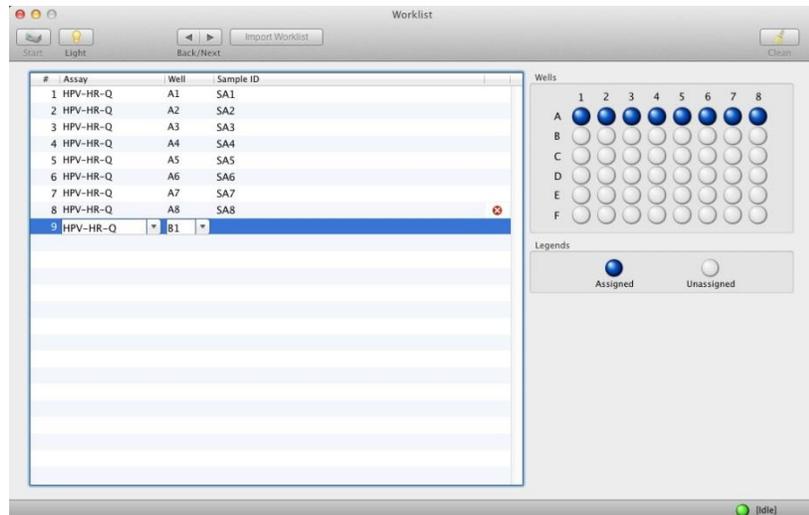
After the first worklist item entry, the assay selection list gets filtered. Only compatible assays with assay selected in first worklist item are available for selection.
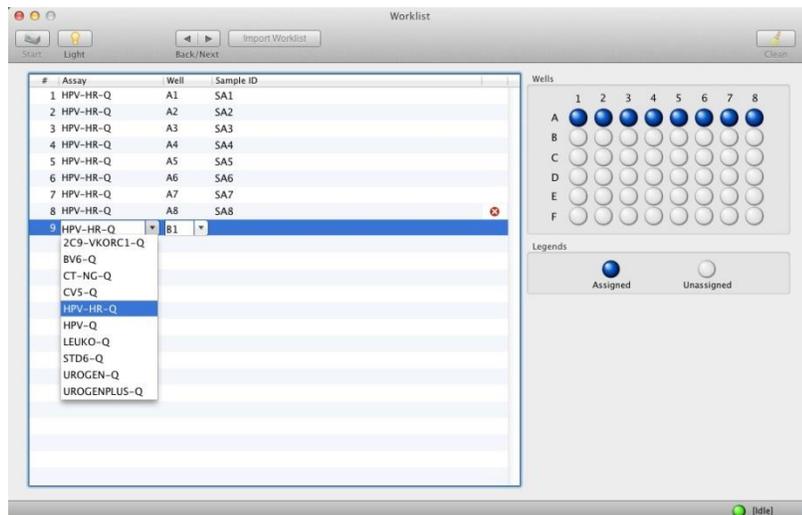
6.6   Loading & Unloading Inventory

6.6.1   Pipette Tip Box

Once the worklist is complete, click the "Next" button". This displays the tip inventory screen. The screen shows "Total Available" and "Total Required" number of tips on screen. If more tips are required, load the new pipette tips boxes and update the available tips after loading them.
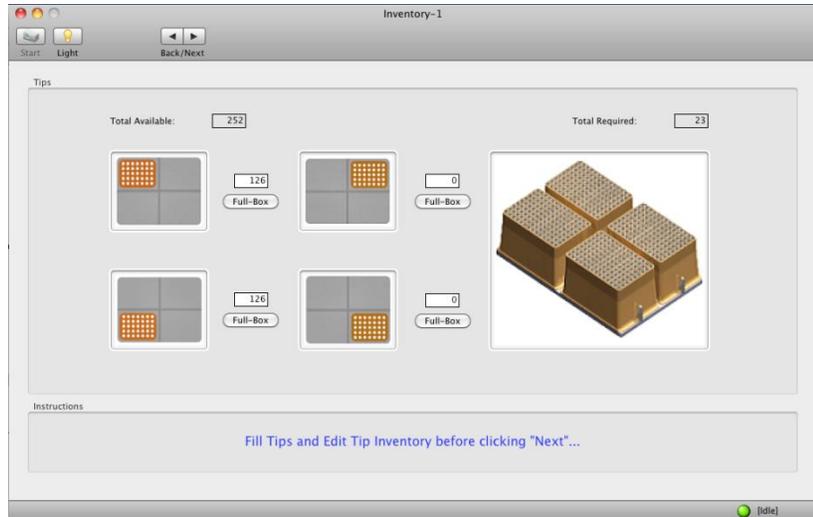
Unload only empty pipette tip boxes by lifting them straight up. Leave partially used boxes in their existing locations. The system remembers tips left in a tip box by location.
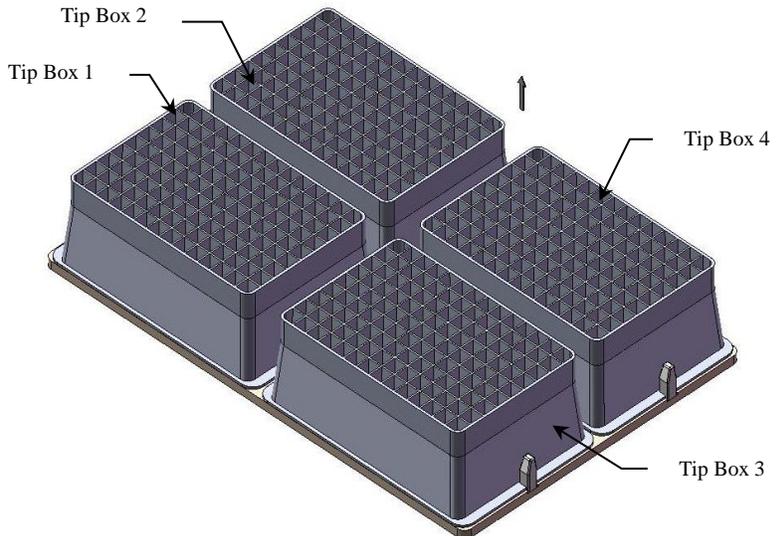
Load full pipette tip boxes by lining up the two notches on the tip box with the posts on the tray.

Click the "Full box" button when adding a full tip box. It will automatically change to 126 tips.

If the available tips are less than the total tips required to process the worklist items, load additional tip boxes.
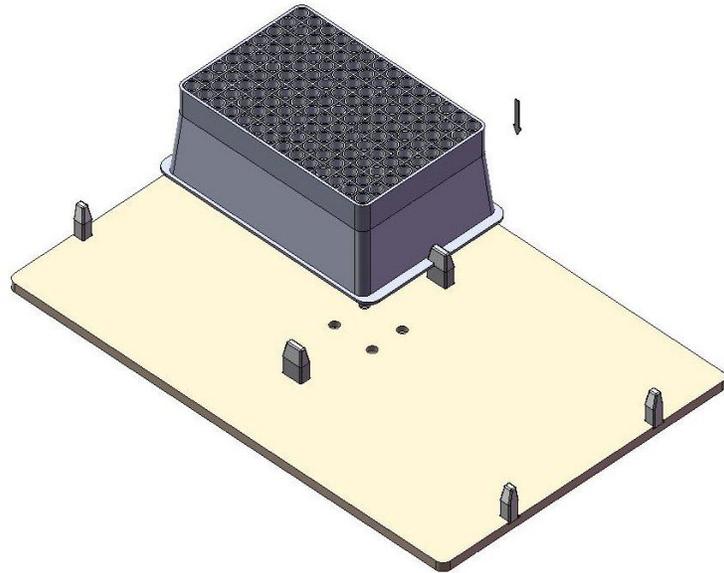
Click the "Next" button to fill the Magazines, Reagent, Buffer and Samples.

The pipette barrel plug should be replaced after 100 samples have been run.
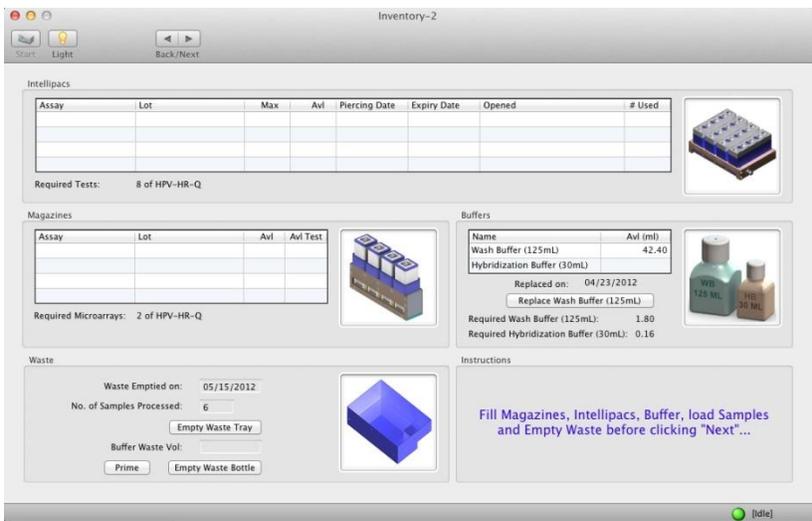
6.6.2   Waste Tray

If necessary, empty the waste tray and dispose of the waste per your lab policy. Clean the stir bar and replace waste tray liner. After cleaning, click the 'Empty Waste' button to update the system information that the waste tray has been emptied.

6.6.3   Sample Tray

Lift off the used lid. Place lid aside for cleaning and reuse (See Routine Maintenance).

Remove the used lid
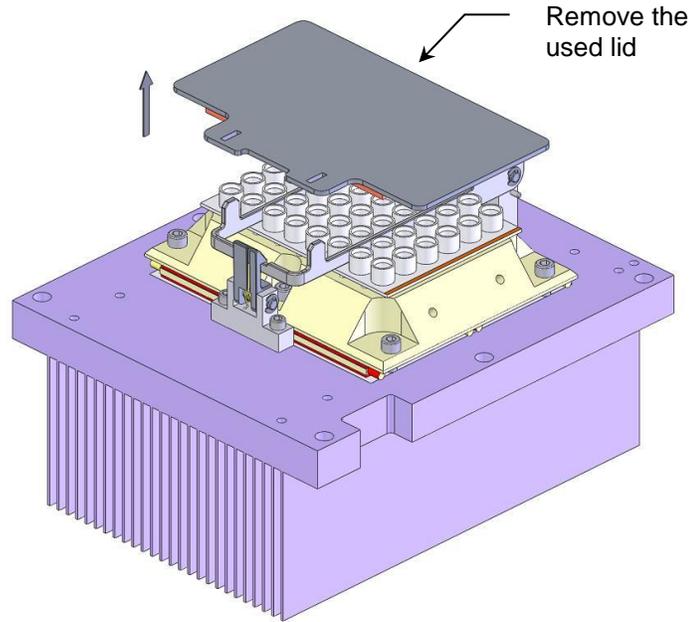
Open the retaining hook and lift up and push back the holding clamp.

Pull the retaining hook back and lift
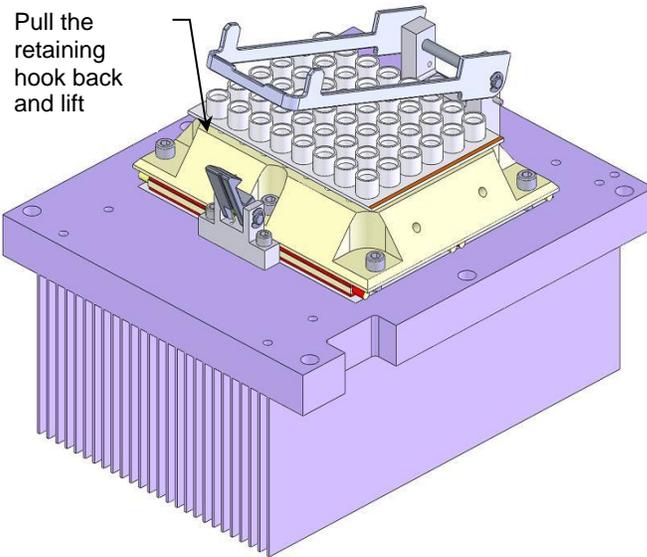
Lift out the used sample plate, if present, and discard the sample plate per your lab policy.

Remove used sample plate
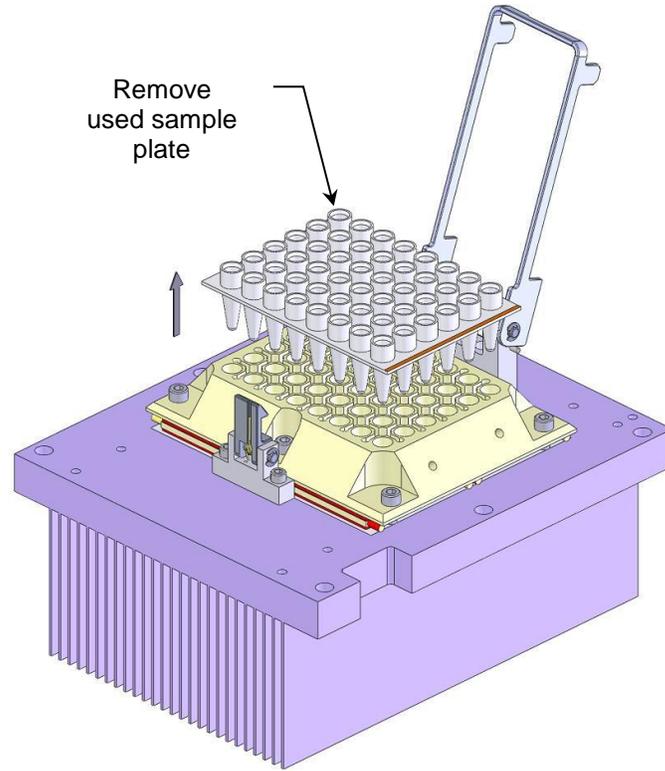
Load a new sample plate with the A-1 well oriented toward the back left of the tray. Close the clamp by pushing it against the hook.

Load new sample plate & close.

Holding Clamp

A1

Colored Stripe

Hook
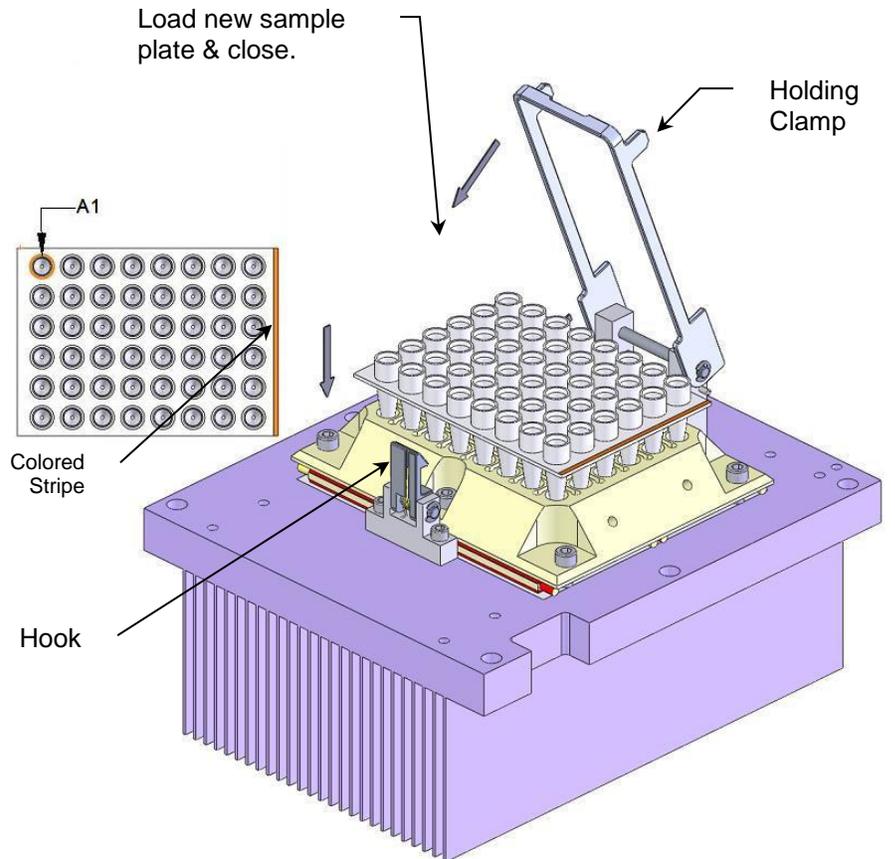
Cover the sample plate with a clean lid. See Routine Maintenance for the lid cleaning procedure.

Load clean lid with silicon facing down
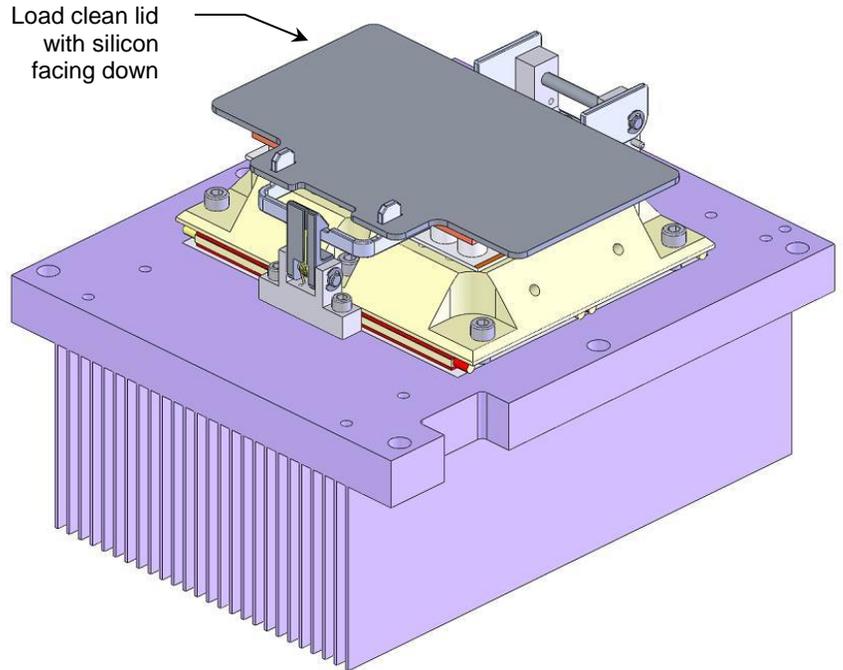
6.6.4 Intellipac® Reagent Tray

Unload the used Reagent modules by unscrewing the locking plate and releasing the hinged bar.

Unscrew locking plate

Open

Remove packs
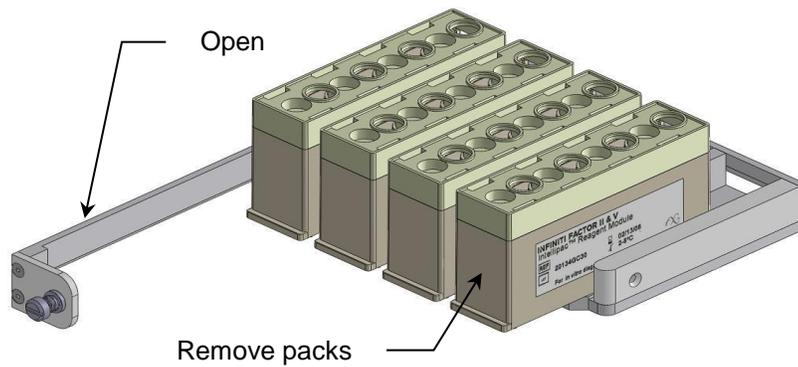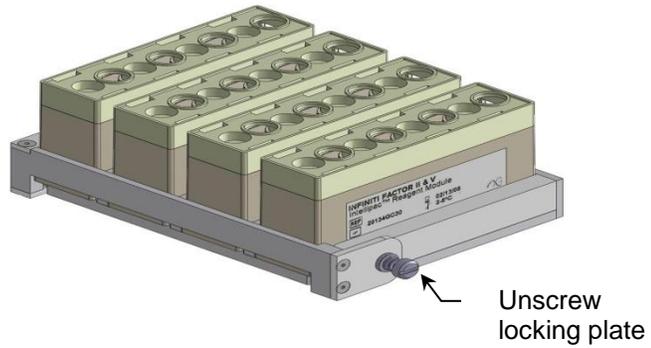
Load the reagent modules from the left side of the tray sequential (do not skip positions) from position 1 (front) to 4 (back). Slide each individual module inside, until it touches the right edge of the tray.

I-Button position

Insert new packs
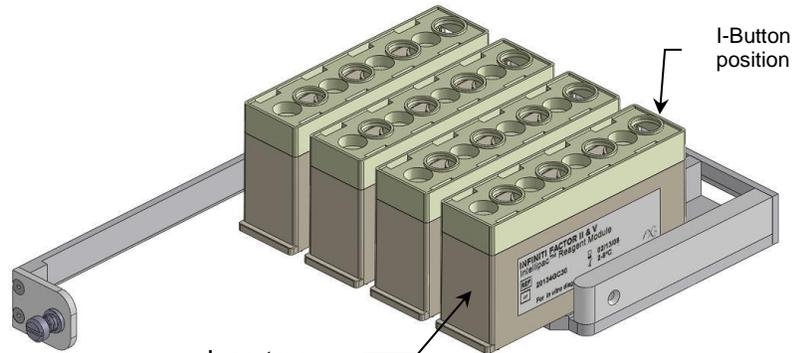
Note: Hex assays like HPV-HR-H requires two reagent modules for processing. Keep these two modules contiguously e.g. position 1 and 2, in reagent tray.

To close the loaded modules, rotate the hinged bar back to its original position and screw in the captive screw.

Close

Tighten screw
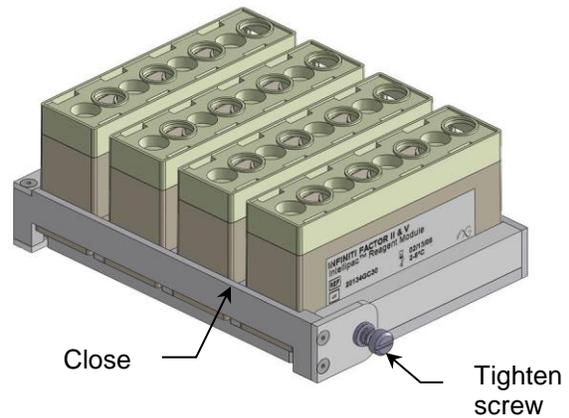
6.6.5 Buffers Bottles
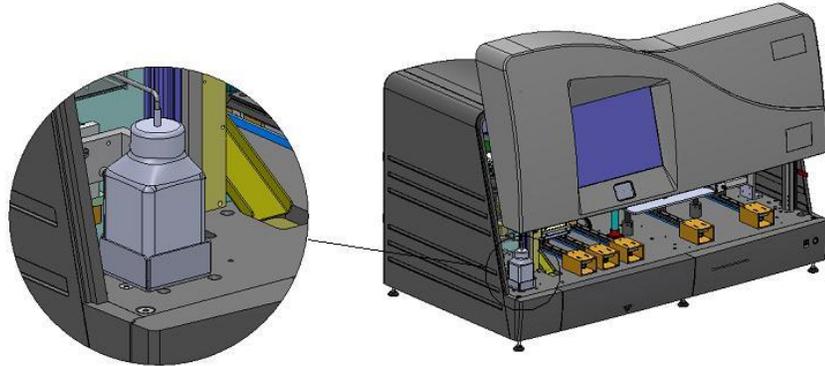
If the wash buffer volume is less than required (wash buffer volume displayed on the screen), replace the Wash buffer (125 ml) bottle. Click on the "Replace Wash Buffer" button to reset the volume (5 mL is the void volume and is not counted). After replacement, click the 'Prime' button to perform priming at least twice until the line is fully primed.

Some assays require an additional buffer.

To unload the empty additional buffer bottle (if present), remove the bottle from the bottle holder by firmly embracing the bottle and pulling straight up.
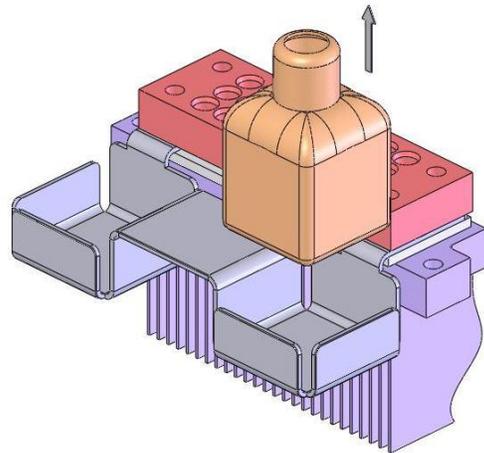
To load any additional buffer bottle, put the buffer bottle in the bottle holder on the right side and ensure that the bottom of the bottle is seated on the bottom of the tray. Also check to see that the bottle is not tilted or spilling liquid onto the instrument. Unscrew the bottle cap when you are ready to run the tests.
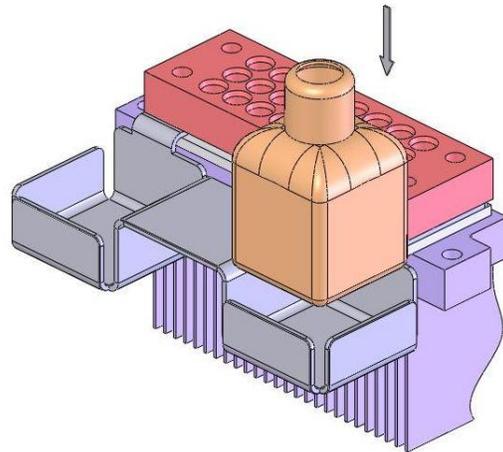
6.6.6   BioFilmChip Magazine

Remove the used magazines by carefully lifting upwards. If the magazine is not empty, slide the sleeve downwards until a snapping sound is heard to keep any unused chips from falling out.
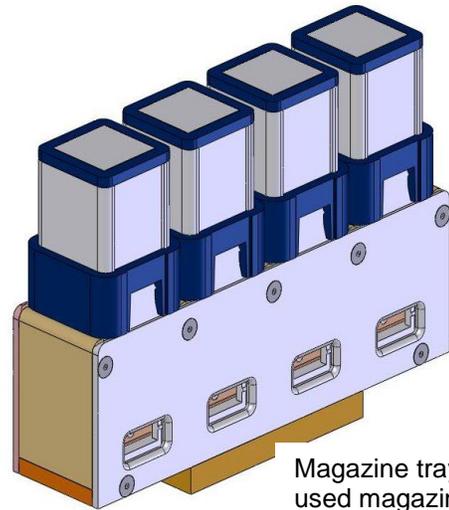
Magazine tray with used magazines

Lift the magazine body to unload the magazine

To load, place the new magazine on magazine tray top
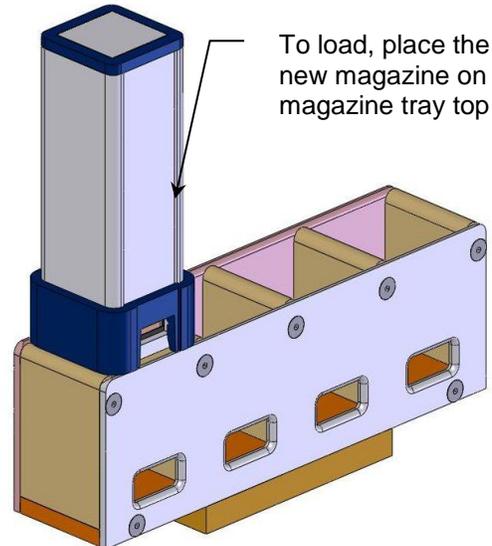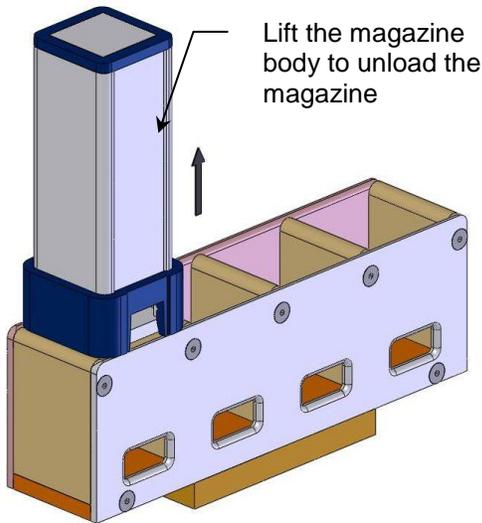
To load the magazine, place it on the magazine tray top and slide it down inside. Ensure that the magazine is well seated in the space by exerting slight pressure on the magazine from the top and wiggling back and forth. Load sequential for the front to the back.

Press down the magazine from
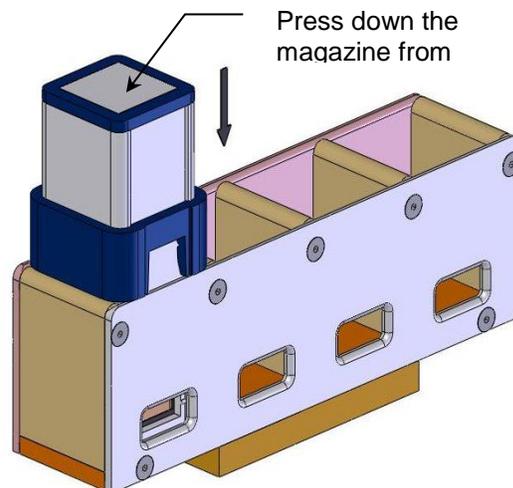
After all of the materials have been loaded, click "Next".

The software checks the available resources and shows all the details of Reagent, Magazine and Buffer. The volume of Buffer required for the run is also shown.

If sufficient resources for the submitted tests are not available, the system shows what and how much is missing. If more inventory is required click the "Back" button and resubmit the additional inventory.

Click "Next" to start the run.
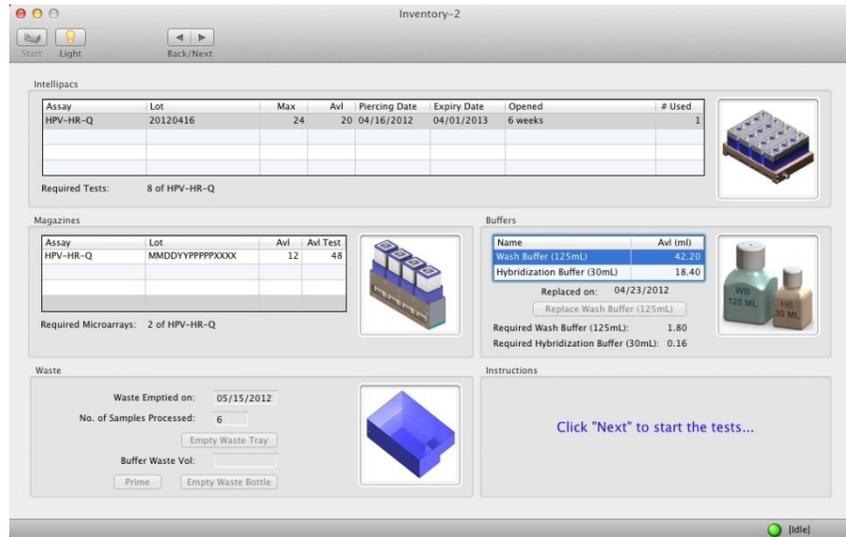
6.7 START THE RUN

At the start of the run, the "Cover" and system status changes to "Busy" and the idle indicator turns red at the bottom right hand corner.

6.7.1   Status

While the system is in process, the operator can see the progress and status of the submitted tests. The status screen displays the current status of submitted tests.

During thermal cycling, the temperature is displayed for all stations along with the number of thermal cycles completed. It also monitors the sample progress.
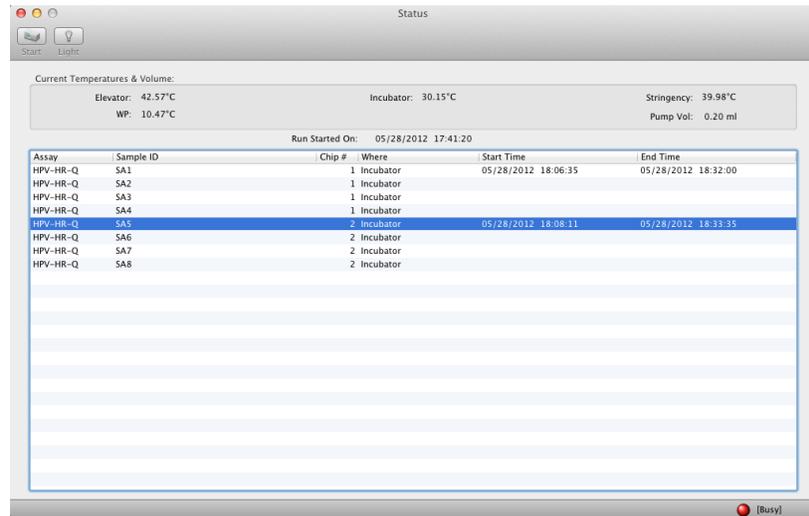
In case of "**chip load error"**, the cover is opened, the magazine tray is moved to the fill position, and the system displays the message box

Operator has to take out the magazine as shown in message box. He needs to count and enter number of micro-arrays left in the magazine.

Chip Load Error

Chip load error while loading chip from Magazine # 2 to Incubator row 3

Enter Number of chips left in Magazine # 2 [   ]

OK

If entered number of micro-arrays does not match with micro-arrays in the magazine, system displays message to give operator one more chance.

Entered number of chips in Magazine # 1 is not correct.Enter correct number

OK

If same mismatch happens again, the system displays this message and aborts the run when the OK is clicked.

Sorry! Entered number of chips does not match with chips in the System.Qmatic will abort on OK click

OK
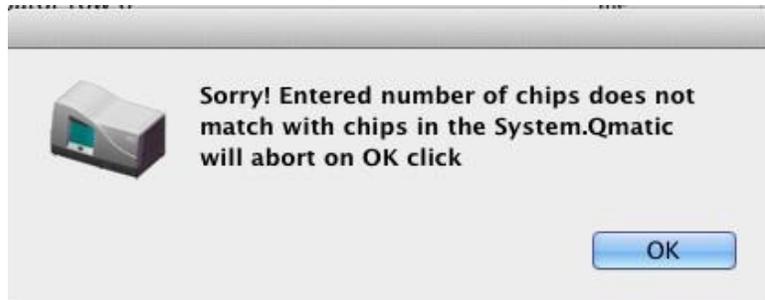
Qmatic displays the message to let the operator know how many micro-arrays chips are to be loaded. Operator will load the magazine with the required number of micro-arrays chips and click OK.

Need to load 8 more chip(s) in Incubator Please replace Magazine(s) and click OK when you are ready to resume

Quit   OK

When the OK button is clicked, the system checks the magazine resources. The same message will be prompted again if the correct number of microarray chips are not found. The operator can reload the magazine again or click "Quit" to abort the run.

If the sufficient amount of resources are found, the cover will close and the run starts from where it stopped.

6.8   END of the RUN

Once the run is completed, the system becomes idle and the cover is opened about 3" at the end of run.

The lower right button is green [idle].

In case of errors, a detailed message describing the issue encountered will be displayed on the result report for the sample in question.

If a numerical code is found, please call technical support for further assistance.
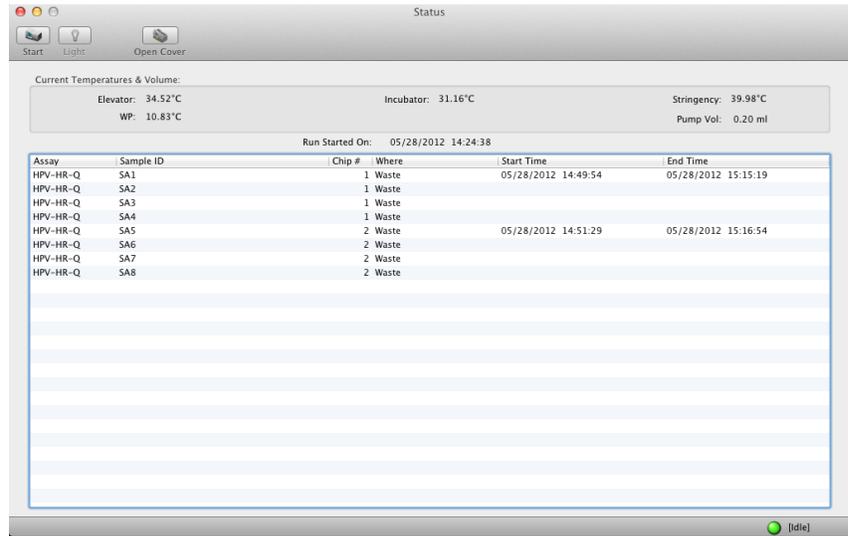
After the system becomes idle, the operator has two choices:

> Click "**Open Cover**" button to remove the inventory.
> Or
> Click the "**Start**" button to start another run.

If the operator clicks "Open Cover":

A message box displays the message to remove inventory.

Remove the reagent packs and micro-array magazines and store them as indicated on their labels.

Remove the sample plate lid. After removal, the lid should be cleaned with the process as described in the Routine Maintenance section.

After completing the above tasks, press the "OK" button.
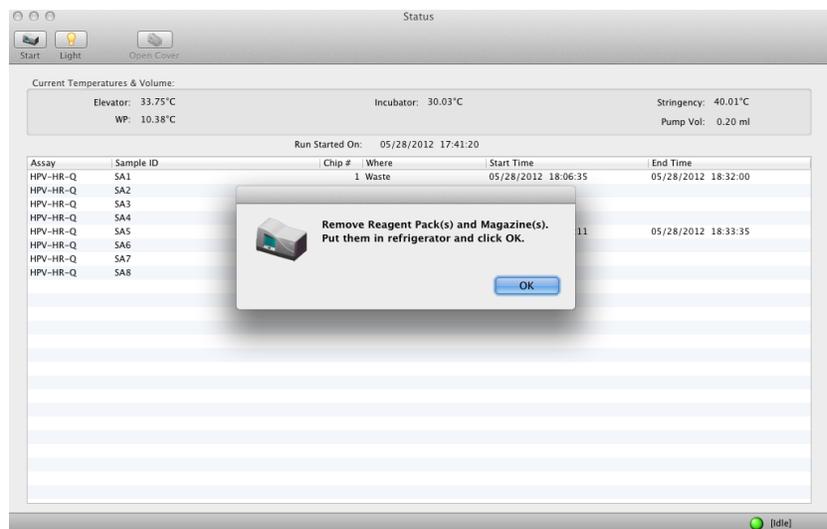
Operator can now either start another run by clicking "Start" button or exit the INFINITI PLUS Analyzer system by clicking red "X" button. Clicking the red "X" button displays a message box with the message "Are you sure you want to exit?" Click 'Yes' to exit and 'No' to continue.

If the operator selects the "Start" button, then follow the same process to submit the worklist and inventory of the next assay run. Click "Run" as described before.

6.9   RESULTS

A separate 'Results' icon [icon] is found on the desktop which indicates the path to the Results screen which is presented separately from the Main Menu Screen. Features of the results module include:

- Update button to get results of the latest samples processed.
- Archive, Delete, Restore, Purge buttons added to perform data maintenance.
- LIS (Laboratory Information System) button to create Results.txt file on the Desktop for LIS reporting.
- The results module displays a chronological storage of various sample results along with sample ID, assay, and the reagents used.

Procedure

[icon]

1. Click on the 'Results' icon [icon] on the desktop.
2. The result screen has a number of icons at the top, which helps in data extraction and management functions.
3. The list of tests performed are displayed in descending date order. This can be viewed in date or assay order by clicking the "Date" or "Assay" column.

4. Erroneous results are displayed in a red color.

5. The following reports can be created at the end of a run:
    a) Legacy report
    b) Detail report
    c) Summary report

6. The following reports may be set up as an option:
    a) LIS report in various optional layouts
    b) A run finished, or a run aborted notification.
    c) Message log and the signals.txt file
    d) The Technical Support folder
    e) Optional emails
        a. Emails run finished mail to desired address at the end of the run
        b. Emails message log and signals.txt at the end of the run
        c. Emails tech support files on button click
        d. Emails run aborted mail at the end of the run

Highlight the data that you want in a report and press the desired report format button at the top to create the report.

Legacy Report:

Result program creates Legacy Report automatically in **Autogenomics/Reports** folder at the end of the run. This report is in PDF format and one report is generated for each run. Report is saved as "ResultsLeg_XXXX.pdf", where XXXX is the RunID number. Select the RunID from the list shown. The operator can view all the reports of the run in **Acrobat Reader** (if available) or **Preview**. Use Up/Down arrow keys to navigate.

Legacy report is in the following format:

Detail Report:

- This report is generated at the end of each run and saved on desktop in a folder name "Reports-YYYYMMDD". There will be only one "Reports-XXXXXX" folder on desktop. This report can also be produced any time by selecting records from result view and clicking the "Detail Report" Icon. The folder name can be changed to save keep the past results.

```
Infiniti-0102  QMatic:8.2E Header:8.2F Results:8.2F
RunID_Well:12472_A1 SampleID:2011122012144001 Date:Dec 20,2011 Time:16:42:23
Assay:HPV-Q       Intell.Lot:20493T51K      Magz.Lot:10011220492W34J
Analyte          RFU      Ratio    Analysis
-------------------------------------------------------------------------
beta-globin               1.00     0.02    neg
HPV16                     1688.00  33.76   POSITIVE
HPV18                     1.00     0.02    neg
HPV31                     1.00     0.02    neg
HPV33                     1.00     0.02    neg
HPV45                     1.00     0.02    neg
HPV35/68         1.00     0.02     neg
HPV39/56         1.00     0.02     neg
HPV51/59         1.00     0.02     neg
HPV52/58         1.00     0.02     neg
HPV6/11          1.00     0.02     neg
BKGD                      50.00    0.00
-------------------------------------------------------------------------
```

Summary Report

This report is produced for **Virus assays only**. This report is also generated in "Reports-YYYYMMDD" on the desktop. It can also be produced later by selecting only records from a single batch run. This one report consists of following three sub reports:

First page shows results that have at least 1 positive analyte as shown below:
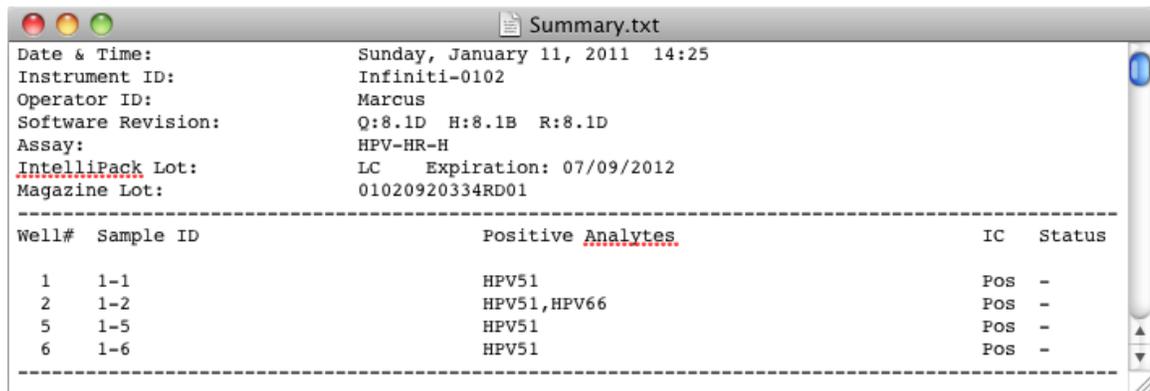
Second page has results of all samples:


```
⊖ ⊖ ⊖                          📄 Summary.txt

Date & Time:             Sunday, January 11, 2011  14:25
Instrument ID:           Infiniti-0102
Operator ID:             Marcus
Software Revision:       Q:8.1D  H:8.1B  R:8.1D
Assay:                   HPV-HR-H
IntelliPack Lot:         LC    Expiration: 07/09/2012
Magazine Lot:            01020920334RD01
---------------------------------------------------------------------------
Well#  Sample ID                     Analysis                 IC   Status

  1    1-1                           HPV51                    Pos   -
  2    1-2                           HPV51,HPV66              Pos   -
  3    1-3                           -                        Neg  #1065
  4    1-4                           -                        Neg  #1065
  5    1-5                           HPV51                    Pos   -
  6    1-6                           HPV51                    Pos   -
  7    2-1                           -                        Neg  #1065
  8    2-2                           HPV66                    Neg  #1065
  9    2-3                           -                        Neg  #1065
 10    2-4                           -                        Neg  #1065
 11    2-5                           -                        Neg  #1065
 12    2-6                           -                        Neg  #1065
 13    3-1                           -                        Neg  #1065
 14    3-2                           HPV66                    Neg  #1065
 15    3-3                           -                        Neg  #1065
 16    3-4                           -                        Neg  #1065
 17    3-5                           -                        Neg  #1065
 18    3-6                           -                        Neg  #1065
---------------------------------------------------------------------------
#1065 IC Negative
```

Third page has results that have all analytes negative:


```
⊖ ⊖ ⊖                          📄 Summary.txt

Date & Time:             Sunday, January 11, 2011  14:25
Instrument ID:           Infiniti-0102
Operator ID:             Marcus
Software Revision:       Q:8.1D  H:8.1B  R:8.1D
Assay:                   HPV-HR-H
IntelliPack Lot:         LC    Expiration: 07/09/2012
Magazine Lot:            01020920334RD01
---------------------------------------------------------------------------
Well#  Sample ID                     Analysis                 IC   Status

  3    1-3                           -                        neg  #1065
  4    1-4                           -                        neg  #1065
  7    2-1                           -                        neg  #1065
  8    2-2                           -                        neg  #1065
  9    2-3                           -                        neg  #1065
 10    2-4                           -                        neg  #1065
 11    2-5                           -                        neg  #1065
 12    2-6                           -                        neg  #1065
 13    3-1                           -                        neg  #1065
 14    3-2                           -                        neg  #1065
 15    3-3                           -                        neg  #1065
 16    3-4                           -                        neg  #1065
 17    3-5                           -                        neg  #1065
 18    3-6                           -                        neg  #1065
---------------------------------------------------------------------------
#1065 IC Negative
```

Buttons on the Result screen:

- **Preferences**: Changes **LIS preferences** for Results and various **Qmatic operations** preferences.

  o Click the "Preferences" button available on the toolbar. This opens the LIS preference window. Select the required preference and make the changes.

  o To change the Qmatic operation preferences, click the "Operation" button available on the toolbar. Select the required preference and make changes.

  o Click the "Close" button to save the changes.

- **Archive**: The "Archive" button is enabled when the number of results in the result file exceeds 3000. "Results" also prompt the message to archive the data. When the operator clicks the "Archive" button, files (e.g. Genomics_Dec08-Mar10.bin) are created in the Archives folder.

- **Tech Support**: Creates support files to be sent to technical support. This report is produced only when the operator clicks the "Tech-Support" icon.

  o Click the "Tech Support" button available on the toolbar.
  o The last 100 or one-month records (Whichever is less) are selected.
  o Before sending mail, a message appears "Sending mail to AutoGenomics Tech Support".
  o A zip file "AGTechsupport.zip" is sent automatically to an email address as defined by tech-support.
  o After sending the email, a message appears "Sent mail to AutoGenomics Tech Support".

     "AGTechsupport.zip" contains following files:

     a. Worklist.txt
     b. Temperature Log (Temperature.txt)
     c. LLS.txt
     d. Cmndtime.xls
     e. Commandlog.txt
     f. Signal-Report (Signals.txt)
     g. Message-Log (Expanded message log file)
     h. Images of two micro-arrays with errors (RunID_sr.tiff)
     i. Instcal.bin (If changed after last Tech-support mail)
     j. Assyname_print.txt (Assay of selected results)

6.10 Lab Information System (LIS)

At the end of each run "ResulLIS.txt" is created at the LIS path as defined in the LIS preferences. Depending on the options (Show assay name, Show RFU and Ratio in LIS preferences) multiple formats of report can be generated.
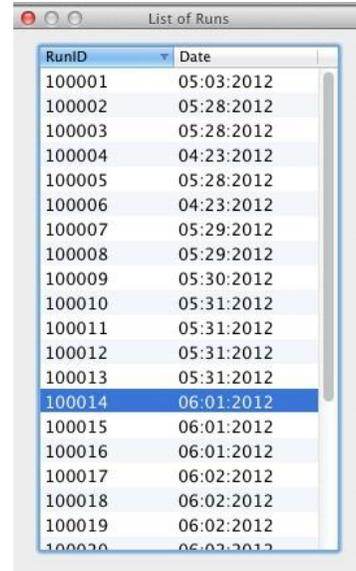
Internet Access

The software uses the Internet to send pertinent information about the instrument performance to AutoGenomics. If the customer agrees, the following notices are sent to the email ids mentioned in the LIS and Tech-support preferences:

- Sent to customer with subject "Run Finished on: XXXX at HH:MM Assay: AAAA Results: NN", where XXXX is the instrument name. This notice is sent at the end of the run.
- Sent to AutoGenomics with subject "Run Finished on: XXXX at HH:MM Assay: AAAA Results: NN", where XXXX is the instrument name. This email has the MessageLog.txt and Signals.txt (optional) attached. This notice is sent at the end of each run.
- Run abort email sent to the customer and AutoGenomics with subject "Run Aborted on: XXXX at HH:MM Assay: AAAA Results: NN Err #NNN", where XXXX is the instrument name.

Note: Click on the Preference icon in the Results screen for settings.

Sending images of selected micro-arrays manually

Retrieving images of desired result:

a) Select the result in view. Note: RunID of **result** from bottom view and the **time** of result creation from top view.
b) Go to /Library/Application Support/Autogenomics/Images/RunID folder. Select the image that is created around the noted time.
c) Copy the image in the "sendmail" folder on the desktop.

Repeat the above steps for all the results for which you want to send images. After getting all the images in the "sendmail" folder, zip the folder and send an e-mail to AutoGenomics.

7   Message Display

Procedure to Access Messages

1. Click on the MessageDisplay icon   available in Applications/Autogenomics.
   It will display messages (file MessageLog.dat) on the screen with column sort capability.
   It displays messages from all programs. (e.g. Qmatic, Image Processing, OptCalCam and Results)
   Messages from the MessageLog.dat will be displayed in the language preferred by the language setting.
   Layout for MessageDisplay:
   a) Error type (Informative, Warning or Critical)
   b) Date and Time
   c) Message number
   d) Details of Message
   e) Message source

	Date	Time	Message #	Message	Message Source
	10:03:2011	10:26:53	#1001	Infiniti powered up	QMatic
	10:03:2011	10:19:27	#1002	Infiniti powered down	QMatic
	10:03:2011	10:16:07	#1001	Infiniti powered up	QMatic
	10:03:2011	10:14:52	#1002	Infiniti powered down	QMatic
⚠	10:03:2011	10:04:02	#1043	Camera Error	QMatic
	10:03:2011	10:03:03	#1001	Infiniti powered up	QMatic
	10:03:2011	10:02:54	#1051	USB error in Read command from switch ID 19	QMatic
	10:03:2011	10:02:52	#1051	USB error in Read command from switch ID 19	QMatic
	10:03:2011	10:02:50	#1051	USB error in Read command from switch ID 19	QMatic
	10:03:2011	10:02:47	#1051	USB error in Read command from switch ID 19	QMatic
	10:03:2011	09:59:36	#1005	Power up after abnormal shutdown	QMatic
⛔	09:30:2011	18:16:55	#1070	Abnormal system shutdown by operator after chip load error	QMatic
⚠	09:30:2011	18:16:30	#1027	BioFilmChip was not loaded in to the incubator	QMatic
	09:30:2011	18:10:28	#1068	Before run – available tests in Reagent Pack for FIIP–FV–MTHFR : 48	QMatic
	09:30:2011	18:10:23	#1004	Tests of FIIP–FV–MTHFR submitted for processing : 48	QMatic
	09:30:2011	18:07:56	#1056	IButton not present	QMatic
	09:30:2011	18:06:55	#1056	IButton not present	QMatic
⚠	09:30:2011	17:58:50	#1043	Camera Error	QMatic
	09:30:2011	17:57:59	#1001	Infiniti powered up	QMatic
	09:30:2011	17:57:54	#1051	USB error in Read command from switch ID 19	QMatic
	09:30:2011	17:57:52	#1051	USB error in Read command from switch ID 19	QMatic

Infiniti powered up

8   Optics Calibration

OptCalCam software calibrates the Camera Optics using the signals of the reference micro-array.

Procedure

1. Insert the "OptCalCamCD" in the optical drive and check that the ChipID.bin file is available on the CD. ChipID is the name of the micro-array written on the back of the Calibration (Reference) micro-array.

2. Click on the OptCalCam icon available in Applications/Autogenomics.
3. Put Dark micro-array on the bridge. Click "Optics Load" to load the micro-array in the Optics file. Click "Dark Image" to capture and save dark micro-array image in the Autogenomics folder.
4. Unload the dark micro-array and put the calibration micro-array on the bridge. **Note the ChipID written on the back of the micro-array before putting the micro-array on the bridge.**
5. Enter the ChipID of the calibration micro-array. Click "Check" to verify that there is a record of ChipID in the ChipID.bin file.
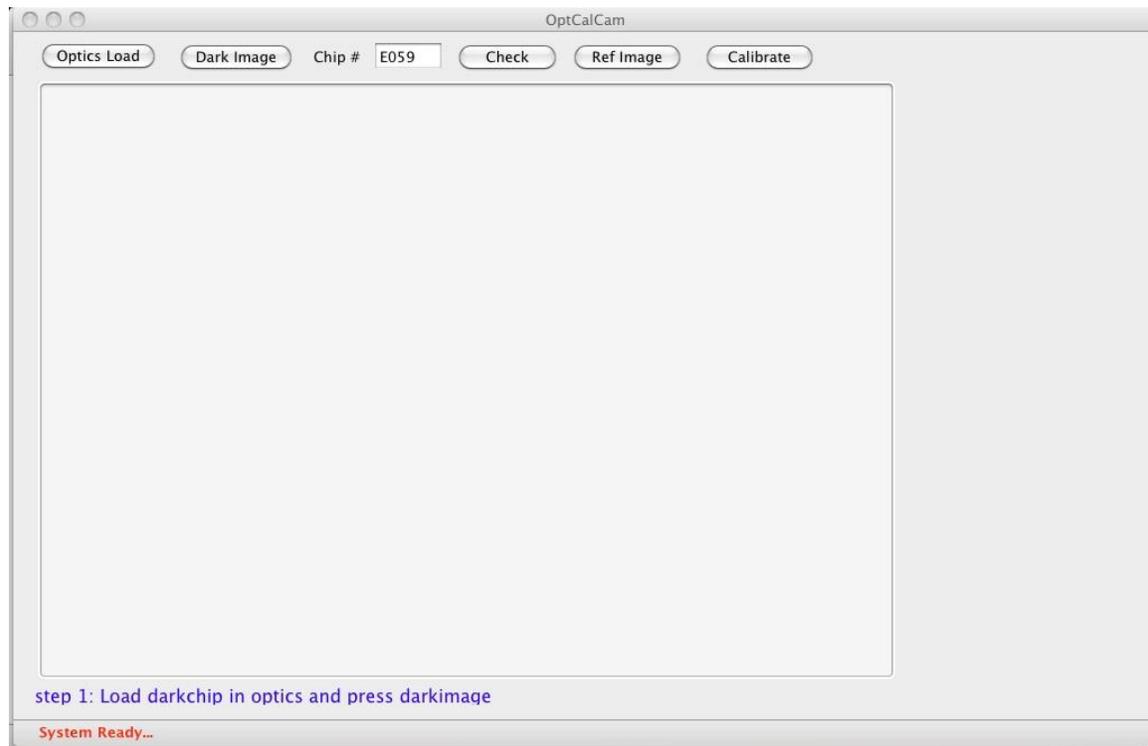
6. Click "Optics Load" to load the micro-array in optics.
7. Click "Ref Image" button to get the image of the micro-array.
8. Click Calibrate.
9. Program will display the calibrated parameters on the screen and saves them in the "image_parameters.dat" file.
10. Signals from the instrument are saved in the ChipID.bin in the Autogenomics folder.
11. Click "Unload" to remove the micro-array.

9 Routine Maintenance

9.1 Lid Cleaning Procedure

- Clean the silicone sample lid with 10% bleach.

- Remove the bleach with 70% isopropyl alcohol or ethanol and wipe the lid with a lint-free wipe.

- Let dry in a clean area without DNA which could contaminate the lid.

    CAUTION: If the bleach is not removed, DNA in your sample could be eliminated.

9.2 Daily (when in use)

- Using lint free cloth, wipe down the Plus base thoroughly, removing any dust.
- Ensure the Plus cover closes during system operations.

9.3 Weekly

- Replace the waste tray liner every week. (**NOTE: Repeated usage of the same liner will cause a waste tray stir bar malfunction error**)
- Wipe down the Plus monitor with a lint free cloth - **Do not use any chemicals**.

- Click the "Clean" button to move trays out for cleaning. Visually inspect the incubator and stringency station for salt deposits. Remove the salt deposits using a lint free cloth with 70 % alcohol solution.
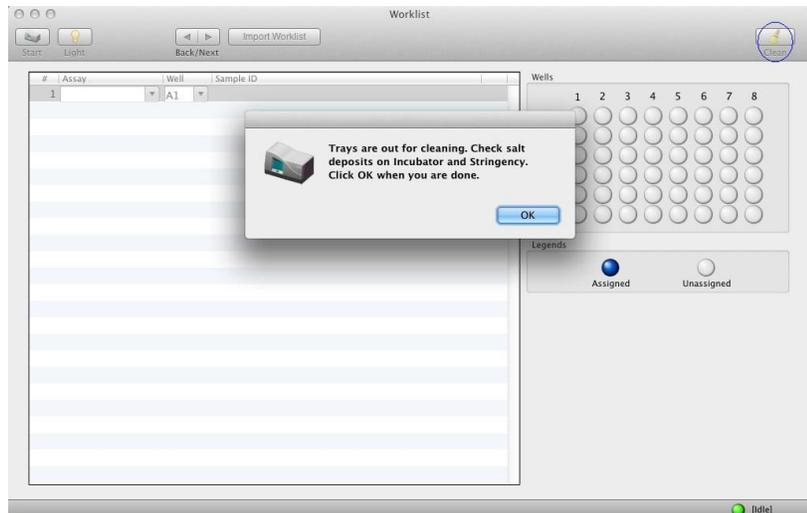
- If salt deposits are present on the pipette barrel, replace the nozzle barrel plug immediately. Otherwise, replace the nozzle barrel plug after approximately 100 samples have been run.

9.4 Monthly

- Wipe down the incubator base and lid using a lint-free cloth with 70% alcohol.
- Visually inspect the pipette nozzle for salt deposits. Remove any observed salt deposits and clean the nozzle using a lint free cloth with 70% alcohol.

10   Disposal

The INFINITI PLUS Analyzer and accessories are made of materials commonly used in laboratories, computers, and electromechanical devices. The materials are considered non-hazardous, non-degradable, and recyclable plastics and metals. These can be disposed of following the same laboratory standard operating procedures set up for similar products and samples.

As part of our compliance to WEEE regulations, please call Tech support for instructions on how to package and ship the INFINITI PLUS Analyzer back to AutoGenomics, Inc.