INFINITI® HTS

Operator's Manual

For *In Vitro* Diagnostic Use

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

CE Authorized EU Agent: Medical Device Safety Service GmbH (MDSS)

Schiffgraben 41, 30175 Hannover, Germany

EM-21348 REV. B (CO 3917) February 2017

Table of Contents

General Introduction 4
HTS Chip Plates 4
1. ASSEMBLING CHIP PLATES 4
2. CHIP PLATES MAINTENANCE 6
INFINITI® INCUBATOR 7
3. INTRODUCTION 7
4. INTENDED USE 7
5. SAFETY 7
6. GENERAL REQUIREMENTS 7
7. INSTRUMENT POSITION 7
8. OPERATING PROCEDURE 8
9. INCUBATOR TEMPERATURE CONTROL 10
10. MAINTENANCE PROCEDURES PERFORMED BY OPERATOR 11
INFINITI® PROCESSOR 13
11. INTRODUCTION 13
12. INTENDED USE 13
13. SAFETY 13
14. GENERAL REQUIREMENTS 13
15. OPERATING PROCEDURE 13
16. OPERATOR MAINTENANCE PROCEDURES 18
17. PREVENTIVE MAINTENANCE 19
INFINITI® ACE Reader 20
18. INTRODUCTION 20
19. INTENDED USE 20
20. SAFETY 20
21. INSTALLATION REQUIREMENTS 20
22. OPERATING PROCEDURE 21

23. RESULTS RETRIEVAL 29

24. OPERATOR MAINTENANCE PROCEDURES 33

25. PREVENTIVE MAINTENANCE 33

General Introduction

The **INFINITI® High Throughput System (HTS)** is a semi-automated multiplexing, microarray platform. It consists of three instruments: INFINITI® INCUBATOR (INC), INFINITI® PROCESSOR (PRO) and INFINITI® ACE Reader (ACE). The HTS is used to perform high throughput genotyping and high sensitivity molecular detection assays using BioFilmChip® microarrays.

The system is capable of producing up to 6,500 test results per day, when using automated liquid handling systems. Processing in the three modules can be staggered, permitting optimal workflow.

INFINITI® INCUBATOR is a hybridization chamber with 8 individually temperature-controlled heating elements (shelves) directly conducting heat to microarray holding HTS Chip Plates.

INFINITI® PROCESSOR is a multichannel peristaltic washing and vacuum drying station providing effective heat-controlled processing for up to 192 BioFilmChip® microarrays.

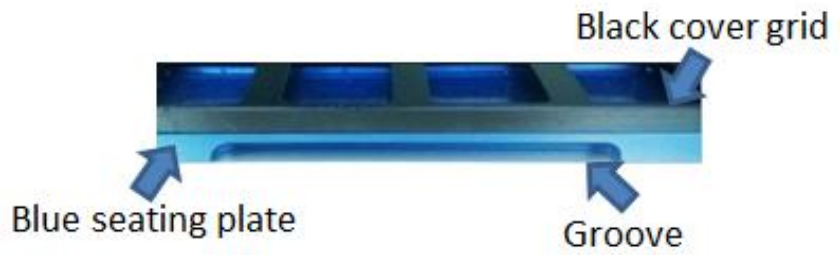
INFINITI® ACE Reader is an automated high resolution scanning fluorimeter with LED excitation and CCD image sensor providing scanning times of less than 15 minutes for 96 BioFilmChip® microarrays.

HTS Chip Plates are used to move up to 96 individual BioFilmChip® microarrays between the instruments and as microarray holders during the processes performed on each instrument.

HTS Chip Plates

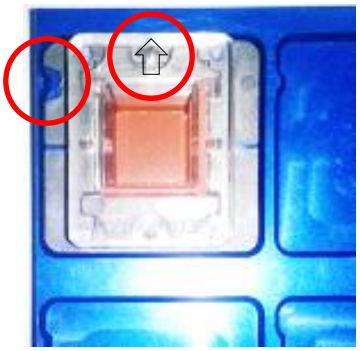
1. ASSEMBLING CHIP PLATES

1.1 Place the Chip Plate on a clean flat surface and orient the Chip Plate such that the singular groove along the length of the Chip Plate is facing the operator (the smooth long side on the top should be away from the operator).



1.2 Remove the black Chip Plate grid by unscrewing the thumbscrews on its surface. Set aside the grid.

1.3 Place into each seat a BioFilmChip® oriented "arrow up" on the Chip Plate and matching the notches on the left side of the chip; see Table 1 (Chip Layout Matrix) on the next page for layout designations.



1.3.1 If running less than a full plate of 96 microarrays, arrange the microarrays vertically (by column) in multiples of 8.

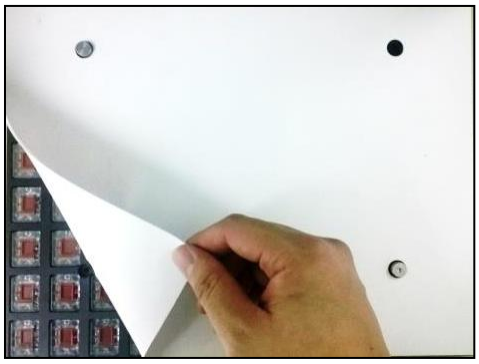
1.3.2 Note that the HTS processes a minimum of 8 microarrays. If running less than 8 microarrays, fill in the rest of the vertical column with used/old/dummy chips. Label these dummy chips with a non-fluorescent marker.

1.4 Replace the black Chip Plate grid and fasten by screwing the thumbscrews through the Chip Grid. Take care to properly orient the grid such that the recessed screw inserts are facing up.

1.5 Proceed to transfer contents of the sample well plate (with hybridization buffer) on to the assigned chip per assay protocol.

Note: Refer to individual assay application notes for detailed instructions on correct volume to transfer.

1.6 Once the well plate contents have been transferred, cover the microarray plate with a clean, dust-free, 96-well chip plate silicon mat (# 11-0160-00), aligning the mat with the cut screw holes over the screws.



2. CHIP PLATES MAINTENANCE

2.1 Chip plates should always be kept in a clean dry place.

2.2 Bleach solutions should not be used on the metal surface of the chip plate. Occasional spills should be treated with extensive washing in purified water.

2.3 Silicon mats should be kept flat at all times (Do not roll or fold). Creases in the mat can affect the sealing properties of the mat when used subsequently for another plate.

2.4 Silicon mats should be washed and treated after each use as described in chapter 10.1.

2.5 Fluorescent or reflective markers should not be used to label chip plates, silicon mats nor microarray chips. They might increase background signals.

INFINITI® INCUBATOR

3. INTRODUCTION

As part of the AutoGenomics high throughput assay workflow, it is necessary to achieve efficient hybridization of labeled primers in a sample to capture probes bound to the BioFilmChip® microarrays before they are washed on the INFINITI® Processor. The INFINITI® INCUBATOR permits hybridization of up to 8 plates, containing 96 microarrays each plate, simultaneously at 40ºC. Heating is provided to each plate conductively to ensure proper heating while reducing evaporation, relative to convectively heated incubators. The instrument comes with a preset 90 minute timer-alert to facilitate process tracking.

4. INTENDED USE

The INFINITI® INCUBATOR is designed to incubate microarray chips used in assays only from AutoGenomics, as part of the INFINITI® High Throughput System workflow. It is not intended for applications other than those specified by AutoGenomics.

5. SAFETY

Ensure that only trained operators are using this instrument. The plate surface may be hot. Use caution when working on or around the instrument.

6. GENERAL REQUIREMENTS

6.1 It is required for all operators to be properly trained to operate the INFINITI® INCUBATOR.

6.2 It is required of all operators that they perform all maintenance and safety checks.

6.3 It is the responsibility of Field Service and Tech Support personnel at AutoGenomics to ensure repairs and major maintenance work are completed as needed.

7. INSTRUMENT POSITION

7.1 Location

7.1.1 The instrument should be located on a flat and level surface capable of supporting 100 lbs. (45kg) (plus any additional weight of additional components, etc.).

7.1.2 The instrument should have at least an 8 cm gap of free space on the right side, top, and back.

7.1.3 The instrument should have at least a 10 cm gap of free space on the left side (door hinge side) to allow for opening the door and comfortable operation.

7.1.4 The instrument should be in close proximity to the INFINITI® PROCESSOR instrument for ease of transfer.

7.2 Electric Connections

7.2.1 The supplied power cable to the back of the INFINITI INCUBATOR should be connected to a wall outlet prior to its use.

Outlet Requirements: 100 ~ 240 VAC
10 A (@ 110 VAC)

MOVING AND INSTALLATION MUST BE PERFORMED BY AUTOGENOMICS TRAINED PERSONNEL ONLY. PLEASE ALERT AUTOGENOMICS TECH SUPPORT at techsupport@autogenomics.com PRIOR TO MOVING THE INSTRUMENT TO A NEW LOCATION.

8. OPERATING PROCEDURE

8.1 Preparing the instrument to Run:

8.1.1 Make sure the instrument is empty with no chip plates inside, and that the instrument door is closed.

8.1.2 Turn on the instrument by switching on the main power switch located on the rear lower right hand side of the instrument.

8.1.3 Wait for the incubator's shelves to reach the operating temperature of 40ºC (approximately 10 minutes).

8.1.4 The initial note on the display "warming up, please wait" will disappear and all the square buttons on the screen will turn green.

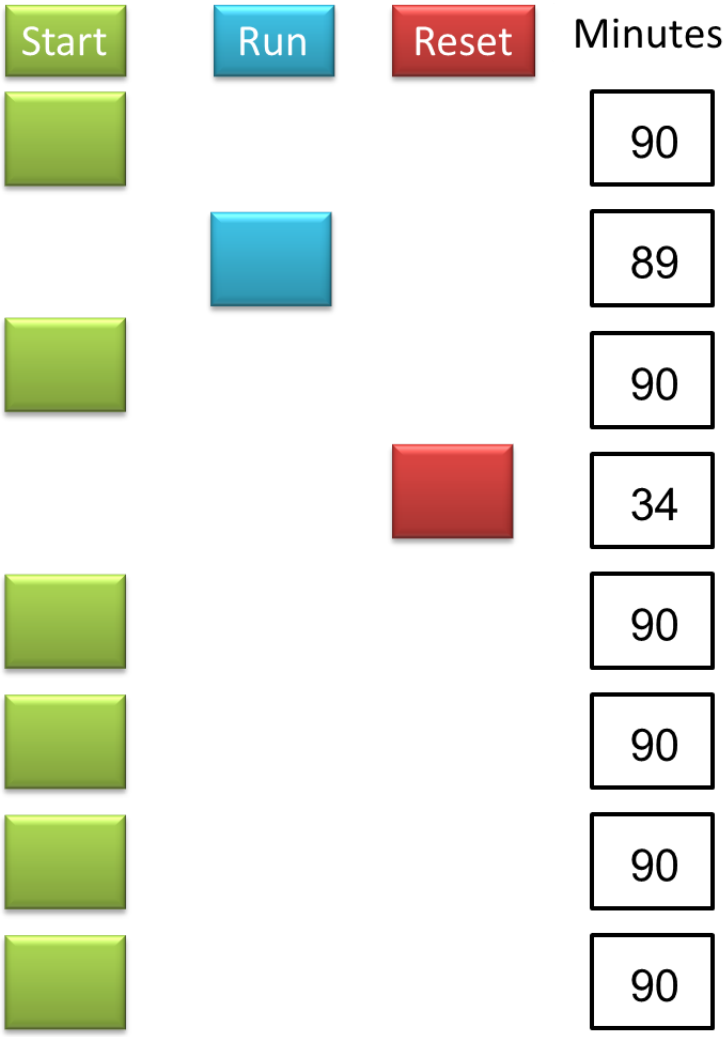
Note: If the instrument is "on" due to a previous run, no additional warm-up time is required.

8.2 Operating the instrument:

8.2.1 Place an assembled, covered Chip Plate on one of the incubation platforms, taking care not to tilt the plate, splash, or spill the liquid.

After the filled chip plate is loaded in the incubator, press the green "Start" button on the touchpad which corresponds to the shelf being used. This will initiate the 90 minute countdown for the loaded chip plate.
Note: A successfully initiated countdown will change the color of the button to blue and move it to the "Run" column.

8.2.2 When a 90 minute cycle is complete, there will be an audible alert, the button will be moved to the "Reset" column and change its color to pink. Press the now pink button to reset the timer and change the button back to green under the "Start" column. Use care not to exceed the normal 90 minute incubation time by any longer than 10 minutes.



8.2.3 Remove the Chip Plate, taking care not to tilt the plate or spill the liquid.

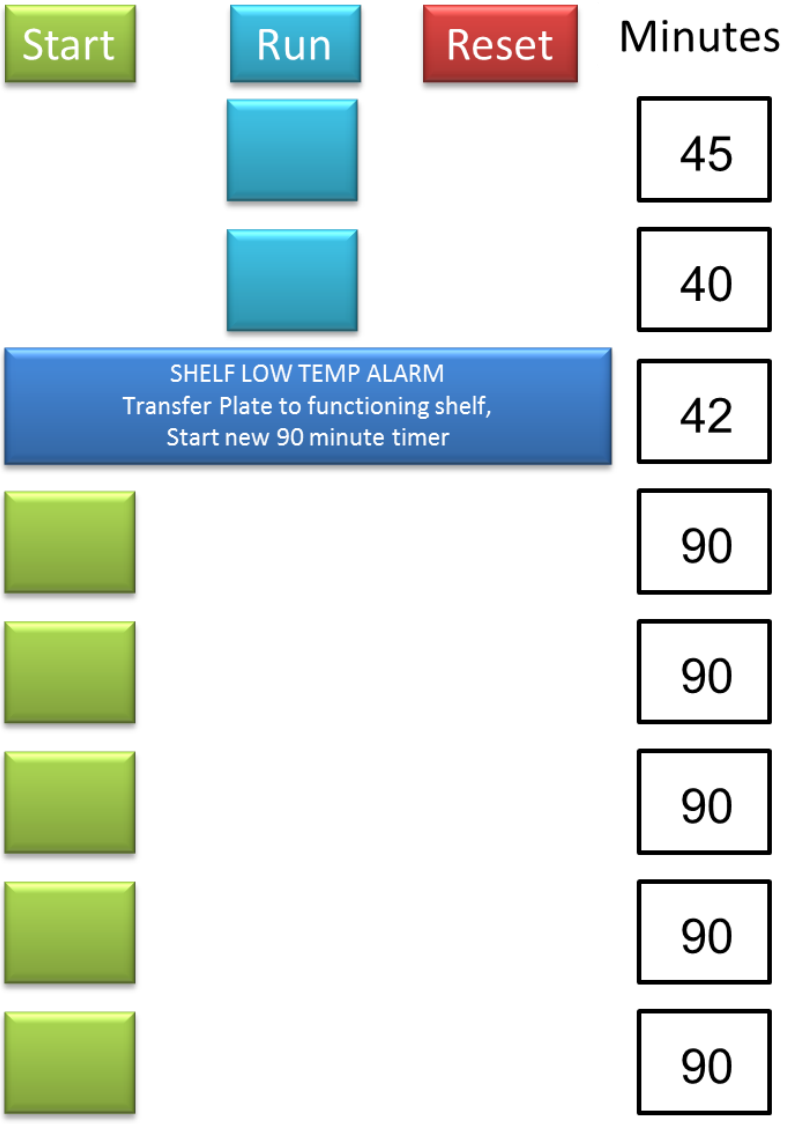
Note: Multiple Chip Plates can be run simultaneously. When an additional covered Chip Plate is introduced into the incubator, simply press the timer button corresponding to that shelf and proceed from the start of the

"Operating the Instrument" section (8.2). The addition of Chip Plates does not affect the incubation runs already underway.

9. INCUBATOR TEMPERATURE CONTROL

9.1 The set point for the incubator is 40° C ± 1° C. AutoGenomics, Inc. certifies that when the incubator is in equilibrium, the shelves will be 40° C ± 1° C.

9.2 A low temperature alarm will be triggered, if the shelf remains for more than 300 seconds below 33°C. Shown below is the error message that will be visible.



9.3 A high temperature alarm is triggered at 44° C. Shown below is the error message which will be visible on the screen.

10. MAINTENANCE PROCEDURES PERFORMED BY OPERATOR

10.1 After each incubator Use:

10.1.1 Open the incubator's acrylic front door.

10.1.2 Take out the Chip Plate and place it on a flat surface with the silicon mat side facing up. If there is a residual condensation, wipe down the silicon mat with a lint-free cloth (e.g., Kimwipes™).

10.1.3 Carefully lift the silicon mat from the Chip Plate and lay flat in the tray.

10.1.4 Wipe the silicon mat with 10% bleach solution or spray each surface of the mat with Activate™ Bleach Sprayer (Deardorff Fitzsimmons Corporation). Silicon mats may be soaked in 10% bleach solution for up to 30 minutes. Use caution and wear protective glasses and cloth, when using bleach solutions or sprayers.

10.1.5 Rinse the mat with purified water until it is bleach-free.

10.1.6 Place the silicon Chip Plate mat (with the side that was facing the chips) on a flat, clean lint-free surface to dry. Any residual condensation on the upper surface of the mat may be removed using a lint-free cloth saturated with 70% alcohol.

10.1.7 Make sure that the mat is flat at all times. Creases in the mat can affect its sealing properties when used again for another plate.

10.2 Weekly Maintenance

10.2.1 Wipe down each incubation shelf in the incubator and the cover with a lint-free cloth e.g., Kimwipes™.

*** Note: Do not use bleach to clean the acrylic cover. Damage will occur.**

INFINITI® PROCESSOR

11. INTRODUCTION

As part of the AutoGenomics high throughput (HTS) assay workflow, it is necessary to achieve efficient microarray washing before the BioFilmChips are analyzed on the INFINITI® ACE Reader. The INFINITI® PROCESSOR permits the automated simultaneous washing of a minimum of 8 and up to 192 microarray chips after incubation on the INFINITI® INCUBATOR.

12. INTENDED USE

The INFINITI® PROCESSOR is designed to automate washing of any microarray chips used in assays from AutoGenomics. It is not intended for any applications other than those specified by AutoGenomics.

13. SAFETY

Only trained operators should use this instrument. Tray surface may be hot. Use caution when working on or around the instrument.

14. GENERAL REQUIREMENTS

14.1 It is required that all operators are properly trained to use the INFINITI® PROCESSOR.

14.2 It is required that all operators ensure that all maintenance and safety checks are performed.

14.3 It is the responsibility of Field Service and Tech Support personnel at AutoGenomics for all repairs and major maintenance work as needed.

15. OPERATING PROCEDURE

15.1 Preparing the Instrument to Run:

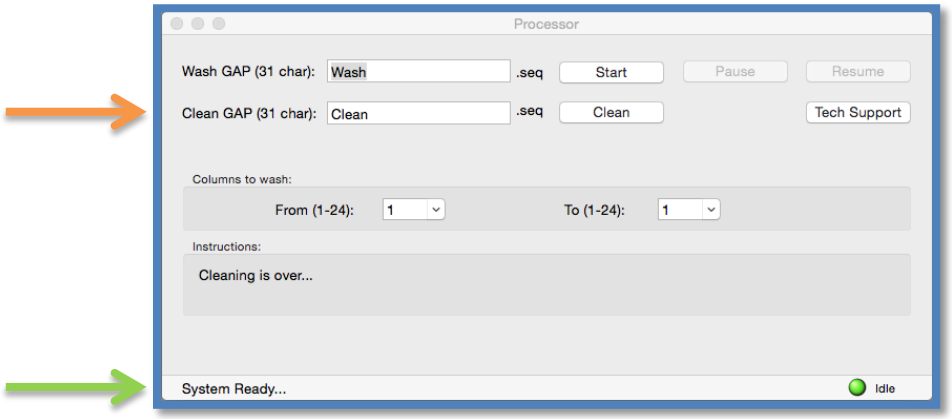
15.1.1 Prior to starting the INFINITI® PROCESSOR, check the wash buffer solution and assure that the buffer level is above the minimum mark. Add buffer if needed (see 16.2). Make sure that the small vent cap on the Buffer bottle is loose.

15.1.2 Check that the waste tank is not full (see Waste Disposal section).

15.1.3 Turn on the computer by pushing the round button on the right side of the instrument and wait for the operating system to load.

15.1.4 Turn on the INFINITI® PROCESSOR by pushing the power switch located on the right side of the Instrument Panel.

15.1.5 On the desktop screen click the "Processor" icon located on the dock. Wait until the program loads and indicates "System Ready".



15.1.6 Click the "Clean" button to prime the dispense tips and purge the lines of any air bubbles or salt left in the lines. Repeat the cleaning by pressing the button one more time.

15.1.7 The instrument is now ready to use.

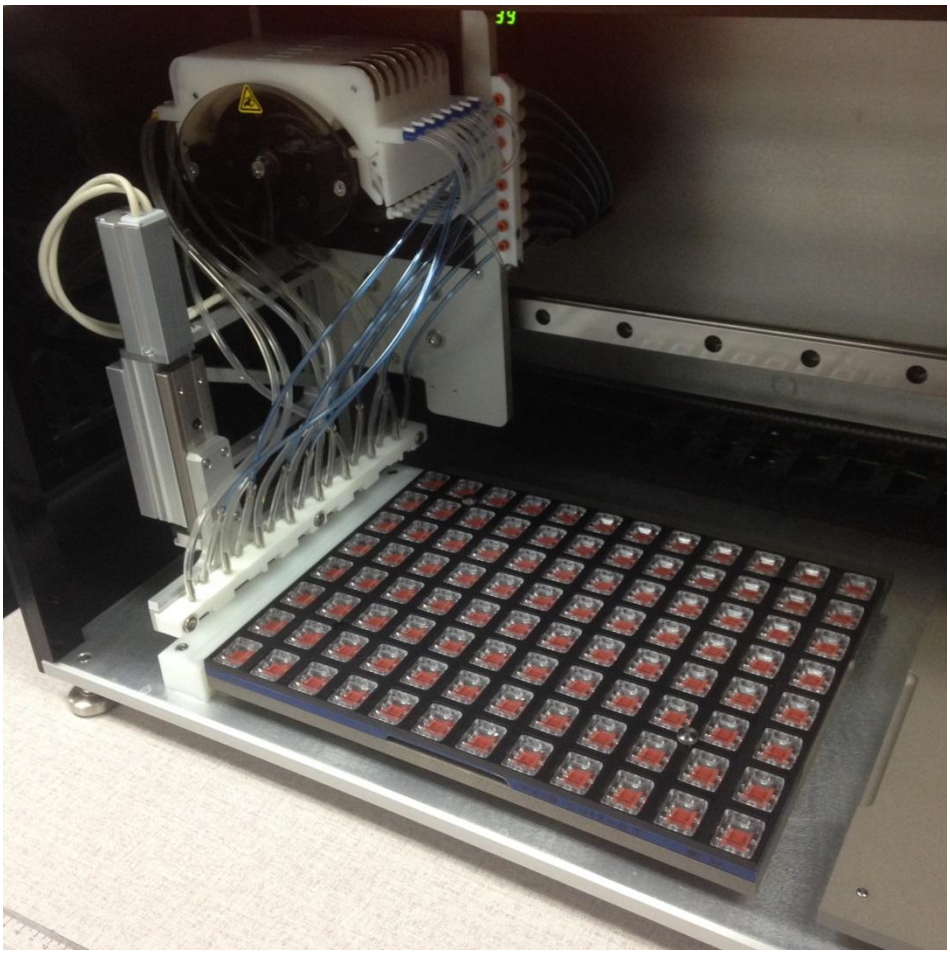
15.2 Loading Chip Plates

15.2.1 The microarray chips should have completed the hybridization process and have been incubated at 40°C for 90 min on board the INFINITI® INCUBATOR to be ready for washing.

15.2.2 Carefully remove the silicon Chip Plate mat from the Chip Plate.

15.2.3 Manually open the front cover of the instrument.

15.2.4 Place the Chip Plate with chips containing samples in the left deck position and orient the Chip Plate such that the singular groove along the length of the Chip Plate is facing the operator (chip position A1 in the back left of the instrument). If loading a second tray it should be placed on the right deck position.



15.2.5 Check to see that both chip plates are sitting completely flat on the heating surfaces using the aligning dowel pins.

15.2.6 Each chip plate should be loaded with microarray chips in proper orientation directed by the small grooves in each slot.

15.2.7 Each column to be washed **must have all 8 vertical slots filled with chips**. Any empty slots will cause buffer to be dispensed onto the tray. Use dummy or used chips in the place of the assay chips to fill any empty slots in the columns being used.

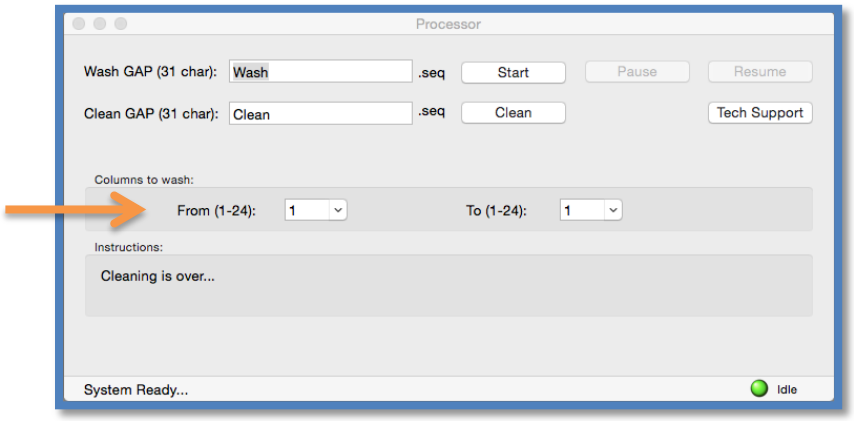
15.2.8 Mark the dummy chips with permanent marker to distinguish the dummies from the assay chips. Use a black non-fluorescent Sharpie or other marking pen. A**void using fluorescent or reflective ink, as this will interfere with the fluorescence coming from the arrays.**

15.2.9 Once the chip plates are loaded, close the INFINITI® PROCESSOR front cover.

15.3 Starting the Wash Program

15.3.1 Close the INFINITI® PROCESSOR front cover before washing the plate(s).

15.3.2 The INFINITI® PROCESSOR can process two chip plates of 12 columns each. **Before performing the wash cycle, it is imperative that the columns to be washed are programmed in "Columns to wash" section.** Set the first column to be washed on the first drop down menu labelled "From (1-24)". Then set the last column to be washed on the second drop down menu "To (1-24)".



15.3.3 Any consecutive set of columns may be washed simultaneously, starting by setting the "From (1-24)" menu to the first column to be washed (even if the columns are spread over two plates located on various processor decks). The columns to be washed must be properly indicated in the washer menus described above before initiating the wash cycle.

Note: "Columns" as mentioned in the interface refers to columns as referenced in Table 1 (Chip Layout Matrix).

Table 1 Chip Layout Matrix.

	1 column	2 column	3 column	4 column	5 column	6 column	7 column	8 column	9 column	10 column	11 column	12 column
A	Chip1	Chip9	Chip17	Chip25	Chip33	Chip41	Chip49	Chip57	Chip65	Chip73	Chip81	Chip89
B	Chip2	Chip10	Chip18	Chip26	Chip34	Chip42	Chip50	Chip58	Chip66	Chip74	Chip82	Chip90
C	Chip3	Chip11	Chip19	Chip27	Chip35	Chip43	Chip51	Chip59	Chip67	Chip75	Chip83	Chip91
D	Chip4	Chip12	Chip20	Chip28	Chip36	Chip44	Chip52	Chip60	Chip68	Chip76	Chip84	Chip92
E	Chip5	Chip13	Chip21	Chip29	Chip37	Chip45	Chip53	Chip61	Chip69	Chip77	Chip85	Chip93
F	Chip6	Chip14	Chip22	Chip30	Chip38	Chip46	Chip54	Chip62	Chip70	Chip78	Chip86	Chip94
G	Chip7	Chip15	Chip23	Chip31	Chip39	Chip47	Chip55	Chip63	Chip71	Chip79	Chip87	Chip95
H	Chip8	Chip16	Chip24	Chip32	Chip40	Chip48	Chip56	Chip64	Chip72	Chip80	Chip88	Chip96

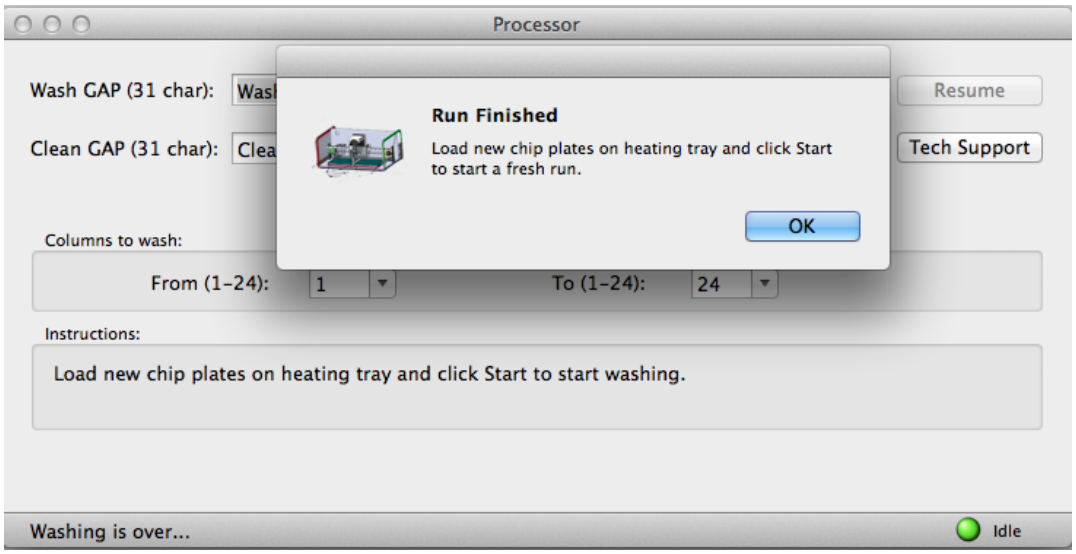
15.3.4 Click "Start" to begin the washing process.

15.3.5 The program will run a total of 5 wash cycles with at least 2 minutes between the start of each cycle. Processing is completed 5 minutes after the instrument stops moving to allow a final drying time.

15.4 Completion of Run

15.4.1 Assure the instrument has completely stopped moving.

15.4.2 A text box indicates that the wash cycle is completed. An "idle icon" on the bottom right of a program, also indicates the completion of a run.



15.4.3 Manually open the front cover and remove the chip plate(s). Check that the chips are uniformly dry.

15.4.4 Close front cover.

15.4.5 The instrument can now be used again to process another batch of Chip Trays.

15.4.6 Note that if a run needs to be stopped or aborted, the entire system must be POWERED DOWN before restarting (see section 15.5) and system initiation must be repeated (see section 15.1).

15.4.7 The processor can be left on when not in use. If it is left on, it is a good idea to run at least two "Clean" cycles at least once each day at start-up as part of the maintenance procedure described in 16.1. Then, just prior to washing the chip plates, run two "Clean" cycles again.

15.5 Power down the INFINITI ® PROCESSOR.

15.5.1 Close the processor window. A dialogue box will ask if you want to exit the processor now. Click on Yes.

15.5.2 Then click on the Apple logo in the upper left corner of the Mac OS X menu bar on the top of the screen. Select "Shut down" option in the drop down menu and follow the instructions on the screen.

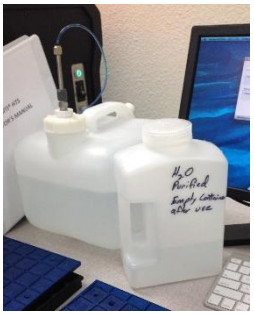
15.5.3 Once the Mac Operating System has shut down, turn off the processor by toggling the black power switch located on the right hand side of the instrument to the off position.

16. OPERATOR MAINTENANCE PROCEDURES

16.1 Weekly Maintenance

16.1.1 Half fill an empty 2L water bottle with purified water. In this case, purified water means clean, fresh water with low concentration of dissolved solids. Filtered, deionized or distilled water are acceptable.

16.1.2 With the Processor software running, remove the intake cap off the buffer tank, and place the intake tube into the rinse bottle, prepared as described above.



16.1.3 Run the clean routine in the Processor software three times by clicking the "Clean" button.

16.1.4 Replace the intake cap on the buffer tank and empty the rinse bottle before leaving the instrument.

16.1.5 Before using the processor to wash plates again, run the clean routine in the Processor software three times by clicking on the "Clean" button. In this instance the water in the lines will be replaced by the wash buffer.

16.2 Refilling Buffer Solution Tanks

16.2.1 Unscrew the cap of the 10 L buffer tank and remove the cap with tube from the tank.

16.2.2 Rest cap and tube on a clean, lint-free towel.

16.2.3 Refill the 10 L buffer tank with INFINITI ® wash buffer (Catalog # 12-0380-00) up to, but not over the "MAX" fill line on tank.

16.2.4 Replace cap on the buffer tank and tighten firmly by hand. The small vent cap on the side spout of the buffer tank should be loose or the tank could implode.

16.3 Priming Dispense Tips

16.3.1 Click the "Clean" button and allow the lines to fill and purge out any air bubbles (see section 15.1.6). Repeat at least once.

16.4 Waste Disposal

16.4.1 Each full run of the INFINITI PROCESSOR will generate approximately 1 L of liquid waste, which is stored in the 10 L waste carboy.

16.4.2 After approximately 8 full runs the waste carboy must be emptied and cleaned:

Rinse the carboy with 10% bleach (9 parts water to 1 part laboratory bleach/sodium hypochlorite solution).

Note: Hypochlorite solutions are classified as irritants and corrosive. Precautions should be taken when using hypochlorite products; read labels carefully, adhering to cautionary warnings and following usage directions.

16.4.3 Swirl/mix and let sit for 2 minutes.

16.4.4 Dispose of the liquid waste into an appropriate liquid waste sink.

17. PREVENTIVE MAINTENANCE

Preventive Maintenance, including instrument calibration, is due once per year and is to be performed ONLY by AutoGenomics personnel.

INFINITI® ACE Reader

18. INTRODUCTION

As the final component of the AutoGenomics high throughput assay workflow, it is necessary to achieve high resolution imaging to enable the proper analysis of BioFilmChips®. The INFINITI® ACE Reader allows for automated imaging and data processing of up to 96 BioFilmChip® microarrays.

19. INTENDED USE

The INFINITI® ACE Reader is designed to automate reading and reporting of any microarrays used in assays from AutoGenomics. It is not intended for use with any programs other than those specified by AutoGenomics.

20. SAFETY

Only trained operators are to use this instrument. Do not open the instrument during the middle of a run as it will not only compromise the results of the run but endanger the operator through exposure to the fast moving optical mechanism. Use caution when working on or around the instrument.

21. INSTALLATION REQUIREMENTS

21.1 The INFINITI® ACE Reader has an electrical requirement of 120VAC 15 AMP. It is recommended to be connected to a power isolated circuit or UPS (uninterruptable power supply).

21.2 The INFINITI® ACE Reader is photo-sensitive during its operation. Avoid exposing the unit or the Chip Plate to moving or modulating sources of light while it is running; including but not limited to stray sunlight and abnormally oscillating fluorescent lights.

Note: The instrument must only be operated with its covers CLOSED.

21.3 The INFINITI® ACE Reader should be placed on a sturdy, heavy table. Do not place any weight on top of or leaning against the instrument, from any of its four sides. The instrument should not be leaning against any other object. The instrument should not be placed on the same table with devices that tend to vibrate, e.g. centrifuges.

22. OPERATING PROCEDURE

22.1 Power on the INFINITI® ACE Reader.

22.1.1 Lift the front cover of the instrument.

22.1.2 Both the silver button which initiates the computer and the black power switch for the ACE, are located inside of the instrument, on the right hand side.

22.1.3 Turn on the computer by pressing the silver button and wait for the operating system to load.

22.1.4 Once the Mac OS X operating system has booted up completely, press the black power switch for the ACE to initiate its operation.

22.1.5 Only then, click on the "AceQMatic" program in the dock at the bottom of the screen (see below).

22.1.6 It is critical to click the "AceQMatic" program prior to opening the results module.

22.1.7 The program will take a few minutes to initialize hardware communications. Once initialization is complete, the message "System Ready" will appear in the message bar at the bottom of the window. Only access the Results files once initialization of the "AceQMatic" program is complete.

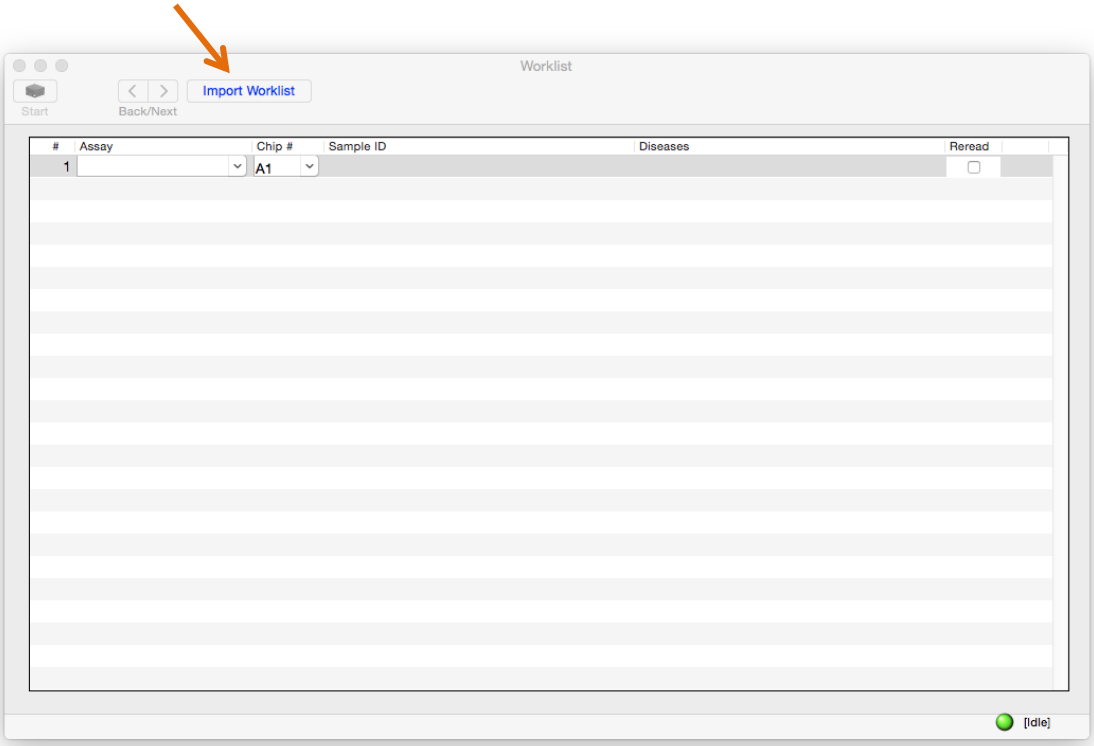
.

22.2 Preparing a Run

22.2.1 Once the program has completed initialization, start the run process by clicking on the "Start" button.

22.2.2 The worklist Dropdown menu will appear in a new window with an empty worklist.

22.2.3 The worklist can be submitted either from LIS system or from the ACE screen. Click on the "Import Worklist" button to populate the worklist with the existing *worklist.txt* in the LIS Path folder on the desktop, or populate the dropdown menus using the manual sample editor as described in 22.4.



22.3 Generating a Worklist using text editor

22.3.1 In Finder click "Go" and open Applications folder on ACE computer. Find in the list of applications and open the TextEdit program.

22.3.2 In the blank TextEdit sheet on the first line, enter the sample name (sample ID). A maximum of 31 characters are allowed for the sample name. Allowable characters are alphanumeric, - (dash), and _ (underscore).

22.3.3 Press Tab on the keyboard then enter the Chip Number (the position of chip on the 12 x 8 Chip Plate as detailed in Table 2 on the next page).

Table 2: Chip Plate Map

	1	2	3	4	5	6	7	8	9	10	11	12
A	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11	A12
B	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12
C	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12
D	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12
E	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12
F	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
G	G1	G2	G3	G4	G5	G6	G7	G8	G9	G10	G11	G12
H	H1	H2	H3	H4	H5	H6	H7	H8	H9	H10	H11	H12

22.3.4 Hit Tab on the keyboard and enter the Assay name. Refer to assay application notes or the manual sample editor dropdown for the proper syntax to use in this field. The correct assay names can also be found in AutoGenomics list of assays.

22.3.5 Hit "Return" and repeat the above steps for each sample to be entered (and read). Save the completed TextEdit file as "*worklist.txt".* An example of a simple worklist for 2D6BC is shown below.

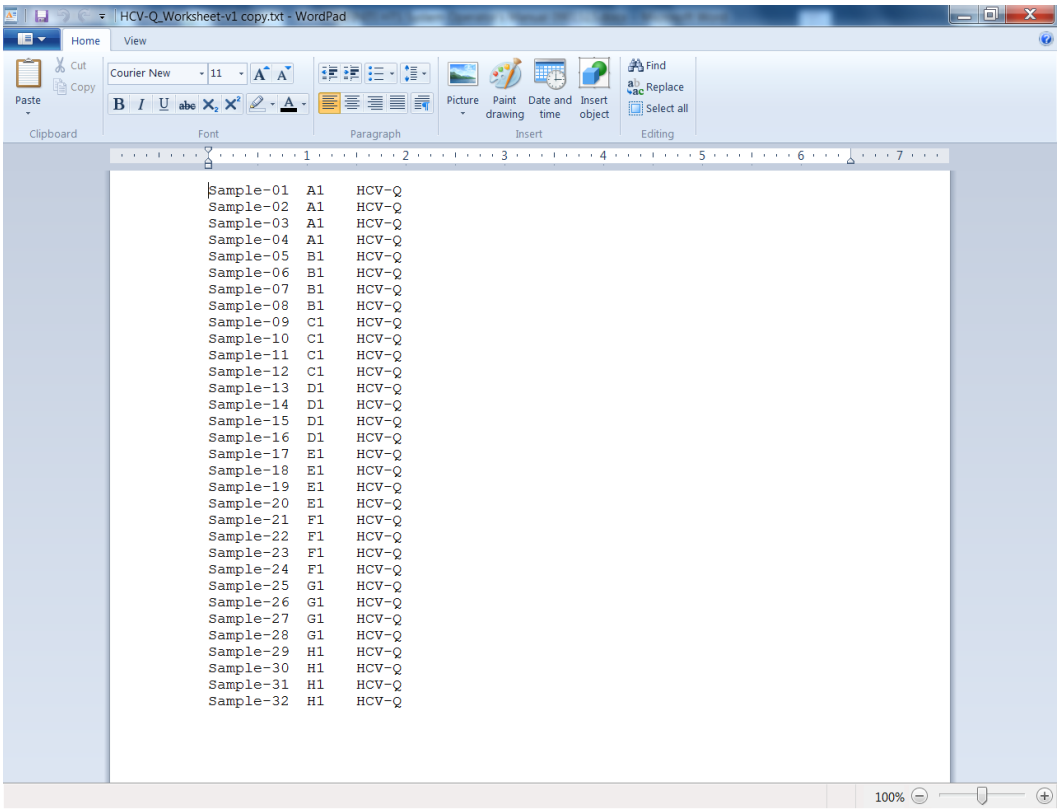
```
Sample_1          A1    CYP2D6BC
Sample_2          B1    CYP2D6BC
Sample_3          C1    CYP2D6BC
Sample_4          D1    CYP2D6BC
Sample_5          E1    CYP2D6BC
Sample_6          F1    CYP2D6BC
Control_12961     G1    CYP2D6BC
Control_15269     H1    CYP2D6BC
Sample_7          A2    CYP2D6BC
Sample_8          B2    CYP2D6BC
Sample_9          C2    CYP2D6BC
Sample_10         D2    CYP2D6BC
TE                E2    CYP2D6BC
H2O               F2    CYP2D6BC
Control_17138     G2    CYP2D6BC
Control_17114     H2    CYP2D6BC
```

22.3.6 Multi-sample assays (Duplex/Quad/Hex/Octa) require items to be submitted in multiples of the number of samples per microarray. Multiple entries must be submitted for each chip corresponding to the number of samples present on the chip (for Duplex assays, the number of worklist items must be entered in multiples

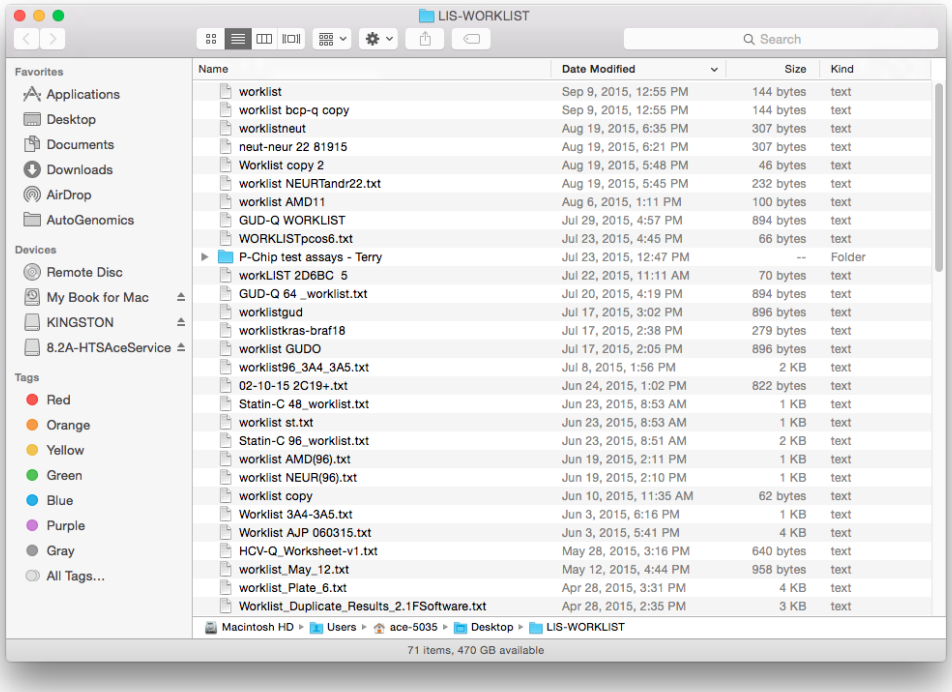
of 2, Quad assay in multiples of 4, etc.). This will produce a separate result for each sample.

22.3.7 File *worklist.txt* can contain as many as 96 different single assays in a single worklist. Also there can be any combination of Single, Duplex, Quad, Hex and Octa assays in a single plate. The maximum is up to 768 samples in *worklist.txt*, when running 96 Octa chips. For single assays, the samples can be in placed in any order. For Multi-sample assays, all samples for one chip must be placed in a worklist together in the correct order.

22.3.8 Shown below is an example of a worklist for the Quad assay, HCV-Q in which 4 samples are loaded per chip.



22.3.9 Once a worklist is completed, save the file "*worklist.txt*" to the LIS folder, which is located on the desktop. The name of this folder may vary, e.g. LIS-Worklist. If a *worklist.txt* file is already present in that folder, rename the pre-existing file (e.g. by using a descriptive name) to retrieve this file later, if needed, or move it to another folder. There cannot be two *worklist.txt* files in the same folder.



22.3.10 Saving a copy of the new worklist with a descriptive name is also recommended, because this saved worklist can be copied and used as a template to generate a new worklist, which is modified for specific plate arrangements. In general, modifications of saved worklist files can be implemented using any simple text editor software, e.g. "TextEdit".

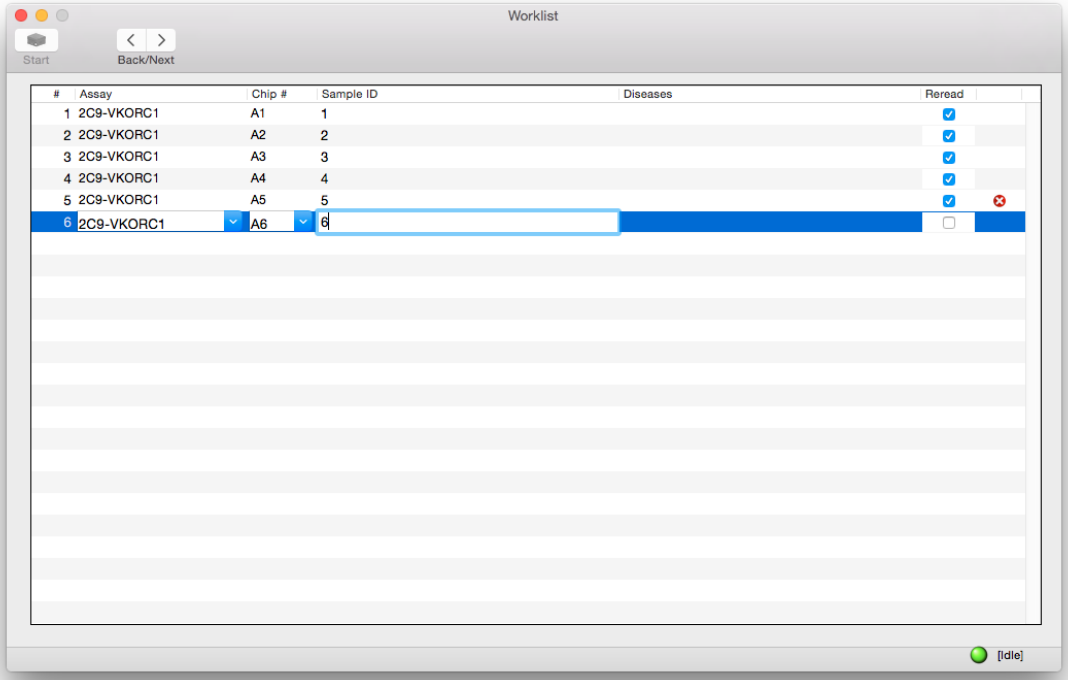
22.3.11 If multiple assays with the same samples are to be run, it may be easier to generate a worklist on a separate computer. The worklist file can be easily modified if sample order differs slightly or additional samples are to be run. Such a file can be created using e.g. Microsoft Excel and a copy can be saved to a flash drive as a tab-delimited text file. Transfer the file from the flash drive to the INFINITI® ACE computer, and follow the directions in 22.3.9.

22.4 Generating Worklists using the Dropdown menu

22.4.1 The dropdown menu appears when one clicks the Start button at the beginning of a run.

22.4.2 Select the assay to be used for each sample and enter the sample position and name in appropriate box on the dropdown menu). The entry of the position can be expedited by clicking on the particular letter of the Alphabet on the keyboard corresponding to the sample position (the next alphanumeric character will be assigned automatically) i.e., if one clicks A on the first sample using the keyboard sample A1 will be entered. If the second sample is in position B1, clicking on the

keyboard will cause B1 to be entered. If an A1 sample had been previously entered using the keyboard, clicking on A again would generate a sample where the A2 position is indicated.



22.5 Loading Chip plates

22.5.1 Prior to loading a Chip Plate into the INFINITI® ACE Reader, it should already have completed the washing step on the INFINITI® PROCESSOR).

22.5.2 Refer to "Assembling Chip Plates" part of this manual (1) or the assay application notes for directions on assembling the Chip Plate.

22.5.3 Lift up the front cover of the INFINITI® ACE.

Place the processed chip plate into the square slot in the base deck of the instrument, with row A at the back of the instrument and row H in the front. Orient the Chip Plate such that the singular groove along the length of the Chip Plate is facing the operator.

Note: Avoid leaving processed Chip Plates with microarrays in direct light. If processing in the ACE is delayed, cover the Chip Plate with a clean silicon mat or aluminum foil.

22.6 Starting the Run

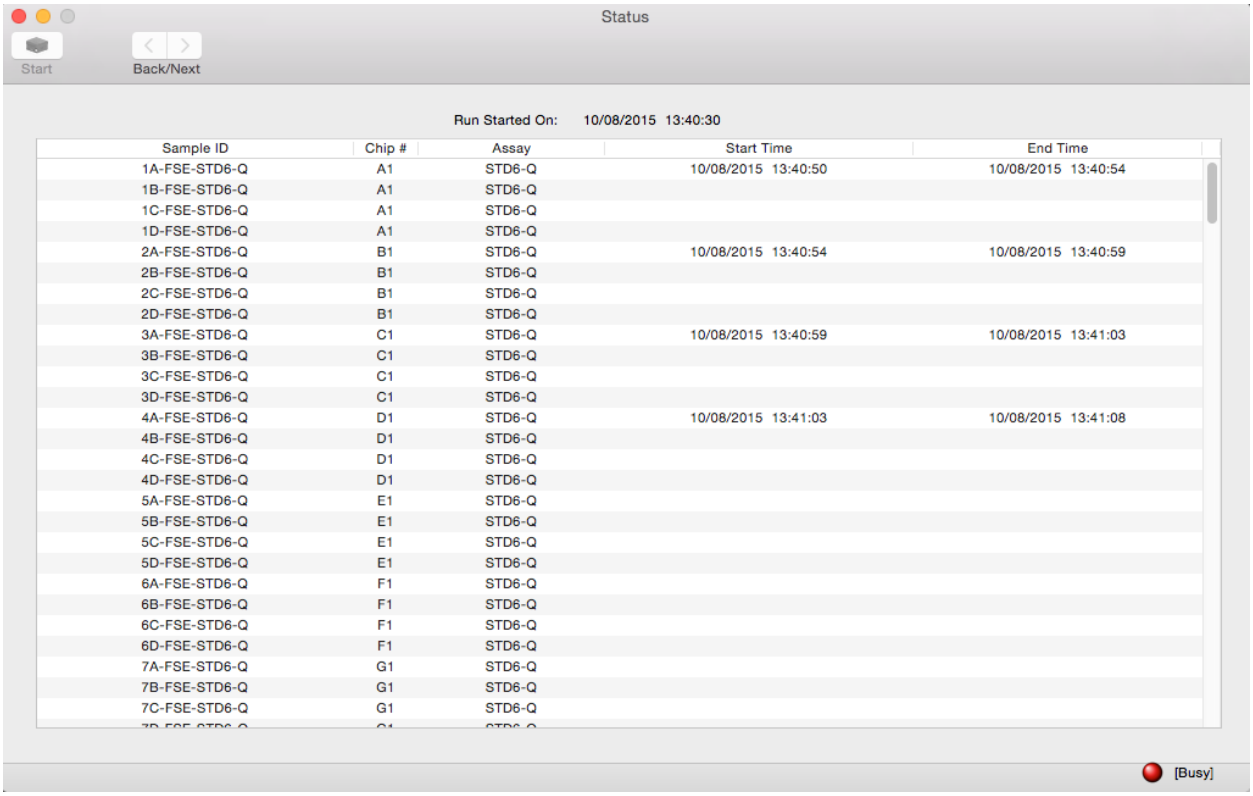
22.6.1 Once the chip plate has been loaded, close the INFINITI® ACE Reader front cover.

22.6.2 Import the worklist by clicking on the Worklist button.

22.6.3 If there are any erroneous items in LIS worklist, those are displayed in red color. On selecting the erroneous record, the related error is displayed in the status bar in red color. All errors in worklist.txt need to be corrected before the worklist can be submitted for processing. For genotyping assays with multiple disorders included in the panel, at least one disorder type needs to be selected per record. If no disease is selected, the record will be treated as erroneous.

22.6.4 Once the worklist is accepted, click the "Next" button to begin reading the microarrays. Processing starts and system status changes to "Busy". While the system is in process, operator can see the progress and status of submitted tests. The status screen displays the current status of submitted tests. The worklist be replaced with a progress window, showing which microarrays have been read. An example of the progress report is shown below:

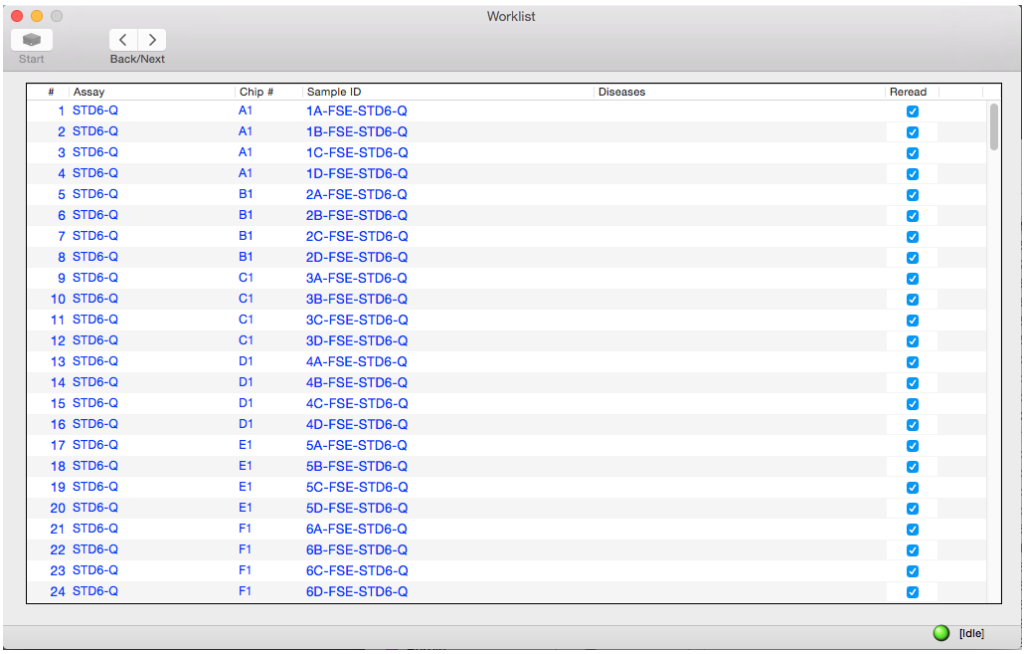
Note: The entire run should take less than 20 minutes. If the instrument does not respond after that time, shut down the Mac OS X and power down the instrument (see section 22.8.3). Wait 20 seconds then repeat the operating procedure from step 21.2



Sample ID	Chip #	Assay	Start Time	End Time
1A-FSE-STD6-Q	A1	STD6-Q	10/08/2015 13:40:50	10/08/2015 13:40:54
1B-FSE-STD6-Q	A1	STD6-Q		
1C-FSE-STD6-Q	A1	STD6-Q		
1D-FSE-STD6-Q	A1	STD6-Q		
2A-FSE-STD6-Q	B1	STD6-Q	10/08/2015 13:40:54	10/08/2015 13:40:59
2B-FSE-STD6-Q	B1	STD6-Q		
2C-FSE-STD6-Q	B1	STD6-Q		
2D-FSE-STD6-Q	B1	STD6-Q		
3A-FSE-STD6-Q	C1	STD6-Q	10/08/2015 13:40:59	10/08/2015 13:41:03
3B-FSE-STD6-Q	C1	STD6-Q		
3C-FSE-STD6-Q	C1	STD6-Q		
3D-FSE-STD6-Q	C1	STD6-Q		
4A-FSE-STD6-Q	D1	STD6-Q	10/08/2015 13:41:03	10/08/2015 13:41:08
4B-FSE-STD6-Q	D1	STD6-Q		
4C-FSE-STD6-Q	D1	STD6-Q		
4D-FSE-STD6-Q	D1	STD6-Q		
5A-FSE-STD6-Q	E1	STD6-Q		
5B-FSE-STD6-Q	E1	STD6-Q		
5C-FSE-STD6-Q	E1	STD6-Q		
5D-FSE-STD6-Q	E1	STD6-Q		
6A-FSE-STD6-Q	F1	STD6-Q		
6B-FSE-STD6-Q	F1	STD6-Q		
6C-FSE-STD6-Q	F1	STD6-Q		
6D-FSE-STD6-Q	F1	STD6-Q		
7A-FSE-STD6-Q	G1	STD6-Q		
7B-FSE-STD6-Q	G1	STD6-Q		
7C-FSE-STD6-Q	G1	STD6-Q		

22.7 Run completion

22.7.1 Assure the instrument has completely stopped moving. Look for an "Idle" icon on the bottom right of the program screen, which indicates the completion of a run. After the system becomes idle, submitted worklist is displayed. If there are any erroneous chips, then items for those chips are shown checked.



#	Assay	Chip #	Sample ID	Diseases	Reread
1	STD6-Q	A1	1A-FSE-STD6-Q		☑
2	STD6-Q	A1	1B-FSE-STD6-Q		☑
3	STD6-Q	A1	1C-FSE-STD6-Q		☑
4	STD6-Q	A1	1D-FSE-STD6-Q		☑
5	STD6-Q	B1	2A-FSE-STD6-Q		☑
6	STD6-Q	B1	2B-FSE-STD6-Q		☑
7	STD6-Q	B1	2C-FSE-STD6-Q		☑
8	STD6-Q	B1	2D-FSE-STD6-Q		☑
9	STD6-Q	C1	3A-FSE-STD6-Q		☑
10	STD6-Q	C1	3B-FSE-STD6-Q		☑
11	STD6-Q	C1	3C-FSE-STD6-Q		☑
12	STD6-Q	C1	3D-FSE-STD6-Q		☑
13	STD6-Q	D1	4A-FSE-STD6-Q		☑
14	STD6-Q	D1	4B-FSE-STD6-Q		☑
15	STD6-Q	D1	4C-FSE-STD6-Q		☑
16	STD6-Q	D1	4D-FSE-STD6-Q		☑
17	STD6-Q	E1	5A-FSE-STD6-Q		☑
18	STD6-Q	E1	5B-FSE-STD6-Q		☑
19	STD6-Q	E1	5C-FSE-STD6-Q		☑
20	STD6-Q	E1	5D-FSE-STD6-Q		☑
21	STD6-Q	F1	6A-FSE-STD6-Q		☑
22	STD6-Q	F1	6B-FSE-STD6-Q		☑
23	STD6-Q	F1	6C-FSE-STD6-Q		☑
24	STD6-Q	F1	6D-FSE-STD6-Q		☑

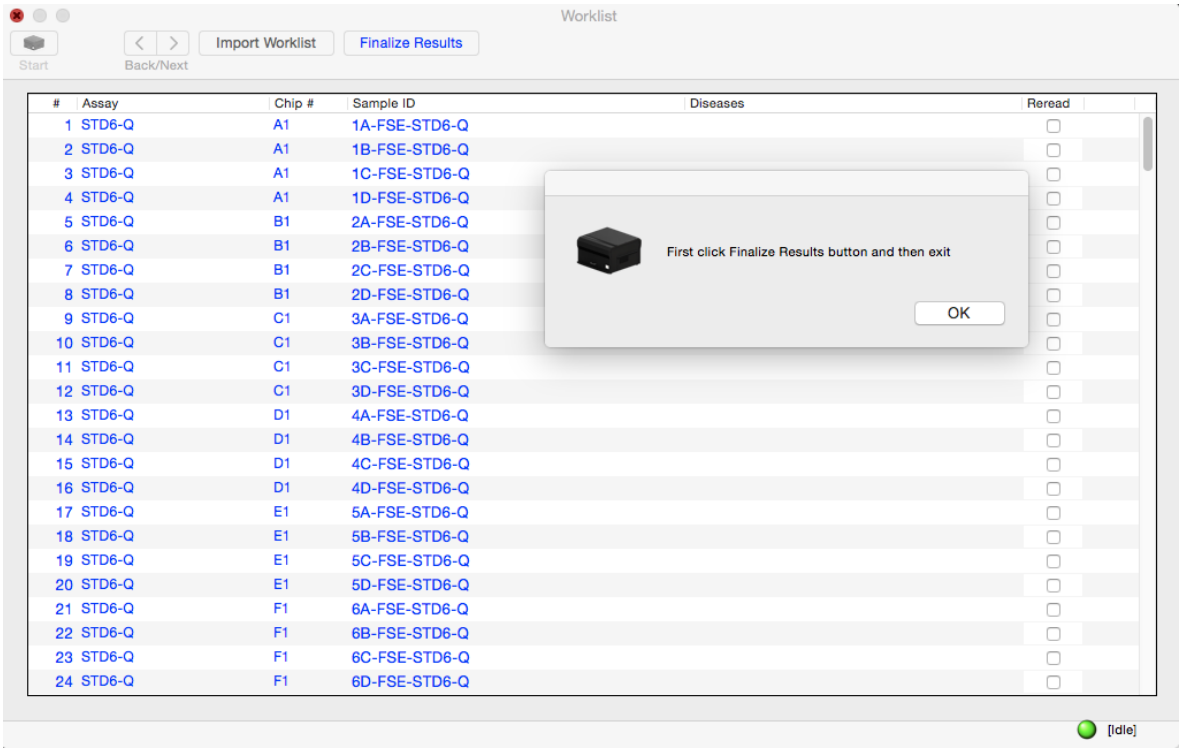
22.8 After completing the ACE run there are three options:

22.8.1 Chips can be reread. To reread the chips, select or deselect any of the available items in the worklist. For multi-sample assays, only the first sample needs to be selected, others will be selected automatically. Click "Next" to reread the chips.

22.8.2 Finalize the results. Click on "Finalize Results" to end the reread session and generate a LIS Report. To read new Worklist, click either "Start" or "Import Worklist" buttons. To change the chip plate, open front cover, replace or remove the chip plate and close front cover.

22.8.3 Power down the INFINITI ® ACE Reader. Finalize Results as described in 22.8.2. Exit from AceQMatic by clicking red "X" button on the top left corner of the worklist window. Follow the information displayed in the window message box to exit the program. Close all active windows (including AceQMatic and Results programs) and click on the Apple logo in the upper left corner of the Mac OS X menu bar on the top of the screen. Select "Shut down" option in the drop down menu. Once the Mac OS X has shut down, lift the front cover of the instrument and turn off the instrument by toggling the black power switch located on the right hand side of the inside of the instrument to the off position. Note, if one unintentionally exits from the ACE

operating system while using the instrument, it is necessary to power down completely as described above and restart as described in Section 22.1.



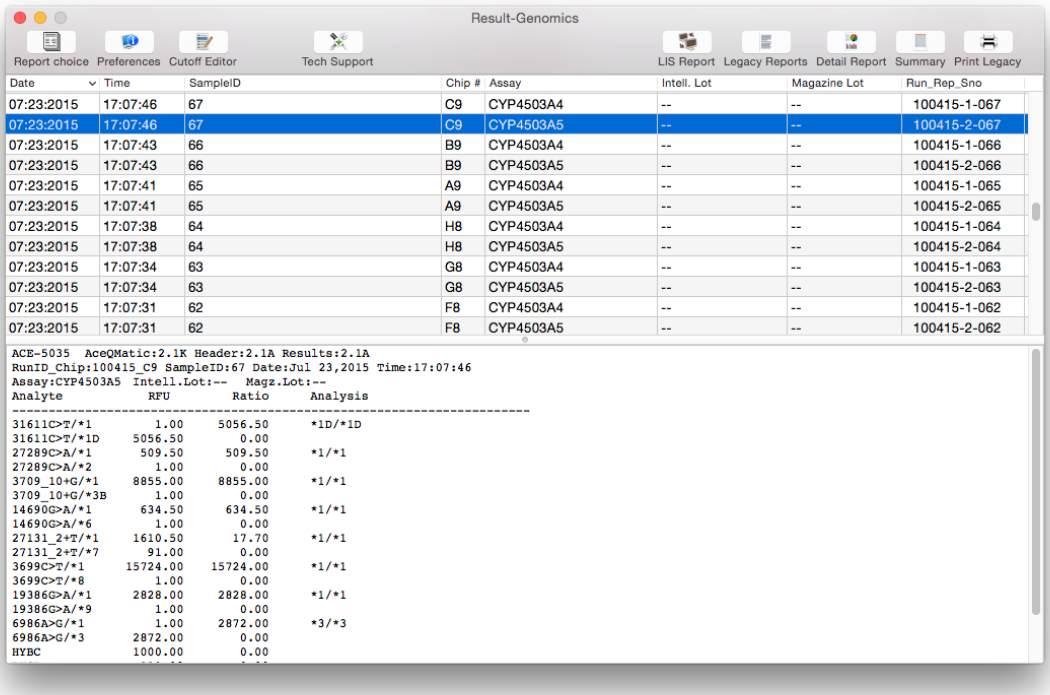
#	Assay	Chip #	Sample ID	Diseases	Reread
1	STD6-Q	A1	1A-FSE-STD6-Q		
2	STD6-Q	A1	1B-FSE-STD6-Q		
3	STD6-Q	A1	1C-FSE-STD6-Q		
4	STD6-Q	A1	1D-FSE-STD6-Q		
5	STD6-Q	B1	2A-FSE-STD6-Q		
6	STD6-Q	B1	2B-FSE-STD6-Q		
7	STD6-Q	B1	2C-FSE-STD6-Q		
8	STD6-Q	B1	2D-FSE-STD6-Q		
9	STD6-Q	C1	3A-FSE-STD6-Q		
10	STD6-Q	C1	3B-FSE-STD6-Q		
11	STD6-Q	C1	3C-FSE-STD6-Q		
12	STD6-Q	C1	3D-FSE-STD6-Q		
13	STD6-Q	D1	4A-FSE-STD6-Q		
14	STD6-Q	D1	4B-FSE-STD6-Q		
15	STD6-Q	D1	4C-FSE-STD6-Q		
16	STD6-Q	D1	4D-FSE-STD6-Q		
17	STD6-Q	E1	5A-FSE-STD6-Q		
18	STD6-Q	E1	5B-FSE-STD6-Q		
19	STD6-Q	E1	5C-FSE-STD6-Q		
20	STD6-Q	E1	5D-FSE-STD6-Q		
21	STD6-Q	F1	6A-FSE-STD6-Q		
22	STD6-Q	F1	6B-FSE-STD6-Q		
23	STD6-Q	F1	6C-FSE-STD6-Q		
24	STD6-Q	F1	6D-FSE-STD6-Q		

23. RESULTS RETRIEVAL

23.1 With the Mac OS X system running and the "AceQMatic" program initiated, click on the "Results" program in the dock at the bottom of the screen (the microarray icon).

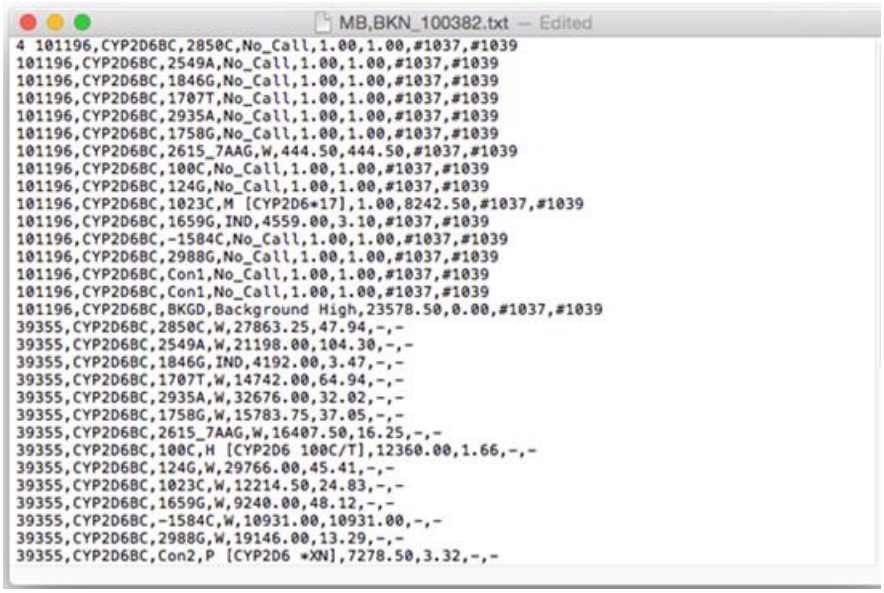
23.2 The new window will display a list of all microarrays which have been read and analyzed by the instrument.

23.3 To view each result, click on the specific entry in the window and the results will be displayed in the bottom portion of the screen.



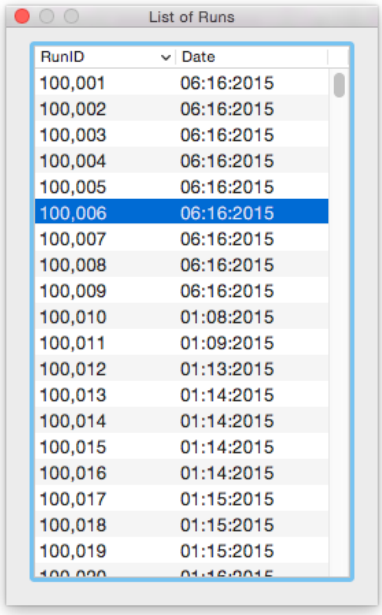
23.4 Click on the desired export option to generate a.txt or.pdf file containing the result(s) selected.

23.5 Clicking on the LIS Button will move the already generated LIS report to the LIS folder. Shown below is a **LIS report**.

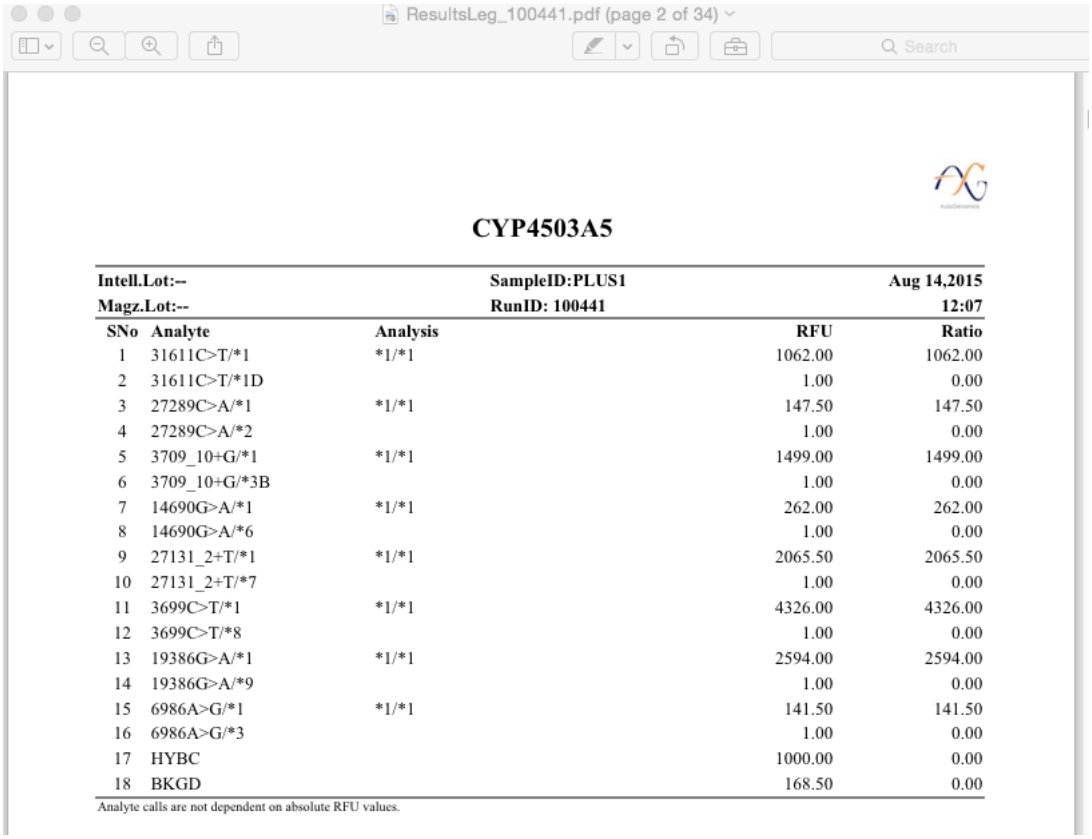


23.6 Legacy reports can be viewed by clicking on the Legacy report icon. The acquisition of the Legacy report requires two steps. First, a window will appear with a list of the Legacy

reports. Select the Legacy report based on the run number and the file will open. All samples in that run will be visible in the report.



23.7 Here is an example of a page from a **Legacy report** for the 3A5 assay:



CYP4503A5

Intell.Lot:--	**SampleID:PLUS1**	**Aug 14,2015**
Magz.Lot:--	**RunID: 100441**	**12:07**

SNo	Analyte	Analysis	RFU	Ratio
1	31611C>T/*1	*1/*1	1062.00	1062.00
2	31611C>T/*1D		1.00	0.00
3	27289C>A/*1	*1/*1	147.50	147.50
4	27289C>A/*2		1.00	0.00
5	3709_10+G/*1	*1/*1	1499.00	1499.00
6	3709_10+G/*3B		1.00	0.00
7	14690G>A/*1	*1/*1	262.00	262.00
8	14690G>A/*6		1.00	0.00
9	27131_2+T/*1	*1/*1	2065.50	2065.50
10	27131_2+T/*7		1.00	0.00
11	3699C>T/*1	*1/*1	4326.00	4326.00
12	3699C>T/*8		1.00	0.00
13	19386G>A/*1	*1/*1	2594.00	2594.00
14	19386G>A/*9		1.00	0.00
15	6986A>G/*1	*1/*1	141.50	141.50
16	6986A>G/*3		1.00	0.00
17	HYBC		1000.00	0.00
18	BKGD		168.50	0.00

Analyte calls are not dependent on absolute RFU values.

23.8 Highlight the samples and click on the **Detail Report** Icon to generate the results in the form of a text file.

ResultsDet.txt

```
ACE-5035  AceQMatic:2.1M HeaderPkg:2.1G  Results:2.1D
RunID_Chip:100510_A8 SampleID:1d Date:Sep 9,2015 Time:13:22:59
Assay:BCP-Q 2.1B Intell.Lot:-- Magz.Lot:--
Analyte                RFU                Ratio          Analysis
--------------------------------------------------------------------------
185AG            8940.00         8940.00          W
185delAG            1.00            0.00
5382ref          9239.50         9239.50          W
5382insC            1.00            0.00
6174T            1607.00            2.46          H BRCA2 [6174delT]
6174delT         3959.00            0.00
BKGD              340.00            0.00
--------------------------------------------------------------------------

RunID_Chip:100510_A8 SampleID:1c Date:Sep 9,2015 Time:13:22:59
Assay:BCP-Q 2.1B Intell.Lot:-- Magz.Lot:--
Analyte                RFU                Ratio          Analysis
--------------------------------------------------------------------------
185AG           11485.50        11485.50          W
185delAG            1.00            0.00
5382ref         11428.00        11428.00          W
5382insC            1.00            0.00
6174T            2659.00            1.80          H BRCA2 [6174delT]
6174delT         4790.50            0.00
BKGD              340.00            0.00
--------------------------------------------------------------------------

RunID_Chip:100510_A8 SampleID:1b Date:Sep 9,2015 Time:13:22:59
Assay:BCP-Q 2.1B Intell.Lot:-- Magz.Lot:--
Analyte                RFU                Ratio          Analysis
--------------------------------------------------------------------------
185AG            8946.50         8946.50          W
185delAG            1.00            0.00
5382ref          9895.50         9895.50          W
5382insC            1.00            0.00
6174T            2157.50            1.78          H BRCA2 [6174delT]
6174delT         3849.50            0.00
BKGD              340.00            0.00
--------------------------------------------------------------------------
```

23.9 If running a disease detection assay, click on the Summary report Icon to generate a Summary of the results in the form of a text file.

Summary.txt

```
Date & Time:                Friday, October 9, 2015 15:21, Run_ID:100538, Positive samples
Instrument ID:              ACE-5035
Software Revision:          Q:2.1M  P:2.1G  H:2.1B  R:2.1D
Assay:                      HCV-Q
IntelliPack Lot:            --    Expiration: 00/00/0000
Magazine Lot:               --
-------------------------------------------------------------------------------------------
Chip#   Sample ID           Positive Analytes                       IC   Status

A1      SA1-4               HCV,Genotype-1,Subtype-1b               Pos  -
-------------------------------------------------------------------------------------------
```

23.10 Files may be downloaded to a flash drive, if desired. Click on "Save as" or "Duplicate" and save the selected files to the flash drive.

23.11 When the run is completed, always click on the Techsupport Icon.

24. OPERATOR MAINTENANCE PROCEDURES

24.1 Daily (when in use) using a lint free cloth, wipe down the inside base of INFINITI® ACE thoroughly, removing any dust/particulates.

24.2 Use care not to touch the lens or camera during cleaning.

24.3 Ensure the INFINITI® ACE covers are properly closed during system operation.

25. PREVENTIVE MAINTENANCE

25.1 Preventive maintenance which includes instrument calibration is due every year, and is to be performed ONLY by AutoGenomics personnel.