



Augury User Manual (Stand-Alone Version)

R_x

Prescription Use Only

IVD

For *In Vitro* diagnostic use

For Emergency Use Authorization (EUA) only.

Corporate Office

9375 E Shea Blvd, Suite 100
Scottsdale, AZ 85260
Phone: (800) 641-5751
www.pathogendx.com

Research and Development

1230 Pennsylvania Street, Ste 102
Tucson, AZ 85714
Tel: (800) 641-2102

Revision History

Version	Date	Comments
Draft 1.0	20JAN16	MSS
Draft 1.1	11FEB16	MSS
Draft 1.2	09MAR16	MSS
Draft 1.3	01JUL19	KOB
Draft 1.4	03AUG20	KOB
Draft 1.5	09APR21	KOB
Draft 1.6	12APR 21	EML

Copyright

Augury™ and Eagle™ are trademarks of PathogenDx

Table of Contents

Contents

Introduction.....	4
Application Overview	4
Warnings.....	4
Initial Installation.....	5
Obtaining TIFF Images	5
Operating the Software.....	7
Dealing with Errors and Error Reports:.....	9
System Maintenance:.....	10
Software Upgrades:.....	10
Technical Support Information	11

Introduction

Application Overview

The software allows the customer to upload their microarray plate images (i.e. TIFFs) to a laboratory computer that has Augury installed. Augury will scan the customer's local folder for uploaded TIFF files and analyze the TIFF and generate a Final Sample Report for each well of each plate that was analyzed, then upload the reports to the customer's local folder for review and approval. The Final Sample Report contains information about the sample that was analyzed, when the analysis was performed, and the results of the analysis (see Figure 1).

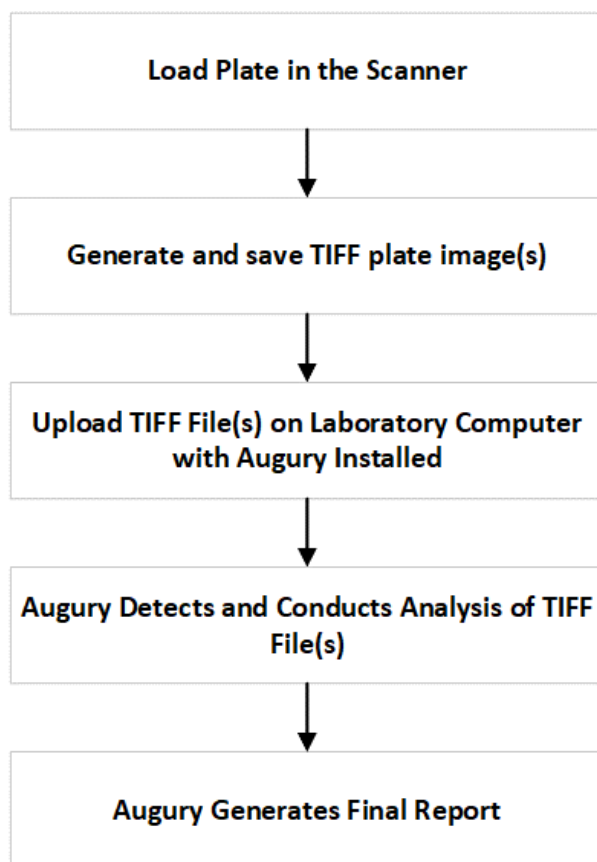


Figure 1

Warnings

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Initial Installation

- I) Install Augury
 - a. Inside the “Augury Install” folder on the USB, there is another folder called “Installation”
 - b. In “Installation”, Double-click on “Setup.exe” & allow it to make changes
 - c. Install Augury to the default location: “C:\Program Files (x86)\Augury\”
 - d. Two errors typically occur during installation; just click “Ignore” if or when they happen
- II) Copy newest Augury & Eagle to computer
 - a. Inside the “Augury Install” folder on the USB there are two programs: Augury & Eagle
 - b. Copy them both to “C:\Program Files (x86)\Augury\”
 - c. Allow the computer to replace the old version already in that folder
- III) Copy Augury files & folders from USB
 - a. From the USB, copy the folder “Augury_Files” directly to the C:\ drive
 - i. The resulting pathway should be “C:\Augury_Files\”
 - b. Eject the USB when finished
- IV) Perform a test run
 - a. Double-click on Augury to run it
 - b. The test images can be found inside “C:\Augury_Files\ImageFolders\9901002218.pdx\”
 - i. Remove the “.pdx” from the directory name
 - ii. Do not remove the barcode from the directory name
 - iii. Augury should automatically begin processing the data
 - c. Once Eagle shuts itself down, the report files should be available inside “C:\Augury_Files\Reports\”
 - d. If desired, you can create shortcuts to Augury, the ImageFolders directory, and the Reports directory onto your Desktop to make them easier to find in the future

Obtaining TIFF Images

Below are a set of generic instructions for the Sensovation SensoSpot scanner. While the specifics may not apply to every scanner, the instructions (in bold) provide the main steps that need to be taken in order to obtain a set of TIFF images using a Sensovation SensoSpot scanner. It is recommended that all users consult the user manual for their specific scanner in order to guarantee accurate results.

If the scanner was shipped from PathogenDx, then an assay file was created for scanning prior to shipping. The microarray layout was configured, and the channels were adjusted to their appropriate settings. The rack configuration was also completed prior to shipping, meaning that the rack file and rack layout were created, and the reference position was set for the correct array size and position



Augury can analyze plates from **Sensovation SensoSpot** plate scanners. If you are using a different scanner, please contact PathogenDx to have Augury configured to analyze TIFFs based on your specific plate scanner.



Once the settings have been configured, there should be no reason to change them. If a setting needs to be changed, save the original settings first, then create a copy where the changes can be made. This will prevent the original configuration from being overwritten.



When using the Sensovation SensoSpot scanner, **NEVER** open or close the tray manually. **ALWAYS** use the **Open Tray/Close Tray** icon. Moving the tray by hand will damage the instrument.

Calibrating the System

1. If your company received a Sensovation SensoSpot scanner from PathogenDx, then the system has already been calibrated.

Preparing to Scan

1. After turning the power ON, select **Start > All Programs > Sensovation > ArrayReader** to start the software, or click the link that is pre-installed on the desktop
2. Click the **Tray Open** icon on the lower right of the main menu to open the tray door and extend the plate rack
3. Load plate in the rack and click the **Tray Close** icon to retract the tray and close the door
4. Click the **Scan** icon on the main menu
5. Select the desired rack configuration from the *Plate Layout* dropdown list and the desired assay from the *Microarray assay* options in the **Scanjob Parameters** window
6. Then, click the → icon to start the scanning process

Defining the Scan Area

1. If your company received a Sensovation SensoSpot scanner from PathogenDx, then the scanning parameters have already been configured prior to shipping
2. To view the scan area, click the **Setup** icon in the upper right of the main menu, then click the **Rack Configuration** icon
3. To view the assay parameters, click the **Setup** icon, then click the **Assay Configuration** icon

Viewing Scanned Plate

1. To view the plate after scanning, or an existing scan job, click the **View** icon on the main menu, then select the scan job from the list of existing scan jobs



If the pre-defined settings set by the PathogenDx technician are altered, proper analysis of the microarray plate data may be adversely affected.

Below is how to properly start-up, operate, and shut down the software, and how to deal with any errors that may arise.

Operating the Software

The Sensovation imager is programmed to image each well three times. The images are saved as TIFF files. If you wish to view them, you can open them up singly using the Paint program on the imager, or you can view them all as thumbnails by opening the folder they are in and choosing “View” and “Extra Large Icons”.

The first TIFF file of the red (Cy5) channel. This image always has the suffix “_1.tif”. Typically, this image will display all the spots printed on the array, as shown here:



The second and third TIFF files are of the green (Cy3) channel, taken at increasing exposure times. They always have the suffixes “_2.tif” and “_3.tif” respectively. These images will display only those spots which have DNA hybridized to them. An example of one of these images is shown here:



Once the imager has finished imaging the entire plate, copy the folder containing the TIFF images into the directory **C:\Augury_Files\ImageFolders** on the laboratory computer with Augury installed, and change the name of the folder to match the barcode of the plate. The first ten characters of the folder name must be the barcode number of the plate. If you wish to include some other information in the folder name it will have to be typed in after the barcode. For instance, a folder named “9901005007-Imager320” will be processed, but a folder named “Imager320-Barcode9901005007” will not be.

If you wish to process only a part of the plate, you can do this by specifying the wells you are interested in after you type the plate barcode. For example, if you only want to process wells 20 through 38, you will type in the barcode, followed by a ".", and then "well020-well038". As shown here, the well numbers must be three-digits long, there must be a dash between the starting well and the ending well, and there should be no spaces. The rest of the folder name will be ignored by the software, so you can include any other information there that you want. Continuing the example above, the correctly formatted folder name would be "9901005007.well020-well038 Imager320". If no wells are specified, Augury will assume all 96 wells are to be processed.

Augury will not begin processing the data until it counts the expected number of TIFF files in the Image Folder. There should always be 3 tiff files per well. In the case of a full 96well plate, Augury will expect to see $96 \times 3 = 288$ TIFF files. If there are fewer than 288 TIFF files in the folder, Augury will not begin processing the image data. In our example above, there are 19 wells in the plate (wells 20 through 38 inclusive), so there should be 57 tiff files in the folder.

After copying the image folder into the aforementioned directory and changing the name of the image folder to match the barcode of the plate as described above, start Augury by double-clicking on the Augury icon on the laboratory computer. Augury will soon detect the image folder and begin processing by spinning off a helper program called Eagle. Once Eagle is finished processing the plate, it will shut itself down. Augury should be allowed to continue to run for a few seconds after Eagle shuts down. Augury may be minimized at any time during this process.

Once Augury has finished processing the TIFF image, a set of reports are created for each well and loaded to the customer's Reports folder. The output reports will be found in **C:\Augury_Files\Reports**. They will be named according to the barcode of the plate that was processed. There are a number of report formats provided, but each contains copies of the same information. One report file is formatted as a PDF file listing the results well-by-well, another is as a CSV file which can best be viewed using MS Excel, and yet another is a MS Word format.

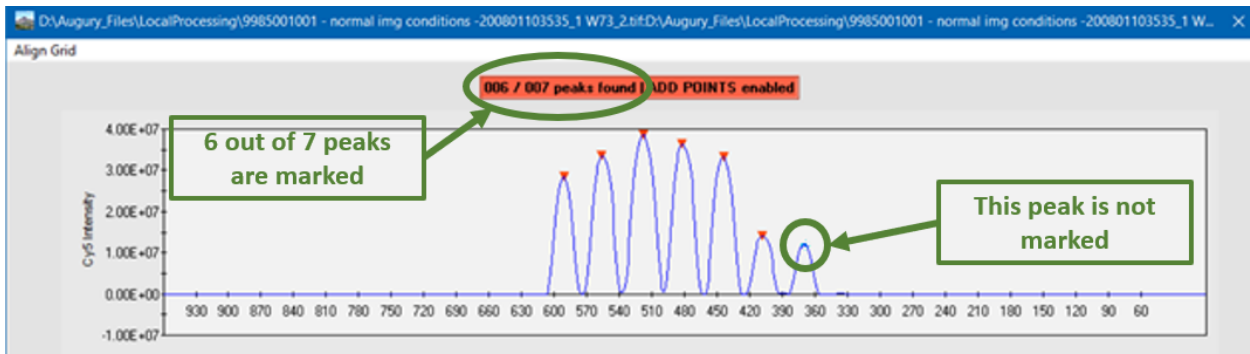
To View a Final Sample Report using MS Word:

1. Navigate to the **C:\Augury_Files\Reports** folder within the local laboratory computer folder.
2. Double-click on the appropriate Final Sample Report in Microsoft Word to read the report.

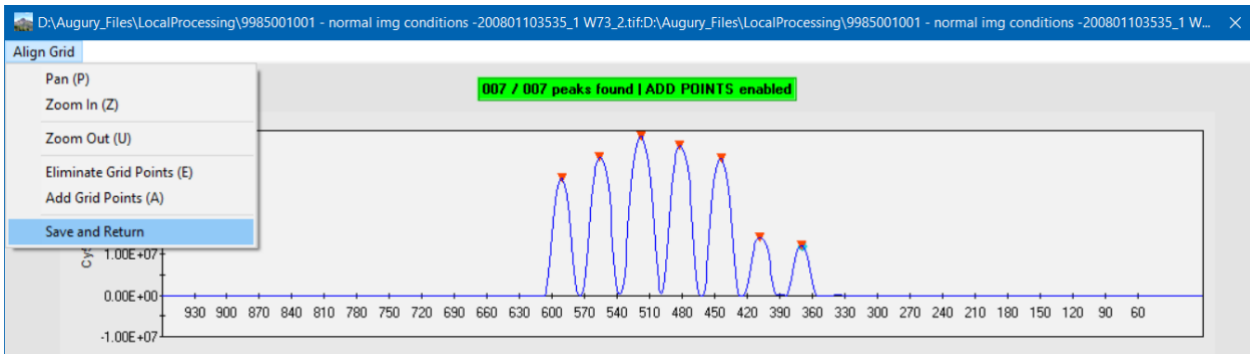
Dealing with Errors and Error Reports:

If Augury encounters a situation which prevents it from processing the data, either of two scenarios may occur. Either (a) Augury pauses and asks you, the operator, what it should do next, or (b) the software automatically decides it can no longer continue the analysis and stops.

- a) In the first scenario, the software will pause and display an interactive graph which tells you the number of peaks the software has found, the number it expects to find, and a graphical representation of the peaks themselves.

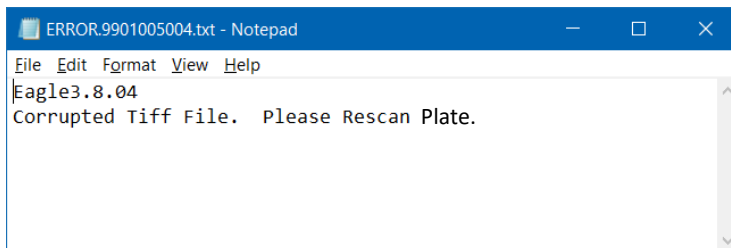



If there are too few peaks marked (as is the case in the figure above), choose “Add Grid Points” from the “Align Grid” pulldown menu and click on the unmarked peaks until the expected number of peaks is marked. If there are too many peaks marked, choose “Eliminate Grid Points” from the pulldown menu, and click on those peaks that should be excluded. When the expected number of peaks is chosen, click on “Save and Return” in the pulldown menu to allow the software to continue processing the plate.



The numerical values displayed along the x-axis of the graph correspond to the pixel values of the TIFF image. If you are having trouble determining where some missing peaks should be, you can open the TIFF image in MS Paint and read the pixel value(s) directly off of the image.


- b) Augury will write a brief error file to **C:\Augury_Files\Reports\ Error.<relevant plate barcode>.txt**. If Augury suddenly ceases operation, look for this error message. It can be opened and read by any text editor and will provide a brief explanation of what caused the error. An example of one of these error files (opened using Notepad) is given here:



	If you have any problems with this or any other aspect of the software, please call tech support at 1-800-641-2102 and we will be happy to assist you.
---	--

System Maintenance:

During normal operation, Augury will store data files. Over time, these files will accumulate on the local laboratory computer with Augury installed, taking up space. It may therefore be necessary to delete data files after transferring any files that need to be retained onto a separate storage drive. Specifically, the contents of the directory **C:\Augury_Files\Sessions** should be transferred and deleted periodically to avoid using disk space to store files which are no longer needed.

	Do NOT delete the directory itself, and do NOT delete any of the files therein while either Augury or Eagle is running, as this will adversely affect your results.
---	---

Software Upgrades:

Augury conducts internal maintenance that validates that all subroutines are properly integrated. As part of a local system, PathogenDx will send out update notifications if there are requirements for Augury base code. Two other updates that are likely to occur include (1) a new probe map is released and (2) additional probes have been added to the array.

The new probe map occurs if a replacement probe is required to be added to the plate. The addition of new probes also occurs when additional capability/content is added to the array. In each of these cases, upgrading to a new version is quite simple.

- a) Upon receipt of a new probe map, all that needs to be done is to copy this new file into the directory **C:\Augury_Files\ProbeMaps**.
- b) Upon receipt of a new pathogen database, all that needs to be done is to delete the old database at **C:\Augury_Files\AuguryFiles\Augury.mdb**, and copy the new database to that same location in its place. For best results, shut down the Augury software before upgrading the database.

- c) Upon receipt of a new copy of either Augury.exe or Eagle.exe (or both)-, first shut down Augury if it is currently running, and then copy the new software files into the directory **C:\Program Files (x86)\Augury**. In so doing, you will be replacing the old files.

If you wish to retain a copy of the old version of either the database or the software programs, make sure you either change the name of the relevant file or else save it to a different directory before following the instructions listed above, in order to ensure it doesn't get overwritten.



If you have any questions about upgrading the software, please call tech support at 1-800-641-2102 and we will be happy to assist you.

Technical Support Information

For technical assistance, please contact our customer support department at
1-800-641-2102