# PathogenDx

# Octa™ AutoPrep Station User Manual



REF Catalog #'s: (P/N: 15-0051) PathogenDx-Octa AutoPrep Station Fungal and Bacterial Nucleic Acid Purification. For investigational use only.

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# INSTALLATION AND OPERATION GUIDE

Model: PathogenDx Octa AutoPrep Station

Document Type: User Manual

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#### 1. General

#### 1.1. Abbreviations and Definitions

Abbreviation	Description
Octa AutoPrep Station	Automated sample preparation device with integrated heater.

#### 1.2. Document Conventions



Safety instructions: Follow these instructions to avoid serious injury or death



This symbol is used to point out additional useful information



This symbol is used to mark important information

# 1.3. Purpose of Document

This manual provides information for the installation, set-up, and use of the PathogenDx Octa AutoPrep Station.

#### 1.4. Intended Use

The Octa AutoPrep Station is an automated sample preparation and nucleic acid purification instrument combining Lysis and OctaTip extraction, for use with Octa Prep Kit. The system is provided with a protocol for sample preparation of bacterial and fungal DNA contamination. It is capable of processing 8 specimens simultaneously. It is suitable for use with PathogenDx 1.2 mL OctaTips and other specific consumables described in this manual and provided with the PathogenDx Octa Prep Kit. The final purified nucleic acid eluate is suitable for downstream analysis using any automation ready PathogenDx assays.

The Octa AutoPrep Station is not recommended for use with other purification chemistries or kits or other downstream analysis tools.

#### 1.5. Use Environment

The Octa AutoPrep Station is intended for use indoors and in a clean, climate-controlled laboratory environment. Ensure that the work surface is sturdy and level. The Octa AutoPrep Station measures approximately 17.75 x 12 x 18 inches (width x depth x height) and space for the accompanying laptop is needed.



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# 1.6. Safety Instructions

Please heed to the warning labels on the instrument and in the manual:

<u> </u>	CAUTION: Do not open the internal housing of the instrument: Potential High Voltage Risk. Instrument should only be serviced by authorized technicians
	Warning: Magnetic Field. A powerful magnet is located on the left side of the instrument and should be a distance of at least 12 inches from any wall, instrument, or source of metal.
	The magnet in the Octa AutoPrep Station can be harmful to those who wear a pacemaker. Please maintain 30 cm (12 in.) between your body and the instrument.
	Keep body parts clear of areas that are considered a crush hazard when system is on.
	Keep body parts clear of rotating components on the instrument
	Keep body parts clear of areas that are considered a pinch point hazard when system is on.
	CAUTION: Laser on system.
	Hot Surface Warning: Caution the surface may be hot.
WARNING Hazardous voltage. This unit is to be serviced by trained personnel only.	High Voltage: Do not open electrical box unless appropriately trained.
WARNING Heavy object. Car cube resided strine or back liphy; Use lifting acts and proper fitting locial support temporary	CAUTION: The instrument is heavy. Use proper lifting techniques when moving the instrument.
<u>^</u>	Caution: Improper use of the instrument can impair instrument function. The instrument may only be used by qualified personnel. Do not use the instrument if any parts are damaged. Do not open the housing of the instrument unless directed to do so. Do not attempt any repairs or alterations except as expressly instructed in this manual.
Î	Please follow these instructions for your own safety and the proper operation of the instrument:  Read the complete Octa AutoPrep Station user manual.  Power cords must be connected to a wall outlet with a grounded conductor.  The environment must be clean, stable, and vibration free.  No objects should be placed on top of the instrument.  Keep liquids away from the computer.  Keep enough space in the back and on the side of the instrument to readily access the power switch.  Follow all applicable biosafety regulations and precautions when working with potentially infectious materials.



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# 1.7. Computer Precautions

Guard against software viruses. Only use original Octa Software on this computer.

# 1.8. Emergency Shut Down

If an immediate stop is required, turn off the power switch located in the back top right hand corner and then contact PathogenDx for assistance.

# 1.9. Package Contents

The Octa AutoPrep Station is supplied with:

- Octa AutoPrep Station
- USB communication cable and power cables
- Laptop Computer
- Power Strip
- Consumables Trays and Heater Strip Holder

#### 2. Instrument Setup

# 2.1. Unpacking and Setting-Up the Instrument

Proper setup of the Octa AutoPrep Station is required for operation:

1. Open the box containing the instrument and remove the laptop computer, cables, power strip, and top insert.

Check for components against the Package Contents list. If any components are missing, contact PathogenDx.

2. Remove the instrument from the box by accessing the recessed handles on the sides of the instrument. This will require TWO people. Do NOT lift by the door on the front of the Octa AutoPrep station.



Caution: Instrument is heavy – two people are required to lift the instrument.

- 3. Once removed, inspect the instrument for damage. Do not attempt to repair any damage, contact PathogenDx regarding any damage.
- 4. Open the front door of the instrument by sliding the front door up and begin removing the packing inserts inside of the workstation
- 5. If damage is observed, take photos of the damages, and contact PathogenDx.
- 6. After the packaging inserts have been removed, remove sticker covering the power cable entry point.

# 2.2. Connecting the Instrument

Prior to connecting the instrument to the laptop ensure all Power and USB cables are present.

1. Electrical and USB cable entry ports are located on the back panel of the Octa AutoPrep Station. Connect the Octa AutoPrep Station to the laptop computer with the supplied USB cable.



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2. Locate the smart power strip and plug the laptop into the "Always On" position (circled in blue) and the instrument into the Outlet position labeled with the green dot sticker, as shown in Figure 1:



Figure 1: Smart power strip outlet positions

- 3. Plug the USB cable from the smart power strip into the laptop.
- 4. Plug the smart power strip into a grounded outlet.

# 3. Startup

- 1. Make sure the power to the Octa AutoPrep Station is turned Off.
- 2. Make sure the USB cable from the Octa AutoPrep Station is connected to the laptop.
- 3. Turn on the laptop.
- 4. Log in to the laptop. The laptop passwords is Octa#[serial number] (e.g. Octa#1601).
- 5. Select the Octa shortcut located on the Desktop. You will see the loading screen appear as shown in Figure 2.



Figure 2: Octa AutoPrep Station software loading screen.

- 6. Turn on the Octa AutoPrep Station using the power switch located on the back panel of the instrument.
- 7. The software will perform an initialization process when both the computer and instrument have been turned on, and the user interface will be displayed as shown in Figure 3. Please contact PathogenDx if any connection issues arise.



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Figure 3: Octa AutoPrep Station User Interface

During initialization, you may hear a relatively loud noise as the syringe pump motor overcomes friction that may arise during prolonged periods of non-use. This noise is normal and should subside once the system is in use.

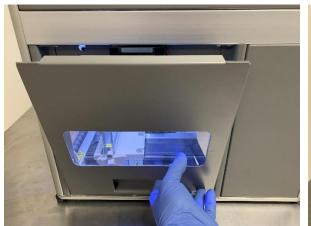
Prior to loading any consumables, open the Octa software, turn on the Octa machine, and allow the Octa to initialize. During initialization, the Plate Deck will move and will be then rehomed to allow loading of consumables and samples.

# 4. Loading Consumables into the Octa AutoPrep Station

All Consumables required for processing samples with the Octa AutoPrep Station are provided with the Octa Prep Kit (P/N 50-0049, Product details in Doc. 40-0247).

#### 4.1. Front View

Samples and consumables are loaded into the Octa AutoPrep Station by lifting the front door open, as shown in Figure 4.



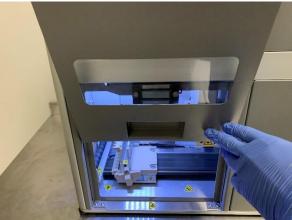


Figure 4: Opening the Octa AutoPrep Station door

OctaTip sleeves with pre-loaded OctaTips, and Prefilled Reagent Plate are loaded onto the Plate Deck using the Consumables Tray, samples are loaded into the Heater using the Heater Strip, as highlighted in Figure 5.



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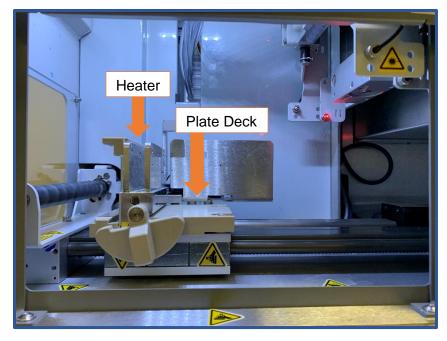


Figure 5: Octa AutoPrep Station Front View with Heater and Plate Deck highlighted

# 4.2. Consumables Tray

The Consumables Tray shown in Figure 6 aligns and secures all consumables provided with the Octa Prep Kit including the Prefilled Reagent Plate and OctaTip Sleeve with pre-loaded OctaTips.

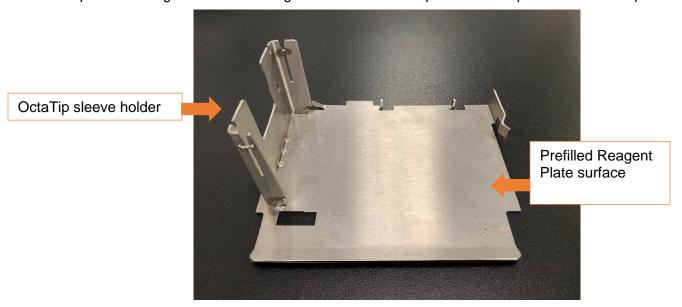


Figure 6: Empty consumable tray with highlighted OctaTip sleeve holder, and surface for the Prefilled Reagent Plate



#### 4.3. Prefilled Reagent Plate

The Prefilled Reagent Plate is secured onto the Consumables Tray by sliding and twisting it into position as shown in Figure 7. Firmly seat the Prefilled Reagent Plate onto the Consumables Tray ensuring that the plate skirt is held tightly in place. Row 1 of the Prefilled Reagent Plate must be aligned towards the left of the Consumables Tray, adjacent to the Octa tip sleeve holder.

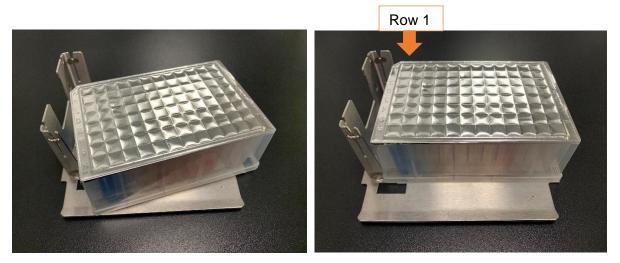


Figure 7: Loading the Prefilled Reagent Plate onto the Consumables Tray

# 4.4. OctaTip Sleeve and pre-loaded OctaTips

The OctaTip sleeve with 8 OctaTips is seated into the OctaTip sleeve holder on the Consumables Tray, as highlighted in Figure 8. The vertical alignment tab of the OctaTip sleeve, highlighted with the orange arrow below, must fit snugly into guide channels in the metal Consumables Tray sleeve holder as shown in Figure 9. When a sample prep protocol starts, the system automatically picks up the 8 OctaTips. When the protocol is complete, the OctaTips are ejected back into the sleeve. The used sleeve and OctaTips must be disposed of in biohazard waste. **Do not re-use OctaTips or OctaTip sleeves for subsequent runs.** 

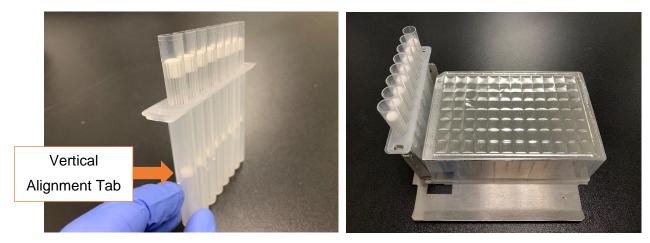


Figure 8: OctaTip sleeve with 8 pre-loaded OctaTips before and after seating onto the Consumables

Tray using the OctaTip sleeve holder



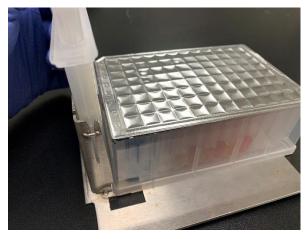




Figure 9: The OctaTip sleeve must be seated fully into the Consumables Tray sleeve holder

Ensure all 8 OctaTips are loaded properly and that they are flush with the surface of the sleeve.

# 4.5. Loading the Consumables Tray

After the Prefilled Reagent Plate and OctaTip sleeve with OctaTips have been secured and seated into the Consumables Tray, the Consumables Tray slides into position on the Plate Deck of the Octa AutoPrep Station, as highlighted in Figure 10. Ensure that the OctaTip sleeve is oriented to the left, adjacent to the Heater Strip.





Figure 10: The Octa AutoPrep Station before (left) and after (right) sliding the Consumables Tray with seated and secured OctaTip sleeve and pre-filled Reagent Plate onto the Plate Deck



# 4.6. Heater Strip, Heater Strip Holder, and Heater

The Heater Strip is filled with a mixture of user sample and Octa Lysis and Binding Buffer. The Heater Strip Holder is supplied with the Octa AutoPrep Station and is used to hold three Heater Strips vertically while the user sample is aliquoted, as illustrated in Figure 11.

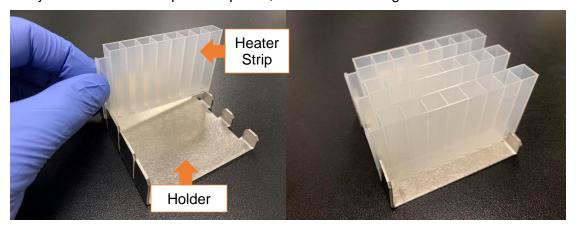
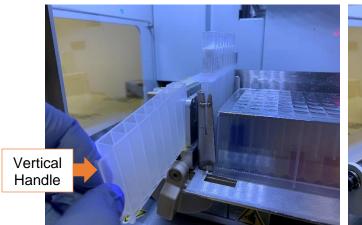


Figure 11: Heater Strip, Heater Strip Holder, and three Heater Strips held upright

# 4.7. Loading the Heater Strip

Once the user sample and Octa Lysis and Binding Buffer have been aliquoted into the Heater Strip, the Heater Strip slides into the Heater of the Octa AutoPrep Station as shown in Figure 12. **Be sure that the vertical handle of the Heater Strip is facing towards the user and the Heater Strip is pushed flush against the back of the Heater.** 



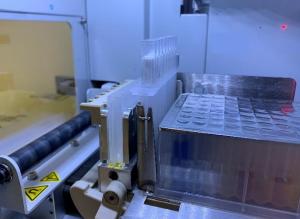


Figure 12: Inserting the Heater Strip into the Octa AutoPrep Station Heater



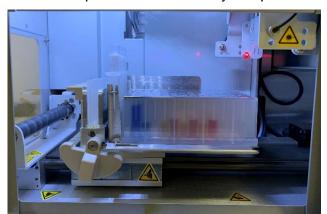
Caution: When the heater is turned on, the surface may be warm to touch.



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#### 4.8. Latching the Consumables into place

Once the Consumables Tray with OctaTip sleeve and Prefilled Reagent Plate and Heater Strip have been inserted into the Octa AutoPrep Station, the user must latch the Consumables into place by rotating the semi-circular latch clockwise until it is seated in the hole on the front of the Consumables Tray, as highlighted in Figure 13. Care must be taken to ensure that the Consumables Tray and Heater Strip are latched securely into place before initiating any automated sample prep protocols.



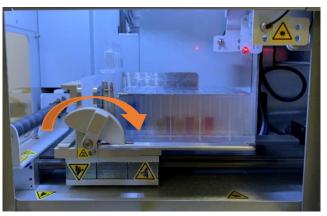


Figure 13: Inserting the Heater Strip into the Octa AutoPrep Station Heater

#### 5. Operating instructions

#### 5.1. Running Octa AutoPrep Station Protocols

Protocols must only be run after your sample mixture in Heater Strip, Prefilled Reagent Plate, and OctaTip sleeve with 8 OctaTips are loaded into the instrument.

- 1. The Octa AutoPrep Station gives the user the option to run either Run 1, Run 2, or Run 3 protocols. These automated protocols correspond to the first, second, and third run of eight samples for a given Prefilled Reagent Plate, respectively.
- 2. Select either Run 1, Run 2, or Run 3, corresponding to the first, second, or third run of eight samples for a given plate.
- 3. During the protocol, the Octa AutoPrep Station will initiate a countdown until the protocol is complete, as shown in Figure 14.



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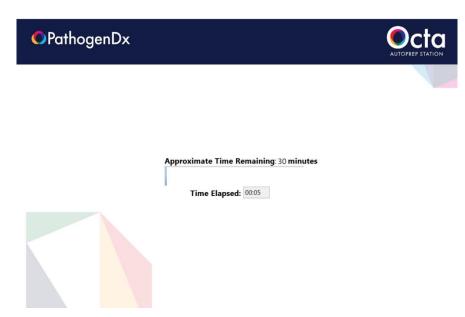


Figure 14: The Octa AutoPrep Station Timer

4. Once your first run is complete, the Octa AutoPrep Station will signal that the run is complete with a tone. A timer is initiated when the protocol ends so that the user knows how long their purified nucleic acids have been eluted into the Prefilled Reagent Plate. The Octa AutoPrep Software also tells the user which column their nucleic acids are eluted into, dependent on whether the user has run Run 1, Run 2, or Run 3, as shown in Figure 15.

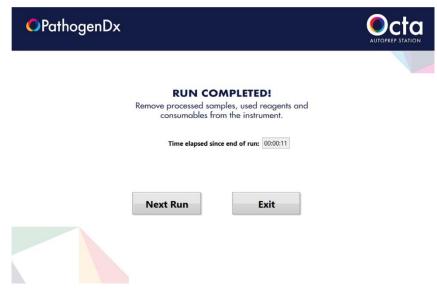


Figure 15: The Octa AutoPrep Station completed run page

- 5. If you are running subsequent samples immediately perform the following steps:
  - a. Remove and replace the Heater Strip with appropriate subsequent samples. The used sleeve and OctaTips must be disposed of in biohazard waste. Do not re-use OctaTips or OctaTip sleeves for subsequent runs.
  - b. Remove and replace the OctaTip sleeve and OctaTips with fresh sleeve and tips. Dispose of used OctaTip sleeve and OctaTips. **Do not re-use OctaTips or OctaTip sleeves for subsequent runs.**



- c. Re-latch the Consumables Tray and Heater Strip into place and initiate subsequent protocol.
- 6. If you are **NOT** running subsequent samples immediately perform the following steps:
  - a. Dispose of the Heater Strip, OctaTip sleeve, and OctaTips in biohazard waste.
  - b. Place foil strips over columns 2 and 3 of the Prefilled Reagent Plate. The foil strips on columns 2 and 3 of the Prefilled Reagent Plate must be removed before the subsequent runs take place.
  - c. Remove the DNA eluate from the appropriate elution column (Run 1: column 10, Run 2: column 11, Run 3: column 12).
  - d. Proceed to PCR setup or store DNA eluate at -20C for future use.

#### 5.2. Shutdown

- 1. When you are finished using the Octa AutoPrep Station, close the Octa AutoPrep Station software by clicking on the close program icon (X) at the top right corner of the screen or clicking the "Exit" button at the end screen.
- 2. The software will then perform a shutdown sequence. The software will prompt the user once the shutdown sequence is complete to turn off the instrument.
- 3. Click OK and then the close program icon (X) to close the user interface and software.
- 4. Turn the Octa AutoPrep Station Off using the power switch on the back panel of the instrument.



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# 6. Troubleshooting

Issue observed	Possible cause	Resolution
Octa is not turning on	Power cable is plugged into the wrong Outlet position on power strip	Ensure that the Octa power cable is plugged into the Outlet position marked with the green dot sticker.
		Check that the Outlet position marked with the green sticker is the one indicated to be on by the small red light on the power strip. If a different Outlet position is indicated to be on by the red light on the power strip, plug the Octa power plug into the indicated Outlet.
	Power strip is not turned on	Ensure the USB of the power strip is plugged into both the power strip and the laptop, and check that the power strip is plugged into a wall outlet. Check that the red light indicating the powered-on Outlet position is turned on.  If no light is on, contact PathogenDx.
OctaTips break upon Tip pickup	OctaTip sleeve was not properly seated in the Consumables Tray sleeve holder	Ensure all 8 OctaTips are loaded properly and that they are flush with the surface of the OctaTip sleeve.  Ensure that the OctaTip sleeve with 8 PathogenDx OctaTips is appropriately seated into the OctaTip sleeve holder on the Consumables Tray and that the vertical alignment tab of the OctaTip sleeve fits snugly into guide channels in the metal Consumables Tray sleeve holder.
	Instrument needs to be rehomed	Turn the laptop and the Octa off, then wait at least 15 seconds before turning both the laptop and Octa back on in the sequence indicated under 4. Operating Instructions in the Octa AutoPrep Station Product Insert.
Octa pierces plate wells off center	Instrument needs to be rehomed	Turn the laptop and the Octa off, then wait at least 15 seconds before turning both the laptop and Octa back on in the sequence indicated under 4. Operating Instructions in the Octa AutoPrep Station Product Insert.
Octa is stuck on executing a step of the program	Octa will execute all steps in each run	Turn the instrument off immediately with the power switch located in the back of the Octa.  Turn the instrument back on and allow to initialize. Remove any items that obstructed the execution of the Run from inside the Octa.



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#### 7. Preventive maintenance

Power on the instrument and launch the Octa Software Interface to initialize the instrument at least every six months if the instrument is not being used. Close the Octa Software Interface and wait for the Software Interface to close before shutting down the instrument.

Turn the laptop computer and the Octa off and on every month while in use.

# 8. Quality Control

OctaTips and reagents are visually inspected and functionally tested against predetermined specifications to ensure consistent product quality.

#### 9. Calibration

Instructions for the Octa calibration procedure are described below but for performing the Octa calibration procedure, use the Octa Calibration Worksheet (P/N: 40-0239).

Equipment	Consumables	Reagents
Multichannel 1000µL pipette	Used Prefilled Reagent Plate	Molecular grade water
Analytical balance	Used Heater Strip	
	8 used Octa Tips	
	Used OctaTip Sleeve	
	1000µL pipette tips	
	Reservoir	

#### Procedure:

#### 1. Traceability Information:

a. Record the serial number of the Octa being calibrated, the serial/lot number of the pipette that will be used, and the lot of molecular grade water that will be used for the Octa calibration.

#### 2. Preparation of Consumables:

- a. Remove and dispose of reagents from a used Prefilled Reagent Plate and Heater Strip.
- b. Fill a secondary container with tap water and soak the used and emptied Prefilled Reagent Plate and Heater Strip for 25-30 minutes.
- c. Rinse the used Prefilled Reagent Plate and Heater Strip under the tap for 5 minutes.
- d. Shake out the used Prefilled Reagent Plate and Heater Strip to dry.
- e. Pipette 900 µL of molecular grade water into each well in column 3 of the dry used Prefilled Reagent Plate.
- f. Load eight used OctaTips in a used OctaTip Sleeve.
- g. Load the metal Consumables Tray with eight used Octa tips in an OctaTip Sleeve and used Prefilled Reagent Plate.
- h. Execute 'Run 1' to rinse and dry the used OctaTips.
- When run is finished, shake out the used Prefilled Reagent Plate to remove liquid.



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# 3. Performing Calibration:

- a. Weigh the dried used Prefilled Reagent Plate and record the weight in Table 2 below (ID: A).
- b. Weigh the dried used Heater Strip and record weight in Table 2 below (ID: D).
- c. Pipette 900 µL of molecular grade water into each well in column 3 of the dry used Prefilled Reagent Plate.
- d. Re-weigh the Prefilled Reagent Plate and record the weight in Table 2 below (ID: B).
- e. Load the Heater Strip into the Octa.
- f. Load the metal Consumables Tray with eight used and dried Octa tips in an OctaTip Sleeve and a used and dried Prefilled Reagent Plate loaded with 900 μL of molecular grade water in each well of column 3.
- g. Execute 'Run 1'.
- h. Weigh the Heater Strip and record the weight in Table 2 below (ID: E).
- i. Weigh the Prefilled Reagent Plate and record the weight in Table 2 below (ID: C).

#### 4. Data analysis:

a. Required weights to be recorded:

ID	Description	
Α	Prefilled Reagent Plate	
В	Prefilled Reagent Plate with water	
С	Prefilled Reagent Plate after 'Run 1'	
D	Heater Strip	
Е	E Heater Strip with water	

#### 5. Calculations:

a. Required Calculations:

Calculations	
(See above table for IDs)	
B-A	
B-C	
E-D	

# 6. Acceptance Criteria

a. "B - A" should be 7.2g ± 0.720g. Range: 6.48g - 7.92g

b. "B - C" should be  $6.4g \pm 0.640g$ . Range: 5.76g - 7.04g

c. "E - D" should be  $6.4g \pm 0.640g$ . Range: 5.76g - 7.04g



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# 10. Appendix

# 10.1. Consumables Required for Procedure

- 12x OctaTip Sleeves with 8x pre-loaded OctaTips each
- 12x Heater Strip
- 4x Prefilled Reagent Plate
- 60mL Lysis and Binding Buffer

# 10.2. **Contact Information**

Email: PathogenDxSupport@PathogenDx.com

Phone: 301-698-0101



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