




PathogenDx

Octa Prep Kit

User Manual

 **REF** Catalog #'s: (50-0049) PathogenDx Octa Prep Kit
Fungal and Bacterial Nucleic Acid Purification. **For investigational use only.**

Corporate Office

9375 E. Shea Blvd, Ste.100

Scottsdale, AZ 85260

Phone: 1-800-641-5751

www.pathogendx.com

Research & Development

1230 E. Pennsylvania St. Suite 102

Tucson, AZ 85714



Table of Contents

General Information	2
Intended Use	2
Kit Contents	2
Summary and Explanation of the Kit	2
Principles of the Procedure	3
Document Conventions	3
Safety Instructions	3
Computer Precautions	4
Emergency Shut Down	4
Nucleic Acid Extraction from liquid Samples.....	5
Software and Instrument Start-Up	5
Reagent Plate Set-up.....	6
Heater Strip Sample Solution Set-up	8
Protocol Set-up and Run	9
Removing Consumables after the Run.....	9
Software and Instrument Shutdown	9
Decontamination	10
Safety Information.....	10
Quality Control	10

GENERAL INFORMATION

Intended Use

The Octa AutoPrep Station is an automated sample preparation and nucleic acid purification instrument combining Lysis and OctaTip extraction, for use with OctaTip disposables. It is capable of processing 8 specimens simultaneously. The Octa Prep Kit is intended for the purification of bacterial and fungal nucleic acid samples. Purified nucleic acids are suitable for downstream amplification and subsequent pathogen detection using any automation-ready PathogenDx assays.

The Octa Prep Kit and the Octa AutoPrep Station are intended for investigational use only. Not for use in diagnostic procedures. No claim or representation is intended relative to the diagnosis, prevention, or treatment of a disease.

Kit Contents

The Octa Prep Kit contains the following supplies for 96 extractions:

- 4x Prefilled Reagent Plates
- 96x 1.2mL OctaTips in 12 OctaTip Sleeves
- 60mL Lysis and Binding Buffer
- 12x Heater Strips

Storage

KIT COMPONENT	RECOMMENDED STORAGE	COMMENTS
ALL NON-REAGENT CONSUMABLES	15°C– 25°C, up to 1 year from manufacture	
OCTA LYSIS AND BINDING BUFFER	15°C– 25°C, away from light, up to 1 year from manufacture	Protect from prolonged exposure to light Do not expose to bleach or acids If precipitate forms, heat the bottle in a warm water bath (56°C) for 5 to 10 minutes and mix gently before use
PREFILLED REAGENT PLATE	15°C– 25°C, away from light, up to 1 year from manufacture	Protect from prolonged exposure to light

Summary and Explanation of the Kit

The Octa Prep Kit contains the reagents and consumables required for automated nucleic acid purification using the Octa AutoPrep Station. The following procedure describes the steps required to set up and run an Octa extraction protocol using the Octa AutoPrep Station and Octa Prep Kit.

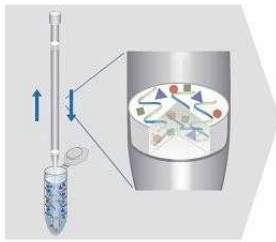
Principles of the Procedure

Overview

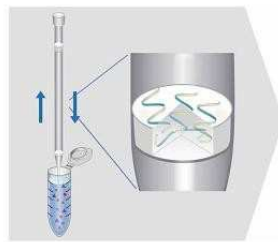
The sample is mixed with the supplied Lysis and Binding Buffer by the user and placed in the Octa AutoPrep Station. The sample is then lysed, passed into the OctaTips, washed, and purified during an automated protocol as illustrated below. The final purified nucleic acids are eluted into the plate, ready for downstream analysis using any automation-ready PathogenDx assays.

Workflow

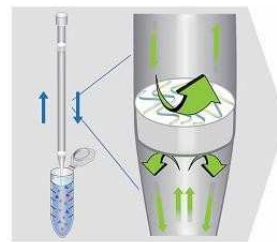
STEP 1: Bind to Matrix



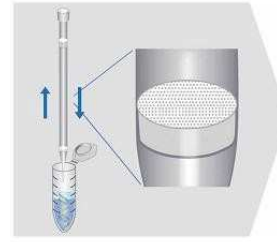
STEP 2: Wash Away Impurities



STEP 3: Air Dry



STEP 4: Elute



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

Safety Instructions

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

	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

	<p>Keep body parts clear of areas that are considered a pinch point hazard when system is on.</p>
	<p>CAUTION: Laser on system.</p>
	<p>Hot Surface Warning: Caution the surface may be hot.</p>
	<p>High Voltage: Do not open electrical box unless appropriately trained.</p>
	<p>CAUTION: The instrument is heavy. Use proper lifting techniques when moving the instrument.</p>
	<p>Caution:</p> <ul style="list-style-type: none"> • 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. <p>Do not attempt any repairs or alterations except as expressly instructed in this manual.</p>
	<p>Please follow these instructions for your own safety and the proper operation of the instrument:</p> <ul style="list-style-type: none"> • 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. <p>Follow all applicable biosafety regulations and precautions when working with potentially infectious materials.</p>

Computer Precautions

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

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.

NUCLEIC ACID EXTRACTION FROM LIQUID SAMPLES

The following steps should be performed in a clean reagent area

Software and Instrument Start-Up

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 computer.
3. Turn on the computer.
4. Double click the Octa shortcut located on the Desktop.
5. Turn on the Octa AutoPrep Station using the power switch located on the back panel of the instrument.
6. The software will perform an initialization process when both the computer and instrument have been turned on.

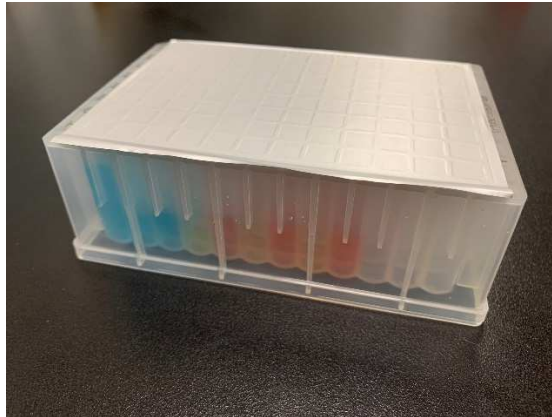
Open the Octa AutoPrep Station door by grabbing the handle and tilting the door towards you. The door can then be moved up and locked in place.



Reagent Plate Set-up

One Octa Prefilled Reagent Plate can accommodate three runs, totaling 24 samples per plate. Eight samples may be processed in a single run. The user selects the Run 1, Run 2, or Run 3 automated protocol in the Octa AutoPrep Station software, depending on whether they are running their first, second, or third batch of samples for a given plate.

Below is an example of the Prefilled Reagent Plate. **Reagents in shipped plates are clear, color in photo below added for clarity.**



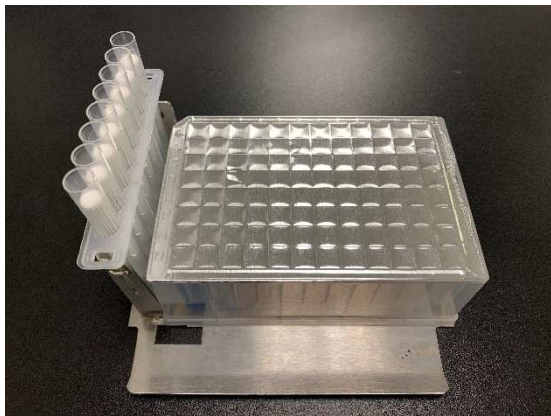
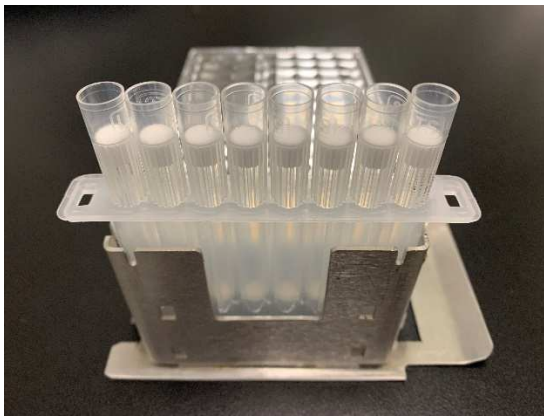
DO NOT TOUCH OR REMOVE TOP FOIL OF PLATE

Inspect the side of the plate to make sure the liquid levels of all reagents are as shown in the photo above. Inspect the top foil seal to ensure uniform sealing.

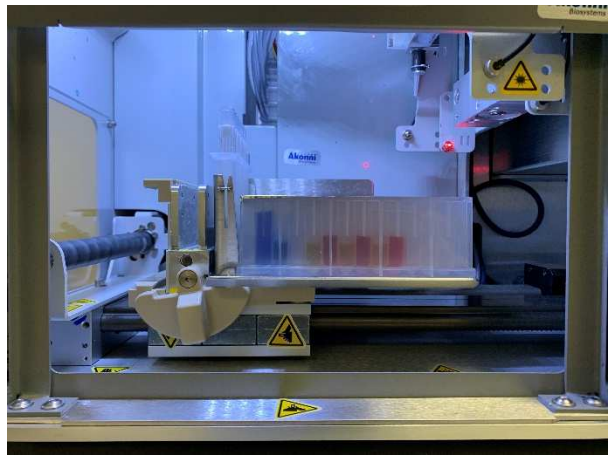
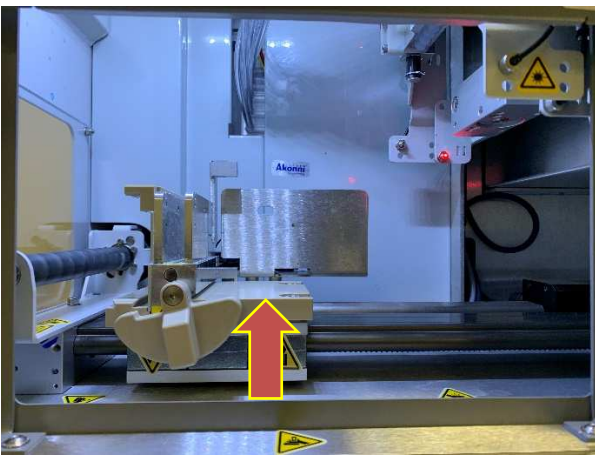
1. Load the Prefilled Reagent Plate onto the Octa AutoPrep Station Consumables Tray by placing the plate on the tray at an angle and then twisting/sliding it into position. Position A1 of the plate will be in the far-left hand corner.



2. Insert OctaTip sleeve into the Holder on the Consumables Tray making sure the sleeve is fully seated.



3. Slide the loaded Consumables Tray onto the Octa AutoPrep Station as indicated below.

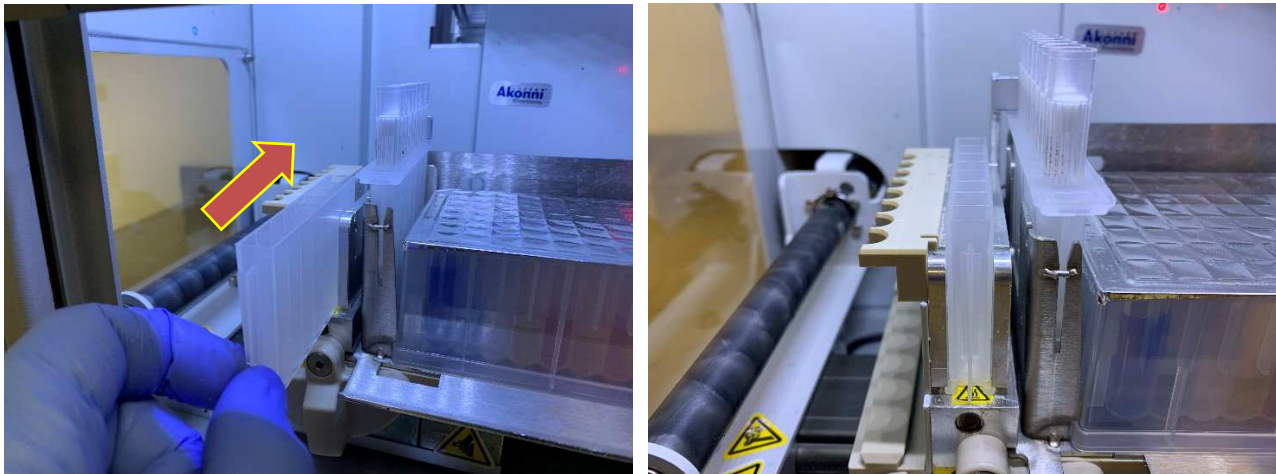


Heater Strip Sample Solution Set-up

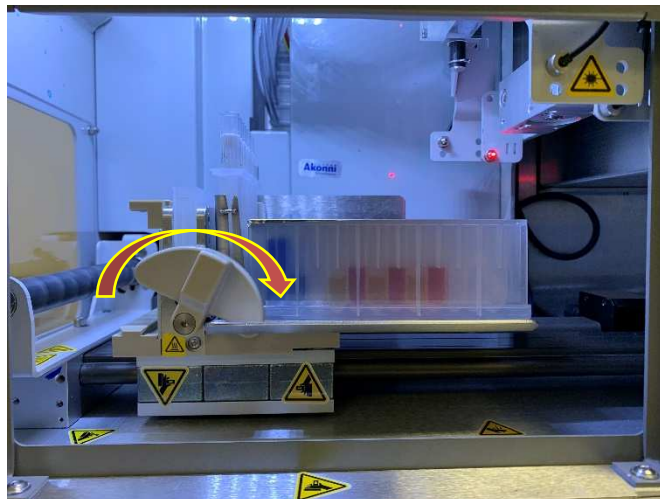
1. Aliquot 600 μ L of Octa Lysis and Binding Buffer into each well of the Heater Strip.

Precipitate will form in the Octa Lysis and Binding Buffer. Heat the entire bottle at 55°C and gently mix by swirling to dissolve prior to use.

2. Aliquot 400 μ L of final sample from Sample Preparation into appropriate well of the Heater Strip.
Note: The Octa AutoPrep Station can accommodate 8 samples per run, 1 sample loaded into each well of the Heater Strip.
3. Slide the Heater Strip into the heater as indicated with the red arrow below.



4. Once all consumables (The Heater Strip with sample mixture, the Prefilled Reagent Plate, and the OctaTip Sleeve with 8 OctaTips) have been loaded, close the Consumables Tray latch, ensuring the latch fits into the opening on the Consumables Tray as indicated with the red arrow below.



5. Close and latch the Octa AutoPrep Station door.

Protocol Set-up and Run

In the Octa AutoPrep Station software, click either Run 1, Run 2, or Run 3, corresponding to whether you are running your first, second, or third batch of samples for your Prefilled Reagent Plate.

Once the protocol begins, you will see the following automated steps take place for each of the eight channels:

1. The OctaTips are loaded onto the nozzles
2. Appropriate reagent and elution wells for your run are pre-pierced in the Prefilled Reagent Plate with dry tips.
3. 75µL of Elution Buffer is transferred to the appropriate elution column.
4. The sample is heated for 10 minutes.
5. 800µL ethanol is transferred from the Prefilled Reagent Plate to the Heater Strip.
6. 1800µL of the sample mixture is passed over the OctaTip column for 5 cycles.
7. The tips move to the first wash column and aspirate/dispense 500µL of Wash Buffer 1 for 4 cycles.
8. The tips move to the second wash column and aspirate/dispense 500µL of Wash Buffer 2 for 3 cycles.
9. The tips move to column 3 and pass forced air through each OctaTip channel for 10 seconds.
10. The tips move to the elution column and aspirate/dispense 75µL of Elution Buffer through the OctaTips for 7 cycles.
11. Air is forced through each OctaTip channel for 1 second.
12. A final aspirate/dispense cycle is performed to elute the extracted nucleic acids.

Removing Consumables after the Run

Purified nucleic acids will be in the elution column corresponding to your run number at the end of the protocol (Run 1: column 10, Run 2: column 11, Run 3: column 12).

1. Open the door latch and remove the Consumables Tray holding the Prefilled Reagent Plate and OctaTips as well as the Heater Strip from the system
2. Discard OctaTip Sleeve with OctaTips, and Heater Strip
 - a. **Caution: The heat block will still be warm.**
3. Each Octa Prefilled Reagent Plate can accommodate three independent runs of eight samples each. If you are running your second and/or third batch of samples immediately, load your next Heater Strip with samples and OctaTip sleeve with eight OctaTips into the Octa AutoPrep Station. Remove your eluted nucleic acids from the appropriate column and place into labeled tubes or microwell plate. If you are not running your next batch of samples immediately, place a foil strip over columns 2 and 3 and the appropriate elution column and store at room temperature until further use.
4. Discard materials according to local regulations.

Software and Instrument Shutdown

1. Close the Octa AutoPrep Station control software. 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.
2. Turn the Octa AutoPrep Station Off using the power switch on the back panel of the instrument.

Decontamination

Once the automated protocol has finished and all samples and consumables have been removed, the system can be decontaminated.

To clean the instrument, spray a paper towel with 10% bleach. **Do not spray bleach directly onto the system.**


Wipe all accessible surfaces of the Octa AutoPrep Station with the bleach-soaked paper towel. This includes the plate deck, heater, and all paneling inside the instrument. Make sure the surfaces are wetted properly.


Wait at least 3 minutes.



Spray a paper towel with 70% ethanol or isopropanol. **Do not spray alcohol directly onto the system.**

With the alcohol-soaked paper towel, wipe all the surfaces that were previously wiped with bleach. Discard paper towels in an appropriate waste receptacle.

SAFETY INFORMATION

 Sample Disclaimer: Octa extraction processes do not necessarily kill 100% of the microorganisms that may be present in a sample. Use appropriate biocontainment and universal biosafety precautions when working with potentially infectious samples.

 **DO NOT** combine bleach or acidic solutions with sample preparation reagents. Bleach or acidic solutions are incompatible with lysis and wash buffers and can react to liberate a toxic gas. If potentially infectious samples and/or sample preparation reagents are spilled on a surface, first wipe the area with water and paper towels, and then clean with a disinfectant to decontaminate the spill.

  Warning: Magnetic Field. Can be harmful to pacemaker wearers. Pacemaker wearers stay back 30 cm (12 in.).

QUALITY CONTROL

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

CONTACT INFORMATION

Email: techsupport@pathogendx.com
Phone: (800) 641-2102