



INSTRUCTIONS FOR NASAL/SALIVA USE – English *Caution: Read all steps before collecting samples.*

DEVICE NAME
 PathoGene™ (PTM-01)
 Respiratory Tract Sample Collection
 Media-Extraction-Less

INDICATION FOR USE
 PathoGene Transport Media is intended for the collection, inactivation, transport and storage of human saliva and nasal specimens suspected of containing infectious disease. This device can be used for the collection, transport, and storage of specimens at ambient temperature. Specimens collected in the PathoGene RNA-Extraction-Less collection device are suitable for use with legally marketed molecular diagnostic tests.

CONTENTS
 PathoGene Order#: PTM-01
 50 units of 800µL vials
 Swabs sold separately.

STORAGE AND STABILITY
Pre-collection: 15 months from date of manufacture, between 15-30° C Transport temperature.

Post-collection: Sample stability and storage 15-30° C. 28 days for nasal specimens, and 33 days for saliva specimens.

Additional information available at www.cygnusmedical.com.

WARNING AND PRECAUTIONS
 For external use and single-use only. DO NOT drink, touch, or remove the buffer from the device. Do Not use if device is broken, leaking, or visibly damaged. These products should only be used in accordance with the instructions provided. Avoid skin and eye contact with the liquid in the tube. If Ingested Call a POISON CENTER. Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Not a Hazardous Combustion Product. Device cap can be a choking hazard. Do not ingest.
 Refer to SDS

DEVICES
 PathoGene Transport Media, (Order#:PTM-01) consists of one device pre-filled with 800µL stabilizing buffer.

SKU	Product Name	Stabilizing Buffer
PTM-01	PathoGene™ Transport Media	800µL x 50 units

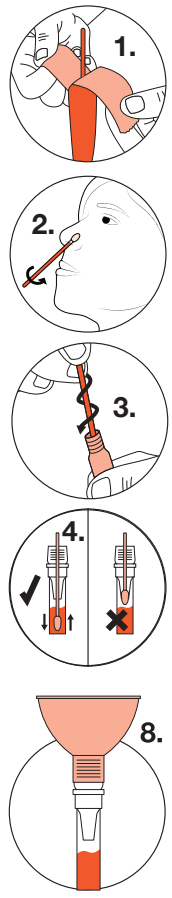
PREPARATION FOR USE:
Before sample collection, verify preferred method of collection with your processing lab.

- It's recommended not to eat, drink, or smoke for 30 minutes before collecting a sample.
- Do not touch swab tips or allow contact with any other object.
- For swab collection, use either 1 or 2 swabs, depending on the test protocol.
- Tap the device gently 2-3 times before collection to concentrate all liquid to the bottom.

If using saliva collection skip to step number 8.
For saliva self-collection, the saliva funnel is purchased separately.

INSTRUCTIONS *(Read all steps before collecting samples).*

- Place device standing up on a flat surface. Peel open bags containing swabs and remove a swab. Unscrew device cap before collecting sample.
- For nasal sample collection:** Insert the swab head into your nostril no more than 3/4" (1.5cm) in. Slowly rotate at least 3 times, gently pressing against the inside of your nostril. Gently remove the swab and repeat this step in your other nostril.
- Pick up tube and hold steady in one hand. Slowly twist swab into the PathoGene™ tube with a corkscrew motion. There will be resistance, but push swab to the bottom of tube.
- Hold tube steady and move swab up and down rapidly inside the tube 10-15 times without moving the swab out of the liquid.
- At this point remove the swab. Hold tube firmly and remove swab by slowly twisting out with a corkscrew motion.
- For a more concentrated sample, a second sample may be collected by repeating steps 2-5 with another swab. Skip this step if unnecessary.
- After all samples have been taken, replace cap tightly. Properly dispose used swabs in the appropriate biohazard waste in accordance with federal, state, and local regulations. The sample is now ready for further testing.
- Saliva Sample Collection (Ignore if using swabs for collection):**
(a) Remove cap from device and place on a clean surface. **(b)** Place PathoGene™ Funnel onto the tube so that it is resting upright as shown in the picture. **(c)** Stimulate saliva production in your mouth. **(d)** Spit 1 or 2 times directly into the funnel. **(e)** Allow several seconds for all saliva to pass through the funnel into the tube. **(f)** Remove funnel and discard in the appropriate biohazard waste in accordance with federal, state, and local regulations. **(g)** Replace cap securely onto tube. **(h)** Gently shake the device 5-10 times to allow mixing. **(i)** The sample is now ready for further testing.
- For Lab or onsite collection:** Proceed with sample processing or storage.



NON-STERILE	SINGLE-USE ONLY	CE MARKING	CATALOG NUMBER
ATTENTION! SEE INSTRUCTIONS FOR USE	DO NOT USE IF PACKAGE IS DAMAGED	IN VITRO DIAGNOSTIC MEDICAL DEVICE	MANUFACTURER
STORAGE TEMPERATURE	LOT NUMBER	FOR IN VITRO DIAGNOSTIC USE. RX ONLY. FOR PROFESSIONAL USE.	
USE BY DATE (COLLECT SAMPLE BY)	CONSULT PACKAGE INSERT BEFORE USE		

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