

Product Code: PKIVD001

Shelf Life: 18 Months

Pack Size: 10 Kits

Kit components

Kit Components	Quantity (Units)
Sample collection vial (with preservative fluid)	1
Sterile cytology brush (cytobrush)	1

Storage

Store preservative fluid without cytological samples at room temperature (2° C to 40° C) in the vials provided. Preservative fluid preserves cells for up to six months at refrigerated temperatures (2° C to 10° C) or up to 4 weeks at room temperature (15° to 30° C). Do not use Preservative Fluid beyond the expiration date printed on the vial.

Principle

Liquid-based cytology kit for cervical screening aims to improve the quality of the conventional cervical smear through an improved slide preparation technique following collection of the sample in the standard way. This is designed to produce a more representative sample of the specimen, with reduced obscuring background material. The liquid-based cytology technique involves not making a smear of the material obtained on the spatula/collection device but rinsing it in a preservative fluid so generating a suspension of cells that is subsequently used to deposit a monolayer of cells on the slide. Almost all of the cells collected from the cervix should thus be present in the fluid. The subsequent stage of the procedure results in a smaller, but more representative cell sample from the cervical specimen than is obtained in a conventional smear.

Material of Construction :

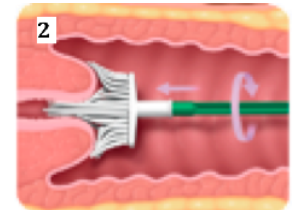
Medical Grade Plastic, Chemical Reagents

Sample Collection procedure:

- Record:** Mention the patient information on the vial and medical history should be recorded on the pathology request form.
- Sampling:** To use the cytobrush (broom-like device), insert the long central bristles into the cervical os until

the lateral bristles bend against the ectocervix and rotate 360° in a clockwise direction 3–5 times in the same direction while maintaining gentle pressure.

- Transfer:** Rinse the cytobrush immediately into the vial by pushing it into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the brush vigorously to further release material. Visually inspect the cytobrush to ensure that no material remains attached. Discard the collection device. Do not leave the head of the cervical sampler in the vial.
- Packing:** Cap the vial tightly. Do not over-tighten. Place the vial and pathology request form in a specimen bag for transportation to the laboratory. Keep the preserved specimen at room temperature or refrigerated (2-8°C). It is recommended to return the specimen to the laboratory as soon as possible after collection.



Technical Assistance

For customer support, please contact our Technical Support: *PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India*
 Customer care No.: +91-7303429198
 Email: info@pathkits.com



Food and Drugs Administration Haryana
SCO-94, SEC-5, Panchkula

From

State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO-94, Sector-5, Panchkula.

To

M/s Pathkits Healthcare Pvt. Ltd.,
28-29, Electronic City,
Gurugram, Haryana

Dated: 04-01-2022

Subject: Regarding additional items.

With reference to your application no. MFG/IVD/2021/50175 dated 15.11.2021 on the subject cited above.

Find enclosed herewith copy of Form MD-5, Lic No MFG/IVD/2021/000069, Endorsement No 4.

Validity unknown
Digitally signed by Manmohan Taneja
Date: 2022.01.04 11:51:15



State Drugs Controller



सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2021/000069

Endorsement No. 4

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Cervical Brush Collection Kit for HPV and Cytology</p> <p>Model No.:PKIVD001 - NA</p> <p>Intended Use:It is used for cervical screening aims to improve the quality of the conventional cervical smear through an improved slide preparation technique following collection of the sample in the standard way.</p> <p>Class of medical device:Class B</p> <p>Material of construction:NA</p> <p>Dimension(if any):Na</p> <p>Shelflife:18 Months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Cervical Brush Collection Kit for HPV and Cytology</p>

Place:

Date04-Jan-22

Validity unknown
Digitally signed by Manmohan Taneja
Date: 2022.01.04 11:57:13



State Licensing Authority