

Human Papillomavirus Self Sample Collection Kit

Instruction for Use

REF Refer to box label

INTENDED USE

This kit is intended for sample collection, transportation and preservation of the cervicals specimen for human papillomavirus analysis in the laboratory.

This kit is for in vitro diagnostic use.

PACKAGING SPECIFICATIONS

1 Set/Kit.

TEST PRINCIPLE

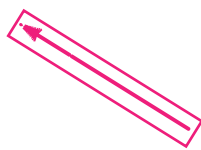
The main component of the preservation solution is Hank's Balanced Salt Solution, which can help to stabilize the virus. Phenol red is added to the preservation solution to indicate the preservation status. Antibiotics are added to prevent the growth of bacteria and fungus.

Keeping the gynecologic sampler in the tube facilitates the subsequent experiments.

THIS KIT MUST INCLUDE FOLLOWING COMPONENTS



Instruction for Use



Gynecologic sampler
(cervical brush)



Sample collection
tube with solution



ID label



Biosafety bag
with fixing tape

SHELF-LIFE, TRANSPORT AND STORAGE

Expiration: 2 years

Storage condition: 2-30°C

- The tube containing the head of the sampler should be transferred to the laboratory for HPV analysis as soon as possible, and make sure it can be delivered to the destination within 7 days.
- Samples need to be tested as soon as possible after they arrive at the laboratory. If the samples can be tested within 7 days, they can be stored at 2-8°C. If storage time exceeds 7 days, the samples should be stored at $(-20 \pm 5)^\circ\text{C}$ for up to 6 months. If longer storage is needed, the samples should be stored at -70°C or colder.

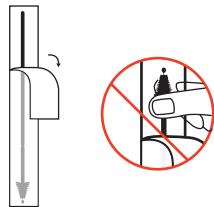
SPECIMEN COLLECTION AND HANDLING

1



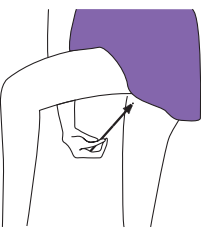
Wash your hands before starting.

2



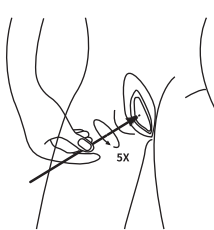
Remove the gynecologic sampler from the packaging. Do not open from the head of the sampler and do not touch head of sampler.

3



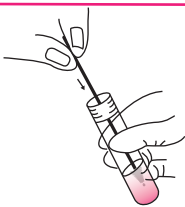
Hold the gynecologic sampler securely in your hand, do not touch the head of the sampler. Assume a comfortable position (such as when you insert a tampon).

4



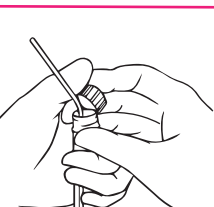
Insert the gynecologic sampler into your vagina as far as possible until you feel a painless resistance (at least 5 cm depth), and gently rotate it clockwise for 4-5 cycles. It is best if the outermost bristles of the sampling head can reach the ectocervix.

5



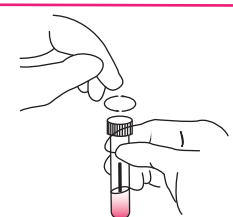
Remove the gynecologic sampler out of the vagina slowly and put it into the sample collection tube with solution.

6



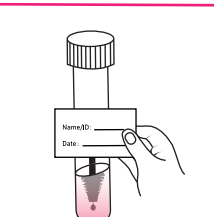
Carefully break the gynecologic sampler along the line of the breakpoint of the handle, and the bottom part containing the sampling head should remain in the tube.

7




Screw the cap of the tube back on with the sampling head inside, and securely tighten.

8



Complete the required information on the label provided and stick the label onto the tube.

9



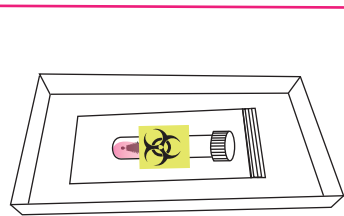
Carefully put the tube with label stuck on, into the biosafety bag provided, and seal the biosafety bag.

10



Peel off the cover film of the fixing tape on the back side of the biosafety bag.

11



Fix the sealed biosafety bag onto the bottom of the outer package provided. Seal the outer package and send it to the local medical service provider according to their instructions. The result of your sample will be reported to you from the local medical service provider.

DO NOT USE THIS PRODUCT UNDER ANY OF THE FOLLOWING CIRCUMSTANCES

- X You are suffering from any gynecological diseases.
- X You are in the middle of a menstrual cycle, or have any vaginal bleeding or injury.
- X You are pregnant or breastfeeding.

PERFORMANCE CHARACTERISTICS

Human papillomavirus samples and related PCR detection reagent were used to evaluate the performance of this product. Results showed that the samples could be stably stored at 42°C for 7 days, 2-8°C for 15 days, and -(20±5)°C for 6 months.

LIMITATIONS

- Performance of the product may be impacted by extreme temperatures and repeated freeze and thaw cycles.
- The performance should be evaluated by combining it with other diagnostic tests which is not mentioned in this instruction booklet.















WARNING AND PRECAUTIONS


- > Please read all instructions carefully and strictly follow the steps shown and explained in this instruction booklet.
- > Do not touch the head of the sampler with hands, or any other items when using the sampler.
- > Do not use the sampler if you notice that the bristles are loose or falling out of the head.
- > Make sure to screw the cap of the tube on tightly once the sampler is inside, to prevent leakage during transportation.
- > Do not reuse or share the product in any way. It is for single use only.
- > Do not use the product if any of the packaging or items are damaged.
- > Do not use the product if the tube containing the liquid is broken, or the liquid is leaking.
- > Do not use this product after the expiry date shown on the box.
- > Do not use this product during a menstrual cycle.
- > Do not use this product during pregnancy, or if you suspect you may be pregnant, or within 3 months of giving birth.
- > Do not use any other vaginal products for at least 2 days before using this product. Vaginal contraceptives, condoms and water based lubricants can be used as normal.
- > Keep out of reach of children.
- > Dispose of any waste packaging in accordance with local authority laws.

If any serious complications or incidents arise in relation to this product, please contact your doctor or gynecologist immediately. Please also contact the manufacturer or its representative, details provided on the product box.

Manufacturing date and expiration date: view on package.

INDEX OF SYMBOLS

	Consult Instructions for Use		Contain <n> tests		Do not use if package is damaged and consult instructions for use
	In vitro diagnostic medical device		Use-by date		Authorized Representative in the European Community
	Catalogue #		Lot Number		Temperature limit 2 to 30°C
	Manufacture Date		Manufacturer		CE conformity marking
	Unique device identifier		Do not reuse		

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