EC REP

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CE

Product Insert – Instruction to Use (Rev 1-2016)

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CY-PREP® Pap Test - Dual Filtration Technology

Intended Use for Gynaecologic Applications

CY-PREP® Pap Test is designed for use with the CY-100 Processor, refer to Operation Manual on instruction to use.

Summary and Explanation of the CY-PREP® Pap Test

The CY-PREP® Pap Test is a liquid based Pap preparation assay for the process of liquid based cytology smears for the evaluation of oncologic cytology, and to enable molecular testing for the detection of HPV, CT and GC from the cervical vaginal material collected in the liquid preservation fluid.

Cervical-vaginal materials are first collected using a broom-like cell sampling device, the Cervix-Brúm®, or the Spatula & Cytobrush combination, and are rinsed into a vial of liquid preservation fluid, the CY-PREP® Preservation Solution. This will ensure at least 95% of the cellular material collected are rinsed into the liquid medium, in contrast to only 20-30% (Hutchinson et. al) of cells are being smeared onto the glass slides by the conventional Pap Smear method.

The cervical-vaginal materials sample are then processed with the CY-100 Processor, which separates the cellular materials from obscuring blood, mucus and unwanted debris, follow by a transfer process, where the cellular materials are transferred onto a positive charged glass slide.

Reagents

For In Vitro Diagnostic Use.

Warnings

Not for external or internal use in humans or animals. Causes eye and skin irritation. Keep away from heat, sparks and flame. Avoid breathing vapour. Keep vial closed when not in use. Use with adequate ventilation. Wash thoroughly after handling.

First Aid Measures

After skin contact : wash thoroughly with running water.
After eye contact : rinse eye under running water.
After inhalation : take deep breath of fresh air ; consult doctor in case of difficulties.

Storage

Store CY-PREP® Preservation Solution vial without cytologic samples at 15º - 30º C.
Do not use CY-PREP® Preservation Solution beyond the expiration date marked on the vial.

Specimen Collection for Gynaecologic Samples

Collect cervical-vaginal samples following the recommended technique and rinsed in the CY-PREP® Preservation Solution as described in the Procedure For Cervical Cells Sampling. Always use good sampling techniques when collecting samples. Poor sampling techniques will produce inadequate samples

Specific Performance Characteristics

When used and stored as described, CY-PREP® Preservation Solution will preserve the integrity of the cells sample in solution for up to 3 weeks at 15º - 30º C.

Limitations

All reagents and materials provided in this kit have been designed to optimally perform on the CY-100 Processor. Supplies from other sources that are not made by FJORD DIAGNOSTICS should not be used, as this will compromised the performance of the product. FJORD DIAGNOSTICS reserved the right to decline responsibility of the product performance should supplies from other sources are used on the CY-100 Processor. All items in this kit are for single used only and not to be reused.

Contents of the CY-PREP® Pap Test Kit

1) Preservation Solution Vial (Qty : 300 vials)
Each vial is pre-filled with 20 ml of CY-PREP® Preservation Solution to maintain gynaecologic specimen integrity During collection, transport and preparation. The CY-PREP® Preservation Solution is an ethanol buffer formulated preservation solution that serves as a transport, preservative, and antibacterial medium for gynaecologic samples.

2) Cervix-Brum® broom-like cervical sampler / or Spatula & Cytobrush cervical samplers (Qty : 300 pouches)
The cervical sampler Cervix-Brum® or Spatula & Cytobrush combination are used for sampling of cervical cells from both the ectocervix and endocervix.

3) Dual Filter (Qty : 300 pieces)
The dual filter is made up of 2 cylindrical housings joined together, with the upper housing being mounted with a larger pore size membrane to sieve out unwanted debris, while the bottom housing is mounted with the optimum pore size membrane to capture and retain cervical cells for cytological investigation.

4) Microscope Glass Slides (Qty : 300 pieces)
Chemical treated white frosted end microscope glass slide with the CY-PREP® Dual Filtration imprint (76 x 26 mm)

Instruction to use for Cervical Cells Sampling

(a) Sampling using the Cervix-Brum®

- Contact the cervix with the Cervix-Brum® and insert the central bristles into the cervical canal deep enough to allow the Shorter bristles to fully contact the ectocervix. While maintaining pressure in the direction of the cervix, gently rotate the Cervix-Brum® 5 times in a clockwise direction by rolling the stem between the thumb and the forefinger.

- Uncap the CY-PREP® Preservation Solution vial, and insert the Cervix-Brum® with the collected cell sample into preservation solution. Rinse the cells collected with the Cervix-Brum® in the preservation solution by swirling around the sides of the vial 10 times and also gently pressing the bristles to the base of the vial to dislodge the cells from the Cervix-Brum®.

- Recap the vial and dispose of the used Cervix-Brum® in accordance with the local Medical Hazardous Waste Practice.

(b) Sampling using the Spatula & Cytobrush combination

- Contact the ectocervix with the Spatula, while maintaining pressure in the direction of the cervix, gently rotate the Spatula 3-5 times in a clockwise direction by rolling the stem between the thumb and the forefinger to collect the ectocervical cells. Uncap the CY-PREP® Preservation Solution vial, and insert the Spatula with the collected cell sample from the ectocervix into preservation solution. Rinse the cells collected by swirling around the sides of the vial 10 times to dislodge the cells from the Spatula. Dispose of the used Spatula in accordance with the local Medical Hazardous Waste Practice.

- Next, insert the Cytobrush into the cervical canal deep enough to collect the endocervical cells by gently rotating the Cytobrush clockwise for a ¾ turn. Note : excessive sampling of more than the required ¾ turn might cause bleeding. Insert the Cytobrush with the collected cell sample from the endocervix into preservation solution, and rinse it by swirling around and pressing the bristles against the sides of the vial to dislodge the cells from the Cytobrush. Recap the vial and dispose of the used Cytobrush in accordance with the local Medical Hazardous Waste Practice.

Warranty

This product is warranted to perform as described in the labelling and in FJORD DIAGNOSTICS literature. FJORD DIAGNOSTICS disclaims any implied warranty of merchantability of fitness for any other purpose and in no event will FJORD DIAGNOSTICS be liable for any inconsequential damages arising out of the aforesaid express warranty.