

# FJORD - URINE HPV RAPID ANTIGEN TEST

World's first Urine HPV Rapid Antigen Test for the screening of Cervical Cancer Risk, providing real-time test result in 15-30 minutes.






Urine tests for HPV, accessible screening for all could just be the key to preventing cervical cancer

- Utilizing the patented SEDIPREP® Sample Preparation Technology in the pre-concentration of HPV viral load of collected first-void urine sample of up to > 40x, transforming it into its final HPV viral load concentration that is now suitable for lateral flow assays.
- Ease of urine sample collection for women, and men.
- Self-administered, no embarrassment, no pelvic examination.
- Non-invasive, no discomfort and pain-free.
- Diagnostic accuracy  
Urine HPV16,18 Ag-RDT vs Cervical HPV PCR - Sensitivity: 82% ; Specificity: 89%  
Urine HPV6,11,16,18,31,33,45,52,58 Ag-RDT vs Cervical HPV PCR - Sensitivity: 84% ; Specificity: 91%

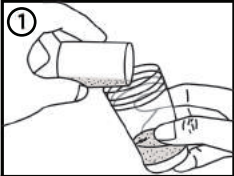
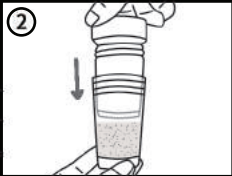

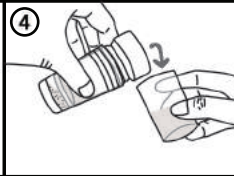




# REFERENCE GUIDE FOR PROCESSING THE URINE HPV RAPID ANTIGEN TEST

## Step 1 : Self-collection of First-Void Urine

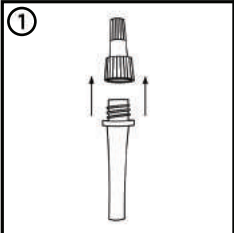
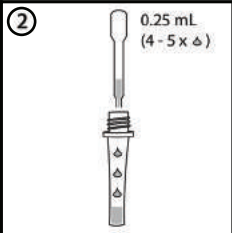
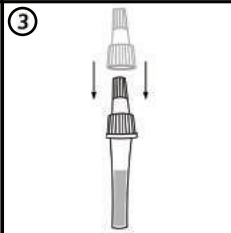
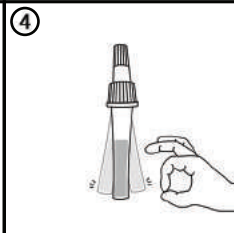
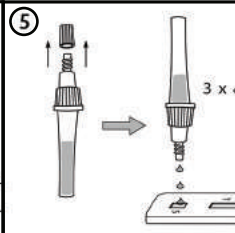
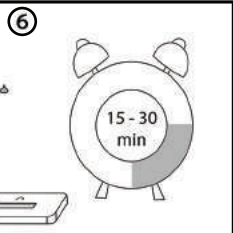
		
<p>Use the yellow cap sample container.</p>	<p>Collect first-void (first-catch) urine into the container, up to 1/3 level full.</p>	<p>First-void urine should be at 1/3 level full.</p>

## Step 2 : Pre-concentration of initial collected urine HPV viral load to > 40x, into final HPV viral load concentration suitable for the Urine HPV Rapid Antigen Test

					
<p>Pour urine sample into the SEDIPREP® Container Unit, up to the calibrated line marking.</p>	<p>Slid the SEDIPREP® Filter Unit axially into the Container Unit.</p>	<p>Fasten the SEDIPREP® Filter Unit into the Container Unit, in a clockwise screw capping action up to maximum.</p>	<p>Decant the filtrate/ supernatant that has entered into the SEDIPREP® Filter Unit during the clockwise fastening step.</p>	<p>Unfasten the SEDIPREP® Filter Unit from the Container Unit in counter-clockwise uncapping action, and discard.</p>	<p>The balance concentrated urine sediment retained in SEDIPREP® Container Unit can now be used for Urine HPV Rapid Antigen Testing.</p>

Repeat the process 3-5 of above flowchart, if balance concentrated urine sediment volume retained is >0.5 ml, or if unsure of volume balance as seen by the naked eye for the sample.

## Step 3 : Processing the Urine HPV Rapid Antigen Test

					
<p>Uncap the blue cap of the Extraction Tube.</p>	<p>Use the dropper pipette to transfer 0.25 mL (4-5 x Δ) of SEDIPREP® pre-concentrated urine sample processed from STEP (2) into the Extraction Tube. Expel excessive sample back into the urine container.</p>	<p>Recap blue cap back onto the Extraction Tube with the urine sample.</p>	<p>Flick the bottom of the tube to mix sample solution for roughly 45-60 seconds.</p>	<p>Take out a test card from the aluminium foil pouch, and place it on a table. Uncap the small white cap of the Extraction Tube, hold it upside down vertically, and squeeze the tube to expel 3-4 drops of sample solution into the loading well on test card. (Note: DO NOT reload sample solution onto a used test card).</p>	<p>Read the result after 15 minutes for optimal detection accuracy. The result is considered inaccurate and invalid after 30 minutes. Dispose of used test card and other waste items into zip-lock pouch provided and discard accordingly.</p>

### INTERPRETATION OF RESULTS

**Positive (+):** Two bands appear at both of T and C line in 15 to 30 minutes.

**Negative (-):** A band appears at C line while no band appears at T line in 15 to 30 minutes after sample loading.

**Invalid:** As long as no band appears at C line, it indicates that the test result is invalid, and should retest the sample with another test card.

