

Gonorrhoea Rapid Test CE

Pack size

20 tests

Product Description

The Biopanda Gonorrhoea Rapid Test qualitatively detects *Neisseria gonorrhoeae* in female cervical swab and male urethral swab specimens. The test is intended for professional use to help diagnose Gonorrhoea infections.



Test Attributes

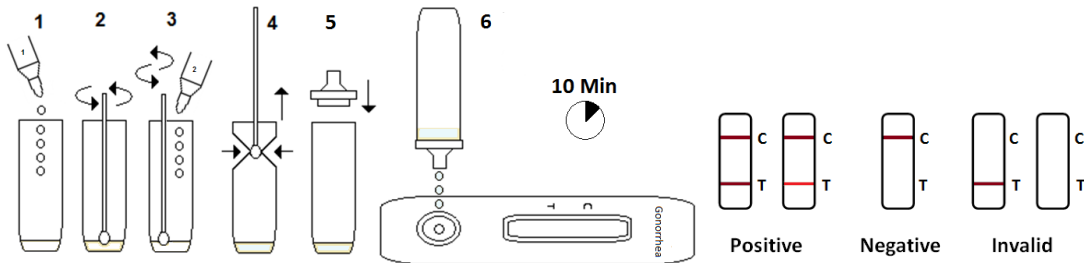
- Female cervical swab and male urethral swab specimens may be used for testing
- Results available in only 10 minutes
- Easy to use
- Results can be read visually
- No need for an analyser
- Cost effective method for assisting in the detection of Gonorrhoea infections

Principle

The Biopanda Gonorrhoea Rapid Test is a qualitative, lateral flow immunoassay for the detection of Gonorrhoea antigen from female cervical and male urethral swab specimens. In the test, antibodies specific to the Gonorrhoea antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Gonorrhoea that is coated onto particles. The mixture migrates laterally to react with the antibody to Gonorrhoea on the membrane and generates a coloured line in the test region. The presence of this coloured line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Test Procedure

1. Remove the test cassette from the seal pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Extract the Gonorrhoea antigen according to the specimen type.
3. Hold the reagent 1 bottle vertically and add **5 drops of reagent 1** (approx. 300 µl) to an extraction tube. Reagent 1 is colourless. Immediately insert the swab, compress to the bottom of the tube and rotate the swab 15 times. Let it stand for 2 minutes.
4. Hold the reagent 2 bottle vertically and add **4 drops of reagent 2** (approx. 200 µl) to the extraction tube. The solution will turn turbid. Compress the bottom of the tube and rotate the swab 15 times until the solution turns clear with a slight green or blue tint. If the swab is bloody, the colour will turn yellow or brown. Let it stand for 1 minute.
5. Press the swab against the side of tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible. Fit the dropper tip on top of extraction tube.
6. Place the test cassette on a clean and level surface. Add 3 full drops of the extracted solution (approx. 100 µl) to the specimen well of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well.
7. Wait for the coloured line(s) to appear. Read the result at 10 minutes. Results read after 30 minutes are considered invalid.



Performance characteristics

| Specimen | Sensitivity | Specificity | Accuracy |
|--------------------------------|-------------|-------------|----------|
| Female Cervical Swab Specimens | 94.4% | 96.9% | 95.9% |
| Male Urethral Swab Specimens | 91.6% | 97.1% | 94.3% |

Storage Conditions

+2 - 30 °C

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