Core tests

Gonorrhea Rapid Test Device

INTENDED USE

Core Tests Gonorrhea Rapid Test Device is designed for the qualitative detection of Gonorrhea in the female cervix and male urethra, serving as a clinical aid in diagnosing Gonorrhea infections. Test results should be confirmed by a clinician in conjunction with symptoms, signs, and other diagnostic findings.

PRINCIPLE

Core Tests Gonorrhea Rapid Test Device uses highly specific antigen-antibody reactions and immunochromatography analysis techniques for the qualitative detection of whether clinical specimens contain Gonorrhea trachomatis antigen. The test kit contains Gonorrhea trachomatis antigen-specific antibodies, which are pre-fixed on the test area (T) on the membrane, and the corresponding antibodies on the quality control area (C). During the detection, the lysed specimens on the cotton swab are titrated into the sampling wells (S) of the test kit, and the specimens react specifically with the Gonorrhea trachomatis antigen of the pre-coated gold particles. Then, the mixture moves upward through chromatography under capillary action. If the result is positive, gold-labeled Gonorrhea will first bind with Gonorrhea trachomatis antigen in the specimens during the chromatography process, then the complex will bind with the specific antibody of Gonorrhea trachomatis antigen, which is fixed on the membrane. A red band will appear within the test area (T). If the result is negative, there will be no red band within the test area (T). Regardless of whether the Gonorrhea trachomatis antigen exists in clinical samples, there will be a red band within the quality control area (C). The red band within the quality control area (C) indicates whether there is sufficient sample and whether the chromatography process meets normal standards. At the same time, it serves as the internal control standard for the test.

WARNINGS AND PRECAUTIONS

- This test is intended for use by qualified professionals for extrinsic diagnosis.
- Do not use the product after its expiry date. Avoid mixing reagents or test kits from different batches. Do not mix solutions A and B.
- Follow all precautionary measures when collecting, processing, storing, or discarding samples, as well as when using the reagents included in the test kit. Treat all samples, reagents, and control substances as potentially infectious materials.
- Extraction solution A contains sodium hydroxide, and extraction solution B contains hydrochloric acid. If either solution comes into contact with the skin or eyes, rinse immediately with water.
- Use only the provided swab or a sterile Dacron or cell brushes for sample collection. Cotton swabs are not suitable for this procedure.
- Eating, drinking, and smoking are strictly prohibited in areas where samples and reagents are handled. Wear protective clothing and gloves when collecting and testing samples.
- The final diagnosis of a patient must not rely solely on the results of this test. Comprehensive judgment should include clinical examination and evaluation by a qualified doctor.

COMPOSITION

Materials Provided

- Manual
- Gonorrhea Test Cassette
- Reagent A
- Reagent B
- Sterilized Swab
- Sample Processing Tube with Dropper Tip

STORAGE AND STABILITY

- Store the test kit in its sealed pouch at room temperature (4-30℃ or 39-86°F). The test kit remains stable until the expiration date printed on the label.
- Once the pouch is opened, the test must be used within one hour.
- Prolonged exposure to a hot and humid environment will cause product deterioration.

SPECIMEN

The quality of the collected specimens is of paramount importance for Gonorrhea detection. The detection quality of Gonorrhea depends on accurate sample collection techniques, which should contain a large number of certain active cellular components, and the samples should not just contain body fluids.

Female cervical sampling:

1. Use the provided swabs. Before sampling, wipe mucus from the cervical extraoral region with other swabs or cotton balls. Insert the sampling swab into the cervical tube through the squamous-columnar epithelium junction until the swab head is virtually invisible. After rotating the swab for 15-20 seconds, take it out. Do not hit the outside of the cervix or vaginal wall. This will ensure the collection of more columnar epithelial cells, while Gonorrhea mainly parasitizes columnar epithelial cells.
2. Cervical samples can also be collected by the use of a cell brush (not provided). **(Note: Pregnant women should not use this method.)** After cleaning the cervical extraoral region, insert a cell brush into the cervical tube through the squamous-columnar epithelial cells junction, and stay for 2-3 seconds. After two cycles of rotating the brush, take it out, being careful not to hit the vaginal wall.
3. If the detection can be carried out immediately, please place the swab in the processing tube after sampling.

Male urethral specimen collection:

1. Sterilized swabs or a cell brush (not provided) can be used for urethral sampling.
2. Patients should not urinate at least 1 hour before sampling.
3. Insert the swab or cell brush into the urethra for 2-4 cm, and after rotating for 3-5 seconds, take it out. If the detection can be carried out immediately, please place the swab in the processing tube after sampling. If you don't perform an immediate test, place the sample in a dry test tube for storage or transportation.
4. Samples can be kept for 4-6 hours at room temperature (15-30℃) or stored at 2-8℃ under cold storage for 7 days. It cannot be frozen. Specimens should be brought back to room temperature before testing. It is highly recommended that testing be performed immediately.

TEST PROCEDURE

A. Sample Processing and Control:

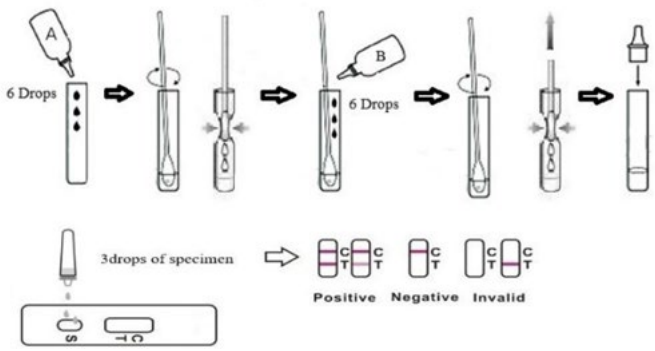
1. Add 6 drops of extraction solution A (approximately 390 µl) into the sample processing tube.
2. Insert the sampling swab into the sample processing tube containing extraction solution A. Continuously rotate and squeeze the swab against the tube wall during the process to extract as much liquid as possible. Repeat this several times over 2 minutes.
3. Add 6 drops of extraction solution B (approximately 390 µl). Rotate and squeeze the swab as thoroughly as possible to extract the liquid. Discard the swab.

4. Fit the dropper tip onto the top of the sample processing tube.
5. If the sample is used within 60 minutes of specimen collection, this will not affect the detection results of the test kit.

Notes: The amount of solution A and solution B added should be equal during swab processing.

B. Detection Steps:

1. Read the instructions for the test kit carefully before starting the procedure.
2. Remove the test kit from the sealed pouch and place it on a clean, dry, and level surface. If the test kit has been stored at a temperature lower than room temperature, allow the test kit and reagents to reach room temperature before use.
3. Add three (3) drops of the processed sample from the sample processing tube into the sampling wells of the test kit.
4. Wait for the results to appear. Results can be interpreted 10 minutes after the sample is added. The appearance time of the red line varies depending on the Gonorrhea content in the swab sample, with some positive samples showing results within 60 seconds. To ensure accuracy, do not interpret the results after 15 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane: one in the control region (C) and another in the test region (T).

NEGATIVE: Only one colored band appears in the control region (C). No colored band appears in the test region (T).

INVALID: The control band does not appear. Results from any test without a control band at the specified read time must be discarded. Please review the procedure and repeat the test with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

A. Minimum detectable quantity

If taking quality control test with Gonorrhea, the minimum detectable quantity should be no higher than $5x10^4$ ml.

B. Specificity

The following microorganisms do not cross-react with the Core Test Gonorrhea Rapid Test Device when they do not exceed $1x10^6$ CFU/ml.

ACINETOBACTER	SALMONELLA TYPHI	NEISSERIA GONORRHOEAE
STAPHYLOCOCCUS AUREUS	PSEUDOMONAS	CANDIDA ALBICANS
ESCHERICHIA COLI	STREPTOCOCCUS FAECALIS	STREPTOCOCCUS FAECIUM
STREPT B	TRICHOMONAS VAGINALIS	

LIMITATIONS OF THE TEST

1. The detection of Gonorrhea trachomatis with this test kit depends on the Gonorrhea content in the sample, sampling methods, and the patient's condition, such as age and venereal disease history. Other symptoms and conditions may also affect detection.
2. When detecting Gonorrhea of different serotypes with this test kit, the minimum detectable level may vary.
3. Improper operation, incorrect techniques or steps, and the presence of other non-listed substances may interfere with detection, leading to inconsistent or erroneous results. Please refer to the Performance Characteristics section for a list of substances that could interfere with detection.

INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
	Stored between 4-30℃		Consult instruction for use
	Caution	LOT	Lot number
	Use by	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged