INTENDED USE
D-Tek One Step Chlamydia Test is a rapid immunosorbent test (RIST) for the qualitative detection of Chlamydia antigen from endocervical or endourethral swab specimens as well as urine from men. It is intended for professional use.

SUMMARY AND EXPLANATION
Chlamydia trachomatis is one of the most common sexually transmitted diseases. It is a major cause of cervicitis, urethritis, endometritis, and pelvic inflammatory disease in women. Serious complications can result in salpingitis, infertility, and ectopic pregnancy. If transmitted to infants during birth, Chlamydia can cause conjunctivitis and pneumonia. 50–70% of infected women are asymptomatic, which makes diagnosis extremely important.\(^1\)

Chlamydiae are related to gram-negative bacteria. They are intracellular in nature and are unable to synthesize adenosine triphosphate (ATP).\(^2\) The extracellular elementary body form is infectious while the intracellular reticulate form is metabolically active. Epidemiological patterns indicate infections of Chlamydia trachomatis parallel or exceed those of Neisseria gonorrhoeae, and the two often occur together.\(^3\) The disease cuts across the socio-economic spectrum. The primary method for detection of Chlamydiae is growth of the organism in cell culture. Other methods include direct fluorescence assays (DFA), enzyme immunoassays (EIA), and nucleic acid probing.\(^4,5\)

PRINCIPLE
D-Tek One Step Chlamydia Test is an immunochromatographic assay which utilizes a unique combination of monoclonal and polyclonal antibodies to selectively identify Chlamydia trachomatis antigen from endocervical or endourethral swab specimens as well as urine from men with a high degree of sensitivity. In the procedure, extraction sample from the swab is allowed to migrate through the absorbent area. If Chlamydia trachomatis antigen is present, the labeled colloidal-gold antibody conjugate binds to it, forming an antibody / antigen complex. As the reaction mixture continues to flow along the test membrane, the complex binds to the anti-Chlamydia antibody coated on the Test Reaction Zone “T” of the membrane, producing a rose-pink to purple color band. Unbound conjugate continues flowing and binds to a non-specific antibody coated on the Control Reaction Zone “C”, producing a second rose-pink color band which demonstrates proper test performance. If no antigen is present, the Test Reaction Zone will remain clear.

REAGENTS AND MATERIALS SUPPLIED

1. Test Devices 20 individually pouched test devices containing dye-conjugated and immobilized anti-Chlamydia antibodies. Each pouch also contains a plastic transfer pipette and a desiccant packet.
2. Extraction Reagent A 1 Bottle of 7 ml
3. Extraction Reagent B 1 Bottle of 11 ml

Note: Extraction Tubes, Positive Control and swabs are not included in the kit.

EXTRACTION PROCEDURE
1. Open the foil pouch at the notch and remove the test device and swab. Hold the dropper vertically and expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube above the extraction mixture. Discard the swab. The extraction mixture can be tested immediately or within 2 hours.

2. Insert the swab into the urethra of the penis. Gently rotate with a high degree of sensitivity. In the procedure, extraction sample from the swab is allowed to migrate through the absorbent area. If Chlamydia trachomatis antigen is present, the labeled colloidal-gold antibody conjugate binds to it, forming an antibody / antigen complex. As the reaction mixture continues to flow along the test membrane, the complex binds to the anti-Chlamydia antibody coated on the Test Reaction Zone “T” of the membrane, producing a rose-pink to purple color band. Unbound conjugate continues flowing and binds to a non-specific antibody coated on the Control Reaction Zone “C”, producing a second rose-pink color band which demonstrates proper test performance. If no antigen is present, the Test Reaction Zone will remain clear.

PROCEDURE NOTES
1. Bring all samples and controls to room temperature (15–30°C) prior to testing.
2. Do not open the foil pouch until ready to perform the test.

ASSAY PROCEDURE

NOTE: Read all test instructions before running patient samples or controls.

Male Patients
1. Insert the swab into the urethra of the penis. Gently rotate with sufficient pressure to dislodge the epithelial cells. Allow the swab to remain inserted for a few seconds after rotating.
2. Carefully remove the swab, avoiding contact with any external surfaces.
3. Follow the standard laboratory procedure for the collection of male sample from urethral area or endocervical area with swab or cytology brush. The swab is not processed immediately, it may be stored for up to 4 hours or 72 hours at 2 – 10 °C.

Female Patients
1. Remove any excess mucus from the potentially infected site.
2. Rub the swab vigorously over the infected endocervical lining and endocervical cells in the canal walls. As Chlamydia are intracellular organisms, firm contact must be made with the canal wall for proper specimen collection. The rubbing action dislodges the endothelial cells and allows the swab to absorb the bacteria. Improper collection will result in poor visual readings and may cause incorrect results.
3. Collection of the columnar or cuboidal epithelial cells from endocervical area is critical to the sensitivity of the tests as those cells are the main reservoir or the chlamydia organism. If the swab is not processed immediately, it may be stored for up to 4 hours or 72 hours at 2 – 10 °C.

Interpretation of Results
Negative: One rose-pink band appears in the Control Reaction Zone “C” with no band in the Test Reaction Zone “T”. This indicates the absence of Chlamydia antigen or the amount of antigen is below the sensitivity level of the assay.
Positive: Two rose-pink bands appear, one in the Control Reaction Zone “C” and one in the Test Reaction Zone “T”. This indicates presence of Chlamydia antigen.
Invalid: If after 10 minutes, a rose-pink band appears in the Test Reaction Zone “T” but not in the Control Reaction Zone “C”, or if no bands appear at all, the test is invalid. Retest the specimen using a new Test Device.
Quality Controls

Internal Controls: D-Tek 'One Step Chlamydia Test Device contains a built-in procedural control. The development of a rose-pink band in the Control Reaction Zone indicates that the sample has been absorbed into the device, that antibody reactivity is normal, and that the procedure has been performed correctly.

External Controls: Good laboratory practice recommends the use of quality controls to ensure proper test performance.

Limitations of the Test
1. For in vitro diagnostic use only.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
3. Cases in which patient swabs test negative while the patient’s clinical symptoms are indicative of Chlamydial infection, it should be investigated further.
4. Repetitive reactive specimens should be confirmed by culture or qualified.
5. For Research use or export only. Do not use beyond expiration date.
6. For optimal test performance, proper sample collection, storage procedures, and assay procedures are critical.

Bibliography

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