INTENDED USE
INSIGHT CHLAMYDIA is a rapid, self-performing, immunochromatographic assay for the detection of Chlamydia Trachomatis specific antigen in human urine, cervical and urethral specimen.

SUMMARY
Chlamydia is a sexually transmitted disease caused by the bacteria Chlamydia trachomatis as is usually spread through vaginal, oral or sexual relations. It is a major cause of cervicitis, urethritis and pelvic inflammatory disease in women. If transmitted to infants during birth, Chlamydia can cause conjunctivitis and/or pneumonia. Many a times, the disease is devoid of symptoms but the test is indicated if the patient experiences symptoms such as changes in vaginal discharge and lower abdominal pain. If untreated, this disease can impair a woman's reproductive organs permanently leading to infertility and ectopic pregnancies. In men, chlamydia infection from the penis and can affect sperm function.

PRINCIPLE
INSIGHT CHLAMYDIA is based on the principle of agglutinating sera on membrane and utilizes the technique of immunochromatography. The conjugate pad is impregnated with monoclonal Chlamydia antibodies conjugated with colloidal gold. As the specimen flow through the membrane assembly of the device, the Chlamydia antibodies conjugated with colloidal gold, binds to the Chlamydia trachomatis antigen of specimen and moves on the membrane due to capillary action. This complex moves further on the membrane to the test region (T) where the immobilized by monoclonal Chlamydia antibodies coated on the membrane, leading to formation of a pink/purple band. The absence of the band in the test region (T) indicates a negative result. The unbound complex if any along with the rabbit IgG conjugated with colloidal gold moves further on the membrane and are subsequently immobilized by goat anti rabbit IgG antibodies coated on the membrane at the control region (C) forming a pink/purple band. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED
A. Each INSIGHT CHLAMYDIA kit contains individual pouches each containing a
   1. Device: Membrane test assembly impregnated with colloidal gold conjugated to anti chlamydia antibody (monoclonal)
      and goat anti rabbit (monoclonal) antibodies at the respective regions.
   2. Desiccant pouch.
   3. Sample dropper.
B. Reagent A in a dropper bottle.
C. Reagent B in a dropper bottle.
D. Package insert.

OPTIONAL MATERIAL REQUIRED
Variable volume precision micropipettes, test tube (12 x 75 mm), stopwatch, sterile swabs, sterile urine containers.

STORAGE AND STABILITY
The sealed pouches in the test kit and the kit components may be stored between 4-30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE
(1) For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE. (2) Do not use beyond expiry date. (3) Read the instructions carefully before performing the test. (4) Handle all specimen as if potentially infectious. (5) Follow standard biosafety guidelines for handling and disposal of potentially infectious material. (6) If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.

SPECIMEN COLLECTION
(1) INSIGHT CHLAMYDIA uses male urine and female secretory specimen from the urogenital system as the test specimen. (2) The patient should not apply any vaginal creams or sprays at least 24 hours prior to testing. (3) The patient should not be allowed to urinate for at least 1 hour before the specimen is collected for testing. (4) The test specimen should be freshly collected using a swab in the following manner: (a) For Male Urine specimens: Directly collect the urine specimen in a sterile, dry container or air tight, self-performing, immunochromatographic assay for the detection of Chlamydia Trachomatis specific antigen in human urine and cervical and urethral specimen in both men and women.

SPECIMEN PREPARATION
For Female Cervical and Urethral specimen:
(1) Dispense 6 drops of Reagent A from the dropper bottle into a test tube. Place the swab containing the test specimen into the test
tube. Ensure that the swab is completely immersed in the Reagent A. (2) Squeeze and swirl the swab gently but thoroughly to extrude the collected specimen (2 minutes should be sufficient). (3) Dispense 6 drops of Reagent B from the dropper bottle to the test tube. Mix well. This is the test specimen. (4) Rotate the swab, squeeze it and discard into a disinfectant container.

For Male Urine specimen:
(1) Collect at least 5 ml of the urine specimen into a test tube. (2) Centrifuge the urine specimen at 1000 rpm for 10 minutes. During centrifugation, the chlamydial infected particles will settle at the bottom of the test tube. Discard the supernatant. (3) Dispense 6 drops of Reagent A from the dropper bottle into the test tube. Mix well. (4) Allow to stand for 2 minutes at room temperature. (5) Dispense 6 drops of Reagent B from the dropper bottle to the test tube. Mix well. Allow to stand for 2 minutes at room temperature. This is the test specimen. 

Note: Ensure that equal volumes of Reagent A (6 drops only) and Reagent B (6 drops only) are dispensed. Any imbalance in volume will produce erroneous results.

TESTING PROCEDURE
(1) Bring the kit components of INSIGHT CHLAMYDIA device to room temperature before testing. (2) Open a foil pouch by tearing along the "notch". (3) Remove the testing device and the sample dropper. (4) Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. Once opened, the device must be used immediately. (5) Label the device with specimen identity. (6) Place the testing device on a flat horizontal surface. (7) Holding the dropper vertically, carefully dispense exactly two drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 100 µl of test specimen into the specimen port (S). (8) Start the stopwatch. Read the test result at the end of 15 minutes. Do not interpret the test result beyond 30 minutes.

INTERPRETATION OF RESULTS
Negative Result:
Only one pink / purple coloured band appears at the Control Region (C). This indicates absence of Chlamydia Trachomatis specific antigen.

Positive Result:
Two pink / purple coloured bands appear at the Control Region (C) and Test Region (T). This indicates that the specimen contains detectable amount of Chlamydia Trachomatis specific antigen.

Invalid Result:
The test result is invalid if no band appears either at the Control Region (C) or Test Region (T). In such cases, verify the test procedure and repeat the test with a new INSIGHT CHLAMYDIA device.

REMARKS
(1) The deliberate slow reaction kinetics of INSIGHT CHLAMYDIA is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity. (2) Most positive results develop within 15 minutes. However, certain sample may take a longer time to flow. Therefore, negatives should be confirmed only at 15 minutes. Do not interpret the results beyond 30 minutes. (3) As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. (4) Discrepant results may arise if the patient is consuming antibiotics or using some sprays or vaginal creams 24 hours prior to testing. (5) Swabs with an excessive amount of mucous or blood may give rise to false positive results. Such swabs should not be used for testing. (6) Reagent A contains Sodium Hydroxide and Reagent B contains Hydrochloric Acid. Avoid contact with skin and eyes. In accident spills, wash immediately with plenty of water. Do not intermix the reagent droppers. (7) Chlamydial infections commonly are chronic and may be asymptomatic or precipitate minor symptoms. INSIGHT CHLAMYDIA should be used as a screening test in clinically suspected cases only, and its results should be confirmed by other supplemental method before taking clinical decisions. (8) Correct collection and extraction of the recommended specimen is crucial to the correct functioning of the test.

WARRANTY
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY