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Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep Legionella Urinary Antigen RapiCard™ InstaTest

REF 176075-1-23

IVD See external Label 4 °C 30°C Σ 25 Tests

INTENDED USE

Cortez Diagnostics, Inc. OneStep Legionella Urinary Antigen RapidCard™ InstaTest is an *in vitro* qualitative immuno-chromatographic assay for the rapid detection of legionella pneumophilia antigens in human urine specimen. The test results are intended to aid in the diagnosis of legionella pneumophila infection and to monitor the effectiveness of therapeutic treatment.

INTRODUCTION

Legionella pneumophila serogroup I is gram-negative bacillus. It is now recognized to be the common cause of community-acquired and nosocomial pneumonia. Infections caused by this bacterium include the pulmonary disease of pneumonia. The infections may spread through the blood circulation or the lymph system to heart, brain, kidney, liver and spleen. In addition, gastrointestinal symptoms are prominent in Legionella pneumonia. Legionellaire's disease can be acquired by the inhalation of aerosols associated with air handing systems, respiratory therapy equipment and whirlpool baths. The elderly are seen as most susceptible to the infection, although children and neonates are also affected. About 5% to 39% of people with legionnaires' disease die. Legionella pneumophila serogroup I antigen has been detected in urine during acuate phase of the disease. It presents an opportunity for rapid detection of the bacterium with non-invasive method. Rapid diagnosis and early initiation of appropriate antimicrobial therapy can significantly reduce the mortality associated with Legionella pneumonia.

TEST PRINCIPLE

Cortez OneStep Legionella Urinary Antigen RapidCard™ InstaTest is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of urine sample is added to the sample well of the test cassette. The sample flows through a label pad containing legionella pneumophila serogroup I antibody coupled to red-colored colloidal gold. If the sample contains legionella pneumophila serogroup I antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which Legionella pneumophila specific antibodies are immobilized. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If rotavirus antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line dose not developed, the test is invalid.

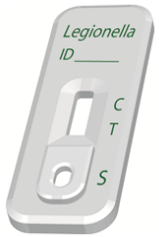
SPECIMEN COLLECTION AND PREPARATION

1. The urine specimen must be collected in a clean, sterile container. Urine specimens may be refrigerated (2-8°C) and stored up to 72 hours prior to assay.
2. For long-term storage of specimens, -20°C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self- defrosting freezers.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. Cortez OneStep Legionella Urinary Antigen RapidCard™ InstaTest. Each cassette contains a test strip with Legionella pneumophila specific antibody on the test region of the membrane and colored Legionella pneumophilia antibody-gold conjugate pad.



Legionella Urinary Antigen Test Card

2. Disposable specimen dropper.

Materials required but not provided

1. Specimen collection container.
2. Timer

REAGENT PREPARATION

Bring all reagents, including test device, to room temperature (8-30°C) before use.

ASSAY PROCEDURE

1. Bring all materials and specimens to room temperature (8 – 30°C).
2. Remove the test card from the sealed foil pouch.
3. Hold the specimen transfer pipet in a vertical position over the sample well of the test card, deliver 3 drops (120 -150 µL) of specimen to the sample well.
4. Read the result at 10 minutes. A strong positive sample may show result earlier

Note: Results after 10 minutes may not be accurate.

RESULTS

- **Positive result:** A distinct pink colored band appears on test line regions, in addition to a pink line on the control line region.
- **Negative result:** No line appears in the test line region. A distinct pink line shows on the control line region.

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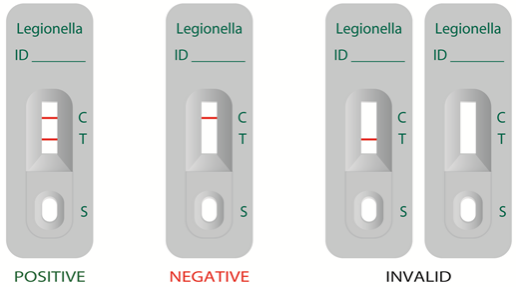
➢ **Invalid result:** The control line next to the test line does not become visible within 15 minutes after the addition of the sample.



PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Cortez OneStep Legionella Urinary Antigen RapidCard™ InstaTest can detect Legionella pneumophila ATCC strain 33152 at about 3000 CFU/mL.

Urine samples form urine tract infection with Klebsiella pneumonia, Enterobacter and E. Coli all showed negative results.

Reproducibility

Reproducibility of Cortez OneStep Legionella Urinary Antigen RapidCard™ InstaTest was determined using negative, low positive, and high positive controls. These samples were tested in replicates of 10 in a blind study by 3 operators working independently in the same laboratory. The agreement of the expected result was 100%.

Adenovirus type 40	$1x10^6$ $TCID_{50}$
Adenovirus type 41	$1x10^6$ $TCID_{50}$
Rotavirus Wa	$1x10^6$ $TCID_{50}$
Campylobacter jejuni	7.63×10^7CFU/ml
Candida albicans	$1x10^8$CFU/ml
Clostridium perfringens A	$1x10^8$CFU/ml
Citrobacter freundii	$1x10^8$CFU/ml
Enterococcus faecalis	$1x10^8$CFU/ml
Escherichia coli	$1x10^8$CFU/ml
Klebsiella pneumonia	$1x10^8$CFU/ml
Listeria monocytogenes	$1x10^8$CFU/ml
Moraxella catarrhalis	$9.9x10^6$CFU/ml
Neisseria gonorrhoeae	$1x10^8$CFU/ml
Pseudomonas aeruginosa	$1x10^8$CFU/ml
Stapylococcus epidermidis	$1x10^8$CFU/ml
Stapylococcus aureus	$1x10^8$CFU/ml
Shigella flexneri	$1x10^8$CFU/ml
Shigella sonnel	$1x10^8$CFU/ml
Streptococcus dysgalactiae	$1x10^8$CFU/ml
Streptococcus agalactiae	$1x10^8$CFU/ml
Streptococcus pyogenes	$1x10^8$CFU/ml

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit may be commercially available.

LIMITATIONS OF PROCEDURE

1. The test is for qualitative detection of legionella pneumophila serogroup I antigen in urine sample and does not indicate the quantity of the antigens.
2. The test is for in vitro diagnostic use only.
3. The test result should be used only to evaluate with patient with signs and symptoms of the disease. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory finding have been evaluated.

EXPECTED VALUES

Cortez OneStep Legionella Urinary Antigen RapidCard™ InstaTest detects the presence of legionella pneumophila serogroup I antigens in urine specimens. Expected values for any given population should be determined for each laboratory. The positivity rate of any given laboratory may vary depending on geographic location, season, and living environment.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Wear protective glove while handling kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed of as potential biohazards.
4. Do not use kit components beyond expiration date.
5. Dispose all used materials in appropriate container. Treat as potential biohazard.

STORAGE INSTRUCTION

1. The expiration date is indicated on the package label.
2. Store Sample Collection Tubes at 4-30°C.
3. Store test device at 4-30°C.

REFERENCE

1. Stout J.E. and Yu V.L., 1997 Legionellosis, N, Engl. J. Med. 337: 682-687
2. Kohler R.B, ct, al., 1984 Onset and duration of urinary antigen excretion in legionnaires' disease. J. Clin. Microbiol. 20: 605-607
3. Bibb W.F. et al., 1984 Detection of Soluble Legionella pneumophila antigens in serum and urine specimens by enzyme-linked immunosorbent assay with monoclonal and polyclonal antibodies J. Clin Microbiol. 20: 478-482

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ISO 13485 ISO 9001 **Diagnostic Automation/ Cortez Diagnostics, Inc. 21250 Califa Street, Suite 102 and 116, Woodland Hills, California 91367 USA**	
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