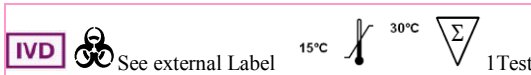


**OneStep
H1N1 RapiDip™ InstaTest**

REF 191000-1-50



INTENDED USE

The Cortez Diagnostics Inc. H1N1 RapiDip™ InstaTest is a lateral flow immunoassay for rapid, qualitative detection of Influenza A H1N1 antigen directly from nasal swab, nasopharyngeal swab, nasal wash and/or nasal aspirate specimens. Test results are available in 10 minutes or less. The test is intended for use as an aid in the diagnosis of Influenza A H1N1 (Swine Flu) infection

SUMMARY AND EXPLANATION

The influenza infection is an acute feverish virus infection, which principally leads to an illness of the respiratory tract and appears as an epidemic or pandemic. The infection mostly results from a droplet infection. The virus spreads from the mucous membrane of the upper respiratory to the whole bronchial tract. There the virus and its toxin can lead to a serious inflammation of the bronchial mucosa and a damage of the vessels. After an incubation time of 1 to 3 days the symptoms appear suddenly followed by a fast increase of temperature, often accompanied by shivering, the catarrhal leading symptom appears, which contribute to the clinical course beside painful dry cough, tracheitis, laryngitis and frequently a rhinitis and conjunctivitis. The Influenza viruses form a virus group with principally similar morphological, chemical and biological features. The types A, B and C were defined, from which many other variants are known. The distinction of the types will be possible by the different antigenicity of their nucleoproteins, which are coated by a matrix protein with type-specific antigenicity, too. However, both internal antigens are of less importance for the immunity. The essential antigens are the hemagglutinin and the neuraminidase. Both

are surface antigens and subject to a permanent change of their antigenicity, which is called drift or shift. The determination of the Influenza type (A, B, and C) gives both the clinician and epidemiologist important indications for further actions. Thus Influenza B often leads to a serious clinical course and an epidemic spread of the virus. Similarly, during Influenza A epidemic, the epidemiological importance and derived measures for the protection of the individual and population primarily stand in the foreground together with the severity of the clinical symptoms.

TEST PRINCIPLE

H1N1 RapiDip™ InstaTest utilizes a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay. Prior to the test, the nasal swab sample is obtained and placed into the Solution buffer vial. If Influenza A H1N1 antigen is present in the sample in concentrations above the detection level (5 x 10⁷ virus/ml) , a labeled specific antibody-dye conjugate binds to it forming an antigen-antibody-dye complex. This complex is migrated up, and then captured by another specific antibody immobilized in the Test Zone ("T") of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of Influenza A H1N1 antigen in the sample. On the other hand, a color band will always appear at the Control zone ("C").

SPECIMEN COLLECTION AND PREPARATION

The quality of the specimen obtained is of extreme important. The swab should be inserted into nasal for around 2 inch of distance. The sample must be tested within eight hours.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. Test strip in foil pouch
2. 1 Extraction buffer glass vial (0.5ml)
3. 1 Swab
4. Positive Control (sold separately)

Materials required but not provided

1. Timing device

PRECAUTION

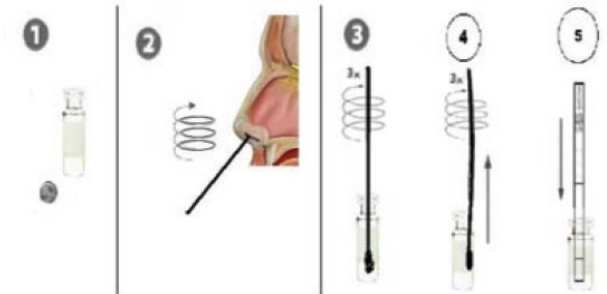
1. Precautions in the collection, handling, storage and disposal of the specimens.
2. For in vitro diagnostic use: Do not use the kit beyond the expiration date printed on the outside of the kit box. Dispose of all used test devices in a proper biohazard container.

ASSAY PROCEDURE

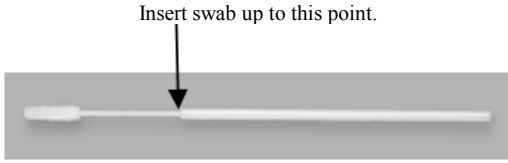
Prior to use, bring all test components and patient samples to room temperature.

EXTRACTION PROCEDURE

1. Carefully insert the sterile swab into the nostril and into the nasopharynx about 2 inch (very important step) and gently roll the swab at least 2 times.
2. Place the swab sample into the Extraction buffer glass vial. Roll the swab at least 3 times while pressing the head against the bottom and the side of the glass vial.
3. Roll the swab head against the inside of the Extraction buffer glass vial as you remove it. Dispose of the used swab in



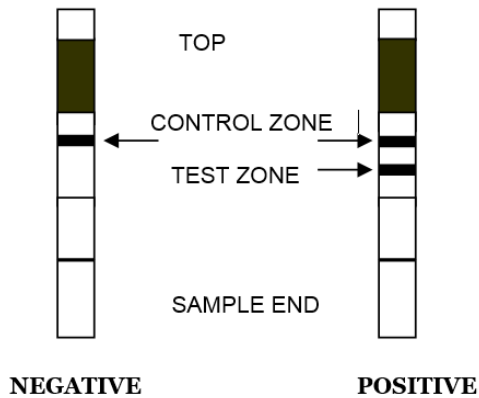
NOTE: A sterile swab is passed gently through the nostril and into the nasopharynx.(about 2 inches)



TEST PROCEDURE

1. Remove the "Test Strip" from the foil pouch.
2. Place the strip into the Extraction buffer glass vial with the arrows on the test strip pointing down.
3. Do not handle or move the test strip until the test is complete and ready for reading.
4. Start timing when fluid reaches the middle of the test area of the test strip.
5. Read the results at 10 minutes. Some positive results may appear sooner. Do not read result after 10 minutes.

INSERT THE TEST STRIP INTO THE EXTRACTION BUFFER GLASS VIAL



RESULTS

Positive Result:

At 10 minutes, any shade of a pink-to-red Test Line and the appearance of a Control Line indicate a positive result for the presence of Influenza A H1N1 antigen.



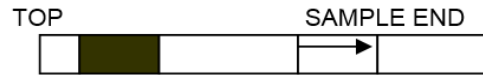
Negative Result:

At 10 minutes, the appearance of ONLY the Control Line indicates the sample is negative for Influenza A H1N1 antigen. A negative result should be reported as a presumptive negative for the presence of influenza antigen.



Invalid Result:

If a color band does not appear in the Control zone "C", the test results are invalid. The Sample may have been added to the wrong window, or the test strip may have deteriorated. The specimen should be re-tested using a new test strip.



SENSITIVITY AND SPECIFICITY

Sensitivity: 1:1000 for H1N1 A/new Caledonia/20/99 (HT 1:256)

QUALITY CONTROL

Although the Kit contains an internal quality control function (pink/rose color band in the Control region), good laboratory practice recommends the daily use of an outside control to ensure proper kit performance. Quality control samples should be tested according to the quality control requirements established by your laboratory.

LIMITATIONS OF PROCEDURE

1. The test is for in vitro diagnostic use only.
2. Detection of Influenza A H1N1 is dependent on the number of organisms present in the specimen. This may be affected by

specimen collection, procedure and patient's factors such as age, presence of symptoms, etc.

3. H1N1 RapiDip™ InstaTest have no cross reaction with other subtype stains of influenza A tested (see the certificate).
4. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.



STORAGE

Store kit at room temperature and out of direct sunlight

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| <p>ISO 13485 ISO 9001</p>  | |
|  <p>Diagnostic Automation/ Cortez Diagnostics, Inc. 21250 Califa Street, Suite 102 and 116, Woodland Hills, California 91367 USA</p> | |
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| EC REP | <p>CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu</p> |