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COVIDscanDX LAMP

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INSTRUCTIONS FOR USE

1 In vitro rapid diagnostic test for the detection of SARS-CoV-2 RdRP RNA in nasopharyngeal secretions

FOR IN VITRO DIAGNOSTIC USE

Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Intended Use

2 COVIDscanDX LAMP test is an in vitro rapid nucleic acid detection assay intended for the qualitative detection of RdRP RNA from SARS-CoV-2 in nasal mucus from individuals with signs and symptoms of infection who are suspected of COVID-19.

Results are for the identification of SARS-CoV-2. The 2019-SARS-CoV-2 RdRP gene is generally detectable in nasal mucus during the acute phase of infection. Positive results are indicative of active infection. Laboratories and health care providers within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The COVIDscanDX LAMP test is intended for use by healthcare professionals at the Point-of-Care. The COVIDscanDX LAMP test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Introduction

3 The Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) responsible for the Coronavirus disease 2019 (COVID-19) first emerged in December 2019 and quickly spread to pandemic proportions. SARS- CoV-2 causes diseases of the respiratory tract leading to severe pneumonia in patients with comorbidities, with many of the fatal cases occurring in the elderly population.

In the absence of a vaccine or specific treatment, the containment of the epidemic relies mainly on rapid identification and isolation of COVID-19 patients. This strategy is based on the availability of rapid diagnostic tests to be performed on any patient who presents specific symptoms. Noteworthy is the reporting of asymptomatic carriage of the virus in infected people and possible prolonged shedding after recovery which may hamper proper control of the epidemic, thus making the availability of sensitive diagnostic tests even more important. Development of point-of-care tests was recommended by a WHO panel of experts on February 11-12, 2020 (COVID 19 Public health emergency of international concern. Global research and innovation forum: towards a research roadmap).

Principle of the Test

4 This test is ready to use and is based on lateral flow technology using colloidal gold nanoparticles and a mobile device reader web application for detection. A nitrocellulose membrane is treated with streptavidin in a test line. Biotin and Fluorescein FITC are tagged to different RdRP primers mixed in isothermal RNA amplification (LAMP) assay. In the presence of SARS-CoV-2 RdRP viral gene the primers bind to the target RNA and make copies of the gene fragment (amplicon) in a highly specific manner. After icubation and application to the lateral flow sample well monoclonal antibodies conjugated to colloidal gold bind to FITC tagged amplicons. Only those amplicons with both biotin and FITC adhere to the lateral flow Test line is conjugated to colloidal gold nanoparticles. The colloidal gold containing antibodies accumulate on Test line area until a visible signal is produced and may be quantified using imaging. A control antibody binding site on the membrane indicates the test conditions are favorable. A second control reaction directed against human RNase P is included as a control to assure the LAMP amplifiction conditions were adequate. The presence of the second test line is expected.

This test detects SARS-CoV-2 in nasopharyngeal secretions (NPS) captured on a swab, aspirate or dispersed in transport medium. The NPS are mixed with a lysis buffer. When this mixture comes into contact with the strip, the conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with the streptavidin on the strip membrane and FITC antibody. If the sample contains tagged SARS-CoV-2 RdRP, the anti-FITC colloidal gold conjugate antibody will be bound to the FITC tagged amplicon. The result is detected by COVIDscanDX mScanner within 25 minutes and positive results may be visible as early as 10 minutes in the form of a pink line (Positive Test Line) that develops on the strip. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second pink line (Control Line). If SARS-CoV-2 virus is absent from the sample or at concentrations below the limit of detection, only two pink lines will be detected at 25 minutes (Control Line). Although the COVIDscanDX LAMP-LFD test may be read visually, it is intended to be used with the COVIDScanDx template card and a mobile device for optimal sensitivity. The COVIDScanDx mScanner web application will return a result of positive, negative, or invalid to the user.

Materials

5 MATERIALS PROVIDED for 5 Tests:
1. COVID-19 sterile self-swab (5) and Viral Transport Media (5 tubes 1.5 mL/each)
2. Lysis RNA extraction buffer (1 mL) for 5 samples (200 uL/sample)
3. 5 x 50 mL conical tube
4. Sterile Swabs (5)

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5. Instruction for Use (1)
6. Quick Reference Instruction (1)
7. Disposable COVIDScanDX mScanner imaging template card with unique product codes (5)
8. COVIDscanDX LAMP Incubator (500 mL) with thermal reading. (1)
9. Foam 200 uL reaction tube holder (1)
10 200 uL clear reaction tubes (5)
11. Tube master mix (1)
12 Tube primer mix (1)
13. Lateral flow test strips (5)
14. Microliter applicator/disposable pipettor (5)
15. Lateral flow running buffer (1mL)
16.lateral flow conical tube 1.5 mL (5)

MATERIALS REQUIRED AND NOT PROVIDED:
1. Timer
2. Approved Mobile Device (tablet or cell phone)
3. Tweezer or Forceps for handling test strips

Specimen Swab Collection 2m

6 Use a flocked tapered swab. Tilt head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at turbinates). Rotate the swab several times against nasal wall and repeat in other nostril using the same swab. 1m

7 Place swab and speciment in tube containing 1.5 mLs VTM and break swab and close cap and keep cool until ready to test.

LAMP testing

8 Add smart lysis buffer with 1:1 ratio in the VTM sample

9 Pipet 24 µl per reaction into desired reaction vessels and add 1 µl of sample. Mix by vortexing or by pipetting if using a plate or similar vessel, centrifuge to collect if necessary. Check that reaction solutions have a bright pink colour, which indicates initial high pH required for successful pH-LAMP reaction.

10 Fill the 50 mL conical tube with ambient temperature water until 50 mL line. Then close tightly and check for leaks. Place the filled tube in the incubator and place the sample tray in place at the top.

11 Add boiling water to fill incubator thermos to bottom of sample tray sample tray. Place the 200 uL reaction tubes into the foam tube holder and let sit with lit of incubator loosely placed on top. Then incubate at 95C for 5 minutes.

12 Remove from tray and add 3 ul to COVIDscanDX LAMP master mix (NB: M1800).Pipette up and down 3 times, close tube and tap it on the table until all the liquid is at the bottom of the tube with no bubbles.

13 Keeping the 50 mL conical inside and the sample tray snaped in place empty the heated water from the incubator. Place 1-5 sample tubes in the sample holder in sample tray and incubate at 65°C for 30 minutes. The reaction should be yellowish in color indicating the control reaction has taken place.

14 Using the microbrush applicator or pipette add 10 ul of the LAMP reaction with 2 drops of running buffer in a 1.5

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conical tube.

15 Load to the LFD strip in the tube of 50 uL reaction and allow it to absorb and develop for 25 minutes.

16 Visualize the bands for internal control and SARS-CoV-2

17 Scan with mReader to record results using https://register.covidscandx.com

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