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Original Research Article

The Success Rate of Rapid Test for Detection of COVID-19 Antigen by Device of Immune Base Diagnosis

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Abstract

The COVID-19 pandemic necessitated the development of efficient diagnostic tools to quickly identify infected individuals and mitigate the spread of the virus. This study evaluates the success rate of rapid tests for the detection of COVID-19 antigens using immune-based diagnostic devices. Rapid antigen tests offer the advantages of speed and ease of use, making them a vital component in large-scale screening efforts. The research involved a comprehensive analysis of various rapid antigen test devices, assessing their sensitivity, specificity, and overall accuracy compared to the gold standard RT-PCR tests. Results indicated that while rapid antigen tests generally provide quicker results, their sensitivity varies significantly, impacting their reliability in different settings. Despite these limitations, the study highlights the importance of rapid antigen tests in complementing other diagnostic methods, particularly in resource-limited environments and for mass screening purposes. The findings underscore the need for continuous improvement and validation of these tests to ensure they meet the necessary accuracy standards for effective pandemic management.

Keywords: Covid-19, Pandemic, RT-PCR, Antigen, Diagnosis.

Introduction

A pandemic of respiratory disease spreading from person to person is caused by a novel (new) coronavirus. The disease has been named 'Corona Virus disease 2019' (Abbreviated COVID-19). This situation is posing a serious public health risk. COVID-19 can cause mild to severe illness; most severe illness occurs in older adults. Coronaviruses, named for the crown-like spikes on their surface having positive-sense RNA viruses that belong to the Coronaviridae subfamily. Alpha and beta coronavirus infect only mammals, usually causing respiratory symptoms in humans and gastroenteritis in other animals. Until December of 2019, only six different coronaviruses were known to infect humans. Four of these (HCoV-NL63, HCoV-229E, HCoV-OC43 and HKU1) usually caused mild common cold-type symptoms in immune competent people and other two have caused pandemics in the past two decades. In 2002-2003, the severe acute respiratory coronavirus (SARS-CoV) caused a SARS epidemic that resulted in a 10% mortality. The director general WHO has declare that the outbreak of 2019-nCoV constitute a Procedure concerning Public Health Emergencies of International Concern (PHEIC). The Covid-19 viral disease has been officially declare as a pandemic by World Health Organization.

Intended Use

Rapid Testing device, Qualitative, immune-chromatographic test for detection of COVID-19 Antigen in nasal swab (Nasopharyngeal swab). This test is for the healthcare professions use only in Public health or government facilities.

Principle

COVID-19 Antigen test consist of lysis buffer and test device. The swab specimen/aspirate added into lysis buffer and mixed to lyse the viral cells to extract the nucleic acids (RNA into buffer). Antigen test device consist of a strip containing NCM, Colloidal gold conjugate pad and sample release pad. NCM (Nitro Cellulose Membrane) is coated with control specific antibodies on control side (C) and SARS-CoV-2 specific monoclonal antibodies on test side (T) Colloidal gold conjugate pad consist of control solution specific antibodies and SARS-COV-19 specific monoclonal antibodies conjugate with colloidal gold nanoparticles. When Sample (Specimen and lysis buffer mixture) is added on sample port of test device, the sample migrates along with the colloidal gold nanoparticles. If sample contains detectable levels of COVID-19 antigen then it react with conjugate monoclonal antibodies in colloidal gold particles to

form Antigen-Antibodies complex. This complex then migrates on the membrane chromatographically and react with the coated SARS-CoV monoclonal antibodies on the test line to form a test band (Coloured line in test side).Control lines shall always be appeared, indicating that the proper volume of specimen has been added, right procedure and all reagents working properly.

Material Provided & Active Ingredients of content of Kit

1. Rapid COVID-19 Ag Test Device
2. Lysis buffer for COVID-19 Antigen test
3. Sample Extractor tubes for COVID-19 Antigen test
4. Package insert
5. Nylon flocked nasopharyngeal swab

Optional Material Required

Timer/stop watch, micropipette, PPEs (Disposable Gloves, mask, safety goggles, lab coat/apron), Biohazard dustbin.

Precaution – Kit Storage and Stability

1. Always read the do's and Don't's on backside or insider leaflet before operating the test. Pay particulate attention to the position of the control and Test line.
2. Do not use after the expiration date printed on the foil pouch.
3. Stored in the sealed pouch in a dry place in between 4-30degree C. Do not freeze (This range is generally for all type of Rapid testing Kit Device).
4. Do not use if pouch is torn or damage
5. Wash hands thoroughly after finishing the test
6. Keep out reach of children

Warnings

1. Do not reuse the test device
2. Use appropriate personal protective equipment.
3. Dispose hygienically in biohazard waste as per local guideline.
4. Do not touch the membrane.
5. Treat sample and use test as potentially infectious.
6. For in-vitro diagnosis use. Not to be taken internally.

Specimen Collection

Nasopharyngeal swabs: sterile swab is inserted into one or both nostrils to the nasopharyngeal area. The swab is allowed to remain in the nostrils for a few seconds to absorb secretions, rotated gently,and then withdrawal. Bend shaft to allow curve of Nasopharynx. For an optimal sample, repeat procedure using another nostril.

Test Procedure

1. Allow the all kit components to reach at room temperature (20-30 degree C).
2. Add 10 drops (Approx 30 units) of lysis buffer provided in the kit in a sample extraction tube.
3. Label the tube with sample ID/ patient ID
4. Collect the swab specimen and put in the sample extraction tube containing lysis buffer. Rotate and mix the swab specimen in lysis buffer.
5. Squeeze the sides of the tubes to obtain as much liquid as possible. Dispose of the swab properly.
6. Apply cap on the sample extraction tube. Use this dissolved specimen as a sample.
7. Keep device on flat surface and 2 drops (Approx. 60 units) of a sample (Dissolved swab specimen lysis buffer) by using a sample extraction tube in sample port of COVID-19 antigen Test device.
8. Start the timer
9. Read resultant at 15 minutes. Do not read the result after 20 minutes.

Figure 1:

1. Positive – COVID-19 antigen (coloured line appear at C).
2. Positive – COVID-19 antigen (with light colour)
3. Negative- COVID-19 (coloured line appear at C& T)
4. Test should be invalid if no line appear

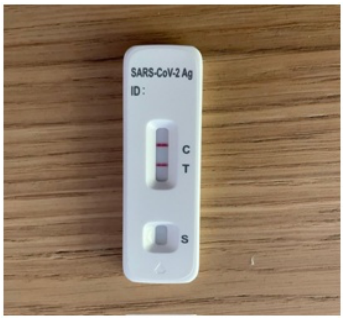

Figure 2:

COVID-19 Antigen Negative: A coloured line appear at C & T

Performance Characteristics

Internal Evaluation: Total 105 COVID-19 Antigen positive samples and 125 negative samples were tested. The test shows 95% correlation with positive sample. While the test shows 100% correlation with negative samples. Cross reactivity studied with influenza A, influenza B positive samples. No cross reactivity observed.

External Evaluation: Rapid Testing Device kit evaluation and approved at "ICMR-VDRL", Department of Health and Research, Ministry of Health and Family Welfare. Government of India.

Limitations

1. There is always possibility that false result occurred due to the presence of interfering substance in the specimen or factors beyond the control of the manufacturer such as technical or procedural errors associated with the testing.
2. Although the test demonstrates the superior accuracy in detecting COVID-19 virus, a low incidence of false result can occur. Therefore, other clinically available test required in case of questionable result. As with all diagnostic test a definitive clinical diagnosis should not be based on the result of single test, but should only be made by the physician after all clinical and laboratory finding have been evaluated.
3. Humidity and temperature can adversely affect results.
4. The instruction for the use of the test should be followed during testing procedure.
5. The product provides qualitative, not quantitative detection of COVID-19 antigen.
6. Lower sensitivity than lab tests. Sensitivity means how well a test can identify a disease or condition.
7. False negatives are more common. A false negative result means your test shows you don't have a disease or condition
8. The all precautions shall be taken to ensure the diagnosis ability and accuracy of this product. This product is utilised outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the result.
9. The Test Provide presumptive diagnosis of COVID-19. A Confirmed COVID-19 infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
10. Safe and correct Disposal is possible with community use.

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