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COVID 19 TEST KIT

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ABSTRACT

Base on the characteristics of the epidemic situation and the authors understanding of related ancient book and documents this paper explor theTest Kit and related information and pathogenesis of corona virus disease(COVID - 19). This artical provide the best information related to COVID - 19 test kit form the standard journal like Elisver and many other.

KEYWORD: Covid - 19, SARS, MERS, test kit.

INTRODUCTION

About Covid 19 Test

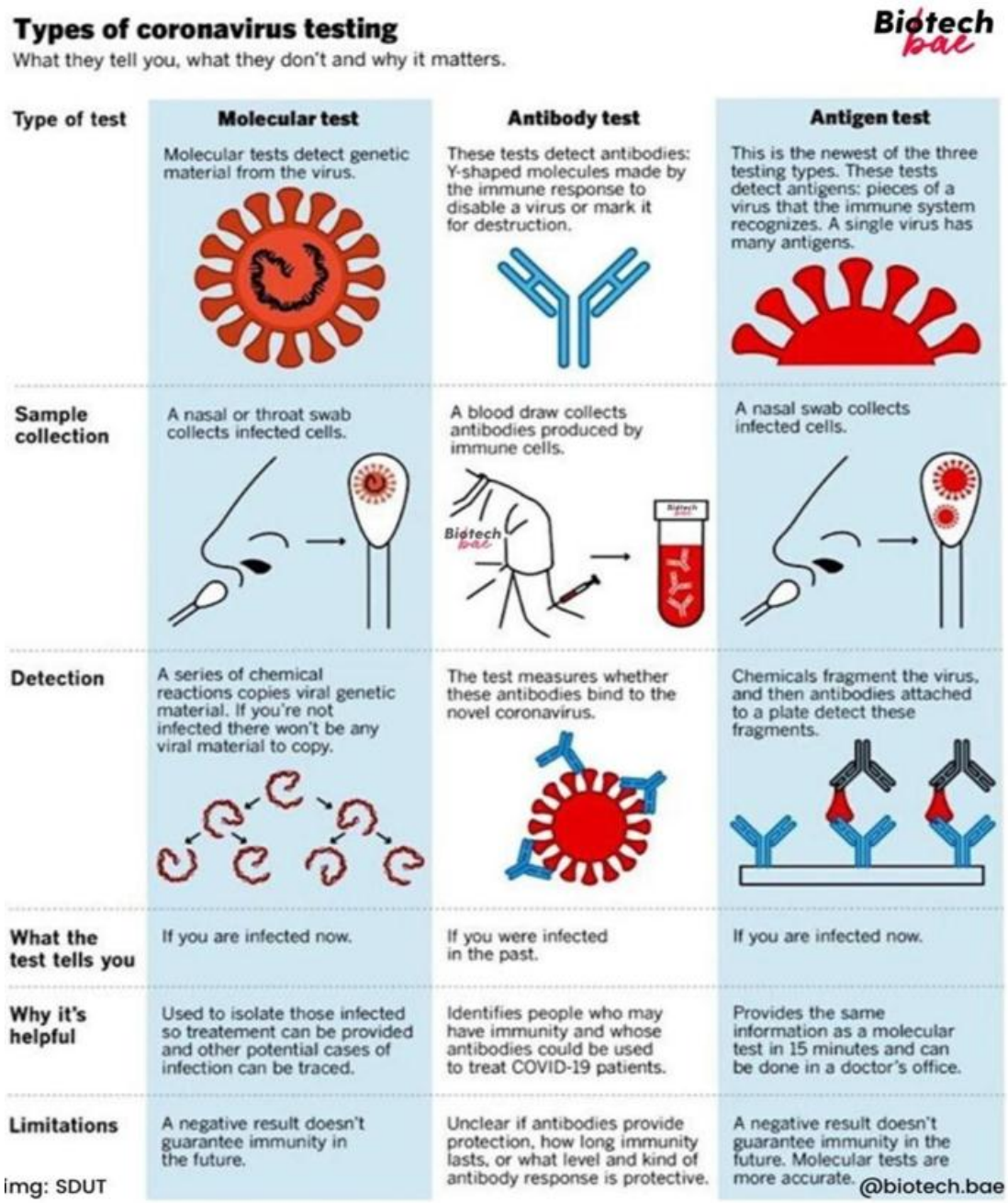
The laboratory diagnostic tests for coronavirus or COVID 19 includes molecular tests and serology tests. As per World Health Organization (WHO) and Centers for Disease Control and Prevention, laboratory testing for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) is conducted by close cooperation between the central, state and local health departments.

- **History of Covid 19 Test Kit**

COVID-19 testing can identify the SARS-CoV-2 virus and includes methods that detect the presence of virus itself (RT-PCR, isothermal nucleic acid amplification, antigen) and those that detect antibodies produced in response to infection. Detection of antibodies (serological tests) can be used both for diagnosis and population surveillance. Antibody tests show how many people have had the disease, including those whose symptoms were minor or who were asymptomatic. An accurate mortality rate of the disease and the level of herd immunity in the population can be determined from the results of this test. However, the duration and effectiveness of this immune response are still unclear.[1]

Due to limited testing, as of March 2020 no countries had reliable data on the prevalence of the virus in their population.[2] As of 29 April, the countries that published their testing data have on average performed a number of tests equal to only 1.4% of their population, and no country has tested samples equal to more than 14% of its population.[3] There are variations in how much testing has been done across countries.[4] This variability is also likely to be affecting reported case fatality rates, which have probably been overestimated in many countries, due to sampling.

Types of test and how these test are done



TEST METHODS

1. Abbott Real Time SARS-CoV-2

A) INTRODUCTION

This Emergency Use Authorization (EUA) package insert must be read carefully prior to use. EUApackage insert instructions must be followed accordingly. Reliability of EUAassay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

- **NAME**

Abbott Real Time SARS-CoV-2

- **INTENDED USE**

The Abbott RealTimeSARS-CoV-2 assay is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from theSARSCoV-2 in nanasa swabs, self-collected at a health care location or collected by a healthcare worker, nasopharyngeal(NP) and oropharyngeal(OP) swabs collected by a healthcare worker, from patients suspected of COVID-19by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Results are for the identification of SARS Co V-2RNA.

The SARS

CoV2RNA is generally detectable in nasal, nasopharyngeal andoro pharyngeal swabs during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not precludeSARSCoV-2 infection and should not be used as the sole basis forpatient management decisions. Negative results must be combined with clinical observation s, patient history, an depidemiological information.

The Abbott Real Time SARS-CoV-2 assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time

PCR and in vitro diagnostic procedures. The Abbott RealTime SARS-CoV-2 assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

- **Summary and Explanation of The Test**

The Abbott Rea Time SARS-CoV- 2 assay is real-time reverse transcription polymerase chain reaction (rRT-PCR)test on the Abbott m2000 System. The SARSCoV-2 primer and probe set sare designed to detect RNA from SARS-CoV-2in nasal, nasopharyngealandoropharyngeal swabs from patients with signs and symptoms of infection who are suspected of COVID-19by their health care provider.

Detection

During the read cycles of amplification on the Abbott m2000rt, the temperature is lowered further to allow fluorescent detection of amplification products as theSARS-CoV-2 and IC probesanneal to their targets (real-time fluorescence detection). The SARS-CoV-2 probes havea fluorescent moiety that is covalently linked to the 5′end and has aquenche rmolecule at its 3′end. In the absence of targetsequences, the probesadopta conformation that brings the quencher close enough to the excited fluorophore to absorb its energy before it can be fluorescently emitted. When the probe binds to its complementary sequence in the target, the fluorophore and the quencher are held apart, allowing fluorescent emission and detection. The IC probe is a single-stranded DNA oligonucleotide with a fluorophore at the 5′ end and a quencher at the 3′ end. In the absence of IC target sequences, probe fluorescenceis quenched. In the presence of IC target sequences, probe hybridization to complementary sequences separates the fluorophoreand the quencher and allows fluorescent emission and detection. The SARS-CoV-2 and IC specific probesare each labeled with a different fluorophore, thus allowing for simultaneous detection of both amplified products.

Prevention of Nucleic Acid Contamination

The possibilityof nucleicacid contamination is minimized because

• Reverse transcription, PCR amplification, and oligonucleotide hybridization occurina sealed Abbott96-Well Optical Reaction Plate.

- Detection is carried out automatically without the need to open the Abbott 96Well Optical ReactionPlate. Pipettes with aerosol barrier tips or disposable transfer pipettes are used for all pipetting.
- The disposable pipettes or pipette tips are discarded after use.

- Separate, dedicated areas are used to perform the Abbott RealTime SARS-CoV-2 assay. Refer to the SPECIAL PRECAUTIONS section of this package insert.

REAGENTS

Abbott Real Time SARS-CoV- 2 Amplification Reagent Kit(ListNo.09N77095)

1. Abbott RealTime SARS-CoV-2 Internal Control (4vials,1.2mLper vial)

• < 0.01% noninfectious Armored RNA with internal control sequences in negative human plasma. Negative human plasma tested and found to be non-reactive by appropriate FDA-licensed, approved, or cleared tests for antibody to HCV, antibody to HIV-1, antibody to HIV-2, HIV-1Ag, HBsAg, and Syphilis. The material is also tested and found to be negative by appropriate FDAlicensed, approved, or cleared PCR methods for HIV RNA, HCVRNA, and HBVDNA. Preservatives:0.1%Pr oClin®300and0.15%ProClin950.

2. AbbottRealTimeSARS-CoV- 2 Amplification Reagent Pack(ListNo.9N77)

(4 packs, 24 tests/pack) 1 bottle (0.141 mL) Thermostable rTth PolymeraseEnzyme (2.9 to 3.5 Units/µL) in buffered solution. 1 bottle (1.0mL)SARS-CoV2Amplification Reagent containing synthetic oligonucleotides (6 primers and 3 probes), and dNTPs in a buffered solution with a reference dye. Preservative:0.10%ProClin300 and 0.15%ProClin950.

1bottle(0.400mL) Activation Reagent. 30mm manganese chloride solution. Preservatives:0.10% Pro Clin 300 and 0.15% ProClin950.

Abbott Real Time SARS-CoV- 2ControlvKit(ListNo.09N77-085)

1. Abbott RealTime SARS-CoV-2 Negative Control (8 vials, 1.3mL per vial) Contains 1.0%ammonium sulfate and 7.9%detergent in a buffer solution.
2. Abbott RealTime SARS-CoV-2 Positive Control (8vials, 1.3mLpervial)Contains non infectious, recombinant Sindbis virus containing SARS-CoV-2RNA sequences, 1.0% ammoniumsulfate, and 7.9% detergent in a buffer solution.

WARNING PRECAUTIONS

For Use Under An Emergency Use Authorization Only.

This assay is only forin vitro diagnostic use underthe FDA Emergency Use Authorization.

For Prescription Use Only.

Safety Precautions Refer to the Abbott m2000sp and Abbott m2000rt Operations Manuals, Hazard Section, for instructions on safety precautions.

Important information regarding the safe handling, transport and disposal of this product is contained in the Safety Data Sheet.

Caution

This preparation contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive by appropriate FDA-licensed, approved, or cleared tests for antibody to HCV, antibody to HIV-1, antibody to HIV-2,HIV-1Ag,HBsAg, and Syphilis. The material is also tested and found to be negative by appropriate FDA-licensed, approved, or cleared PCR methods for HIV RNA, HCVRNA, and HBV DNA. No known test method can offer complete assurance that products derived from human sources or inactivated microorganism swill not transmit infection. These reagents and human specimens should be hand ledas if infectious using laboratory safety procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories, 1OSHA Standards on Blood borne Pathogens, 2CLSI Document M29-A4,3 and other appropriate biosafety practices.4Therefore all human sourced materials should be considered infectious.

These precautions include, but are not limited to, the following

- Wear gloves when handling specimen sor reagents.
- Do not pipette bymouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect spills of specimens by including the use of a tuberculo cidal disinfectant such as 1.0%sodium hypochlorite or other suitable disinfectant.1
- Decontaminate and dispose of all potentially infectious materials in accordance with local, state, and federal regulations.
- The Sample Preparation Area is dedicated to processing samples (specimens and Abbott RealTime SARS-CoV-2 Controls) and to adding processed samples and controls to the 96-Well Optical Reaction Plate. All reagents used in the Sample Preparation Area should remain in this dedicated area at all times. Laboratory coats, pipettes, pipette tips, and vortexers used in the Sample Preparation Area must remain in this area and not be moved to the Amplification Area. Do not bring amplification product into the Sample Preparation Area.

- The Amplification Area is dedicated to the amplification and detection of amplified product. Laboratory coats and equipment used in the Amplification
- Area must remain in this area and not be moved to the Sample Preparation Area.

- Components contained within a kit are intended to be used together. Do not mix components from different kit lots. For example, do not use the negativecontrolfromcontrolkitlotX with the positivecontrolsfromcontrolkitlotY.
- Do not use kits or reagents after the expiration dates shown on kit labels.
- Work area and instrument platforms must be considered potential sources of contamination. Change gloves after contact with potential contaminants (specimens, eluates, and/oramplified product) beforehandlingunopenedreagents, negativecontrol, positivecontrols, or specimens.

Refer to the Abbott m2000sp and Abbott m2000rt Operations Manuals for instrument cleaning procedures

- If the Abbott m2000sp instrument run is aborted, dispose of all commodities and reagents according to the Abbott m2000sp Operations Manual.
- If the Abbott m2000sp master mix addition protocol is aborted, seal the Abbott 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott m2000sp Operations Manual, Hazards section, along with the gloves used to handle the plate.
- If the Abbott m2000rt instrument run is interrupted or aborted, seal the Abbott 96Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott m2000rt Operations Manual along with the gloves used to handle the plate.
- Decontaminate and dispose of all potentially biohazardous materials in accordance with local, state, and federalregulations.4All materials should be handled in a manner that minimizes the chance of potential contamination of the work area.

STORAGE INSTRUCTIONS

Abbott Real Time SARS-CoV- 2Amplification Reagent Kit(ListNo.09N77095)

-25°C

-15°C

- Abbott Real Time SARS Co V2 Amplification

Reagent Packs and Internal Control(IC) vials must be stored at –25 to – 15°C when not in use. Care must be taken to separate the Abbott Rea lTimeSARS Co V2 Amplification Reagent Pack that is in use from direct contact with samples and controls.

Abbott Real Time SARS-CoV- 2Control Kit (ListNo.09N77-085) -15°C -25°C

- The Abbott RealTimeSARS-CoV-2Negative and Positive Controls must be stored at– 25 to –15°C.

CONCLUSION

The worldwide control of covid - 19 has become a challenge to control. It has already declared as pardemic with more than 10, 922,324 affected across 196 countries till July 2020. An aggressive approach is required to take care of criticaly compramise patients in addition to stop transmission of disease. Currently many GOV. Agencies and pharmaceutical companies working toward the effective medicine and vaccines.

However cordinated effort is needed globaly to help prepar the health care framework with the ungricedented challenge of COVID - 19.

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