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VTRUST COVID-19 Antigen Rapid Test (Model: TD-4531)

Clinical Evaluation Study

1. Purpose:

This clinical evaluation study is intended to evaluate the clinical sensitivity and clinical specificity of VTRUST COVID-19 Antigen Rapid Test (Model: TD-4531) by comparing the test results to an **FDA EUA RT-PCR test**.

Clinical sensitivity and specificity of fresh nasopharyngeal swab specimens will be measured by:

(1) Trained CLIA moderate(M) or high(H) clinical laboratory personnel in CLIA moderate(M) or high(H) laboratory.

(2) Non-laboratory personnel in point-of-care settings or near-patient sites.

Tests should demonstrate a minimum clinical sensitivity of ≥ 80% for claimed sample types according to FDA COVID-19 In Vitro Diagnostics EUA Antigen Template for Manufacturers (May 11, 2020).

2. Comparison method:

This clinical evaluation study should use the SARS-CoV-2 molecular diagnostic test authorized by the FDA EUA as a comparison method: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

3. Study Site:

The requirements for the clinical site are as follows:

a. Laboratories should have international qualification certificates (ex: CLIA / CAP / ISO 15189, etc.). Laboratories are certified under the Clinical Laboratory Improvement Amendments of 1988 (**CLIA**), 42 U.S.C. §263a, that meet the requirements to perform **high, moderate, or waived** complexity tests or by **similarly qualified** non-U.S. laboratories and as applicable.

b. **Point of Care (POC)** or **near-patient sites**, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

4. Study Operator:

This clinical evaluation plan should be conducted by at least (but not limited to) 2 operator at each clinical site. The requirements for the operator are as follows:

a. **Medical professional operators** from laboratories which certified under the Clinical Laboratory Improvement Amendments of 1988 (**CLIA**), 42 USC §263a, that meet the requirements to perform **high, moderate, or waived** complexity tests or by **similarly qualified** non-US laboratories and as applicable.

b. **If the test is performed at the point of care (POC) or near-patient sites, the device operator should be non-laboratory medical personnel.**

5. Study Subjects:

After screening in accordance with the inclusion criteria and exclusion criteria, a minimum of **60** COVID-19 RT-PCR (+) specimens and **80** COVID-19 RT-PCR (-) specimens are recruited in this clinical evaluation plan in a randomized blinded fashion.

Inclusion Criteria:

a. Subjects are at least 18 years old.

b. Subjects participating in this study were judged by the physician that have symptoms or signs compatible with COVID-19, including: fever, cough, shortness of breath, chills, muscle pain, loss of new taste or smell, vomiting or diarrhea and / or throat pain. The date of nasopharyngeal swab collection is **between 7 to 14 days after the subject has first symptoms or signs of COVID-19**. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

c. Persons without symptoms who are prioritized by health departments or physicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

Exclusion Criteria:

a. Subjects are less than 18 years old.

b. Subjects participated in other drug clinical research.

c. Subjects suffers from any other conditions where the clinical evaluation cannot be followed and completed.

6. Study Overview:

Site	Operator	COVID-19 (+)	COVID-19 (+)
CLIA High/ Moderate Lab	operator 1	15 subjects	25 subjects
	operator 2	15 subjects	25 subjects
Point-of-care site (Near-patient site) CLIA Waiver	operator 1	15 subjects	15 subjects
	operator 2	15 subjects	15 subjects
Total	4 operators	60 subjects	80 subjects

VTRUST MEDICAL INSTRUMENT

IVD Rx ONLY CE

VTRUST COVID-19 Antigen Rapid Test

Model: TD-4531

- Easy to perform
- Fast results in 15 minutes
- Visual interpretation
- For In Vitro diagnostic use
- No need any special equipment
- Technical cooperation with Academia Sinica (Taiwan's top research institution)
- Prescription use only
- For use under the Emergency Use Authorization (EUA) only

Performance and Features

Test Principle	Lateral Flow Chromatographic Immunoassay
Target Antigen	SARS-CoV-2 Nucleocapsid Protein
Sample Type	Fresh Nasopharyngeal Swab Specimen
Reaction time	15 minutes

Box Contents:

20-Test Kit/Box:

1. Sterile Nasopharyngeal Swabs (20)
2. Test Cassette (20)
3. Extraction Tube (20)
4. Extraction Tube Dripper (20)
5. Extraction Buffer (2)

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VTRUST MEDICAL INSTRUMENT

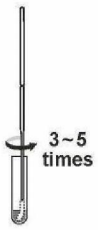
VTRUST COVID-19 Antigen Rapid Test (Model :TD-4531)

Instruction for Use

1

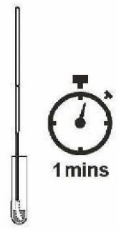
Add 10 drops (500 µL) of Extraction Buffer into the Extraction Tube.

2



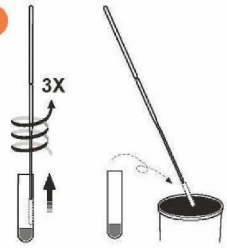
Immerse the patient nasopharyngeal swab sample into the extraction tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Extraction Tube.

3



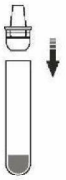
Leave the swab in the extraction buffer for 1 minute.

4



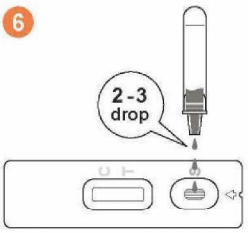
When removing, roll the swab head toward the inside of the extraction tube. Dispose of the used swab in your biohazard waste.

5



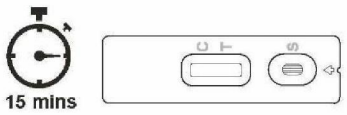
Cover with the dripper and press tightly.

6



Add 2 drops (100 µL) of the processed sample into the sample well.

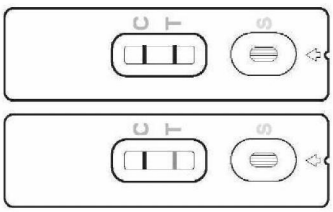
7



Visual interpretation at 15 minutes after the processed sample was added into the sample well. Do not read the result after 15 minutes.

Interpretation of Results

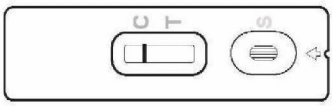
Positive



1 Positive result

Both colored test line and colored control line appear on the test strip.
Within the specified observation time, a weak colored test line should be judged as a positive result.

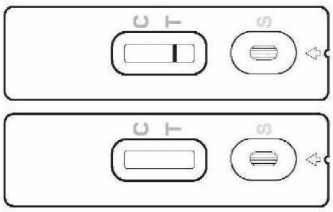
Negative



2 Negative result

Only the colored control line appears on the test strip. The absence of the test line indicates a negative result.

Invalid Assay



3 Invalid result

There should always be a colored control line in the control region regardless of test result.
If control line is not seen, repeat the assay with a new device.

Manufactured by TaiDoc Technology Corporation