Clinical Protocol BIOZEK

Title:	**"Open label, Single-Center Study utilizing BIOZEK COVID-19 Antigen Rapid Test as compared to standard testing technique."** Test performed by a professional versus self-collection and standard of care.
Short title:	Comparison of BIOZEK Antigen Rapid Test to COVID-19 RT-PCR.
Protocol Number:	Biozek-ARTC-US/001/3-5-2021
Product:	BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)

Contract Research Organization (CRO): Jeanetta Stega, MD, PhD

Principal Investigator:	Damian Stega, M.D.
Co-Principal Investigator:	Angela Khaitova
Study Management and Monitoring:	Sophia Dalia
Study Coordinator:	Sophia Dalia
Version:	Final 1.0
Date:	March 5, 2021

CONFIDENTIALITY STATEMENT

The information contained in this document, particularly unpublished data, is the property or under control of Biozek medical and is provided to you in confidence as an investigator, potential investigator, or consultant, for review by you, your staff, and an applicable Institutional Review Board or Independent Ethics Committee. The information is only to be used by you in connection with authorized clinical studies of the investigational drug described in the protocol. You will not disclose any of the information to others without written authorization from Biozek Company, except to the extent necessary to obtain informed consent from those persons to whom the test may be performed.

1. Protocol Synopsis

Title:	**"Open label, Single-Center Study utilizing BIOZEK COVID-19 Antigen Rapid Test as compared to standard testing technique."** Test performed by a professional vs self-collection and standard of care.
Study Site Sample Collection:	Mobile Covid Services LLC 3050 Whitestone Expressway, Suite 402 Flushing, NY, 11354 Sigmund Laboratory for RT-PCR test 78 John Miller Way Ste 1001 Kearny, NJ 07032
Number of Subjects Planned:	Up to 250 Subjects, minimum of 30 positive and 30 negative tests.
Study Objectives:	Primary: To assess sensitivity and specificity of BIOZEK COVID-19 Antigen Rapid Test on a sample collected by a healthcare professional. Secondary: To assess sensitivity and specificity of BIOZEK COVID-19 Antigen Rapid Test on a self-collected sample. To assess if the result of each BIOZEK COVID – 19 Antigen Rapid Test performed by the subject are the same as the results of the test performed by a healthcare professional.
Target Population:	Subjects, at least 18 years of age who desire a Covid-19 RT-PCR test. Subjects must meet inclusion and exclusion criteria.
Investigational Product:	BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)
Comparator:	Type of test: **RT-PCR** Name of test: **Lyra Direct SARS-CoV-2 Assay** Manufacturer: **Quidel Corporation**
Study Design:	Up to 250 symptomatic subjects of age 18 or older that meet the inclusion and exclusion criteria and are willing to participate will be enrolled into the BIOZEK study. All subjects will be required to sign an informed consent form. Participants will complete a personal information form and a testing site personnel will collect medical history and vital signs will be recorded.

Medical clearance will be obtained prior to performing any sample collection.

Subject will have 3 tests performed in a manner described below:

1.RT-PCR test (by medical staff prior to enrollment as a standard of care procedure), Additionally Ct value will be requested. Turnaround time for RT-PCR test results is 1-2 days.

2.BIOZEK COVID-19 Antigen Rapid Test (via self-collection),
Nasopharyngeal samples will be collected via self-collection and the test will be performed by the subject. The participants will follow instructions for use provided by Biozek together with the test. The subject's performance during self-collection and test performance will be monitored and recorded in a performance form. Results in 15 minutes.

3. BIOZEK COVID-19 Antigen Rapid Test (by medical staff).
Second, a nasopharyngeal sample will be collected and a test will be performed by a medical professional. Results for the test in 15 minutes. A coordinator will monitor patient concerns during and after collection and an image will be captured of the results of both tests for record and in subject's CRF. Compliant to all procedures for disposal of biohazardous waste.

Results will be retrieved from the PCR test when available and all three samples will be analyzed and compared.

Criteria for Evaluation:

Safety Criteria: During self-collection the subject will be closely monitored according to standard of care and any adverse effects will be captured. During the test performed by a healthcare professional, the subjects in this study will not be exposed to additional risk from interventional procedures, because the ones to be used are the standard of clinical practice.

Efficacy Criteria: Sensitivity and Specificity will be calculated separately for BIOZEK COVID-19 Antigen Rapid Test on a sample collected by healthcare professionals and for BIOZEK COVID-19 Antigen Rapid Test on the self-collected sample.

Additionally, the result of each test performed by the subject will be compared to the test performed by a healthcare professional.

End Points: Primary: Sensitivity and Specificity of BIOZEK COVID-19 Antigen Rapid Test on a sample collected by healthcare professionals.

Secondary: Sensitivity and Specificity of BIOZEK COVID-19 Antigen Rapid Test on self-collected sample.

Tertiary: Number of tests with overlapping results.

Table of Contents

2. Introduction

Widespread testing is the cornerstone of COVID-19 control around the world. However, U.S. testing to identify people with infected SARS-CoV-2 has been slow to start and continues to lag. An important feature of SARS-CoV-2 is that it can be transmitted while a host is unaware of infection (asymptomatic). Epidemiologic evidence has demonstrated that pre-symptomatic and asymptomatic transmission of virus has driven the current epidemic[1]. Antigen tests have a great potential for screening asymptomatic people[2]. To limit outbreaks, testing is needed to identify as many individuals who are transmitting infection as quickly as possible. Antigen Tests have the potential to readily identify an individual who is at or near peak infection. Rapid Tests, while less sensitive, perform best during the early stages of COVID-19 infection; when viral load and potential for spread is high.

There is an unmet need to provide broad testing that can serve high risk and low resource communities. The FDA's authorization for antigen tests for home use is helping to expand Americans' access to testing, reducing the burden on laboratories and test supplies[3]. The Biozek Antigen Rapid Test can be easily performed by untrained personnel with results in less than 15 minutes. The increased potential for repeated testing, remote or at home testing, could help contain the COVID-19 pandemic.

3. Background

In December 2019, an outbreak emerged identifying a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The World Health Organization (WHO) declared it a global pandemic in March 2020. Testing in the U.S. appeared to be insufficient for optimal early containment of the virus. With the resurgence of the disease (COVID-19), the U.S. has recently seen the highest number of hospitalizations since the beginning of the pandemic and rates are expected to increase in future weeks[4]. Given the continued community transmission of SARS-CoV-2 in the US, there has been sustained focus on the role of testing to reduce the spread. Presently, the gold standard polymerase chain reaction (PCR) test is used to diagnose COVID-19 by detecting the presence of specific genetic material of the virus. PCR test requires laboratory processing and it may take days to obtain results. In turn, an individual could be negative at time of testing but positive by the time the result is returned[5]. PCR testing is performed by a trained healthcare professional at an approved testing facility. In contrast, The BIOZEK Rapid Antigen Test detects specific proteins on the surface of the virus and it can be self-administered. Results are generated in 15 minutes and can be performed at home or any remote location. In efforts to meet the exponential demand in testing, the introduction of a new and effective Rapid Test could potentially end the spread of COVID-19.

4. Study Objectives:

The primary objective of the study is to assess sensitivity and specificity of BIOZEK COVID-19 Antigen Rapid Test on a sample collected by healthcare professionals.

Secondary objectives are to assess sensitivity and specificity of BIOZEK COVID-19 Antigen Rapid Test on self-collected samples.

Additionally, the objective is to achieve the same results from the tests performed via self-collection and by the healthcare professionals. Such a comparison would demonstrate any distinctions between tests performed by healthcare professionals and by the subject.

RT-PCR Ct Values will be requested and analyzed.

5. Investigational Product

The BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human nasopharyngeal swab specimens. SARS-CoV-2 antibody is coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in the test line region.
If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in the test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Materials provided in the BIOZEK-COVID-19 Antigen Rapid Test kit includes: Test cassettes, Sterile Swabs, Extraction tubes and tips, Extraction Buffer, Workstation, Package Insert.

Materials Provided

Description		Option 1	Option 2	Option 3
Test Cassettes		30	30	30
Sterile Swabs		30	30	30
Work Station		1	1	1
Package Insert		1	1	1
Extraction Buffer (NaCl 5g/L, Tris 3g/L, Proclin300, 0.02%, BSA 5g/L, TritonX-100 2g/L, pH 8.5)	in pre-filled integrated buffer tube	30	/	/
	in disposable buffer vial	/	/	30
	in 10mL buffer bottle	/	2	/
Extraction Tubes and Tips		/	30	30

Materials Required But Not Provided

•Timer • Specimen Transport Tubes

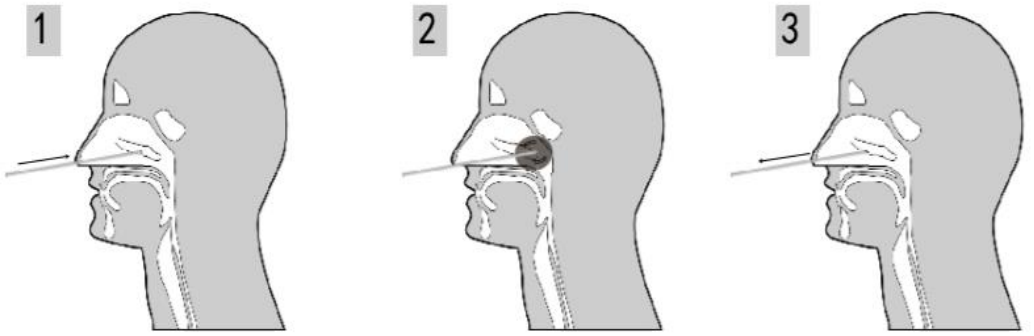
Contents of Biozek Covid-19 Antigen Rapid test.

Disposable sampling Swab:

Production: Jiangsu Hanheng Medical Technology Co
Place of Origin: Jiangsu, China
Brand Name: HanHeng
Disinfecting Type: EO sterilization
Size: 15.2cm with 8.5cm breakpoint
Shelf Life: 5 years
Material: 100% Nylon, Nylon floss tip +PP rod
Quality Certification: ce
Safety standard: EN 149 -2001+A1-2009
Product name: nasal swab
Property: sample collection
Certificate: CE/ISO13485
Product Certification
CE Certified. Valid from 2019-11-25 until 2024-05-27

Description of Test Steps:

Specimen Collection
1. Insert a provided sterile swab into the nostril of the patient carefully, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx gently.
3. Withdraw the sterile swab from the nasal cavity.



4.

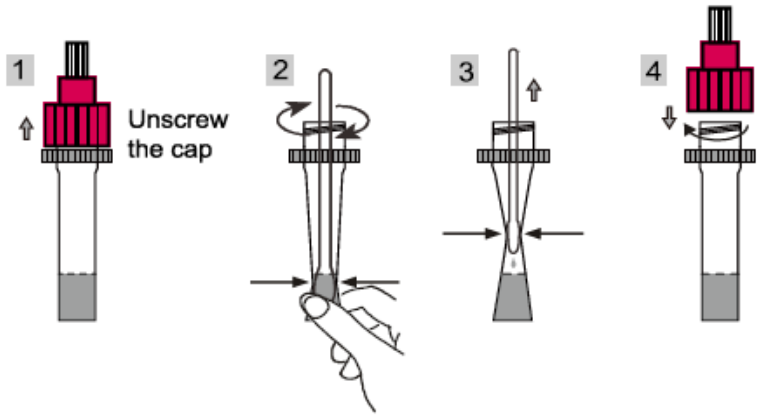
Swab specimens should be extracted and tested as soon as possible after swab specimen collection.

Specimen Extraction

Only the extraction buffer and/or tubes provided in this kit is to be used for specimen extraction.

Swab specimen extraction with pre-filled integrated buffer tube (Option 1)

1. Unscrew the cap of the extraction tube with the extraction buffer inside.
2. Place the swab specimen into the extraction buffer, for better mixture and extraction to release antigen, rotate the swab for approximately 10 seconds while pressing the swab head against the inner wall of the tube at least 5 times to release the antigen.
3. Remove the swab while squeezing the swab head against the inner wall of the tube to get maximum solution left inside the extraction tube. Dispose of the used swab in your biohazard waste.
4. Tighten the cap onto the sample extraction tube. Use the extracted sample solution as a final sample for testing as soon as possible.

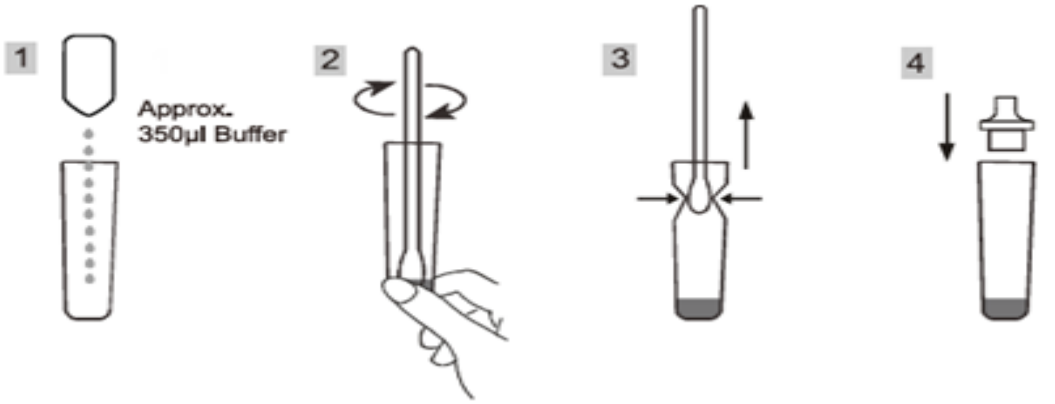


Swab specimen extraction with extraction buffer and tube separately (Option 2&3)
(Extraction buffer in 10mL buffer bottle or disposable buffer vial)

1. Place the extraction tube in the workstation and add approx. 350µL Extraction Buffer into the extraction tube as following:
Extraction buffer in 10mL bottle: Add 10 drops of extraction buffer into the tube.
Extraction buffer in disposable buffer vial: Tear to open the small disposable vial and add the Entire Extraction Buffer into the tube.
2. Place the swab specimen into the extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inner wall of the tube 5 times to release the antigen.

3. Remove the swab while squeezing the swab head against the inner wall of the tube to get maximum solution left inside the extraction tube. Dispose of the used swab in your biohazard waste.
4. Fit the tip onto the top of the extraction tube. Use the extracted sample solution as a final sample for testing as soon as possible.

NOTE: For extraction buffer in 10mL bottle, it is suggested not to use the extraction buffer beyond 3 months after opening the extraction buffer bottle.



Viral Transport Media (VTM) specimen extraction
1. VTM should not contain guanidinium.
2. When using Viral Transport Media (VTM) specimen, it is important to ensure that the VTM containing the swab specimen has been balanced to room temperature (15- 30°C).
3. Using a pipette to transfer 350µL VTM specimen into the specimen extraction tube with approx.350µL extraction buffer inside, shake to mix it well for extraction. Use the extracted sample solution as a final sample for testing as soon as possible.

NOTE: The storage of the extracted specimen is stable for 2 hours at room temperature or 24 hours at 2-8°C.

Standard Testing Procedure
Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

Invert the specimen collection tube and add 3 drops of the extracted specimen (approx.75µl) to the specimen well(S) and then start the timer. |

Wait for the colored line(s) to appear. Read the result in 15 minutes. Do not interpret the result after 20 minutes.

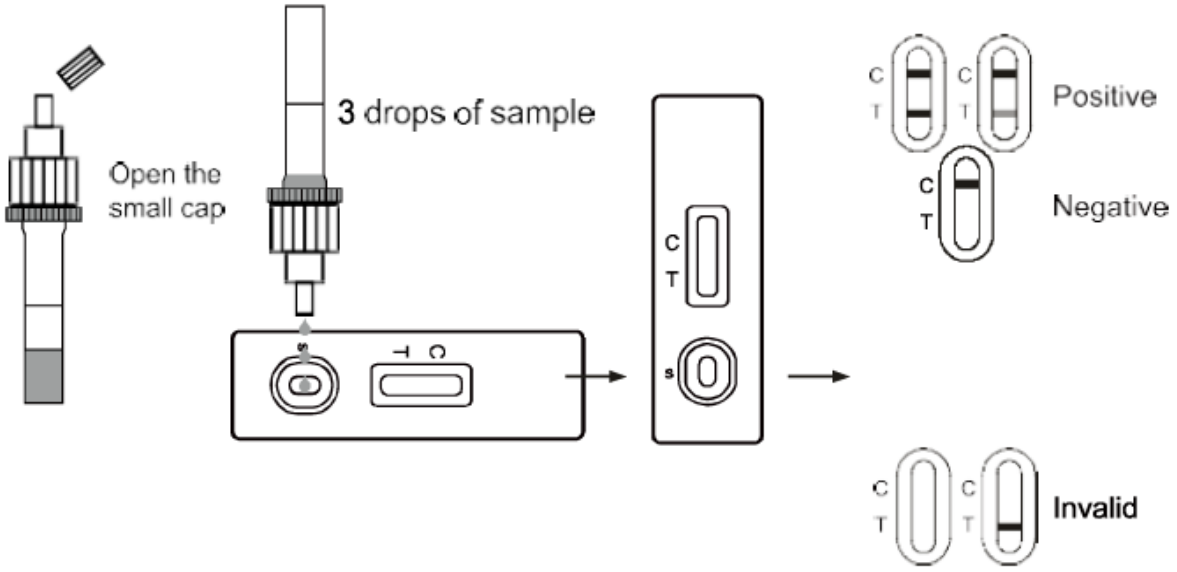


Figure 1: Interpretation of Results for Test Cassette

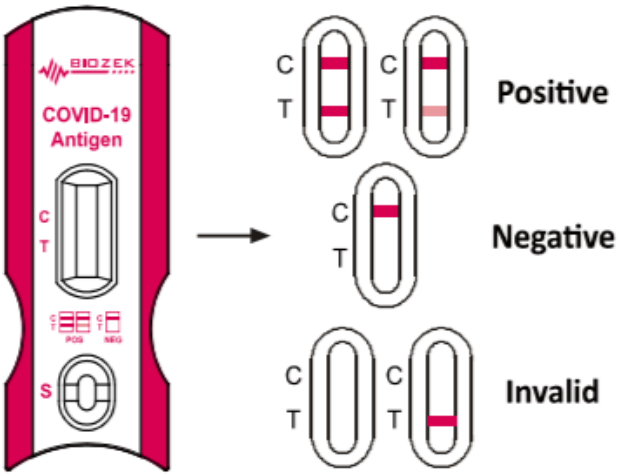
After the test is performed, remaining material should be disposed of in biohazard disposal.

Control Material:
Internal Quality Control
An internal procedural control is included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

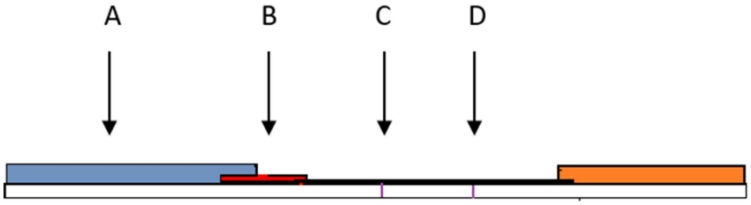
External Quality Control
Positive and negative controls are not included in this kit.

Interpretation of results
POSITIVE: * Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T). A positive result in the Test region indicates detection of COVID-19 antigens in the sample.
*NOTE: The intensity of the color in the test line region (T) will vary based on the amount of COVID-19 antigen present in the sample. Any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T). INVALID: Control line fails to appear in the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue.



If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in the test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.



As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). COVID-19 antigen present in the specimen binds to the conjugate, forming a colored antibody-antigen complex. The Anti-SARS-CoV2 immobilized in the test zone of the membrane captures the test region (C). The formation of a visible colored line in the test region indicates a positive result (C). The absence of a colored line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (D) confirms the control line.

How to Store Biozek COVID-19 Antigen rapid test.

Store the BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) packaged in the sealed pouch and extraction buffer at room temperature or refrigerated (2-30°C). The test and extraction buffer are stable through the expiration date printed on the sealed pouch and buffer label. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use the kit beyond the expiration date. Do not use the kit if the package of the test cassette or buffer is damaged.

6. Study Population

6.1 Inclusion Criteria

Subjects must be ≥18 years of age and have had an RT-PCR test performed prior to enrollment. Subjects must be able to understand and willingly sign a written informed consent. Additionally, participants need to meet at least 1 of the criteria listed below:

- Currently experiencing symptoms of COVID-19.
- Be clinically diagnosed or suspected to have COVID-19.
- Recent past (3 weeks) exhibited symptoms of COVID-19.
- Be capable of performing a self-collection of a nasopharyngeal sample with use of nasal swab kit.
- Interacted with a COVID-19 positive individual.

6.2 Exclusion Criteria

Subjects who meet any of the following exclusion criteria may not be enrolled in this study:

- Cannot perform self-collection of a nasopharyngeal sample with use of nasal swab kit.
- Have a deviated nasal septum.
- Cognitively impaired individuals resulting in the inability to provide informed consent

6.3 Sample Size

Up to 250 subjects will be enrolled in the study. The study shall be continued until at least 30 positive and 30 negative tests results are obtained.

6.4 Confirmation of Patient Enrollment

Patient enrollment into the study will be confirmed by onsite Study Monitor.

6.5 Patient Identification

During the study, the Study Monitor will submit a daily summary to Quality Research and Invention LLC, with the total number of subjects enrolled that day to the study. Patient numbers will be assigned sequentially as patients are enrolled at the site. Once assigned, patient numbers will not be re-used. Each patient's screening number will be recorded on every page of the CRF. In any correspondence or communication with the Sponsor, patients should be referred to by the screening number and initials only.

6.6 Removal, Replacement, or Early Withdrawals of Subjects

Patients who withdraw following the commencement of study treatment due to any reason will not be replaced.

7. Overview of Investigational Plan

7.1 Enrollment

- Participants will be recruited;
- Subject to be screened and deemed eligible by the study personnel for enrollment;
- Patient details to be entered onto the information form;
- Site enrolls patients and assigns patient screening numbers.

7.2 Material and Methods

Enrollment will take place at the Mobile Clinic. The Enrollment population consists of up to 250 symptomatic patients scheduled for an appointment, at a Mobile Clinic, to perform an RT-PCR test for SARS-CoV-2 as the standard of care procedure. After arrival, all patients who have received an RT-PCR test will complete a COVID Screening Intake Form and will be asked if they are willing to participate in the BIOZEK study after their scheduled RT-PCR test has been performed. After obtaining medical clearance, a medical staff member will collect samples for RT-PCR test and will send it to the Sigmund Laboratory for testing. The results will be available in 1-2days. Results and Ct value of the RT-PCR test from subjects enrolled to the study will be collected by study personnel.

If the subject is age 18 or older and meets the inclusion and exclusion criteria, they will sign an Informed Consent Form and will be enrolled into the BIOZEK study. A study coordinator will take the subject's body's surface temperature and will capture it in the CRF.

An additional two samples will be collected for the BIOZEK COVID-19 Antigen Rapid Test. The first test will be performed by the subject, via self-collection of the sample, following instructions provided by Biozek Company. The second test will be performed by a trained medical professional.

Subject will open the Biozek package with a test and will read instructions in package insert. Materials provided in the BIOZEK-COVID-19 Antigen Rapid Test kit includes: Test cassettes, Sterile Swabs, Extraction tubes and tips, Extraction Buffer, Workstation.

First sample collection- BIOZEK COVID-19 Antigen Rapid Test

A nasopharyngeal sample will be collected via self-collection and the test will be performed by the subject. The subject will follow simplified instruction provided with the test. (Instructions listed below and the full instruction is also attached). Medical professionals will monitor and record any difficulties.

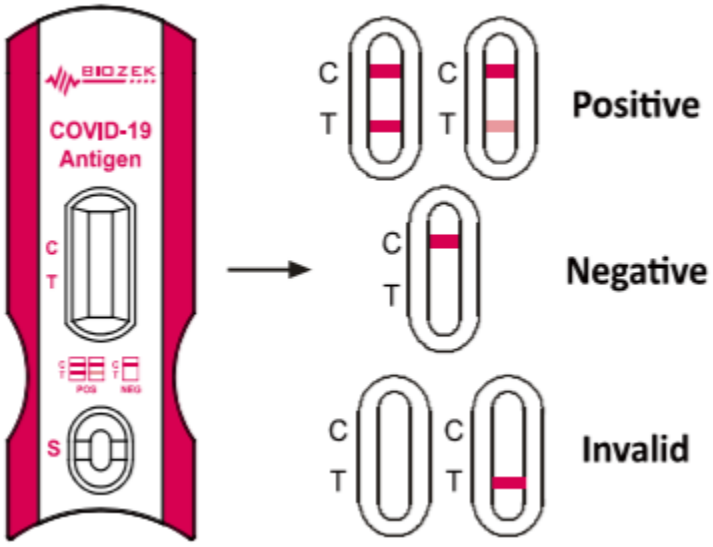
BIOZEK COVID-19 Rapid Test

DIRECTIONS

Read all of these directions before starting

1. Open the swab package.
2. Twist top off the small plastic vial and squeeze the liquid into the plastic specimen tube, making sure the specimen tube stays upright.
3. Collect the specimen from your nose.
    a. Gently insert the swab into your nose, all the way to the back of the nasal cavity. (NOTE: Aim the swab towards the back of your head, not towards the top, as your nasal cavity connects back to your ears)
    a. When the swab can't be pushed any further (inserted about 3") rotate it 3 times and gently and carefully remove the swab.
4. Insert the swab into the specimen tube.
    a. Rotate the swab for 10 seconds against the wall of the tube.
    b. Squeeze the bottom of the tube several times while stirring.
5. Remove the swab while squeezing the tube to get the maximum solution out of the swab.
6. Place the plastic tip on the specimen tube.
7. Open the test cassette and place it on a level surface.
8. Shake the specimen tube for 10 seconds.
9. Invert the specimen tube and put 3 drops into the specimen well of the cassette test kit.
10. Wait for 15 minutes and read the results.

Test Results



After interpreting the results, the coordinator will take an image of the cassette to be recorded and captured in the CRF. Compliant to all procedures required for disposal of biohazardous waste.

Second sample collection- BIOZEK COVID-19 Antigen Rapid Test

A nasopharyngeal sample collection and the test will be performed by a medical professional. The medical professional is trained and will not require instructions to perform the test.
After specimen collection, the coordinator records any indication of an adverse event and it is captured in the CRF. All data collected is to be captured in the subject's CRF.
The swab specimens should be extracted and tested as soon as possible after specimen collection.
After interpreting the results, the coordinator will take an image of the cassette to be recorded and captured in the CRF. Compliant to all procedures required for disposal of biohazardous waste.
RT-PCR test collection and processing will follow the standard of care procedure. In addition, Ct values will be requested from the laboratory. Turnaround time for RT-PCR test results is 1-2 days. When the results from PCR test will be available study personnel will collect them from Sigmund Laboratory. All three results will be compared.

All data collected from the three samples will be transferred to Quality Research and Invention, LLC for analysis.

7.3 Premature Discontinuation

Patients may be withdrawn from the study for the following reasons:

- at patient's own request or at the request of their legally authorized representative
- if, in the opinion of the Investigators, continuation in the study would be detrimental to the subject's well-being
- at the specific request of the Sponsor.

Patients must be withdrawn from the study under the following circumstances:

- intolerable sample collection procedure
- any event that in the judgment of the Investigators poses an unacceptable safety risk to the patient
- study closure

In all cases, the reason for withdrawal must be recorded in the CRF and in the patient's medical records.

7.4 Protocol Violations

Protocol violations include any deviations from this protocol, regardless of prior approval of the violation. A major protocol violation would include the following:

- enrollment of a patient who does not meet the inclusion/exclusion criteria
- enrollment of a patient who has not signed an informed consent form
- the patient has missed the sample collection visit(s)

Any protocol violation must be reported immediately to the Sponsor and to the IRB.

7.5 Compliance

This study will be conducted in accordance with ICH-Good Clinical Practice guidelines.

7.6 Risks

During self-collection the subject will be closely monitored according to standard of care and any adverse effects will be documented. During the test performed by healthcare professionals the subjects in this study will not be exposed to additional risk from interventional procedures, because the ones to be used are the standard of clinical practice.

8. Data analysis

The data will be collected and analyzed by Quality and Invention team.
Results of RT-PCR, BIOZEK COVID-19 Antigen Rapid Test on a sample collected by healthcare professionals, BIOZEK COVID-19 Antigen Rapid Test on self-collected samples will be analyzed. Additionally, Ct values for RT-PCR will be obtained.
RT-PCR is a golden standard in diagnosis of Covid-19. The results obtained by Biozek tests will be compared to results of RT-PCR test.
Sensitivity and specificity will be calculated.

9. Ethics

9.1 BRANY Institutional Review Board

Prior to initiation of the study, the Principal Investigators will submit the study protocol, sample Informed Consent Form, and any other documents that may be requested to their respective BRANY IRB for review and approval. The Principal Investigators will request that the BRANY IRB provide written approval of the study and will keep on file records of approval of all documents pertaining to this study.

The BRANY IRB will have at all times the right to review all source documents.
The BRANY IRB will be notified of any amendments to the protocol. Those amendments will require approval of the BRANY/IRB prior to being incorporated into the study.

9.2 Ethical Conduct of the Study

This trial will be conducted in compliance with the protocol, Good Clinical Practices (GCP), and the applicable regulatory requirements.

9.3 Subject Information and Consent

Prior to screening for the study, each subject will be informed in detail about the study procedure, and the nature of the clinical investigation with its risks and discomforts to be expected. The principles of informed consent as specified by ICH-GCP will be followed. Any amendments to the Informed Consent form will need to be approved by the BRANY IRB. Written consent will be obtained from each subject to be involved in the clinical trial by using the BRANY IRB-approved Informed Consent Form. Consent will be verified by the Principal Investigator and a witness (where applicable). Each subject will be given a copy of the Informed Consent Form. The subjects will also be instructed that they are free to withdraw their consent and discontinue their participation in the study at any time without prejudice.

10.References

1) Manabe, Y., Sharfstein, J. and Armstrong, K., 2021. *The Need for More and Better Testing for COVID-19*.

2) Rubin, R., 2021. *The Challenges of Expanding Rapid Tests to Curb COVID-19*.

3) U.S. Food and Drug Administration. 2021. *Coronavirus (COVID-19) Update: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19*. [online] Available at: <https://www.fda.gov/news-events/press-

4) Centers for Disease Control and Prevention. 2021. *COVIDView, Key Updates*. [online] Available at: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html> [Accessed 11 February 2021].

5) Centers for Disease Control and Prevention. 2021. *COVID-19 and Your Health*. [online] Available at: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html> [Accessed 11 February 2021].