Clinical Protocol BIOZEK

Title:	**"Open label, Single-Center Study utilizing BIOZEK COVID-19 Antigen Rapid Test."** Comparison of Biozek COVID-19 Antigen Rapid test results performed on self-collected samples by the subjects, to results of COVID-19 RT-PCR as a standard of care.
Short title:	Comparison of BIOZEK Antigen Rapid Test to COVID-19 RT-PCR.
Protocol Number:	Biozek-ARTC-US/002/4-12-2021
Product:	BIOZEK COVID-19 Antigen Rapid Test Cassette Nasopharyngeal Swab BIOZEK COVID-19 Antigen Rapid Test Cassette Oral Fluid
Principal Investigator: **Co-Principal Investigator**:	Janetta Stega, M.D., PhD Damian Stega, M.D
Study Coordinator:	Sophia Dalia
Version:	Final 4.0
Date:	June 1, 2021

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1. Protocol Synopsis

Title:	**"Open label, Single-Center Study utilizing BIOZEK COVID-19 Antigen Rapid Test."** Comparison of Biozek COVID-19 Antigen Rapid Test results performed on self-collected samples by the subjects, to results of COVID-19 RT-PCR as a standard of care.
Number of Subjects Planned:	Up to 250 Subjects, minimum of 30 positive and 30 negative tests.
Study Objectives:	To assess sensitivity and specificity of BIOZEK COVID-19 Antigen Rapid Test on a self-collected sample and self-performed test by subject (nasopharyngeal swab and oral fluid). To assess subject's performance to collect samples and conduct BIOZEK COVID-19 Antigen Rapid Test.
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 BIOZEK COVID-19 Antigen Rapid Test Cassette Oral Fluid
Comparator:	Type of test: RT-PCR Name of test: Atila BioRad BioFire Luminex Aires
Study Design:	Up to 250 (30 positive and 30 negative) 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. A

study personnel will collect demographics information from the subjects.

A medical staff member will measure body surface temperature 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 and/or FAM values will be requested. The Ct (cycle threshold) is defined as the number of cycles required for the fluorescent signal to cross the threshold (i.e., exceeds background level). The lower the Ct level the greater the amount of target nucleic acid in the sample. FAM (Fluorescein) the is most commonly used fluorescent dye attachment for oligonucleotides and is compatible with most fluorescent detection equipment.

2.BIOZEK COVID-19 Antigen Rapid Test Cassette- Nasopharyngeal Swab
(via self-collection - nasopharyngeal swab sample).
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 included 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 Cassette- Oral Fluid
(via self-collection - oral fluid sample)
Oral fluid sample 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 included 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.

Results will be retrieved from the RT-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 events will be captured.
Efficacy Criteria:	Sensitivity and Specificity will be calculated separately for BIOZEK COVID-19 Antigen Rapid Test - on a self-collected, nasopharyngeal sample and for BIOZEK COVID-19 Antigen Rapid Test on the self-collected oral fluid sample. Additionally, the result of each test performed by the subject will be compared to the RT-PCR test result.
End Points:	Sensitivity and Specificity of BIOZEK COVID-19 Antigen Rapid Test on self-collected nasopharyngeal sample. Sensitivity and Specificity of BIOZEK COVID-19 Antigen Rapid Test on self-collected oral fluid sample.

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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:

To assess sensitivity and specificity of BIOZEK COVID-19 Antigen Rapid Test on a self-collected sample and self-performed test by subject (nasopharyngeal swab and oral fluid).

To assess subject's performance to collect samples and conduct BIOZEK COVID-19 Antigen Rapid Test.

5. Investigational Product

The BIOZEK COVID-19 Antigen Rapid Test Cassette is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human nasopharyngeal swab specimens and in oral fluid 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.

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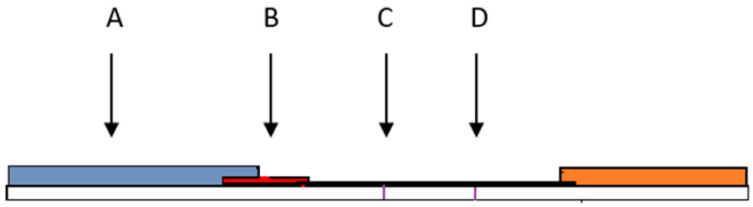
Name	Description	Dosage (Swab)	Dosage (Oral Fluid)
Goat anti-mouse IgG	Liquid, capture in the NC membrane	0.150-0.300μg/test	0.150-0.300μg/test
Mouse IgG	Liquid, detection in the label pad	0.050-0.200μg/test	0.050-0.200μg/test
Mouse anti-Nucleocapsid protein	Liquid, capture in the NC membrane	0.0100-0.400μg/test	0.080-0.800μg/test
Mouse anti-Nucleocapsid protein	Liquid, detection in the NC membrane	0.080-0.350μg/test	0.100-0.400μg/test

Table.1 Amounts, concentrations, or quantities of antibodies in each test.



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.
Materials provided in the BIOZEK-COVID-19 Antigen Rapid Test kit includes:
Nasopharyngeal Swab: 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

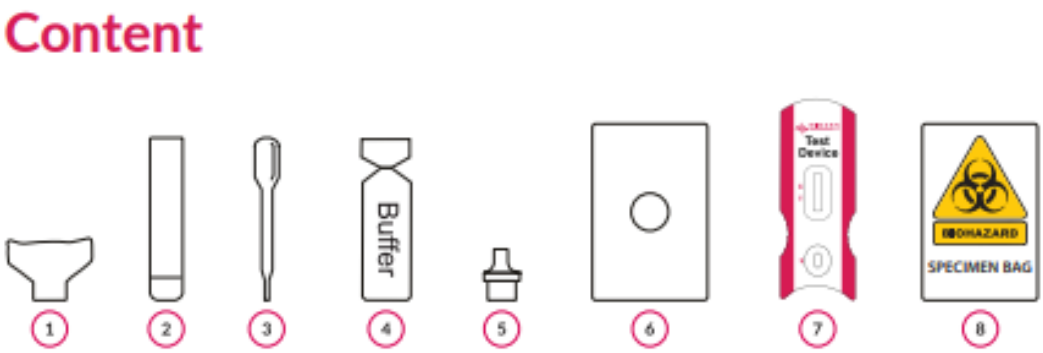
Materials Required But Not Provided

- Timer
- Specimen Transport Tubes

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

Oral Fluid: Test cassette, Collection Device (Funnel, Extraction Tube and Tip, Dropper), Extraction Buffer, Biosafety Bag, Workstation, Package Insert, Instruction for Use.



Materials Provided

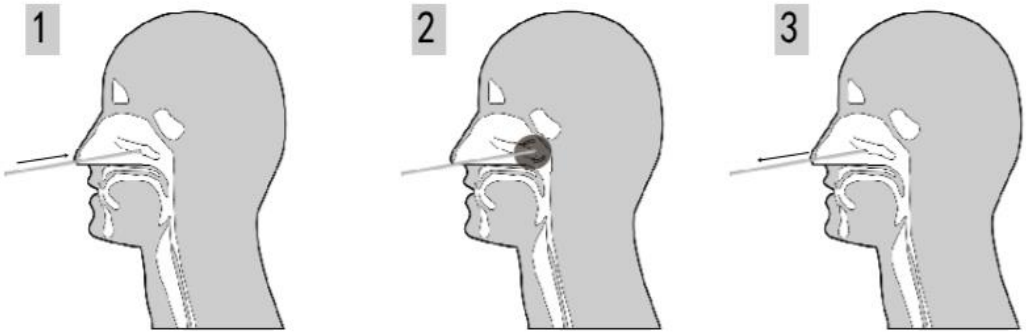
Description		Quantity
Test Device		20
Collection Device	Funnel	20
	Extraction Tube & Tip	20
	Dropper	20
Extraction Buffer (NaCl 5g/L, Tris 3g/L, TritonX-100 5g/L, BSA 5g/L, Proclin300 0.02%, pH 8.5)		20
Biosafety Bag		20
Work Station		1
Package Insert		1
Instruction Guide		1

Materials Required But Not Provided

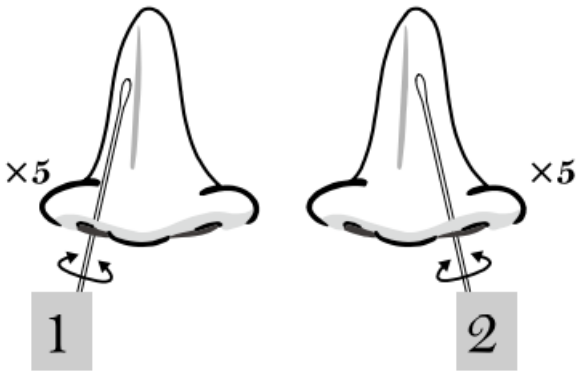
Description of Test Steps:

Biozek Covid-19 Antigen Rapid Test
Specimen Collection - Nasopharyngeal Swab

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.

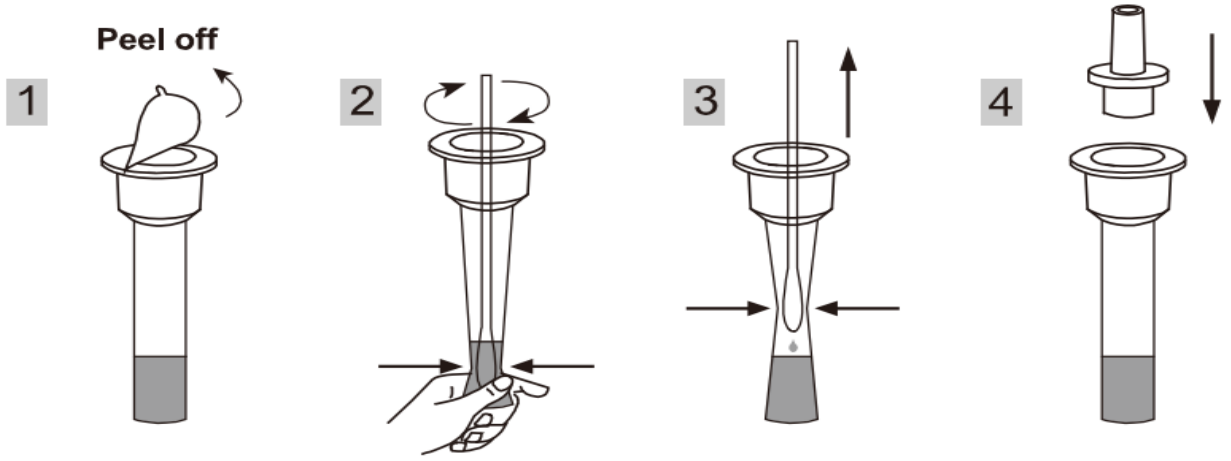


Nasal Swab Specimen Collection
1. Insert a sterile swab less than one inch (about 2 cm) into a nostril (until resistance is met at the turbinate).
2. Rotate the swab 5-10 times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril.
3. Withdraw the sterile swab, avoid excess volume and high-viscous nasal discharge.



Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

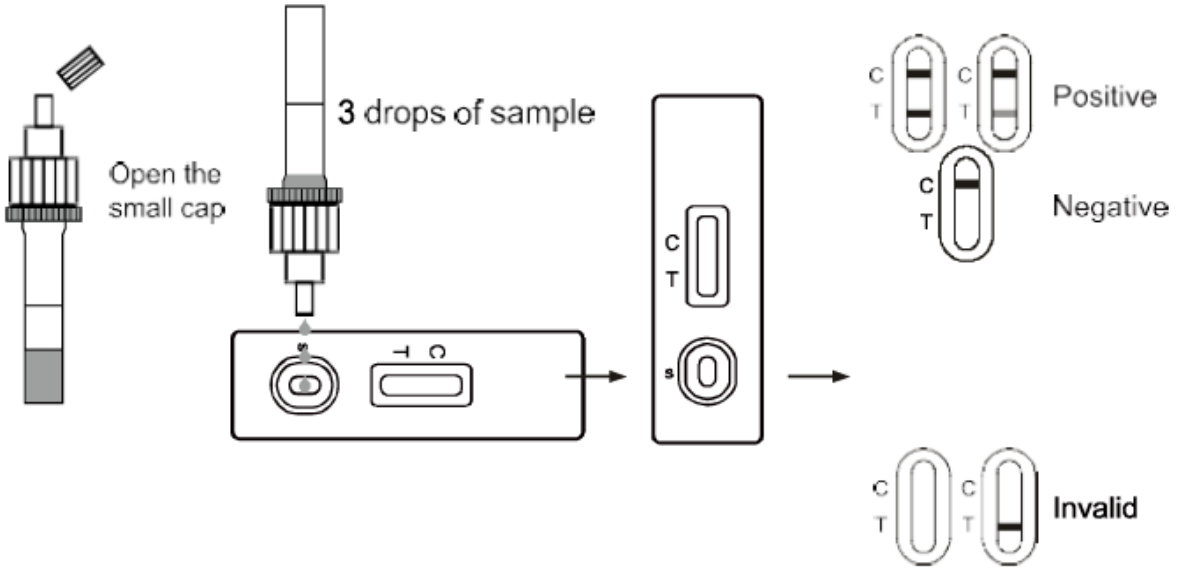
Specimen Extraction –Nasopharyngeal Swab
Only the extraction buffer provided in this kit is to be used for specimen extraction.
1. Peel off the sealing on the extraction tube with extraction buffer inside.
2. Place the swab specimen into the extraction buffer, for better mixture and extraction to release the 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. Fit the tip onto the top of the extraction tube. Use extracted sample solution as final sample for testing as soon as possible.



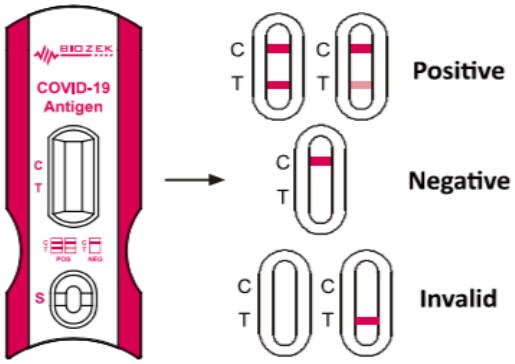
NOTE: The storage of the extracted specimen is stable for 2 hours at room temperature or 24 hours at 2-8°C.

Testing Procedure – Nasopharyngeal Swab
Allow the test cassette, extracted sample solution and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. 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.
2. Shake the extracted sample solution to mix it well. Invert the sample extraction tube and add 3 drops of the Extracted Sample Solution (approx.75-100µL) to the specimen well(S) of the

cassette. Start the timer.
3. Wait for the red line(s) to appear and read the result at 15 minutes. Do not interpret the result after 20 minutes.



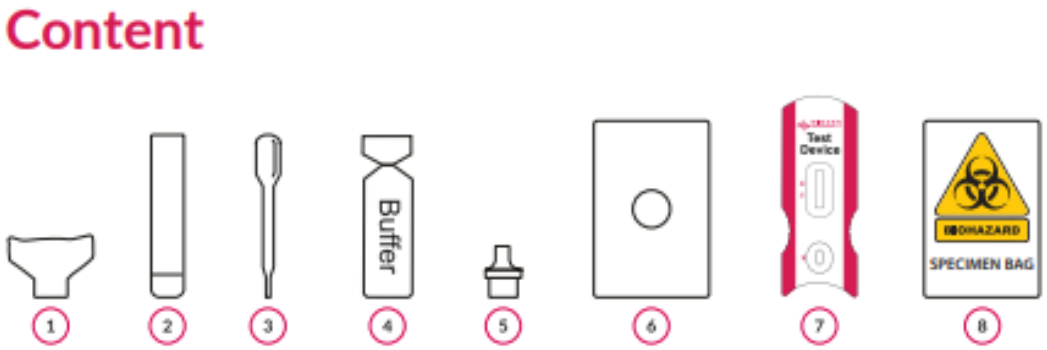
Interpretation of results - Nasopharyngeal Swab
POSITIVE: * Two red lines appear. One red line should be in the control region (C) and another red line should be in the test region (T). Positive result in the test region indicates detection of COVID-19 antigens in the sample. *NOTE: Red color line intensity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



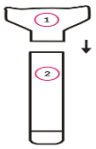
NEGATIVE: One red line appears in the control region (C). No apparent red line appears in the test region (T) indicates a negative COVID-19 antigen test result.

INVALID: No red line appears in the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedures and repeat the test with a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local BIOZEK products distributor.

Specimen Collection - Oral Fluid



Advise the patient not to consume food, beverages, chewing gum, tobacco, and other substances at least 10 minutes prior to specimen collection.

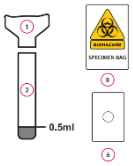


Step 1
Connect the plastic tube (number 2) to the mouthpiece (number 1). Press the plastic tube as far as possible into the mouthpiece.

Step 2
If you are having trouble collecting saliva in your mouth, try closing your mouth and wiggling your tongue. Gently rubbing the outside of your cheeks, just behind your back teeth. Making chewing motions with your mouth.

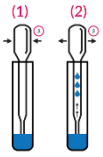
NOTE: We recommend carrying out this step in the morning.

Step 3
Spit the oral fluid into the mouthpiece. There should be about 0.5 ml of liquid in the plastic tube. This corresponds to the bottom line on the plastic tube.



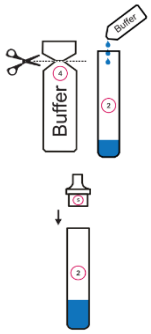
Step 4a
Remove the mouthpiece (number 1) and dispose of it in the specimen bag (number 8). Place the plastic tube in the holder (number 6).

Step 4b (only follow this step if there is too much saliva)
More than 0.5 ml of liquid? Take the pipette (number 3). Press and hold the bulb until the pipette protrudes into the solution of the plastic tube (1). Release the balloon slowly, so that the pipette sucks up the solution (2). Bring the liquid level to the bottom line (0.5 ml).

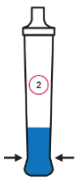


Specimen Extraction – Oral Fluid

Step 5
Take the buffer (number 4) and remove the seal at the top (by cutting/breaking it). Squeeze the contents of the buffer into the plastic tube (number 2) containing the mucus/spittle.

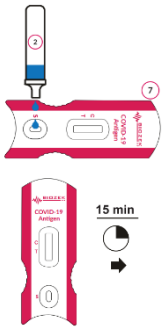


Step 6
Put the cap (number 5) on the plastic tube (number 2).



Step 7
Knead the bottom of the plastic tube firmly (number 2) for 10 seconds to mix the buffer well with the mucus/spit.

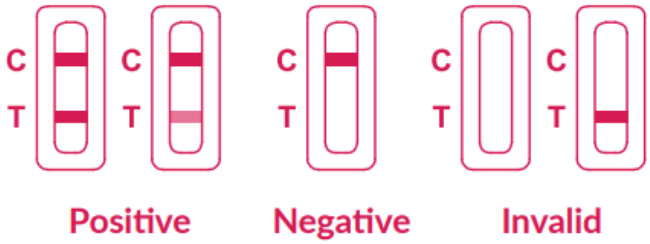
Testing Procedure – Oral Fluid



Step 8
Tear open the test package and remove the test cassette. Turn the plastic tube (number 2) upside down and let 2 drops of liquid fall into the opening next to the letter S on the cassette (number 7).

Step 9
Wait 15 minutes.

Step 10
Read the result Positive: You have tested positive for COVID-19 antigens, so please contact your doctor. Negative: You have tested negative, so the test did not detect any antigens in your sample. However, if you have COVID-19 related complaints, please contact your doctor. Invalid: The test cannot be displayed, so contact your supplier for further instruction. Do not throw the test away. If necessary, take a Positive Negative Invalid photo of the contents and packaging.



How to Store Biozek COVID-19 Antigen rapid test.

Store the BIOZEK COVID-19 Antigen Rapid Test Cassette 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.
- Be capable of performing a self-collection of an oral fluid sample with use of oral fluid collection 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.
- Cannot perform self-collection of an oral fluid sample with use of oral fluid collection 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 on-site 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

The Enrollment population consists of up to 250 (minimum of 30 positive and 30 negative samples) symptomatic patients. Enrollment will take place at the subject's home during scheduled visits to patients appointed for an RT-PCR test, as the standard of care procedure, performed by a medical staff member. Medical staff members will perform the RT-PCR test and the samples will be sent to A2Z Diagnostics Laboratory. The results will be available in 1-3 days. Results including Ct and/or FAM values of the RT-PCR test from subjects enrolled to the study will be collected by study personnel.

After completion of the RT-PCR Test, the patients will be asked if they are willing to participate in the BIOZEK Study. 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 personnel will collect demographics information from the subjects; in addition, they will take the subject's body's surface temperature and capture it in the CRF.

Subject will perform 2 additional tests performed in a manner described below:

1.BIOZEK COVID-19 Antigen Rapid Test Cassette-Nasopharyngeal Swab
(via self-collection - nasopharyngeal swab sample),
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 included 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.

2. BIOZEK COVID-19 Antigen Rapid Test Cassette-Oral Fluid
(via self-collection - oral fluid sample)
Oral fluid sample 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 included 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

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.

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

8. Data analysis

The data will be collected and analyzed by Quality Research and Invention team.
Results of RT-PCR, BIOZEK COVID-19 Antigen Rapid Test on self-collected nasopharyngeal sample and BIOZEK COVID-19 Antigen Rapid Test on self-collected oral fluid samples will be analyzed.
Additionally, Ct and/or FAM 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].