BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

SUBJECT INFORMATION AND INFORMED CONSENT FORM

Protocol 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.

Protocol #:	Biozek-ARTC-US/001/3-5-2021
Sponsor:	BIOZEK
Principal Investigator:	Damian Stega, MD
Co-Principal Investigator:	Angela Khaitova
Institution:	Mobile Covid Services LLC 3050 Whitestone Expressway, Suite 402 Flushing, NY, 11354
Telephone:	(347)-337-2300

KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a subject in a research study because you currently experiencing symptoms of COVID-19, have been clinically diagnosed or suspected to have COVID-19, have recently (past 3 weeks) have exhibited symptoms of COVID-19, or have interacted with a COVID-19 positive individual.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This is a research study to evaluate the Sensitivity and Specificity of BIOZEK COVID-19 Antigen Rapid Test on samples collected by a healthcare professional versus self-collection; and to perform analysis to compare results. In addition, to obtain RT-PCR test results, performed prior to enrollment, and compare all three results.
Experimental/ Investigational	Investigational BIOZEK COVID-19 Antigen Rapid Test
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	There will be one study visit. Length of participation is one day.
Procedure	The BIOZEK COVID-19 Antigen Rapid Test is used for the detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals who are suspected of having COVID-19. There will be one study visit. Body surface temperature will be measured. Two nasopharyngeal specimens will be collected from the study subject

	from both nostrils. The first sample will be collected, via self-collection, by the study subject and the second collection will be performed by a healthcare professional. The process for specimen collection and extraction will follow the same procedure for both samples. For specimen extraction only the materials in the kit must be used. 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, Package Insert. **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). The study coordinator will monitor the performance of the study subject during self-collection and observe for any indication of an adverse event. **Second sample collection- BIOZEK COVID-19 Antigen Rapid Test** A nasopharyngeal sample collection 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. 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 the 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.
Risks	The BIOZEK COVID-19 Antigen Rapid Test is non-invasive and does not pose a significant risk.

	The study coordinator will explain the risks of this research to you before you decide about participation.
Benefit	The BIOZEK COVID-19 Antigen Rapid Test is a high quality, user-friendly, very convenient test for use in resource poor settings. Same day results provide timely treatment interventions.
Costs	Cost of the Biozek COVID-19 Antigen Rapid test will be fully covered by the Sponsor.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information. Your data will only be shared in a format where it is combined with other test subjects. In any correspondence or communication with the Sponsor, patients will be referred to by the screening number and initials only.

INSTRUCTIONS FOLLOWING THE TEST
Not applicable.

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding whether or not to participate.

INFORMED CONSENT FORM
This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve, and the risks and benefits. Ask the study personnel to explain anything in this form you do not understand or if you want additional information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS
BIOZEK, the sponsor of this study, is providing funds to Mobile COVID Services LLC, on a per subject basis for conducting this research study.

PURPOSE OF THE STUDY
The purpose of this study is to evaluate the Sensitivity and Specificity of BIOZEK COVID-19 Antigen Rapid Test on samples collected by a healthcare professional vs self-collection. Perform an analysis of the results from the BIOZEK COVID-19 test to assess if the results collected by a healthcare professional are comparable to the self-collected sample. In addition, to obtain results from the RT-PCR test performed prior enrollment, the standard of care procedure, and compare the results from all three samples.

BIOZEK COVID-19 Antigen Rapid test is already approved for use in Europe and is in the process of applying for FDA approval for Emergency Use Authorization in the United States. The swab that is included in the package is already used for standard of care.

There will be one study visitwhere you will sign this Informed Consent Form and in addition to the RT-PCR test, will be required to provide two additional samples for testing. The first sample and test will be collected via self-collection, performed by you while following detailed instructions provided in writing on the package insert, by a healthcare professional. The second sample collection and test will be performed by a healthcare professional. The results from RT-PCR test performed prior to enrollment will be collected for the study sponsor. The additional samples, collected in this study, will be analyzed and compared to the standard of care results.

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION
About 250 subjects are expected to participate in this study at a single center research site in the United States. Your participation in this study is expected to be one day. The duration of the entire study is up to two weeks.

STUDY PROCEDURES There will be one study visit. Your temperature will be measured. Two nasopharyngeal specimens will be collected from the study subject from both nostrils. The first sample will be collected, via self-collection, and the test will be performed by the study subject and the second collection and test will be performed by a healthcare professional. The process for specimen collection and extraction will follow the same procedure for both samples.

For specimen extraction only the materials in the kit must be used.

You 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, Package Insert.

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 you. 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

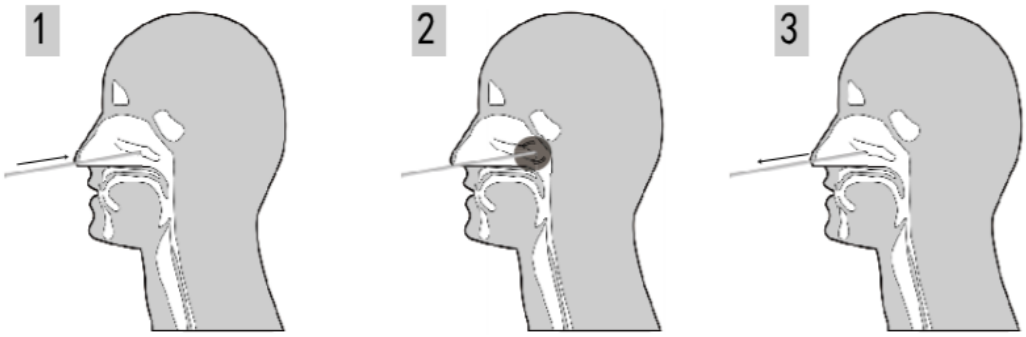
DIRECTIONS

Read all of these directions before starting

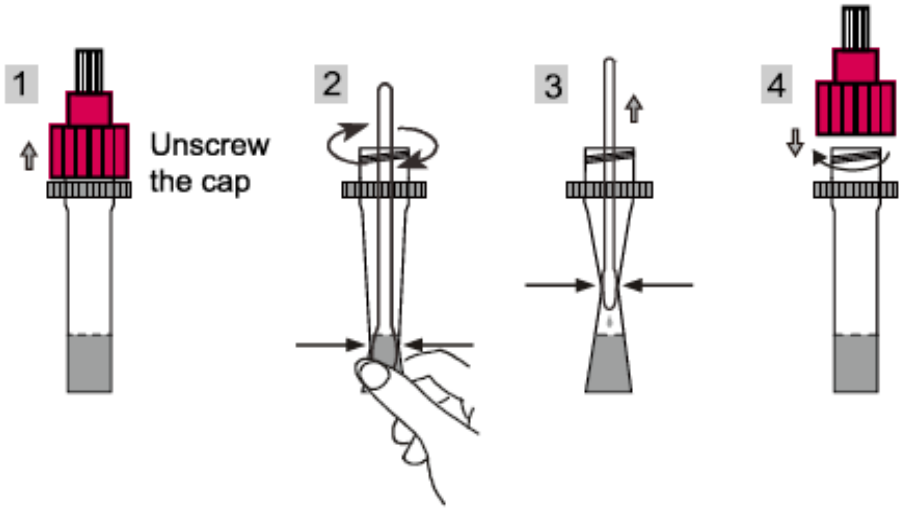
1. Open the swab package.

2. Twist top off the small plastic vial and squeeze the liquid into the plastic specimen tube, making sure the specimen tube stays upright.

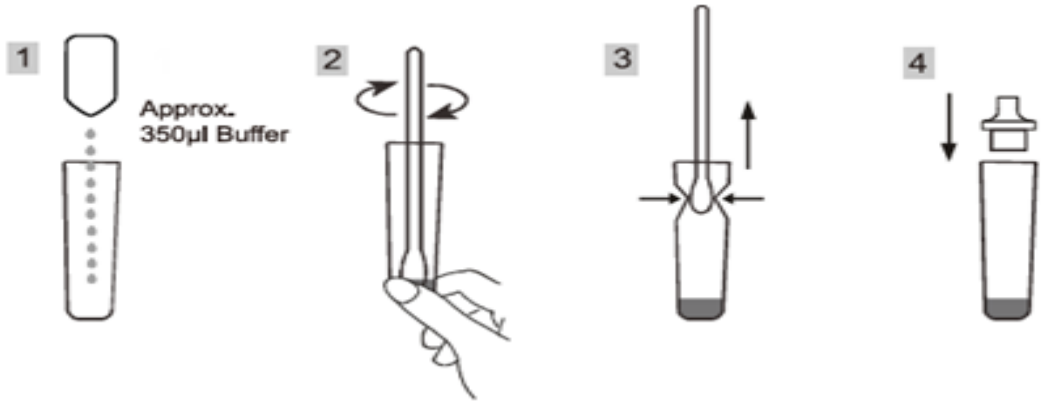
3. Collect the specimen from your nose.
   a. Gently insert the swab into your nose, all the way to the back of the nasal cavity. (NOTE: Aim the swab towards the back of your head, not towards the top, as your nasal cavity connects back to your ears)
   a. When the swab can't be pushed any further (inserted 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.

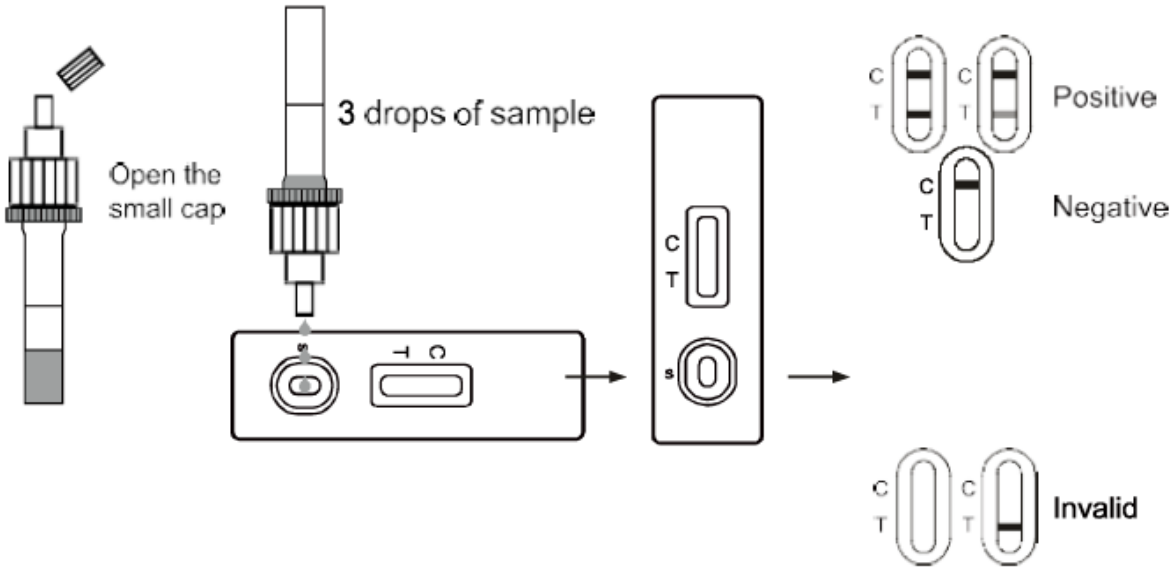


6. Place the plastic tip on the specimen tube.

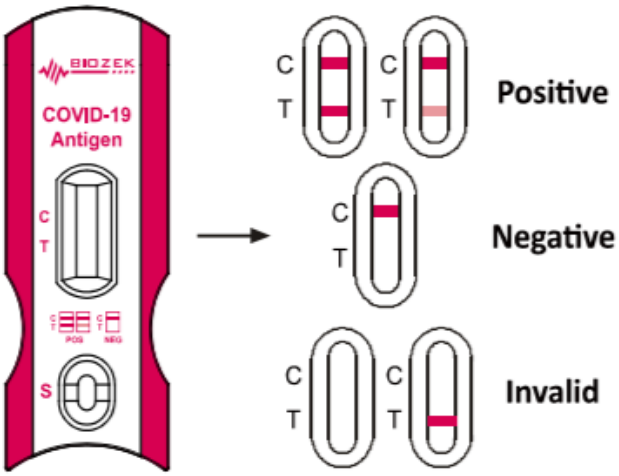
7. Open the test cassette and place it on a level surface.

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.



The study coordinator will monitor your performance during self-collection and observe for any indication of an adverse event.

After interpreting the results, the coordinator will take an image of the cassette to be recorded and captured in the CRF

Second sample collection- BIOZEK COVID-19 Antigen Rapid Test

A nasopharyngeal sample collection performed by a medical professional.
The resultswill be recorded.
After interpreting the results, the coordinator will take an image of the cassette to be recorded and captured in the CRF.
RT-PCR test collection and processing will follow the standard of care procedure. RT-PCR test results is 1-2 days. The study personnel will collect the results from the Sigmund Laboratory. All three results will be compared.

SUBJECT RESPONSIBILITIES

As a subject in this study, you will have certain responsibilities, including the following:

- Attend one study visit.
- Provide standard of care test results, RT-PCR, to be used in comparison to study results
- Follow instructions to perform self-collection of nasopharyngeal specimens
- Follow instructions to conduct the BIOZEK COVID-19 Antigen Rapid Test using the self-collected sample
- Tell the study staff any time you do not feel well or if you have any side effects

RISKS AND DISCOMFORTS

The BIOZEK COVID-19 Antigen Rapid Test is noninvasive and does not pose a significant risk. Nasopharyngeal Swab sample collection can cause nasal bleeding, nasal discomfort, runny nose, headache, ear discomfort.

Clinically Relevant Research Results

The overall results of this study may or may not be available to you at the end of the study.

The study coordinator will also explain if and when you will receive individual research results that may have clinical significance.

BENEFITS

There may be no benefit to you for participating in The BIOZEK COVID-19 Antigen Rapid Test.

ALTERNATIVES TO STUDY PARTICIPATION

You may chose not to participate in the study and only have the standard SARS-CoV-2 test. Your decision will not affect your care.

COSTS OF PARTICIPATION

There is no cost to you to participate in this study. Cost of the Biozek COVID-19 Antigen Rapid test will be fully covered by the sponsor.

You and/or your insurance company will be responsible for the costs of all items and services during the research study, which you would have received for your condition if you were not enrolled in this research study and/or that your physician believes are medically necessary to treat you. You should discuss possible costs of study participation with the study staff and/or your insurance company.

COMPENSATION FOR INJURY

For medical emergencies, call 911. If you become ill or are hurt while you are in this study, contact your doctor and study personnel immediately. The study personnel will assist you in obtaining appropriate medical treatment.

No other compensation will be offered by the sponsor or Mobile COVID Services LLC, or the Biomedical Research Alliance of New York.

You are not waiving any legal right to seek additional compensation through the courts by signing this form.

Reimbursement for time and travel

You will receive a $50 in cash for time and travel reimbursement at the end of the study visit.

Your biospecimens, with or without identifiers, may be used for commercial profit and you will not share in this profit.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at

meetings or in publications; however, you will not be identified in these presentations and/ or publications. In any correspondence or communication with the Sponsor, patients should be referred to by the screening number and initials only.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study personnel must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study personnel will get personal information about you. This may include information that might identify you. The study personnel may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study personnel. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It

may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study personnel at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Collection of Identifiable Private Information or Identifiable Biospecimens:

- Identifiers might be removed from your identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (or consent from your legally authorized representative).

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study personnel.

Your participation in this study may be stopped without your consent at any time and for any reason by the study personnel, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study site office for a final study visit for your safety.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Damian Stega at (917) 499-0737 (Principal investigator of the study).

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research

Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

STATEMENT OF CONSENT - SIGNATURES

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

_____

Subject: Name (Print) Signature Date

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Person Obtaining Consent: Name (Print) Signature Date