MGC Health COVID-19 & Flu A+B Home Multi Test Usability Study

Protocol No: MGC-1001

NCT05732610

Version Number 1.0

16 January 2023

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PROTOCOL APPROVAL PAGE

Study Title:	MGC Health COVID-19 & Flu A+B Home Multi Test Usability Study
Protocol Number	MGC-1001
Version Number	1.0
Date of Issue	16 January 2023
Sponsor Name and Address:	Medical Group Care 1035 Collier Center Way, Suite 5 Naples, FL 34110

I, the undersigned have read and approve this protocol and agree on its content. It is confirmed that the information and guidance given in this protocol complies with scientific principles.

	Name and Title	Signature and Date
Reviewed and approved by:	Name: Title: _____	

INVESTIGATOR PROTOCOL AGREEMENT

Protocol Title: MGC Health COVID-19 & Flu A+B Home Multi Test Usability Study

Protocol Number: MGC-1001

By my signature, I

1. Agree to conduct the study in accordance with the relevant, current protocol and will only deviate from the protocol when necessary to protect the safety, rights, or welfare of the subject.
2. Agree to personally conduct or supervise the described investigation.
3. Agree to inform any patients, or any persons used as controls, that the study product is being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.
4. Agree to report to the sponsor adverse experiences that occur in the course of the investigation in accordance with the protocol. I have read and understand potential risks and side effects of the study product.
5. Agree to ensure all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
6. Agree to maintain adequate and accurate records.
7. Ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects and others. I will not make any changes in the research protocol without consent from the sponsor and will not institute those changes in the research protocol until after approved by the sponsor and IRB, except where necessary to eliminate apparent immediate hazards to human subjects.
8. Agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 812.

_____ _____

Investigator's Signature Date

_____

Print Name

Abbreviations

AE	Adverse Event
C	Control
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
COVID-19	Coronavirus Disease 2019
CRF	Case Report Form
CRO	Contract Research Organization
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
ID	Identification
IRB	Institutional Review Board
LIVD	Laboratory In Vitro Diagnostics
LOINC	Logical Observation Identifiers Names and Codes
QRI	Quick Reference Instructions
SAE	Serious Adverse Event
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SNOMED	Systematized Nomenclature of Medicine
T	Test (detection zone)
US	United States

Study Synopsis

Title	MGC Health COVID-19 & Flu A+B Home Multi Test Usability Study
Protocol Number	MGC-1001
Protocol Date	16 January 2023
Protocol Version	1.0
Study Sponsor	Medical Group Care
Study Purpose	The purpose of this study is to evaluate the usability of the MGC Health COVID-19 & Flu A+B Home Multi Test in home use.
Investigational Material/Product	The MGC Health COVID-19 & Flu A+B Home Multi Test is a lateral flow immunochromatographic antibody assay intended for the simultaneous qualitative detection and differentiation of the nucleocapsid antigen from SARS-CoV-2, influenza A and/or influenza B directly from anterior nasal swab specimens obtained from individuals, who are suspected of respiratory viral infection within five (5) days of symptom onset. This test is intended for non-prescription home use with self-collected direct anterior nares swab samples from individuals ages 14 years and older or adult lay user collected anterior nares swab samples from individuals aged 2 to 13 years.
Study Objective	The objective of the study is to determine the usability of the MGC Health COVID-19 & Flu A+B Home Multi Test in a simulated home use environment.
Study Design	This is an open label study to evaluate the usability of the MGC Health COVID-19 & Flu A+B Home Multi Test using information from the Quick Reference Instructions (QRI).
Inclusion Criteria	Subjects are eligible for inclusion if the following criteria are met: 1. An Institutional Review Board (IRB) approved informed consent / assent, if applicable, is signed and dated prior to any study related activities. 2. Male and female subjects 2 years of age and older. 3. Subject is willing to provide a self-collected nasal swab sample. (If the subject is under the age of 14, an adult lay user will collect the sample.) 4. Subject agrees to complete all aspects of the study.
Exclusion Criteria	A subject is not eligible for inclusion if any of the following criteria apply: 1. Subject has a visual impairment that cannot be restored with glasses or contact lenses. 2. Subject has prior medical or laboratory training. 3. Subject uses home diagnostics, e.g., glucose meters, HIV tests. 4. Subject has prior knowledge of their current COVID-19 or flu infection status.

Target Population/ Sample Size	A minimum of 30 completed subjects with a minimum of 15 subjects testing themselves and a minimum of 15 subjects testing another person (child 2 to 13 years old).
Site Requirements	1 testing site in the United States
Study Duration	The overall study duration is expected to be less than one (1) month, with subject participation completed in one visit of approximately one hour.
Study Endpoints	Primary Endpoints 1. Assess the usability of the Quick Reference Instructions (QRI) based upon observer evaluation. 2. Assess the usability of the kit for home use based upon subject evaluation.

1 INTRODUCTION

1.1 Background

COVID-19 is a contagious respiratory illness, caused by infection with the novel coronavirus Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). This communicable disease is easily transmitted through aerosolized droplets containing the infectious virus. Infections with SARS-CoV-2 can have varying degrees of signs and symptoms, ranging from asymptomatic to severe. Individuals infected with SARS-CoV-2 are believed to be contagious from as early as two days prior to symptom onset to at least ten days after the onset of symptoms.

Influenza (Flu) is a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and lungs. This communicable disease is also transmitted through droplets containing the virus. Influenza (flu) can cause mild to severe illness, and at times can lead to death. There are two main types of influenza (flu) viruses: types A and B. The influenza A and B viruses that routinely spread in people (human influenza viruses) are responsible for seasonal flu epidemics each year. Individuals infected with Flu are believed to be the most contagious in the first three to four days after the onset of symptoms, however, they may still spread the virus and have no symptoms. Infants and individuals with weakened immune systems who are infected with flu viruses may be contagious for longer than seven days.

The rapid detection of infections and contacts and the implementation of infection control measures are critical for mitigation of these viruses.

The MGC Health COVID-19 & Flu A+B Home Multi Test is a lateral flow immunochromatographic antibody assay intended for the simultaneous qualitative detection and differentiation of the nucleocapsid antigen from SARS-CoV-2, influenza A and/or influenza B directly from anterior nasal swab specimens obtained from individuals, who are suspected of respiratory viral infection within five (5) days of symptom onset. This test is intended for non-prescription home use with self-collected direct anterior nares swab samples from individuals ages 14 years and older or adult lay user collected anterior nares swab samples from individuals aged 2 to 13 years.

1.2 Study Purpose

The purpose of this study is to evaluate the usability of MGC Health COVID-19 & Flu A+B Home Multi Test in Home Use.

1.3 Risk and Benefit Assessment

1.3.1 Potential Risks

The only study-related procedure that could impact subject safety is in the collection of nasal specimens from the anterior nares using a nasal swab. The risks of collecting a specimen using a

nasal swab may include symptoms associated with standard collection practices, such as slight pain and/or a small amount of bleeding in the nose.

All subject(s) will be de-identified using a study-specific number at the time of enrollment. All study forms, Case Report Forms (CRFs) and study samples will be labeled with the de-identified subject ID number. No identifiable patient information will be provided to Medical Group Care. No patient treatment or management decisions will be based on any results generated during this study.

Information collected for this study is confidential. However, officials of the FDA or other regulatory agencies may research records during the ordinary course of conducting their functions. A sponsor representative may also inspect research records to make certain the study data is accurate. The investigator, institution, regulatory agencies, and sponsor will protect the confidentiality of the records.

1.3.2 Potential Benefits

The information obtained in this study will not benefit the study subjects directly but may aid future patients by helping to rapidly and accurately detect infection caused by SARS-CoV-2, influenza A and/or influenza B.

1.4 Study Device Description

The MGC Health COVID-19 & Flu A+B Home Multi Test is a lateral flow immunochromatographic antibody assay intended for the simultaneous qualitative detection and differentiation of the nucleocapsid antigen from SARS-CoV-2, influenza A and/or influenza B directly from anterior nasal swab specimens obtained from individuals, who are suspected of respiratory viral infection within five (5) days of symptom onset. This test is intended for non-prescription home use with self-collected direct anterior nares swab samples from individuals ages 14 years and older or adult lay user collected anterior nares swab samples from individuals aged 2 to 13 years.

1.5 Device Output

The MGC Health COVID-19 & Flu A+B Home Multi Test detects influenza A and B viral antigens and COVID-19 antigen through visual interpretation of color development on the test cassette.

Nasal swab samples are loaded into the sample port of the test cassette. The extracted specimen reacts with anti- influenza A, B and COVID-19 antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with the reagents on the membrane. If there is sufficient influenza A and/or B viral antigens or COVID-19 antigens in the specimen, a pink colored band(s) will form in the test region(s) of the membrane, i.e., COVID-19, Flu A and/or Flu B, as illustrated in Figure 1.

If no color bands appear in any of the test regions, this is an indication of a negative result, as illustrated in

Negative Test

The appearance of a pink line in the control region (C) and the absence of a pink line in the test region(s) indicates a negative test result, as shown in Figure 2.

Figure 2.

The appearance of a colored band at the control region (C) serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the Control line (C) does not appear, as illustrated in Figure 3, the result is invalid, and the test should be repeated.

Positive Test

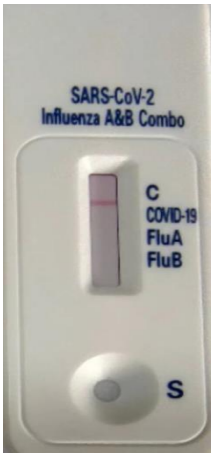
The appearance of a pink line in the control region (C) and a pink line in the test region(s) COVID-19, Flu A, and/or Flu B indicates a positive result for the particular viral antigen. Figure 1 depicts positive test results.

Figure 1: Positive Results

Negative Test

The appearance of a pink line in the control region (C) and the absence of a pink line in the test region(s) indicates a negative test result, as shown in Figure 2.

Figure 2: Negative Result



Invalid Test

The absence of both a pink control line (C) and a pink line in the test regions or the absence of a pink control line (C) with the appearance of a pink line in the test region(s) indicates the test was invalid and must be repeated. This is illustrated in Figure 3.

Figure 3: Invalid Test Result

1.5.1 Intended Use

The MGC Health COVID-19 & Flu A+B Home Multi Test is a lateral flow immunochromatographic antibody assay intended for the simultaneous qualitative detection and differentiation of the nucleocapsid antigen from SARS-CoV-2, influenza A and/or influenza B directly from anterior nasal swab specimens obtained from individuals, who are suspected of respiratory viral infection within five (5) days of symptom onset. This test is intended for non-prescription home use with self-collected direct anterior nares swab samples from individuals ages 14 years and older or adult lay user collected anterior nares swab samples from individuals aged 2 to 13 years.

Results are for the simultaneous identification of SARS-CoV-2, influenza A, and influenza B. The MGC Health COVID-19 & Flu A+B Home Multi Test is not intended to detect influenza C antigens. These viral antigens are generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the MGC Health COVID-19 & Flu A+B Home Multi Test should self- isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative SARS-CoV-2 results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Negative influenza A and B test results should be treated as presumptive. It is recommended these results be confirmed by viral culture or an FDA cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19 or influenza, such as in individuals without known exposures to COVID-19 or influenza or residing in communities with low prevalence of these infections. Individuals who test negative and continue to experience symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 or influenza and should seek follow-up care from their healthcare provider. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC.

1.6 For Investigational Use Only

The MGC Health COVID-19 & Flu A+B Home Multi Test is a lateral flow immunochromatographic antibody assay intended for the simultaneous qualitative detection and differentiation of the nucleocapsid antigen from SARS-CoV-2, influenza A and/or influenza B directly from anterior nasal swab specimens obtained from individuals, who are suspected of respiratory viral infection within five (5) days of symptom onset. This test is intended for non-prescription home use with self-collected direct anterior nares swab samples from individuals ages 14 years and older or adult lay user collected anterior nares swab samples from individuals aged 2 to 13 years. The performance characteristics of the test using nasal swabs have not been established. The results obtained from this study will not be used for diagnostic purposes or patient management.

Results are intended for the simultaneous identification of SARS-CoV-2, influenza A, and/or influenza B, which are generally detectable in nasal samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

1.7 Study Sites

Study enrollment for this study will be conducted at one (1) testing site in the US. The site will attempt to enroll a diverse demographic patient population with varying educational backgrounds.

The applicable Institutional Review Board (IRB) will review and approve the study protocol, informed consent and assent, Quick Reference Instructions (QRI), and subject questionnaire and test illustrations prior to enrolling subjects into this study.

1.8 Study Objectives

The objective of this protocol is to determine the usability of the MGC Health COVID-19 & Flu A+B Home Multi Test in a simulated home use environment.

1.9 Study Design

This is an open label observational study to evaluate the usability of the MGC Health COVID-19 & Flu A+B Home Multi Test.

Each subject will be provided a MGC Health COVID-19 & Flu A+B Home Multi Test and asked to conduct the test on themselves or another subject using the Quick Reference Instructions (QRI) for the MGC Health COVID-19 & Flu A+B Home Multi Test while being monitored by an observer.

A member of the clinical study staff will observe the subject while they are conducting the test. The observer will note the completion and/or correct performance of critical steps which, if not performed correctly, could lead to an inaccurate test result.

The observer will note whether or not they agree with the subject's interpretation of the test results. A photograph of the test cartridge will be taken showing the results.

Subjects will be asked to provide their perspective on the use of the test at the end of the testing process.

In addition, a set of illustrations of test results will be provided to each subject for interpretation. Results of the testing will be used to determine whether further refinement of the QRI may be needed. The results of the testing will not be used for patient management or treatment decisions.

2 STUDY ENROLLMENT AND WITHDRAWAL

2.1 Study Population

Enrollment must include 15 subjects ages 14 and older, and 15 subjects ages 2-13 who present to the office location for COVID-19 and/or flu testing. The intent is to enroll subjects with varying educational levels and socioeconomic backgrounds.

2.2 Enrollment Criteria

Subjects are eligible for enrollment only if all of the inclusion criteria are met and none of the exclusion criteria apply.

2.2.1 Inclusion Criteria

1. An Institutional Review Board (IRB) approved informed consent / assent, if applicable, is signed and dated prior to any study-related activities.
2. Males and females ages 2 and older.
3. Subject is willing to provide a self-collected nasal swab sample. (If the subject is under the age of 14, an adult lay-user will collect the sample.)
4. Subject agrees to complete all aspects of the study.

2.2.2 Exclusion Criteria

1. Subject has a visual impairment that cannot be restored with glasses or contact lenses.
2. Subject has prior medical or laboratory training.
3. Subject uses home diagnostics, e.g., glucose meters, HIV tests.
4. Subject has prior knowledge of their current COVID-19 or flu infection status.

2.3 Study Duration

The overall study duration is expected to be less than one (1) month, with subject participation completed in one visit of approximately one hour.

2.4 Subject Withdrawal

Subjects may discontinue their participation in the study at any time. A subject may be withdrawn from the study at any time at the discretion of the investigator.

A subject may be considered withdrawn for the purpose of this study if:

- The subject or parent / legal guardian of the subject withdraws consent for study participation
- The subject is non-compliant with study procedures
- The investigator determines to withdraw the subject if study participation is no longer in the subject's best interest.

3 STUDY PROCEDURES

3.1 Set Up

Testing will take place in a room to simulate the home environment. A table with chairs will be available. The observer will stand or sit to the side of the subject providing enough space to: 1) ensure there is no interference with the subject's activities and 2) allow adequate view of the subject's interaction with the test kit. Other than providing the test kit and QRI, the observer will not provide any other directions on how to use the kit.

Each box of the MGC Health COVID-19 & Flu A+B Home Multi Test contains one (1) each of the following: sterile nasal swab, test cassette, and the sample collection tube with nozzle lid. Upon completion of the testing, the used test components will be disposed of properly per local regulations.

At the conclusion of testing and the subject's completion of the questionnaire, the observer will present ten (10) images of different test results and ask the subject to interpret each test result.

3.2 Informed Consent

Study staff trained in basic human research subjects protection will explain the study protocol, procedures, and objectives to the subject and obtain written informed consent and assent, if applicable, for participation in the study from each subject prior to performing any study procedures. The study staff will review all information in the consent / assent, if applicable, allowing subjects ample time to review the form(s), ask questions and have their questions answered to the satisfaction of the subject. Subjects willing to participate will sign the consent / assent, if applicable, and will be provided a copy for their records.

3.2.1 Vulnerable Populations

The study will be conducted in accordance with the relevant articles of the Declaration of Helsinki. The Declaration of Helsinki defines vulnerable individuals as having "An increased likelihood of being wronged or of incurring additional harm." (World Medical Association 2013) For the purpose of this study, we define vulnerable individuals as those whose capacity to protect or exercise their rights is restricted due to their mental, social, economic, or ethnical status, age, or health condition. Subjects deemed vulnerable by the IRB and/or the principal investigator will not be eligible for this study.

This study involves children who have not attained the legal age for consent to treatment or procedures involved in research and are a vulnerable population. Children are a group already burdened by COVID-19 and flu and while there is no benefit to study participants, the anterior nares swabs for this study does not pose greater than a minimum risk to children.

3.3 Subject Enrollment

Once informed consent is obtained, the subject will be assigned a subject ID number. The subject ID number will consist of the study site number followed by a 3-digit sequentially assigned subject number. For example, the first subject enrolled at site 01 will be assigned 01-001, with subsequent enrolled subjects assigned 01-002, 01-003, etc. The site will maintain an enrollment log that correlates the subject ID number to the subject's name.

The unique subject ID number will be written on each page of the Case Report Form (CRF) and all other documentation related to the subject. All data will be captured on the paper CRF.

3.4 Baseline Data

The site will provide a narrative describing how the testing simulated a home environment. For example, whether a table and chair were provided, how subjects could sanitize their hands, positioning of the subject such that they could not observe others conducting the test, and position of the observer.

Upon confirmation of eligibility to participate in the study, the following information will be obtained:

- Age (For subjects under 14 years of age, the age of the person collecting and testing the sample will also be recorded.)
- Sex
- Race
- Ethnicity
- Educational Level (For subjects under 14 years of age, the educational level of the person performing the test will be recorded.)

- Occupation (For subjects under 14 years of age, the occupation of the person performing the test will be recorded.)
- Exposure to someone with COVID-19, and the number of days prior to the visit the exposure occurred.
- Presence or absence of respiratory symptoms: fever or chills; cough; shortness of breath; difficulty breathing; muscle or body aches, new loss of taste or smell. Subjects will be asked the date each symptom appeared.
- COVID-19 vaccine status and number of doses, manufacturer, and date of last vaccine.
- Flu vaccine status and date of vaccine, if applicable.

3.5 Test Procedure

The observer will provide the subject the MGC Health COVID-19 & Flu A+B Home Multi Test and the QRI. The lot number and expiration date of the kit will be recorded. The observer will ask the subject to conduct the test. The subject will be expected to collect the sample, conduct the test, read and interpret the test result.

The observer will complete an observation form that will assess how well the subject followed the QRI to perform the critical steps for the test and interpret the test result.

The critical steps that each subject should perform accurately are as follows:

- Swab each nostril, rotating swab against nostril at least 5 times.
- Rotate the nasal swab in the sample collection tube liquid at least 5 times.
- Lift the swab out of the liquid in the collection tube and squeeze the tube against the swab tip 3 times.
- Squeeze the sample collection tube while removing the nasal swab.
- Press the nozzle lid firmly onto the sample collection tube.
- Transfer 3 drops from the sample collection tube into the sample well of test cassette.
- Do not move or lift the test cassette.
- Read the results between 15 and 20 minutes.

The subjects will interpret the test result and the observer will assess whether they agree or do not agree with the reading of the result. If they do not agree, they will provide the reason.

The observer will label each cartridge with the subject ID, protocol number, and date and will take a photograph of each test cartridge immediately after the subject has interpreted the result. Each photograph will be saved as an image titled with the subject's ID number.

After completion of the test process, the subject will complete a questionnaire on the clarity of the instructions provided, ease of performing the test, and ease of reading and interpreting their results.

The subjects will then be presented with 10 sample images of test results (1 negative, 7 positive, and 2 invalid) to confirm their ability to use the QRI to read and interpret all possible test results. The provided images will be as follows:

Image 1 - invalid test (no lines);

Image 2 – positive Flu A

Image 3 – positive COVID-19, Flu A, and Flu B

Image 4 – invalid test (Flu A line, no C line)

Image 5 – positive Flu B

Image 6 – positive Flu A, and Flu B

Image 7 - negative

Image 8 – positive COVID-19 and Flu A

Image 9 – positive COVID-19 and Flu B

Image 10 – positive COVID-19

The observer will record the subject's interpretation of the sample test results in the CRF.

Participation in the study should be completed in under one hour.

4 PREMATURE STUDY TERMINATION OR SUSPENSION

4.1 Termination or Suspension

This study may be suspended or prematurely terminated by the sponsor or the investigator immediately upon notice for any cause. Written notification via email or post, documenting the reason for study suspension or termination, will be provided by the suspending, or terminating party. If the study is prematurely terminated or suspended, the principal investigator will promptly inform the IRB and will provide the reason(s) for suspension or termination.

4.2 Circumstances Warranting Termination or Suspension

Circumstances that may warrant termination include, but are not limited to:

1. Insufficient adherence to protocol requirements.
2. Data that are not sufficiently complete and/or evaluable.

3. Determination of futility

5 SAFETY CONSIDERATIONS

5.1 Safety Warnings and Precautions

All samples should be handled as potentially infectious. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.

5.2 Definition of Adverse Events

An Adverse Event (AE) is any untoward medical event that occurs to the subject during the course of a study (with onset after the first study-specific procedure), whether or not that event is considered study-related.

An adverse event may be mild, moderate, or severe and is usually unexpected.

All adverse events observed by the principal investigator or reported by the subject must be reported to the sponsor within 24 hours. To report an adverse event, the principal investigator will complete an adverse event form or relevant form located in the CRF.

Adverse events will be considered study-related if the event follows a reasonable temporal sequence from a study related procedure and could readily have been produced by that study procedure. For the purpose of this study, only the collection of nasal nares swab is considered to be the study procedure.

5.3 Reporting of Serious Adverse Events

A Serious Adverse Event (SAE) is any adverse event that:

- led to death
- led to a serious deterioration in the health of the subject that either resulted in a life-threatening illness or injury, or a permanent impairment of a body structure or a body function, or in-patient hospitalization or prolongation of existing hospitalization, or in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- led to fetal distress, fetal death, or a congenital abnormality or birth defect

Hospitalization is defined as greater than 24 hours in hospital.

All serious adverse events must be reported to the sponsor by telephone within 24 hours of the principal investigator becoming aware of it.

The sponsor will be contacted using the following information:

Contact Name: Tomaz Lovse

Telephone Number: 239-631-1907

The principal investigator should institute appropriate therapeutic and follow-up measures in accordance with good medical practice but should notify the monitor of such actions and record them in the subject's CRF. Each telephone reported reaction must be reported in writing to the sponsor within 10 working days of the event.

It is also the responsibility of the principal investigator to inform the representative of the appropriate local IRB in a timely manner.

5.4 Possible Risks Associated with Study Procedures

The only study-related procedure that could impact subject safety is in the collection of a direct anterior nares (nasal) swab. The risks of collecting a nasal nares swab may include symptoms associated with standard collection practices such as slight pain and/or minor bleeding.

Information collected for this study is confidential. Subjects will be identified using a study specific number at the time of enrollment. All study forms will be labeled with the study number. No identifiable patient information will be provided to the sponsor. However, officials of the FDA or other regulatory agencies may research records during the ordinary course of conducting their functions. A sponsor representative may also inspect research records to make certain the study data is accurate. The investigator, institution, regulatory agencies, and the sponsor will protect the confidentiality of the records.

No medical decisions will be based on investigational assay results generated as part of the study.

6 REGULATORY AND ADMINISTRATIVE REQUIREMENTS

6.1 Good Clinical Practice

The investigator will ensure that this study is conducted in full compliance with the principles of the "Declaration of Helsinki" (as amended in Edinburgh, Tokyo, Venice, Hong Kong, and South Africa), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines, or with the laws and regulations of the country in which the research is conducted, whichever affords the greater protection to the study subject. For studies conducted under a United States investigational new drug application, the investigator will ensure that the basic principles of "Good Clinical Practice (GCP)," as outlined in 21 CFR 312, subpart D, "Responsibilities of Sponsors and Investigators," 21 CFR, part 50, 1998, and 21 CFR, part 56, 1998, are adhered to. This study is also subject to and will be conducted in compliance

with 21 CFR, part 320, 1993, "Retention of Bioavailability and Bioequivalence Testing Samples."

6.2 Responsibility of Investigator

The principal investigator is responsible for the proper conduct of the study at their site(s). The investigator will ensure that the study is conducted in compliance with the protocol, the Clinical Study Agreement, and applicable regulations in 45 CFR 46, and any other applicable regulatory requirements. These requirements include:

- Obtaining IRB approval for the study and related documents before study initiation enrolling subjects.
- Obtaining informed consent from each subject in accordance with 21 CFR Part 50, as applicable.
- Protecting the rights, safety, and welfare of subjects under their care.
- Reporting adverse events.
- Coordinating and providing reasonable medical care to subjects for an adverse event related to study participation.
- Reporting protocol deviations to the sponsor and IRB per IRB requirements.
- Maintaining traceability and secured storage of all test kits and study samples.
- Ensuring confidentiality of all study documents, procedures, and study samples.

6.3 Sponsor Responsibility

The sponsor has the overall responsibility for the conduct of the study, including assurance that the study meets regulatory requirements as applicable.

The sponsor's study-related duties and functions may be transferred to a contract research organization (CRO).

6.4 Protocol Deviations

A protocol deviation is a failure to comply with the requirements specified within the clinical study protocol or IRB requirements. Investigators are not allowed to deviate from the protocol except when a deviation is necessary to protect a subject's rights and well-being, or the scientific integrity of the study.

6.5 Changes to Protocol

In the event the study protocol is amended, the monitor will provide the principal investigator with the protocol amendment(s) and a revised protocol.

Protocol amendments that affect the subjects' rights or safety must be submitted to and approved by the IRB.

6.6 Reconciliation of Study Material, Supplies and Samples

The sponsor will supply sufficient quantities of study materials and supplies to enable the site to complete the study. The site will return all unused materials and supplies to the sponsor or will dispose of unused materials and supplies, according to provided instructions. The site is required to maintain the inventory of the materials provided and will document the reconciliation of these materials. If materials are disposed of at the study site, the investigator must provide the sponsor with a signed record of disposition.

7 STATISTICAL CONSIDERATIONS

Except where otherwise specified, the following general principles apply to the planned statistical analyses. All statistical analysis will be conducted using a current version 9.4 (or later) of SAS (SAS Institute Inc., Cary, NC), Excel version 2010 or later, or other widely accepted statistical or graphical software as required. Categorical variables (e.g., sex) will be summarized with frequency counts and percentages.

7.1 Usability Study and Risk Mitigation for User Errors

The results will be analyzed to confirm the proper use of the QRI and usability of the MGC Health COVID-19 & Flu A+B Home Multi Test. The usability of the MGC Health COVID-19 & Flu A+B Home Multi Test will be considered valid if:

- The mean score of the subjects' response scores in the questionnaire are ≤ 3 for those questions with a score response between 1 and 5.
- 80% of the critical steps were performed correctly based upon the observer's assessment.
- 80% of the interpretation of the sample image results were correct.

The subject questionnaires and observer notes will be used to modify the QRI, if necessary, and additional usability testing will be conducted if needed.

8 ETHICAL CONSIDERATIONS

The investigator and site study staff will be responsible for the ethical conduct of this study in accordance with 45 CFR 46, 21 CFR 50, 21 CFR 56 governing IRB review and informed consent.

8.1 Institutional Review Board

The participating site must provide for review and approval of this protocol and associated informed consent by an appropriate IRB. Any amendments to the protocol or consent materials must also be reviewed and approved by the IRB prior to use.

Prior to study initiation, the Institutional Review Board (IRB) responsible for the studies to be conducted at the site must provide written approval of the protocol and informed consent. The investigator will provide IRB documentation for all applicable IRB submissions to the sponsor. If IRB approval is withdrawn, the investigator will immediately report this to the sponsor.

8.2 Informed Consent Process

Informed consent is a process that is initiated prior to the potential subject's agreement to participate in the study and continues throughout the study participation. The principal investigator must explain to each potential subject the nature of the clinical study, including any risks and benefits, its purpose, and procedures, and expected duration of involvement in the clinical study. Each potential subject must be informed that participation in the clinical study is voluntary and non-participation will not affect his / her right to the most appropriate treatments or affect the doctor/clinician-patient relationship. Each potential subject must be given sufficient time to decide whether they wish to participate and have all their queries addressed prior to signing the IRB-approved consent form(s). A copy of the signed consent form(s) must be provided to the potential subject. Study specific procedures will not be initiated until the potential subject has signed and dated the appropriate consent form(s). Subjects have full rights to withdraw from the clinical study at any time, irrespective of their initial consent.

Each potential subject must also give their permission for representatives of the sponsor, auditor, and regulatory authorities to review their hospital records for the purposes of source data verification.

Written informed consent from the potential subject must be obtained before any clinical investigation related procedures are performed.

8.3 Subject Confidentiality

Confidentiality of subject data will be maintained at all times. Subject anonymity will be guaranteed and all documentation relating to a subject will be kept in a secure location.

Study documents provided to the sponsor will be stored in a secure location with access. None of the stored documents will contain any personal identifying information or direct identifiers.

Study files will be made available to the IRB, regulatory authorities, sponsor (or designee) and/or clinical study staff should they request access for auditing purposes.

9 DATA MANAGEMENT

The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All data collection should be completed in a neat, legible manner to ensure the accurate interpretation of data.

9.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the investigator. Data must be recorded using black ink and any changes or corrections made must be done by drawing a single line through the original entry. The corrected entry must be initialed and dated by the individual making the corrections. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL. The investigator or designee must review unanticipated problems.

9.2 Study Records Retention

The principal investigator will retain all copies of the records as directed by the sponsor for a period of at least 2 years after the latter of the following two dates: the date on which the study is terminated or completed, or the date the declaration of emergency is rescinded. In all cases, the principal investigator must obtain written consent from the sponsor prior to disposing of any records related to the clinical study.

10 LITERATURE REFERENCES

1. Template for Developers of Molecular and Antigen Diagnostic COVID-19 Test for Home Use. Version October 6, 2021

2. Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing. Version October 6, 2021

3. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013 Nov 27;310(20):2191-4. doi: 10.1001/jama.2013.281053. PMID: 24141714.

4. Atchison C, Pristera P, Cooper E et al. Usability and Acceptability of Home-based Self-testing for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antibodies for Population Surveillance. CID 2021:72 (1 May)

11 SUBJECT QUESTIONNAIRE

The following questionnaire will be presented to subjects after completion of the MGC Health COVID-19 & Flu A+B Home Multi Test.

Subject Questions

1. Overall, how easy or difficult was it to understand the instructions to conduct the test?
    1. Very easy to understand
    2. Fairly easy to understand
    3. Easy
    4. Fairly difficult to understand
    5. Very difficult to understand

2. How easy or difficult was it to open the test cassette package?
    1. Very easy
    2. Fairly easy
    3. Easy
    4. Fairly difficult
    5. Very difficult

3. How easy or difficult was it to remove the sealed film covering from the sample collection tube?
    1. Very easy
    2. Fairly easy
    3. Easy
    4. Fairly difficult
    5. Very difficult

4. How easy or difficult was it to understand the instructions on how to collect the sample from your nose or from another person?

    1. Very easy to understand
    2. Fairly easy to understand
    3. Easy
    4. Fairly difficult to understand
    5. Very difficult to understand

5. How easy or difficult was it to understand the instructions to swirl the swab in the collection tube?

    1. Very easy to understand
    2. Fairly easy to understand
    3. Easy
    4. Fairly difficult to understand
    5. Very difficult to understand

6. How easy or difficult was it to understand the instructions on how to lift the swab out of the liquid and squeeze the collection tube?

    1. Very easy
    2. Fairly easy
    3. Easy
    4. Fairly difficult
    5. Very difficult

7. How easy or difficult was it to insert the nozzle lid onto the sample collection tube?

    1. Very easy
    2. Fairly easy
    3. Easy
    4. Fairly difficult
    5. Very difficult

8. How easy or difficult was it to understand the instructions to add the sample from the collection tube to the sample well of the test cassette?

    1. Very easy to understand
    2. Fairly easy to understand
    3. Easy
    4. Fairly difficult to understand
    5. Very difficult to understand

9. How easy or difficult was it to add the 3 drops into the test cassette?

    1. Very easy
    2. Fairly easy
    3. Easy
    4. Fairly difficult
    5. Very difficult

10. How easy or difficult was it to read the test results?

1. Very easy
2. Fairly easy
3. Easy
4. Fairly difficult
5. Very difficult

11. How easy or difficult was it to understand the instructions on how to interpret the results of the test**?**

1. Very easy to understand
2. Fairly easy to understand
3. Easy
4. Fairly difficult to understand
5. Very difficult to understand

Additional Comments: