PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

TITLE:	Clinical Validation of the Aptitude Medical Systems Metrix COVID/Flu Test for Detection of SARS-CoV-2 and Influenza A/B in Point-of-Care and Non-Laboratory Settings
PROTOCOL NO.:	TP-23-003 WCG IRB Protocol #20233649 NCT# NCT06191393
SPONSOR:	Aptitude Medical Systems Inc.
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]
PARTICIPANT ID:	_____

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

1. INTRODUCTION

Dear Participant

You are being invited to take part in a research study. A person who takes part in a research study is called a research participant.

In this consent form "you" generally refers to the research participant. If you are being asked as the parent or guardian to permit the participant to take part in the research, "you" in the rest of this form generally means the research participant.

You are encouraged to ask as many questions as needed in order to ensure that you understand the study procedures, including possible risks and benefits. If you have any questions that are not properly explained or answered in this information leaflet, please feel free to ask a study staff member to give you more information. You are welcome to take this document home with you and to discuss your possible participation in the study with your family and friends.

The study has been reviewed by both the Pharma-Ethics Research Ethics Committee and SAHPRA for compliance with medical and ethical standards. In addition, the study will be conducted according to the 2013 Declaration of Helsinki, *Guidelines for good practice in the conduct of clinical trials with a human participant in South Africa* (third edition, 2020) and *Ethics in Health Research: Principles, Processes and Structures* which deals with your rights as a research participant, and which guide the study doctor (investigator) in health research involving human participants.

The study staff has received funding from the European Union (EDCTP) for this research.

2. What should you know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

If we find out that you did not provide the correct information or did not follow the guidelines in this document and the study protocol, you may be withdrawn from the study at any time.

3. Why is this research being done?

The purpose of this research is to demonstrate the sensitivity and specificity of the experimental Metrix COVID/Flu Test Saliva Test and Metrix COVID/Flu Test Swab Test for SARS-CoV-2, Influenza A, and Influenza B detection when performed by non-laboratory personnel and lay-users in the Point of Care and "At-Home" settings. This study will be performed with saliva samples and nasal swab samples. You have the option to participate with both sample types or one of your choice. These samples can be taken if you are currently experiencing symptoms of respiratory infection (such as those of COVID-19 and/or Flu). These results will be compared to nasopharyngeal swab samples run on RT-PCR molecular assays in a laboratory by trained personnel.

4. How long will I be in this research?

We expect that your taking part in this research will last 1.5-2 hours or until you get results from the Metrix COVID/Flu Test for SARS-CoV-2, Influenza A, and Influenza B. You will need to wait at least 15 minutes between each test.

5. What happens to me if I agree to take part in this research?

You will be screened with inclusion and exclusion criteria by the coordinator.

Inclusion Criteria:

1. Written informed consent obtained prior to study enrollment.
2. Male or female aged 2 years or older
3. Participant is currently exhibiting fever, or one or more symptoms associated with COVID-19 and/or influenza (such as, but not limited to, chills, cough, shortness of breath or difficulty breathing, fatigue, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting or diarrhea). Participant must still be exhibiting symptoms on the day of sample collection.
4. Participant has not eaten, drunk a beverage, smoked, brushed their teeth, gargled with mouth wash, or chewed gum for 30 minutes prior to collecting a saliva sample.
5. Participant or guardian will read each of the saliva and/or nasal (AN) swab instructions (QRI) prior to beginning the operation of each of the Metrix COVID/Flu Test.
6. The participant, or legal guardian, is able and willing to contribute the required saliva and/or swab samples for testing and understands and is able and willing to sign the study informed consent.

Exclusion Criteria:

1. The participant does not understand or is not able and willing to sign the study informed consent and/or assent.
2. Participant or guardian is not able to comply with saliva or nasal swab collection requirements following the QRI.
3. Participant has previously provided a sample for this study or previous Aptitude study using the Metrix device.
4. Participant has had seasonal influenza and/or the SARS-CoV-2 vaccine within the past 5 days.
5. The participant is not able to tolerate sample collection.
6. Participant is currently undergoing antiviral treatment such as baloxavir marboxil (trade name Xofluza®), oseltamivir (Tamiflu®), zanamivir (Relenza®), and peramivir (Rapivab®).
7. Participants currently undergoing treatment and/or within the past thirty (30) days with prescription medication to treat novel Coronavirus SARS-CoV-2 infection, which may include but is not limited to Remdesivir (Veklury), Paxlovid, molnupiravir or receiving convalescent plasma therapy for SARS-CoV-2.

8. Participants who have had a nasal wash or aspirate as part of their standard of care treatment on day of study visit prior to the study sample collection.
9. Participants who have had recent craniofacial injury or surgery, including to correct deviation of the nasal septum, within the previous six (6) months.

You will provide demographics information including:

- Age, gender, race, education level, and ethnicity

Following this, you will be provided with a Metrix COVID/Flu Test and Metrix reader. Using only the Quick Reference Instruction including a video, and interactive set of directions, you will self-collect one saliva or nasal swab sample and follow the steps to conduct the testing. You will be asked to perform two tests: one for saliva and one for nasal swab samples. You may however, elect to provide only one sample, for nasal swab. You will be supervised, but you will not be provided with any other guidance or be able to ask questions about how to use the test. You will wait for results, which will take about 30 minutes.

Please indicate below by **initialing** the applicable line for the sample option/s you agree to:

_____ Nasal Swab

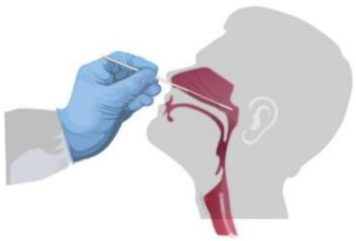
_____ Saliva

_____ Nasal Swab and Saliva

You will also supply an additional nasal swab and / or saliva sample with the assistance of a healthcare professional to be used as a comparator depending on the sample option/s you agreed to above.

A licensed healthcare professional will take a nasopharyngeal sample in the back of the nose and the nasopharynx. This is a common sample collection and should cause only minor discomfort. See below for collection procedure. The additional saliva sample will be obtained for a saliva-specimen comparator.

Nasopharyngeal Swab Collection



6. What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Read the Quick Reference Instruction thoroughly and completely and follow its instructions exactly.
- Watch the demonstration video.
- Provide a self-administered saliva sample and/or nasal swab.
- Provide an observed saliva sample and/or nasal swab.
- Summit a healthcare provided nasopharyngeal and saliva sample.

7. What will happen to your saliva sample?

The saliva samples you collect for the home use portion and/or the point-of-care portion of the study will be tested on site. The extra saliva sample that you provide at the end of the study will be tested by an off-site laboratory and the results will be compared to those obtained on-site. Your sample will not be stored or used for any other purpose other than those listed in this study.

8. Could being in this research hurt me?

****ALL SITES:** The following risk information from [START] through [END] cannot be altered without submission of supporting documentation and/or Sponsor approval of changes. Submitted changes without appropriate documentation will be reverted during Board review.

[START]

The risk is minimized by having a healthcare professional collect the nasopharyngeal sample, but collection could cause you:

- To feel discomfort, but you shouldn't feel any pain.
- You may have a minor nosebleed afterwards.
- If done improperly the collection could cause infection and sepsis.

The anterior nares, nasal swab could cause you:

- Pain
- If inserted too far it could cause damage and infection in your nasal pathway.

There is the slight possibility that there are Privacy risks (for example, disclosure of private information. There is the slight possibility of Economic risks (for example, having to pay money out-of-pocket for medical expenses.

There may be risks which are unknown at this time.
[END]

9. Will it cost me money to take part in this research?

Taking part in this research may lead to added costs to you, such as: if a sample collection causes you injury you and your insurance will be billed for the cost of treatment.

In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be billed to pay. There is insurance for the study should your insurance not cover the costs of injury due to complication from sample collection.

10. Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include the investigator(s) may learn more about a superior way to detect SARS-CoV-2 and Flu. It is not expected that you will personally benefit from this research.

Possible benefits to others include a fast and accurate way to test for SARS-CoV-2 and Flu in the home or point of care setting.

11. What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include:

- Going to an approved testing site
- Seeing your doctor

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

12. What happens to the information collected for this research?

Your private information and your results will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration (FDA) and Regulatory authorities.
- Ethics committees, including WCG IRB

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Under data protection law “Protection of Personal Information Act 2013”, your study site and the sponsor will be jointly responsible as ‘controllers’ of the data to ensure that your information is safeguarded.

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.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

By signing this consent form you are giving permission for the following experts or their representatives to have access to and inspect sections of your medical and research records related to this study: representatives of Aptitude Medical Systems Inc and its related funding programs, local Department of Health, South African Health Products Regulatory Authority (SAHPRA), the National Health Research Ethics Council (NHREC) and Pharma-Ethics Research Ethics Committee, the clinical investigator (study doctor) and other employees of TASK involved with the research study, as well as applicable Institutional Review Boards. These persons will treat the information as confidential, but on rare occasions disclosure to third parties may be required by law. Therefore, absolute protection of confidentiality cannot be promised.

13. Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

14. What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

15. Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointment

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

16. What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can:

- Stop all testing and use of your data
- Remove your data and information from data set

If you decide to leave the research early, there are no risks with this decision. You may leave the study at any time.

17. Will I be paid for taking part in this research?

For taking part in this research, you may be paid $50 in the form of an Amazon gift card. This will be upon completion of testing the device and all sample collection.

Scientific investigation involving your specimens may contribute to the commercialization of a product and eventual commercial profit. You will not be entitled to a share of such commercial profit.

- All children are required to assent, unless the investigator determines that the capability of the participant is so limited that the participant cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

18. Statement of Consent

- I have read or had read to me the information sheet and consent form, for this study.
- I understand that this is a research study and what is means.
- The purpose and procedures of this trial have been explained to me and I understand them.
- I understand my responsibilities as a trial participant.
- I understand that participation in the trial is voluntary and that I can refuse to participate or withdraw at any time, without it affecting my ongoing care.

- I have been informed of the possible risks, harm and inconvenience of participating.
- I have been informed of the expected benefits of the trial.
- I have been informed of any payment or reimbursement I may receive, as well as any anticipated expenses that I may incur while participating in the trial.
- I have had sufficient time to ask questions and they were answered to my satisfaction.
- I have been given time to discuss the trial with others and to decide whether or not to take part.
- I am aware that the results of the trial, including personal details about me and my health information may be reasonably disclosed to the sponsor, regulatory authorities, and research ethics committees, if required by law.
- I will be offered a signed and dated copy of this informed consent form.
- I agree to participate in this trial.

By signing/initialing below, I confirm that I have read each one of the above statements and agree with each one.

Initial	Date

Your signature documents your consent to take part in this research.

Printed Full Name and Surname of Participant	Date
Signature of participant	Date
Printed Full Name and surname of person obtaining consent (If other than Investigator)	
Signature of person obtaining consent (If other than Investigator)	Date

Printed Name of Investigator

Signature of Investigator | Date

By signing the below, I hereby verify that verbal informed consent was obtained by the above participant. The participant has been informed about the risks and the benefits of the research, understands such risks and benefits and is able to give consent to participation, without coercion, undue influence or inappropriate incentives.

*Printed Full Name and Surname of Witness

*Signature of Witness
*Where applicable and if thumbprint affixed to consent | Date

For child subjects:

Printed Name of child subject's parent, or individual authorized to consent to the child subject's general medical care

Signature of adult subject capable of consent, child subject's parent, or individual authorized to consent to the child subject's general medical care | Date

❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining assent
(Investigator/Coordinator) | Date

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

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 doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject **Date**