**PARTICIPANT INFORMATION AND INFORMED CONSENT FORM**

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| **TITLE:** | Clinical Validation of the Aptitude Medical Systems Metrix COVID-19 Test for Detection of SARS-CoV-2 in Point-of-Care and At-Home (OTC)/Non-Laboratory Settings |
| **PROTOCOL NO.:** | TP-24-028 |
| **SPONSOR:** | Aptitude Medical Systems Inc.<br>WCG IRB Protocol #20240342 |
| **INVESTIGATOR:** | Name<br>Address<br>City, State, Zip<br>Country |
| **STUDY-RELATED PHONE NUMBER(S):** | Site Contact Name<br>Phone Number<br>Phone Number (24 hours)<br>[24-hour number 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.

## Introduction

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

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

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provide the correct information or did not follow the guidelines in this document and the study protocol, you may be withdrawn from the study at any time.

## Why is this research being done?

The purpose of this research is to demonstrate the sensitivity and specificity of the experimental Metrix COVID-19 Test for SARS-CoV-2 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 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.

## How long will I be in this research?

We expect that your taking part in this research will last approximately 40 minutes or until you get results from the Metrix COVID-19 Test for SARS-CoV-2.

## 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. Participant or guardian understands and is able and willing to provide written informed consent, and assent where applicable, prior to study enrollment.
2. Male or female aged 2 years or older
   Participant has not eaten, consumed a beverage, smoked, brushed their teeth, gargled with mouth wash, or chewed gum for 30 minutes prior to collecting a saliva sample.

3. Participant or guardian agrees to read, and is able to read with understanding, the AN (Anterior Nares) swab QRI (Quick Reference Instructions) prior to beginning the operation of each of the Metrix COVID-19 Test.
4. Participant or guardian is able and willing to contribute the required swab samples for testing and understands and is able and willing to sign the study informed consent.

**Exclusion Criteria:**

1. Participant does not understand and/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 nasal swab collection requirements following the QRI.
3. Participant has previously provided a sample for the study.
4. Participant is not able to tolerate sample collection.
5. Participant is currently undergoing antiviral treatment such as baloxavir marboxil (trade name Xofluza®), oseltamivir (Tamiflu®), zanamivir (Relenza®), and peramivir (Rapivab®).
6. 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.
7. 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.
8. Participants who have had recent craniofacial injury or surgery, including to correct deviation of the nasal septum, within the previous six (6) months.
9. Participants who do not understand/read the English language.

You will provide demographics information including:

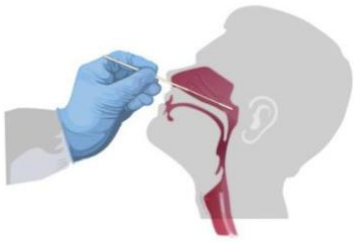
- Age, gender, race, education level, and ethnicity

Following this, you will be provided with a Metrix COVID-19 Test and Metrix reader. Using only the Quick Reference Instruction including a video, and interactive set of directions, you will self-collect one nasal swab sample and follow the steps to conduct the testing. 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.

An additional nasal swab sample will be collected and stored for later analysis to support future research validation studies.

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.

**Nasopharyngeal Swab Collection**



## 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 nasal swab.
- Provide an observed nasal swab.
- Submit a healthcare professional collected nasopharyngeal and saliva sample.

## What will happen to your saliva and nasal swab samples?

The swab 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 nasal swab sample that you provide will be stored for later analysis to support future research validation studies.

## Could being in this research hurt me?

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.

## 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 may be required to pay.

## 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. 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 in the home or point-of-care setting.

## 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.

## What happens to the information collected for this research?

Your private information and your medical record 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)
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research
- Tricore Research Laboratory

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

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. Sites in California, Delaware, Indiana, Illinois, and Washington, this permission will be good until December 31, 2073.

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.

## 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 at the beginning of this form.

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 clientcare@wcgclinical.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.

## 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. No other payment is routinely available from the study doctor or sponsor.

## 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.

## 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.

## Will I be paid for taking part in this research?

For taking part in this research, you will be paid $50 in the form of an Amazon gift card. This will be upon completion of testing the device and collection of the comparator nasopharyngeal sample. You will be paid an additional $20 (in the form of an Amazon gift card) if you choose to provide an extra AN swab sample.

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.

## Assent Instructions:

- 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.

## 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 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 |
| --- | --- |
| | |

## Statement of Consent for Nasal Sample(s) and Nasopharyngeal Sample:

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

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|---|---|
| Printed Name of adult subject capable of consent | |
| Signature of adult subject capable of consent | Date |
| Signature of person obtaining consent (Investigator/Coordinator) | Date |

## Subjects unable to consent are required to assent for Nasal Sample(s) and Nasopharyngeal Sample:

If assent is obtained, have the person obtaining assent document assent on the consent form.

Your signature documents your permission for you, or the individual named below to take part in this research.

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|---|---|
| **Printed Name** of adult subject capable of consent, 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 |
| **Printed** name of subject<br>(Not required if subject personally provided consent) | 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<br>(Investigator/Coordinator) | Date |

**Certificate of Confidentiality**

This research is covered by a Certificate of Confidentiality (CoC) from the Biomedical Advanced Research and Development Authority, Administration for Strategic Preparedness and Response, a US Federal Government entity under Health and Human Services.

This means that the staff of Aptitude Medical Systems and [Insert Site Name(s)] cannot share or give to any other person not connected with this research your name, information about you, documents, or samples that may identify you in any action or suit unless you say it is okay.

A CoC protects your private information from all legal proceedings. Your information can't be used as evidence even if there is a court subpoena. All copies of your information are immune from the legal process, and cannot, be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding unless you say it is okay.

The information about you CAN be shared for other research if it is allowed by Federal regulations. We will let you know beforehand if this is something we will do.

The Certificate DOES NOT stop the reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA).

You should understand that a CoC does not keep you from voluntarily releasing information about yourself or your involvement in this research. It also does not prevent you from having access to your own information. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide specific consent to allow the researchers to release it.

****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/Parent Guardian** **Date**