RESEARCH SUBJECT CONSENT FORM

Title: SDI DROID At-Home Test (Lateral flow digital immunoassay) and SDI Rapid Antigen- Anterior Nasal in a home-based setting

Protocol No.: SDI-001

Sponsor: SDI Labs Inc.

Investigator: STEPHENSON CHEA

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Study-Related Phone Number(s): 1-877-509-0376
1-877-509-0376 (24 hours)

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last three days.

Why is this research being done?

The purpose of this research is to measure the Usability Study of the SARS-CoV-2 (COVID-19) SDI DROID At-Home Test (Lateral flow digital immunoassay) and SDI Rapid Antigen- Anterior Nasal in a home-based setting.

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

If you decide to take part in this research study, the general procedures include you attending a Screening Visit and Visit One (1) on the same day. You will be provided a Usability Study of the SARS-CoV-2 (COVID-19) SDI DROID At-Home Test (Lateral flow digital immunoassay) and SDI Rapid Antigen- Anterior Nasal in a home-based setting. You will also answer a questionnaire electronically. You will have a video call with a staff member when you go home to take the Antigen test. On Day three (3), you will receive an email to check your study results.

Will anything in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include discomfort from the nasal swab.

A potential risk of False Positive results leading to unnecessary clinical care which may include medications and additional diagnostic tests.

A potential risk of False Negatives which may delay potential therapeutic care, and in severe cases may delay critical lifesaving care. Negative results cannot be proven negative.

Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include the stopping of spread of the SARS-CoV-2 (COVID-19 to others.

DETAILED RESEARCH CONSENT

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 legally authorized representative, 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 I 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.

Why is this research being done?

The purpose of this research is to measure the Usability Study of the SARS-CoV-2 (COVID-19) SDI homebased Lateral Flow Antigen Test.

About 100 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last three (3) days until you receive your test results.

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

- You will be electronically consented to participate in the research.
- You will be provided with the SARS-CoV-2 (COVID-19) SDI homebased lateral flow antigen test.
- You will enroll into the DROID application for the Anbio AN Ag kit electronically.

- You will take the test at home with the study representative via Video.
- You will mail your study results.
- You will complete the questionnaire.
- You will receive an alert via the Droid application to check your results.

100 subjects for non-prescription (OTC) tests and 30 subjects for prescription-only tests and take place in an actual use environment or simulated environment.

For OTC tests for use at non-laboratory sites, we will split the usability study into two sections: 50 subjects testing themselves and 50 subjects testing another person (child or adult, depending on your intended use population).

Study population should include individuals across all ages 2y-65+y

- <14 years of age (target ~20%)
- 14-24 years of age (target ~10-15%)
- 24-64 years of age (24-64y target ~30-35%)
- ≥65 years of age (target ~35%)

You will fall into the relevant study group based upon your age as stated above.

You will be using the SARS-CoV-2 (COVID-19) SDI homebased lateral flow antigen test which has not been approved by the Food and Drug Administration (FDA) yet and is experimental.

A Questionnaire will need to be completed one time after the test is taken.

You will receive a copy of your results through the Droid application.

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

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

- Attend your Video visit.
- Take the test per the video visit instructions.
- Mail the test kit.
- Review the test results within three days.
- There may be nasal discomfort from the applicator when taking the test.

- A potential risk of False Positive results leading to unnecessary clinical care which may include medications and additional diagnostic tests.

- A potential risk of False Negatives which may delay potential therapeutic care, and in severe cases may delay critical lifesaving care. Negative results cannot be proven negative.

- Please quarantine while waiting for results.

Could being in this research hurt me?

- There may be nasal discomfort from the applicator when taking the test.

- A potential risk of False Positive results leading to unnecessary clinical care which may include medications and additional diagnostic tests.

- A potential risk of False Negatives which may delay potential therapeutic care, and in severe cases may delay critical lifesaving care. Negative results cannot be proven negative.

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

Taking part in this research will not cost you anything.

Will being in this research benefit me?

If there are no expected benefits to the subject but possible benefits to others/ scientific knowledge:

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include additional spreading of the SARS-CoV-2 (COVID-19).

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

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

- WCG IRB, the Institutional Review Board (IRB) that reviewed this research
- Since this is a communicable disease testing, we are mandated to disclosure by state-law.

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.

If the research does not require listing on www.clinicaltrials.gov, but will be listed anyway, you may use this language or a variation of this language. The IRB does not require this information when not required by FDA, even if the study will be listed.

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.

You give the company paying for this research study the right to use, copy, and give out the pictures taken of your head and scalp. The purpose for taking the photos is to show if there was improvement in hair growth as a result of your participation in the research.

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.

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.

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:

- The research is canceled by the FDA or the sponsor

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 not to participate after you get home with the test, you must return the test to the Investigator.

Will I be paid for taking part in this research?

You will not be paid for taking part in this research.

Statement of Consent:

- All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted
- 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.

Signature of adult subject capable of consent, child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care	Date
Printed name of subject (not required if subject personally provided consent)	Date
Signature of person obtaining consent	Date

❑ 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	Date