NCT07399249

CLN-019-01 - Informed Consent Form v1.0

Study Title: CLN-0019 Usability and Clinical Validation of the NowFuture Digital Flu - COVID Test in Anterior Nasal Samples for Over-the-Counter (OTC) Use

IRB Approval: 08 January 2026

RESEARCH PARTICIPANT CONSENT FORM

TITLE:	Usability and Clinical Validation of the NowFuture Digital Flu - COVID Test in Anterior Nasal Samples for Over-the-Counter (OTC) Use
PROTOCOL NO.:	CLN-0019 WCG IRB Protocol #20255195
SPONSOR:	Sapphiros LLC
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

Please check the appropriate box:

☐ You are 18 years of age (or age of majority in your state) or older and you are being asked to take part in this study.

☐ You are the parent or guardian being asked to grant your child permission to take part in this study.

In this consent form, "you" refers to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

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.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This section 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.

How long will I be in this research?
Your participation in this research will last for one visit and the visit should take about 60 minutes.

Why is this research being done?
The purpose of this research is to evaluate the performance and the usability of an investigational (study) test called NowFuture Digital Flu/COVID Test. The study test has not been approved by the FDA and therefore its use is investigational.

What happens to me if I agree to take part in this research?
You will be asked to provide two swab samples from your nose. One of the samples will be collected and tested by you or a participant tester (for example, a parent, guardian or another adult who is not a parent or guardian, other than the research staff), using only the investigational test instructions. A second sample will be collected by the research staff and will be shipped to a laboratory for testing. If the investigational test yields an invalid result, you may be asked to provide an additional swab sample for retesting.

Research staff will observe you or the participant tester during the collection and testing procedures.

You or the participant tester may be asked to interpret a set of mock (pretend) test results and complete a user comprehension and readability questionnaire about your experience using the test.

Could being in this research hurt me?
The most important risks that you may expect from taking part in this research include possible pain or soreness at the sample collection site, discomfort or nosebleed. There is a risk of loss of confidentiality and there may be risks that are unknown at this time.

Will being in this research benefit me?
You will not personally benefit from this research. Your participation in this study may help others in the future.

What other choices do I have besides taking part in this research?
Instead of being in this research, your alternative is not to participate.

What else should I know about this research?
Other information that may be important for you to consider so you can decide whether to take part in this research is:

- You can be tested by your doctor because of your symptoms, without being part of this study.
- You may ask the research staff questions about the study at any time.
- You may stop participating at any time, and it will not affect your ability to receive regular medical care from your healthcare provider.
- You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.
- You will not have any costs for being in this research study. You will receive payment for completing the study visit.

There is a possibility that personal identifiers will be removed from your private information or biospecimens and then used or distributed for future research studies without your additional informed consent.

DETAILED RESEARCH CONSENT

You are being asked 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.

In this consent form, if you are 18 years of age (or age of majority in your state) or older "you" refers to you as the research participant.

If your child is less than 18 years of age (or under the age of majority in your state), "you" means "your child" as the research participant.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form, you agree to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

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?

Your participation in this research will last for one visit and the visit should take about 60 minutes.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to evaluate the performance and the usability of the investigational (study) test, the NowFuture Digital Flu/COVID Test. You, or the participant tester (for example, a parent, guardian or another adult who is not a parent or guardian, other than the research staff), will be asked to use the investigational test instructions to correctly prepare the test components, collect a sample, perform the test and interpret the results. The study test is intended for self-use, or for another user doing the testing on another person, in a home setting. The study test is the NowFuture Digital Flu/COVID Test, and it has not been cleared by FDA and therefore its use is investigational.

WHY AM I BEING ASKED TO BE IN THIS STUDY?

You are being asked to be in this study because you have symptoms of COVID-19 or Flu.

WHAT HAPPENS TO ME IF I AGREE TO TAKE PART IN THIS RESEARCH?

Your participation in this study is voluntary. You will be asked to read this consent form and ask any questions you may have before agreeing to participate. If you agree to be in this study, you will sign and date this consent form to document your agreement. A copy of the signed informed consent will be provided to you. Information will be collected about you, which may determine if you are eligible to participate in the study. There is a possibility that, after consenting and after a further review of your symptoms and history, you may not qualify to participate.

As part of this study, we will collect some basic information such as your age, race, educational background, medications, existing comorbidities (other diseases or conditions you may have), if you have any vision impairment such as wearing glasses or contacts, your symptoms and if you've been vaccinated for COVID-19 or Flu. If another person is serving as your participant tester, we will also collect the age, race and educational background of the participant tester.

If you are performing the test yourself, you will be asked to review the investigational test instructions for the study test and prepare the components for testing. Next, you will self-collect one nasal swab from both of your nostrils, test the swab sample using the investigational (study) test, and then interpret the test result.

If you are having a participant tester perform the test for you, the participant tester will be asked to review the investigational test instructions for the study test and prepare the components for testing. Next, the participant tester will be asked to collect one nasal swab from both of your nostrils and test the swab sample using the study test. The participant tester will then interpret the test result.

If you (or your participant) obtain an invalid result on the first test, you may be asked to provide another swab sample for retesting.

If the site is participating in the Usability portion of the study, and you are selected to participate in the Usability assessment, research staff will observe and record all the test procedures you or the participant tester performed, and any difficulties encountered. You will be asked to interpret a mock (pretend) set of test results and then complete a user comprehension questionnaire about your experience performing the test. If a participant tester performs the test for you, the participant tester will be asked to complete the questionnaire.

Someone from the research team will also collect one nasal swab sample from you, and then the swab will be placed in a collection tube. The sample will be sent to a reference lab for comparator testing. A minimum of 15 minutes is required between the study and comparator sample collections.

Leftover samples may also be stored frozen and used for additional testing or future testing by the Sponsor, you will be asked about your permission for this in the section titled, "WILL YOU SAVE MY RESEARCH INFORMATION AND SAMPLES TO USE IN FUTURE RESEARCH STUDIES?"

It is important that you understand that the study test is not cleared or approved by the FDA, and you cannot use the test result to confirm any current infection status. You will know the result of this test, but it cannot be used for any healthcare decisions. If you have questions regarding your current infection status, you can test yourself with an approved home test for COVID-19 and/or Flu that is available over the counter or ask your healthcare provider about COVID-19 and/or Flu testing. Please seek additional care from your healthcare provider if you are concerned or confused about your health status.

As part of this study, we are obtaining data from you. This data may be used for commercial profit. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

WILL BEING IN THIS RESEARCH BENEFIT ME?

There is no direct medical benefit to you or to the individual that you are collecting samples from, but the information learned from this study could benefit other people in the future.

WHAT OTHER CHOICES DO I HAVE BESIDES TAKING PART IN THIS RESEARCH?

Your alternative is not to participate. You can be tested for COVID-19 and/or Flu by your healthcare provider because of your symptoms without being part of this study, or you can test yourself with a home test for COVID-19 and/or Flu that is available over the counter.

HOW MANY PEOPLE WILL PARTICIPATE?

Up to 1,500 or more people will take part in this study.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for one visit that will take about 60 minutes.

> ****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.

WHAT ARE THE RISKS OF THIS STUDY?

[START]
There is a risk of receiving an incorrect test result from the study test.

You, or the individual giving the sample, may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. The collection of nasal swabs may cause the following:

- Nose irritation or soreness
- Nosebleed
- A tickling sensation
- Pain

[END]
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will make our best efforts to keep the information about you confidential. Please see the section in this consent form regarding confidentiality for more information.

Though there are no reasonably foreseeable risks to a fetus, embryo, or nursing infant, such risks may exist.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses including any testing for COVID-19 and/or Flu that may be done outside of the research study.

WILL I BE PAID FOR PARTICIPATING?

You will receive a payment of $[Amount] for completing the study. The payment will be given to you at the end of your study visit.

If the site is participating in the Usability portion of the study and you are enrolled to participate in the Usability portion of the study, you will receive an additional $[Amount] at the end of your study visit.

WHO IS FUNDING THIS STUDY?

Biomedical Advanced Research and Development Authority "BARDA", a US Federal Government entity under Health and Human Services, is funding this research study. This means that BARDA is supporting all the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from BARDA for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

If you believe that an injury has occurred, you should contact your study doctor who will provide treatment or refer you for care. The Sponsor has no plans to pay for any of your medical treatments that are part of your standard care. All costs related to the treatment of an injury will be billed to you or your insurance company as usual for your medical care.

By agreeing to the above, you do not give up any of your legal rights which you otherwise would have as a patient.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research.

Other people such as those indicated below may become aware of your participation in this study and may use or disclose records pertaining to this research, only in certain circumstances or under certain conditions, according to the Standards of Privacy of Individually Identifiable Health Information regulations. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law. These entities are required to comply with all applicable laws related to the Protection of Human Subjects Regulations (21 CFR parts 50 and 56).

- The U.S. Food and Drug Administration (FDA).
- Sapphiros LLC (Boston, MA) and their representatives (CovarsaDx Corp).
- Representatives of Sapphiros LLC (Boston, MA) responsible for conducting the study may also inspect any part of your medical record for the purpose of auditing the conduct of the study.
- Global Initiative on Sharing All Influenza Data GISAID, which is an initiative to track COVID-19 variants and influenza subtypes.
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response, a US Federal Government entity under Health and Human Services.
- WCG IRB, The Institutional Review Board that has reviewed this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.
- Any of the above-mentioned groups may look at your records to make sure the study has been done the right way.
- They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the 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.

To help protect your confidentiality, we will assign you a study ID number that will be linked to you. Your ID will be used on study data. The list that links your ID to your identifier will be available only to the research team and stored separately from the study data. Data will be stored securely by the research team.

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 Sapphiros LLC, CovarsaDx Corp and this study site 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.

The research team will only send study results to the Sponsor, Sapphiros LLC or to CovarsaDx Corp (Sponsor representative). Information sent to Sapphiros LLC or CovarsaDx Corp will be de-identified. De-identified information is not considered PHI. In the future, Sapphiros LLC may continue to use specific health information that is collected as part of this study. For example, Sapphiros LLC may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study test, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. Sapphiros LLC may also share information from the study with regulatory agencies in foreign countries.

Protected Health Information (PHI) is health information that individually identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section regarding confidentiality.

The research team will only use and share your information as talked about in this form or as permitted or required by law. Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the site investigator listed at the beginning of this form.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are otherwise entitled.

However, if you do not sign this consent form and give your permission to use your PHI, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- For sites in California, Delaware, Indiana, Illinois, and Washington, this permission will be good until December 31, 2070. For all other states, this authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
- To revoke your authorization, you must send written notice to the site investigator listed in this document.
    - **If you revoke your authorization:**
        - The research team may only use, and share information already collected for the study.
        - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
        - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, or you withdraw your authorization, you won't be penalized or lose any benefits for which you are otherwise entitled.

COULD I BE WITHDRAWN FROM THE STUDY?

Your study doctor may withdraw you from the study based on their clinical judgement at the time.

WHAT IF I DECIDE TO WITHDRAW FROM THE STUDY?

You may withdraw by telling the research team you are no longer interested in participating in the study. Any data collected about you will remain in the study, but no new information will be collected.

WHAT IF I HAVE QUESTIONS?

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(s) 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 participant.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.

- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

WILL YOU SAVE MY RESEARCH INFORMATION AND SAMPLES TO USE IN FUTURE RESEARCH STUDIES?

Identifiable research information and identifiable samples will not be used for current or future research studies.

We would like to use the data and specimens we are obtaining in this study, that have been de-identified, for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding COVID-19, Flu A/B, or other diseases or conditions, including research to develop investigational tests that are not approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data and swab specimens you give up any property rights you may have in the data and specimens. *Your samples will not be used for human genetic research.*

If you change your mind and do not want us to store and use your data and swab specimens for future research, you should contact the research staff member identified at the top of this document. The data and samples will then no longer be used for research purposes. However, if some research with your data and samples has already been completed, the information from that research may still be used. Also, if your information has been shared with other researchers it might not be possible to withdraw the information to the extent it has been shared.

Please initial and select a Yes or No response for the statement below. If this is left blank or not selected and initialed, it will be interpreted as 'No.'

My data and samples and the data from the participant tester, if applicable, may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

Identifiers will be removed from your private information including data and samples and may be used for future research or shared with others. If this occurs, we will not ask you for additional consent.

Your signature indicates that this research study has been explained to you that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Assent instructions for participants who are under 18 years of age (or age of majority in your state)

- 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 as the research participant (person who provided the study samples):

_____

Printed Participant Name

Signature of adult participant capable of consent, participant's parent, or guardian authorized under state or local law to consent to the participant's general medical care.	Date

Relationship to participant

Signature of Witness (if applicable)	Date

I have fully explained this informed consent to the participant named above and/or the participant's Parent/Legal Guardian:

Signature of person obtaining consent	Date

Printed name of person obtaining consent

PARTICIPANT/TESTER: If you are a research participant tester (a parent/legal guardian or another adult who is not the parent/guardian, who collected and tested a sample from the participant):

_____
Research Participant Tester Name (printed)

_____ _____
Research Participant Tester Signature Date

Statement of Person Who Obtained Assent

- ❑ Not applicable, participant does not require assent.

OR

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

OR

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

_____ _____
Signature of person obtaining assent Date

_____
Printed name of person obtaining assent

****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 research 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 Participant/ Parent or Legal Guardian	**Date**

Authority of Parent / Legal Guardian
(Relationship to Participant)