Participant ID#: _____

Louisiana State University Health Sciences Center - New Orleans

Consent to Participate in Research

STUDY TITLE:	Validation of Nasal and Saliva Testing for SARS-COV2
PRINCIPAL INVESTIGATOR:	Lucio Miele, MD, PhD
EMERGENCY CONTACT:	Dr. Miele 504-568-888
STUDY SPONSOR:	LSUHSC Department of Genetics

1. Invitation to be Part of a Research Study

Lucio Miele, MD, PhD and associates from the LSUHSC Department of Genetics at the Louisiana State University Health Sciences Center in New Orleans (LSUHSC-NO) are conducting a research study. A research study is a scientific way to improve or develop new methods of health care. Studies are designed to answer specific questions on how to prevent, diagnose, or treat diseases and disorders. This study is being funded by LSUHSC Department of Genetics. The research team is asking you to be in this study because you are being tested for COVID10 coronavirus through a traditional nasopharyngeal swab (deep nose/back of the throat). **Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this consent form will help you decide if you want to participate. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.
- Even if you choose to participate, you can decide to stop participating at any time.

In this consent form, "you" always refers to the participant. If you are a legally authorized representative, please remember that "you" refers to the study participant.

2. Important Information about this Research Study

This section lists the key characteristics of this study and the basic reasons why you may or may not want to take part. It is only a summary. The sections following this summary have more details, including contact information for people who can answer any questions or concerns you may have. Please take time to read this whole document and ask questions before deciding if you want to take part in this research study.

Things you should know:

- The purpose of the study is to evaluate the performance of saliva and nasal samples as compared to traditional nasopharyngeal samples in two types of molecular tests for COVD-19 coronavirus: the Seegene Allplex PCR test and the CovidSeq NGS test.

- In order to participate, you must be tested for COVID-19 coronavirus through a traditional nasopharyngeal swab (deep nose/back of the throat) and provide two samples. One will be saliva (spit) into a tube. The other will be a different type of swab that will be inserted in your nostrils but not into the back of your throat.
- If you choose to participate, you will be first asked to spit saliva into a tube. Then the nasal swab will be inserted into both your nostrils. Then you will receive the standard nasopharyngeal swab for your clinical test. This will prevent spillover of virus from the back of your throat into your nostrils or your saliva, which would confuse the results. You will not receive results from the tests conducted on your saliva (spit) or your nasal (nostril) sample, as these are being performed for research purposes. You will be in the study for one (1) visit on the day of your COVID-19 test if you decide to stay for the whole study.
- The main risks of being in the study possible discomfort or other complications that can happen insertion of a swab in your nostrils. Spending time providing a saliva (spit) sample.
- You might benefit from being in the study because the results will help physicians determine whether it's possible to use less uncomfortable ways to test for COVID-19 coronavirus. The results of this test may help speed up testing and limit the spread of COVID-19 to your family and others in your community.
- Taking part in this research study is voluntary; you do not have to participate. If you do take part, you can stop at any time.

3. Why is this study being done?

The purpose of the research is to evaluate the performance of saliva and nasal samples as compared to traditional nasopharyngeal samples in two types of molecular tests for COVD-19 coronavirus: the Seegene Allplex PCR test and the CovidSeq NGS test. Both tests are authorized by the U.S. Food and Drug Administration through an Emergency Use Authorization (EUA). We wish to determine if less-invasive samples including nasal (nostril) swabbing and saliva (spit) can be used to detect the virus in our tests as accurately as the traditional nasopharyngeal (deep nose/back of the throat) swabs.

4. What will happen if I take part in this study?

Up to eighty (80) people will take part in this study, 40 positive and 40 negative for SARS-CoV2 (COVID19 coronavirus).

You are being tested for COVID-19 coronavirus through a traditional nasopharyngeal swab (deep nose/back of the throat).This is the method validated in our laboratory to reliably detect the coronavirus using the Seegene Allplex test. This is a clinically indicated test and you will receive your results through your electronic medical record patient portal, and a telephone call from our clinic staff if your test is positive. In addition to your regular test, you

will be asked to provide two samples. One will be saliva (spit) into a tube. The other will be a different type of swab that will be inserted in your nostrils but not into the back of your throat. The saliva (spit) and the nasal (nostril) swab will be tested separately for coronavirus, and the results will be compared to those of your clinical test. Your identity will be confidential to personnel performing the tests and the individuals involved in the new device submission process. You will not receive results from the tests conducted on your saliva (spit) or your nasal (nostril) sample, as these are being performed for research purposes. You will be first asked to spit saliva into a tube. Then the nasal swab will be inserted into both your nostrils. Then you will receive the standard nasopharyngeal swab for your clinical test. This will prevent spillover of virus from the back of your throat into your nostrils or your saliva, which would confuse the results.

The results of the study of your samples from this project will be used for research purposes, to determine whether the less invasive sampling techniques perform comparably to the nasopharyngeal swabs.

Before you begin the study

Before you begin the study, you will need to be scheduled to get a test for COVID-19 coronavirus.

During the study

If you agree to take part in this study, you will be first asked to spit saliva into a tube. Then the nasal swab will be inserted into both your nostrils. Then you will receive the standard nasopharyngeal swab for your clinical test. This will prevent spillover of virus from the back of your throat into your nostrils or your saliva, which would confuse the results.

6. How many people will take part in this study and how long will it last?

Eighty (80) people will take part in this study at LSUHSC-NO. In total, approximately 80 people will participate in this study locally.

If you complete the entire study, your participation will last 15-30 minutes.

7. What are the risks of taking part in this study?

Known risks and discomforts

The known risks and discomforts from the study procedures are possible discomfort or other complications that can happen insertion of a swab in your nostrils. Spending time providing a saliva (spit) sample.

8. Are there any benefits to participating in this study?

Possible benefits to you

There will be no direct benefit to you from participating in this study.

Possible benefits to others or society

This study will help the researchers learn more about whether it's possible to use less uncomfortable ways to test for COVID-19 coronavirus. The results of this test may help speed up testing and limit the spread of COVID-19 to your family and others in your community.

9. What other choices do I have if I don't take part in this study?

The alternative is not to participate.

10. How will my information be kept confidential?

The researchers will protect your information by not retaining any identifiable information. We will make every effort to maintain your privacy but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.

The following people or groups may review your study records for purposes such as quality control or safety:

- Representatives of LSUHSC-NO and the LSUHSC-NO Institutional Review Board
- Officials of the Department of Health and Human Services or the Federal Food and Drug Administration
- Other organizations or agencies if required by law.

If any publications and/or presentations result from this study, they will not identify you by name.

11. Will my information or specimens be used for future research?

We will not use or share any of your information and/or samples collected as part of this study for future research, even if identifiers are removed. Any samples obtained for this study will be discarded or destroyed once they have been used for their intended purpose(s) in this study, once our study has been completed, data have been analyzed and if warranted, published.

12. Will there be any costs to me for taking part in this study?

If you take part in this study, you will not have any expenses beyond the routine costs for patients with similar conditions. The procedures and all other research-related activities are provided free of cost.

The study sponsor will supply or pay for the cost of: Procedures; nasal swab and saliva sample collection

We do not have money to pay for any disability, damages such as lost wages, or similar outcomes that you may experience.

13. Will I be paid or for taking part in this study?

You will receive a gift card or ClinCard for the value of $25 your participation in this study. Payments will occur after your nasal and saliva (spit) samples are collected. You will be responsible for any taxes assessed on the compensation.

The study team will release your name, address, social security number and amount of payment to Accounting Services. If the total payment for your participation in research is greater than $600 in a year, Accounting Services will report this amount to the Internal Revenue Service as income as required by law.

14. Who can profit from study results?

Not Applicable

Use of My Specimens

Your samples will not be used for commercial profit.

15. What should I do if I get sick or injured during the study?

If you believe the research procedures have made you sick or caused an injury to you, immediately seek medical advice and/or treatment by:

- Contacting the Principal Investigator and/or the Co-Investigator whose phone numbers are listed in the next section; and/or
- Calling the Research Injury phone number listed in the next section; and/or
- Contacting your regular medical doctor; and/or
- Contacting the treatment center of your choice.

In the event of study-related harm, the principal investigator will arrange for medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. This will be provided on a fee-for-service basis. If the insurance company does pay for the care and treatment of study-related injury, you may be responsible for any co-payments and deductibles.

16. Who can I contact if I have questions about this study?

The research team:

You may contact the following individuals with any questions or concerns about the research or your participation in this study.

Principal Investigator

Name: Lucio Miele, MD, PhD

Address: 533 Bolivar Street, New Orleans, LA 70112

Phone #: 504-568-8088

24-Hour Phone #: 504-568-8088

Co-Investigator

Name:

Address:

Phone #:

Research Injury Phone #:

Office of the Chancellor, LSU Health Sciences Center - New Orleans:

You may contact the Office of the Chancellor by phone at (504) 568-4801, if

- you have questions about your rights while taking part in this study, or
- you have any concerns or suggestions, and
- want to talk to someone other than the researchers about the study.

17. What will happen if I cannot complete the study?

There are several reasons why you may not complete the study.

The researchers or the study sponsor might decide to stop the study at any time.

The researchers may end your participation in this study, without your permission, for a number of reasons including:

- Your safety and welfare are at risk.
- You do not follow instructions.
- You miss scheduled visits.
- You fail to complete study activities.

You also may decide on your own to stop participating in the study. If you are thinking about withdrawing, let the researcher know so he/she may remove you from the study safely. You also should seek medical advice for alternative treatments. The researcher will inform you of any significant new findings during the study that may impact your willingness to continue participation.

If you decide to stop being in the study, or the study is stopped, or you are removed from the study, the researcher will ask you to:

- Complete an exit telephone interview

You are not required to complete these tasks but some of them may be for your own safety.

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Information collected about you up to the point of withdrawal will remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

18. Your Participation in this Study is Voluntary

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason or no reason at all. No matter what you decide, there will be no penalty to you and you will not lose any services, benefits or rights you would normally have. If you want more information about your rights as a research participant, please visit https://www.lsuhsc.edu/administration/academic/ors/participant_information.aspx.

If you are a LSUHSC-NO student or faculty/staff member, you may choose not to be in the study or to stop being in the study before it is over at any time. Your decision will not affect your grades or job status at LSUHSC-NO. You will not be offered or receive any special consideration if you take part in this research study.

19. Your Consent

By signing this document, I acknowledge or am aware that:

- The researcher(s) discussed the study with me and answered all my questions.
- I will receive a copy of the consent form.
- I do not waive any of my legal rights by signing this consent document.
- I can contact the study team or the Chancellor's Office using the contact information provided above if I have any questions or concerns after signing the consent form.

Signature of Participant:

I agree to take part in this study.

_____

Participant Signature Printed Name Date

Signature of Person Obtaining Consent:

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

Participant ID#: _____

Signature of Person Obtaining Consent	Printed Name	Date