A Comparative Evaluation of Specimen Adequacy of a Traditional Nasopharyngeal Swab as Compared to Nasopharyngeal Saline Wash, Saliva, and Serum to Test for Respiratory Viruses and Antibody Response

NCT05864118

Informed Consent Form

2025-02-14

CONSENT FORM

Title of this Research Study

A comparative evaluation of specimen adequacy of a traditional nasopharyngeal swab as compared to nasopharyngeal saline wash, saliva, and serum to test for respiratory viruses and antibody response

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

Purpose: The reason for this study is to test four different ways of obtaining a sample from you check for respiratory viruses. The investigational devices used in this study has not been reviewed by the Food and Drug Administration (FDA).
Methods: You will be asked to provide the following specimens:
1) You will be asked to spit into a small testing tube to provide a saliva sample.
2) You will be asked to chew on a soft study device with your teeth, as you bite on the study device it will collect the your saliva.
3) A study device will be inserted into your nose and used to wash the inside of your nose with less than 1 teaspoon of sterile salt water. The salt water will be recollected by the device.
4) The researcher will use a small needle to prick your finger to collect a small blood sample.

You will also be asked to complete a study survey.

Risks: There is a small risk of you could breathe the salt water into your lungs. There is a slight risk of infection. There is a risk of a nose bleed related to the salt water irrigation process. There is a small risk that someone outside the research could see information about you.
Benefits: You will not benefit directly from participating. We hope that the results

from this study will potentially help us develop more comfortable testing methods for respiratory infections.
Alternatives: You can choose to not be in this study.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are an adult 19 years of age or older, are a patient in the emergency department, and your doctors ordered a nose swab test for you. This study will recruit a total of 1000 participants.

What is the reason for doing this research study?
The reason for doing this research study is to test different ways of obtaining samples from you to test for respiratory viruses. The study devices are investigational and have not been reviewed nor approved by the United States Food and Drug Administration (FDA).

What will be done during this research study?
Your participation in this study should only take about 10-15 minutes. As part of the study, you will be asked to provide four specimens.
1) You will be asked to spit into a small testing tube to provide a saliva sample.
2) You will be asked to chew on a soft study device with your teeth, as you bite on the study device it will collect the your saliva.
3) A study device will be inserted into your nose and used to wash the inside of your nose with less than 1 teaspoon of sterile salt water. The salt water will be recollected by the device.
4) The researcher will use a small needle to prick your finger to collect a small blood sample.
You can choose to provide some or all four of the specimens listed above.

You will also be asked to complete a survey survey.

We will collect your name and medical record number so we can review your virus test results when they are available.

The sample we collect will not be used for other research studies by us, or by any other investigator after this research is over.

There are no plans to perform any genetic tests (including whole genome sequencing) on your sample.

What are the possible risks of being in this research study?
There is a possible risk the salt water may drain down your throat and cause some discomfort.
There is a possible risk the washing procedure may cause a nosebleed.
There is a possible risk the washing procedure may cause an infection.
There is a possible risk that someone outside the research could see information about you.i.e., a loss of confidentiality.

You could have other side effects that we do not know about yet.

What are the possible benefits to you?
You will not benefit directly from being in this research.

What are the possible benefits to other people?
This study can potentially help us develop more comfortable testing methods for respiratory infections.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part.

What will being in this research study cost you?
You will have to pay any insurance deductibles and co-payments as related to your emergency room visit today, but there is no additional cost to you to be in this research study. If you want to speak with someone about your insurance, just tell us.

Will you be paid for being in this research study?
You will be given a $20 Walmart gift card for being in the study.

Who is paying for this research?
This research study is being paid for by the Department of Emergency Medicine and the Emerging Pathogens Laboratory of the University of Nebraska Medical Center.

Dr. Thang Nguyen, the Principal Investigator on this study, and Dr. Michael Wadman, receives money (stock/stock options) for participating on an advisory board for University Medical Devices, a start-up company who has licensed this intellectual property and is providing gift cards to participants for enrollment.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical

problem or some other kind of problem because of the study, call someone listed at the end of this consent form.

How will information about you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.

The information will not be used for other research by us, or by any other researcher.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)
- The Food and Drug Administration (FDA)

The Privacy Rule may not apply to all these groups. Once disclosed outside of UNMC federal privacy laws may no longer protect your PHI. Ask the investigator (or contact the Office of Regulatory Affairs at IRBORA@unmc.edu) if you have questions.

How will results of the research be made available to you during and after the study is finished?

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: thang.nguyen@unmc.edu.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research (withdraw) up to the time your specimen is sent to the lab for storage or testing. Just call the researcher or any research staff. If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of "What Do I Need to Know Before Being in a Research Study?" If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If

you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
  - Thang T. Nguyen, PhD, MSN, APRN
  - Telephone: (402) 559-7884
  - Email: thang.nguyen@unmc.edu
- Institutional Review Board (IRB)
  - Telephone: (402) 559-6463
  - Email: IRBORA@unmc.edu
  - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
  - Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____Date_____

Authorized Study Personnel
Principal

* Nguyen, Thanh (Thanh)
phone: 402-559-7884
alt #: 402-559-7884
degree: PhD

Secondary

* Barksdale, Aaron
phone: 402-559-9994
alt #: 402-559-9994
degree: MD

* Brett-Major, David
phone: 402-559-8283
alt #: 202-618-0589
degree: MD MPH

* Broadhurst, Jana (Jana)
phone: 402-836-9775
alt #: 541-521-1698
degree: MD PhD

* Marx, Jared
phone: 402-559-6638
alt #: 402-559-4000
degree: MD

* Schnaubelt, Andy (Andy)
alt #: 402-960-3345
degree: PhD, MS

* Wadman, Michael
phone: 402-559-6948
alt #: 402-559-6948
degree: MD

* Zeger, Wes (Wes)
phone: 402-559-6841
alt #: 402-559-4000
degree: MD

Participating Personnel

* Carstens, Julie (Julie)
phone: 402-559-4828
alt #: 402-559-4847
degree: MS

* Williamson, Jan (Jan)
phone: 402-836-9775
alt #: 402-559-4847
degree: BS

Lead Coordinator

* Zimmerman, Brooklin
phone: 402-559-5237
alt #: 402-836-9405
degree: MSN, BA, RN

Other Coordinator

* Angell, Kathleen

* Longacre, Lauren

alt #: 402-559-8283
degree: MPH

phone: 402-559-1992
alt #: 402-813-6053
degree: BS

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ...

... to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

... to freely decide whether or not to take part in the research.

... to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

... to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

... to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

... to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

... to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.