Institutional Review Board

AGREEMENT TO PARTICIPATE IN A RESEARCH STUDY
MEDICAL RESEARCH INFORMED CONSENT
Ascension St. John Hospital

Title of research study: **Comparison of the ID NOW and Accula Point-of-Care Assays for the Detection of SARS-CoV-2**

Investigator: **Melphine M. Harriott, Ph.D., (ABMM)**

Sponsor: **Mesa Biotech, CA**

PARTICIPANT NAME _____

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being asked to participate in this research study because your doctors has ordered a test to determine if you have the SARS-CoV-2 virus (also called COVID-19) and are being seen at Ascension St. John Hospital.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.

- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Currently, we use a test called the Abbott ID NOW SARS-CoV-2 to determine if a patient has the virus that causes Covid-19. There is a new, faster test that has been developed by Mesa Biotech, called the Accula SARS-CoV-2 test. We would like to compare the new test to the current test, by analyzing a swab or your nose or throat using both systems. Bothe tests have already received the FDA's Emergency Use Authorization so they are considered investigational but the information from this study will help us determine how accurate the new test is compared to the test already being used here.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 20 minutes.

If your doctor ordered a rapid test, you will be asked to have 1 additional swab collected in addition to the nose swab your doctor ordered for COVID testing. The additional swab will be collected from your nose. There may be some mild discomfort due to the additional collection. If you have already been confirmed positive by PCR, you will have two swabs collected, one for the Accula test and one for the ID Now test.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There is a chance you may experience minimal risk or discomfort associated with collecting nose specimens. Collecting swab samples from your nose is a standard, non-invasive medical procedure commonly performed in doctor's offices and hospitals.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Being in this study will not help you directly but may help determine if this new rapid test for SARS-CoV-2 is accurate enough to use for patient testing in the future.

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 using a better test to detect COVID in the future.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Instead of being in this research study, you will just have the one swab from your nose collected for the COVID test your doctor ordered.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at

313-343-6878 (day) or 313-343-4768 (24 hours); Ask for Dr. Harriott

This research has been reviewed and approved by the Ascension St. John Hospital Institutional Review Board ("IRB"). You may talk to them at (313) 343-3863 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 100 people here will be in this research study out of 200 people in the entire study nationwide.

What happens if I say yes, I want to be in this research?

- A nasal swab will be collected for the COVID test your doctor ordered.
- A second nasal swab will then be collected.
- The first nasal swab will be used for the COVID test your doctor ordered and results will be provided to your doctor.

- These swabs will be assigned a unique number that will be linked to your first COVID test swab.
- The second nasal swab will be used for a different COVID test.
- The research team will compare the results of the first COVID test to the second COVID test.
- If the new test results are as good as the first test results, the new test can may be recommended to use for testing COVID patients in the future.

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

If you take part in this research, you will be responsible for only the time spent collecting the swabs and signing the paperwork.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. There are no consequences for leaving the study. If you decide to leave the research, contact the investigator so that the investigator can remove your swab sample from the study.

Is there any way being in this study could be bad for me? (Detailed Risks)

You may experience some discomfort after collection of the swab from your nose. There is also a risk of loss of confidentiality. We will assign your swabs a study ID and you will only be identified by the study ID.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay (just for the tests ordered from the doctor, not for the tests performed from this study).

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

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

Will the researchers benefit from my participation in this study?

Ascension St. John Hospital and the researchers on this study will not receive any financial benefits from your participation.

Participant HIPAA Authorization to Use and Disclose Protected Health Information (PHI)

Your participation in this study will require the use and disclosure of certain medical and other information about you. The information that may be used or disclosed includes: all health care records such as: laboratory, pathology and/or radiology results; scans; x-rays; and Protected Health Information (PHI) previously collected for research purposes.

Your PHI will be used in the following ways: To conduct the research and to ensure that the research meets legal, institutional or accreditation requirements.

Your authorization to use and disclose the above information has no expiration date.

Your PHI may be seen, used or disclosed to the following:

☒ The researchers and members of the research team.

☒ Other health care providers or employees of Ascension St. John Hospital who provide services to you for this study.

☒ Representatives of the Institutional Review Board (IRB), the FDA (Food and Drug Administration), or other governmental agencies involved in research monitoring.

☒ Other agencies as required by law.

You have the right to review your PHI. However, if you agree to participate in the research study and sign below, you will not be able to look at your research information until the research study is completed.

You do not have to sign this authorization. If you decide not to sign the authorization it will not affect your treatment or eligibility for health benefits. However, if you do not sign this authorization you may not participate in this study.

You may withdraw your authorization at any time by notifying the principal investigator in writing, but the withdrawal will not affect any information already disclosed. However, you need to be aware that your written withdrawal of this Authorization may result in the termination of the research-related treatment being provided to you.

Melphine M. Harriott, Ph.D., D(ABMM)
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When you sign this authorization, your health information may be re-disclosed by the researcher if permitted or required by applicable federal or state law.

Your signature documents your permission to take part in this research. Please keep a copy of this Informed Consent for your records.

Signature of Participant	Date

Printed name of Participant

Signature of person obtaining consent	Date

Printed name of person obtaining consent

Signature of Legally Authorized Representative	Date

Printed name of Legally Authorized Representative

Check Relationship to Subject:

☐ Legal Guardian or Legally Authorized Representative for Medical Care (LARM)
☐ Spouse ☐ Adult Son or Daughter ☐ Mother or Father ☐ Adult Brother or Sister
☐ Other, explain:

Reason subject is unable to sign for self: