

Research Subject Information Sheet

Title: A Clinical Performance Evaluation of the SARS-COV-2 Direct Antigen Rapid Test: “DART.”

Protocol No.: E25001
WIRB® Protocol: 20200985
Sponsor: E25 Bio

Principal Investigator: Kleper de Almeida, MD
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Other Research Sites: Kendall Regional Medical Center
11750 SW 40th St,
Miami, FL 33175

Aventura Hospital & Medical Center
20900 Biscayne Blvd,
Aventura, FL 33180

**Study Related
Phone Numbers:** JFK: 561-655-8448 (24 hours)
Aventura: (305) 682-7000
Kendall: (305) 223-3000

In general, what is the purpose of the research, how long will you be involved?

To collect information about the performance of a new experimental rapid test to detect the virus responsible for COVID-19. Your participation is expected to only involve the sample collection and to last no longer than 1 or 2 days

What is involved with your participation, and what are the procedures to be followed in the research?

A medical professional with the research staff will collect 2 swabs from inside your nose and well as a sample of your saliva. They will also potentially collect some of the serum from your blood samples that you have already given.

What are the likely risks or discomforts to you?

This is identical to the sample nasal swab collection you already provided. Temporary irritation and possible sensation of needing to sneeze or cough. It is very unlikely but possible that the technician causes temporary injury to your nasal passage which may include minor bleeding. Possible inaccurate test result that leads to an additional test. There is no anticipated risk or discomfort in providing your saliva. There is also no anticipated risk or discomfort in collecting the serum since this will be from already collected blood samples.

What are the likely benefits to you or to others from the research?

You should not expect any direct benefit to yourself; however, should this product become available to everyone, then it may provide cheaper and more rapid testing of this virus which may ultimately save lives.

What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Since you have already been tested with the hospital standard for diagnosing this virus, there are no further testing procedures to you unless an additional swab is necessary.

Additional and more detailed information is provided within the remainder of this information sheet

What will be done only because you are in this research study?

As mentioned previously, the only activities for you include this informed consent process and the collection of a nasal swab, saliva, and potential serum. Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

If you have any questions now or at any time during this Research Study, please contact the study doctor at the phone number listed on the first page of this consent.

What are the possible discomforts and risks?

If you have had a nasal swab before, then this will be no different. The way your sample is analyzed by the technicians is the only difference. The nasal swab can be uncomfortable and may make you want to sneeze or cough, but should not cause any permanent problems. There is always a risk of extended irritation or minor injury to your nasal passage, but the swabs used are standard and designed for this collection. Because you have already tested positive or negative for the virus, this additional test should provide very minimal risk of additional risk of false positive or false negative results that may require another confirmatory test. There is no anticipated risk or discomfort in providing your saliva. There is also no anticipated risk or discomfort in collecting the serum since this will be from already collected blood samples.

There is also a risk of loss of confidentiality. Your private information 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
- The Institutional Review Board (IRB) that reviewed this research

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.

How could the researchers benefit from this research study?

The sponsor is paying the study site for their time and expertise on this study. In general, presenting research results helps the career of a scientist. Therefore, the study doctor may benefit if the results of this study are presented at scientific meetings or in scientific journals.

If you choose to take part in this study, will it cost you anything?

There will be no cost to you by taking part in this study.

What if you are injured because of the research study?

If you experience an injury or have questions about any discomforts that you experience while participating in this study, please contact the study doctor at the phone number listed on the first page of the consent.

Do you have to be in this study?

Your participation in this study 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 leave this study for any reason, please contact the study doctor at the phone number listed on the first page of this consent. They will tell you how to stop your participation safely.

Can you be withdrawn from this research study?

Since this a short study, the likelihood of withdrawal by the investigator is low.

Who would you call if you have any questions?

Kleper de Almeida, M.D. is the person in charge of this research study. If you or your representative(s) have any questions regarding your participation in this study, if you have any questions, concerns, or complaints about the research, or in case of study-related injuries, contact Dr. de Almeida at the phone number listed on the first page of this consent.

If you have any questions about the rights you have while taking part in this study or if you have questions, concerns, inputs or complaints about the research, please contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue, SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Assent:

- Assent of children and adults lacking capacity is required if the investigator determines the subject is capable of providing consent.
- Documentation of assent is not required.