Pilot study to compare serology results from blood collected using Tasso-SST OnDemand device compared to venipuncture

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Purpose of the Study

The purpose of this pilot study is participant user acceptance testing of the Tasso-SST OnDemand device to collect blood for antibody testing. The study will also compare antibody testing results from blood collected using the Tasso-SST On-Demand device compared to blood collected by phlebotomy.

Background & Significance

Coming into a research clinic site is an exposure risk for participants and staff. Coming into a research clinic site is a study burden for participants. The Tasso-SST OnDemand device could provide a means for participants to collect samples at home and ship directly to the lab.

The Tasso-SST OnDemand device, specifically the SST tube, is not approved for sars-cov-2 serology. We are testing it in a pilot study to confirm similar result from serum processed from blood collected by Tasso-SST OnDemand device and standard venipuncture (collection by standard venipuncture is part of study procedures for the MURDOCK C3PI Study (Pro00105703)). Results from this pilot study will help inform the possibility of at-home specimen collection for serology testing. We also hope to gain insight from participants about the instructions, and their willingness and ability to use it on their own, at home, in the future.

Design & Procedures

Prospective participants will receive an invitation from the PI via recruitment email to review the electronic consent form in Duke REDCap. Participants are instructed to call or email the Duke CTSI Office in Kannapolis with any questions. We will use the e-consent module in Duke REDCap. We have engaged DOCR to ensure that the e-consent used for the study is compliant. The identity of the consenting participant will be verified by the following steps: 1) participant will enter first and last name, date of birth, and email address, which will be verified against our records on file. Study team will be alerted to any discrepancies. The identity of participants will be further confirmed at the study visit, and done prior to completion of any study procedures.

At the study visit, participants will collect a small blood sample using the Tasso-SST OnDemand device during a serology blood draw visit already scheduled for the MURDOCK C3PI Study (Pro00105703). Participants will be provided a kit that includes written, step-by-step instructions that include pictures. Participants will also have the option to watch a brief video on using the device, available online at the Tasso website, prior to collection (https://www.tassoinc.com/tasso-sst-help). The Tasso-SST OnDemand device collects whole capillary blood, at a minimum volume of 80ul. In section 3100 of this application as the iRIS does not take any decimals' and hence have 1ml as the max amount of blood drawn.

A standard blood draw will also be done as described in the MURDOCK C3PI Study research summary and informed consent (Pro00105703). Both blood samples will be spun and processed for serum. Serum will be frozen and shipped to the lab at Duke for antibody testing. Antibody results will be compared between the two methods.

Participants will be sent a brief survey to learn about their experience using the Tasso-SST OnDemand device.

Selection of Subjects

Inclusion Criteria

- Must be a study participant enrolled in the MURDOCK C3PI Study (Pro00105703), participating in the testing cohort of the study.
- Participants are therefore 18 years of age or older, and willing to read and complete the consent process.

No exclusion criteria; however, only up to 100 participants will be enrolled. If more than 100 participants sign consent, some interested participants may not take part in the study.

Study Interventions

Participants will collect blood on their own using the Tasso-SST OnDemand device, following instructions provided in the kit. The Tasso-SST OnDemand device collects whole capillary blood, at a minimum volume of 80ul. Collected blood is spun into serum, frozen and shipped to the lab for analysis.

The Tasso-SST OnDemand device sticks to the skin with a light adhesive. When the button is pressed, a vacuum forms and a lancet pricks the surface of the skin. The vacuum draws blood out of the capillaries and into a tube attached to the bottom of the device.

Data Analysis & Statistical Considerations

We will evaluate correlation between results from blood collected by the two methods in this pilot study and qualitatively exam participant survey results. Summary statistics will be generated for survey responses, and qualitative data will be reviewed.

Data & Safety Monitoring

Participants will be instructed to follow the provided directions, step-by-step, and have the option to watch an instructional video prior to use. Participants will be observed by trained staff in a clinical research setting while using the Tasso device. The participant may choose not to participate at any time.