Biomedical Device Trial of Validation of Point of Care Liver Function Tests

NCT NUMBER: PENDING
NOVEMBER 28, 2018

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPPA AUTHORIZATION FORM

PROTOCOL TITLE: **Validation of Point of Care of Liver Function Testing: Validation POC-LFT**

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Why am I being asked to volunteer?

You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may

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find some of the medical language difficult to understand. Please ask the investigator and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

You are being asked to participate in a research study because you have been prescribed a liver function blood panel to be collected today.

What is the purpose of this research study?

The purpose of this research study is to test how accurate the point of care device is at testing liver function labs compared to a traditional blood draw. You are being asked to participate in this study because you are having liver function blood tests drawn today.

How long will I be in the study?

The expected length of your participation is one study visit completed during a scheduled clinic visit. Approximately 300 patients will participate in the study.

What am I being asked to do?

If you agree to participate in the study and meet the inclusion criteria, we will collect a finger prick and the results from the liver function panel that will be collected today. The finger stick test is an experimental procedure, it is not FDA cleared or approved. The results from the finger stick test will not be shared or returned to you.

What are the possible risks or discomforts?

You may experience mild discomfort or pain from the finger prick but no more than a standard blood draw. There should be no adverse events associated with the finger prick sample or collection lab results.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

There are no direct benefits to you from participating in this study. However, the results of this study will help the development and approval of the study device.

What other choices do I have if I do not participate?

Participation in this study is voluntary. This means that you are free to choose whether you want to be a part of the study or not. You do not have to take part in the study in order to receive care at the University of Pennsylvania. If you decide not to take part in the study or change your mind about being part of the study, there will be no penalties or loss of any benefits to which you are otherwise entitled.

Will I be paid for being in this study?

You will not receive any monetary payments for taking part in this study.

Will I have to pay for anything?

There is no cost to enroll in this study. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay.

When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- Dr. Khungar, the Primary Investigator, feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

Results from your laboratory test and the study will be shared with Group K diagnostics. Your identity will not be disclosed and information and results from your blood samples will be identified using a randomized study number.

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Every effort will be made to maintain confidentiality of your personal and medical information during and after the study. Your data will be stored in a secure, password protected database under your study number. This database will be available to research team and the IRB at the University of Pennsylvania.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.
Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

What information about me may be collected, used or shared with others?

If you agree to participate in the study and sign your name on the last page, you will be giving the University of Pennsylvania and other providers involved in your care permission to disclose your medical information to the researchers. The following personal information will be collected and used for research and may be disclosed or released to the researchers during your involvements with this research study:

- Name, date of birth, Medical Record Number
- Results from blood tests

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator and members of the research team at the University of Pennsylvania
- University of Pennsylvania medical staff who are directly or indirectly involved in your care related to this study.
- Offices that oversee or revaluate research and care activities at the University of Pennsylvania (e.g. finance department, billing department, Institutional Review Board, Office of Human Research)

Who, outside of the School of Medicine, might receive my information?

- Group K Diagnostics
- The Department of Health and Human services
- The National Institutes of Health
- The Office of Human Research Protections

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date