INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Study GKD001

NCT # Not Yet Assigned

IRB Approved Date 6/23/2022

INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Group K Diagnostics / "Collection of Blood Products for Use in the Development and Validation of Point-of-Care In Vitro Diagnostic Liver Function Test Devices"**
Protocol Number:	**GKD001**
Principal Investigator:	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Introduction
You are being asked to participate in a research study to develop and validate an investigational diagnostic test platform. This document describes the research study and what the study will involve. Please read this document carefully and do not hesitate to ask any questions at any time. Your participation in this study is completely voluntary. It is up to you to decide whether you want to participate. Choosing not to participate will involve no penalty. If you decide to participate, you will receive a signed copy of this document for your records. You may withdraw from future participation at any time.

What should you know about this research study?
- The sponsor is developing a new diagnostic test platform designed to allow many tests to be run in healthcare provider offices rather than requiring a blood sample to be sent to a clinical testing laboratory.
- In order to develop and validate blood tests on the diagnostic test platform, fresh samples of human blood are required.
- The purpose of this clinical research study is to collect small blood samples from participants for use in completing the investigational work needed to submit new diagnostic tests for clearance by the FDA.
- Participation in this clinical research study is completely voluntary.
- About 150 participants will participate in this study.

What does participation in this study involve?
- Contacting the clinical study phone line by text or call.
- Answering the following screening questions:
  - Are you 18 years of age or older?
  - Can you read and understand an informed consent form written in English?
  - Are you currently pregnant?
- Based on your answers to these questions, you may be invited to enroll in this study.
- If you are invited to enroll, you will be scheduled to have a blood sample drawn at the study site.
- When you arrive for your scheduled visit, you will be asked the screening questions again for confirmation. Based on your answers, you will be given this consent form to read and

discuss with study staff. You may ask any questions about the conduct of this study that you wish.
- Your signature on this consent form will constitute enrollment in this study.
- Once enrolled, the following information will be gathered from you:
    - Your full name.
    - Your date of birth.
    - Phone number where you can be reached.
    - If you are feeling healthy today.
    - If you have any diagnosed liver conditions or if you are on any medications that may affect your liver function, and if so, what these are.
- Once your enrollment data is recorded, a phlebotomist on the study staff will perform a standard venous blood draw to collect roughly 3 mL (0.6 tsp.) of blood. (At a later phase in the research study, participants will also have 0.03 mL (0.006 tsp.) of blood taken by finger stick).
- You will be monitored for any immediate adverse effects of the blood collection procedure.
- You will be provided with a copy of this consent form and invited to contact the Principal Investigator should any questions or concerns arise after leaving the study site.
- You will be given a $25 pre-loaded gift card to reimburse you for your time and transportation to the study site.

What if you choose to end or extend your participation after your blood draw?
- Contact the Principal Investigator at the telephone number on the first page of this consent form.
- You may ask that no further research be conducted on the blood sample you have already provided. Any stored remainder of your sample will be destroyed.
- You may ask to further your participation by contributing another blood sample 6 days or more after your previous blood draw.
- There are no negative consequences to you for withdrawing your blood sample from use in further research.

The Principal Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

What are the risks of participating in this research study?
You may experience mild discomfort or pain from the finger prick or the standard blood draw. Some slight risks of standard venous blood draws are:

- Pain from the needle going through your skin into the vein;
- Mild bruising;
- Clots under the skin;
- Lightheadedness;
- Possible fainting; and
- Rarely, infection.

We do not anticipate any adverse events associated with the finger prick sample. Adverse events are any unintended signs, symptoms, or diseases that are associated with the study plan. There may be other risks that are unknown.

What are the benefits of participating in this research study?
There are no direct benefits to participants in this research study. No test results from diagnostic tests under development will be communicated to study participants. Blood samples obtained during this study could lead to a commercial product that you will not financially benefit from in any way.

What are the alternatives to participation in this research study?
This research study is for research purposes only. The only alternative is to not participate in this study.

What if there are new findings?
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Will there be any costs involved in this research study?
There will be no charge to you for your participation in this study.

Authorization for Release of Health Information and Confidentiality Statement

In order to participate in this research study, you must authorize the release of your health information related to and used for purposes of this research study. The Principal Investigator is responsible for overseeing the use and disclosure (sharing) of your health information. Any information about you or your treatment obtained from this research including your liver function test results will be kept confidential and never identified in any report. Should results of this study be reported in medical journals or at meetings, the names of all participants will remain anonymous. Only authorized representatives, such as the sponsor, Group K Diagnostics, and their representatives, will have access to sample identification code that links your blood sample to your name. Investigational test results submitted to the FDA and/or other regulatory agencies, and the Institutional Review Board (IRB, a research ethics and study participant protection committee), may include de-identified demographic information for purposes of classifying the samples used in the investigational study. All medical information examined will be coded and kept confidential. However, because of the potential need to release information to these parties, absolute confidentiality cannot be guaranteed. The organizations listed above monitor medical research to ensure studies are conducted appropriately and ethically and any disclosure would only occur in your best interests.

This authorization to release your health information is limited to the analysis of the present study and is effective from the date you sign this consent and authorization form until statistical analysis is completed on the submitted data (study results).

Your authorization to release your study-related health information is required for your participation in this study.

You may withdraw your authorization at any time, in writing, by notifying the Principal Investigator. Your withdrawal of authorization will be effective upon receipt of this written notice and will allow the Principal Investigator to use only the health information that was gathered up until your withdrawal to the extent necessary to preserve the integrity of (follow through and properly complete) the research study. Your withdrawal from participation in the study itself, as discussed above, will automatically withdraw your authorization to use your health information data.

What else do I need to know?
We do not anticipate adverse events during your participation in this research study. However, if you believe that you have been harmed, you should notify the Principal Investigator as soon as possible at the telephone number on the first page of this consent form. If you experience a medical emergency, first seek medical treatment by calling 911 or contacting your medical provider.

The sponsor of the study, Group K Diagnostics, Inc will pay the cost of medical expenses for the treatment of a study-related injury if your injury is a direct result of your participation in the study and you have properly followed all study required procedures. Adverse events, illnesses, or complications associated with the study procedure as outlined in the risk section of this document are not considered study-related injuries. The sponsor will not pay for treatment if your injury is the result of procedures that would have been performed for routine care if you were not participating in the study.

You will not be paid for losses, damages, lost wages, or discomfort resulting from any injury incurred as a result of your participation. By signing this form, you are not giving up any of your legal rights, including the right to seek compensation to which you might be entitled under the law.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Whom to contact about this study?
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Principal Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures.

Please contact the Principal Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00064273.

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

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. You will receive a signed copy of this consent form.

Printed Participant Name	
Participant's Signature	Date (Mo/Day/Yr.) Time
Printed Name of Person Obtaining Consent	
Signature of Person Obtaining Consent	Date (Mo/Day/Yr.)
Printed Name of Witness #1 **(Above line must be filled in, or write N/A)**	
Signature of Witness #1 **(Above line must be filled in, or write N/A)**	Date (Mo/Day/Yr.)