Official Title: Fast Antibiotic Susceptibility Testing for Gram Negative Bacteremia Trial (FAST)

NCT: NCT06174649

IRB Document Date: June 22, 2022

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Title of Study	Fast antibiotic susceptibility testing for Gram-negative bacteremia trial (FAST).
Protocol Number	20-0021
Sponsor	Antibacterial Resistance Leadership Group (ARLG) Duke University 2200 W Main Street Suite 710, Durham, NC 27708
Principal Investigator (study doctor):	_____
Site name and address:	_____ _____ _____
Site's Data Protection Officer (DPO) (where this figure is available):	_____

1 WHY HAVE I BEEN GIVEN THIS FORM?

This Informed Consent Form is for use in a research study that may include patients who do not have the legal capacity or ability to consent to joining the study. When reading this form, please note that the words "you" and "your" refer to the person in the study rather than to a legally authorized representative or responsible person who might sign this form on behalf of the person in the study. If you are a legal representative or responsible person giving consent for your family member (or the person you are legally authorized to represent) to join, "you" and "your" should be read as referring to your family member or the person you are legally authorized to represent.

You have been informed by your medical doctor of your positive blood culture (bacteria identified in your blood) for Gram-negative bacteria (GNB) during your hospitalization. You are being invited to take part in the "Fast Antibiotic Susceptibility Testing for Gram-Negative Bacteremia (FAST)" clinical research study. This study will compare health outcomes in people with infections who have blood samples tested using the Reveal™ technology or your hospital's usual testing method called "standard of care" or SOC. Reveal™ can provide rapid antimicrobial susceptibility test (AST) results, which means it can quickly provide information about whether a bacteria can be killed by a panel of antimicrobials (drugs that kill bacteria and other germs).

The random selection of the blood test to be used, SOC or Reveal+SOC, and the testing of your blood sample, have already been carried out, and this is a request for your consent to include data from your medical records in the analysis of the 2 test methods.

The clinical research study is being sponsored by the Antibacterial Resistance Leadership Group (ARLG) ("the Sponsor"). The sponsor has signed a contract with the Hospital Management, which includes paying the hospital and investigator for performing this study.

The study has been approved by the responsible Ethics Committees according to the legislation on 3 July 2007, Law 14/2007 on biomedical research.

Reveal™ uses a sensor technology to detect the growth of bacteria and provides results in about 5 hours. This is faster than the several days it takes to get results using the SOC testing method. Reveal™ is approved for use in the European

Union. The study will be conducted in countries where it is approved for use and will be implemented for its approved indication and according to the manufacturer's instructions.

Before you decide if you want to take part in this study, it is important for you to understand,

- why the research is being done,
- what the study will involve,
- the possible benefits, risks, and discomforts for you when you take part in this study, and
- how your information will be used

If there is anything you do not understand or if you would like more information, please ask the study doctor or study staff. You may also discuss the study with family members, friends, and your own doctor if you wish. If you decide that you want to take part in this study, you will be asked to sign below the statement at the end of this form. You will be given a copy of this form to take home with you.

2 DO I HAVE TO TAKE PART?

It is up to you to decide if you want to take part in this study. Even if you choose not to take part in this study, you will not be disadvantaged in any way; you will receive all medical treatment and care that you have the right to receive. If you choose to take part, you may change your mind and leave the study at any time for any reason. You will not need to explain your reasons for leaving the study. If you do leave the study, there will not be any penalty or loss of benefits about your future care.

Your participation in the study may be stopped at any time by the study doctor or the Sponsor (for medical or business reasons), regulators, or ethics groups. Ethics groups make sure that your rights are not violated. The reason(s) for stopping the study will be explained to you, and you will be given advice about continued care for your condition, if this is proper.

If you decide not to be in the study, you will still get the SOC for your medical situation. After deciding not to be in the study, no further data will be collected from you, however, the limited data that already have been collected will still be kept.

3 WHAT IS THE STUDY ABOUT?

The main purpose of this study is to find out whether use of a rapid AST improves participants' health compared to use of SOC AST methods. In other words, the purpose of the study is not to test whether Reveal™ technology works but to determine if the use of this method adds value to patient care.

This study will also find out:

- Whether there are differences in outcome and antibiotic use for participants whose blood samples were tested using Reveal™ compared with SOC methods.
- Discrepancies between Reveal™ and SOC methods.

After your blood sample was determined to have GNB by SOC methods, you were assigned by a computer to either the Reveal™ group, or the Control (SOC) group, the assignment to one group or the other is completely by chance. There is a one in two chance of being assigned to either group, like flipping a coin. Each of the two groups will either get standard bacterial culture and AST, or, Reveal™ testing plus standard culture and AST. Your study doctor will not know which group your sample is in, so the starting choice of antibiotic will not be affected by which group your sample is assigned to. Once Reveal™ and SOC results become available, a dedicated team of clinicians (Antimicrobial Stewardship Group) in your hospital will make antibiotic treatment suggestions to your doctors based on the results. Your study doctors may or may not decide to change your medicines based on the Reveal™ or SOC results. This information will be collected through your medical records by the study staff and will be used to determine whether the use of Reveal™ can improve your health.

You will be one of about 900 participants in this study at about 10 study centers around the world. You will be in the study for about 30 days, and the total length of the study will be about 48 months.

You will not be able to take part in this study if you have any condition(s) that disqualify you from being in this study. The study doctor will determine your eligibility and will let you know if you have any condition(s) that will stop you from taking part in this study.

4 WHAT WILL HAPPEN TO ME DURING THE STUDY?

The study does not involve direct interaction with you, and study related analyses will only be done on the blood sample taken for blood testing as part of the SOC. This means that all health data collected about you will be part of regular health care that you would have gotten anyway.

4.1 Study Procedures and Schedule

For this study, all information (measurement and assessment results) will be taken from your medical records. Your Study Doctor may need to contact and obtain previous medical history or data from your other treating physician(s). This is done for your own safety. After it was determined that your blood sample contained GNB, it was assigned to either the SOC+Reveal™ group, or the SOC group. Below are the steps that will be taken during the study:

Activity	Screening	Enrollment/baseline (Day 0)	Data Collection up to 30 Days
Record date and time of blood test results	x[2]		
Find out whether you are eligible to be in the study	x		
Randomization		x	
Perform AST based on assigned group		x	
Record demographics[1]		x[2]	
Record medical history		x[2]	
Record the severity of your illness		x[2]	
Record whether you are on comfort care		x[2]	
Record details of antibiotics you get		x[2]	x[2]
Record admission information		x[2]	
Record bacteria information and type of infection			x[2]
Record results of AST			x[2]
Record suggestions for changes in your treatment			x[2]
Record the date you leave the hospital and how well you recovered			x[2]
Record whether or not you had to come back to the hospital			x[2]

[1] Data about you, such as your age, race, sex at birth, and ethnicity will be recorded
[2] Information is recorded from your medical record if you agree to participate in this study

4.2 Blood Tests

This study has used a blood sample collected for routine clinical care according to Laboratory practice. No additional blood will be drawn for this study. The existing blood sample has undergone standard bacterial culture and AST. For participants assigned to the Reveal™ group, the sample has also undergone Reveal™ rapid AST.

5 WHAT WILL I HAVE TO DO DURING THE STUDY?

If you choose to take part in this study, you will need to sign this consent form. All of the other things needed for the study will be collected from your medical records. If you do not give your consent, your medical data will not be included in the study.

6 WHAT ARE THE POSSIBLE RISKS?

Results of this study may affect future treatment of people with GNB in their blood. As with all research studies, the study procedures may involve unknown risks.

6.1 Potential Risks

This study poses minimal risk to participants. This study will use the results of blood samples taken for health care purposes and does not include other blood draws. All participants randomized to the Reveal™ group will also have blood culture evaluation using SOC methods.

This study poses minimal risk of breach of privacy. Both the sponsor and the site shall ensure that the principles of data protection regulations, both national and European, are complied with. Only coded information will be taken, and the study will have things in place to protect your privacy. All participants will have antibiotic management overseen by a dedicated team in the hospital. Thus, your welfare will not be affected in any negative way by being in the study.

7 WHAT ARE THE POSSIBLE BENEFITS?

The Reveal™ test might quickly identify that the bacteria in your blood are resistant to certain antibiotics, and your medicines may be changed to better treat your infection. However, there may also be no direct benefit to you at this time. We hope that the results from this study will be used to assess a potential benefit and informed strategies to improve diagnostic testing for GNB bacteremia.

8 ARE THERE ALTERNATIVE TREATMENTS?

You do not have to be in this study to get treatment for your infection. Evaluation of your medical condition will use local SOC methods to determine the best treatment for your infection.

9 WILL I INCUR ANY EXPENSES OR GET ANY PAYMENTS?

You will not be charged for being in this study or paid for your participation or future commercial profits from this research.

Your participation in this study will not entail any different additional costs from those associated to your usual treatment. Your routine care should be paid by the Social Security, by your medical insurance company or by you in private sites. If you need any additional medical care or tests which are not part of the study but needed for your regular healthcare, you may have to pay for these if they are not covered by your government's health plan or your private insurance.

10 WHAT IF I AM INJURED DURING THE STUDY?

The study will use the blood sample that was collected before you were eligible for the study. No new blood will be drawn as a part of your research participation. No injury is expected as a result of being in this study.

We inform you that it is possible that your participation in this study may modify the general and particular conditions (coverage) of your insurance policies (life, health, accident, etc.). Therefore, we recommend that you contact your insurer to determine whether your participation in this study will affect your existing insurance policy.

11 WHAT WILL HAPPEN IF THERE IS ANY NEW INFORMATION?

The study doctor or his/her staff will tell you in a timely manner if any new information becomes available which may influence your decision to stay in this research study.

12 WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

This section will give you additional information about and explain your rights under the General Data Protection Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on Personal Data Protection (GDPR) and the current in force Spanish Personal Data Protection laws (Spanish Organic Law 3/2018 of 5 December on the Protection of Personal Data and the Guarantee of Digital Rights.

According to GDPR, the processing of your personal information is carried out under the responsibility of the Site and the Sponsor, both acting as Data Controllers.

Data collection is the responsibility of the study staff at the site under the supervision of the site study doctor. During the study, the study doctor must keep complete and accurate documentation for the study.

By signing this form, you consent to the study doctor and study staff collecting and using your personal and study data for the study. These data include:

- Personal data including demographics, medical history, blood bacteria identification and AST, hospitalization records, and antibiotic treatment
- Study data and things about you including results from the tests and examinations performed during this study

The study protocol, documentation, data, and all other information generated by this study will be kept in a secure and confidential manner. Access to the database with your study information will be limited to study personnel who are issued a unique user identification and password. Study personnel will enter data at each site. No information about the study or the data will be released to any third party without prior written approval of the Sponsor.

The data shared with the Sponsor is protected using a code specifically assigned to you. The study doctor is in control of the code needed to connect your personal data to you.

All data that identify you by name will be kept private and will not be made publicly available. This means that such data will be kept in locked files, or electronic files with proper levels of security. Only staff with proper approvals will be able see or refer to these files. However, the study doctor, the personnel approved by the Sponsor and its representatives, and, under certain circumstances, the regulators and members of the ethics groups will be able to inspect private data that identify you by name. This will be done without violating your privacy to the extent permitted by the applicable laws and rules.

By signing this consent form, you allow permission for personal data and medical information about you (your study data) to be made available to authorized or approved regulators and government agencies. You also give permission for your personal data to be made available to the Sponsor auditors, the study monitor and other study personnel, and ethics groups. At the end of the study, a copy of the database with personal things about you (such as your name) removed will be stored for future use.

Your coded data and study data may be sent to other countries since some of the people who will look at your data are based outside of your country. When your personal data is sent to another country, it is either controlled by other government data privacy authorities or by the Sponsor's rules which have been approved by data privacy authorities. Personal things about you will still be kept completely private, no matter which country it goes to, even if that country does not have the same level of protection for personal things about you as does your country. All data recipients will sign/agree to a Data Transfer Agreement or equivalent terms of use agreement in which they agree not to attempt to re-identify research participants.

The study records will be saved per local or national rules. At a minimum, study records and documents about this study will be kept for at least 6 years after final reporting and/or publication of the results.

The data collected during this study, including your personal data, may also be used by the Sponsor or other researchers to answer questions related to the study. The Sponsor will protect your information and will only use and share coded data for such research.

Your coded data may be used by the Sponsor or others for administrative purposes. For example, such coded data may be used to track the overall progress of this study. Your data may also be stripped of any information that could be used to identify you or combined with other data by the Sponsor or others as part of their efforts to protect personal things about you.

Appropriate protective measures shall be taken to protect the coded data during and after the trial, including:

- Access to coded data will be limited to persons subject to confidentiality obligations (including the obligation not to attempt to re-identify patients or decode clinical data).
- Coded data shall be protected by security measures to prevent alteration, loss and unauthorised access and additional measures may be applied to prevent identification.
- A data protection impact assessment will be applied to identify and mitigate potential privacy risks, if any, associated with each scientific research.
- Coded data will not be shared for direct marketing purposes or for other purposes that are not legal obligations or are not considered scientific research in accordance with current data protection legislation. In particular, it will not be used to make decisions about future services that may be offered to you, such as insurance.

If you take back your consent for being in this study, your personal and study data that were collected before you took back your consent may still be used, but the Study Doctor will not be able to continue obtaining new Study Data of you or provide it to others except the data needed for safety follow-up. Once you have taken back your consent for being in the study, no further data will be collected about you unless you agree otherwise, for example, if you agree to have further tests and examinations. If you do agree to have further data collected after you have taken back your consent, these study data may also be used. By signing this consent, you agree that if you decide to leave the study, your medical data (and samples) collected prior to leaving may still be used along with other data collected as part of the study. If you prefer that your samples be destroyed, you must notify your study doctor in writing.

With respect to your data, you have the following rights that you may exercise with the principal investigator and/or site:

- You can ask at any time what data is being stored (right of access), who is using it and for what purpose; you can request a copy of your personal data for your own use.
- You may request to receive a copy of the personal data provided by you in order to transmit it to other persons (portability).
- You can correct personal data provided by you and limit the use of data that is incorrect (right of correction and deletion).
- You can object to or restrict the use of your personal data (right of objection).

With regard to your rights over your personal data, we remind you that there are some limitations in order to ensure the validity of the research and to comply with the legal duties of the sponsor and drug authorisation requirements. If you decide to stop participating in the trial or withdraw your consent to the processing of your data, the data collected up to that point may not be deleted. You should be aware that withdrawing consent to the processing of your data may result in your termination of participation in the trial. If you wish to make a request, you can contact Duke's Data Protection Officer at privacy@duke.edu.

Besides, if you have questions about your rights as a research participant, you should contact the data protection officer of the site, listed in the first page of this document.

The results of this study may be published in a medical journal and shown at medical meetings. You will not be identified (by name or any other means, for example, a photo) in any of these publications. Researchers might ask to use information from this study, including your coded data, for other related research. The researchers may combine the results from this study with results from other studies. If the Sponsor lets them have your personal data, the Sponsor will make sure that they cannot find out who you are and that such research is in line with this document.

You may have a right to object to the use of your personal data for this other research. If you wish to object to such use, please contact your study doctor.

A description of this study will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

13 WHAT IF I HAVE QUESTIONS?

If you have questions about the study, or have a problem related to the study, you may contact the study doctor or his/her staff at the telephone number below.

Dr._____

Telephone Number: _____

INFORMED CONSENT FORM

Study Title:	Fast antibiotic susceptibility testing for Gram-negative bacteremia trial (FAST)
Protocol Number:	20-0021

I confirm that:

- I have received verbal information on the above study and have read the attached written information. I have been given the chance to discuss the study and ask questions and all of my questions have been answered to my satisfaction.
- I voluntarily consent to join in this study, including all evaluations, lifestyle, and restrictions requirements.
- I understand that I am free to leave the study at any time. I understand that if I choose to not join or to leave the study, my current medical care will not be affected by this decision.
- I agree that my primary doctor may be told of my participation in this study.
- I agree that my primary doctor may be asked to give information about my medical history.
- I agree that my personal data, including data relating to my physical or mental health or condition may be used as described in this consent form.
- I agree and authorize that my coded personal data may be transferred within and outside to countries, where personal data may not have the same level of statutory protection as in my country.
- I agree and authorize that samples collected from me for the purposes described in this consent form will be processed in coded form within and outside my country, where personal data may not have the same level of statutory protection as in my country, by the Sponsor, its affiliates, representatives and collaborators for scientific and regulatory purposes and that these samples will not be stored after completion of AST.
- I understand that I will get and may keep a copy of this signed and dated consent form.

By signing and dating this consent form, I have not given up any of the legal rights that I would have if I were not a participant in a medical research study.

Signature of Participant *(Please date your own signature at the time of signing)*	Date (mm/dd/yyyy)	Printed Name of Participant
Signature of Witness (if applicable) *(Please date your own signature at the time of signing)*	Date (mm/dd/yyyy)	Printed Name of Witness
Signature of Legally Acceptable Representative (if applicable) (*Please date your own signature at the time of signing*)	Date (mm/dd/yyyy)	Relationship with Patient and Printed Name of Legally Acceptable Representative

STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION

I, the undersigned, certify that to the best of my knowledge, the participant signing this consent form had the study fully and carefully explained and clearly understands the nature, risks, and benefits of participation in this research study.

Signature of Investigator (Study Doctor) *(Please date your own signature at the time of signing)*	Date (mm/dd/yyyy)	Printed Name of Investigator (Study Doctor)