THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Informed Consent for Participation in a Research Study

Title of Research Study: Urgent Care Management of Respiratory Illness Enabled with Novel Testing Pathway (URGENT): A Randomized Control Trial of Respiratory PCR versus Standard Care

Investigator: Dr. Andrew Meltzer, Department of Emergency Medicine

Investigator Contact Information: 202-741-2952

Study Coordinator: Seamus Moran, B.S.

Study Coordinator Contact Information*: *202-677-6425

KEY INFORMATION:

You (or your child) are being asked to voluntarily participate in a research study This page will give you (or your child) key information to help you decide whether or not you (or your child) want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process and use the contact information on this form to ask questions later. You do not have to participate in this study. If you choose to participate, you (or your child) will have a nasal swab performed and will complete two follow up satisfaction calls, the first of which will be completed today, shortly after discharge from the clinic and the second, 7-days from enrollment by our research team. Participants randomized to the Biofire group will receive their results on the same day as enrollment in person or via follow up phone call after discharge from the clinic. Results take 45 to 60 minutes. Other participants will receive their results per standard turn-around time. Additionally, patients will be contacted in one week (day-7) to evaluate the course of symptoms, assess patient satisfaction, and to assess other relevant medical information. Participation in this study could offer future clinical benefit for those with respiratory illness symptoms. Participation in this study has the potential for accidental disclosure of confidential information and discomfort associated with the nasal swab.

Why am I being invited to take part in a research study?

We invite you (or your child) to take part in a research study because you (or your child) have come into the urgent care clinic with self-reported symptoms that may be related to an upper respiratory illness.

What should I know about a research study?

- Someone will explain this research study to you (or your child). You (or your child) may ask all the questions you (or your child) want before you (or your child) decide whether to participate.
- Participation is voluntary; whether or not you (or your child) take part is up to you (or your child).

- You (or your child) can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you (or your child).

- Your decision will not affect the medical care you (or your child) receive from GW. If you (or your child) decide not to take part, you (or your child) can still receive medical care from GW.
- You (or your child) may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study.

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you (or your child). At most, the website will include a summary of the results. You (or your child) can search this website at any time.

Who can I talk to if I have questions?

If you (or your child) have questions, concerns, or complaints, or think the research has hurt you (or your child), talk to the Principal Investigator at ***202-445-7044***

This research is being overseen by an Institutional Review Board ("IRB"). You (or your child) may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You (or your child) have questions, concerns, or complaints that are not being answered by the research team or if you (or your child) wish to talk to someone independent of the research team.
- You (or your child) have questions about your rights as a research subject.

Why is this research being done?

This research study will test a laboratory test called the BioFire® Respiratory 2.1-EZ Panel. The RP EZ 2.1 panel has been approved under Emergency Use Authorization (EUA) by the FDA. This lab test can identify the bacteria or virus that may be causing your symptoms. This test will enable the urgent care provider to better understand the cause of your symptoms to try to determine the best treatment. The primary goal of this study is to determine if testing urgent care patients who complain of upper respiratory illness symptoms will lead to improved patient and provider satisfaction and more optimal treatment strategies.

How long will I be in the study?

We expect that you (or your child) will be in this research study for 7 days. This includes 2 follow up phone calls.

How many people will take part in this research study?

We expect about 360 people will take part in the entire study.

What happens if I agree to be in this research?

Once you (or your child) have agreed to participate in this research study a trained member of our study team will swab the inside of your nose. Before you (or your child) provide the nasal swab, you (or your child) will be randomized to one of two groups. This means that the group you (or your child) are in will be determined by chance, kind of like flipping a coin. You (or your child) will know which group you (or your child) are assigned. If you are randomized to the experimental arm, you will be tested with Biofire RP EZ panel which leads to a result in 45-minutes to one hour. If you are

randomized to the standard of care arm, you will receive your results once they have been processed by LabCorp. Both the provider and the patient will receive the results of the testing as soon as possible on the same day as enrollment. If the patient has been discharged by the time of result, the patient will receive the results via phone-call on the day of enrollment.

Group One receives usual care per treating urgent care clinician. Usual care will include a COVID-19 PCR test. The course of usual care will be ordered at your treating physician's discretion. Group One will receive their test results when processed by LabCorp. LabCorp is a well-established company for reliable lab testing, whom your providers use for their off-site testing.

Group Two will have their nose swab collected in triage (or as soon as possible). BioFire® Respiratory 2.1-EZ Panel test will be performed as soon as possible and the results will be communicated to treating urgent care clinician. In addition, this group will still receive usual care per treating urgent clinician. Group Two will receive the test results likely at the follow-up call completed at Day 0.

The research team will gather the following information from you (or your child) or from your health care record. This will take about 15-20 minutes:

- Vaccination status
- Insurance status
- Pre-existing medical conditions
- Current symptomatology
- Surgical History
- Final Diagnosis
- Contact Information to complete follow-up calls and mail your gift card after study completion

Once you (or your child) are discharged from the clinic, the research coordinator will contact you (or your child) for a follow up call on Day 0 and Day 7 following your urgent care visit. These calls will consist of a short questionnaire relating to course of symptoms, additional medical care you (or your child) received and other relevant medical information. These calls will take about 15-20 minutes. In case the research coordinator is unable to reach you (or your child), the research coordinator will call the emergency contact listed on your patient information form to inquire about follow-up and/or your new contact information.

What are my responsibilities if I take part in this research?

If you (or your child) take part in this research, you (or your child) will be responsible to provide a nasal swab and complete the two follow up calls on Day 1 and Day 7 following your urgent care visit.

What other choices do I have besides taking part in the research?

You (or your child) do not have to agree to be in this study to be treated for your upper respiratory symptoms. Your alternative is to not be in this study.

What happens if I agree to be in research, but later change my mind?

You (or your child) may refuse to participate or you (or your child) may discontinue your participation at any time without penalty or loss of benefits to which you (or your child) would otherwise be entitled. This will not have no effect on your healthcare treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you (or your child) do not

give permission to use your Protected Health Information (PHI), you (or your child) may not take part in this study because your PHI is needed in order to conduct the study.

However, you (or your child) may cancel this authorization at any time. Even if you (or your child) cancel this authorization, the researchers may still use the protected health information they already have collected about you (or your child). However, no new PHI will be collected from you (or your child) after you (or your child) cancel your permission

Is there any way being in this study could be bad for me?

The risks and discomforts associated with participation in this study are not greater than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests.

There are limited physical risks associated with participation in this study. This laboratory test, BioFire® Respiratory 2.1-EZ Panel test, is a test that is already available for clinicians to order in for patients within the emergency department setting.

There is a low risk that information that we collect about you (or your child) in this study may be seen by people who are not on the study team. To prevent loss of confidentiality, all data will be encrypted and no identifiable information about you (or your child) will be stored with data. "The personally identifiable information collected from your medical record will be coded using a unique ID number. The coded lists are only accessible to the research team. The information that has your personally identifiable information will be kept separately from the rest of your data and will be destroyed following study completion. All study documents both electronic and hard copy will be either locked in file drawers in the study coordinator's office or on password-protected computers.

You (or your child) and your insurance company will be charged for the health care services that you (or your child) would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You (or your child) should check with your insurance to see what services will be covered by your insurance and what you (or your child) will be responsible to pay.

Finally, there is a risk of physical discomfort associated with the nasal swab. However, staff are well-trained and will attempt to minimize physical discomfort as much as possible.

What happens if I believe I am injured because I took part in this study?

The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you (or your child) still may experience medical complications or side effects from participating in this study. You (or your child) should promptly notify the study doctor in the event of any illness or injury as a result of being in the study.

If you (or your child) believe that you (or your child) have been injured or have become ill from taking part in this study, you (or your child) should seek medical treatment from GWU Hospital and/or the

GWU MFA or through your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you (or your child) or your insurance company.

You (or your child) will not receive any financial payments from Biofire Diagnostics LLC, GWU, GWU Hospital and/or the GWU MFA for any injuries or illnesses. You (or your child) do not waive any liability rights for personal injury by signing this form.

Will being in this study help me in any way?

You (or your child) will not receive any direct benefits from participating in this research. The information form this research study may lead to a better standard of care in the future for people with upper respiratory illness symptoms.

Can I be removed from the research without my permission?

The person in charge of the research study or the sponsor can remove you (or your child) from the research study without your approval. Possible reasons for removal include

1. The study doctor thinks it is necessary for your health or safety
2. You (or your child) do not follow study protocol.
3. Administrative reasons require your withdrawal.
4. Bio Fire Diagnostics LLC has stopped payments to support the study.

We will tell you (or your child) about any new information that may affect your health, welfare, or choice to stay in the research.

What happens to my information collected for the research?

If you (or your child) are in this study, your medical records may become part of this research. They may be seen by a number of other people or groups associated with the study. We will be collecting information about medical procedures performed and discharge information.

Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be limited to research study personnel.

Except as required by law, name, social security number, address, telephone number, or any other direct personal identifier will not identify you (or your child). The results of this research study may be presented at a scientific or medical meeting or published in scientific journals. However, your identity will not be disclosed.

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of your health information. This section tells you (or your child) about your rights regarding your health information. You (or your child) are free to not allow these uses. If you (or your child) do that though, you (or your child) cannot participate in the study.

Protected Health Information (PHI) that may be used and released (disclosed) in this study includes information such as:

- This consent form

- Demographic information (age, sex)
- Information about your medical history from your medical records (medications, past medical history, social history, vital signs)
- Results of physical examination
- Admission and discharge information
- Health care expenses (the cost of standard work-up)
- Questionnaires that you (or your child) complete
- Laboratory Results (results of BioFire® Respiratory 2.1-EZ Panel test and other tests ordered)

By signing this form, you (or your child) allow the use, sharing, copying and release of your medical records to carry out the study by your healthcare providers and by the study doctor and his research team. By signing this form, you (or your child) agree to be potentially contacted by our research team for participation in other studies in our department.

You (or your child) also allow the study doctor and the research team to release your health information to:

- GWU Institutional Review Board (the "IRB") to ensure protection of the rights of research subjects
- Office of Human Research at GWU to ensure safety in research
- Accrediting agencies and GWU legal counsel
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care.
- Bio Fire Diagnostics LLC. Any data that is released to Bio Fire will be de-identified, i.e. name and contact info will be removed.
- Food and Drug Administration (FDA)

You (or your child) may request to review or have a copy of your medical record collected during this study. This right to review and copy your PHI only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

Your data will be treated confidentially to the extent permitted by applicable laws and regulations. Once your health information from this study is used or released as explained in this section, it is no longer protected by the Privacy Rule.

By signing this form, you (or your child) authorize the Study Doctor and members of the research team to use

health information which will be shared and protected. By signing this form, you (or your child) are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form. To cancel your authorization, you will need to send a letter to your study doctor. This letter must be signed and dated and sent to this address:

Dr. Andrew Meltzer
2120 L Street NW
Suite 450
Washington, DC 20037

The use and release of protected health information is for the purpose of collecting data for this study.

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:

Hospitals, clinics, health care providers, and health plans that provide health care to you (or your child) during the study

By signing this form, you (or your child) allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team;
- Other healthcare providers such as labs which are part of the study;
- Institutional officials who are responsible for compliance;

Some of the tests in this study may have been done as part of your regular care. These test results will be used both to treat you (or your child) and to complete this research. The test results will be recorded in your medical record. Patients who test positive for certain conditions, such as COVID-19 and Pertussis will have their results reported to local public health department per standard protocols. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your medical record.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you (or your child) do not give permission to use your health information, you (or your child) may not take part in this study because your health information is needed in order to conduct this study.

Are there any costs for participating in this research?

There are no charges for your participation. Neither you (or your child) nor your insurance will be billed. Standard of Care procedures will be billed in the usual manner.

Will I be paid for my participation in this research?

If you (or your child) agree to take part in this research study, we will pay you (or your child) $20 for your time and effort. This gift card will be mailed following study completion.

What else do I need to know?

This research is being funded by Biofire Diagnostics LLC.

Signature Block for Adult

By signing below, you (or your child) agree that the above information has been explained to you (or your child) and you (or your child) have had the opportunity to ask questions. You (or your child) understand that you (or your child) may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. Your signature documents your permission to take part in this research.

_____

Printed name of subject

_____ _____

Signature of subject Date

_____ _____

Signature of person obtaining consent Date

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____ _____

Signature of witness to consent process Date