Title of research study:

Pilot Randomized clinical trial of multi-respiratory pathogen testing versus standard of care in emergency department (ED) patients with symptoms of upper respiratory infection

Investigators:

Larissa May, MD, MSPH

A Special Note About Wording in this Document:

In this document, the word "you" refers to you or your minor child, whoever is being considered for enrollment into this study.

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

We invite you to take part in a research study because you are a patient at the UC Davis Medical Center Hospital Emergency Department (ED) who is being evaluated for a influenza (flu)-like illness or upper respiratory infection.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a copy of this document.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 916-734-5010.

For 24 hour non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to the attending physician in Pod D. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-admin/.You may talk to a IRB staff member at (916) 703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

The BioFire FilmArray is a new test that can detect different kinds of viruses and bacteria in people with respiratory infections. The study will find out if test results can decrease the number of patients who receive unnecessary antibiotics to treat their respiratory infection.

How long will the research last?

We expect that you will be in this research study for the time you are in the ED. After your discharge, we will evaluate your treatment and whether having the additional test result made a difference.

How many people will be studied?

We expect about 325 people will be in this research study.

What happens if I say yes, I want to be in this research?

If you consent to participating in this research, you will be randomly selected to receive one of two treatment options: standard of care (a treatment plan that the majority of the medical community would accept as appropriate) *and* the new test, or standard of care by itself.

The treatment option you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of getting the new test or not. If you are one of the patients randomly selected to receive the new test, you will have a cotton swab collected from your nose. The doctor or nurse will insert the swab about 3 inches into your nose to collect the specimen properly. The swab sample will be tested on the BioFire FilmArray Respiratory device and results will be reported to your physician in the ED within 2 hours. The test will be performed once and will be ordered shortly after you sign this document. Treating Physicians will to use the test result to help determine your best treatment.

If you are randomly selected for the second group, you will not be tested by the BioFire FilmArray Respiratory device and you will receive standard of care as ordered by your treating physician.

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

If you take part in this research, you will be responsible to provide consent to having a swab collected from your nose and tested by the BioFire Film Array Respiratory Panel.

What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. After withdrawing from this study, research personnel will discard your remnant swab sample and are no longer able to obtain new information about you and your health. However, researchers may still use and disclose protected health information they already have obtained about you as necessary to maintain the integrity or reliability of the research.

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

There is no significant risk to you as a patient in this study. The swab collection is brief but can be uncomfortable, and may cause you to sneeze or to have a small nosebleed. There is also a slight risk of loss of confidentiality due to the need to record and store personal health information. Every effort will be made to ensure that we only collect the minimum information about you that is needed for the study. At the completion of data entry and analysis, all of the identifying information will be removed from the data (de-identified) and only combined data will be reported.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved treatment and decreased length of stay in the hospital. General benefits to the public resulting from this study may include improved clinical and public health outcomes.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

During your participation in this research, data will be collected about you. The data and any specimens, such as the swab, that are taken from you for this study, will become the property of the University of California. The specimens may be used in this research, may be used in other research, and may be shared with other organizations. The specimens could lead to discoveries or inventions that may be of value to the University of California or to other organizations. Under state law you do not have any right to money or other compensation stemming from products that may be developed from the specimens.

If you agree to share the biological specimen(s) collected from you, please initial here. _____

Otherwise, your specimen will be destroyed at the end of this study.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your research records to conduct and oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If

that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

What else do I need to know?

This research is being funded by BioFire Diagnostics, Inc., also called the sponsor. Sponsors may change or be added. Dr. May, the Principal Investigator for this study, has received a consulting fee on two occasions from BioFire. These payments are in addition to the salary that Dr. May receives from the University of California.

UC Davis is being paid to conduct this study, but the research staff, aside from Dr. May as described above, have not received any direct income from the sponsor.

You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered. Only the costs of research or experimental procedures will be paid by the study including the BioFire FilmArray test, if applicable**.**

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

You will not be compensated for taking part in this study.

The results of this study, including specimens collected, may have commercial value to the sponsors, UC Davis, and/or the researchers. You will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected. You will receive results of all of the laboratory testing related to this study by your treating physician in the same manner other test results will be reported back to you during your visit.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

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
Printed name of person witnessing consent process	

For IRB Use

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
894097	March 23, 2018

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject

Signature of legally authorized representative | Date

Printed name of legally authorized representative

Signature of person obtaining consent | Date

Printed name of person obtaining consent

Assent

☐ Obtained
☐ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

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

Printed name of person witnessing consent process

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Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

☐ Parent

☐ Individual legally authorized to consent to the child's general medical care (See note below)

Printed name of parent or individual legally authorized to consent to the child's general medical care

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

☐ The IRB determined that the permission of one parent is sufficient.

☐ Second parent is deceased

☐ Second parent is unknown

☐ Second parent is incompetent

☐ Second parent is not reasonably available

☐ Only one parent has legal responsibility for the care and custody of the child

Assent

☐ Obtained

☐ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

☐ Waived by the IRB because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent

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

Printed name of person witnessing consent process

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