# Evaluation of the MeMed BV® Test in Adult Emergency Department Patients With Fever and Acute Respiratory Symptoms

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# University of Wisconsin-Madison
# Consent to Participate in Research
# and
# Authorization to Use Protected Health Information for Research

**Title of Study:** Evaluation of the MeMed BV® Test in Adult Emergency Department Patients with Fever and Acute Respiratory Symptoms

**Lead Researcher:** Michael Pulia, MD, PhD

**Where Lead Researcher works:** BerbeeWalsh Department of Emergency Medicine in the University of Wisconsin Madison School of Medicine and Public Health

## Invitation

We invite you to take part in a research study that is looking to see if a blood test called the MeMed BV® would be useful for UW doctors to diagnose respiratory infections. The MeMed BV® may help doctors tell the difference between viral and bacterial respiratory infections which would help doctors determine the best treatment for your illness. We are inviting you because you are 18 years of age or older and you came to the Emergency Department today with signs or symptoms of a respiratory infection, and you have had a fever in the last 7 days.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

This study includes the enrollment of subjects with impaired decision making capacity. In cases where a subjects is determined to lack consent capacity, the subject will be asked to provide their assent, and a surrogate (or legally authorized representative (LAR)) will be asked to provide consent. If you are serving as a LAR, please read references to “you” throughout this form as referring to the patient-subject.



IRB Approval Date: 1/19/2023
University of Wisconsin – Madison

## Why are researchers doing this study?

The purpose of this research study is to see if the MeMed BV® test would help healthcare providers correctly identify bacterial and viral respiratory infections. This research is being done because it is hard for providers to know what type of respiratory infections patients have. If we are able to show that the MeMed BV® test can help distinguish bacterial and viral infections, in the future providers may use the MeMed BV® test with respiratory infections.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about 200 people will participate in this study.

Funding for this study is provided by the BerbeeWalsh Department of Emergency Medicine in the University of Wisconsin-Madison School of Medicine and Public Health and the Gordon and Betty Moore Foundation in the National Academy of Sciences.

## What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to do the following study activities:

- Answer questions about infectious symptoms, antibiotic use and questions about swallowing. You may skip any questions that you do not wish to answer.

- Provide a sputum sample (cough hard to bring up material from lungs). The sputum sample will identify the bacteria in your lungs to see if it is related to swallowing and other health outcomes.

- Collect one 3.5 mL (approximately two teaspoons) blood tube which we will use to obtain a MeMed BV® test.

- Collect one 3.5 mL (approximately two teaspoons) blood tube if you are not already receiving laboratory testing as part of routine care. We will use the blood to obtain a c-reactive protein (CRP) and a procalcitonin which are infection biomarkers.

- Collect information from your medical records about who you are (demographics), past medical history, and clinical encounter variables about this visit.

- Collect information about emergency department, clinic or hospital visits that you have in the six months after you leave the hospital.

## How we will use your protected health information (PHI)

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researcher about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history, your diagnosis, lab test results, imaging results, medications given and prescribed. We will get this information from your health care providers such as UW Health.

## How long will I be in this study?

You will be part of the study starting today and lasting for six months from the day you get discharged from the Emergency Department. Your only study visit will occur today while you are in the Emergency Department and we anticipate it will take about 20 minutes. You are giving us permission to look at your medical records starting today and for the next six months.

## How is being in this study different from my regular health care?

If you take part in this study, the main difference between your regular care and the study is that you may have additional blood work like the MeMed BV® test, CRP and procalcitonin completed on your behalf. This study is not part of your health care; however, healthcare providers may suggest additional follow-up care based on the results that are entered into your medical record. The MeMed BV® test results will not be used to make treatment decisions or alter your treatment. You (or your insurance company) will be responsible for costs related to follow-up care.

## Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.

To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher,

Michael Pulia, MD, PhD
Department of Emergency Medicine
800 University Bay Drive,
Suite 310, Mailcode 9123
608-263-6690
mpulia-lab@medicine.wisc.edu

## Will being in this study help me in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about how to use the MeMed BV® test can differentiate between bacterial and viral respiratory infections.

This study is not a substitute for your regular medical care. You should continue to see your regular medical provider.

## Will I receive the results of research tests?

A medical record may be created for you if you do not already have one. Your medical record might say that you participated in this study, and a copy of this consent and authorization form might go in your medical record. CRP, procalcitonin, and sputum culture results will be released into your medical record. You should be able to access these medical results via MyChart. The results of the MeMed BV® test and your survey answers will not be released into your medical record, and you will not receive these results. If you have questions about the results or concerns about your health, contact your primary care provider. Both you and your UW Health providers will be able to see these results. You (or your insurance company) will be responsible for costs related to any follow-up care.

## What are the risks?

There is a risk that your information could become known to someone not involved in this study, which might make you uncomfortable.

Collecting venous blood may lead to bleeding, bruising, and rarely an infection.

Coughing hard during sputum sample collection may lead to some slight discomfort.

## Will being in this study cost me anything?

There will be no cost to you to participate in this study.

## Will I be paid or receive anything for being in this study?

We will pay you $25 for completion of study activities.

## What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular healthcare provider.
- Call the Lead Researcher, Michael Pulia, at 608-263-6690 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

## How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may require us to show information to university or government officials and to the National Academy of Sciences. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you or your legally authorized representative is authorizing this access to your records. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

## Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

## Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, National Academy of Sciences
- The U.S. Food and Drug Administration (FDA)

## Will information from this study go in my medical record?

- Some of the information we collect for this study will go in your medical record. This includes informed consent, CRP, procalcitonin and sputum culture results. Both you and your UW Health providers will be able to see these results.

- The following information from research procedures will NOT go in your medical records: results from MeMed BV® test and results from questionnaires.

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. At most, the website will include a summary of the results. You can search this website at any time.

## What if I have questions?

If you have questions about this research, please contact the lead researcher, Michael Pulia, MD, PhD, at 608-263-6690. If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

## Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the research team has answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Printed Name of [Participant]

_____

Signature of Research [Participant] Date and Time

If you are a Legally Authorized Representative (LAR) for the person being invited to take part in this study, you are deciding whether the person can be in this research study. You do not have to sign this form. If you refuse to sign, however, the person cannot take part in this research study. If you sign the line below, it means that:

- you believe the person wants, or would want, to be in the study;
- OR, if you cannot find out if the person wants to take part, you believe that participating in the study is in the person's best interest
- you give authorization for the person's protected health information to be used and shared as described in this form

As a legally authorized representative, I _____
(Printed Name of Legally Authorized Representative)

Authorize the participation of _____in this research study
(Print Name of Participant)

_____
Signature of Legally Authorized Representative Date & Time

Note: The legally authorized representative consent will only be obtained if it has been determined that the patient-subject lacks consent capacity.

Signature of Person Obtaining Consent and Authorization Date and Time

Are you willing to be contacted about future research? Yes ☐ No ☐
If yes, how do you prefer to be contacted?

Phone: _____ or Email: _____

****YOU WILL RECEIVE A COPY OF THIS FORM****