

SUMMARY OF RESULTS



The Antibacterial Resistance Leadership Group (ARLG) seeks to prioritize, design, and execute clinical research that will reduce the public health threat of antibacterial resistance. The ARLG, along with the team of study doctors, scientists, and research coordinators, are pleased to describe the results from the **Rapid Diagnostics in Categorizing Acute Lung Infections (RADICAL)** study.

We appreciate the time and commitment of the research participants who provided blood samples to the RADICAL study and, in doing so, played such an important role in advancing medical science.

WHY WAS THE RESEARCH NEEDED?

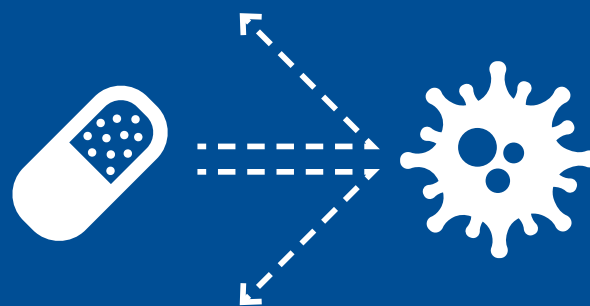
Antibiotics are drugs that treat infections caused by bacteria, but they do not work on viruses, such as colds and the flu. Taking antibiotics when you do not need them can be harmful to you. It can also create drug-resistant bacteria, which is a serious public health issue that can lead to antibiotics that do not work and increased health care costs.

Doctors could better know when to prescribe an antibiotic if they had an easy and quick way to diagnose whether it was a virus or bacteria that caused a patient's infection.

Although doctors can use laboratory tests to help identify what's causing the illness, these tests can be slow, inaccurate, and are often unavailable where patients receive care. Rather than trying to test for the presence of a virus or bacteria, the RADICAL study focuses on how patients respond to the infection. This is possible because, the body's immune responses to bacterial and viral infections are different. Specific genes are turned on or off depending on what type of infection you have. This is called gene expression, or gene activity, and measuring this can help doctors know whether the cause of infection is viral or bacterial.

The RADICAL study team collaborated with a company called BioFire to develop an automated, simplified test that would run on the BioFire FilmArray system. By measuring a patient's gene activity, this test could help doctors separate bacterial infections from viral infections accurately and quickly.

**DRUG-RESISTANT BACTERIA
ARE BACTERIA THAT ARE
NOT CONTROLLED OR KILLED
BY ANTIBIOTICS.**



**WHEN WAS THE
STUDY CONDUCTED?**



2014
The study began
in 2014 and
continues today.

WHO PROVIDED FUNDING FOR THIS STUDY?

The National Institute of Allergy and Infectious Diseases of the National Institutes of Health through the Antibacterial Resistance Leadership Group provided funding for this study.

WHO WAS INVOLVED?

The study used blood samples from 385 patients with suspected acute respiratory illness. Looking back at the medical records of these patients and following a detailed process to confirm the cause of their illness, researchers learned the following:

117

People had a bacterial infection

165

People had a viral infection

103

People had a noninfectious illness. This is an illness caused by something besides a virus or bacteria, such as another disease, smoking, or the environment.

WHAT HAPPENED DURING THE STUDY?

RADICAL researchers used special BioFire FilmArray pouches to test the gene activity of the blood samples to determine which type (viral, bacterial, or noninfectious) of illness the patients had.



WHAT DID RESEARCHERS LEARN FROM THE STUDY?

The study found that the RADICAL test on the FilmArray system is:

- Accurate—the test showed whether an infection was bacterial or viral with about 80% overall accuracy. This is far better than any other test currently available.
- Quick—results were returned in less than one hour.

This summary was completed on August 2018. Since this summary was written, newer information may exist.



HOW CAN THIS STUDY HELP PATIENTS AND RESEARCHERS?

Having a test available that will provide accurate and quick results to doctors about whether an illness is bacterial, viral, or noninfectious is of great benefit to patients, doctors, and the public. These results can help both patients and doctors make informed health care decisions that may lead to better use of antibiotics. Using antibiotics more appropriately not only helps the patient but also helps to decrease antibiotic resistance in the community.



WHERE CAN I LEARN MORE?

Visit: www.arlg.org



WHAT'S NEXT?

This was the first test of a simplified system that measures gene activity in patients with infection. Researchers are interested in conducting additional studies to understand how rapid results can be used to identify and treat different types of infection.

Of note, the tests used in the study have not been reviewed by regulatory agencies for in vitro (by culture) diagnostic use.

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