SUMMARY
OF RESULTS

MASTER-GC
Antibacterial Resistance Leadership Group

The Antibacterial Resistance Leadership Group (ARLG) funds, designs, and conducts clinical research that will help prevent, diagnose, and treat infections caused by bacteria that are resistant to antibiotics.

The ARLG, along with the team of doctors, scientists, and researchers who ran the study, are pleased to describe the results from a study testing for throat and rectal gonorrhea and chlamydia.

The ARLG appreciates the time and commitment of the research participants who provided samples to this study and, in doing so, played such an important role in advancing medical science.

WHAT IS THE STUDY TITLE?

Short title: Master Protocol - Gonorrhea and Chlamydia testing of Extragenital Specimens

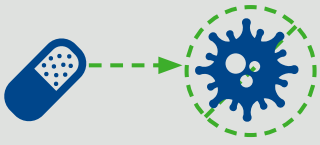
Long title: Performance of Nucleic Acid Amplification Tests for the Detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in Extragenital Sites (pNAAT)

WHAT IS THE PURPOSE OF THE RESEARCH?

The purpose of this study was to look at how well three different tests would work to diagnose gonorrhea and chlamydia in the throat and the rectum. These tests are currently approved to diagnose gonorrhea and chlamydia in the urinary and genital tracts.

The study tested samples from the throat and rectum on the three tests with the results being positive, negative, unclear, or no result. Researchers compared the results across tests to determine whether people were infected and the accuracy of the tests in detecting gonorrhea and chlamydia.

WHY IS THIS RESEARCH IMPORTANT?



Gonorrhea and chlamydia are infections transmitted sexually. It is important to be able to accurately diagnose and treat these infections as they can cause infertility, chronic pain in the pelvis, and increase the risk of HIV infection. It is also important to limit further spread to sexual partners to protect public health. Gonorrhea infections in the throat are particularly concerning because they can be resistant to antibiotics.

Before this study, there were no approved tests by the Food and Drug Administration (FDA) for detecting these infections in the throat and the rectum.

Improved detection of these infections will allow for better treatment and help to prevent the spread of resistant gonorrhea.

Changes to your healthcare should not be made based on information in this summary without first consulting a doctor. If you have questions about these results, speak with your doctor.

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WHO WAS INVOLVED?

Adult participants (18 or older) seeking sexually transmitted disease testing at nine clinics in seven U.S. states were asked to volunteer for the study. Participants could have had symptoms of infection or they could have been symptom-free. Overall, the study enrolled 2767 people, of whom 2598 were included in the study analysis.

WHEN DID THE RESEARCH TAKE PLACE?

December 2014 – March 2018

WHAT HAPPENED DURING THE STUDY?

- This study consisted of a single clinic visit. During this visit, participants were asked to allow their care provider to collect 4 swabs from their throat and 4 swabs from their rectum (8 total swabs). These swabs were then tested for gonorrhea and chlamydia using the three tests.
- Participants were also asked to provide their age, race, ethnicity, sex, gender, and to describe any symptoms of infection.
- 79% of participants were male (as assigned at birth) and the vast majority had no symptoms in both the throat (88%) and the rectum (91%). Half of the overall participants were white (49%) and 36% were black.
- Over 99% of the samples obtained from enrolled and eligible participants were evaluated. A small number of specimens had problems with collection or storage so were not included in the analysis. One participant was uncomfortable during the rectal swab collection and decided not to continue with the study.

WHAT DID RESEARCHERS LEARN FROM THIS STUDY?

For the detection of both gonorrhea and chlamydia, the three tests showed very good agreement when compared to a reference test.

HOW WILL THE RESULTS HELP PATIENTS AND DOCTORS?

The results led the FDA to approve tests for use in the diagnosis of gonorrhea and chlamydia in the throat and rectum, the first tests approved for this use.

WHAT'S NEXT?

This study used samples collected by medical professionals and did not evaluate self-collected methods, which are preferred in many settings and should be evaluated in future studies.

WHERE CAN I LEARN MORE?

Read published papers about at the study:

DOI:10.1093/cid/ciz1105

DOI:10.1016/j.jmoldx.2020.03.004

Read about the study on clinicaltrials.gov.

Visit the ARLG website.

This summary was completed in June 2020. Newer information generated since this summary was written may now exist.

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Research reported here was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number UM1AI104681. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

DCRI COMMUNICATIONS 22JUN2020

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