Meet our Committees
Diagnostics and Devices

Chair: Robin Patel

The ARLG scientific agenda focuses on four high priority areas: infections caused by gram-negative bacteria, infections caused by gram-positive bacteria, primarily MRSA and VRE, stewardship of our remaining antibiotics, and rapid diagnostics. The objective of the Diagnostics and Devices Committee is to develop and evaluate rapid diagnostics for antibacterial resistance to expedite clinical trials and to inform appropriate use of antibacterial therapy in clinical practice with a goal of providing meaningful improvements in patient outcomes and/or impact on antibacterial resistance.

The Diagnostics and Devices Committee is soliciting clinical studies to:

- Evaluate methods or platforms, which may include biomarkers or host-response markers to rapidly detect and identify bacterial pathogens and infections (e.g., sepsis, lower respiratory tract infection). Approaches may include simple and rapid point-of-care diagnostics to detect specific bacteria and associated antibacterial resistance, guide antibacterial therapy, and/or support clinical trials.

- Evaluate rapid, accurate methods for antimicrobial susceptibility testing of cultured bacteria.

The long-term objectives of the Diagnostics and Devices Committee are to identify, develop, and design studies to validate diagnostics that will enable early detection of drug resistant bacteria in clinical trials to facilitate the conduct of such studies, to determine whether novel diagnostics for bacterial infections improve patient outcomes, reduce antibacterial resistance and/or lower cost of care, and to examine whether precisely targeted antibacterial therapy based on novel diagnostics is better than traditional, empirical approaches.

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<th>Committee Member</th>
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<td>Robin Patel (Chair)</td>
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<td>Robert Bonomo</td>
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<td>Angela Caliendo</td>
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<td>Melissa Miller</td>
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<td>Christopher Woods</td>
<td>Duke University</td>
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A host-based mRNA classifier for differentiating viral and bacterial etiologies of acute respiratory tract infection (RADICAL)

Principal Investigator: Christopher W. Woods, MD, MPH

The aim of the protocol is to design an accessible, rapid, near patient diagnostic that provides a binary “viral vs. bacterial” classification with a high degree of fidelity has the potential to impact inappropriate antimicrobial prescribing practices.
The overall purpose of this study is to aid in the development of better diagnostic tools for infectious patients. The study will test samples from up to 800 subjects (300 banked specimens, 500 prospectively collected specimens) with suspected acute respiratory tract (ARI) infection in order to determine the underlying etiology, collect data and outcomes from all standard of care evaluations and treatments, and conduct a post-hoc analysis of the accuracy and analytical characteristics of the host-based diagnostic test as well as potential impact on prescribing practices. Current enrollment is at 309 subjects.

**ARLG Project Spotlight**

**SCOUT-CAP**

A Phase IV Double-Blind, Placebo-Controlled, Randomized Trial to Evaluate Short Course vs. Standard Course Outpatient Therapy of Community Acquired Pneumonia in Children (SCOUT-CAP)

*Principal Investigators: W. Charles Huskins, MD, MSc & Theoklis Zaoutis, MD, MCSE*

A 2011 Infectious Diseases Society of America (IDSA) guideline for management of CAP in children provide recommendations for antibiotic therapy. The guideline identified clinical trials that provide information on the “shortest duration of therapy to decrease the development of antimicrobial resistance and the risk of antimicrobial toxicity” as a priority for future research.

The primary aim of SCOUT-CAP is to compare the proportion of treatment failures among children 6 months to <6 years of age with CAP assigned to short (5-day) vs. standard (10-day) course outpatient therapy with beta-lactam antibiotics through the Test-of-Cure Visit (TOC, Day 11-14 after starting antibiotic treatment).

To accomplish this, SCOUT-CAP has been designed as a multi-center, centrally randomized, double-blind, placebo-controlled non-inferiority clinical trial. The eligible population will be limited to children 6 months to <6 years of age with suspected bacterial pneumonia initially treated as outpatients using oral amoxicillin, amoxicillin-clavulanate or cefdinir. Children who receive 1 dose of intramuscular ceftriaxone as initial treatment as an outpatient, followed by continued treatment using an oral antibiotics listed above, are also eligible.

**Recent Publications**


