Title: Impact of a CLIA-waived molecular respiratory panel in a pediatric clinic

Date: January 31, 2018

PI: Stacy G. Beal, MD
352-594-4952
StacyGBeal@ufl.edu

Study Team:
Jennifer Reppucci, DO, Pathology Resident
Maira Gaffar, MD, Pathology Resident
Molly Posa, MD, Department of Pediatrics
Maria Kelly, MD, Department of Pediatrics, Clinic Medical Director
Ken Rand, MD, Department of Pathology
Whitney Spellicy, Department of Pediatrics, Clinic Manager

In 2016, the FDA approved the FilmArray Respiratory Panel EZ (Biofire Diagnostics, Salt Lake City, Utah), a CLIA-waived respiratory pathogen PCR assay which tests for 14 of the most common pathogens causing respiratory infections, including 11 viruses and 3 bacteria[1]. The assay requires minimal hands-on time and takes approximately 1 hour to complete. It qualitatively reports results for Adenovirus, Coronavirus, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae. Because the test is CLIA-waived, it can be performed by most clinic staff including nurses and medical assistants as long as the clinic has a Certificate of Waiver[2], which is held by all of our pediatric clinics. Tests are given a CLIA-waiver if they are simple to perform and have low risk of erroneous results. While molecular based respiratory panels have become common and shown benefits in hospital and emergency department settings[3,4] they are rarely used for outpatients due to the turn-around time, cost, and other factors. More commonly, rapid antigen tests for influenza and respiratory syncytial virus (RSV) are performed, which suffer from limited sensitivity compared with nucleic acid testing[5,6]. Therefore, the clinical impact of a rapid, point-of-care (POC) diagnostic test for numerous respiratory pathogens is unknown in this outpatient clinical setting and warrants further investigation.

Aims of the study:
Does the EZ lead to more appropriate clinical management of respiratory infections (which may be supportive care only, reduction in antibiotics prescribed)?
Does the EZ lead to fewer healthcare follow-up visits (repeat outpatient clinic visits, ED visits, phone calls, radiologic or laboratory testing, etc.)?
Does the EZ lead to shorter time for a patient to spend in the pediatric clinic?
What organisms are identified in a general outpatient pediatric clinic?

Role of the medical student:

1. Obtain training on the BioFire Respiratory Panel Unit and perform respiratory panel PCR testing on previously collected frozen samples.
2. Complete electronic medical record chart reviews on affected patients as a component of the descriptive analysis of patient demographics and clinical outcome.

Benefits to the medical student:

1. The student would be mentored through the Health Outcomes and Policy track to formulate their own angle of the investigation.
2. MSRP HOP students will have the opportunity to attemd attend biweekly seminars with their peers to develop their research presentation skills.
3. Researchers will offer support to the medical student to present their findings at the National Medical Student Research Forum at Walt Disney World.

References:

1. FDA. *510(k) Summary, BioFire Diagnostics, LLC: FilmArray Respiratory Panel EZ (RP EZ).* 2016.

2. CDC. CLIA: Waived Tests. 2015; https://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx. Accessed June 21, 2017.

3. Xu M, Qin X, Astion ML, et al. Implementation of filmarray respiratory viral panel in a core laboratory improves testing turnaround time and patient care. *Am J Clin Pathol.* Jan 2013;139(1):118-123.

4. Rogers BB, Shankar P, Jerris RC, et al. Impact of a rapid respiratory panel test on patient outcomes. *Arch Pathol Lab Med.* May 2015;139(5):636-641.

5. Beckmann C, Hirsch HH. Diagnostic performance of near-patient testing for influenza. *J Clin Virol.* Jun 2015;67:43-46.

6. Boku S, Naito T, Murai K, et al. Near point-of-care administration by the attending physician of the rapid influenza antigen detection immunochromatography test and the fully automated respiratory virus nucleic acid test: contribution to patient management. *Diagn Microbiol Infect Dis.* Aug 2013;76(4):445-449.

7. Quidel. QuickVue Influenza A+B Test. https://www.quidel.com/immunoassays/rapid-influenza-tests/quickvue-influenza-test. Accessed June 21, 2017.