GREAT BASIN'S ROLE IN ANTIMICROBIAL STEWARDSHIP

What is an Antimicrobial Stewardship Program?

Antimicrobial stewardship programs in hospitals seek to optimize antibiotics prescribing to improve patient care, reduce hospital expenses and slow the spread of antibiotic resistance. With antibiotic resistance on the rise globally and few new drugs in development, antimicrobial stewardship programs are more important than ever in ensuring the continued efficacy of available antimicrobials [1].

What is MRSA?

Methicillin Resistant *Staphylococcus aureus*, is a dangerous Staph bacterium that is difficult to treat in humans in that it is hard to diagnose and is resistant to penicillin-related antibiotics used to treat ordinary Staph infections [2]. Considered a superbug, MRSA is one of the leading Hospital Acquired Infections (HAI) – targeting those who have been hospitalized or who are in outpatient centers receiving invasive procedures or long-term care. Because MRSA is difficult to treat, the infection spreads easily and can become life threatening, particularly for at-risk people, such as the elderly, the very young, and those with compromised immune systems [3].

The difficulty in accurately diagnosing MRSA has led to the wide-scale use of Vancomycin to all unstable patients suspected of having a Staph infection. While Vancomycin has been considered the treatment standard for MRSA infections, over-use of the antibiotic has been cited as one possible reason for its documented clinical failure in treating MRSA [4].

What is CoNS?

Coagulase-negative Staphylococcus. CoNS is an organism found all over the human body. It is part of the normal flora of human skin and is typically non-pathogenic. An example is *S. epidermidis*, which is present on all skin, and will create a positive blood culture result if the skin is not thoroughly cleansed prior to the blood draw [5].

Why should we care about CoNS?

CoNS can signal a positive blood culture because of external contamination and not an infection in the patient's bloodstream. *S. lugdunensis* is highly virulent CoNS that is always considered a true pathogen when isolated from positive blood cultures. Unfortunately, most rapid diagnostic tests on the market do not distinguish the pathogen S. *lugdunensis* from other non-pathogenic CoNS, which has contributed to the widespread misuse of antibiotics in hospital settings and increased healthcare costs.

What is the prevalence of the pathogenic versus non-pathogenic CoNS?

S. *lugdunensis,* a pathogenic CoNS, is a clinically significant HAI that, while low in prevalence, is challenging to treat due to the frequency with which it is resistant to penicillin (90-95% of the time) and methicillin (80% of the time). Patients at risk of *S. lugdunensis* are those with catheters and implanted medical devices. Non-pathogenic CoNS, which constitute most CoNS, is considered relatively avirulent and does not require antibiotic treatment [6]. Due to the lack of adequate diagnostic testing to determine whether a patient has non-pathogenic CoNS or a true pathogen, patients are empirically treated with antibiotics as standard protocol, adding to a significant global problem in over-prescription of antibiotics.

What is the Staph ID/R Blood Culture Panel from Great Basin?

Great Basin's Staph ID/R Blood Culture Panel is an Identification (ID) and Resistance (R) Panel for *Staphylococcus aureus* (including MRSA), Staphylococcus *species, Staphylococcus lugdunensis, and mecA* gene that confers antibiotic resistance when found in any of these organisms. Patients with bacteria in their bloodstream are often the sickest and most expensive patients in the hospital. The Great Basin Staph ID/R panel provides results in hours as opposed to days using only traditional methods to aid in the proper treatment protocols for patients.

What are the key advantages of Great Basin's Staph ID/R Blood Culture panel?

- **Results in under 2 hours** means clinicians have answers they need to treat with appropriate therapy.
- **Detects *S. aureus* (MRSA and MSSA) and the *mecA* gene (methicillin resistance)**, which will inform the accurate selection of antibiotic therapy for the patient.
- **Detects CoNS contaminants**, which clears the patient for step-down therapy (off Vancomycin) and discharge.
- **Identifies *S. lugdunensis***, a CoNS that is always considered a true pathogen requiring antibiotic therapy.
- **One-step, true sample-to-result** – pipette sample into the test cartridge, insert panel into the analyzer and press "start." Our system is simple to use, easy to learn and can be run 24/7.
- **Staph ID/R provides results in HOURS as opposed to DAYS using only traditional methods.**

Why did Great Basin Scientific develop the Staph ID/R panel?

Our customers were asking for it. They wanted a Staph ID/R assay that could run on our easy to use, simple platform. What we ended up developing was a test unlike anything on the market in that it detects CoNS, which may not require antibiotic therapy. Thus, our Staph ID/R panel could contribute to reducing the number of unnecessary antibiotic prescriptions written to patients, saving hospitals valuable resources and reducing costs.

Is there a strong need for this panel in the diagnostics market?

There is not another sample-to-result panel targeted to gram positive blood cultures that will only distinguish MRSA from MSSA, or confirm if it's a non-pathogenic CoNS contaminant. This is a simple, streamlined, cost-effective and fast way to get clinicians answers they need to provide patients with the best treatment. As hospitals adopt formal antimicrobial stewardship programs, they will need diagnostic solutions to develop better prescription protocols. The Great Basin molecular diagnostic platform, including the Staph ID/R panel, could be used to help curb the over-prescription of antibiotics and lower hospitals costs by discharging people who don't need to be in the hospital. (The CDC estimates that roughly 47 million prescriptions written for antibiotics in the US annually are unnecessary.)

Why should microbiology labs be interested in the Staph ID/R panel?

Staph ID/R is very easy to run, with a simple workflow, so it can be a 24/7 STAT test. It costs less than competitive panels, which don't offer the same clinically relevant answers, and there is no charge for instrumentation, which allows more hospitals – including Critical Access Hospitals that may not normally have access to sophisticated diagnostic solutions – to offer molecular diagnostics without capital expense. Great Basin is committed to customer success and offers training and unlimited customer service without additional fees or contracts to help get labs up and running quickly and providing actionable results to better treat patients.

How can hospitals specifically benefit from the Staph ID/R panel?

The biggest benefits of rapid diagnostic testing are significant cost benefits to hospitals and shorter stays for patients. One study using found that associated patient costs from rapid intervention went from $45,709 to $26,162, while mean length of stay went from ~11 days to ~9 days [7]. Staph ID/R provides results in hours as opposed to days using only traditional methods.

How does the Staph ID/R panel fit within antimicrobial stewardship?

The CDC estimates that there are 47 million unnecessary prescriptions for antibiotics written each year in the U.S. These scripts have and will continue to lead to the development of superbugs that are resistant to available antibiotics. The CDC estimates that over 10 million Americans will die from untreatable superbugs by 2050. The Staph ID/R panel is the only rapid blood culture product currently on the market that only distinguishes CoNS from MRSA/MSSA, enabling hospitals to correctly administer antibiotics when there is a true infection versus administering empirically. Rapid blood culture testing has been shown to improve time to optimal therapy leading to reduced antibiotic resistance, reduced costs and improved patient outcomes.

What should clinicians, pharmacists and microbiology lab directors and supervisors know about this panel?

The barriers to implementing rapid blood culture diagnostics have traditionally included capital costs, service contract costs, high reagent cost, and the need for greater ease of use. Great Basin's platform removes these barriers, enabling every lab of any size the ability to offer Standard of Care for their patients.

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[3] The Center for Disease Control and Prevention, "Methicillin-resistant Staphylococcus aureus (MRSA)," 20 October 2016. [Online]. Available: http://www.cdc.gov/mrsa/community/index.html.

[4] Micek, S.T., "Alternatives to Vancomycin for the Treatment of Methicillin-Resistant Staphylococcus aureus Infections," 20 October 2016. [Online]. Available: http://cid.oxfordjournals.org/content/45/Supplement_3/S184.long.

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[7] Perez, K.K., Olsen, R.J., et al, "Integrating Rapid Pathogen Identification and Antimicrobial Stewardship Significantly Decreases Hospital Costs," 2013 September. [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmed/23216247.