GenMark Dx

WHITE PAPER
Templated Report Comments
December 2021

Rapid Blood Culture Identification:

Drive More Efficient Clinical Action by Streamlining the Interpretation of Test Results

BACKGROUND

The availability of rapid, multiplexed technologies for the comprehensive detection of infectious diseases is creating a paradigm shift regarding the role of the laboratory in impacting patient outcomes, infection control and antimicrobial stewardship. The drastically improved turnaround time from test order to reported result removes the laboratory as a bottleneck in patient care. However, this new capability has created the need for enhanced synergy between the laboratory, nurses, physicians, pharmacy, and antimicrobial stewardship programs (ASP).[1]

One area where this is particularly relevant is in the diagnosis and treatment of sepsis. While rapid, multiplex molecular tests can identify the potential causative agent and associated resistance genes nearly 1-2 days sooner than traditional methods[2,3], the rapid report may not drive rapid clinical decisions such as modification of antimicrobial therapy. Some healthcare providers have challenges linking a rapid diagnostic result to a patient treatment action. Again, in the example of sepsis diagnosis, the positive identification of the potential causative organism and resistance gene may be provided within 3 hours after gram-stain, but the physician may be unable to act on the result without guidance from pharmacy, infection control, or an ASP. In the most extreme case, if the result is provided at 4 PM, but pharmacy consultation and action is delayed until 7 AM the next day then the benefit of a <3 hour diagnostic result is negated by a treatment bottleneck of 15 hours.

The ePlex® instrument delivers several key solutions designed for the patient and optimized for the lab. Given the prior examples, ePlex instrument software can offer a novel solution for Patient Centered Care and Sample-to-Answer benefits with the ePlex Templated Comments (TC) module. The ePlex TC module delivers the capability to match an assay detection result with user-customizable algorithms which can drive patient treatment immediately without the need for further consult or delay. Throughout this white paper, we will demonstrate the capability and unique benefits the ePlex TC module can deliver to healthcare providers.

TEMPLATED COMMENTS MODULE

The ePlex TC module provides a rules-based engine which enables users to create customizable conditions based on ePlex panel results to communicate interpretive comments on the result report and through to the laboratory information system (LIS). Users can define rules in a logical IF, THEN structure. In the following example of using the ruled-based engine to enable automation of the local antibiogram and related treatment algorithm,

ePlex
Designed for the Patient,
Optimized for the Lab®

the ePlex TC module could be customized as follows:

- IF: Staphylococcus, Detected, AND, Staphylococcus aureus Detected and (mecA Detected or mecC Detected)
- THEN add comment: mecA detected. Probable methicillin-resistant Staphylococcus aureus (MRSA); further testing in progress. MRSA is predictably resistant to beta-lactam antibiotics (except ceftaroline). Patient requires contact precautions if hospitalized. Semi-Urgent Result.[2]

The goal of including templated comments directly on the results report is to drive more efficient clinical action by streamlining the interpretation of results. While the ePlex TC module can have multiple applications, the most obvious impact is to enable laboratories to automate collaboration with infectious disease clinicians, infection control and pharmacy services to guide clinicians with crucial information to make more rapid clinical assessment and optimize patient care.

IMPLEMENTATION OF TEMPLATED COMMENTS

As part of GenMark's commitment to Long-Term Partnership, we provide hands-on training and tools to configure and implement the ePlex TC module. We will help facilitate engagement with Pharmacy, Infectious Disease and Antimicrobial Stewardship teams regarding the functional capability of Templated Comments and what that may provide for your institution.

Each institution can align the antibiogram to specific targets with a recommended clinical action plan. The outcome of these discussions will be a blood culture identification (ID) recommended action plan which we can then load directly into the ePlex TC module. GenMark will train your team on how to enter and edit this information directly in the ePlex TC module and will assist with educating patient care staff on the implementation, utilization and benefits of templated comments.

IMPACT OF TEMPLATED COMMENTS IN THE HOSPITAL

The addition of templated comments onto the results report can streamline patient management and provide greater synergy between the laboratory, treating physician, pharmacy, and antimicrobial stewardship team. Instead of receiving just an organism and resistance gene identification, the physician will now see how these other key stakeholders would interpret and provide direction on the result immediately upon receiving the report via the LIS. Typically, without this type of result driven action plan on the report, the physician would consult other groups (e.g., pharmacy, infectious disease) or await direction from pharmacy and others leading to delays to optimal therapy for the patient. ePlex Templated Comments removes that potential bottleneck and enhances the overall management of sepsis patients.

Several studies have highlighted the importance and impact of combining rapid multiplex molecular BCID testing with an effective ASP and rapid action plan. One such study highlighted reduction in time to effective therapy and higher rates of de-escalation when results were coupled with ASP.[3] Another study concluded rapid molecular results are more impactful at influencing clinical decision making when delivered with an action plan or automated antimicrobial stewardship program in real-time.[2] The rapid detection of the organism and antimicrobial resistance genes when applied with local epidemiology of antimicrobial resistance, agreed 100% with subsequent phenotypic susceptibility testing[4], thus, allowing for targeted therapy recommendations directly in the results report to the clinician.

Given the increasing threat of antimicrobial resistance, many countries are instituting new standards regarding antimicrobial stewardship. In the US, the Joint Commission standards for medication management and antimicrobial stewardship is just one example of increasingly stringent requirements.[5]

The ePlex BCID Panel with the ePlex TC module can:

- Provide rapid detection of >95% of the organisms responsible for sepsis and bloodstream infection, saving days compared to conventional culture methods
- Automate the interpretation of the local antibiogram to guide the choice of appropriate antimicrobial therapy based on ePlex Panel results
- Integrate rapid results with automated ePlex Templated Comments to fast-track treatment intervention improving Antimicrobial Stewardship Programs and Infection Control

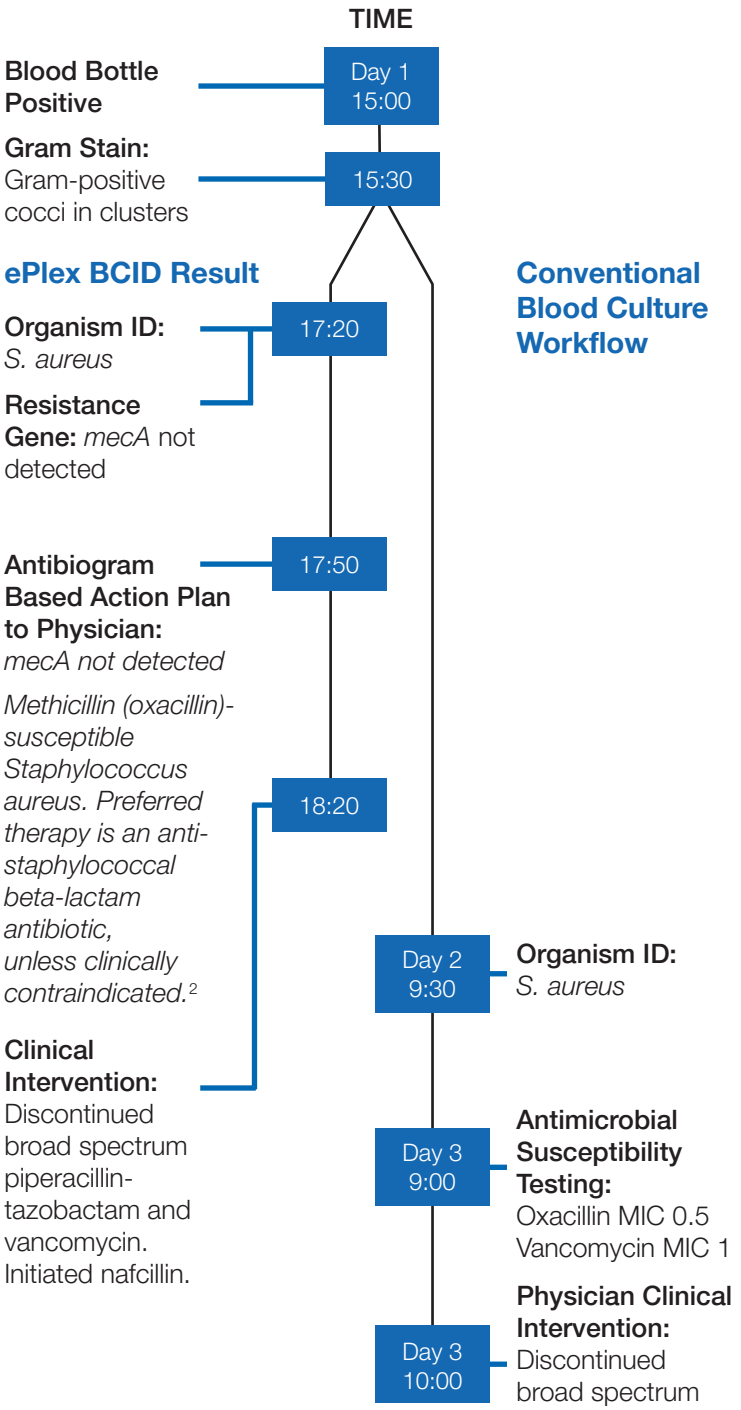
CASE STUDY EXAMPLES

The following two theoretical cases illustrate the impact of ePlex BCID Panels with the ePlex TC module compared to alternative approaches to blood culture identification testing for sepsis. In both theoretical cases, ePlex BCID Panels led to more rapid identification of both the causative organism and resistance gene than the alternative algorithms. The use of a prepared templated comment action plan led to more rapid physician action, Infectious Disease physician consult and off-hour clinical intervention. In the case study examples, the combination of the rapid and comprehensive ePlex BCID Panel with prepared templated comments led to 10-12x reduction in time from test order to physician report and clinical intervention.

Case Study #1:

ePlex BCID Panel compared to Traditional Culture and AST

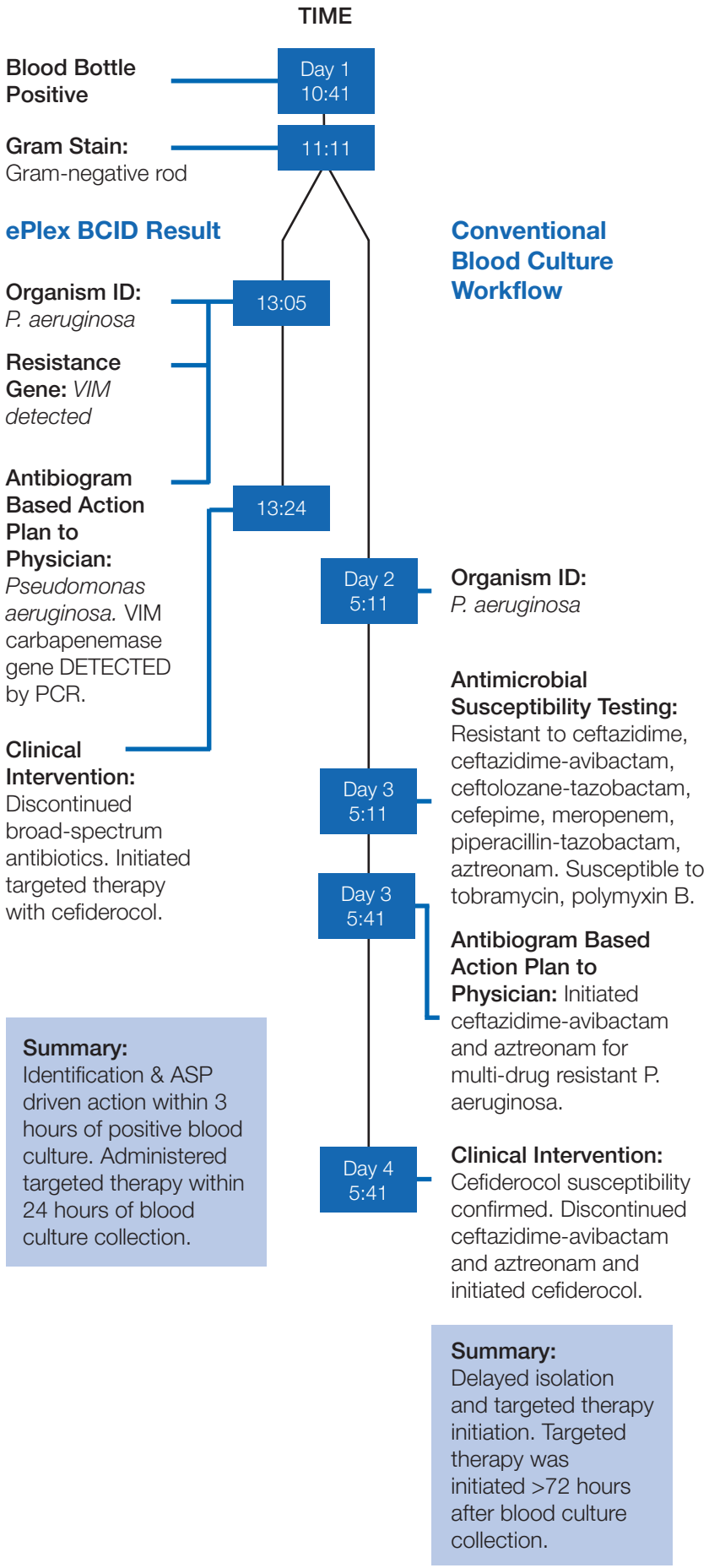
Patient arrives to emergency department with suspected sepsis at 07:00 and blood cultures were obtained at 08:00 and broad-spectrum antibiotics (piperacillin-tazobactam and vancomycin) were initiated. Blood bottles ring positive at 15:00 (7 hours after collection) beginning the diagnostic synopsis and timeline to the right.



Case Study #2

ePlex BCID Panel compared to other multiplex molecular methods and traditional AST

A hospitalized patient develops urosepsis after a urological procedure. Blood cultures are collected and incubated at 14:05.[6] Patient is started on broad spectrum antibiotics. Blood bottles ring positive at 10:41 the next day (21 hours after obtaining blood cultures) beginning the diagnostic synopsis and timeline to the right.



CONCLUSION

GenMark is dedicated to Patient Centered Care and, with ePlex BCID Panels combined with the ePlex TC module, we deliver the most comprehensive solution for rapid, routine blood culture identification and clinical decision making for suspected sepsis patients. Getting results quickly removes the laboratory from being a bottleneck in executing more effective Antimicrobial Stewardship Programs and driving rapid clinical action. However, rapid BCID results are most effective when all stakeholders in the hospital work to automate the local antibiogram and design an action plan to help treating physicians utilize these rapid results to improve patient treatment.

GenMark is ready to help educate your hospital patient care staff regarding ePlex solutions for sepsis. We can also deliver a complete implementation plan to deliver a more effective way to manage sepsis in your hospital.

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Dr. Tiffeny Smith received her Bachelor of Science degree in Microbiology and Nursing from the University of Oklahoma and her Doctor of Pharmacy degree from the University of Oklahoma College of Pharmacy in 2013. She completed a Pharmacy and Infectious Diseases Residency at the Johns Hopkins Hospital. From 2015 to 2018, she was a part of a multidisciplinary antimicrobial stewardship team at the Medical University of South Carolina and UT Southwestern Medical Center where she ensured coordination of stewardship activities that included prospective audit of positive cultures from critical sites, conducted medication use evaluations, created and implemented institutional based guidelines, and conducted research on infectious diseases related topics. Tiffeny obtained her Board Certification in Infectious Diseases Pharmacotherapy in 2018 and is passionate about the integration of rapid diagnostics into stewardship programs.

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Dr. Natalie Whitfield previously served as the Director of Scientific and Medical Affairs at GenMark Diagnostics. Dr. Whitfield has over 18 years of academic, clinical, industry and business development experience in previously held positions including Sr. Director, Laboratory and Technical Operations at OpGen, Assistant Clinical Professor in the Department of Pathology at the University of Arizona and Division Chief of Clinical and Molecular Microbiology at Banner University Medical Center-Tucson. Dr. Whitfield holds a B.S. in Biological Sciences from the University of Texas-El Paso and received her Ph.D. in Cellular Molecular Biology from the University of Michigan. She is a Certified Diplomate of the American Board of Medical Microbiology (ABMM).

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