PROVIDING INNOVATIVE SOLUTIONS
WHEN—*AND WHERE*— THEY'RE NEEDED MOST.

Executive Summary

Compliance Considerations When Evaluating a New Request for POCT was the focus of Part 2 in our webinar series featuring healthcare professionals in government, academia, hospital labs and industry. Education and shared information are critical in helping to navigate compliance in a changing point-of-care landscape.

Speakers

T. Scott Isbell, PhD, DABCC, FACB, Assistant Professor of Pathology, Saint Louis University School of Medicine

Roger Bertholf, PhD, Professor, Department of Pathology and Laboratory Medicine & Director, Clinical Chemistry, Toxicology and Point of Care Testing, University of Florida Health-Jacksonville

Presentation Summary

- POCT is growing due to a number of factors including the rising prevalence of chronic and infectious diseases, technological advances and a decreasing number of technicians in central labs.
- At the local level, this results in increased requests for POCT from different services such as outpatient settings, the OR and ER.
- Considerations when evaluating requests for a new POCT may include a) how the device performs analytically (e.g., accuracy, precision), b) the patient on which it should be used, c) environment in which it will be performed and d) the number of operators and their training.
- Utilizing a medical device off-label is permissible by law provided regulatory and compliance requirements are met.
- When taking a decision to use a medical device off-label, a medical director should a) be aware of the limits of the manufacturer regarding the device; and b) be guided by good laboratory and medical practice. In using a device off-label, a laboratory or medical director is now making claims, which must be supported by data. The resulting data should be stored for inspectors.

Discussion Summary

- **Regarding validation studies for modified use:** In Dr. Isbell's institution, validation is designed to demonstrate that the instrument performs the same way across patient populations in which it is believed to be appropriate for use. This may include patients in whom the test has been validated according to manufacturer's PI and in whom it has not. Per CLIA, his institution ensures the analytical integrity of results and draws on peer-reviewed literature. Questions they consider:
    1. Have we defined the patient population we need to sample?
    2. What do we agree is sufficient coverage around medical decision points and do we have enough?
    3. Have we examined published data?
    4. Should we do some precision studies as well?

  PLEASE NOTE: Every institution has its own criteria and may implement validation and accuracy studies differently.

- **Regarding education requirements for non-lab testing personnel for non-waived POCT,** the two speakers suggest referring back to CLIA guidelines, especially as they relate to high-complexity testing.

- **Information that should be included in requests for non-waived testing vs. waived testing in clinical sites varies by institution.** Some institutions have Standard Operating Procedures in place and/or forms that include questions about what the test is, how it will and will not be used, and in whom.

- **In encouraging users of POCT to comply with regulatory requirements**, speakers suggested the following:
    - Developing and then auditing an approach
    - Working with nurse management to develop and then ensure SOPs are followed
    - Setting up checks and balances

- Establishing a standardization committee that includes Compliance and Nursing
- Having sufficient staff to oversee a POCT program