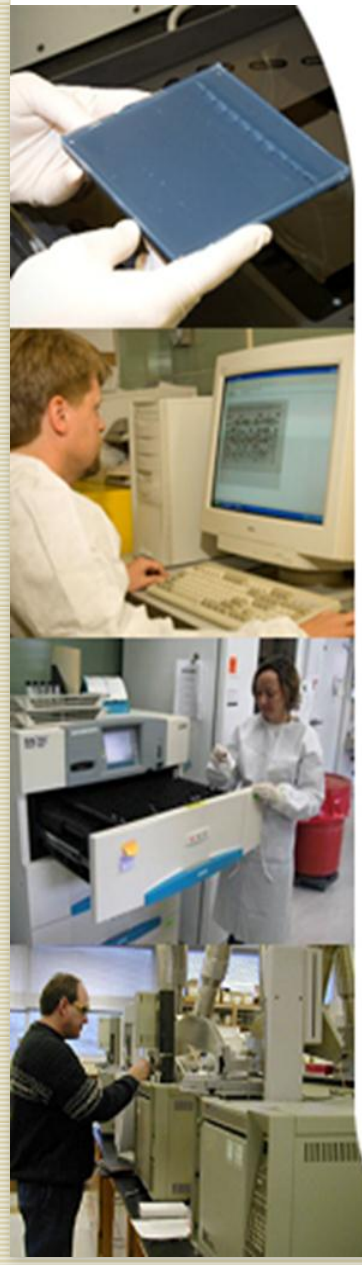
Wisconsin State Laboratory of Hygiene

UNIVERSITY OF WISCONSIN–MADISON



Performing Quality Molecular and Emerging Technology Testing Workshop

April 23, 2014

PRE-TEST

1.) Which of the following statements is false? If your laboratory runs the same test method on multiple units of the same instrument or performs the same test method at multiple testing sites, your laboratory must…

A. Demonstrate that multiple instruments produce equivalent test results prior to offering a new test
B. Demonstrate that multiple instruments produce equivalent test results at least twice a year after implementing the test
C. Perform a complete assay verification on each instrument or at each testing site if the sites operate on the same CLIA certificate
D. Demonstrate equivalent performance of each instrument by alternating the quality control material among the instruments
E. None of the above

PRE-TEST

2.) For an unmodified, FDA-cleared or –approved test the laboratory is required to verify the manufacturer's performance specifications. Which of the following is NOT a specification that requires verification?

A. Accuracy
B. Sensitivity
C. Precision
D. Reportable range
E. Reference range

PRE-TEST

3.) The verification that a laboratory can repeatedly test the same samples on the same day, and on different days, and get comparable result with several testing personnel performing the test is a measure of…?

A. Accuracy
B. Sensitivity
C. Precision
D. Reference Range
E. Calibration

PRE-TEST

4.) What is CAP's purpose of monitoring the positive rate of a PCR assay? (MIC.63252)

A. The prevalence of positives is used to monitor for community outbreaks.
B. It is a way to monitor for potential false positive results in your test system.
C. It is used to compare to other areas of Wisconsin for epidemiology.
D. Using statistics are so fun and it gives you something to do when you have spare time.
E. A and C

PRE-TEST

5.) I want to run a sample type that has not been validated by the manufacturer, but I only will get this type of sample a couple of times a year. (MIC.64770)

A. CAP requires a full validation before reporting the patient result.
B. The sample type is so rare that it would take at least 10 years to validate so I can't report it.
C. Report out the result with a disclaimer stating that the sample type has not been validated.
D. If the sample type is encountered *rarely*, results may be reported without a complete validation.
E. C and D

PRE-TEST

6.) I have a C. diff PCR to perform, but the tech scraped out the container for send outs and didn't leave an adequate sample. Now what? (MIC.63322)

A. Go to the send out area and scrape some back into the original container so you can run the test.
B. Ask for a new specimen as CAP requires no aliquot ever be returned to the original container.
C. Since PCR is so sensitive just try testing the residual specimen anyway and hope for the best.
D. Use the container from the send out area knowing that other stool samples are being processed there and that the tech never changes his gloves between stools specimens.
E. Reject the test as QNS.

PRE-TEST

7.) Which of the following are reasons a laboratory should consider implementing molecular testing?

A. Demand for greater sensitivity/specificity
B. Decrease turnaround time
C. PT failure using current methods
D. Increase reimbursement/revenue
E. All of the above

PRE-TEST

8.) Which of the following is not included in a business plan/case?

A. The business need or requirement
B. The options to best address the business need or requirement and your recommendation for the preferred option.
C. Analysis of the benefits and costs of the options
D. Implementation Strategy
E. A list of how many other labs in the area have the option that you are requesting.

PRE-TEST

9.) All of the following manufacturers make FDA cleared rapid positive blood culture identification assays except?

A. Biofire
B. Nanosphere
C. Siemans
D. Cepheid
E. AdvanDx

PRE-TEST

10.) In addition to rapid identification of the bacteria in a positive blood culture what other information can some of these assays provide?

A. The time to positivity for the blood culture
B. The bacterial load in the patient's blood
C. The strain type of *E. coli*
D. If the bacteria is capable of causing necrotizing fasciitis
E. Detection of certain bacterial gene(s) associated with antimicrobial resistance

PRE-TEST

11.) Which of these systems has the potential to rapidly identify the widest range of bacteria in a positive blood culture?

A. Nanosphere Blood Culture –Gram-Negative/Positive
B. Bruker MALDI-TOF
C. Biofire BCID Panel
D. AdvanDx Gram-Negative/*S. aureus* -CNS QuickFISH BC
E. Cepheid Xpert MRSA/SA BC