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Autore	Teodorescu P. P
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susceptibility test (AST) systems? -- How can analytical sensitivity be assessed for multiplex molecular systems? -- References -- Chapter 11 Performance Characteristic: Analytical Specificity -- What is analytical specificity? -- How many and what types of samples should be used to assess analytical specificity? -- How does a laboratory assess analytical specificity? -- What should we do if cross-reactivity or interfering substances are identified? -- How can analytical specificity be assessed for matrix-assisted laser desorption ionization-time of flight (MALDI-TOF) identification systems? -- How can analytical specificity be assessed for antimicrobial susceptibility test (AST) systems? -- How can analytical specificity be assessed for multiplex molecular systems? -- References -- Chapter 12 Additional Performance Characteristics -- What additional performance characteristics could be considered, and how are they assessed? -- References -- Chapter 13 Unacceptable Results and Resolution -- What should we do if there are significant discrepancies between our new assay and the comparator assay? (Accuracy) -- We are using a less sensitive method as our comparator method, and our new test is showing poor agreement and increased "false positives." What should we do? (Accuracy) -- Our assay shows significant cross-reactivity with a particular organism. What should we do? (Analytical specificity) -- References -- Chapter 14 Documentation for Verification and Validation Studies -- What documentation is necessary for a verification or validation study? -- What should be included in a verification/validation plan? -- What should be included in a verification/validation summary? -- How long is the laboratory required to keep verification/validation documentation?. What do I do if my laboratory's legacy assays do not have verification/validation documentation?.

Sommario/riassunto

"Laboratory accreditation is a vital and necessary process for clinical laboratories, and the requirements coming from the oversight bodies, CAP, CLIA, and FDA. And although information are freely accessible, they are often confusing and difficult to execute in the lab. Every clinical microbiology laboratory director, manager, and supervisor must interpret the requirements and work to keep the laboratory in compliance while responding to novel microbe outbreaks in addition to the regular workflow of testing. This resource gathers information from many different sources into one place and addresses the "how-tos" of implementing regulations around laboratory activities"--