

How To: Accreditation of Blood Cultures' Proceedings. A Clinical Microbiology Approach for Adding Value to Patient Care

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Abstract: Quality assurance and quality management are driving forces for regulating blood culture best practices but should not be disconnected from the end-point target, i.e. patient value.

Aim: This article is calculated to help microbiologists implement blood culture certificate that is actually beneficial to patient management.

Sources: Experience from a nationwide taskforce for promoting quality assurance and competence in clinical microbiology laboratories, guidelines on blood culture.

Content: Experience in blood culture certificate according to International standard ISO 15189 standards is provided in this review, with a particular focus on critical points that are specific to blood culture.

Blood culture test method: Verification is based on risk analysis, and evaluation of the test method's performance is based on the literature review and suppliers' data. In addition, blood culture performance relies largely on the quality of its pre-analytical phase, and the test method should be monitored based on key performance indicators such as the volume of blood cultured, the contamination rate and time to transportation.

Introduction: Given today's high standards for quality and competence, a test method must be shown to be fit for purpose such that a facility's customers can have confidence in the results produced. Quality management systems in medical laboratories are specified by international standard ISO 15189. Objective evidence must be provided of this confidence, which is achieved through method validation, quality and technical requirements, quality management and a process of continual quality improvement; these factors are clear driving forces for controlling blood culture best practices. Method validation is challenging in clinical microbiology because living microorganisms represent an extra source of uncontrollable variation that can affect results and because test methods are the sum of sequential and conditional sub-processes. Indeed, the opportunity costs associated with an overemphasis on the technical aspects of a process, with the associated marginal gains, With the deliberate aims of

combating this danger and promoting an approach that is helpful to patient care, several initiatives have been developed. One such initiative is the French Society for Microbiology's national Committee for Quality in Microbiology (QUAMIC), which guides laboratories in appropriate method verification achievement, preventing excessive controls and promoting improved patient care.

Method accreditation versus method validation: The scope of accreditation for a test method includes three phases (pre-analysis, analysis, and post-analysis), and control of the entire process is reached by quality management that includes procedures, personnel qualification and monitoring of key indicators. Method validation is more strictly centred on the analysis phase. Blood culture represents a particular process with very few equivalents in laboratory tests because the entire volume of a specimen is taken for analysis, and this sample volume critically determines disease detection. Consequently, it is difficult to separate the pre-analytical and the analytical phases for method validation.

Blood culture test method verification: The question of how to achieve method validation of blood culture can be greatly clarified by considering that a test method is a complex process involving several simple processes). Validation includes validating every sub-process used to report negative or positive results. Because blood culture has been extensively assessed and is currently the reference standard for diagnosing bloodstream infection, test method validation is limited to 'verification', provided that the user respects general and supplier guidelines. The laboratory still needs to confirm its ability to apply the method, Direct antimicrobial susceptibility testing from broth of positive bottles instead of antimicrobial susceptibility testing from colony is such an example at the time of this review's publication.

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Blood culture test method verification the question of how to achieve method validation of blood culture can be greatly clarified by considering that a test method is a complex process involving several simple processes. Validation includes validating every sub-process used to report negative or positive results. apply the method, but the workload is considerably lower compared with that associated with the validation of a method that has been developed in-house. When users practice a sub-process that differs from guidelines and for which the level of evidence in the literature does not ensure enough confidence for safe patient management, this particular sub-process should be validated and not only verified until enough evidence is available. Most of the suggested KPIs can be monitored in every laboratory, although some may be tedious to collect, and few information technology systems currently enable a relevant, convenient and fully automated analysis. Some efforts in this area should be made by blood culture instrument manufacturers, information technology systems and local information technology service departments

Results: To improve smooth monitoring and to provide help for efficient actions. Additionally, such indicators, when standardized, can be used for inter-laboratory comparisons. Analyzing data at the population level (laboratories) can improve visibility and monitoring efficiency. Determining whether a result of 'moderate performance' is indeed a 'very good' or a 'poor' outlier result compared with those of the paired group is insightful. Such programmes for blood culture key indicators are currently not available in many European countries, although they have been implemented for decades in the USA [23,46e48]. These types of programmes should be promoted, given the power of this approach.

Conclusion: The main questions raised by the accreditation of blood culture and improved awareness of critical steps of the process lead to improved blood culture, bloodstream infection diagnosis and patient care practices. ISO 15189 accreditation is therefore a good policy for laboratories for receiving credit for their performance, but caution calls for the inappropriate escalation of quality measures that would lead to false security and be counterproductive to patient management to be addressed. Every quality assurance initiative must be implemented

with the basic requirement of achieving an actual contribution to patient care.