QUALITY CONTROL OF MICROBIOLOGY IDENTIFICATION SYSTEMS

Quality control of microbiology identification systems at BD Diagnostic Systems is done on the individual substrate level and the organism identification level. For example, with the BD Phoenix™ Automated Microbiology System the identification portion of a given panel lot is tested to ensure that each individual substrate is performing acceptably, and that proper identifications are achieved. This is accomplished by testing multiple replicates of a battery of organisms so that each and every substrate produces at least one positive and one negative result. In addition, the identification results for each replicate of each organism are checked for accuracy. Finally, each lot of panels is tested for bioburden to ensure that the substrates are free from contamination and stable.

Because of the scope of internal testing performed, our customer recommendations are to test a minimal number of QC strains. A correct identification obtained for these strains gives sufficient evidence that the panels are performing acceptably upon receipt.