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Compounding Facility Cited For Several Aseptic, Microbiology, And Rapid Methods Issues



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The observations regarding this rapid sterility test method were interesting. In the method utilized, there were issues with the "background" being too high. According to the individual's interviewed, this meant that there were too many events present and the sample was not completely examined. (e.g., This type of event can happen with many of the fluorescent technologies. The test was likely conducted using solid phase laser scanning microscopy.) The problem happened when these types of samples were automatically discarded. In fact, more than 20...

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