

## Primary Validation Of The Growth Direct Environmental Monitoring System And Media



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By

Feb 23, 2020 8:00 am EST

**INTRODUCTION** In 2015 Murphy and Schwedock published a paper outlining the statistics to be used to validate a Rapid Microbial Method. Since that time new versions of the USP and EP have been published with updated statistics. The current EP 5.1.66 chapter has more clearly defined the requirement for suppliers of Rapid Microbial Methods (RMM) to supply the formal validation data obtained using their method. The analytical testing is well defined in the chapter however the statistical analysis is not as clear. The USP has made a clear choice to focus on equivalence or non-inferiority for most...

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