

UPDATED FOR 2023 • REQUIREMENTS HAVE CHANGED

# USP <797>

## REGULATORY SOLUTIONS

### FOR ENVIRONMENTAL MONITORING

Compliance  
has never been  
so EASY!

A robust environmental monitoring sampling plan to test for bacteria and fungi is a central component of USP <797> and crucial to mitigating contamination threats.



#### VIABLE VOLUMETRIC IMPACT AIR SAMPLING

Per USP <797> "A monitoring program for viable airborne particles must be developed and implemented to assess microbiological air quality in all classified areas."

Viable volumetric impact air sampling is the preferred method for detecting microorganisms in the clean room. Gravimetric sampling (settling plates) is not sufficient for meeting the requirements of USP <797>. TRIO.BAS™ impact air samplers utilize standard agar plates for detecting and analyzing bacterial and/or fungal colony count. Testing must be done at least every 6 months for Categories 1 and 2, and every month for Category 3.



Cat. no.  
BAS243K



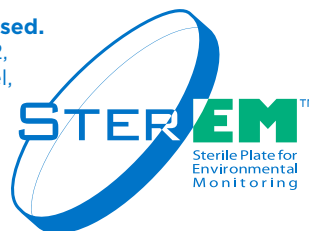
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W520

#### GLOVED FINGERTIP SAMPLING

The frequency which to perform gloved fingertip sampling has increased.

Per USP <797> "Before beginning to compound Category 1, Category 2, or Category 3 CSPs or have direct oversight of compounding personnel, personnel must successfully complete an initial garbing competency evaluation no fewer than 3 separate times."

"The garbing competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands" for all compounding categories. USP <797> mandates using TSA (Tryptic Soy Agar) containing a disinfectant neutralizer, such as Lecithin and Tween® 80. Must be tested every 6 months for Categories 1 and 2, and every 3 months for Category 3.



#### VIABLE SURFACE SAMPLING

Your general environmental monitoring program must include surface sampling per USP <797> and the frequency for surface sampling is now defined in the 2023 revision. Monitoring surfaces for microbial contamination can include taking samples from any surface that personnel, materials, or produced compounds are exposed to. Surface samples are collected using TSA with Lecithin and Tween® contact plates, (Cat. no. P520) paddles, or swabs. Must be tested every month for Categories 1 and 2, and every week for category 3.



Cat. no.  
SRK55



Cat. no.  
P520



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