Self-Serve Sampling Kits for Environmental Monitoring

USP <797> USP <1116>

Regulations

The new version of USP Chapter 797 is official on November 1, 2023. It is critical to understand and comply with the key regulatory changes, which include:

- Monthly Surface Sampling is now required for Category 1 or 2 sterile preparations
- Surface Sampling needs to be performed after Media-fill and Fingertip Sampling

Self-Serve Sampling Kits

TSS' Self-Serve Sampling Kits are a convenient, cost-effective, and timely way to comply with USP <797> and USP <1116>.

Kits are available for:

- Air Samples
- Surface Samples
- Glove Fingertip / Thumb Samples (GFT)
- Media Fill / Aseptic Techniques

Training and Certification:

- TSS offers instructional videos for air and surface sampling
- · Certificate of competence is issued upon course completion and knowledge test
- Sampling SOP included with kit subscription

Sample Analysis and Reporting:

- Sampling media are analyzed in TSS' accredited microbiology laboratories
- QA-reviewed Microbial Analysis Report (MAR) is issued for each sample
- Species-level identification is included at no additional cost for USP <797>
- Results are typically available within 10 business days after receipt by the lab



For more information or to start self-serve sampling, contact: SamplingKits@TechSafety.com

Why TSS Self-Serve Sampling?

- Microbial testing for USP <797> USP
 <1116> compliance
- Wide range of sampling kits
- Comprehensive online training and certification
- In-house, accredited microbiology laboratories
- Kits are convenient, cost-effective, and timely



Self-Serve Sampling is Easy as 1-2-3!

1

3

You determine the type of sample media and quantity, the level of analysis, and the frequency of sampling.

Fill out the appropriate forms: USP <797> & USP <1116>.

E-mail the completed forms back to TSS to set up your subscription.

TSS will send everything you need to collect your own samples.



TSS also sells and rents air sampling equipment.

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Self-Serve Sample Kits include everything needed:

- Sampling media
- Sample labels
- Chain of custody form
- Shipping container with cold packs and return shipping label

Media types available: TSA, SDA, or MEA

