



Environmental Monitoring *Product Showcase*

A ROBUST AND WELL-THOUGHT-OUT ENVIRONMENTAL MONITORING program is integral to achieving compliance with USP Chapter <797> and to ensuring the sterility of your compounded sterile preparations. The proposed revisions to <797>, currently in review, require the use of an active air sampler to monitor the levels of microbial bioburden in your controlled environments. Furthermore, the revisions support the monitoring of surface and personnel contamination via agar media contact plates as a best practice. Air and surface sampling media must be subsequently incubated at specified temperatures and then evaluated to identify the colony forming units present in the media, as well as their potential source.

Selecting the appropriate products to support your environmental monitoring program is of the utmost importance. For example, electronic (volumetric) air samplers should meet the criteria outlined in the proposed changes to <797>, and air and surface sampling media should be accompanied by a certificate of analysis (CoA), indicating the media has passed growth-promotion tests. Also, media for surface sampling should contain ingredients to neutralize any disinfectants present on controlled environment surfaces and personnel fingertips. In addition, the temperature range of your selected incubator must include the range of its intended use. These are just a few of the consid-

erations to keep in mind while making informed purchases.

For more in-depth information regarding the development of an appropriate and <797>-compliant environmental monitoring program, we strongly encourage you to visit www.pppmag.com to download the following past articles:

- “<797>’s Proposed Gloved Fingertip Sampling Requirements”: www.pppmag.com/documents/V3N9/8-12.pdf
- “Selecting an Incubator for Your Health-System Pharmacy”: www.pppmag.com/documents/V3N8/P24-26.pdf
- “Understanding the Microbiology Behind USP <797>”: www.pppmag.com/documents/V3N7Supp_CC/Environment.pdf
- “A Review of USP’s Updates to Chapter <797>”: www.pppmag.com/documents/V3N5/V3N5p8-10chapter797.pdf
- “Quality Assurance and <797> Compliance: Fact Versus Fiction”: www.pppmag.com/documents/V3N4/v3N4p20-23factsfiction.pdf

The following product showcase highlights a selection of the products available to support your environmental monitoring program. To request more information about any of these products, simply circle the corresponding number on the reader service card bound in this issue.

Hardy Diagnostics

▶ Spin Microbial Air Sampler

The portable Spin Microbial Air Sampler spins a petri dish, while drawing in a defined amount of air, resulting in the sampled air fully covering the agar surface. The sampler helps ensure accurate microbial counts by reducing the probability of two or more particles impacting the plate in the same location, which can result in a falsely lowered microbial count. The battery-powered unit samples a volumetric amount of air and can use 100-mm or 60-mm petri dishes.



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▶ Contact Plates

Hardy Diagnostics’ 60-mm Tryptic Soy Agar with Lecithin and Tween contact plates are slightly overfilled with nutrient agar. The plate has a grid molded into the bottom to aid in the counting of microorganisms. Tryptic soy agar acts as a nutritious medium for microorganisms, and germicidal or disinfectant (quaternary ammonia compounds, hexachlorophene, and ethanol) residue is neutralized by lecithin and Tween.



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▶ EnviroTrans Environmental Monitoring Swab

The EnviroTrans Environmental Monitoring Swab is intended for the monitoring of irregular surfaces within a cleanroom or hood. Each kit contains 20 15-by-75-mm tubes with 3 mLs of sterile neutralizing broth and an attached dacron swab.



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▶ Incubators

Hardy’s compact incubators have dimensions of 13 by 14 by 16.25 inches and weigh 19 pounds. With a temperature range of ambient +5°C to 60°C, the incubator features an LCD temperature indicator, accommodates a maximum of four shelves, and is supplied with two removable, zinc-plated steel shelves.



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Bioscience International

▶ SAS DUO Super 360 Air Sampler

Designed to use standard contact or Petri plates, SAS air samplers can serve as a cost-effective approach for complying with current and anticipated USP <797> viable particle air monitoring requirements. The DUO Super 360 model allows two selective media plates, e.g. MEA and TSA, to sample the air concurrently and aspirates 360 liters of air per minute. With AISI 316 stainless steel sampling heads, eight-hour battery life, and rapid sampling speeds, SAS models can facilitate compliance with USP <797>.



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Lab Safety Corporation

▶ The EnviroAssay <797> Microbial Monitoring Kit

Lab Safety introduces the EnviroAssay Microbial Monitoring Kit, including a self-contained, disposable BioCassette, which attaches to a 30 LPM, metered electric pump to facilitate active air monitoring. In addition, the EnviroAssay Microbial Monitoring Kit incorporates contact plates for surface monitoring your controlled environment surfaces and compounding personnel fingertips. After obtaining the requisite samples, BioCassettes can be sent to Lab Safety Corporation for incubation and analysis. Lab Safety then sends reports to the pharmacy QA administrator via e-mail.



Circle reader service number 12 or visit www.valiteq.com

Q.I. Medical, Inc.

► **GroMed Pharmacy Incubators**

Q.I. Medical offers two sizes of pharmacy incubators: one with 0.7 cubic feet of interior space and another with 2.0 cubic feet of interior space. Both models feature one fixed and two adjustable shelves and maintain temperatures up to 62°C within +/- 0.5 degrees. Large dial thermometers aid temperature monitoring and clear doors allow viewing of incubating samples. The incubators are UL listed and have two-year parts and labor warranties.



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or visit www.qimedical.com

Remel

► **Plated Media**

Remel offers a choice of irradiated and non-irradiated contact plate media, allowing you to select the highest level of sterility assurance available to monitor surfaces and personnel in controlled environments.



Remel media are manufactured in a Class 10,000 cleanroom with Class 100 work zones to ensure sterility.

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or visit www.remel.com

Biotest Diagnostics Corporation

► **The HYCON System**

Biotest's HYCON System includes the RCS High Flow Microbial Air Sampler, which takes the required sample of 100 liters of air in 10 minutes; the APC Handheld Particle Counter for spot checking in between six-month certification periods; and Biotest Contact Slides for Surface Sampling, which come individually wrapped and allow for room temperature storage.



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