



## ENVIRONMENTAL TESTING

The environmental conditions under which a product is manufactured can have an impact on the number and types of microorganisms in and on the finished product. Seasonal fluctuations, cleaning methods, employee training, room conditions and manufacturing changes all have the potential to influence the number and types of organisms recovered.

WuXi AppTec can assist with the design and interpretation of microbial sampling and environmental monitoring programs for cleanrooms or controlled environments.

### Environmental Monitoring Programs

The goal of an environmental monitoring program is to reveal the microbial levels of controlled and critical areas and to assess the impact on the quality of the product. By determining the quantity and species of organisms present, manufacturers can design a program to ensure the effectiveness of various control measures, such as HEPA filtration, cleaning, disinfection, maintenance, gowning and aseptic handling procedures.

The experts at WuXi AppTec can help you design and implement such a program. WuXi AppTec can also supply equipment and products used in environmental monitoring.

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## MICROBIAL SAMPLING TESTS

<p><b>1701000</b></p> <p><b>Environmental Air Sample</b></p>	<p>Growth on each environmental sample unit (either plates or strips) is enumerated. Gram stain and/or identification is available. <i>[See Page E-3.]</i></p> <p><b>SAMPLE REQUIREMENTS</b> Client provides air sample(s) for incubation and enumeration.</p> <p><b>PREFERRED SHIPPING</b> Overnight air. Protect from temperature extremes.</p> <p><b>TURNAROUND TIME</b> 7-10 days</p>
<p><b>1702000</b></p> <p><b>Environmental Surface Sample</b></p>	<p>Growth on each surface sample (either RODAC or swab sample) is enumerated. Gram stain and/or identification is available. <i>[See Page E-3.]</i></p> <p><b>SAMPLE REQUIREMENTS</b> Client provides surface sample(s) for incubation and enumeration.</p> <p><b>PREFERRED SHIPPING</b> Overnight air. Protect from temperature extremes.</p> <p><b>TURNAROUND TIME</b> 7-10 days</p>
<p><b>170300 – 100 mL</b> <b>170400 – 1 mL</b></p> <p><b>Water System Microbial Counts</b></p>	<p>Sample aliquots obtained from a water system are evaluated for number of viable microorganisms in each 100 mL or 1 mL sample.</p> <p><b>SAMPLE REQUIREMENTS</b> 100 mL or 1 mL sample in sterile sealable container. (Client provides sterile collection containers.) Keep refrigerated.</p> <p><b>PREFERRED SHIPPING</b> Overnight air. Ship with cold packs.</p> <p><b>TURNAROUND TIME</b> 7-10 days</p>
<p><b>107500</b></p> <p><b>Water System Coliform Count</b></p>	<p>Used as an indicator of the quality of water. Samples are screened for coliform bacteria, a major intestinal bacterial pathogen.</p> <p><b>SAMPLE REQUIREMENTS</b> 100 mL. Keep refrigerated.</p> <p><b>PREFERRED SHIPPING</b> Overnight air. Ship with cold packs.</p> <p><b>TURNAROUND TIME</b> 4-6 days</p>
<p><b>107501</b></p> <p><b>Water System Microbial Counts and Water System Coliform Count</b></p>	<p>In this test, both Water System Microbial Counts (Test Code: 170300/170400) and Water System Coliform Counts (Test Code: 107500) are performed.</p> <p><b>SAMPLE REQUIREMENTS</b> 110 mL or 200 mL. Keep refrigerated.</p> <p><b>PREFERRED SHIPPING</b> Overnight air. Ship with cold packs.</p> <p><b>TURNAROUND TIME</b> 7-10 days</p>

## MICROBIAL IDENTIFICATION TESTS

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Differential staining technique used to categorize microorganisms.

**TURNAROUND TIME** 1-3 days

**190601**

**Gram Stain**

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Description of an organism's macroscopic appearance as a colony on agar, including shape, color and texture.

**TURNAROUND TIME** 1-3 days

**190640**

**Colony Morphology**

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Description of an organism's macroscopic appearance as a colony on agar, including shape, color and texture, plus differential staining to determine organism category.

**TURNAROUND TIME** 1-3 days

**190630**

**Gram Stain and  
Colony Morphology**

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Determination of the genus and species of a bacterial isolate.

**TURNAROUND TIME** 3-14 days (depending on method)

**190401**

**Bacterial / Microbial  
Identification**

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Determination of the genus *or* genus and species of a fungi or yeast isolate.

**TURNAROUND TIME** 3-14 days

**190650**

**Fungal (Yeast / Mold)  
Identification**

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## ENVIRONMENTAL SAMPLING PRODUCTS

170500

**Rental of RCS Impact Sampler**

The RCS impact sampler is used in the detection of microbes in air samples from manufacturing zones.

*[See Environmental Air Sample test, Page E-2.]*

170501

**RCS Impact Sampler Strips –  
Tryptic Soy Agar**

These strips have Tryptic Soy Agar (TSA) for isolation and cultivating a variety of aerobic microorganisms.

*[See Environmental Air Sample test, Page E-2.]*

170503

**RODAC Sample Plates –  
Tryptic Soy Agar with  
Lecithin & Polysorbate 80**

These plates, with Tryptic Soy Agar (TSA), contain neutralizing agents to inactivate residual disinfectants when the sample is being collected and are used for isolating and cultivating a variety of aerobic microorganisms from a surface or air (fallout) sample. Surface sampling is used to determine the quality of routine cleaning and sanitization procedures. The RODAC method will semiquantify the amount of microbial content on the surface.

*[See Environmental Surface Sample test, Page E-2.]*

**Collection supplies are also available and can be ordered by contacting WuXi AppTec's Atlanta facility or your Account Manager.**