



BIOLOGICS TESTING SOLUTIONS

## Media and Media Component Testing

### Available assays include:

- Sterility
- Mycoplasma
- Endotoxin
- Bovine and porcine adventitious virus testing
- Analytical testing

### Rightsource<sup>SM</sup>

- Insourcing/  
outsourcing options

Media and media supplements provide the basis for expansion of cell stocks in both R&D and GMP manufacturing situations. As a supplier of these components, it is essential to our clients that they provide their customers with high quality contaminant-free products. We support our clients' efforts in ensuring their product's purity through our comprehensive catalog of assays. Customers trust our clients' products to be manufactured safely, and we share this critical responsibility and expectation.

### Assays Available

#### Sterility

Our sterility testing is compliant with the requirements of the USP, EP, and current FDA regulations. Sterility testing is conducted by direct inoculation or membrane filtration methods and can be performed in either an isolator or cleanroom environment. In conjunction with the sterility test, a bacteriostasis/fungistasis test is performed to assess whether the test article is inhibitory to the growth of microorganisms.

#### Mycoplasma

There are various methods that can be used to test for a variety of mycoplasma species, including culture, indicator cell culture, and qPCR assays.

- **Culture Method:** Test items are inoculated onto agar plates and into broth. These are maintained under atmospheric conditions as specified in the various guidelines. The broth is subsequently subcultured onto agar plates and observed for evidence of contamination.
- **Indicator Cell Culture Method:** For non-cultivable species, the test material is cultured in the presence of an indicator cell line, like Vero cells. The cells are subsequently stained with a DNA binding fluorochrome stain (Hoescht) and evaluated microscopically for the presence of an infection.

EVERY STEP OF THE WAY

- **qPCR Methods:** Different qPCR options are available through Charles River, offering a variety of options including both broth culture and co-cultivation methods with or without growth enrichment. The addition of the growth enrichment step allows for differentiation between viable and nonviable mycoplasma.

### **Endotoxin**

The *in vitro* bacterial endotoxin tests (BET) are performed to meet all pharmacopeia requirements, including gel-clot, which is a qualitative assay, and kinetic turbidimetric and chromogenic methods, which are quantitative assays. Our line of Endosafe® rapid testing systems provide quick, accurate, and quantitative endotoxin analysis, glucan contamination testing, and Gram identification to simplify endotoxin detection from in-process to final lot release testing. Our highly flexible platforms all utilize our USP/BET-compliant FDA-licensed cartridges as well as a variety of non-regulated cartridges for simple, 15-minute testing, allowing users to receive results right at the point of sample collection, eliminating bottlenecks, improving sample management and, most importantly, assuring that products are free of endotoxin (pyrogen) within limits set by the pharmacopeias. Our bacterial endotoxin testing services laboratory can also provide support with methods development, stability testing, and product validation programs.

### **Bovine/Porcine Adventitious Virus Testing**

In our porcine and bovine virus assays, samples are incubated together with either bovine or porcine cells and examined for viruses based on cytopathic effects and using fluorescent antibody staining techniques. In addition, we offer specific PCR testing for bovine and porcine viruses. We accommodate many other virus-specific assays to include in testing panels, depending on the clients' samples and specific needs.

### **Analytical Testing**

We have various analytical testing techniques available to support the release of media and media components, including:

- Osmolality
- Appearance
- pH
- Amino acid analysis
- Growth factors by ELISA
- Water soluble vitamins by HPLC

### **RightSource<sup>SM</sup>**

Another option available to media manufacturers is our RightSource<sup>SM</sup> program. RightSource<sup>SM</sup> allows companies to evaluate strategic insourcing/outsourcing options for their testing. We work with companies to evaluate their quality control (QC) testing programs by reviewing their current testing structure and selecting the best-suited and most affordable mix of insourcing and outsourcing options. Dedicated project managers are also incorporated to ensure the proper management of the program and promote open communication to the client. RightSource<sup>SM</sup> allows media manufacturers to focus on their product development and distribution and not worry about the day-to-day QC activities.