eurofins | BioPharma Product Testing

Autologous Cell Therapy

Autologous Cell Therapies are an advancement in personalized medicine using a person's own cells to effectively treat a disease. Due to the immediate nature required of returning the cells to patients, rapid biosafety testing approaches must be utilized to demonstrate the cells have not been contaminated during cellular processing. Eurofins GMP rapid test methods meet and exceed the quality standards our clients and regulatory reviewers expect from a GMP service provider.

Eurofins BioPharma Product Testing offers GMP-validated biosafety assays to test for the presence of microbial, mycoplasma, and endotoxin contaminations in less than half the time of the traditional methods.

Why Choose Eurofins BioPharma Product Testing?

We provide a 3-day interim Certificate of Analysis (CoA) for our GMP rapid sterility method. We provide the final CoA for both mycoplasma PCR and endotoxin within 3 days.

Our large and flexible Microbiology team of 80 microbiologists provides expansive capacity and over 40 years of experience serving the bio/pharmaceutical industry.

Our industry leading online data portal, LabAccess, provides customers access to our LIMS system, allowing 24-hour access to data.

Our dedicated Project Management team focuses on biosafety, rapid testing, and client communications to assure on time delivery in our GMP environment.

Rapid Sterility Testing

Using the BacT/Alert® system, our rapid sterility approach is qualified against the organisms listed in USP <71>. In order to start the testing as soon as possible, Eurofins provides quality control released BacT bottles for our clients to inoculate on-site during cell processing. The BacT test method has a lab duration of 10 days with the majority of the organisms detected by day 3-7. To enable patients to receive their cells, Eurofins has built in a 3-day interim read that is shared by a Certificate of Analysis to our clients to help make an informed decision in patient dosing.

Rapid Mycoplasma Testing

The Eurofins mycoplasma PCR test method, utilizing the MycoSEQ platform, has a 3-day turnaround for the final Certificate of Analysis. The method is qualitative and is validated to have a limit of detection of ≤10CFU/mL or ≤10IU/mL. Eurofins verified the MycoSEQ method's limit of detection by performing the method on mock samples, inoculated with a live organism at or below the claimed limit of detection by the vendor. The mycoplasma PCR method meets or exceeds the USP <63>, Ph. Eur. 2.6.7, and JP Chapters limit of detection requirements.

Endotoxin Testing

Chromogenic endotoxin testing, using LAL, is also necessary to demonstrate that the cell processing technique did not introduce an endotoxin contamination. The final report for this test method can be provided in 3 days to offer endotoxin safety data. The test method has been verified and validated using USP <85>, Ph. Eur. 2.6.14, and JP 4.01.

The three test methods described here are the common rapid tests performed to assess the cellular product and gather information on potential contaminants prior to patient administration. Eurofins BioPharma Product Testing focuses on client timelines to execute the GMP testing rapidly. Our focus on quality is a driver behind providing accurate biosafety information, enabling patients to receive their cells without the concern of a potential contaminant.

Open lines of communication are critical to execute rapid testing in the GMP environment. Eurofins has a dedicated project management team focused on the GMP biosafety testing, including the Autologous Cell Therapy rapid test requirements. Our highly trained project management team is a crucial component in communication plans between clients and Eurofins testing.

The table listed below provides general information on the Autologous Cell Therapy test methods performed at Eurofins BioPharm Product Testing. Please reach out to your business development representative or project manager today to learn more about Eurofins' rapid GMP Biosafety Testing services.

Rapid Testing Supporting Autologous Cell Therapies

Test	Methodology	Sample Requirement	TAT	Test Code	Shipping
Sterility Suitability	BacT	<10mL	Varies	QL1GK	Refrigerated*
Sterility GMP Routine		<10mL	11 Days	QL1GJ	Refrigerated*
Sterility 3-day Interim Read		N/A	3 Days	QL1GL	N/A
Mycoplasma PCR Interference	PCR	11mL	3 Days	QL1GV	Frozen
Mycoplasma PCR GMP Routine		11mL	3 Days	QL1GU	Frozen
Endotoxin Suitability	Chromogenic	10mL	3 Days	QL1GT	Refrigerated or Frozen
Endotoxin GMP Routine		10mL	3 Days	QL1GS	Refrigerated or Frozen

*Inoculated bottles should be shipped refrigerated. Samples to inoculate may be shipped frozen.

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