



# CERTIFICATE OF ACCREDITATION

**The ANSI National Accreditation Board**

Hereby attests that

**Embryotech Laboratories Inc.**

**140 Hale Street  
Haverhill, MA 01830**

Fulfills the requirements of

**ISO/IEC 17025:2017**

and

**Good Laboratory Practice for Nonclinical Laboratory Studies, Title 21  
CFR Part 58 Accreditation Program**

In the field of

**TESTING**

This certificate is valid only when accompanied by a current scope of accreditation document.  
The current scope of accreditation can be verified at [www.anab.org](http://www.anab.org).

A handwritten signature in black ink, appearing to be 'J. Stine', is positioned above a horizontal line.

Jason Stine, Vice President

Expiry Date: 19 November 2025

Certificate Number: AT-1415



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.  
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory  
quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



**SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017**  
**GOOD LABORATORY PRACTICE for NONCLINICAL LABORATORY STUDIES,**  
**TITLE 21 CFR PART 58 ACCREDITATION PROGRAM**

**Embryotech Laboratories Inc.**

140 Hale Street  
Haverhill, MA 01830

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**TESTING**

Valid to: **November 19, 2025**

Certificate Number: **AT-1415**

**Biological**

<b>Specific Tests and/or Properties Measured</b>	<b>Specification, Standard, Method, or Test Technique</b>	<b>Items, Materials or Product Tested</b>	<b>Key Equipment or Technology</b>
Mouse Embryo Assay (MEA) 1-Cell Method	MEA Internal SOP or Customer Specified Method	Raw Materials, Media and Devices Intended for use in the Medical industry	CO <sub>2</sub> Incubator Dissecting Microscope
Mouse Embryo Assay (MEA) 2-Cell Method	MEA Internal SOP or Customer Specified Method	Raw Materials, Media and Devices Intended for use in the Medical industry	CO <sub>2</sub> Incubator Dissecting Microscope
Mouse Embryo Assay (MEA) Invitro-Fertilization	MEA Internal SOP or Customer Specified Method	Raw Materials, Media and Devices Intended for use in the Medical industry	CO <sub>2</sub> Incubator Dissecting Microscope
Sperm Motility Index (SM)	Human Sperm Internal SOP or Customer Specified Method	Raw Materials, Media and Devices Intended for use in the Medical industry	Incubator Inverted Microscope
Sperm Penetration Assay (SPA)	Human Sperm Internal SOP or Customer Specified Method	Raw Materials, Media and Devices Intended for use in the Medical industry	Incubator Inverted Microscope
Human Sperm Survival Assay (HSSA)	Human Sperm Internal SOP or Customer Specified Method	Raw Materials, Media and Devices Intended for use in the Medical industry	Incubator Inverted Microscope
Computer Assisted Sperm Analysis (CASA)	Human Sperm Internal SOP or Customer Specified Method	Raw Materials, Media and Devices Intended for use in the Medical industry	Incubator Computer with Integrated Microscope
Endotoxin (LAL) Gel-Clot Method	Gram negative bacteria detection, Internal SOP	Raw Materials, Media and Devices Intended for use in the Medical industry	Water bath

**Biological**

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Endotoxin (LAL) Kinetic Method	Gram negative bacteria detection, Internal SOP	Raw Materials, Media and Devices Intended for use in the Medical industry	Plate Reader Tube Reader
pH	pH Internal SOP	Raw Materials, Media and Devices Intended for use in the Medical industry	pH meter
Osmolarity (OSMO)	OSMO Internal SOP	Raw Materials, Media and Devices Intended for use in the Medical industry	Osmometer
Bioburden Membrane Filtration Method	Bioburden Internal SOP, or Customer Specified Methods according to ISO 11737-1 requirements	Raw Materials, Culture Media and Devices Intended for use in the Medical industry	Membrane Filtration System, Reciprocating Shaker, Incubator, Optical Biological Microscope, Hand-held Colony Counter and Magnifier

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1415.



Jason Stine, Vice President