



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.

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 19 November 2023
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.

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TESTING

Valid to: November 19, 2023

Certificate Number: AT-1415

Biological

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|---|---|---|---|
| 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 ₂ 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 ₂ 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 ₂ 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 |

Note:

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



R. Douglas Leonard Jr., VP, PILR SBU

