



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

Embryotech Laboratories Inc.

140 Hale Street

Haverhill, MA 01830

has been assessed by ANAB and meets the requirements of international standard

ISO/IEC 17025:2017

and the

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

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

AT-1415

Certificate Number

ANAB Approval

Certificate Valid Through: 11/19/2021
Version No. 005 Issued: 09/30/2019



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).



ANSI National Accreditation Board

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

Embryotech Laboratories Inc.

140 Hale Street
Haverhill, MA 01830

Cheryl Mills, Joel Lopez 978-373-7300
cmills@embryotech.com jlopez@embryotech.com
www.embryotech.com

TESTING

Valid to: **November 19, 2021**

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.



Vice President