



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board/AClass
500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

Molecular Epidemiology, Inc. (MEI)
dba IEH Laboratories and Consulting Group
15300 Bothell Way, NE
Lake Forest Park, WA 98155

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

ISO/IEC 17025:2005

while demonstrating technical competence in the field(s) of

TESTING

Refer to the accompanying Scope(s) of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-1516

Certificate Number

AClass Approval

Certificate Valid: 01/31/2011-01/31/2013
Version No. 001 Issued: 02/01/2011



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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 January 2009).



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Molecular Epidemiology, Inc. (MEI)
dba IEH Laboratories and Consulting Group

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TESTING

Valid to: January 31, 2013

Certificate Number: AT – 1516

I. Microbiological Testing 3

Table with 4 columns: ITEMS, MATERIALS OR PRODUCTS TESTED; SPECIFIC TESTS OR PROPERTIES MEASURED; SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED; *DETECTION LIMIT/ RANGE/ EQUIPMENT. Rows include tests for E. coli, Total Coliform, Aerobic Plate Count, and Salmonella.



ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*DETECTION LIMIT/ RANGE/ EQUIPMENT
Food Products, Pharmaceuticals, Environmental Samples	Detection of <i>E. coli</i> O157 / EHEC / STEC and <i>Salmonella</i> sp.	MB217 IEH <i>E. coli</i> O157, Stx-producing <i>E. coli</i> (STEC) with Intimin and <i>Salmonella</i> Test System (AOAC-RI PTM 100701)	Multiplex PCR System
Food Products, Pharmaceuticals, Environmental Samples	Detection of EHEC / STEC	MB218- MEI Detection of EHEC/STEC by Multiplex Method (AOAC-RI PTM 100701)	Multiplex PCR System
Food Products, Pharmaceuticals, Environmental Samples	Detection of <i>Shigella</i> sp.	MB222 Detection of <i>Shigella</i> sp. in Food and Environmental Samples by Multiplex PCR	Multiplex PCR System
Food Products, Pharmaceuticals, Environmental Samples	Lactic Acid Bacteria Count	MB231 Compendium of Methods for the Microbiological Examination of Food Products 4 th ed.	Pour Plate
Food Products, Pharmaceuticals, Environmental Samples	Detection of <i>Salmonella</i> sp.	MB315-MEI Detection of <i>Salmonella</i> sp. in Food and Environmental Samples by Multiplex PCR (AOAC-RI PTM 100701)	Multiplex PCR System
Food Products, Pharmaceuticals, Environmental Samples	Detection of <i>Listeria sp</i> and <i>L. monocytogenes</i>	MB316-MEI Detection of <i>Listeria sp.</i> and <i>L. monocytogenes</i> by Multiplex Method	Multiplex PCR System
Food Products, Pharmaceuticals, Environmental Samples	Subtyping of <i>E. coli</i> O157:H7, <i>Salmonella</i> sp. and <i>L. monocytogenes</i>	MB331-MEI Pulsed Field Gel Electrophoresis (<i>E. coli</i> O157:H7, <i>Salmonella</i> sp., <i>L. monocytogenes</i>)	Gel Electrophoresis
Food Products, Pharmaceuticals, Environmental Samples	Microbial Source Tracking	MB333-MEI Microbial Source Tracking (MST) by rRNA Typing	rRNA Typing Apparatus
Food Products, Pharmaceuticals, Environmental Samples	Lactic Acid Bacteria Count	MB343-MEI Lactic Acid Bacteria Count Petrifilm	Petrifilm Anaerobic incubation
Food Products, Pharmaceuticals, Environmental Samples	Bacterial Sub-typing by MRF	MB431-MEI Bacterial Subtyping by Micro Restriction Fingerprinting (MRF)	Micro Restriction Fingerprinting
Food Products, Pharmaceuticals, Environmental Samples	Detection and Enumeration of <i>Staphylococcus aureus</i>	MB443 Detection and Enumeration of <i>Staphylococcus aureus</i> Petrifilm (AOAC 2003.07, 2003.08, 2003.11)	Petrifilm



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Food Products, Pharmaceuticals, Environmental Samples	Enterobacteriaceae Plate Count	MB444-MEI Enumeration of Enterobacteriaceae - Petrifilm (AOAC 2003.01)	Petrifilm
Food Products, Pharmaceuticals, Environmental Samples	Epifluorescent Bacterial Count	MB448-MEI Acridine Orange Direct Count: Total Bacterial Count (Epifluorescence Bacterial Count)	Epifluorescence Microscopy
Food Products, Pharmaceuticals, Environmental Samples	Identification of Microorganisms by DNA Sequencing	MB450-MEI Identification of Microorganisms by DNA Sequencing	DNA Sequencing
Food Products, Pharmaceuticals, Environmental Samples	Bacterial Sub-typing by Pulsed Field Gel Electrophoresis	MB454-MEI Bacterial Sub-typing by Pulsed Field Gel Electrophoresis	Pulsed Field Gel Electrophoresis
Food Products, Pharmaceuticals, Environmental Samples	Microscopic Analysis of Microorganisms	MB457-MEI Microscopic Analysis of Microorganisms	Light Microscope
Food Products, Pharmaceuticals, Environmental Samples	Phenotypic Analysis of Microorganisms	MB473-MEI Phenotypic Analysis of Microorganisms	IEH Method VITEK Analyzer
Food Products, Pharmaceuticals, Environmental Samples	<i>Bacillus</i> Diarrheal Enterotoxin Visual Immunoassay	MB476-MEI <i>Bacillus</i> Diarrheal Enterotoxin Visual Immunoassay	Immunoassay
Food Products, Pharmaceuticals, Environmental Samples	Process Control Index (PCI) Testing	MB491 Process Control Index (PCI) Testing	Multiplex PCR System
Food Products, Pharmaceuticals, Environmental Samples	Yeast & Mold Count	MB492-MEI Yeast & Mold Count - Petrifilm (AOAC 997.02)	Petrifilm
Food Products, Pharmaceuticals, Environmental Samples	<i>Bacillus cereus</i> L ₂ Toxin	MB496-MEI Detection of <i>Bacillus cereus</i> Enterotoxin L ₂ by Using the BCET-RPLA® Diagnostic Kit	Diagnostic Kit
Food Products, Pharmaceuticals, Environmental Samples	<i>Bacillus cereus</i> Group Toxins	MB505-MEI Detection of <i>Bacillus cereus</i> Group Toxins by PCR	Multiplex PCR System
Food Products, Pharmaceuticals, Environmental Samples	IEH-APC-MPN (12 hours)	MB704 Enumeration of Aerobic Bacteria by IEH-MPN Method (IEH-APC-MPN, 12 hours)	IEH Method



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Food Products, Pharmaceuticals, Environmental Samples	IEH-ACE-MPN (24 hours)	MB705 Enumeration of Aerobic Bacteria, Total Coliforms and Generic <i>Escherichia coli</i> by IEH-MPN Method (IEH-ACE-MPN, 24 hrs)	IEH Method
Food Products, Pharmaceuticals, Environmental Samples	<i>Salmonella</i> sp.	MB921 BAX System PCR Assay <i>Salmonella</i> USDA MLG 4 (AOAC 992.11)	BAX Method
Food Products, Pharmaceuticals, Environmental Samples	<i>E. coli</i> O157:H7	MB922 BAX System PCR Assay <i>E. coli</i> O157:H7 MP USDA MLG 5	BAX Method
Food Products, Pharmaceuticals, Environmental Samples	3-Tube MPN and 5-Tube MPN Coliform / FC / generic <i>E. coli</i>	MB923 Multiple Tube Fermentation Method FDA BAM, 8 th ed. (SM9221)	Multiple Tube Fermentation
Food Products, Pharmaceuticals, Environmental Samples	Total Coliforms / Fecal Coliforms / <i>E. coli</i>	MB926 Examination of Water and Wastewater for Total Coliforms, Fecal Coliforms and <i>E. coli</i> (SM 9221)	Multiple Tube Fermentation
Raw ground beef, Raw beef trim	<i>E. coli</i> O157	MB927: Detection of <i>E. coli</i> O157:H7 in Food Samples by SDIX RapidChek Lateral Flow Assay	Lateral Flow EIA
Food Products, Pharmaceuticals, Environmental Samples	Total Coliforms / <i>E. coli</i>	MB928 Detection and Enumeration of Both Total Coliforms (TC) and <i>Escherichia coli</i> (<i>E. coli</i>) by Membrane Filtration USEPA 1604	Membrane Filtration
Food Products, Pharmaceuticals, Environmental Samples	Pathogenic <i>E. coli</i>	MB929 Isolation and Identification of Pathogenic <i>E. coli</i> (BAM: Diarrheagenic <i>E. coli</i> Bacteriological Analytical Manual Chapter 4a)	FDA BAM Method

Notes:

1. * = As Applicable
2. This scope is part of and must be included with the Certificate of Accreditation No. AT- 1516
3. Microbial testing is performed in compliance with the AOAC International Accreditation Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Foods, Feeds, and Pharmaceutical Testing and in compliance with US FDA cGMP requirements as specified in 21CFR Parts 210 and 211.

Kath. Summary

Vice President

