

ANSI-ASQ National Accreditation Board/ACLASS

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005 and AOAC FOOD LABORATORY Requirements

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

15300 Bothell Way NE, Lake Forest Park, WA 98155 Jonathan Collins Phone: 206-522-5432 jcc@iehinc.com www.iehinc.com

TESTING

Valid to: January 31, 2017 Certificate Number: AT – 1516

I. Microbiological ³

| ITEMS, MATERIALS OR PRODUCTS TESTED | SPECIFIC TESTS OR PROPERTIES MEASURED | SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED | *KEY EQUIPMENT OR TECHNOLOGY |
|--|---|--|---------------------------------|
| Food Products, Pharmaceuticals, Environmental Samples | Food Analytical Prep | MB001-MEI Sample Preparation for Microbial Analyses | IEH Method |
| Food Products, Pharmaceuticals, Environmental Samples | E. coli O157 / STEC | MB038: USDA Cultural Confirmation Only USDA MLG 5 | Lateral Flow EIA |
| Food Products, Pharmaceuticals, Environmental Samples | Detection of Salmonella | MB094-MEI Detection of Salmonella in Meat, Poultry and Environmental Samples - Salmonella Confirmation (USDA MLG 4) | USDA Method |
| Food Products, Pharmaceuticals, Environmental Samples | Pathogenic <i>E. coli</i> | MB929 Isolation and Identification of Pathogenic E. coli (BAM: Diarrheagenic E. coli Bacteriological Analytical Manual Chapter 4a) | FDA BAM Method |
| Plant / Food Material, Animal Tissue, Bacterial Cells | Nucleic acids | MB541 Nucleic acid extraction procedure | Enzymatic Digestion |
| Food Products, Pharmaceuticals, Environmental Samples | Detection of E. coli O157 | MB217-MEI Detection of <i>E. coli</i> O157:H7 by Multiplex PCR (AOAC-RI PTM 100701) | Multiplex PCR System |
| Food Products, Pharmaceuticals, Environmental Samples | Detection of EHEC / STEC | MB217- MEI/IEH Stx-producing <i>E.coli</i> (STEC/EHEC) with Intimin (AOAC-RI PTM 100701) | Multiplex PCR System |

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| Food Products, Pharmaceuticals, Environmental Samples | Detection of E. coli O157 / EHEC / STEC and Salmonella sp. | MB217 IEH E. coli O157, Stx-producing E. coli (STEC/EHEC) with Intimin and Salmonella Test System (AOAC-RI PTM 100701) | Multiplex PCR System |
| Food Products, Pharmaceuticals, Environmental Samples | Detection of Salmonella sp. | MB217 MEI/IEH Salmonella Test System (AOAC-RI PTM 100701) | Multiplex PCR System |
| Food Products, Pharmaceuticals, Environmental Samples | Detection of Salmonella sp. | MB315-MEI Detection of Salmonella sp. in Food and Environmental Samples by Multiplex PCR (AOAC-RI PTM 100701) | Multiplex PCR System |
| Food Products, Pharmaceuticals, Environmental Samples | Detection of Shigella sp. | MB222 Detection of <i>Shigella</i> sp. in Food and Environmental Samples by Multiplex PCR | Multiplex PCR System |
| Food Products, Pharmaceuticals, Environmental Samples | Detection of <i>Listeria</i> sp. and <i>L. monocytogenes</i> | MB316-MEI Detection of <i>Listeria</i> sp. and <i>L. monocytogenes</i> by Multiplex Method | Multiplex PCR System |
| Food Products, Pharmaceuticals, Environmental Samples | Process Control Index (PCI) Testing | MB491 Process Control Index (PCI) Testing | Multiplex PCR System |
| Plant / Food material | GMO Detection Screening elements: P35S, NOS, FMV; Corn: T25, CBH351, MON810, GA21, Bt176, Bt11, NK603,TC1507, Mon863, DAS 59122, MIR 604, Event 3272, MON 88017, MON 89034, MIR 162; Soy: A2704-12, A5547-127, GTS 40-3- 2, FG72, MON 87701, MON 89788, DP305426, DP356043, Cotton: 3006-213, Event 1, COT67B, GHB614, LL cotton25, MON 15985, MON 1445; Potato: 1210amk, EH92-527-1; Sugarbeets: H7-1 | MB544 Detection and Identification of GM crops by Multiplex PCR | Multiplex PCR System |

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| Food Products | Detection and Identification of Allergens | MB 547 Detection and Identification of Allergens by PCR | Multiplex PCR System |
| Meat | Meat Authentication (Beef, Pork, Lamb, Horse, Turkey and Chicken) | MB542 Meat Authentication PCR | Multiplex PCR System |
| Food Products, Pharmaceuticals, Environmental Samples | Bacillus cereus Group Toxins | MB505-MEI Detection of <i>Bacillus cereus</i> Group Toxins by PCR | Multiplex PCR System |
| Food Products, Pharmaceuticals, Environmental Samples | Salmonella sp. | MB921 BAX System PCR Assay Salmonella USDA MLG 4 (AOAC 992.11) | BAX Method |
| Food Products, Pharmaceuticals, Environmental Samples | E. coli O157:H7 | MB922 BAX System PCR Assay E. coli O157:H7 MP USDA MLG 5 | BAX Method |
| 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 | Total Coliform / E. coli Count | MB072-MEI Total Coliform / E. coli Count Petrifilm (AOAC 991.14) | Petrifilm |
| Food Products, Pharmaceuticals, Environmental Samples | Aerobic Plate Count | MB078-MEI Aerobic Plate Count Petrifilm (AOAC 990.12) | Petrifilm |
| Food Products, Pharmaceuticals, Environmental Samples | Yeast & Mold Count | MB492-MEI Yeast & Mold Count - Petrifilm (AOAC 997.02) | Petrifilm |
| Food Products, Pharmaceuticals, Environmental Samples | Enterobacteriaceae Plate Count | MB444-MEI Enumeration of Enterobacteriaceae - Petrifilm (AOAC 2003.01) | Petrifilm |

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| Food Products, Pharmaceuticals, Environmental Samples | Lactic Acid Bacteria Count | MB343-MEI Lactic Acid Bacteria Count Petrifilm | Petrifilm Anaerobic incubation |
| Food Products, Pharmaceuticals, Environmental Samples | Detection and Enumeration of Staphylococcus aureus | MB443 Detection and Enumeration of Staphylococcus aureus Petrifilm (AOAC 2003.07, 2003.08, 2003.11) | Petrifilm |
| 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 | IEH- <i>E. coli</i> -MPN 12 hrs | MB081-MEI Enumeration of Generic E. coli by IEH-MPN Method (IEH- E. coli -MPN, 12 hr) | IEH Method |
| 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 |
| Food Products, Pharmaceuticals, Environmental Samples | IEH-ACE-MPN (24 hours) | MB705 Enumeration of Aerobic Bacteria, Total Coliforms and Generic Escherichia coli by IEH-MPN Method (IEH-ACE-MPN, 24 hrs) | IEH 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 / E. coli | MB923 Examination of Water and Wastewater for Total Coliforms, Fecal Coliforms and E. coli (SM 9221) | Multiple Tube Fermentation |
| Food Products, Pharmaceuticals, Environmental Samples | Total Coliforms / E. coli | MB928 Detection and Enumeration of Both Total Coliforms (TC) and Escherichia coli (E. coli) by Membrane Filtration USEPA 1604 | Membrane Filtration |
| Food Products | Gluten | MB538 Detection of Gliadin (Gluten) by ELISA | ELISA system |

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|---|---|--|---------------------------------|
| Food Products | Various | MB539 Detection of Allergen Residue by ELISA | ELISA system |
| Food Products | Sesame protein | MB540 Detection of Sesame seed protein Residue by ELISA | ELISA system |
| Food Products | Gluten | MB 548 Detection of Gluten/Gliadin by Lateral Flow Device | Lateral Flow Device |
| Food Products | Allergen Residue | MB546 Detection of allergen residue by Lateral Flow Device | Lateral Flow Device |
| Beef Blood Meal, Cat Food, Dog Food, Feather Meal, Fish Meal, Pet Treats, Pork Blood Meal, Pork Meat & Bone Meal, Poultry Meal, Turkey Meal | Ruminant material | RE121.02 Reveal Procedure for Ruminant in MBM | Immunoassay |

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.

Vice President





