

## CERTIFICATE OF ACCREDITATION

## The ANSI National Accreditation Board

Hereby attests that

# Biogen Laboratory Developments, LLC dba Biogen Food Labs Food, Supplement and R&D Lab

36740 E. Historic Columbia River Hwy Corbett, OR 97019

Fulfills the requirements of

**ISO/IEC 17025:2017** 

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 <a href="https://www.anab.org">www.anab.org</a>.

Jason Stine, Vice President

Expiry Date: 13 July 2024 Certificate Number: AT-2604









#### SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

#### Biogen Laboratory Developments, LLC dba Biogen Food Labs Food, Supplement and R&D Lab

36740 E. Historic Columbia River Hwy Corbett, OR 97019

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#### **TESTING**

Valid to: July 13, 2024 Certificate Number: AT-2604

#### Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Aerobic Plate Count	AOAC 966.23 based on FDA BAM Online Ch.3; CMMEF 5 <sup>th</sup> Ed.	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Culture – Pour Plate
Aerobic Plate Count (Rapid)	AOAC 2015.13	Food Products, Supplements, Packaging Materials, and Environmental Samples	Petrifilm
Anaerobic Plate Count	SOP 202 based on AOAC 966.23; FDA BAM Online Ch.3; CMMEF 5 <sup>th</sup> Ed.	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Culture – Pour Plate
Total Coliform	AOAC 991.14	Food Products, Supplements, Packaging Materials, and Environmental Samples	Petrifilm
Total <i>E. coli</i> (Generic)	AOAC 991.14	Food Products, Supplements, Packaging Materials, and Environmental Samples	Petrifilm
Total Coliform	SM9223B	Drinking Water	Colilert
Total <i>E. coli</i> (Generic)	SM9223B	Drinking Water	Colilert



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Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Yeast and Mold	SOP 220 based on FDA BAM Online Ch.18; CMMEF 5 <sup>th</sup> Ed.	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Culture – Pour Plate
Yeast and Mold (Rapid)	AOAC 2014.05	Food Products, Supplements, Packaging Materials, and Environmental Samples	Petrifilm
Total Probiotic Count	CMMEF 5 <sup>th</sup> Ed.	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Culture – Pour Plate
Lactic Acid Bacteria	CMMEF 5 <sup>th</sup> Ed.	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Culture – Pour Plate
Lactic Acid Bacteria	AOAC RI 041701	Food Products, Supplements, Packaging Materials, and Environmental Samples	Petrifilm
Staphylococcus aureus	AOAC 2003.07	Food Products, Supplements, Packaging Materials, and Environmental Samples	Petrifilm
Total Enterobacteriaceae	AOAC 2003.01	Food Products, Supplements, Packaging Materials, and Environmental Samples	Petrifilm
Microbial Environmental Sampling	CMMEF 5 <sup>th</sup> Ed. SOP 300	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Aseptic Sampling
Genetically Modified Organisms (GMO)	TaqMan PCR SOP 350	Food Products, Supplements, Nutraceuticals	PCR
Salmonella sp.	AOAC 2020.02 PEPRL 0007.10	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	GENE-UP® PCR
Listeria sp.	AOAC 2019.10	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	GENE-UP® PCR





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Listeria monocytogenes	AOAC 2019.11	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	GENE-UP® PCR
E. coli O157:H7	AOAC 2019.03	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	GENE-UP® PCR
EHEC Series: STEC – EAE & STX STEC - top 6	AOAC PTM 121806	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	GENE-UP® PCR & Vidas® Immunoassay
Cronobacter sp.	AOAC 2019.01	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	GENE-UP® PCR
Salmonella sp.	AOAC 2013.01	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Vidas® UP Immunoassay
Listeria sp.	AOAC 2013.10	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Vidas® UP Immunoassay
Listeria monocytogenes	AOAC 2013.11	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Vidas® Xpress Immunoassay
Listeria monocytogenes	AOAC 2004.02	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Vidas® LMO2 Immunoassay
E. coli O157:H7	AOAC PTM 060903	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Vidas® UP Immunoassay
Campylobacter	AOAC PTM 051201 USDA FSIS MLG 41.01	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Vidas® Immunoassay





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Salmonella sp.	AOAC 2013.02	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	BAX® System PCR
Listeria sp.	AOAC PTM 081401 AOAC PTM 050903	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	BAX® System PCR
Listeria monocytogenes	AOAC PTM 121402 AOAC PTM 080901	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	BAX® System PCR
E. coli O157:H7	AOAC PTM 102003 AOAC PTM 031002 USDA FSIS MLG 5.09/5A.04	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	BAX® System PCR
EHEC Series: STEC – EAE & STX STEC – Panel 1 & 2	AOAC PTM 091301 USDA FSIS MLG 5B.05	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	BAX® System PCR
Campylobacter	AOAC PTM 040702 USDA FSIS MLG 41.04, 41A.00	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	BAX® System PCR
Vibrio cholerae/ parahaemolyticus/ vulnificus	AOAC PTM 050902	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	BAX® System PCR
Salmonella sp.	AOAC RI 051303	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	QuantStudio 5 SureTect™ PCR
Listeria sp.	AOAC RI 071304	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	QuantStudio 5 SureTect™ PCR
Listeria monocytogenes	AOAC RI 061302	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	QuantStudio 5 SureTect™ PCR





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E. coli O157:H7	AOAC RI 021501	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	QuantStudio 5 SureTect <sup>TM</sup> PCR
Salmonella sp.	AOAC RI 080601	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	RapidChek Immunoassay
Listeria sp.	AOAC RI 020401	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	RapidChek Immunoassay
Listeria monocytogenes	AOAC RI 011805	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	RapidChek Immunoassay
E. coli O157:H7	AOAC RI 070801	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	RapidChek Immunoassay

#### Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Pesticide Analysis	AOAC 2007.01 mod.	Fruit, Plant Tissue, Supplements, Nutraceuticals	LC-MS/MS
Pesticide Analysis	AOAC 2007.01 mod.	Fruit, Plant Tissue, Supplements, Nutraceuticals	GC-MS/MS
Herbicide Analysis	AOAC 2007.01 mod.	Fruit, Plant Tissue, Supplements, Nutraceuticals	LC-MS/MS
Pesticide Analysis	LC-MS/MS SOP 630 AOAC 2007.01 mod.	Cannabis, Oils, Distillates	LC-MS/MS





#### Chemical

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Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Pesticide Analysis	GC-MS/MS SOP 630 AOAC 2007.01 mod.	Cannabis, Oils, Distillates	GC-MS/MS
Cannabinoid Profile	HPLC SOP 620	Cannabis, Oils, Distillates	HPLC
Gliadin R5 / Gluten	AOAC RI 061201	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Sesame Allergen	ELISA SOP 262	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Egg Allergen	ELISA SOP 251	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Milk Allergen	ELISA SOP 252	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Soy Allergen	ELISA SOP 253	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Peanut Allergen	AOAC RI 030403	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Crustacea Allergen	ELISA SOP 255	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Tree Nut Allergen	ELISA SOP 259	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Reveal Immunoassay
Patulin	AOAC 995.10 (Modified)	Food Products, Supplements, Nutraceuticals	HPLC





#### Chemical

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Mycotoxins: Aflatoxin B1, B2, G1, G2	AOAC RI 050901	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Mycotoxin: Aflatoxin M1	ELISA SOP 271	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Mycotoxin: DON / Vomitoxin	AOAC RI 090901	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Mycotoxin: Ochratoxin	ELISA SOP 273	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	ELISA
Water Activity	AOAC 978.18 Meter	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Aw Meter
Moisture	AOAC 925.10	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Gravimetric
Solids	AOAC 925.10	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	Gravimetric
pН	AOAC 981.12; AOAC 960.19	Food Products, Supplements, Nutraceuticals, Packaging Materials, and Environmental Samples	pH Meter

#### Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2604.

Jason Stine, Vice President

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