

Certifications and Validations for BAX[®] System Assays

AOAC Performance Tested MethodSM

Real-Time <i>Campylobacter jejuni, coli, lari</i>	#040702
<i>E. coli</i> O157:H7 MP, X5 <i>E. coli</i> O157:H7	#050501
Real-Time <i>E. coli</i> O157:H7 EXACT	#102003
Real-Time <i>E. coli</i> O157:H7	#031002
Real-Time STEC Screening Suite	#091301
Genus <i>Listeria</i> , X5 Genus <i>Listeria</i>	#030502
Genus <i>Listeria</i> 24E	#050903
Real-Time Genus <i>Listeria</i>	#081401
<i>L. monocytogenes</i> , X5 <i>L. mono</i>	#070202
<i>L. monocytogenes</i> 24E	#080901
Real-Time <i>L. monocytogenes</i>	#121402
<i>Salmonella</i> 2, X5 <i>Salmonella</i>	#100201
Real-Time <i>Salmonella</i>	#081201
Real-Time <i>Staphylococcus aureus</i>	#120701
Real-Time <i>Vibrio cholerae, parahaemolyticus, and vulnificus</i>	#050902
Yeast and Mold	#010902

AOAC OMA

<i>L. monocytogenes</i>	#2003.12
<i>Salmonella</i> 2	#2003.09
Real-Time <i>Salmonella</i>	#2013.02

NordVal

<i>Salmonella</i> 2, X5 <i>Salmonella</i>	#30
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BAX[®] System PCR Assays for *E. coli*



BAX[®] System PCR Assays for Genus *Listeria*



BAX[®] System PCR Assays for *Listeria monocytogenes*

Certifications and Validations for BAX[®] System Assays

AFNOR

<i>E. coli</i> O157:H7 MP, X5 <i>E. coli</i> O157:H7	QUA 18/04 - 03/08
Real-Time <i>E. coli</i> O157:H7	QUA 18/07 - 07/10, QUA 18/11 - 12/20
Real-Time STEC Screening Suite	QUA 18/11 - 12/20
Genus <i>Listeria</i> 24E, X5 Genus <i>Listeria</i>	QUA 18/06 - 07/08
Real-Time Genus <i>Listeria</i>	QUA 18/09 - 01/19
<i>L. monocytogenes</i> 24E, X5 <i>L. mono</i>	QUA 18/05 - 07/08
Real-Time <i>L. monocytogenes</i>	QUA 18/10 - 01/19
Real-Time <i>Salmonella</i>	QUA 18/08 - 03/15
<i>Salmonella</i> 2, X5 <i>Salmonella</i>	QUA 18/03 - 11/02

Health Canada MFLP

<i>E. sakazakii</i> (<i>Cronobacter</i> spp.)	#27
<i>E. coli</i> O157:H7 MP	#30
Real-Time <i>E. coli</i> O157:H7	#76
Real-Time <i>E. coli</i> O157:H7 EXACT	#115
Real-Time Genus <i>Listeria</i>	#79
Genus <i>Listeria</i>	#15 (with BAX [®] System <i>Listeria</i> media only)
<i>L. monocytogenes</i>	#28
Real-Time <i>L. monocytogenes</i>	Pending
<i>Salmonella</i> 2	#29
Real-Time <i>Salmonella</i>	#114 pending publication

USDA-FSIS

Real-Time STEC Screening Suite	MLG 5B.05 (adoption)
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BAX[®] System PCR Assays for *Salmonella*



BAX[®] System PCR Assay for *Cronobacter*



BAX[®] System PCR Assay for *Campylobacter*



BAX[®] System PCR Assay for *Staphylococcus aureus*



BAX[®] System PCR Assay for *Shigella*



BAX[®] System Real-Time PCR Assay for *Vibrio*



BAX[®] System PCR Assay for Yeast & Mold

Campylobacter (*C. jejuni*, *C. coli*, *C. lari*)

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
Real-Time <i>Campylobacter jejuni</i> , <i>coli</i> , <i>lari</i>	Poultry carcass rinses and RTE turkey	AOAC PTM #040702

Cronobacter (*E. sakazakii*)

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
<i>E. sakazakii</i> (<i>Cronobacter</i> spp.)	Powdered infant formula, dry dairy and soy ingredients, environmental samples	Health Canada MFLP #27

E. coli

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
<i>E. coli</i> O157:H7 MP, X5 <i>E. coli</i> O157:H7	Raw meats (including ground beef, beef trim, raw pork, bovine and chicken meats), raw milk, fruits, vegetables (including spinach and lettuce), ready-to-eat meals	AFNOR QUA 18/04-03/08
	Raw ground beef, beef trim, spinach, lettuce, red leaf lettuce	AOAC PTM #050501
<i>E. coli</i> O157:H7 MP	Dairy products, raw meat products, ready-to-eat meat and poultry products, fruit- and vegetable-based products, dry cereal, dry animal feed products	Health Canada MFLP #30
Real-Time <i>E. coli</i> O157:H7 EXACT	Ground beef, beef trim, leafy greens, raw dairy, beef trim sampling cloths, dried hemp flowers, dried cannabis flowers	AOAC PTM #102003
	Raw and raw processed meats	Health Canada - MFLP #115
Real-Time <i>E. coli</i> O157:H7	Ground beef, beef trim, spinach, lettuce	AFNOR QUA 18/07-07/10, AOAC PTM #031002
	Raw beef meats, raw dairy, and vegetable	AFNOR QUA 18/11-12/20
	Raw ground meat and meat trim	Health Canada MFLP #76
Real-Time STEC Screening Suite	Raw beef meats, raw dairy, and vegetable	AFNOR QUA 18/11-12/20
	Beef trim, ground beef, ground beef with soy, flour, beef trim sampling cloths, dried hemp flowers, dried cannabis flowers	AOAC PTM #091301
	Meats products, carcass, environmental sponges	USDA-FSIS MLG 5B.05 (adoption)

Listeria

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
Genus <i>Listeria</i> 24E, X5 Genus <i>Listeria</i>	All human food products and environmental samples: composite foods, meat, seafood, dairy, fruits and vegetables, environmentals	AFNOR QUA 18/06-07/08
Genus <i>Listeria</i> , X5 Genus <i>Listeria</i>	Frankfurters, smoked salmon, spinach and other vegetables, cheese, environmental swabs and surfaces	AOAC PTM #030502
Genus <i>Listeria</i>	Environmental surfaces	Health Canada MFLP #15 (with BAX® System <i>Listeria</i> media only)
Genus <i>Listeria</i> 24E	Frankfurters, spinach, cooked shrimp, queso fresco cheese and stainless steel	AOAC PTM #050903
Real-Time Genus <i>Listeria</i>	All surfaces	Health Canada MFLP #79
	Food products and environmental production samples: Composite foods, RTE and RTRH, meat, raw and processed dairy, vegetables, seafood, environmental samples except primary productions samples.	AFNOR QUA 18/09 -01/19
	Frankfurters, spinach, cooked shrimp, queso fresco cheese and environmental surfaces (stainless steel, sealed concrete and plastic)	AOAC PTM #081401

Vibrio (*V. cholerae*, *V. parahaemolyticus* and *V. vulnificus*)

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
Real-Time <i>Vibrio cholerae</i> , <i>parahaemolyticus</i> and <i>vulnificus</i>	Shrimp (raw and cooked), tuna (raw), scallops, oysters	AOAC PTM #050902

Staphylococcus aureus

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
Real-Time <i>Staphylococcus aureus</i>	Ground beef, infant formula, soy protein isolate	AOAC PTM #120701

Listeria monocytogenes

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
<i>L. monocytogenes</i> 24E, X5 <i>L. mono</i>	All human food products and environmental samples: composite foods, meat, seafood, dairy, fruits and vegetables, environmentals	AFNOR QUA 18/05-07/08
<i>L. monocytogenes</i>	Raw meat/poultry, processed meat (RTE), dairy, seafood, fruits and vegetables (except radishes), fruit juice, environmental surface (plastic)	AOAC PTM #070202 OMA #2003.12
X5 <i>L. mono</i>	Raw meat/poultry, processed meat (RTE), dairy, seafood, fruits and vegetables (except radishes), fruit juice, environmental surface (plastic)	AOAC PTM #070202
<i>L. monocytogenes</i>	Raw meat and poultry, eggs and egg products, seafood, dairy products, composite foods, fruits and vegetables (except radishes), low moisture foods (chocolate), cereals, animal feed, environmentals	Health Canada MFLP #28
<i>L. monocytogenes</i> 24E	Frankfurters, spinach, cooked shrimp, queso fresco cheese and stainless steel	AOAC PTM #080901
Real-Time <i>L. monocytogenes</i>	Food products and environmental production samples: Composite foods, RTE and RTRH, meat, raw and processed dairy, vegetables, seafood, environmental samples except primary productions samples.	AFNOR QUA 18/10 -01/19
	Composite foods, dairy (raw and processed), RTE meat and poultry, fruits and vegetables, seafood	Health Canada - Pending
	Frankfurters, spinach, cooked shrimp, smoked salmon, queso fresco cheese and environmental surfaces (stainless steel, sealed concrete and plastic)	AOAC PTM #121402

Salmonella

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
Salmonella 2 X5 Salmonella (OMA not for X5)	Food products, animal feed and environmental samples (excluding primary production system): Composite (RTE, RTRH), raw beef and poultry, seafood, produce, dairy, eggs, peanut butter, cocoa, dry pet food, animal feed, vegetables, environmental samples	AFNOR QUA 18/3-11/02
	All foods and a variety of environmental surface samples: Processed and raw dairy, seafood, chocolate/bakery products, fruits and vegetables, raw poultry, spices, environmental samples	Health Canada MFLP #29
	Food products, animal feed and environmental samples (excluding primary production system): Composite (RTE, RTRH), raw beef and poultry, seafood, produce, dairy, eggs, peanut butter, cocoa, dry pet food, animal feed, vegetables, environmental samples	NordVal #30
	All human food products, animal feed and environmental samples - raw beef and poultry, beef trim, seafood, produce, dairy, eggs, peanut butter, cocoa/chocolate and bakery, pasta, RTE foods, dry pet food, animal feed, surfaces, fruits and vegetables, spices, soy protein flour	AOAC PTM #100201 OMA #2003.09
Real-Time Salmonella	Broad range of foods (excluding milk powders) animal feed and environmental samples (except primary production samples): Meat, seafood, vegetables, pet food, production samples, egg products, raw beef, raw meats, raw seafood, dairy products, chocolate	AFNOR QUA 18/08-03/15
	Variety of food and environmental samples: Raw poultry, dairy, RTE meat and poultry, fruits and vegetables, eggs, chocolates/bakery, environmental samples	Health Canada - #114 (Pending Publication)
	Broad range of foods including ground beef, chicken carcass rinses, bagged lettuce, cream cheese, pet food, stainless steel, milk chocolate, chocolate liquor, cocoa powder, shell egg, plastic, dried cannabis flower, dried hemp flowers and beef trim sampling cloths; SalQuant™ Method on ground turkey, ground chicken, whole poultry carcass rinses, ground beef, beef trim, ground pork, pork trim, and Microtally on beef trim and pork trim, BAX® MPN alternative method for whole poultry carcass rinses and beef trim	AOAC PTM #081201
	Ground beef with soy (85% lean), beef trim, frankfurters (beef), shrimp, ground turkey, chicken wings, dried eggs (whole, powdered), shell eggs, frozen peas, orange juice, instant nonfat dry milk, ice cream (12% fat), peanut butter (52% fat), cocoa (unsweetened), white pepper, milk-based infant formula, ceramic tile, and plastic surfaces.	OMA #2013.02

Yeast and Mold

ASSAY	APPROVED MATRICES	VALIDATION REFERENCE
Yeast and Mold	Yogurt, cornstarch, milk-based infant formula	AOAC PTM #010902