

Foodborne Pathogen Test Kits Validated by Independent Organizations

FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e. *Salmonella*, *Campylobacter*, *E. coli* O157:H7, *Listeria* spp. including *L. monocytogenes*, and non-O157 STECs). These lists are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.

While FSIS does not require the use of any particular test method, the method chosen by an establishment should be:

- 1) Validated for testing relevant foods by:
 - a) a recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), or
 - b) a U.S. regulatory body (i.e. FSIS MLG or FDA BAM), or an ISO method
- 2) The validated method should be:
 - a) Fit for the intended purpose and application, and
 - b) Performed under validated conditions by a laboratory that assures the quality of the analytical results.

The table below contains a list of foodborne pathogen test kits that meet criterion 1a as described above; i.e., are validated by recognized independent organizations (e.g., AOAC, AOAC-RI, AFNOR, MicroVal, NordVal). None of the test kits listed below are implicitly approved by USDA FSIS. A validated test kit must also be fit for purpose (i.e. validated for the appropriate matrix and sample size) and appropriate for the specific application in a food safety program. Additionally these methods should be performed as per the conditions of the validated protocol by a laboratory that assures the analytical results. FSIS has published further guidance for choosing a microbiological laboratory (<http://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>). The sampling methodology and frequency must be appropriate to answer the food safety question that is asked. Finally, sample transport and storage should be appropriate to ensure the integrity of the sample and the result.

The methods listed here are not necessarily equivalent or appropriate for all specific testing applications. Please refer to other FSIS guidance on fitness for purpose for specific applications. As an example, AskFSIS provides guidance on appropriate test portions for *E. coli* O157:H7 testing and application of non-culture confirmation methods to confirm screening test results. For *Listeria* food contact surface and other environmental samples, FSIS has provided the following additional guidance for sampling and testing; i.e., validated methods should include an enrichment step for the entire sponge, swab or sampling device. Methods listed below do not necessarily meet all of these criteria. For more detail on RTE *Listeria*, FSIS has published RTE *Listeria* Compliance Guidelines (<http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>).

On a case-by-case basis, FSIS has reviewed robust studies using the FSIS MLG method as a reference method. For these reviews, FSIS uses the FSIS Test Kit validation guidelines to evaluate the study design, results, and data analysis for these alternative methods (http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES). These alternative methods are not included in the lists below because they are not externally validated by an independent organization.

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S001	3M™ Molecular Detection Assay <i>Salmonella</i>	<i>Salmonella</i> spp.	3M Health Care	AFNOR # 3M 01/11 - 11/12	All human food products (except spices, aromatic herbs, instant coffees and teas, bouillon cubes/concentrates, milk powders and cocoa powders) and environmental samples (except primary production stage environment)	25g
S002a	3M™ TECRA™ <i>Salmonella</i> Visual Immunoassay	<i>Salmonella</i> spp.	3M Microbiology	AOAC-OMA # 989.14	All foods	25g
S002b	3M™ TECRA™ <i>Salmonella</i> Visual Immunoassay	<i>Salmonella</i> spp.	3M Microbiology	AOAC-OMA # 998.09	All foods	25g
S003a	3M™ TECRA™ Unique <i>Salmonella</i>	<i>Salmonella</i> spp.	3M Health Care	AFNOR # TEC 24/03-12/03	All human food products and animal feeding stuffs	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S004	ADIAFOOD Detection System: <i>Salmonella</i> species	<i>Salmonella</i> spp.	AES Chemunex Canada	AOAC-RI # 070402	Cottage cheese, boneless pork, ground beef, chicken breast, cooked ham, chicken wings, clam chowder, apple juice, cauliflower, tortellini	25g
S005	ADIAFOOD <i>Salmonella</i>	<i>Salmonella</i> spp.	AES Chemunex	AFNOR # AES 10/09 - 07/10	All human food and animal feeding stuffs and environmental samples (excluding samples from primary production stage)	25g
S006a	ANSR™ for <i>Salmonella</i>	<i>Salmonella enterica</i> and <i>Salmonella bongori</i>	Neogen Corporation	AOAC-RI # 061203	Raw ground beef (25g), hot dogs (25g, 325g), chicken carcass rinse (30mL), raw ground turkey (25g), oat cereal (25g), surfaces (stainless steel, plastic, sealed concrete, ceramic tile, rubber)	See "Validated Matrices"
S006b	ANSR™ for <i>Salmonella</i>	<i>Salmonella enterica</i>	Neogen Corporation	AFNOR # NEO 35/02 - 05/13	Meat products, dairy products, seafood and vegetables	N/A
S007a	Assurance GDS® <i>Salmonella</i>	<i>Salmonella</i> spp.	BioControl Systems, Inc.	AFNOR # TRA 02/12 - 01/09	All human foodstuffs, animal feed and environmental samples	25g
S007b	Assurance GDS® <i>Salmonella</i>	<i>Salmonella</i> spp.	BioControl Systems, Inc.	AOAC-OMA # 2009.03	Meats, poultry, poultry rinse, seafood, dairy products, fruits and vegetables, egg, pasta, peanut butter, and environmental surfaces	25g
S007c	Assurance GDS™ <i>Salmonella</i>	<i>Salmonella</i> spp.	BioControl Systems, Inc.	AOAC-RI # 050602	Nonfat dry milk, liquid milk, egg, raw beef, raw pork, ground turkey, chicken rinse, raw shrimp, stainless steel, rubber, concrete	25g
S008	Assurance Gold EIA <i>Salmonella</i>	<i>Salmonella</i> spp.	BioControl Systems, Inc.	AOAC-OMA # 999.08	All foods	25g
S009	Assurance® <i>Salmonella</i> Enzyme Immunoassay (EIA) Test Kit	<i>Salmonella</i> spp.	BioControl Systems, Inc.	AOAC-OMA # 992.11	All foods	25g
S010	Atlas™ <i>Salmonella</i> Detection Assay	<i>Salmonella enterica</i>	Roka Biosciences, Inc.	AOAC-RI # 031201	Fresh raw ground beef (375g), frozen raw ground beef (375g), raw ground chicken, cooked deli turkey (325g), cooked deli chicken (325g), pasteurized dried whole egg, raw cod, creamy non-organic peanut butter, romaine lettuce (375g), tomatoes, instant nonfat dry milk, string cheese (mozzarella), milk chocolate, cocoa powder (375g), raw cookie dough, dry pet food, dry pasta, shell eggs, nacho cheese seasoning, black pepper, soy flour, environmental surfaces (stainless steel, plastic, sealed	25g except where noted in "Validated Matrices"
S011a	BAX® <i>Salmonella</i> PCR (BAX® Classic and BAX® Q7) BAX® System with Automated Detection PCR Assay for Screening <i>Salmonella</i>	<i>Salmonella</i> spp.	Oxoid, Thermo Fisher Scientific	NordVal # 030	Dairy products, meat, fish, vegetables, pastries, egg products, ready to eat meals, animal feed, and environmental samples	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S011b	BAX® System PCR Assay for <i>Salmonella</i>	<i>Salmonella</i> spp.	DuPont Qualicon	AOAC-RI # 100201	Milk (2%), custard, nonfat dry milk, liquid egg, chipped ham, cooked chicken, hot dogs, ground beef, cooked fish, prawns, frozen peas, orange juice, peanut butter, alfalfa sprouts, black pepper, dry pet food, chilled ready-meal, chocolate, elbow macaroni, pizza dough, isolated soy protein	25g
S011c	BAX® System PCR Assay <i>Salmonella</i> spp (automated)	<i>Salmonella</i> spp.	DuPont Qualicon	AFNOR # QUA 18/03 - 11/02	All human food products, animal feed and environmental samples (excluding environment of primary production stage)	25g
S011d	BAX® System <i>Salmonella</i>	<i>Salmonella</i> spp.	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AOAC-OMA # 2003.09	Frankfurters, raw ground beef, raw ground chicken, moz za rella cheese, raw frozen tilapia fish, and orange juice	25g
S012	BBL™CHROMagar™ <i>Salmonella</i>	<i>Salmonella</i> spp.	Becton Dickinson and Company	AOAC-RI # 020502	Shell eggs, raw chicken, raw ground beef, raw fish, lettuce	N/A
S013	BioControl 1-2 TEST	Motile <i>Salmonella</i> spp.	BioControl Systems, Inc.	AOAC-OMA # 989.13	All foods	25g
S014	Biotest MMB <i>Salmonella</i> Prep and MMB <i>Salmonella</i> V, R, LC Kits	<i>Salmonella</i> spp.	CONGEN Biotechnologie GmbH	MicroVal # RQA2008LR22	Meat products, poultry products, milk & dairy products, composite foods and feeding stuffs	25g
S015	Check&Trace <i>Salmonella</i> (previously marketed as PermiTest <i>Salmonella</i>)	<i>Salmonella</i> spp.	Check-Points	AOAC-RI # 121001	Pure cultures	N/A
S016	Colorimetric GENE-TRAK <i>Salmonella</i> Assay	<i>Salmonella</i> spp.	GENE-TRAK Systems/Neogen Corp.	AOAC-OMA # 990.13	All foods	25g
S017	foodproof® <i>Enterobacteriaceae</i> plus <i>E. sakazakii</i> combined with foodproof® <i>Salmonella</i> Detection Kit	<i>Enterobacteriaceae</i> , <i>Salmonella</i> spp.	BIOTECON Diagnostics GmbH	MicroVal # 2011-LR39	Powdered infant formula, probiotic culture powders, ingredients	Up to 100g
S018a	foodproof® <i>Salmonella</i> Detection Kit, Hybridization Probes and foodproof® <i>Salmonella</i> Detection Kit, 5' Nuclease with foodproof® Shortprep I Kit	<i>Salmonella</i> spp.	BIOTECON Diagnostics GmbH	NordVal # 023	Foods, feeds and environmental samples (100cm ²)	25g except where noted in "Validated Matrices"
S018b	foodproof® <i>Salmonella</i> Detection Kit, Hybridization Probes for <i>Salmonella</i> spp. and foodproof® <i>Salmonella</i> Detection Kit, 5' Nuclease for <i>Salmonella</i> spp. in combination with foodproof® ShortPrep I Kit or StarPrep One Kit	<i>Salmonella</i> spp.	BIOTECON Diagnostics GmbH	AOAC-RI # 120301	Milk powder, ice cream, egg powder, chicken breast, minced meat, sliced sausage, sausage, smoked fish, watermelon, sliced cabbage, coconut, white pepper, cumin, wet pet food, dry pet food, dough, food dye, milk chocolate, cocoa powder, pasta	25g
S019	GeneDisc® Plate Pathogenic <i>E. coli</i> O157 & <i>Salmonella</i> spp.	<i>E. coli</i> O157 & <i>Salmonella</i> spp.	Pall GeneDisc Technologies	AOAC-RI # 021104	Raw ground beef (25g) and raw beef trim (25g)	See "Validated Matrices"
S020	GeneDisc STEC & <i>Salmonella</i> spp.	Shigatoxigenic <i>E. coli</i> & <i>Salmonella</i> spp.	Pall GeneDisc Technologies	AOAC-RI # 021105	Raw ground beef (25g) and raw beef trim (25g)	See "Validated Matrices"
S021a	GeneDisc® <i>Salmonella</i> spp.	<i>Salmonella</i> spp.	Pall GeneDisc Technologies	AFNOR # GEN 25/05 -11/08	All human food products and animal feeding stuffs	25 g
S021b	GeneDisc® <i>Salmonella</i> spp.	<i>Salmonella</i> spp.	Pall GeneDisc Technologies	AOAC-RI # 021101	Raw ground beef (25g) and raw beef trim (25g)	See "Validated Matrices"
S022a	GeneQuence® <i>Salmonella</i>	<i>Salmonella</i> spp.	Neogen Corporation	AOAC-OMA # 2007.02	Raw turkey, dried, liquid and liquid frozen pasteurized eggs, milk chocolate, and dry pet food	See Manufacturer's guidance

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S022b	GeneQuence® <i>Salmonella</i>	<i>Salmonella</i> spp.	Neogen Corporation	AOAC-RI # 030201	Dried whole egg, nonfat dry milk, cheese powder, raw pooled shell egg, raw ground pork, beef franks, raw ground turkey, raw ground chicken, raw fish fillet, surimi, dried fruit, fresh mushrooms, frozen fruit, black pepper, dry pet food, dry cake mix, shelled walnuts, semi-sweet chocolate, refrigerated cookie dough, soy flour, egg	25g
S023	GENE-TRAK <i>Salmonella</i> DLP Assay	<i>Salmonella</i> spp.	Neogen Corporation	AOAC-RI # 961101	food, animal feed, environmental samples	25g
S024	HQS <i>Salmonella</i> spp. Sybr	<i>Salmonella</i> spp.	ADNucleis	AFNOR # ADN 33/03 - 04/10	All human food products	25g
S025	IBISA®	<i>Salmonella</i> spp.	AES Chemunex	AFNOR # AES 10/11 - 07/11	All human food and animal feeding stuffs and environmental samples (except environment of primary production stage)	25g
S026	IEH <i>E. coli</i> O157 (Stx-producing <i>E. coli</i> (STEC) with Intimin and <i>Salmonella</i> Test System	<i>E. coli</i> O157, Stx-producing <i>E. coli</i> (STEC) with intimin & <i>Salmonella</i> ** <i>E. coli</i> O26, O45, O103, O111, O121 & O145	IEH Laboratories & Consulting Group	AOAC-RI # 100701	Raw ground beef, raw beef trim, raw poultry, RTE turkey (omitted for STEC) & mixed leafy greens	25g
S027	InstantLabs® <i>Salmonella</i> Species Food Safety Kit	<i>Salmonella</i> spp.	InstantLabs Medical Diagnostics Corporation	AOAC-RI # 031202	Raw ground beef (375g), raw chicken breast (25g), raw ground chicken (25g), lettuce (25g), rolled oats (750g), oat flour (750g), wheat flour (750g)	See "Validated Matrices"
S028a	iQ-Check™ <i>Salmonella</i> II Kit	<i>Salmonella</i> spp.	Bio-Rad Laboratories	AFNOR # BRD 07/06 - 07/04	All human and animal feeding stuffs and environmental samples (excluding environment of primary production stage)	25g
S028b	iQ-Check™ <i>Salmonella</i> II Kit	<i>Salmonella</i> spp.	Bio-Rad Laboratories	AOAC-RI # 010803	Eggs, raw beef, raw chicken, cantaloupe, environmental surfaces (ceramic, concrete, plastic, stainless steel), dry dog food, wet cat food	25g
S028c	iQ-Check™ <i>Salmonella</i> II Kit	<i>Salmonella</i> spp.	Bio-Rad Laboratories	NordVal # 038	Meat products, dairy products, fish-based and vegetable products, egg products, animal feed, and environmental samples	25g
S029	IRIS <i>Salmonella</i> ®	<i>Salmonella</i> spp.	SOLABIA SAS	AFNOR # BKR 23/07 - 10/11	All human food products, animal feeding stuffs and production environment samples (except primary production stage environment)	25g
S030	LOCATE® <i>Salmonella</i> Assay Kit	<i>Salmonella</i> spp.	Rhone-Poulenc	AOAC-OMA # 997.16	All foods	25g
S031	LUMIprobe 24 <i>Salmonella</i> species	<i>Salmonella</i> spp.	EUROPROBE SA	AFNOR # EUR 15/2 - 11/00	All human and animal food products	25 g
S032	Microgen GNA ID	<i>Salmonella</i> spp. & <i>E. coli</i>	Microgen Bioproducts Limited	AOAC-RI # 061101	pure culture	N/A
S033a	MicroSEQ® <i>Salmonella</i> spp.	<i>Salmonella</i> spp.	Life Technologies	AFNOR # ABI 29/02 - 09/10	All human food products (including meat products) and animal feeding stuffs, animal feces, and environmental samples from primary production stage	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S033b	MicroSEQ® <i>Salmonella</i> spp. Detection Kit	<i>Salmonella</i> spp.	Life Technologies	AOAC-RI # 031001	Brie Cheese, shell eggs, raw ground beef, raw chicken wings, raw shrimp, cantaloupe, black pepper, dry pet food, chocolate, peanut butter, dry infant formula	25g
S035	Molecular Detection Assay <i>Salmonella</i>	<i>Salmonella</i> spp.	3M	AOAC-RI # 031208	Pasteurized liquid whole egg, raw ground beef, cooked breaded chicken, raw shrimp, bagged spinach, wet pet food (375g)	25g except where noted in "Validated Matrices"
S036	Nestec Laboratory Instruction LI-00.713-5 (dd 5-5-2009) for the detection of <i>Salmonella</i>	<i>Salmonella</i> spp.	Nestlé	Microval # 2007-LR06	dairy products, dairy products containing probiotics, chocolate products, other products, animal feed and environmental samples	25g
S037a	Oxoid <i>Salmonella</i> Rapid Test	<i>Salmonella</i> spp.	OXOID Ltd	AOAC-RI # 960902	Food, animal feed, environmental samples	25g
S037b	Oxoid <i>Salmonella</i> Rapid Test (OSRT)	<i>Salmonella</i> spp.	OXOID Ltd	AFNOR # UNI 03/01 - 05/91	All human and animal food products and environmental samples (excluding breeding samples)	25g
S038	Pathatrix® Pooling System for <i>Salmonella</i> species	<i>Salmonella</i> spp.	Matrix MicroScience, Inc.	AOAC-RI # 090203C	Cooked ham, chocolate, chopped tomatoes	25-375g
S039	Pathotec Cytochrome Oxidase Test MICRO-ID® Identification Kit	<i>Salmonella</i> spp., <i>E. coli</i> , and other Enterobacteriaceae	Remel	AOAC-OMA # 989.12	N/A	N/A
S040	PDX-SIB	<i>Salmonella</i> spp.	Paradigm Diagnostics, Inc.	AOAC-RI # 071102	Environmental surfaces (Stainless steel, plastic, ceramic tile & sealed concrete)	N/A
S041a	RAPID' <i>Salmonella</i> (Latex confirmation test)	<i>Salmonella</i> spp.	Bio-Rad Laboratories	AFNOR # BRD 07/11 - 12/05	All human and animal food products and environmental samples (excluding those from primary production environment)	25g
S041b	RAPID' <i>Salmonella</i> Agar	<i>Salmonella</i> spp.	Bio-Rad Laboratories	AOAC-RI # 050701	Eggs, raw beef, raw chicken, cantaloupe, environmental surfaces (ceramic, concrete, plastic, stainless steel), dry dog food, wet cat food	25g
S041c	RAPID' <i>Salmonella</i> Agar (short protocol and double enrichment (24hr) protocol), Rapid' <i>Salmonella</i> LATEX confirmation test	<i>Salmonella</i> spp.	Bio-Rad Laboratories	NordVal # 032	Foods, animal feeds, and environmental samples	25g
S042a	RapidChek® SELECT <i>Salmonella</i>	<i>Salmonella</i> spp.	SDIX	AFNOR # SDI 34/01 - 04/10	All human food, animal feed and environmental samples (excluding breeding samples)	25g
S042b	RapidChek® SELECT™ <i>Salmonella</i>	<i>Salmonella</i> spp.	Romer Labs, Inc.	AOAC-RI # 080601	Liquid eggs, raw ground beef, raw ground chicken, chicken carcass rinsates, sliced cooked turkey, environmental surfaces (painted concrete, plastic, rubber, stainless steel)	25g
S043	RapidChek® SELECT™ <i>Salmonella</i> Enteritidis Test System & RapidChek CONFIRM <i>Salmonella</i> Enteritidis Immunomagnetic Separation (IMS) Kit	<i>Salmonella</i> Enteritidis and other D1 serovars	Romer Labs, Inc.	AOAC-RI # 111002	Poultry house environmental drag swabs, egg pools, chicken carcass rinsates	N/A

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S044	RapidChek™ <i>Salmonella</i> Lateral Flow Test Kit	<i>Salmonella</i> spp.	Romer Labs, Inc.	AOAC-RI # 030301	Whole milk, liquid eggs, raw ground beef, raw ground pork, raw ground chicken, raw ground turkey, chicken carcass washes and deli turkey, orange juice, raw cabbage	25g
S045a	RayAL <i>Salmonella</i> OPTIMA	<i>Salmonella</i> spp.	RayAL Ltd.	AFNOR # RAY 32/02 - 06/08	Food and feed products and environmental samples (excluding breeding samples)	25g
S045b	<i>Salmonella</i> ELISA Test OPTIMA, RayAI <i>Salmonella</i> OPTIMA	<i>Salmonella</i> spp.	Bioline Aps	NordVal # 010	Foods and feeds	N/A
S046a	Reveal® 2.0 <i>Salmonella</i>	<i>Salmonella</i> spp.	Neogen Corporation	AFNOR # NEO 35/01 - 10/11	All human food products and animal feeding stuffs	25g
S046b	Reveal® 2.0 <i>Salmonella</i>	<i>Salmonella enterica</i> of serogroups A-E	Neogen Corporation	AOAC-RI # 960801	powdered milk, ice cream, raw ground beef, raw ground chicken, raw ground pork, raw ground sausage, raw ground turkey, cooked chicken, hot dogs, ready-to-eat meal product, chicken carcass rinse, beef skin, pork skin, picked crab meat, raw shrimp, cantaloupe, fresh spinach, peanut butter, liquid eggs, frozen whole eggs, dry pet food, soybean meal, poultry feed, sprout irrigation water, environmental surfaces (stainless steel)	25g
S048a	RIDASCREEN® <i>Salmonella</i>	<i>Salmonella</i> spp.	R-Biopharm AG	AFNOR # RBP 31/01 - 06/08	All human food products, animal feed and environmental samples (except samples of primary production)	25g
S048b	RIDASCREEN® <i>Salmonella</i>	<i>Salmonella</i> spp.	R-Biopharm AG	MicroVal # 2009-LR21	Meat products, milk products, seafood and vegetables, miscellaneous, animal feed and environmental samples	25g
S049	<i>Salmonella</i> detection method by real-time PCR	<i>Salmonella</i> spp.	Danish Technological Institute, DMRI	NordVal # 041	Raw meat, swabs from cattle and pig carcasses, poultry faeces sock swabs	25g
S050	<i>Salmonella</i> ELISA Test SELECTA, RayAI <i>Salmonella</i> SELECTA	<i>Salmonella</i> spp.	Diatek AG	NordVal # 028	Food and animal feed	25g
S051	R.A.P.I.D. LT Food Security System (FSS) for <i>Salmonella</i> Detection	<i>Salmonella</i> spp.	Idaho Technology, Inc	AOAC-RI # 030803	Liquid whole egg, cooked ham, raw ground beef, raw chicken, lettuce, chocolate, dry pet food, environmental surfaces (stainless steel)	25g
S052	<i>Salmonella</i> Precis™	<i>Salmonella</i> spp.	OXOID Ltd	AFNOR # UNI 03/06 - 12/07	All human and animal food products and environmental samples (excluding breeding samples)	25g
S053	<i>Salmonella</i> Rapid Culture Method using ONE Broth <i>Salmonella</i> & Brilliance™ <i>Salmonella</i>	<i>Salmonella</i> spp.	ThermoFisher Scientific	AOAC-RI # 120802	Ground beef, ground chicken, lettuce, shrimp & shell eggs	25g
S054	<i>Salmonella</i> -Tek ELISA Test System	<i>Salmonella</i> spp.	Organon Teknika Corp.	AOAC-OMA # 993.08	All foods	25g
S055	<i>Salmonella</i> -Tek Screen Kit	<i>Salmonella</i> spp.	Organon Teknika Corp.	AOAC-OMA # 986.35	All foods	25g
S056	<i>Salmonella</i> -Tek Screen Kit	<i>Salmonella</i> spp.	Organon Teknika Corp.	AOAC-OMA # 987.11	All foods other than raw foods or foods with a high microbial load	25g
S058	SAS™ Molecular Tests <i>Salmonella</i> spp. Detection Kit	<i>Salmonella</i> spp.	SA Scientific, Ltd.	AOAC-RI # 021202	Raw ground beef (25g & 375g), raw beef trim (375g), raw ground turkey, chicken carcass rinses, bagged mixed lettuce (200g), fresh spinach (200g)	25g except where noted in "Validated Matrices"

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#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S059	SESAME <i>Salmonella</i> Test	<i>Salmonella</i> spp.	SOLABIA SAS	AFNOR # BKR 23/04 - 12/07	All human and animal food products and environmental samples (with the exception of environment of primary production stage)	25g
S060	Simple Method for <i>Salmonella</i> (SMS™)	<i>Salmonella</i> spp.	AES Chemunex	AFNOR # AES 10/04 - 05/04	All food products, animal feed and environmental samples (excluding rearing environment)	25g
S061	Singlepath® <i>Salmonella</i>	<i>Salmonella</i> spp.	Merck KGaA	AOAC-RI # 060401	Dried skimmed milk, Raw ground beef, raw ground turkey, cooked peeled frozen prawns, desiccated coconut, black pepper, dried net food	25g
S062a	Surefood PATHOGEN <i>Salmonella</i> PLUS	<i>Salmonella</i> spp.	CONGEN Biotechnologie GmbH	MicroVal # RQA2008LR43	Meat products, poultry products, milk & dairy products, composite foods and feeding stuffs	25g
S062b	SureFood PREP <i>Salmonella</i> & SureFood PATHOGEN <i>Salmonella</i> PLUS V/R/LC	<i>Salmonella</i> spp.	CONGEN Biotechnologie GmbH	AOAC-RI # 041103	Salami, pork minced meat, bacon, fresh ground chicken, fresh chicken carcass, frozen marinated chicken filets, semi-skim milk powder, raw goat milk cheese, chocolate ice cream, salad with mayonnaise, paella, cream based pastry, dehydrated poultry proteins, wheat based flour, pet food pellets	N/A
S063	TAG 24 <i>Salmonella</i>	<i>Salmonella</i> spp.	BioControl Systems, Inc.	AFNOR # TRA 02/09 - 07/07	All human food products and animal feeding stuffs	25g
S064a	TaqMan® <i>Salmonella enterica</i> Detection Kit	<i>Salmonella enterica</i>	Applied Biosystems	AFNOR # ABI 29/01 - 09/07	All human food products and animal feeding stuffs	25g
S064b	TaqMan® <i>Salmonella enterica</i> Detection Kit	<i>Salmonella enterica</i>	Applied Biosystems	AOAC-RI # 020803	Ground beef, chicken wings, cheddar cheese, & dry pet food	25g
S065a	TRANSIA® PLATE <i>Salmonella</i> Gold	<i>Salmonella</i> spp.	BioControl Systems, Inc.	AFNOR # TRA 02/08 - 03/01	Food, animal feeding stuffs and environmental samples (excluding breeding samples)	25g
S065c	TRANSIA® PLATE <i>Salmonella</i> Gold	<i>Salmonella</i> spp.	BioControl Systems, Inc.	NordVal # 001	Meat products, dairy products, seafood products, vegetables and environmental samples	25g
S066	VIDAS® <i>Salmonella</i> Xpress (SLMX)	<i>Salmonella</i> spp.	bioMérieux, sa	AFNOR # BIO 12/26 - 07/09	Raw beef and veal meats (including frozen, not flavored) and pasteurized egg products	25g
S066a	VIDAS® Easy <i>Salmonella</i>	<i>Salmonella</i> spp.	bioMérieux, sa	AFNOR # BIO 12/16 - 09/05	All human and animal food products and environmental samples (except stock farming environment)	25g
S066b	VIDAS® <i>Salmonella</i> (VIDAS SLM) Dual selective enrichment	<i>Salmonella</i> spp.	bioMérieux, sa	AFNOR # BIO 12/1 - 04/94	All human food products and pet food	25g
S066c	VIDAS® <i>Salmonella</i> (VIDAS SLM) Single selective enrichment	<i>Salmonella</i> spp.	bioMérieux, sa	AFNOR # BIO 12/10 - 09/02	All human food products and pet food	25g
S066d	VIDAS® <i>Salmonella</i> (SLM) Assay Kit	<i>Salmonella</i> spp.	bioMérieux, Inc.	AOAC-OMA # 2004.03	Foods	25 g
S066e	VIDAS® <i>Salmonella</i> (SLM) Assay	<i>Salmonella</i> spp.	bioMérieux Vitek, Inc.	AOAC-OMA # 996.08	All foods	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S066f	VIDAS® <i>Salmonella</i> (SLM) Assay method Easy SLM with ChromID™ <i>Salmonella</i> (SM2) Agar	<i>Salmonella</i> spp.	bioMérieux, sa	AOAC-RI # 020901	Turkey, roast beef, raw ground pork, pork sausage, raw chicken breast, raw peeled shrimp, raw cod, cantaloupe, ground black pepper, bagged spinach, pecans, peanut butter, ice cream, liquid eggs, whole milk, non-fat dry milk, orange juice, dry pasta, cake mix, dry pet food, spent irrigation water	Sample preparation and enrichment as per FSIS MLG Ch. 4 for meat/poultry/egg and environmental samples
S067a	VIDAS® Immuno-Concentration <i>Salmonella</i> (ICS) Kit	<i>Salmonella</i> spp.	bioMérieux, sa	AOAC-OMA # 2001.07	All foods	25g
S067b	VIDAS® Immuno-Concentration <i>Salmonella</i> (ICS) Kit and Selective Plate (HE BS XLD) Screening	<i>Salmonella</i> spp.	bioMérieux, sa	AOAC-OMA # 2001.08	All foods	25g
S067c	VIDAS® Immuno-Concentration <i>Salmonella</i> (ICS) Kit and Selective Plate (HE BS XLD) Screening <i>Salmonella</i> (SLM) Enzyme-Linked Immunofluorescent Assay (ELFA)	<i>Salmonella</i> spp.	bioMérieux, sa	AOAC-OMA # 2001.09	All foods	25g
S068a	VIDAS® Immuno-Concentration <i>Salmonella</i> II (VIDAS ICS2) + Plate	<i>Salmonella</i> spp.	bioMérieux, sa	AFNOR # BIO 12/23 - 05/07	All human and food products (except raw milk) and pet foods	25g
S068b	VIDAS® Immuno-Concentration <i>Salmonella</i> II (VIDAS ICS2) + SLM	<i>Salmonella</i> spp.	bioMérieux, sa	AFNOR # BIO 12/22 - 05/07	All human and food products (except raw milk) and pet foods	25g
S069	VIDAS® <i>Salmonella</i> (SLM) Easy <i>Salmonella</i>	<i>Salmonella</i> spp.	bioMérieux, sa	AOAC-OMA # 2011.03	Liquid egg, vanilla ice cream, spinach (frozen and fresh), raw shrimp, peanut butter, deli turkey, roast beef, raw ground pork, turkey, pork sausage, raw chicken breast, dry pet food, moist pet food, whole milk, raw cod, spent irrigation water, pecans, dry pasta, cake mix, ground black pepper, NFDM, dried egg yolk, dark chocolate, cantaloupe,	Sample preparation and enrichment as per FSIS MLG Ch. 4 or FDA BAM Ch. 5
S070a	VIDAS® Up <i>Salmonella</i>	<i>Salmonella</i> spp.	bioMérieux, sa	AFNOR # BIO 12/32 - 10/11	All human food products (except raw milk cheese), animal feeding stuffs and production environmental samples (except samples of primary production stage)	25g
S070b	VIDAS® UP <i>Salmonella</i> (SPT)	<i>Salmonella</i> spp.	bioMérieux, sa	AOAC-RI # 071101	Raw ground beef (25g, 375g), deli roast beef, chicken carcass rinsate, raw ground turkey (375g only), instant NFDM (25g, 375g), vanilla ice cream, processed american cheese, bagged lettuce (25g, 375g)(mixed leaves), peanut butter, shrimp (cooked, peeled), raw cod, liquid eggs, powdered eggs, ground black pepper, almonds (375g only), dark chocolate (375g only), dry dog food (375g only), environmental surfaces (stainless steel, plastic,	25g except where noted in "Validated Matrices"

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S070c	VIDAS® UP <i>Salmonella</i> (SPT)	<i>Salmonella</i> spp.	bioMérieux, sa	AOAC-OMA # 2013.01	Raw ground beef (25 and 375 g), processed American cheese (25 g), deli roast beef (25 g), liquid egg (25 g), peanut butter (25 g), vanilla ice cream (25 g), cooked shrimp (25 g), raw cod (25 g), bagged lettuce (25 and 375 g), dark chocolate (375 g), powdered eggs (25 g), instant nonfat dry milk (25 and 375 g), ground black pepper (25 g), dry dog food (375 g), raw ground turkey (375 g), almonds (375 g), chicken carcass rinsates (30 mL), and stainless steel, plastic, and ceramic	See "Validated Matrices"
S071	VIP Gold for <i>Salmonella</i> Assay	<i>Salmonella</i> spp.	BioControl Systems, Inc.	AOAC-OMA # 999.09	All foods	25g
S072	Vitek GNI+ Screening System	<i>Salmonella</i> spp. and other Enterobacteriaceae	bioMérieux, sa	AOAC-OMA # 991.13	N/A	N/A
S073	Vitek® 2 Gram-Negative (GN) Biochemical Identification System	Gram-negative bacteria	bioMérieux, Inc.	AOAC-OMA # 2011.17	N/A	N/A
S075	QIAGEN <i>mericon</i> <i>Salmonella</i> spp	<i>Salmonella</i> spp.	QIAGEN Inc.	AFNOR # QIA 36/01 - 02/13	All human food products, animal feed and environmental samples (except primary production stage environment)	25g
S076	Solus <i>Salmonella</i> ELISA	<i>Salmonella</i> spp.	Solus Scientific	AFNOR # SOL 37/01 - 06/13	Food and feed products	N/A?
S077	Atlas™ <i>Salmonella</i> G2 Detection Assay	<i>Salmonella enterica</i>	Roka Biosciences, Inc.	AOAC-RI # 041303	Fresh raw ground beef (25 g and 375g), fresh raw ground turkey (375g), cooked deli turkey (325g), romaine lettuce (375 g), oat cereal, environmental surfaces (stainless steel, plastic, sealed concrete)	25g except where noted in "Validated Matrices"
S078a	Thermo Scientific™ Sure Tect™ <i>Salmonella</i> species PCR Assay	<i>Salmonella</i> spp.	Thermo Fisher Scientific	AOAC-RI # 051303	Raw ground beef, raw chicken breast, chilled ready-to-eat dinner, pork frankfurters, raw ground pork, cooked shrimp, non-fat dried milk powder, fresh bagged lettuce, pasteurized liquid whole egg and stainless steel	N/A
S078b	Thermo Scientific SureTect <i>Salmonella</i> species PCR Assay	<i>Salmonella</i> spp.	OXOID Thermo Fisher Scientific	AFNOR # UNI 03/07 - 11/13	Non-seasoned raw ground beef meat	N/A
S079	3M™ Petrifilm™ <i>Salmonella</i> Express	<i>Salmonella</i> spp.	3M Food Safety	AOAC-RI # 061301	Raw ground beef (25g), raw ground pork (25g), raw ground chicken (25g), cooked chicken nuggets (325g), pasteurized liquid whole egg (100g)	See "Validated Matrices"
S080	<i>mericon</i> ™ <i>Salmonella</i> spp. Kit	<i>Salmonella</i> spp.	Qiagen GmbH	AOAC-RI # 071204	Fresh raw ground beef (25g), chicken carcass rinses, creamy non-organic peanut butter, fresh spinach, pasteurized whole milk, instant nonfat dry milk, milk chocolate, shell eggs	25g, See "Validated Matrices"
S081	BAX® System Real-Time PCR Assay for <i>Salmonella</i>	<i>Salmonella</i>	DuPont Qualicon	AOAC-RI # 081201	Raw ground beef (25g, 375g), chicken carcass rinse (30mL), cream cheese, bagged lettuce, dry pet food (375g), and stainless steel	See "Validated Matrices"

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S082	Pathatrix® Auto <i>Salmonella</i> spp Kit Linked to Selective Agar Detection	<i>Salmonella</i> spp.	Life Technologies	AFNOR # ABI 29/06 - 11/13	Cooked meat products and raw beef meat, heat treated milk and dairy products	N/A
S083	Pathatrix® Auto <i>Salmonella</i> spp Kit Linked to MicroSEQ® <i>Salmonella</i> spp. Detection Kit	<i>Salmonella</i> spp.	Life Technologies	AFNOR # ABI 29/07 - 11/13	Cooked meat products and raw beef meat, heat treated milk and dairy products	N/A
S084	3M™ Molecular Detection Assay (MDA) <i>Salmonella</i> Method	<i>Salmonella</i> spp.	3M Food Safety	AOAC-OMA # 2013.09	Raw ground beef (25 g), processed breaded chicken (325 g), liquid egg (100 g), shrimp (25 g), fresh spinach (25 g) and wet dog food (375 g)	See "Validated Matrices"
S085	BAX® System Real-Time PCR Assay for <i>Salmonella</i>	<i>Salmonella</i> spp.	DuPont Nutrition & Health Diagnostics	AOAC-OMA # 2013.02	Raw ground beef (25g and 375g), ground beef with soy (25g and 325g), beef trim (25g and 325g), frankfurters (325g), shrimp (25g), ground turkey (25g), chicken wings (25g), poultry rinse (30mL), whole powdered (dried) eggs (25g), shell eggs (1000mL), fresh bagged lettuce (25g), frozen peas (25g), orange juice (pasteurized; 25mL), cream cheese (25g), nonfat dry milk (25g), ice cream (25g), peanut butter (25g), cocoa (25g), white pepper (25g), milk-based infant formula (25mL), and dry pet food (375g), and on stainless steel, ceramic tile, and plastic surfaces.	See "Validated Matrices"
S086	ANSR® <i>Salmonella</i> Confirmation Test	<i>Salmonella</i> spp.	Neogen Corporation	AOAC-OMA # 2013.14	N/A	N/A

** N/A = Not available

Foodborne Pathogen Test Kits Validated by Independent Organizations

FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e. *Salmonella*, *Campylobacter*, *E. coli* O157:H7, *Listeria* spp. including *L. monocytogenes*, and non-O157 STECs). These lists are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.

While FSIS does not require the use of any particular test method, the method chosen by an establishment should be:

- 1) Validated for testing relevant foods by:
 - a) a recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), or
 - b) a U.S. regulatory body (i.e. FSIS MLG or FDA BAM), or an ISO method
- 2) The validated method should be:
 - a) Fit for the intended purpose and application, and
 - b) Performed under validated conditions by a laboratory that assures the quality of the analytical results.

The table below contains a list of foodborne pathogen test kits that meet criterion 1a as described above; i.e., are validated by recognized independent organizations (e.g., AOAC, AOAC-RI, AFNOR, MicroVal, NordVal). None of the test kits listed below are implicitly approved by USDA FSIS. A validated test kit must also be fit for purpose (i.e. validated for the appropriate matrix and sample size) and appropriate for the specific application in a food safety program. Additionally these methods should be performed as per the conditions of the validated protocol by a laboratory that assures the analytical results. FSIS has published further guidance for choosing a microbiological laboratory (<http://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>). The sampling methodology and frequency must be appropriate to answer the food safety question that is asked. Finally, sample transport and storage should be appropriate to ensure the integrity of the sample and the result.

The methods listed here are not necessarily equivalent or appropriate for all specific testing applications. Please refer to other FSIS guidance on fitness for purpose for specific applications. As an example, AskFSIS provides guidance on appropriate test portions for *E. coli* O157:H7 testing and application of non-culture confirmation methods to confirm screening test results. For *Listeria* food contact surface and other environmental samples, FSIS has provided the following additional guidance for sampling and testing; i.e., validated methods should include an enrichment step for the entire sponge, swab or sampling device. Methods listed below do not necessarily meet all of these criteria. For more detail on RTE *Listeria*, FSIS has published RTE *Listeria* Compliance Guidelines (<http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>).

On a case-by-case basis, FSIS has reviewed robust studies using the FSIS MLG method as a reference method. For these reviews, FSIS uses the FSIS Test Kit validation guidelines to evaluate the study design, results, and data analysis for these alternative methods (http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES). These alternative methods are not included in the lists below because they are not externally validated by an independent organization.

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
C001	ADIAFOOD Rapid Pathogen Detection System for <i>Campylobacter</i> Quantification	<i>Campylobacter jejuni</i> ; <i>Campylobacter coli</i> ; <i>Campylobacter lari</i>	AES Chemunex Canada	AOAC-RI # 050603	Poultry rinses	20mL
C002	BAX® System Real-Time PCR Assay for <i>Campylobacter jejuni</i> , <i>coli</i> , and <i>lari</i>	<i>Campylobacter jejuni</i> ; <i>Campylobacter coli</i> ; <i>Campylobacter lari</i>	DuPont Nutrition & Health Diagnostics	NordVal # 039	Faeces on cloacae swabs (levels above 100 cfu/g)	N/A
C003	BAX® System Real-Time PCR Assay for <i>Campylobacter jejuni</i> , <i>coli</i> , and <i>lari</i>	<i>Campylobacter jejuni</i> ; <i>Campylobacter coli</i> ; <i>Campylobacter lari</i>	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AOAC-RI # 040702	Ready-to-eat turkey product & chicken carcass rinses	25g, 30mL

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
C004a	CampyFood® Agar (CFA)	<i>Campylobacter</i> spp.	bioMérieux, sa	AFNOR # BIO 12/30 - 05/10	Meat products and production environmental samples	25g
C004b	CampyFood® Agar (CFA)	<i>Campylobacter</i> spp.	bioMérieux, sa	AOAC-RI # 071201	Fresh raw pork, raw chicken breast, processed chicken nuggets, chicken carcass rinsate, turkey carcass sampled with sponge	25g
C004c	CampyFood® Agar (CFA)	<i>Campylobacter</i> spp.	bioMérieux, sa	MicroVal # 2009LR28	Poultry products, meat products, environmental samples	25g
C005	<i>Campylobacter</i> real-time PCR	<i>Campylobacter</i> spp.	Eurofins Steins, Denmark	NordVal # 017	Raw chicken meat, faeces on cloacae swabs, sock swabs	N/A
C006	CASA (<i>Campylobacter</i> Selective Agar)	<i>Campylobacter</i> spp.	AES Chemunex	MicroVal # RQA2010LR38	Meat products, poultry products & environmental samples	N/A
C007	iQ-Check™ <i>Campylobacter</i>	<i>Campylobacter jejuni</i> ; <i>Campylobacter coli</i> ; <i>Campylobacter lari</i>	Bio-Rad Laboratories	AOAC-RI # 031209	Chicken carcass rinse, turkey carcass sponge, raw ground chicken	25g, 30mL
C008	Oxoid Brilliance™ CampyCount Agar (BCCA)	<i>Campylobacter</i> spp.	Oxoid/Thermo Fisher Scientific	MicroVal # 2008-LR12	Poultry products	N/A
C009	Singlepath® <i>Campylobacter</i> Lateral Flow Assay	<i>Campylobacter jejuni</i> ; <i>Campylobacter coli</i>	Merck KGaA	AOAC-RI # 120401	Raw ground chicken, raw ground turkey, pasteurized milk	25g
C010	Veriflow™ <i>Campylobacter</i>	<i>Campylobacter</i> spp.	Invisible Sentinel, Inc.	AOAC-RI # 101201	Chicken carcass rinse	N/A
C011a	VIDAS® <i>Campylobacter</i> (CAM)	<i>Campylobacter</i> spp.	bioMérieux, sa	AFNOR # BIO 12/29 - 05/10	Meat products and production environmental samples	25g
C011b	VIDAS® <i>Campylobacter</i> (CAM)	<i>Campylobacter</i> spp.	bioMérieux, sa	AOAC-RI # 051201	Fresh raw pork, raw chicken breast, processed chicken nuggets, chicken carcass rinsate, turkey carcass sampled with sponge	25g

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 - b) a U.S. regulatory body (i.e. FSIS MLG or FDA BAM), or an ISO method
- 2) The validated method should be:
 - a) Fit for the intended purpose and application, and
 - b) Performed under validated conditions by a laboratory that assures the quality of the analytical results.

The table below contains a list of foodborne pathogen test kits that meet criterion 1a as described above; i.e., are validated by recognized independent organizations (e.g., AOAC, AOAC-RI, AFNOR, MicroVal, NordVal). None of the test kits listed below are implicitly approved by USDA FSIS. A validated test kit must also be fit for purpose (i.e. validated for the appropriate matrix and sample size) and appropriate for the specific application in a food safety program. Additionally these methods should be performed as per the conditions of the validated protocol by a laboratory that assures the analytical results. FSIS has published further guidance for choosing a microbiological laboratory (<http://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>). The sampling methodology and frequency must be appropriate to answer the food safety question that is asked. Finally, sample transport and storage should be appropriate to ensure the integrity of the sample and the result.

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On a case-by-case basis, FSIS has reviewed robust studies using the FSIS MLG method as a reference method. For these reviews, FSIS uses the FSIS Test Kit validation guidelines to evaluate the study design, results, and data analysis for these alternative methods (http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES). These alternative methods are not included in the lists below because they are not externally validated by an independent organization.

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L001	3M™ Petrifilm™ Environmental <i>Listeria</i> Plate	<i>Listeria monocytogenes</i> ; <i>Listeria innocua</i> ; <i>Listeria welshimeri</i>	3M Food Safety	AOAC-RI # 030601	Environmental surfaces (stainless steel, ceramic tile, plastic & sealed concrete)	N/A
L002	3M™ TECRA™ <i>Listeria</i> Visual Immunoassay (TLVIA)	<i>Listeria</i> spp.	3M Microbiology	AOAC-OMA # 995.22	Dairy foods, seafoods, poultry, meats (except raw ground chuck), and leafy vegetables	25g
L003	3M™ Tecra™ <i>Listeria</i> Visual Immunoassay (VIA)	<i>Listeria</i> spp.	3M Food Safety	AOAC-RI # 091201	Environmental surfaces (stainless steel, concrete)	N/A

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L004	3M™ TECRA™ <i>Listeria</i> Visual Immunoassay using 3M™ TECRA™ <i>Listeria</i> Enrichment Broth	<i>Listeria</i> spp.	3M Microbiology	AOAC-OMA # 2002.09	Raw meats, fresh produce/vegetables, processed meats, seafood, dairy foods cultured/noncultured, fruit and fruit juices	25g
L005	AccuProbe <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	bioMérieux, sa	AFNOR # BIO 12/4 -02/95	All human food products and environmental samples of production	25g
L006	ACTERO™ <i>Listeria</i> Enrichment Media	<i>Listeria</i> spp. (not <i>L. grayi</i>)	FoodChek Systems, Inc	AOAC-RI # 111201	Environmental surfaces (stainless steel, plastic)	N/A
L007	ADIAFOOD Advanced Detection System: <i>Listeria</i> spp. environmental sample testing	<i>Listeria</i> spp.	AES Chemunex Canada	AOAC-RI # 021109	Environmental surfaces (stainless steel, ceramic, plastic & sealed concrete)	N/A
L008	ADIAFOOD Detection System: <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	AES Chemunex Canada	AOAC-RI # 040402	Yogurt, brie cheese, mayonnaise, raw ground pork, raw pork chops, sausages, raw beef cubes, raw cod fillet, green beans, fruit salad	25g
L010	ADIAFOOD <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	AES Chemunex	AFNOR # AES 10/08 - 12/09	All human food products and environmental samples	25g
L011	AL Detection	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	Bio-Rad Laboratories	AFNOR # BRD 07/16 -01/09	All human food products and environmental samples	25g
L012	AL Enumeration	<i>Listeria monocytogenes</i>	Bio-Rad Laboratories	AFNOR # BRD 07/17 -01/09	All human food products and environmental samples	N/A
L013	ALOA® Count	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	AES Chemunex	AFNOR # AES 10/05 - 09/06	All foodstuffs for human consumption	N/A
L014	ALOA® One Day	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	AES Chemunex	AFNOR # AES 10/03 – 09/00	All foodstuffs for human consumption and environmental samples	25g
L015	ANSR™ for <i>Listeria</i>	<i>Listeria</i> spp. (<i>L. grayi</i> variable)	Neogen Corporation	AOAC-RI # 101202	Environmental surfaces (stainless steel, plastic, sealed concrete, ceramic tile, and rubber)	N/A
L016	Assurance GDST™ for <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	BioControl Systems, Inc.	AOAC-RI # 070702	Liquid pasteurized milk, mexican soft cheese, frankfurter, deli turkey, raw fish, raw green beans, environmental surfaces (stainless steel, rubber, concrete, plastic)	25g
L017	Assurance GDST™ for <i>Listeria</i> species	<i>Listeria</i> species including <i>L. monocytogenes</i> , <i>L. innocua</i> , <i>L. seeligeri</i> , <i>L. welshimeri</i> , <i>L. ivanovii</i> and <i>L. grayi</i>	BioControl Systems, Inc.	AOAC-RI # 070701	Liquid pasteurized milk, mexican soft cheese, frankfurter, deli turkey, raw fish, raw green beans, environmental surfaces (stainless steel, rubber, concrete, plastic)	25g

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#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L018	Assurance® <i>Listeria</i> EIA	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	BioControl Systems, Inc.	AOAC-OMA # 996.14	Dairy foods, red meats, pork, poultry and poultry products, seafood, fruits, vegetables, nutmeats, pasta, chocolate, eggs, bone meal, and from environmental surfaces	25g
L019	Assurance™ EIA for <i>Listeria</i>	<i>L. monocytogenes</i> , <i>L. innocua</i> , <i>L. seeligeri</i> , <i>L. welshimeri</i> , <i>L. ivanovii</i> , <i>L. grayii</i>	BioControl Systems, Inc.	AOAC-RI # 060802	Liquid pasteurized milk, mexican soft cheese, raw beef trim, ready to eat turkey, raw green beans, raw fish, environmental surfaces (stainless steel, rubber, plastic)	N/A
L097	Atlas® <i>Listeria monocytogenes</i> LmG2 Detection Assay	<i>Listeria monocytogenes</i>	Roka Bioscience, Inc	AOAC-RI # 111301	Hot dogs, cured ham, deli turkey (125 g), chicken salad, environmental surfaces (stainless steel), frozen chocolate cream pie, frozen cheese pizza, vanilla ice cream	25g except where noted in "Validated Matrices"
L020	BAX® system <i>L. monocytogenes</i>	<i>Listeria monocytogenes</i>	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AOAC-OMA # 2003.12	Dairy products, fruits and vegetables [except radishes], seafoods, raw and processed meats and poultry	25g
L021a	BAX® System PCR Assay for Genus <i>Listeria</i> 24E	<i>Listeria</i> spp.	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AOAC-RI # 050903	Bagged spinach, processed cheese, frankfurters, cooked shrimp, environmental surfaces (stainless steel)	25g
L021b	BAX® System PCR Assay for Genus <i>Listeria</i> 24E	<i>Listeria</i> spp. excluding <i>L. grayi</i>	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AFNOR # QUA 18/06 - 07/08	All human food products and environmental samples	25g
L022a	BAX® System PCR Assay for <i>Listeria monocytogenes</i> 24E	<i>Listeria monocytogenes</i>	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AOAC-RI # 080901	Bagged spinach, processed cheese, frankfurters, cooked shrimp, environmental surfaces (stainless steel)	25g
L022b	BAX® System PCR Assay for <i>Listeria monocytogenes</i> 24E	<i>Listeria monocytogenes</i>	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AFNOR # QUA 18/05 - 07/08	All human food products and production environmental samples	25g
L023	BAX® System PCR Assay for <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AOAC-RI # 070202	Raw meats, fresh produce/vegetables, processed meats, seafood, dairy cultured/non-cultured, egg and egg products, and fruit juices	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L024	BAX® System PCR Assay for Screening Genus <i>Listeria</i>	<i>Listeria</i> spp. including <i>L. monocytogenes</i> , <i>L. innocua</i> , <i>L. ivanovii</i> , <i>L. seeligeri</i> , <i>L. welshimeri</i>	DuPont (DuPont Nutrition & Health Diagnostics)	AOAC-RI # 030502	Processed cheese, frankfurters, smoked salmon, spinach, environmental surfaces (plastic ceramic, tile, rubber, painted wood surfaces, unpainted wood, sealed concrete, cast iron, air filter material, drain swabs)	25g
L026	BBL™ CHROMagar™ <i>Listeria</i>	<i>Listeria monocytogenes</i> , <i>Listeria ivanovii</i>	Becton Dickinson and Company	AOAC-RI # 060501	Raw ground beef, smoked salmon, lettuce, brie cheese	N/A
L027	CHROMagar™ <i>Listeria</i>	<i>Listeria monocytogenes</i>	CHROMagar	AFNOR # CHR 21/01 -12/01	All human food products and environmental samples	25g
L028	CHROMagar™ <i>Listeria</i> (Enumeration)	<i>Listeria monocytogenes</i>	CHROMagar	AFNOR # CHR 21/02 -12/06	All human food products and environmental samples	N/A
L029	ChromID Lmono Agar	<i>Listeria monocytogenes</i>	bioMérieux, sa	AFNOR # BIO 12/31 - 05/11	All human food products and production environmental samples	25g
L030	ChromID Lmono Agar (LMO-F) for <i>Listeria monocytogenes</i> enumeration	<i>Listeria monocytogenes</i>	bioMérieux, sa	MicroVal # 2010LR35	All food categories & environmental samples	N/A
L032	ChromID™ Ottaviani Agosti Agar (OAA)	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	bioMérieux, sa	AFNOR # BIO 12/14 - 04/05	All human food product and environmental samples	25g
L031	ChromID™ Ottaviani Agosti Agar (OAA) (Enumeration)	<i>Listeria monocytogenes</i>	bioMérieux, sa	AFNOR # BIO 12/24 - 03/08	All human food products	N/A
L033	Compass® <i>Listeria</i> Agar (Detection)	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	SOLABIA SAS	AFNOR # BKR 23/02-11/02	All human food products and production environment samples	25g
L034	Compass® <i>Listeria</i> Agar (Enumeration)	<i>Listeria monocytogenes</i>	SOLABIA SAS	AFNOR # BKR 23/05-12/07	All human food products and production environment samples	N/A
L035	Dupont® Lateral Flow System <i>Listeria</i> species	<i>Listeria</i> spp.	DuPont Qualicon	AOAC-RI # 080501	Ice cream, soft cheese, milk, deli turkey, pepperoni, hot dogs, roast beef, cooked shrimp, smoked fish, potato salad, environmental surfaces (rubber, painted concrete, stainless steel)	25g
L036	FoodChek™ <i>Listeria</i> spp.	<i>Listeria</i> spp. (not <i>L. grayi</i>)	FoodChek Systems, Inc	AOAC-RI # 111202	Environmental surfaces (stainless steel, plastic)	N/A
L037a	foodproof® <i>Listeria monocytogenes</i> Detection Kit in combination with the foodproof® ShortPrep II Kit	<i>Listeria monocytogenes</i>	BIOTECON Diagnostics GmbH	AOAC-RI # 070401	Dried whole eggs, dry whole milk, vanilla ice cream, Harzer cheese, sausage, raw ground chicken, raw ground pork, ham, gravlax, pollack fillet, melon cubes, white cabbage, bean sprouts, paprika emulsion dye, parsley flakes, dry pet food, peanut butter, milk chocolate, pizza,	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L037b	foodproof® <i>Listeria monocytogenes</i> Detection Kit, Hybridization Probes and foodproof® <i>Listeria monocytogenes</i> Detection Kit, 5' Nuclease in combination with foodproof® ShortPrep II Kit	<i>Listeria monocytogenes</i>	BIOTECON Diagnostics GmbH	NordVal # 025	Foods and environmental samples	25g
L039a	GeneDisc® <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	Pall GeneSystems (Pall GeneDisc Technologies)	AFNOR # GEN 25/08 - 07/10	All human food products and production environment samples	25g
L040a	GeneDisc® <i>Listeria</i> spp.	<i>Listeria</i> spp.	Pall GeneSystems (Pall GeneDisc Technologies)	AFNOR # GEN 25/07 - 07/10	All human food products and production environment samples	25g
L038	GeneDisc® Plate <i>Listeria</i> DUO Detection Kit	<i>Listeria</i> spp. & <i>Listeria monocytogenes</i>	Pall GeneDisc Technologies	AOAC-RI # 031206	Deli roast beef, hot dogs, deli turkey, raw shrimp, cold smoked salmon, romaine lettuce, pasteurized whole milk, vanilla ice cream, Brie cheese, liquid eggs, environmental surfaces (stainless steel, sealed	N/A
L041	GeneDisc® Plate <i>Listeria</i> Identification Kit	<i>L. monocytogenes</i> , <i>L. innocua</i> , <i>L. ivanovii</i> , <i>L. seeligeri</i> , <i>L. welshimeri</i> & <i>L. grayi</i>	Pall GeneDisc Technologies	AOAC-RI # 031207	Pure colonies from OXA, MOX, OAA, PALCAM, Rapid' <i>L.mono</i> agar & Nutrient Agar	N/A
L039b	GeneDisc® Plate <i>Listeria monocytogenes</i> Detection Kit	<i>Listeria monocytogenes</i>	Pall GeneDisc Technologies	AOAC-RI # 031204	Deli roast beef, hot dogs, deli turkey, raw shrimp, cold smoked salmon, romaine lettuce, pasteurized whole milk, vanilla ice cream, Brie cheese, liquid eggs, environmental surfaces (stainless steel, sealed	N/A
L040b	GeneDisc® Plate <i>Listeria</i> spp. Detection Kit	<i>Listeria</i> spp.	Pall GeneDisc Technologies	AOAC-RI # 031205	Deli roast beef, hot dogs, deli turkey, raw shrimp, cold smoked salmon, romaine lettuce, pasteurized whole milk, vanilla ice cream, Brie cheese, liquid eggs, environmental surfaces (stainless steel, sealed	N/A

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L042	GeneQuence™ <i>Listeria</i> Microwell Test	<i>Listeria</i> spp.	Neogen Corporation	AOAC-RI # 010403	Parmesan cheese, brie cheese, pasteurized milk, ice cream, cottage cheese, mayonnaise, ground beef, deli turkey, hot dogs, ground pork, deli ham, lettuce, mixed vegetables, alfalfa sprouts, raw shrimp, pasteurized crab meat, smoked salmon, environmental surfaces (stainless steel, ceramic, cast iron, plastic, concrete, painted)	25g
L044	GENE-TRAK <i>Listeria</i>	<i>Listeria</i> spp.	Neogen Corporation	AOAC-OMA # 993.09	Dairy products, meats, and seafoods	25g
L045	GENE-TRAK <i>Listeria</i> DLP Assay	<i>Listeria</i> spp.	Neogen Corporation	AOAC-RI # 981201	Dairy products, meats, seafood, and environmental samples	25g
L046	IEH <i>Listeria</i> spp. & <i>Listeria monocytogenes</i> Test System	<i>Listeria</i> spp. & <i>Listeria monocytogenes</i>	IEH Laboratories & Consulting Group	AOAC-RI # 021201	Raw beef trim, ready-to-eat turkey, environmental surfaces (stainless steel, plastic)	25-375 g
L094	InstantLabs® <i>Listeria monocytogenes</i> Food Safety Kit	<i>Listeria monocytogenes</i>	InstantLabs Medical Diagnostics Corporation	AOAC-RI # 051302	Hot dogs, deli turkey, romaine lettuce, raw shrimp, cheddar cheese, vanilla ice cream, pasteurized whole milk, and environmental surfaces (stainless steel, sealed concrete)	25g
L093	InstantLabs® <i>Listeria</i> Species Food Safety Kit	<i>Listeria</i> spp.	InstantLabs Medical Diagnostics Corporation	AOAC-RI # 041304	Hot dogs, raw Shrimp, cheddar cheese, and environmental surfaces (stainless steel, sealed concrete)	25g
L047a	iQ-Check™ <i>Listeria monocytogenes</i> II	<i>Listeria monocytogenes</i>	Bio-Rad Laboratories	AFNOR # BRD 07/10 - 04/05	All human foodstuffs and environmental samples	25g
L048	iQ-Check™ <i>Listeria monocytogenes</i> II	<i>Listeria monocytogenes</i>	Bio-Rad Laboratories	NordVal # 037	Foods and environmental samples	25g
L047b	iQ-Check™ <i>Listeria monocytogenes</i> II Real Time PCR	<i>Listeria monocytogenes</i>	Bio-Rad Laboratories	AOAC-RI # 010802	Smoked salmon, cottage cheese, hot dogs, deli turkey	25g
L049	iQ-Check™ <i>Listeria</i> species	<i>Listeria</i> spp.	Bio-Rad Laboratories	AFNOR # BRD 07/13 - 05/07	All human foodstuffs and environmental samples	25g
L050	iQ-Check™ <i>Listeria</i> spp. Real-Time PCR	<i>Listeria</i> spp.	Bio-Rad Laboratories	AOAC-RI # 090701	Environmental surfaces (stainless steel, plastic, ceramic, sealed concrete)	N/A

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L051	<i>Listeria</i> LT	<i>Listeria</i> species (<i>Listeria innocua</i> , <i>L. ivanovii</i> , <i>L. monocytogenes</i> , <i>L. seeligeri</i> , <i>L. welshimeri</i>)	Idaho Technology, Inc	AOAC-RI # 010901	Turkey deli meat, mexican soft cheese, environmental surfaces (plastic, stainless steel & ceramic)	25g
L052	<i>Listeria</i> Precis™ (Detection)	<i>Listeria monocytogenes</i>	OXOID Ltd	AFNOR # UNI 03/04 -04/05	All human food products and environmental samples	25g
L053	<i>Listeria</i> Precis™ (Enumeration)	<i>Listeria monocytogenes</i>	OXOID Ltd	AFNOR # UNI 03/05 -09/06	All human food products and environmental samples	N/A
L054	<i>Listeria</i> -Tek ELISA	<i>Listeria monocytogenes</i>	Organon Teknika Corporation	AOAC-OMA # 994.03	Meat, meat products, fish, dairy products	25g
L055	LUMIprobe 24 <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	EUROPROBE SA	AFNOR # EUR 15/03 - 12/05	All human food products (except French cheeses "cantal" and "salers") and environmental samples	25g
L056	Microgen™ <i>Listeria</i> -ID	<i>Listeria</i> spp.	Microgen Bioproducts Ltd	AOAC-RI # 060402	Pure culture	N/A
L057	MICRO-ID <i>Listeria</i>	<i>Listeria</i> spp.	Organon Teknika Corporation	AOAC-OMA # 992.18	Foods and environmental samples	N/A
L058	MicroSEQ <i>Listeria monocytogenes</i>	<i>Listeria</i> spp.	Life Technologies SAS	AFNOR # ABI 29/05 - 12/11	Human food and environmental samples	25g
L059	MicroSEQ <i>Listeria</i> spp.	<i>Listeria</i> spp.	Life Technologies SAS	AFNOR # ABI 29/04 - 12/11	Human food and environmental samples	N/A
L060	MicroSEQ® <i>Listeria monocytogenes</i> Detection Kit	<i>Listeria monocytogenes</i>	Applied Biosystems	AOAC-RI # 011002	Pasteurized whole milk, dry infant formula, ice cream, roast beef, cured bacon, lox (cold-smoked salmon), lettuce, salad dressing and mayonnaise	25g
L061	MicroSEQ® <i>Listeria</i> spp. Detection Kit	<i>Listeria</i> spp.	Applied Biosystems	AOAC-RI # 021108	Pasteurized whole cows milk, dry infant formula, hot dogs, roast beef, lox (smoked salmon), environmental surfaces (stainless steel, plastic cutting board, ceramic tile, rubber sheets, concrete sealed with Seal Hard®)	N/A
L062	MIT 1000 Rapid Microbial Identification System	<i>Listeria</i> spp.	Micro Imaging Technology, Inc	AOAC-RI # 060901	Pure Culture	N/A
L063	Molecular Detection Assay <i>Listeria</i>	<i>Listeria</i> spp.	3M	AOAC-RI # 081203	Environmental surfaces (stainless steel, concrete, plastic)	N/A
L065	Oxoid <i>Listeria</i> Rapid Test	<i>Listeria</i> spp.	Oxoid Ltd	AOAC-RI # 960701	Food and environmental samples	25g
L064	Oxoid <i>Listeria</i> Rapid Test (OLRT)	<i>Listeria</i> spp. excluding <i>L. grayi</i> subsp <i>grayi</i> and <i>L. grayi</i> subsp <i>murrayi</i>	OXOID Ltd	AFNOR # UNI 03/02 - 04/95	All human food products and environmental samples	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L066	PATHATRIX Pooling <i>Listeria</i> species Test System	<i>Listeria</i> spp.	Matrix MicroScience Limited	AOAC-RI # 090201B	Pasteurized milk, raw ground beef, cooked sliced ham, milk powder, orange juice, ground black pepper, chocolate, soft cheese, lettuce, raw fish, and lasagna ready meal	25g
L067	PDX- LIB	<i>Listeria</i> spp. including <i>L. monocytogenes</i> , <i>L. innocua</i> , <i>L. ivanovii</i> , <i>L. welshimeri</i>	Paradigm Diagnostics, Inc.	AOAC-RI # 040501	Environmental surfaces (ceramic tile, stainless steel, plastic, & sealed concrete)	N/A
L069	RapidChek® <i>Listeria</i>	<i>Listeria</i> spp.	Romer Labs Technology, Inc.	AOAC-RI # 020401	Ice cream, soft cheese, pasteurized whole milk, deli turkey, pepperoni, hot dogs, roast beef, cooked shrimp, smoked fish, potato salad, environmental surfaces (rubber, painted concrete, stainless steel)	25g
L068c	RAPID'L. mono	<i>Listeria monocytogenes</i>	Bio-Rad Laboratories	AOAC-RI # 030406	Brie cheese, surimi, mixed salad, & deli turkey	N/A
L068d	RAPID'L. mono	<i>Listeria</i> spp.	Bio-Rad Laboratories	NordVal # 022	Foods and environmental samples	25g
L068a	RAPID'L. mono (Detection)	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	Bio-Rad Laboratories	AFNOR # BRD 07/04 - 09/98	All human food products and environmental samples	25g
L068b	RAPID'L. mono Agar (Enumeration)	<i>Listeria monocytogenes</i>	Bio-Rad Laboratories	AFNOR # BRD 07/05 - 09/01	All human food products and environmental samples	N/A
L070a	RAPID' <i>Listeria</i> spp.	<i>Listeria</i> spp.	Bio-Rad Laboratories	AFNOR # BRD 07/12 - 12/06	All human food products and environmental samples	25g
L070b	RAPID' <i>Listeria</i> spp.	<i>Listeria</i> spp.	Bio-Rad Laboratories	AOAC-RI # 080701	Environmental surfaces (stainless steel, plastic, ceramic, sealed concrete)	N/A
L071	RAYAL <i>Listeria</i>	<i>Listeria</i> spp.	RAYAL Ltd.	AFNOR # RAY 32/03 - 07/10	All human food products and production environment samples	25g
L072	Reveal® 2.0 <i>Listeria</i> Test System	<i>Listeria</i> spp. excluding <i>L. grayi</i>	Neogen Corporation	AOAC-RI # 041101	Pasteurized liquid egg, ice cream, parmesan cheese, 2% milk, deli turkey, hot dogs, frozen cooked hamburgers, pepperoni, pasteurized crab meat, smoked salmon, environmental surfaces (stainless steel, ceramic tile, plastic, concrete)	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L074	Roka <i>Listeria</i> Detection Assay	<i>Listeria</i> spp.	Roka Bioscience, Inc	AOAC-RI # 011201	Pasteurized whole milk, ice cream, Brie cheese, hot dogs, cured ham, deli chicken, chicken salad, cold-smoked salmon, romaine lettuce, environmental surfaces (stainless steel, sealed concrete, plastic)	25g
L075	SDIX RapidChek™ <i>Listeria</i> ™ F.A.S.T. Environmental Test System	<i>Listeria</i> spp.	Strategic Diagnostics, Inc.	AOAC-RI # 101102	Environmental surfaces (stainless Steel, plastic, rubber, painted concrete)	N/A
L091	Solus <i>Listeria</i> ELISA	<i>Listeria</i> spp.	Solus Scientific	AFNOR # SOL 37/02 - 06/13	Human food products and environmental samples	N/A
L096	Thermo Scientific™ SureTect™ <i>Listeria monocytogenes</i> PCR Assay	<i>Listeria monocytogenes</i>	Thermo Fisher Scientific	AOAC-RI # 061302	Raw ground beef, pork frankfurters, salami, cooked sliced turkey, fresh bagged spinach, cantaloupe, processed cheese, ice cream, smoked salmon, cooked prawns, stainless steel and plastic	N/A
L076	TRANSIA® PLATE <i>Listeria</i>	<i>Listeria</i> spp.	BioControl	NordVal # 002	Foods and environmental samples	25g
L077	TRANSIA® PLATE <i>Listeria</i> spp.	<i>Listeria</i> spp.	BioControl Systems, Inc.	AFNOR # TRA 02/06 - 11/95	All food products and environmental samples	25g
L078	TRANSIA® Plate <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	BioControl Systems, Inc.	AFNOR # TRA 02/11 - 03/08	All human food products and environmental samples	N/A
L095	Veriflow™ <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	Invisible Sentinel	AOAC-RI # 051304	Beef hot dogs (14% fat), deli turkey (2% fat), stainless steel, ceramic tile, concrete, plastic	N/A
L079a	VIDAS® <i>L. monocytogenes</i> Xpress (VIDAS LMX)	<i>Listeria monocytogenes</i>	bioMérieux, sa	AFNOR # BIO 12/27 - 02/10	All human food products and environmental samples	25g
L080a	VIDAS® <i>Listeria</i> (LIS)	<i>Listeria</i> spp.	bioMérieux, sa	AFNOR # BIO 12/02 - 06/94	All human food products and production environment samples	25g/25mL
L080b	VIDAS® <i>Listeria</i> (LIS)	<i>Listeria</i> spp.	bioMérieux, sa	AOAC-OMA # 2004.06	Dairy products, vegetables, seafood, raw meats and poultry, and processed meats and poultry	25g
L080c	VIDAS® <i>Listeria</i> (LIS)	<i>Listeria</i> spp.	bioMérieux, sa	AOAC-OMA # 999.06	Dairy products, vegetables, seafoods, raw meats and poultry, and processed meats and poultry	25g
L081	VIDAS® <i>Listeria</i> Assay	<i>Listeria</i> spp.	bioMérieux, sa	AOAC-RI # 981202	Raw meats and poultry, cooked and processed meats and poultry, seafood, vegetables, dairy products, & environmental samples	25g
L082a	VIDAS® <i>Listeria</i> DUO (LDUO)	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	bioMérieux, sa	AFNOR # BIO 12/18 - 03/06	All human food products and environmental samples	25g/25mL

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L082b	VIDAS® <i>Listeria</i> DUO (LDUO) with Ottaviani Agar	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	bioMérieux, sa	AOAC-RI # 100702	Cheddar cheese, camembert cheese, pasteurized milk, yogurt, vanilla ice cream, raw pork, meat frankfurters, frozen ground beef, ham, roast beef, chicken frankfurters, raw ground chicken, raw cod, frozen cooked shrimp, crab meat, frozen green beans, cauliflower	25g
L083	VIDAS® <i>Listeria monocytogenes</i> 2 (VIDAS LMO2) (Enrichment at 30°C)	<i>Listeria monocytogenes</i>	bioMérieux, sa	AFNOR # BIO 12/09 - 07/02	All human food products (except raw products) and environmental samples	25g
L084	VIDAS® <i>Listeria monocytogenes</i> 2 (VIDAS LMO2) (Enrichment at 37°C)	<i>Listeria monocytogenes</i>	bioMérieux, sa	AFNOR # BIO 12/11 -03/04	All human food products and environmental samples	25g
L079b	VIDAS® <i>Listeria monocytogenes</i> Express (LMX) Assay	<i>Listeria monocytogenes</i>	bioMérieux, sa	AOAC-RI # 091103	Processed cheese, ice cream (AOAC), live pate, raw fermented sausage (USDA & MFHPB30), turkey hot dogs, deli ham, deli turkey (USDA & MFHPB30), shrimp, smoked fish (BAM), spinach, peanut butter (BAM)	25g
L085	VIDAS® <i>Listeria</i> species Xpress (LSX)	<i>Listeria</i> spp.	bioMérieux, sa	AOAC-OMA # 2010.02	Dairy products, vegetables, seafood, raw meats and poultry, and processed meats and poultry	25g
L086b	VIDAS® <i>Listeria</i> species Xpress (LSX) Test with Ottaviani Agosti Agar (OAA)	<i>Listeria</i> spp.	bioMérieux, sa	AOAC-RI # 100501	Raw pork, frozen minced beef, meat-based Frankfurter sausages, roast beef, ham, camembert cheese, yoghurt, cheddar cheese, pasteurized milk, vanilla ice cream, frozen green beans, fresh cauliflower, frozen minced chicken, chicken-based Frankfurter sausages, crabmeat, cod filets, prawns, mexican soft cheese, Environmental surfaces (stainless steel, plastic, rubber, ceramics, wood,	25g
L086a	VIDAS® <i>Listeria</i> species Xpress (VIDAS® LSX)	<i>Listeria</i> spp.	bioMérieux, sa	AFNOR # BIO 12/12 - 07/04	Meat products, dairy products, vegetables and environmental samples	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
L087	VIDAS® LMO2	<i>Listeria monocytogenes</i>	bioMérieux, sa	AOAC-OMA # 2004.02	Dairy products, vegetables, seafood, raw meats and poultry, and processed meats and poultry	25g
L088	VIDAS® UP <i>Listeria</i>	<i>Listeria</i> spp.	bioMérieux, sa	AFNOR # BIO 12/33 - 05/12	Human food products and production environment samples	N/A
L089b	VIP® for <i>Listeria</i>	<i>L. monocytogenes</i> , <i>L. seeligeri</i> , <i>L. welshimeri</i> , <i>L. ivanovii</i> , <i>L. grayii</i>	BioControl Systems, Inc.	AOAC-RI # 060801	Liquid pasteurized milk, mexican soft cheese, raw beef trim, ready to eat turkey, raw green beans, raw fish, environmental surfaces (stainless steel, rubber, plastic)	25g
L089a	VIP® Gold for <i>Listeria</i>	<i>Listeria monocytogenes</i> and <i>Listeria</i> spp.	BioControl Systems, Inc.	AOAC-OMA # 997.03	Dairy foods, red meats, pork, poultry and poultry products, seafood, fruits, vegetables, nutmeats, pasta, chocolate, eggs, bone meal, and environmental surfaces	25g
L092	VITEK® 2 Gram Positive (GP)	Gram-positive bacteria, including <i>Listeria</i> spp. and <i>Staphylococcus</i> spp.	bioMérieux, sa	AOAC-OMA # 2012.02	N/A	N/A
L090	Vitek GPI and GNI+	<i>Listeria</i> spp.	bioMérieux, sa	AOAC-OMA # 992.19	N/A	N/A

** N/A = Not available

Foodborne Pathogen Test Kits Validated by Independent Organizations

FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e. *Salmonella*, *Campylobacter*, *E. coli* O157:H7, *Listeria* spp. including *L. monocytogenes*, and non-O157 STECs). These lists are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.

While FSIS does not require the use of any particular test method, the method chosen by an establishment should be:

- 1) Validated for testing relevant foods by:
 - a) a recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), or
 - b) a U.S. regulatory body (i.e. FSIS MLG or FDA BAM), or an ISO method
- 2) The validated method should be:
 - a) Fit for the intended purpose and application, and
 - b) Performed under validated conditions by a laboratory that assures the quality of the analytical results.

The table below contains a list of foodborne pathogen test kits that meet criterion 1a as described above; i.e., are validated by recognized independent organizations (e.g., AOAC, AOAC-RI, AFNOR, MicroVal, NordVal). None of the test kits listed below are implicitly approved by USDA FSIS. A validated test kit must also be fit for purpose (i.e. validated for the appropriate matrix and sample size) and appropriate for the specific application in a food safety program. Additionally these methods should be performed as per the conditions of the validated protocol by a laboratory that assures the analytical results. FSIS has published further guidance for choosing a microbiological laboratory (<http://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651-b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab-062013.pdf?MOD=AJPERES>). The sampling methodology and frequency must be appropriate to answer the food safety question that is asked. Finally, sample transport and storage should be appropriate to ensure the integrity of the sample and the result.

The methods listed here are not necessarily equivalent or appropriate for all specific testing applications. Please refer to other FSIS guidance on fitness for purpose for specific applications. As an example, AskFSIS provides guidance on appropriate test portions for *E. coli* O157:H7 testing and application of non-culture confirmation methods to confirm screening test results. For *Listeria* food contact surface and other environmental samples, FSIS has provided the following additional guidance for sampling and testing; i.e., validated methods should include an enrichment step for the entire sponge, swab or sampling device. Methods listed below do not necessarily meet all of these criteria. For more detail on RTE *Listeria*, FSIS has published RTE *Listeria* Compliance Guidelines (<http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>).

On a case-by-case basis, FSIS has reviewed robust studies using the FSIS MLG method as a reference method. For these reviews, FSIS uses the FSIS Test Kit validation guidelines to evaluate the study design, results, and data analysis for these alternative methods (http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e-4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES). These alternative methods are not included in the lists below because they are not

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated matrices	Validated Test Portion Size**
EC001	3M™ Tecra™ <i>E. coli</i> O157 Visual Immunoassay	<i>E. coli</i> O157	3M Tecra International Pty Ltd	AOAC-RI # 001101	Raw ground beef, cooked ground beef, raw ground chicken, cooked ground chicken	25g
EC002	ADIAFOOD Detection System: <i>E. coli</i> O157 (No longer available for sale in the US)	<i>E. coli</i> O157	AES Chemunex Canada	AOAC-RI # 010408	Ground beef	25g
EC003	ADIAFOOD Detection System: <i>E. coli</i> O157:H7 (No longer available for sale in the US)	<i>E. coli</i> O157:H7	AES Chemunex Canada	AOAC-RI # 010409	Ground beef	25g
EC004	ADIAFOOD <i>Escherichia coli</i> O157:H7 (single well) (No longer available for sale in the US)	bioMérieux, SA	AES Chemunex	AFNOR # AES 10/12 - 10/11	Raw beef meat	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated matrices	Validated Test Portion Size**
EC005	Assurance GDS for <i>E. coli</i> O157:H7	<i>E. coli</i> O157:H7	BioControl Systems	AOAC-OMA # 2005.04	Raw ground beef, beef trim, orange juice, apple juice, fresh vegetables, and sprout process water	25g
EC006	Assurance GDS Shigatoxin Genes	<i>E. coli</i> O157:H7 and <i>E. coli</i> O157:H7 nonmotile (NM)	BioControl Systems	AOAC-OMA # 2005.05	Raw ground beef, beef trim, orange juice, fresh vegetables, and sprout process water	25g
EC007	Assurance® Enzyme Immunoassay (EIA)	<i>E. coli</i> O157:H7 (EHEC)	BioControl Systems	AOAC-OMA # 996.10	Dairy foods, meats, poultry products, fruits, nutmeats, seafood, pasta, liquid eggs, raw and cooked beef	25g
EC008a	BAX® Real-Time PCR Assay <i>E. coli</i> O157:H7	<i>E. coli</i> O157:H7	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AFNOR # QUA 18/07 - 07/10	Raw beef and vegetables	25g
EC008b	BAX® Real-Time PCR Assay <i>E. coli</i> O157:H7	<i>E. coli</i> O157:H7	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AOAC-RI # 031002	Lettuce & spinach; Beef trim (375g) & ground beef (65g)	25g except where noted in "Validated Matrices"
EC009a	BAX® System <i>E. coli</i> O157:H7 MP	<i>E. coli</i> O157:H7	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AFNOR # QUA 18/04 - 03/08	Raw beef meat, raw milk, fruits, vegetables, Ready-to-Eat meals, raw pork meat, raw ovine meat, and raw chicken meat	25g
EC009b	BAX® System PCR Assay for Screening <i>E. coli</i> O157:H7 MP and the BAX® System MP media	<i>E. coli</i> O157:H7	DuPont Qualicon (DuPont Nutrition & Health Diagnostics)	AOAC-RI # 050501	Raw ground beef, beef trim, spinach & lettuce	25g
EC011	BBL™ CHROMagar™ O157	<i>E. coli</i> O157:H7	Becton Dickinson and Co.	AOAC-RI # 090501	Raw ground beef, unpasteurized apple cider	N/A
EC012	Duopath® Verotoxin	Verotoxin producing <i>E. coli</i>	Merck KGaA	AOAC-RI # 020402	Pure culture	N/A
EC013	DuPont Lateral Flow System <i>E. coli</i> O157 Test Kit	<i>E. coli</i> O157	DuPont Qualicon	AOAC-RI # 010601	Boneless beef, ground beef, apple cider	25g
EC014	<i>E. coli</i> O157:H7 Test Kit	<i>E. coli</i> O157:H7	Idaho Technology, Inc.	AOAC-RI # 100901	Raw ground beef, uncooked spinach	25g
EC015	FoodChek™ <i>E. coli</i> O157	<i>E. coli</i> O157:H7	FoodChek Systems, Inc.	AOAC-RI # 060902	Raw ground beef (375g), raw beef trim (375g)	See "Validated Matrices"
EC016a	foodproof® <i>E. coli</i> O157 Detection Kit in combination with foodproof® ShortPrep II Kit	<i>E. coli</i> O157	BIOTECON Diagnostics GmbH	NordVal # 026	All foods	25g
EC016b	foodproof® <i>E. coli</i> O157 Detection Kit in combination with foodproof® ShortPrep II Kit	<i>E. coli</i> O157	BIOTECON Diagnostics GmbH	AOAC-RI # 100601	Camembert cheese, egg salad, raw milk, mayonnaise, hamburger meat, brockwurst sausage, coalfish, fresh salmon, apple juice, raw vegetables	25g
EC017a	GeneDisc <i>E. coli</i> O157:H7	<i>E. coli</i> O157:H7	Pall GeneDisc Technologies	AFNOR # GEN 25/06 - 11/08	Raw beef meats, dairy products, and vegetables	25g
EC017b	GeneDisc Pathogenic <i>E. coli</i> O157	<i>E. coli</i> O157	Pall GeneDisc Technologies	AOAC-RI # 021102	Raw ground beef and raw beef trim	25g, 375g
EC018	GeneDisc Plate Pathogenic <i>E. coli</i> O157 & <i>Salmonella</i> spp.	<i>E. coli</i> O157 & <i>Salmonella</i> spp.	Pall GeneDisc Technologies	AOAC-RI # 021104	Raw ground beef, raw beef trim	25g
EC019	HQS <i>E. coli</i> O157:H7 Sybr	<i>E. coli</i> O157:H7	ADNucleis	AFNOR # ADN 33/01 - 02/10	Dairy and meat products	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated matrices	Validated Test Portion Size**
EC021	IEH <i>E. coli</i> O157 (Stx-producing <i>E. coli</i> (STEC) with Intimin and Salmonella Test System	<i>E. coli</i> O157, Stx-producing <i>E. coli</i> (STEC) with intimin & <i>Salmonella</i> ** <i>E. coli</i> O26, O45, O103, O111, O121 & O145	IEH Laboratories & Consulting Group	AOAC-RI # 100701	Raw ground beef, raw beef trim, raw poultry, RTE turkey (omitted for STEC) & mixed leafy greens	25g
EC022a	iQ-Check <i>E. coli</i> O157:H7 Kit	<i>E. coli</i> O157:H7	BIO-RAD	AOAC-RI # 020801	Raw ground beef, fresh spinach, and apple cider	25g
EC022b	iQ-Check <i>E. coli</i> O157:H7 Kit	<i>E. coli</i> O157:H7	BIO-RAD	AFNOR # BRD 07/15 - 06/08	Raw beef	25g
EC023a	MicroSEQ® <i>E. coli</i> O157:H7 Detection Kit	<i>E. coli</i> O157:H7	Applied Biosystems	AFNOR # ABI 29/03 - 03/11	Raw beef meat and fresh vegetables	25g
EC023b	MicroSEQ® <i>E. coli</i> O157:H7 Detection Kit	<i>E. coli</i> O157:H7	Applied Biosystems, sa	AOAC-RI # 071001	Raw ground beef & raw beef trim (375g); ground beef & raw beef trim (25g); spinach, orange juice, apple juice (25g)	See "Validated Matrices"
EC024	Molecular Detection Assay <i>E. coli</i> O157 (including H7)	<i>E. coli</i> O157 (including H7)	3M	AOAC-RI # 071202	Raw ground beef (325g, 375g), fresh bagged spinach (200g), alfalfa sprouts (25g)	See "Validated Matrices"
EC025	Pathatrix ULTRA/Auto <i>E. coli</i> O157 Test System	<i>E. coli</i> O157	Matrix MicroScience, Ltd.	AOAC-RI # 030202	Raw ground beef	375g
EC026	RapidChek® <i>E. coli</i> O157 (including H7) Lateral Flow Test Assay	<i>E. coli</i> O157	Strategic Diagnostics, Inc.	AOAC-RI # 070801	Raw ground beef & boneless beef trim; raw ground beef & beef trim samples (375g)	See "Validated Matrices"
EC027a	RAPID® <i>E. coli</i> O157:H7/Agar	<i>E. coli</i> O157:H7	BIO-RAD	AOAC-RI # 060701	Raw ground beef and fresh spinach	Sample preparation, enrichment, and IMS as per FSIS MLG Ch 5
EC027b	RAPID® <i>E. coli</i> O157:H7/Agar	<i>E. coli</i> O157:H7	BIO-RAD	AFNOR # BRD 07/14 - 09/07	All human food products and environmental samples	25g/25mL
EC028a	Reveal for <i>E. coli</i> O157:H7 Test in Selected Foods and Environmental Swabs	<i>E. coli</i> O157:H7	Neogen Corporation	AOAC-OMA # 2000.14	Raw ground beef, raw beef cubes, apple cider, iceberg lettuce rinse, environmental swabs of stainless steel	25g, 375g (20hr enrichments)
EC028b	Reveal for <i>E. coli</i> O157:H7 Test System in Selected Foods	<i>E. coli</i> O157:H7	Neogen Corporation	AOAC-OMA # 2000.13	Raw ground beef, raw beef cubes, iceberg lettuce rinse	25g (8hr enrichments), 375g (12hr enrichments)
EC029	Reveal® 2.0 <i>E. coli</i> O157:H7 Test System	<i>Escherichia coli</i> serotypes O157:H7 & O157:NM	Neogen Corporation	AOAC-RI # 011103	Raw beef trim, raw ground beef	65g, 375g
EC030	SAS™ Molecular Tests <i>Escherichia coli</i> O157 Detection Kit	<i>E. coli</i> O157	SA Scientific, Ltd.	AOAC-RI # 031203	Raw ground beef (25g, 375g), raw beef trim (375g), bagged mixed lettuce (200g), fresh spinach (200g)	See "Validated Matrices"
EC031	Singlepath® <i>E. coli</i> O157 Lateral Flow Assay	<i>E. coli</i> O157 (including H7)	Merck KGaA	AOAC-RI # 010407	Raw ground beef & pasteurized milk	25g
EC032a	VIDAS® <i>E. coli</i> O157 (ECO)	<i>E. coli</i> O157	bioMérieux, sa	AFNOR # BIO 12/08 - 07/00	All human food products	25g
EC032b	VIDAS® <i>E. coli</i> O157 (ECO)	<i>E. coli</i> O157 (including H7)	bioMérieux, sa	AOAC-RI # 010502	Raw Ground Beef	25g

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated matrices	Validated Test Portion Size**
EC033	VIDAS® UP <i>E. coli</i> O157 (including H7) (ECPT) Test with VIDAS Immuno Concentration (ICE) & ChromID O157:H7 Agar	<i>E. coli</i> O157:H7	bioMérieux, sa	AOAC-RI # 060903	Ground beef, beef trimmings (with sample sizes: 25g, 75g & 375g composite & wet pooled samples 75g & 375g), bagged lettuce, fresh spinach & irrigation water	25g except where noted in "Validated Matrices"
EC034	VIDAS® UP <i>E. coli</i> O157 including H7 (VIDAS ECPT)	<i>E. coli</i> O157	bioMérieux, sa	AFNOR # BIO 12/25 - 05/09	All human food products and production environmental samples	25g, and 50-375g for raw beef/veal
EC035	Visual Immunoprecipitate Assay (VIP®) Assay	<i>E. coli</i> O157:H7	BioControl Systems	AOAC-OMA # 996.09	Dairy products, meats, poultry, fruits, nutmeats, seafood, pasta, liquid eggs, vegetables, raw beef, cooked beef	25g
EC036	3M Molecular Detection Assay <i>E. coli</i> O157 (including H7)	<i>E. coli</i> O157 (including H7)	3M France	AFNOR # 3M 01/12-03/13	Raw beef meats, raw dairy products, raw fruits and vegetables	25g
EC037	MultiPath System™ E for <i>Escherchia coli</i> O157	<i>E. coli</i> O157	Crystal Diagnostics Corporate	AOAC-RI # 041301	Raw ground beef (375g), fresh raw spinach (200g)	See "Validated Matrices"
EC038	GeneDisc STEC	Shigatoxigenic <i>E. coli</i>	Pall GeneDisc Technologies	AOAC-RI # 021103	Fresh raw ground beef (25 g, 375 g) fresh raw beef trim (25 g, 375 g)	See "Validated Matrices"
EC039	iQ-Check™ STEC VirX and iQ-Check™ STEC SerO	<i>Stx1</i> , <i>Stx2</i> , <i>eae</i> , O26, O45, O103, O11, O121, O145, O157:H7	Bio-Rad Laboratories	AOAC-RI # 121203	Raw beef trim	N/A
EC040	GeneDisc STEC & <i>Salmonella</i> spp.	Shigatoxigenic <i>E. coli</i> and <i>Salmonella</i> spp.	Pall GeneDisc Technologies	AOAC-RI # 021105	Raw ground beef, raw beef trim	25g
EC041	Atlas <i>E. coli</i> EG2 Detection Assay	<i>E. coli</i> O157:H7	Roka Bioscience, Inc	AOAC-RI # 011401	Fresh raw high fat ground beef (375g), romaine lettuce (375g)	See "Validated Matrices"
EC042	Atlas STEC EG2 Combo Detection Assay	<i>E. coli</i> O157:H7 & non-O157 STEC	Roka Bioscience, Inc	AOAC-RI # 011402	Fresh raw ground beef (73% lean, 375g), fresh raw beef trim (375g), romaine lettuce (375g)	See "Validated Matrices"
EC043	InstantLabs <i>E. coli</i> O157 (including H7) Food Safety Kit	<i>E. coli</i> O157 (including H7)	InstantLabs Medical Diagnostics Corporation	AOAC-RI # 011403	Fresh raw ground beef (27% fat, 375g), fresh raw beef trim (375g), fresh raw ground chicken, romaine lettuce, pasteurized apple juice	25g except where noted in "Validated Matrices"

** N/A = Not available

Foodborne Pathogen Test Kits Validated by Independent Organizations

FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e. *Salmonella*, *Campylobacter*, *E. coli* O157:H7, *Listeria* spp. including *L. monocytogenes*, and non-O157 STECs). These lists are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.

While FSIS does not require the use of any particular test method, the method chosen by an establishment should be:

- 1) Validated for testing relevant foods by:
 - a) a recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), or
 - b) a U.S. regulatory body (i.e. FSIS MLG or FDA BAM), or an ISO method
- 2) The validated method should be:
 - a) Fit for the intended purpose and application, and
 - b) Performed under validated conditions by a laboratory that assures the quality of the analytical results.

The table below contains a list of foodborne pathogen test kits that meet criterion 1a as described above; i.e., are validated by recognized independent organizations (e.g., AOAC, AOAC-RI, AFNOR, MicroVal, NordVal). None of the test kits listed below are implicitly approved by USDA FSIS. A validated test kit must also be fit for purpose (i.e. validated for the appropriate matrix and sample size) and appropriate for the specific application in a food safety program. Additionally these methods should be performed as per the conditions of the validated protocol by a laboratory that assures the analytical results. FSIS has published further guidance for choosing a microbiological laboratory (http://www.fsis.usda.gov/PDF/Guidance_Selecting_Micro_Testing_Lab.pdf). The sampling methodology and frequency must be appropriate to answer the food safety question that is asked. Finally, sample transport and storage should be appropriate to ensure the integrity of the sample and the result.

The methods listed here are not necessarily equivalent or appropriate for all specific testing applications. Please refer to other FSIS guidance on fitness for purpose for specific applications. As an example, AskFSIS provides guidance on appropriate test portions for *E. coli* O157:H7 testing and application of non-culture confirmation methods to confirm screening test results. For *Listeria* food contact surface and other environmental samples, FSIS has provided the following additional guidance for sampling and testing; i.e., validated methods should include an enrichment step for the entire sponge, swab or sampling device. Methods listed below do not necessarily meet all of these criteria. For more detail on RTE *Listeria*, FSIS has published RTE *Listeria* Compliance Guidelines (<http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>).

On a case-by-case basis, FSIS has reviewed robust studies using the FSIS MLG method as a reference method. For these reviews, FSIS uses the FSIS Test Kit validation guidelines to evaluate the study design, results, and data analysis for these alternative methods (http://www.fsis.usda.gov/PDF/Validation_Studies_Pathogen_Detection_Methods.pdf). These alternative methods are not included in the lists below because they are not externally validated by an independent organization.

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated matrices	Validated Test Portion Size**
STEC001	GeneDisc STEC	Shigatoxigenic <i>E.coli</i>	Pall GeneDisc Technologies	AOAC-RI # 021103	Fresh raw ground beef (25g, 375g), fresh raw beef trim (25g, 375g)	See "Validated Matrices"
STEC002	GeneDisc Plate STEC Top 6	STECs including O26, O103, O111, O145, O45, O121	Pall GeneDisc Technologies	AOAC-RI # 021106	Fresh raw ground beef (25g, 375g), fresh raw beef trim (25g, 375g)	See "Validated Matrices"
STEC003	iQ-Check™ STEC VirX and iQ-Check™ STEC SerO	<i>Stx1</i> , <i>Stx2</i> , <i>eae</i> , O26, O45, O103, O11, O121, O145, O157:H7	Bio-Rad Laboratories	AOAC-RI # 121203	Raw beef trim	N/A
STEC004	GeneDisc STEC & <i>Salmonella</i> spp.	Shigatoxigenic <i>E.coli</i> and <i>Salmonella</i> spp.	Pall GeneDisc Technologies	AOAC-RI # 021105	Raw ground beef (25g) and raw beef trim (25g)	See "Validated Matrices"

** N/A = Not available

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated matrices	Validated Test Portion Size**
STEC005	IEH <i>E. coli</i> O157 (Stx-producing <i>E. coli</i> (STEC) with Intimin and Salmonella Test System	<i>E. coli</i> O157, Stx-producing <i>E. coli</i> (STEC) with intimin & <i>Salmonella</i> ** <i>E. coli</i> O26, O45, O103, O111, O121 & O145	IEH Laboratories & Consulting Group	AOAC-RI # 100701	Raw ground beef, raw beef trim, raw poultry, RTE turkey (omitted for STEC) & mixed leafy greens	25g
STEC006	BAX® System Real-Time PCR Assay Suite for detecting non-O157:H7 Shiga Toxin Producing <i>Escherchia coli</i> (STEC)	Shiga Toxin producing <i>E. coli</i> (1 & 2), <i>eae</i> , O26, O45, O103, O111, O121, O145	DuPont Nutrition & Health Diagnostics	AOAC-RI # 091301	Raw beef trim (375g), raw ground beef (375g), raw ground beef plus soy (325g)	See "Validated Matrices"
STEC007	Assurance GDS MPX Top 7 STEC	STECs including: O26, O45, O103, O111, O121, O145, & O157	BioControl Systems	AOAC-RI # 071301	Raw beef trim, raw ground beef, raw spinach, and raw mixed greens (baby lettuces and other leafy green vegetables)	375g
STEC008	Atlas STEC EG2 Combo Detection Assay	<i>E. coli</i> O157:H7 & non-O157 STEC	Roka Bioscience, Inc	AOAC-RI # 011402	Fresh raw ground beef (73% lean, 375g), fresh raw beef trim (375g), romaine lettuce (375g)	See "Validated Matrices"
STEC009	GeneDisc Plate STEC Top 7	<i>E. coli</i> O157:H7 & non-O157 STEC	Pall GeneDisc Technologies	AOAC-RI # 031401	Fresh raw ground beef (20% fat, 375g), fresh raw beef trim (20% fat, 375g)	See "Validated Matrices"

** N/A = Not available