

## **Validated Matrices for BAX® System Assays**

| Organism                              | Assay   | Approved Matrices  | Validation Reference        |
|---------------------------------------|---|--|-----------------------------|
| Campylobacter<br>(C. jejuni, C. coli, | BAX® System Real-<br>Time PCR Assay for<br><i>Campylobacter</i><br>jejuni/coli/lari<br>(Kit# D12683449;<br>KIT2018) | Poultry carcass rinses,<br>processed turkey              | AOAC-RI 040702              |
|                                       |   | Chicken cloacae swabs                                    | NordVal Certificate #39     |
| C. lari)                              |   | For screening in poultry rinses, sponge and raw products | USDA FSIS MLG 41.04, 41A.00 |

| Organism                      | Assay   | Approved Matrices   | Approval Reference     |
|-------------------------------|---|---|------------------------|
| Cronobacter<br>(E. sakazakii) |   | Powdered infant formula,<br>powdered infant formula*,<br>dry dairy and soy ingredients,<br>environmentals,<br>environmental sponges | Internally Validated   |
| (2) Sandzanny                 | BAX® System PCR Assay<br>for E. sakazakii (Kit<br>#D11801836;<br>KIT2001) | Dairy (dry ingredients),<br>environmentals (food<br>production), powdered infant<br>formula, soy ingredients                        | Health Canada #MLFP-27 |



| Organism | Assay   | Approved Matrices  | Approval Reference   |
|----------|---|--|--|
|          | BAX® System X5 PCR Assay for <i>E. coli</i> O157:H7 (Kit#D15407214; KIT2022)                              | Raw ground beef, beef trim,<br>spinach and lettuce   | AOAC-RI 050501   |
|          |   | Raw beef meats, raw milk,<br>fruits and vegetables, ready-<br>to-eat and ready-to-reheat<br>dishes, raw pork,<br>ovine and chicken meats | AFNOR QUA 18/04 - 03/08<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |
|          | BAX® System PCR   | Raw ground beef, beef trim, spinach and lettuce  | AOAC-RI 050501   |
| E. coli  | Assay for <i>E. coli</i><br>O157:H7 MP<br>(Kit #D12404903;<br>KIT2004)                                    | Raw beef meats, raw milk,<br>fruits and vegetables, ready-<br>to-eat and ready-to-reheat<br>dishes, raw pork,<br>ovine and chicken meats | AFNOR QUA 18/04 - 03/08<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |
|          | BAX® System Real-<br>Time PCR Assay for <i>E.</i><br><i>coli</i> O157:H7<br>(Kit #D14203648;<br>KIT2000)  | Raw ground beef, beef trim, spinach and lettuce  | AOAC-RI 031002   |
|          |   | Raw beef meats, raw<br>vegetables  | AFNOR QUA 18/07-07/10 (Validation study performed in accordance with EN ISO 16140-2)         |
|          |   | Meat products and carcass and environmental sponges  | USDA FSIS MLG 5.09/5A.04   |
|          | BAX® System Real-<br>Time PCR Assay for<br>STEC Screening: stx<br>and eae<br>(Kit #D14642964;<br>KIT2021) | Raw ground beef, raw ground<br>beef with soy, raw beef trim,<br>flour  | AOAC-RI 091301   |
|          |   | Raw beef, raw beef mixes,<br>beef trim, trim components,<br>environmental sponges and<br>carcass sponges, flour                          | USDA FSIS MLG 5B.05  |



|         | BAX® System Real-<br>Time PCR Assay for<br>STEC Panel 1: E. coli<br>O26, O111, and O121<br>(Kit #D14642970;<br>KIT2008) | Raw ground beef, raw ground beef with soy, raw beef trim, flour                 | AOAC-RI 091301      |
|---------|---|---|---------------------|
|         |   | Shiga toxin confirmation in meat products and carcass and environmental sponges | USDA FSIS MLG 5B.05 |
| E. coli | BAX® System Real-<br>Time PCR Assay for<br>STEC Panel 2: E. coli<br>O45, O103, and O145<br>(Kit #D14642987;<br>KIT2009) | Raw ground beef, raw ground<br>beef with soy, raw beef trim,<br>flour           | AOAC-RI 091301      |
|         |   | Shiga toxin confirmation in meat products and carcass and environmental sponges | USDA FSIS MLG 5B.05 |

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|----------|---|---|--|
|          | BAX® System X5 PCR<br>Assay for                       | Environmental sponges,<br>environmental swabs,<br>frankfurters, smoked salmon,<br>spinach and other vegetables,<br>cheese | AOAC-RI 030502   |
| Listeria | Genus <i>Listeria</i><br>(Kit #D15407193;<br>KIT2024) | All human food products and production environmental samples  | AFNOR QUA 18/06-07/08<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |



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| Listeria | BAX® System PCR<br>Assay for Genus<br><i>Listeria</i><br>(Kit #D11000147;                        | Frankfurters, smoked salmon, spinach and other vegetables, cheese, environmental sponges, environmental swabs, multiple environmental surfaces   | AOAC-RI 030502   |
|          | KIT2016)   | Environmental sponges and swabs  | Health Canada #MLFP-15   |
| Listeria | BAX® System PCR<br>Assay for Genus<br><i>Listeria</i> 24E<br>(Kit #D13608135;<br>KIT2003)        | Frankfurters, shrimp, spinach,<br>queso fresco cheese, stainless<br>steel  | AOAC -RI 050903  |
|          |  | All human food products and production environmental samples   | AFNOR QUA 18/06-07/08<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |
| Listeria | BAX® System Real-<br>Time PCR Assay for<br>Genus <i>Listeria</i><br>(Kit #D15131113;<br>KIT2019) | Frankfurters, cooked shrimp,<br>spinach, bagged lettuce, queso<br>fresco cheese,<br>environmental surfaces   | AOAC-RI 081401<br>(Includes Actero™ Elite<br>Enrichment Media from FoodChek™)              |
| Listeria | BAX® System X5 PCR Assay for <i>L.</i> monocytogenes (Kit #D15407201; KIT2023)                   | Ground beef, ground pork, ground chicken, ground turkey, deli turkey, frankfurters, pepperoni, fish sticks, surimi, langostinos, smoked salmon, ice cream, milk (2%), yogurt, queso fresco, cabbage slaw, peas, spinach, strawberries, apple juice, orange juice, and environmental surfaces | AOAC-RI 070202   |
|          |  | All human food products and production environmental samples   | AFNOR QUA 18/05-07/08<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |



|          |  | Raw and processed meats,<br>fresh fruits and vegetables,<br>seafood, cultured and non-<br>cultured dairy products,<br>fruit juice and environmental<br>surfaces   | AOAC-RI 070202   |
|----------|--|---|--|
| Listeria | BAX® System PCR<br>Assay for <i>Listeria</i><br><i>monocytogenes</i>                                     | Dairy products, fruits,<br>vegetables (except radishes),<br>seafood, raw and processed<br>meats, and poultry  | AOAC-OMA 2003.12   |
|          | (Kit #D11000157;<br>KIT2017)   | Meat, poultry, ready-to-eat siluriformes and egg products, and environmental sponge samples   | USDA FSIS MLG 8.10/8A.06   |
|          |  | Raw and ready to eat meat and poultry, eggs and egg products (processed and unprocessed), seafood, dairy, chocolate/bakery products, shelf stable foods, spices, composite foods, fruits and vegetables, cereals, animal feed, environmentals | Health Canada #MFLP-28   |
| Listeria | BAX® System PCR<br>Assay for <i>Listeria</i><br><i>monocytogenes</i> 24E<br>(Kit #D13608125;<br>KIT2002) | Frankfurters, shrimp, spinach, cooked shrimp, queso fresco cheese, stainless steel surfaces   | AOAC -RI 080901  |
|          |  | All human food products and production environmental samples  | AFNOR QUA 18/05-07/08<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |
| Listeria | BAX® System Real-<br>Time PCR Assay for<br>Listeria<br>monocytogenes<br>(Kit #D15134303;<br>KIT2005)     | Frankfurters, frozen cooked shrimp, cold smoked salmon, bagged spinach, queso fresco cheese, environmental sponges (stainless steel, plastic, sealed concrete)  | AOAC-RI 121402<br>(Includes Actero™ Elite<br>Enrichment Media from FoodChek™)              |



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|------------|--|---|--|
| Salmonella | BAX® System X5 PCR<br>Asssay for Salmonella<br>(Kit #D15407187;<br>KIT2025)    | Frankfurters, chipped ham, cooked chicken, peanut butter, alfalfa sprouts, chocolate, nonfat dry milk, black pepper, Custard, liquid milk, nonfat dry milk chilled ready meal, cooked fish, seafood-prawns, elbow macaroni, pizza dough, frozen peas, orange juice, dry pet food, environmental sponges (finished product areas), ground beef, beef trim, spinach and lettuce | AOAC-RI 100201   |
|            |  | All human products, feed products, and production environmental samples (except primary production environment)   | AFNOR QUA 18/03 - 11/02<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |
| Salmonella | BAX® System PCR Assay<br>for <i>Salmonella</i><br>(Kit #D14368501;<br>KIT2012) | Frankfurters, chipped ham, cooked chicken, peanut butter, alfalfa sprouts, chocolate, nonfat dry milk, black pepper, Custard, liquid milk, nonfat dry milk chilled ready meal, cooked fish, seafood-prawns, elbow macaroni, pizza dough, frozen peas, orange juice, dry pet food, environmental sponges (finished product areas), ground beef, beef trim, spinach and lettuce | AOAC-RI 100201   |



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|------------|---|--|--|
|            |   | Hot dogs and frankfurters,<br>beef/raw ground beef,<br>chicken/raw ground chicken,<br>fish/raw frozen tilapia fish,<br>fruit juices/orange juice,<br>cheese/mozzarella cheese  | AOAC-OMA 2003.09   |
|            |   | All human food products, feed products, and production environmental samples (except primary production environment)   | AFNOR QUA 18/03 - 11/02<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |
| Salmonella | BAX® System PCR Assay<br>for Salmonella | Drag swabs, fecal samples,<br>dust, chick pads, meconium   | NPIP   |
|            | (Kit #D14368501;<br>KIT2012)            | Food, animal feed and environmental samples  | NORDVAL Certificate #030   |
|            |   | Ready-to-eat meat, poultry, and siluriformes foods, Raw poultry products, raw meat and raw beef mixed products, poultry carcass and environmental sponges, meat carcass, whole bird rinses, pasteurized liquid, frozen, or dried egg products, raw siluriformes products, fermented products, dried products (breading mixes, dehydrated sauces, dried milk) | USDA FSIS MLG 4.09/4C.07   |
|            |   | Dairy, eggs, meat and poultry,<br>seafood, vegetables and other<br>foods   | Health Canada MFLP-29  |



|            |  | Frankfurters, chipped ham, cooked chicken, peanut butter, alfalfa sprouts, chocolate, nonfat dry milk, black pepper, Custard, liquid milk, nonfat dry milk chilled ready meal, cooked fish, seafood-prawns, elbow macaroni, pizza dough, frozen peas, orange juice, dry pet food, environmental sponges (finished product areas), ground beef, beef trim, | AOAC-RI 100201   |
|------------|--|---|--|
| Salmonella | BAX® System PCR Assay<br>for <i>Salmonella</i> 2<br>(Kit #D14368501;<br>KIT2011) | spinach and lettuce  Hot dogs and frankfurters, beef/raw ground beef, chicken/raw ground chicken, fish/raw frozen tilapia fish, fruit juices/orange juice, cheese/mozzarella cheese   | AOAC-OMA 2003.09   |
|            |  | Broad range of food and<br>animal feed and production<br>environmental samples<br>(excluding primary<br>production samples)   | AFNOR QUA 18/03 - 11/02<br>(Validation study performed in<br>accordance with EN ISO 16140-2) |



| Salmonella | BAX® System Real-Time<br>PCR Assay for <i>Salmonella</i><br>(Kit #D14306040;<br>KIT2006) | Beef/raw ground beef, beef/ground beef with soy, beef/beef trim, hot dogs and frankfurters/frankfurters, turkey/ground turkey, chicken/chicken wings, poultry/poultry rinse, fish/shrimp, eggs and egg products (dried whole eggs, shell eggs), cheese/cream cheese, milk/nonfat dry milk, dairy products/ice cream, infant formula/milk-based infant formula, vegetables/fresh bagged lettuce, frozen vegetables/peas, fruit juices/orange juice, nuts and nut products/peanut butter, cacao bean and its products/cocoa, spices and condiments/white pepper, pet foods/dry pet food, environmental surfaces (ceramic, plastic, stainless | AOAC-OMA 2013.02<br>(Includes Actero™ Elite Enrichment<br>Media from FoodChek™)                      |
|------------|--|--|--|
|            |  | Raw ground beef, poultry carcass rinse, bagged lettuce, cream cheese, dry pet food, milk chocolate, chocolate liquor, cocoa powder, shell egg, stainless steel surfaces, plastic surfaces  All human food products, pet food and production environmental samples (except primary production   | AOAC-RI 081201  AFNOR QUA 18/08-07/08 (Validation study performed in accordance with EN ISO 16140-2) |



| Organism | Assay  | Approved Matrices   | Approval Reference   |
|----------|--|---|----------------------|
|          |  | Frankfurters  | Internally Validated |
| Shigella | BAX® System Real-Time<br>PCR Assay for <i>Shigella</i><br>(Kit #D14812018;<br>KIT2007) | Cooked meats, raw pork,<br>dessert gelatin, ready-to-eat<br>prepared dishes, non-<br>fermented soy products, lunch<br>meals, granulated white sugar | Internally Validated |

| Organism                 | Assay  | Approved Matrices  | Approval Reference |
|--------------------------|--|--|--------------------|
| Staphylococcus<br>aureus | BAX® System Real-<br>Time PCR Assay for<br>Staphylococcus aureus<br>(Kit #D12762689;<br>KIT2020) | Presence/absence testing on<br>soy and milk-based powdered<br>infant formula; Threshold<br>testing on ground beef and soy<br>protein isolate | AOAC-RI #120701    |

| Organism | Assay   | Approved Matrices  | Approval Reference |
|----------|---|--|--------------------|
| Vibrio   | BAX® System Real-Time PCR Assay for Vibrio cholerae/parahaemolyt icus /vulnificus (Kit #D12863877; KIT2010) | Tuna, shrimp and scallops (presence/absence), tuna, shrimp and scallops (MPN), oysters (MPN) | AOAC-RI #050902    |

| Organism     | Assay   | Approved Matrices   | Approval Reference |
|--------------|---|---|--------------------|
| Yeast & Mold | BAX® System PCR Assay<br>for Yeast & Mold<br>(Kit #D12522091;<br>KIT2015) | Validated on using the enriched protocol for yogurt, corn starch and milk-based powdered infant formula (for thresholds of 10-1000 cfu/g) | AOAC-RI #010902    |



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