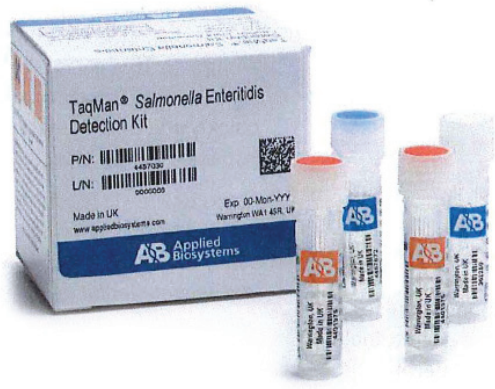
applied biosystems
by life technologies™

TaqMan® *Salmonella* Enteritidis Detection Kit

Clear eggs in hours, not days

- Fastest *Salmonella* Enteritidis detection method available—clear eggs and respond to environmental contamination up to 10 times faster
- FDA-BAM method equivalency—*Salmonella* Enteritidis detection in eggs and environmental samples
- NPIP interim approval as a rapid screening method for *Salmonella* Enteritidis in environmental samples
- Confident results and minimized chances for false positives—molecular PCR-based detection workflow brings high levels of specificity and sensitivity
- Highly automated workflow—easy to use and consistent results with minimal user input



Salmonella Enteritidis in poultry eggs and poultry houses

One of the most common causes of foodborne illness is *Salmonella*, a genus of bacteria responsible for an infection called salmonellosis. In particular, *Salmonella enterica* subspecies *enterica*, serovar Enteritidis—or *Salmonella* Enteritidis (SE)—is an important pathogen whose transmission has been linked to the consumption of eggs.

A common organism in the digestive tract of poultry, *Salmonella* Enteritidis has the unique ability to enter and colonize the reproductive tract of hens and potentially enter the egg before the shell is formed. In an effort to prevent the contamination of shell eggs with *Salmonella* Enteritidis during egg production, the FDA has issued a rule that requires shell egg producers to implement measures to prevent *Salmonella* Enteritidis from contaminating eggs on the farm and from further contamination during storage and transportation.

FDA Egg Safety Final Rule

In July 2010, in order to minimize the potential for foodborne illness from eggs containing *Salmonella* Enteritidis, the FDA implemented new regulations for the egg industry, which include requiring large-scale egg producers to begin *Salmonella* Enteritidis monitoring programs in their poultry houses and potentially on their products.

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As part of the new FDA Egg Safety Final Rule, producers must enact regular environmental screening for *Salmonella* Enteritidis in their houses. If *Salmonella* Enteritidis is detected in the environment of the poultry house, the producer is required to test 200 unique 1-liter (1 L) pooled egg samples from the house before these eggs can be sold at market as fresh eggs.

The new challenge for the egg industry

In order to meet the new testing standards enacted by the FDA and minimize the impact to their current production, egg and poultry producers will need rapid tests to specifically monitor for *Salmonella* Enteritidis in their houses and in their eggs.

Traditional *Salmonella* Enteritidis culture tests (such as the FDA-BAM method) can take upwards of 10 days to confirm the presence of the *Salmonella* Enteritidis serovar in egg samples, and roughly 3 days to confirm presence or absence in environmental samples. Slow time-to-results means holding large numbers of eggs in inventory while test results are generated, as well as further spreading of the pathogen in the environment and delayed corrective actions.

In addition, other more rapid commercially available kits that use immunodetection methods still require multiple days and multiple enrichment steps to determine the presence or absence of *Salmonella* Enteritidis (Figure 1). They also are based on antibody-antigen interactions and have the potential for false positives as a result of nonselective binding and cross-reactivity with closely related organisms.

Fast and accurate answers with the TaqMan® *Salmonella* Enteritidis Detection Kit

The TaqMan® *Salmonella* Enteritidis Detection Kit is part of a comprehensive workflow to detect *Salmonella* Enteritidis in poultry egg and environmental samples. The workflow utilizes TaqMan® chemistries and polymerase chain reaction (PCR) to detect *Salmonella* Enteritidis in egg and environmental samples in approximately 27 hours—the fastest time-to-results currently available for an FDA-equivalent and NPIP-approved method.

Get results in hours, not days—ship eggs and respond to contamination faster.

With the 27-hour total time-to-results, egg producers can clear implicated eggs in the shortest time currently available, roughly 10 times faster than the FDA-BAM method (Figure 1, Table 3). Speeding the time from query to cleared product allows producers to reduce inventory costs and get the freshest possible product to market.

In addition, the 27-hour total time-to-results for environmental samples allows rapid detection of *Salmonella* Enteritidis in the environment (Figure 1). This gives producers the ability to take corrective actions quickly and minimize the potential impact to operations.

Have confidence in your results—helps you to be compliant with the FDA Egg Safety Rule and know that your egg and environmental samples are free of Salmonella Enteritidis.

The FDA has determined that the TaqMan® *Salmonella* Enteritidis Detection Kit and workflow are equivalent to the method from the FDA Bacteriological Analytical Manual (BAM, December 2007 Edition, Chapter 5, *Salmonella*) in accuracy, precision, and sensitivity for the detection of *Salmonella* Enteritidis in both environmental and pooled egg samples (Table 1). In addition, the kit holds NPIP interim approval as a rapid screening method for *Salmonella* Enteritidis in environmental samples in poultry houses.

FDA equivalency and NPIP approval require rigorous internal and external testing to show that the quality and accuracy of the data generated are not being sacrificed in order to gain the significant time savings of the PCR-based method.

Minimize chances for false positives with the high specificity and sensitivity offered by a PCR-based method.

The molecular PCR-based detection technology uses unique signatures in *Salmonella* Enteritidis genes to specifically identify the presence or absence of *Salmonella* Enteritidis with high levels of sensitivity.

Due to the high sensitivity of a PCR-based assay, the method can detect as few as 1–5 CFU *Salmonella* Enteritidis present in environmental samples as well as in 1 L pooled egg samples. In addition, the increased specificity allows the user to identify only *Salmonella* Enteritidis in the sample and specifically exclude other nonregulated and unrelated organisms (Tables 2 and 3).

These factors help to minimize the potential for false positive results while still maintaining high levels of sensitivity to detect *Salmonella* Enteritidis in the smallest amounts.

Highly automated workflow—easy-to-use system with consistent results and minimal user input.

The TaqMan® *Salmonella Enteritidis* Detection Kit workflow utilizes a

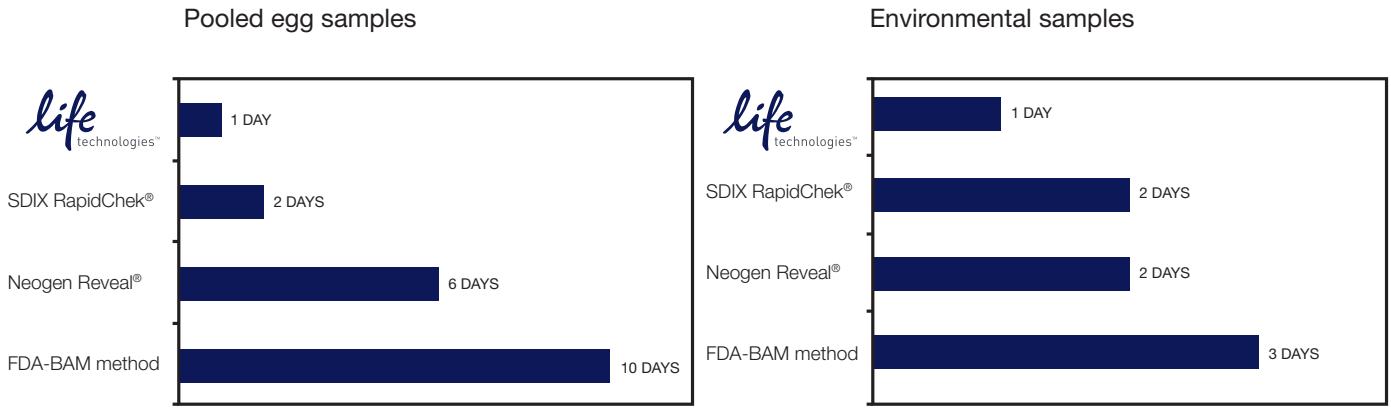

Figure 1. Compared to typical time-to-results of other methods for *Salmonella* Enteritidis testing, the TaqMan® *Salmonella* Enteritidis Detection Kit provides results in significantly less time.

Table 1. *Salmonella* Enteritidis detection in pooled egg samples: TaqMan® *Salmonella* Enteritidis Detection Kit compared to the FDA-BAM culture method. In a single experiment with 25 *Salmonella* Enteritidis fractional-positive samples, the TaqMan® *Salmonella* Enteritidis Detection Kit perfectly correlated with the FDA-BAM method.

Sample	FDA-BAM	TaqMan® *Salmonella* Enteritidis Detection Kit
1	–	–
2	+	+
3	–	–
4	+	+
5	–	–
6	+	+
7	+	+
8	–	–
9	–	–
10	+	+
11	+	+
12	–	–

Sample	FDA-BAM	TaqMan® *Salmonella* Enteritidis Detection Kit
13	+	+
14	+	+
15	–	–
16	+	+
17	–	–
18	+	+
19	–	–
20	+	+
21	–	–
22	+	+
23	–	–
24	–	–
25	+	+

Table 2. Up to 100% specificity of the TaqMan® *Salmonella* Enteritidis Detection Kit. PCR-based molecular detection is highly specific to *Salmonella* Enteritidis and specifically excludes all non–*Salmonella* Enteritidis *Salmonella* and non-*Salmonella* pathogens tested.

Target	Number detected	Comments
Inclusivity of *Salmonella* Enteritidis strains	50/50	Multiple strains and sources of *Salmonella* Enteritidis
Exclusivity of non–*Salmonella* Enteritidis *Salmonella* strains	0/38	Multiple serovars of *Salmonella* including non–*Salmonella* Enteritidis Group D organisms
Exclusivity of non–*Salmonella* organisms	0/15	Multiple gram–negative and gram–positive pathogens tested

Table 3. The TaqMan® *Salmonella* Enteritidis Detection Kit offers up to 100% specificity. The TaqMan® *Salmonella* Enteritidis Detection Kit can potentially reduce false positive and false negative calls (compared to competing antibody-based tests) due the test's high level of specificity and selectivity for *Salmonella* Enteritidis. The results of a study performed by a third-party contract laboratory are shown here. The Neogen Reveal® *Salmonella* Enteritidis test incorrectly detected two additional group D1 organisms and failed to detect an *Salmonella* Enteritidis phage type. The SDIX® RapidChek® SELECT™ *Salmonella* Enteritidis test incorrectly detected all four non-SE group D1 organisms tested. This shows the potential for false positive and false negative results when using antibody-based detection to monitor *Salmonella* Enteritidis. Samples were assayed according to the manufacturers' instructions on pure cell cultures, tested at 1 log above limit of detection (LOD) of each respective test.

Strain	Serogroup	TaqMan® *Salmonella* Enteritidis	SDIX® RapidChek®	Neogen Reveal®
S. Enteritidis Phage Type 2	D1	+	+	+
S. Enteritidis Phage Type 24	D1	+	+	+
S. Enteritidis Phage Type 28	D1	+	+	+
S. Enteritidis Phage Type 8	D1	+	+	+
S. Enteritidis Phage Type 4	D1	+	+	+
S. Enteritidis Phage Type 11	D1	+	+	–
S. typhimurium	B	–	–	–
S. newport	C2	–	–	–
S. kentucky	C3	–	–	–
S. tennessee	C1	–	–	–
S. heidelberg	B	–	–	–
S. berta	D1	–	+	+
S. dublin	D1	–	+	+
S. javiana	D1	–	+	–
S. panama	D1	–	+	–

A complete workflow solution

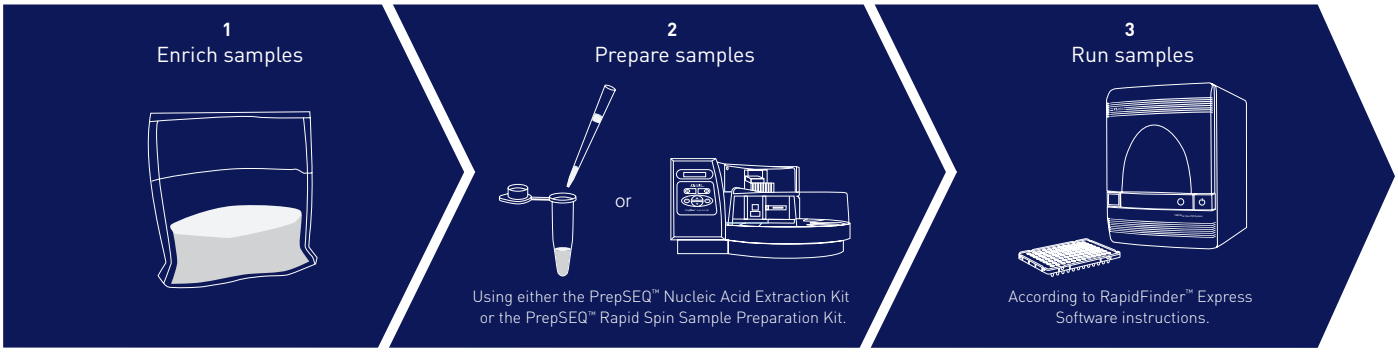

Figure 2. The TaqMan® *Salmonella* Enteritidis Detection Kit enables fast and accurate results for *Salmonella* Enteritidis detection in three simple steps.

MagMAX™ Express-96 magnetic bead processor and PrepSEQ® chemistry for completely automated DNA sample preparation from a single overnight enrichment of 1 L of pooled eggs or nonregulated organisms, including closely related species of *Salmonella* such as non–*Salmonella* Enteritidis group D1 *Salmonella*.

Simply prepare the instrument, add a small amount of the enriched sample, and press "Start" for completely automated DNA extraction and purification of up to 96 samples. All 96 samples can then be immediately transferred for PCR-based detection using the TaqMan® *Salmonella* Enteritidis Detection Kit (Figure 2).

A Life Technologies real-time PCR solution

With the TaqMan® *Salmonella* Enteritidis Detection Kit workflow, you get a complete sample-to-answer workflow solution for the rapid detection of *Salmonella* Enteritidis. The kit is part of the Food Pathogen Detection System, a complete product portfolio for the rapid detection of multiple food pathogens, including *Salmonella* spp., *Listeria* spp., *Listeria monocytogenes*, and *E. coli* O157:H7. Life Technologies is committed to your success by offering a full suite of instruments, reagents, and software designed for your needs, and also the most comprehensive technical service and support organization available.

Our global teams of dedicated in-house research scientists and engineers are committed to continued innovation, and strive to provide reliable systems and fast solutions for the food-testing industry.

For more information about the TaqMan® *Salmonella* Enteritidis Detection Kit and our other solutions for food pathogen testing, please contact your local Life Technologies sales representative or go to **lifetechnologies.com/foodsafety**.

Ordering information

Detection kit	Cat. No.
TaqMan® *Salmonella* Enteritidis Detection Kit	4457030
Sample preparation	
PrepSEQ® Nucleic Acid Extraction Kit	4428176
Instrumentation	
Food Pathogen Detection System Package: 7500 Fast Real-Time PCR System with PC Tower and RapidFinder™ Express Software	4445785
Food Pathogen Detection System Package: 7500 Fast Real-Time PCR System with Notebook Computer and RapidFinder™ Express Software	4445787
MagMAX™ Express-96 Deep Well Magnetic Particle Processor	4400079
Consumables	
MagMAX™ Express-96 Deep Well Tip Combs	4388487
MagMAX™ Express-96 Deep Well Plates	4388476
MagMAX™ Express-96 Standard Plates	4388475
MicroAmp® Fast Optical 96-well Reaction Plate (0.1 mL)	4346906
MicroAmp® Optical Adhesive Film, PCR compatible	4311971
MicroAmp® Clear Adhesive Film	4306311

For testing of Food and Environmental samples only.