FAST FACTS

TaqMan® *Salmonella* Enteritidis Detection Kit FAST FACTS

FDA-Approved for Eggs

applied biosystems by life technologies™

DESCRIPTION

The TaqMan® *Salmonella* Enteritidis Detection Kit is an FDA-approved real-time PCR assay designed to detect the presence of *Salmonella* Enteritidis from pre-enriched poultry egg samples. The kit contains reagents for 100 detection assays and is part of a complete workflow that uses the PrepSEQ® NA(E) kit and MagMAX™ Express(96) for automated DNA extraction and the 7500 Fast instrument for PCR detection.

Component	Volume (µL)
2x Environmental Master Mix 2.0, 2 tubes	750 each
10x *Salmonella* Enteritidis Target Assay Mix, 1 tube	300
Negative Control, 1 tube	1000

PATHOGEN

Salmonella Enteritidis

Salmonella enterica subsp. *enterica* serovar Enteritidis, or *Salmonella* Enteritidis (SE), is an important bacterial pathogen that has been linked to illness caused by consumption of infected eggs. A common organism in the digestive tract of poultry, SE can infect the reproductive tract of chickens and enter shell eggs before the shell is formed. Since the levels of SE are often low, highly sensitive and specific detection methods are required for robust and reliable detection of the pathogen.

REGULATION

FDA Final Rule for the Egg Industry

Effective July 9, 2010, the FDA Final Rule for the US egg industry requires all large-scale egg producers (approximately 80% of the US egg industry) to begin SE-testing programs in their facilities. If environmental monitoring tests yield a positive result for *Salmonella* Enteritidis, the producer will need to use an FDA-approved method to perform tests on 200 unique 1-liter egg pools from eggs produced in that area before these implicated eggs can be cleared for sale as fresh eggs.

TARGET AUDIENCE

Primary Audience

- Large-scale egg producers (facilities with more than 50,000 hens) that are required to test per the new FDA regulations
- Third-party labs that do external testing for producers (FDA labs, university labs, private contract labs like Siliker)

Secondary Audience

- Egg distributors looking to do internal QA/QC, but not required to do so by FDA
- Food manufacturers that use egg as raw ingredients and want an assay for raw ingredient QA/QC testing

QUALIFYING A LEAD

Situation Questions	1. Are you impacted by the new FDA regulation? How? 2. Do you test eggs if a positive environmental sample is found, or do you immediately divert all implicated eggs for homogenization and sell as non-fresh egg product? 3. If you test eggs, what method do you use (FDA BAM, lateral flow)? 4. How often do you encounter positive environmental SE samples (what is your environmental incidence rate for *Salmonella* Enteritidis? 5. What are your preferences for instruments? 6. What are your vendor preferences?
Problems Questions	1. How long does it take for you to release eggs to market?
Implication Questions	1. How much money do you lose per year waiting for SE test results?
Needs/Payoff Questions	1. If you could test 200 unique samples for SE in 27 hours, how much money could you save? If you used a test that detected down to the SE serotype, how much time would you save?

COMPARISON WITH OTHER METHODS

Brand	Product	Technology	Specificity	TTR	Ease of Use	Validation
Traditional FDA BAM method	MLS (traditional microbiology)	Traditional microbiology	High	10 days	Low (labor-intensive/multiple enrichments)	FDA for eggs
SDIX	RapidChek Select SE Lateral Flow	Lateral flow	Mid (only to group D)	2 days	Mid (multiple enrichments but easy detection)	FDA and AOAC for eggs, environment
Idaho Technologies	Lyophilized real-time assay in development	qPCR	Unknown	Est. 1-2 day	Est. to be High	None
Neogen	Reveal SE Test System	Lateral flow	Mid	6 days for eggs 2 days for environmental	Mid (multiple enrichments but easy detection)	FDA and AOAC for eggs, environment
Life Technologies	**TaqMan® SE Detection Kit**	**qPCR**	**High (SE-specific)**	**27 hours**	**High (1 enrichment, automated sample prep)**	**FDA for eggs**

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PRODUCT INFORMATION

Value Proposition for Egg Testing

The FDA-validated TaqMan® *Salmonella* Enteritidis Detection Kit workflow for *Salmonella* Enteritidis detection in eggs produces the fastest time-to-results available on the market, roughly 10 times faster than the current FDA BAM method (27 hours vs. 10 days to confirm presence of *Salmonella* Enteritidis serovar presence). Fast results allow producers to hold less inventory and to conform to the new FDA safety standards with minimal effects on their current supply chain and time-to-market.

Time-to-Results

Approximately 27 hours, including pre-enrichment and sample prep

- 24-hour pre-enrichment
- 1-hour automated sample prep
- 2-hour real-time PCR detection run

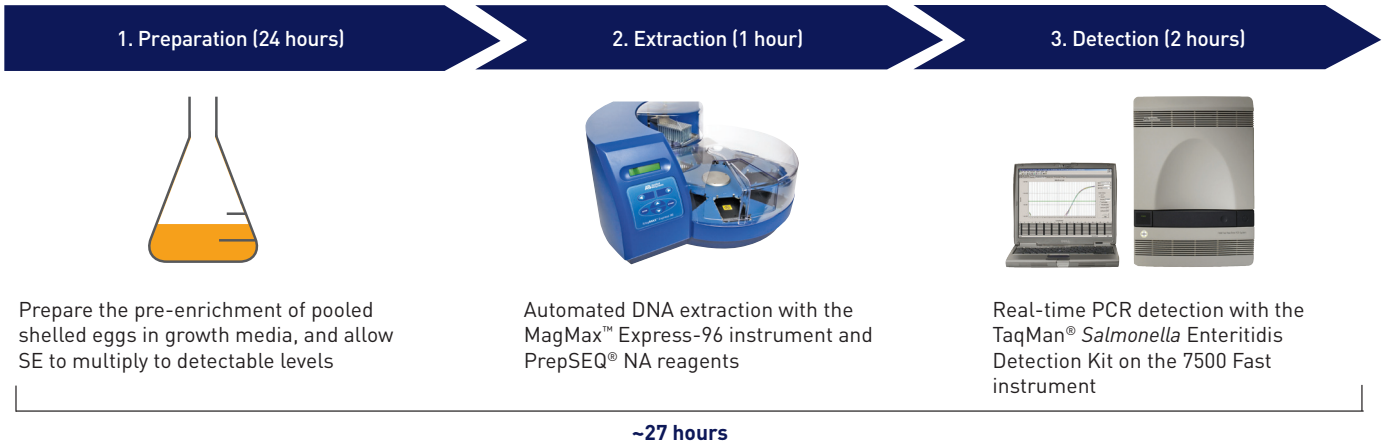
Specificity

Detects down to the SE serotype, while most competing methods only detect down to group D (still need to perform 3-day serotyping to confirm target is *Salmonella* Enteritidis).

ORDERING INFORMATION

Product Description	Size	Part Number
TaqMan® *Salmonella* Enteritidis Detection Kit	100 reactions	4457030
PrepSEQ® Nucleic Acid Extraction Kit	300 reactions	4428176
MagMAX™ Express-96 Magnetic Particle Processor	1 instrument	Contact your local Life Technologies Representative
7500 Fast Real-Time PCR Instrument	1 instrument	Contact your local Life Technologies Representative
Additional parts are listed in the TaqMan® *Salmonella* Enteritidis Detection Kit Protocol (PN 4402744)		

WORKFLOW



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Qualitative real-time PCR assay for the detection of ***Salmonella* Enteritidis from pre-enriched poultry egg samples. For Research Use Only. Caution: Not for use in human or animal therapeutic or diagnostic procedures.**

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