FAST FACTS

TaqMan® Salmonella Enteritidis Detection Kit FAST FACTS
FDA-Approved for Eggs

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.

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 Stiliker)

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

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

**Product Information**

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Size</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>TaqMan® <em>Salmonella</em> Enteritidis Detection Kit</td>
<td>100 reactions</td>
<td>4457030</td>
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<tr>
<td>PrepSEQ® Nucleic Acid Extraction Kit</td>
<td>300 reactions</td>
<td>4428176</td>
</tr>
<tr>
<td>MagMAX™ Express-96 Magnetic Particle Processor</td>
<td>1 instrument</td>
<td></td>
</tr>
<tr>
<td>7500 Fast Real-Time PCR Instrument</td>
<td>1 instrument</td>
<td></td>
</tr>
</tbody>
</table>

Additional parts are listed in the TaqMan® *Salmonella* Enteritidis Detection Kit Protocol (PN 4402744)

**Workflow**

1. Preparation (24 hours)

Prepare the pre-enrichment of pooled shelled eggs in growth media, and allow SE to multiply to detectable levels

2. Extraction (1 hour)

Automated DNA extraction with the MagMAX™ Express-96 instrument and PrepSEQ® NA reagents

3. Detection (2 hours)

Real-time PCR detection with the TaqMan® *Salmonella* Enteritidis Detection Kit on the 7500 Fast instrument

~27 hours

Life Technologies offers a breadth of products DNA | RNA | protein | cell culture | instruments

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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