



# DNABLE® Molecular Detection Kit for *Salmonella*

## Highlights:

- Molecular Detection of *Salmonella*
- Rapid amplification and detection in 15 minute assay

## Contents of DNABLE Kit:

- RB1 Reaction Buffer
- *Salmonella* Master Mix
- Flat caps

## Materials Not Provided:

- Sample Extraction Set\* (Part #11717 or 11718)
- *Salmonella* Supplement\* (Part #12035)
- Precision pipette capable of delivering 5 µL
- Precision multi-channel pipette capable of delivering 50 µL
- Pipette tips
- DNABLE Reader\*
- Laptop\*
- Optional: DNABLE *Salmonella* Positive Control\* (Part #11768)

\* available through EnviroLogix

Catalog No. DF 026

Part #11716

## Intended Use

This test kit is intended for the qualitative detection of *Salmonella* DNA as an indication of *Salmonella* presence. Samples should be enriched in 2% Modified Buffered Peptone Water (mBPW), using DNABLE *Salmonella* Media Supplement (Part #12035) and prepared for DNA amplification using the appropriate *Salmonella* Extraction Set (Part #11717 or #11718) before using this Detection Kit. This kit is certified as a *Performance Tested Method*<sup>SM</sup> #041404 by the AOAC Research Institute using DNABLE *Salmonella* Supplement (Part #12035), DNABLE *Salmonella* Sample Extraction Set 2 (Part #11718), and DNABLE T16 Reader (Part #10208) as part of the DNABLE *Salmonella* assay for use for dry pet food, stainless steel surfaces and poultry environmental drag swabs.

## Intended User

The DNABLE *Salmonella* assay is designed to be simple and user friendly. It is designed for use by personnel with appropriate training in handling human pathogens, and in Microbiology and Molecular Assay techniques. Training specific to the DNABLE *Salmonella* assay will be provided by EnviroLogix; contact Technical Service or visit [envirologix.com/salmonella](http://envirologix.com/salmonella) for more information.

## Test Principle

Three products are used to enable qualitative *Salmonella* DNA detection. DNABLE *Salmonella* Media Supplement (Part #11622) provides a selective agent and components that facilitate growth of stressed *Salmonella* organisms. DNABLE Sample Extraction Set (Part #11717 or 11718) includes reagents and protocols for sample preparation. The DNABLE Molecular Detection Kit for *Salmonella* contains lyophilized reagents for isothermal DNA amplification

and detection arrayed in 8 well strips. DNABLE is an isothermal technology enabling rapid amplification of a specific DNA target. Portions of cultured and prepared sample are added to a reaction buffer. This mixture is transferred to the lyophilized master mix, containing all the reagents needed to specifically recognize, amplify and detect a *Salmonella* specific DN sequence. The amplified *Salmonella*-specific DNA is detected in real-time and the results are displayed and interpreted within 15 minutes using the DNABLE Reader.

## Limit of Detection

DNABLE assay performance (culture, sample preparation and isothermal amplification) was compared to US FDA defined culture methods in matrix studies. The probability of DNABLE *Salmonella* detection for these samples was statistically equivalent to the reference methods indicating that the DNABLE *Salmonella* assay has a limit of detection comparable to culture.

## Precautions and Notes

DNABLE is a highly sensitive assay. Therefore the following precautions are recommended to reduce the chance of sample contamination:

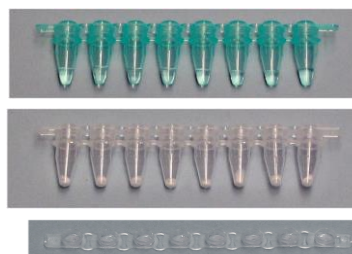
- Separated work areas are recommended for each of the following:
  - DNABLE culture
  - DNABLE sample preparation
  - DNABLE amplification and detection



- **Important:** Never open reaction tubes after reaction has occurred, as this will release amplified material into the environment and may contaminate subsequent reactions.
- Clean the work station and pipettes with 10% bleach before and after use.
- Do not reuse kit disposables
- Change pipette tips in between samples
- Wear gloves and change between handling of samples
- Avoid delays between sample preparation steps and between sample preparation and DNA amplification.
- The kit may be stored refrigerated at 4-8°C up to 6 months past the manufacture date. See expiration date on kit box label.
- **Controls:** *Salmonella* Amplification Positive Control is available as an accessory, Part #11768, to enable user verification of performance. Instructions on the use of this positive control, and optional use of DNable extraction buffer as a negative control, are included with this accessory kit.
- Results may be confirmed using procedures defined in the US FDA the Bacteriological Analytical manual, BAM, (<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>).
- **Safety:** *Salmonella* is pathogenic and is classified as a Biosafety Level 2 organism. Personnel should be appropriately trained and should use personal protective equipment. Laboratories should follow appropriate local safety and environmental regulations and guidelines for containment and disposal as described in the Center for Disease Control and Prevention Manual, "Biosafety in Microbiological and Biomedical Laboratories" (<http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf>).

## Kit Components

- A. RB1 Reaction Buffer: Provided in green 8-well strip tubes (6 per kit)
- B. Salmonella Master Mix: Lyophilized reagents provided in clear 8-well strip tubes (6 per kit)
- C. Flat Caps: used for capping the clear tubes prior to assay start (6 per kit)



## How to Run the DNable Amplification Assay

**Note:** Before beginning assay, extract sample(s) according to sample preparation instructions included with each Sample Extraction Set.

### Before Testing

1. Remove needed DNable Detection Kit reagents from refrigerated (4-8°C) storage. Allow reagents to come to room temperature (22-26°C) before opening sealed white pouch.
2. Important: Remove green RB1 Reaction Buffer tubes (A) from bag and tap down to ensure that the liquid is at the bottom of the tube.
3. Add 5 µL of extracted sample to RB1 Reaction Buffer (Green Tube). Recap with green strip caps and gently flick tubes to mix sample with buffer.
4. Start up and prepare DNable Reader for testing including test code, User Name, Lot ID, etc. prior to initiating work flow.
5. Assure all assay reagents, multichannel pipette and tips, and flat caps are ready for use. Set up Master Mix strip tube and green Reaction Buffer strip tube so that pipet transfer step occurs from front to back (not side to side or back to front). This will help avoid cross-contamination of samples.

**Important:** Gently tap down the Master Mix tubes to ensure that the white lyophilized pellet is at the bottom of the tubes.

**Important:** Label tube for orientation at the top of the tube (writing on the bottom half of the tube will interfere with results interpretation).

6. Prepare DNable Reader:

DNable T16 Reader	AmpliFire Reader
<ul style="list-style-type: none"> <li>• Turn on the DNable Reader in remote mode and connect to the computer (see Reader Instructions).</li> </ul>	<ul style="list-style-type: none"> <li>• Turn the instrument "ON" using a switch on the right panel of the instrument.</li> </ul>

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|---|---|
| <ul style="list-style-type: none"> <li>To prepare the machine, Press "Run" and select "Program 1" from the drop down menu.</li> <li>Correctly label the User Name, Lot ID (DNAbLe Kit Lot), and Sample ID fields in the software prior to starting the assay workflow.</li> </ul> | <ul style="list-style-type: none"> <li>On the AmpliFire screen, select "Execute Reaction" then "Scan Product Code". Use QR code provided on the master mix foil pouch to scan the Salmonella protocol on the AmpliFire Reader. "Salmonella_(lot#)" will display. Select "Next".</li> <li>Under "Reaction Name" enter the run information. Select "Next" and then "Finish" to skip well-specific sample entry if desired.</li> </ul> |
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**DNAbLe assay protocol:**

- Using a multichannel pipette transfer **50 µL** from **green Reaction Buffer Tubes** (5 µL of Extracted Sample + Reaction Buffer) to the **clear Master Mix Tubes**.
- Re-cap with "Flat Caps" provided. (Quickly repeat Steps 7 and 8 for a second 8-well strip if 16 tests will be performed). Mark one side of flat cap with marker for orientation – do not label sides of tubes.

**Important:** Ensure that tubes are completely sealed with flat caps

OK OK NO NO NO OK

**Important:** Ensure that any bubbles that may exist in the bottom of the tubes are removed by gently tapping or flicking the tubes.



- Read the results

**DNAbLe T16 Reader**

- Quickly place the **clear resuspended Master Mix** strip tubes into the DNAbLe Reader. Close lid of DNAbLe Reader and immediately click "Start" on software.

**Important:** It is critical to perform this step as soon as possible after placing the re-suspended Master Mix tubes in the instrument.

- After 15 minute assay time, the software will display results as negative (-), positive (+), or invalid (?).

**Important:** Results will be interpreted only after the assay is complete. Typically there is a short delay between completion of the assay and display of results. Do not initiate a new assay until results are displayed. An invalid result is generated if the well is empty, if the sample has excessively high background signal (often indicative of incorrect sample processing), or if the internal control curve varied from expected (can be an indication of amplification inhibition or delay in starting the amplification reaction). Users are advised to repeat the analyses starting with sample transfer to RB1 buffer through amplification and detection. Contact EnviroLogix Technical Customer Support for further questions.



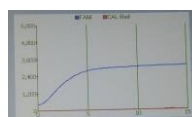
- Gently remove the completed reaction tubes from the DNAbLe Reader and place back in original

**AmpliFire Reader**

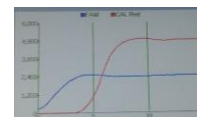
- When the instrument is ready push "Start". Place resuspended, capped clear strip tube into the AmpliFire Reader and press "Ok".
- After 15 minutes, the AmpliFire Reader will produce a short beeping sound and display final results. Results will be interpreted as Not Detected (-), Positive (+), or Invalid (!).

Note: Positive results may be interpreted prior to assay completion, but the full assay time must be complete for interpretation of negative results. An invalid result is generated if the well is empty, if the sample has excessively high background signal (often indicative of incorrect sample processing), or if the internal control curve varied from expected (can be an indication of amplification inhibition or delay in starting the amplification reaction). Users are advised to repeat the analyses starting with sample transfer to RB1 buffer through amplification and detection. Contact EnviroLogix Technical Customer Support for further questions.

- Following are the examples of the amplification curves pertaining to the valid negative and valid positive on AmpliFire Reader.



Valid Negative



Valid Positive

<p>zippered pouch prior to disposal. <b>Do not open tubes.</b></p> <ul style="list-style-type: none"> <li>The assay data file (.json) may be saved with a user-defined name using the "Save As" function. A results summary including the sample ID and amplification graphs is also available using the Print function.</li> </ul>	<ul style="list-style-type: none"> <li>After completion of the assay, carefully <b>remove run reaction strip tubes from instrument and place in opened foil pouch</b> (used to store master mix), seal and discard in waste container.</li> </ul>
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