IFU

Instructions for Use

POULTRY SAMPLING DEVICES

Cat. no. EB50	EnviroBootie™, Whirl-Pak® Bag Containing Two Fabric Booties, Pre-moistened with Skim Milk, 2X (Double Strength Skim Milk) Broth	2 units/bag, 50 bags per box
Cat. no. EB100	EnviroBootie™, Whirl-Pak® Bag Containing One Fabric Bootie, Pre-moistened with Skim Milk, 2X (Double Strength Skim Milk) Broth	1 unit/bag, 100 bags per box
Cat. no. C14019WA	Plastic Boot Cover for Cross Contamination Control*	50 covers/box
* Item sold separately.		

INTENDED USE

Hardy Diagnostics EnviroBootie™ with Skim Milk, 2X Poultry Sampling Devices are designed for environmental sampling of poultry floor litter for pathogenic microorganisms, including *Salmonella* spp.

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

Egg-associated salmonellosis is an important world-wide public health concern, and monitoring *Salmonella* contamination at the farm level is an important step in resolving this issue.[2-4,7,10,11] The bacterium, *Salmonella enterica* serovar Enteritidis (SE), can infect the ovaries of healthy hens and contaminate their eggs before the calcified shell has formed.[3,8,10] SE can grow undetected inside perfectly normal-appearing eggs, and result in illness when raw or undercooked eggs, or associated egg products, are consumed.

To reduce the risk of *Salmonella* contamination in livestock shelters, many government agencies and members of the egg industry have taken steps to reduce the potential for SE outbreaks.[2,6,7] Traditional testing methods used to identify all *Salmonella* serotypes in environmental samples have been used to detect SE as a result of contamination in hen houses and holding facilities.[1,5,8-11] Farm-based environmental monitoring for SE has been incorporated as part of the egg safety program, created to reduce the risk of SE laying hens; thereby, reducing the number of SE contaminated eggs that reach the consumer. Environmental testing is also used in facilities that have been implicated in USDA tracebacks from food-borne SE outbreaks in an effort to control the spread of this bacterium.[2,7,8]

Hardy Diagnostics EnviroBootie™ devices consist of one or two irradiated fabric booties, pre-moistened with Skim Milk, 2X (Double Strength Skim Milk) Broth packaged in a Whirl-Pak ® bag. They are designed to be used with a Plastic Boot Cover (Cat. no. C14019WA) to prevent cross-contamination; the Boot Cover consists of a single use, over-the-shoe disposable boot cover with a handy tie closure. The Plastic Boot Cover is worn under an EnviroBootie™ to prevent cross-contamination. In addition, Skim Milk, 2X Broth has been shown to exhibit good maintenance of a wide range of bacterial species obtained from environmental samples, without loss or over representation of *Salmonella* populations.[1,5,7-11] The unique design of EnviroBootie™ allows for highly efficient collection, secure transport, and pre-enrichment of samples in a single container.

FORMULA

Ingredients per liter of deionized water:*

Skim Milk Powder	200.0gm

Final pH 6.3 +/- 0.3 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC away from direct light. These product should not be used if there is any sign of deterioration, discoloration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

All samples should be obtained under aseptic conditions or best practices to prevent excessive contamination or cross-contamination.[8,9,10] Best practices should include the use of sterile sampling materials and disposable gloves. If there is any uncertainty as to the proper sampling procedures or materials, contact your local testing laboratory before sampling.

Samples should be transported directly to the laboratory immediately after collection. If it is anticipated that collection and transport time to the laboratory will be greater than six hours, use a cooler with ice packs or refrigerate the samples prior to shipment.[7] DO NOT FREEZE.

All samples must be properly labeled for identification and placed into an insulated transport container with ice packs to keep contents cool during shipping. Shipments should also include the appropriate collection reports for proper laboratory analysis and identification.

Types of Collecting Samples

Fresh samples should be collected randomly and at intermittent time periods within the livestock facility, using a sampling plan specific to the monitoring program. Environmental samples from nest boxes, bulked litter, bulked dust, residual feed, walkways, rows/banks or anywhere manure may accumulate, etc. can be used in conjunction with the Poultry Sampling Device line, in order to gather a composite number of sample sites representative of the facility and its holdings.[8-11] If possible, samples should be collected from beneath drinkers or other moist areas within the facility.

On-Farm Sampling

1. Wash hands prior to using one of the EnviroBootie™ Poultry Sampling Devices and wear gloves to protect hands from conditions encountered during sampling and to protect from cross-contamination. Immediately proceed to start of sampling area to facilitate specimen collection.

2. Immediately before sampling, slip a disposable Plastic Boot Cover (Cat. no. C14019WA) over each shoe or boot used with an EnviroBootie™ to protect personal clothing and to prevent against cross-contamination of the sample from shoe sole carryover.

3. Disinfect the outside of the Whirl-Pak® bag using 70% ethanol or use a pre-moistened alcohol wipe.

4. Remove the pre-moistened EnviroBootie™ from the Whirl-Pak ® bag and place it securely over the plastic boot cover outlined in step 2. Reseal the bag immediately after removing the bootie to prevent contamination from airborne debris or insects

5. Walk the entire length of one side of the row/bank in the livestock facility covering an area of 12 to 15 meters or 40 to 50 feet in length.[11] If sampling multiple rows/banks, use fresh gloves, a fresh EnviroBootie™ device and a fresh Plastic Boot Cover for each row/bank. Follow disinfection procedures outlined in step 3. Repeat testing is recommended for sample areas (e.g. row/bank or equipment surface).[11]

6. Immediately after collection, carefully remove the EnviroBootie™ and return it to its original container. Use appropriate measures to ensure there is a good seal on the Whirl-Pak ® bag and wipe down the outside to remove any residual debris.

7. Submit samples to the laboratory promptly for analysis.

Laboratory Analysis

8. Upon laboratory receipt, samples should be checked for completeness of information and condition of the sample. If samples cannot be processed immediately upon receipt, store samples refrigerated at 2-8ºC (35.6 - 46.4ºF).

9. Disinfect the outside of the Whirl-Pak® bag using 70% ethanol or use a pre-moistened alcohol wipe prior to opening. Aseptically add 100ml of a pre-enrichment media, such as Buffered Peptone Water (Cat. no. U143) or Tetrathionate Broth (Cat. no. U165), to the container and shake or mix the contents vigorously. Make sure the seal is completely closed on the Whirl-Pak ® bag and massage the sample with the enrichment broth to mix thoroughly.

10. Make sure there is ample residual air remaining in the sealed Whirl-Pak ® bag to permit the growth of aerobic microorganisms and incubate the sample for 24 +/- 2 hours at 35ºC.

11. Following pre-enrichment, consult listed references for information on subculturing to an appropriate selective media and for further biochemical and molecular testing procedures.[2,7,8,10]

INTERPRETATION OF RESULTS

Consult listed references for specific information on the interpretation of specimens and for the appropriate biochemical and molecular testing procedures for complete identification.[2,4,5,7,8,10]

LIMITATIONS

EnviroBootie™ should not be used if there is any evidence of leakage, if the seal is compromised on the Whirl-Pak ® bag, if the bootie has dried out, or if contamination is present before use.

The product will work best if sampling is restricted to a single row/bank of the livestock facility; the product is not intended to be worn for an extended time period or to sample multiple rows/banks. Overburdening sampling devices with a large sampling area or excessive debris will diminish absorbency and result in a reduction in product performance. Repeat testing is recommended for improved recovery.[11]

Skim Milk broth is recommended for storage and maintenance of bacteria and should always be used with enrichment procedures and subsequent plating to selective media.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, Buffered Peptone Water (Cat. no. U143), Tetrathionate Broth (Cat. no. U165), other culture media, Plastic Boot Covers (Cat. no. C14019WA), incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

USER QUALITY CONTROL

The Poultry Sampling Devices are tested for sterility only.

PHYSICAL APPEARANCE

Contents of the EnviroBootie™ should appear light tan in color. Skim Milk, 2X should appear straw to light yellow in color.

REFERENCES

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4. Hong, Y., M.E. Berrang, T. Liu, C.L. Hofacre, S. Sanchez, L. Wang and J.L. Maurer. 2003. Rapid detection of *Campylobacter coli*, *C. jejuni*, and *Salmonella enterica* on poultry carcasses by using PCR-Enzyme-Linked Immunosorbant Assay. *Appl. and Environ. Micro* . Vol. 69, No. 6.

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6. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*. APHA, Washington, D.C.

7. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

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11. U.S. Food and Drug Administration. Food Science and Research Laboratory Methods. US FDA. Silver Springs, MD. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070149.htm.

Whirl-Pak is a registered trademark of Nasco Industries, Inc.

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

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