IFU

Instructions for Use

COMPACT DRY™ SL

Cat. no. 54085	Compact Dry™ SL, 60x75mm Tray with 10x60mm Well	240 trays/box

INTENDED USE

Hardy Diagnostics Compact Dry™ SL is a ready-to-use test method recommended for the isolation and differentiation of *Salmonella* in raw materials, finished products, or on environmental surfaces pertaining to food and related industries.

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

SUMMARY

Salmonella was discovered in 1895 by Theobald Smith, laboratory assistant for Dr. Daniel Elmer Salmon, after whom the genus is named. The bacterium, *Salmonella enterica* var. Choleraesuis, was identified as the causative agent of hog cholera, though this identification later proved false. However, continued research with this bacterium showed that *Salmonella* is an important agent of foodbourne disease. Today,*Salmonella* is estimated to cause more than 1.2 million illnesses each year in the United States alone. Of these, 23,000 cases result in hospitalization and 450 result in death. *Salmonella* is transmitted via a fecal-oral route, which is most often acquired through consumption of contaminated foods. Thus, it is of great importance that food manufacturers screen for and detect any food contaminated with the bacterium.

Compact Dry™ SL is a ready-to-use chromogenic medium for performing isolation and differentiation of *Salmonella* that contains dehydrated culture media and a cold water-soluble gelling agent in a non-woven cloth matrix. The medium is instantly hydrated when inoculated with a sample, and capillary action diffuses the sample evenly over the matrix to form a gel within seconds. Compact Dry™ SL contains a chromogenic substrate that causes *Salmonella* colonies to turn green when utilized.

Compact Dry™ SL comes in ready-to-use trays that save space and greatly reduce the time needed to perform microbiological testing. Compared to other commonly used culture systems, Compact Dry™ has a longer shelf life, can be stored at room temperature, does not require manual sample spreading, is rigid, stackable and easy to label, and allows for direct colony picking for further subculture.

FORMULA

Compact Dry™ SL contains dehydrated culture media, a gelling agent, and a chromogenic substrates to assist in detecting and differentiating *Salmonella* bacteria.

Final pH 7.0 +/- 0.2 at 25°C.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 1-30ºC. away from direct light. Media should not be used if there are any signs of

deterioration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing. If foil pouch is opened and not all plates are used, return remaining plates to pouch and reseal until next use. Opened packages should be used as soon as possible.

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 quality control 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

Prior to Use: Refer to listed references for appropriate methods of collection, preparation, and dilution of samples under investigation. [*1-5*]

For environmental samples or to test uneven surfaces of equipment, swab surface of test area with EnviroTrans™ (e.g. Cat. no. SRK05 or SRK35).

For raw material and food testing, prepare and dilute samples using an appropriate diluent such as Dilu-Lok™ II (e.g. Cat. no. D590 or D599).

General Dilution Guidelines:

For Making 1:10 Serial Dilutions

1. Using a sterile pipet or scoop, aliquot 10ml or 10gm of test sample to a 90ml pre-filled Dilu-Lok II™ dilution vial to yield a 1:10 dilution. Mix thoroughly.

2. From the 1:10 dilution vial in step 1, use a fresh sterile pipet and aliquot 10ml from this dilution vial into a second 90ml pre-filled Dilu-Lok II™ vial to yield a 1:100 dilution. Mix thoroughly.

3. Continue aliquoting 10ml dilutions into 90ml pre-filled Dilu-Lok II™ vials until the desired concentration of test sample is achieved. Each subsequent dilution increases by a factor of 10. A separate sterile pipet should be used with each dilution. Each subsequent dilution increases by a factor of 10. A separate sterile pipet should be used with each dilution.

For Making 1:100 Serial Dilutions

1. Using a sterile pipet or scoop, aliquot 1ml or 1gm of test sample to a 99ml pre-filled Dilu-Lok II™ dilution vial to

yield a 1:100 dilution. Mix thoroughly.

2. From the 1:100 dilution vial in step 1, use a fresh sterile pipet and aliquot 1ml from this dilution vial into a second 99ml pre-filled Dilu-Lok II™ vial to yield a 1:10,000 dilution. Mix thoroughly.

3. Continue aliquoting 1ml dilutions into 99ml pre-filled Dilu-Lok II™ vials until the desired concentration is achieved. Each subsequent dilution increases by a factor of 100. A separate sterile pipet should be used with each dilution.

Method of Use Direct Inoculation:

1. Enrich sample in a 1:9 ratio in Buffered Peptone Water (Cat.no. D080) for 20-24 hours at 35-37 degrees C.

2. Remove the set of four trays from the foil pouch and separate each individual tray by gently bending along the connecting edge until each tray snaps free. Alternatively, if setting up a dilution series of the same sample, trays can be left connected to facilitate reading similar samples. Trays that are not used immediately should be resealed in the foil pouch. Refer to the "Storage and Shelf Life" section for proper storage of unused trays.

3. Remove the lid of the tray using two fingers to hold down one end of the lid and the thumb to lift the opposite end. Lids are easier to remove using a "peel back" method as opposed to a "pull off" method.

4. Inoculate by pipetting 0.1 ml of sample onto the dry sheet about 1 cm from the edge of the tray, being careful not to touch the surface of the matrix with the pipet tip. The dispensed sample will remain at the point of inoculation and will not spread across the whole plate.

5. After inoculation of the enriched culture, pipet 1 ml of sterilized water at the opposite side of the plate from where the specimen was dropped. Once dispensed, the sterile water will automatically diffuse across the surface by capillary action to form a gel; manual spreading of the inoculum is discouraged.

6. Replace the lid and label the tray with appropriate information, including the sample dilution factor.

7. Invert the tray and incubate, upside down with the medium on top, at 41-43°C for 20-24 hours. NOTE: Use the appropriate temperature/time designation according to the legal specification of the prescribed food analysis regulation.

8. Colonies can be counted when illuminated from the backside of the tray to calculate CFU/ml using the Scan® 100 colony counter (Cat. no. 435000) or comparable back lighting. If the colony count is high, use the 1cm x 1cm molded grid on the back of the tray to assist in colony counting. Use a sheet of white paper with gridded lines to diffuse the light if the molded grids in the tray are difficult to visualize with a light box.

Method of Use Membrane Filtration:

1. Remove the lid on a Compact Dry™ plate and pipette 1.0ml of sterile purified water into the middle of the plate to activate the matrix just before use.

2. Using a membrane filtration set-up, filter 100-250ml of a water sample under reduced pressure through a sterile 0.45µm membrane filter.

3. Keep the set-up running and rinse the inside of the filter funnel using 20-30ml of sterile purified water. Repeat this step two to three times to ensure all of the sample has been filtered through the membrane.

4. Remove the membrane from the funnel using sterile forceps (e.g. Cat. no. 800000) and apply it filter side up (trap side away from the matrix) to the surface of the pre-moistened Compact Dry™ plate. Gently press the membrane onto the surface, making sure to remove bubbles so the membrane is completely flush and centered on the matrix.

5. Replace the lid and incubate the tray right-side-up using the information outlined above.

6. Count colonies and record results as outlined above.

INTERPRETATION OF RESULTS

After incubation, read colonies against a white or illuminated background such as with the Scan® 100 colony counter (Cat. no. 435000) or comparable back lighting.

Green or blue-green colonies with or without black centers and on a yellow background are indicative of *Salmonella*.

Bacteria other than*Salmonella* may grow and produce a yellow background at the site of inoculation, such as *Pseudomonas*spp., but will not produce green colonies.

LIMITATIONS

Counting colonies on this medium may be difficult to perform with automated instruments.

Shigella sonnei is known to produce a positive reaction on these plates.

During inoculation, do not touch the surface of the medium and be careful to avoid any contamination by airborne microorganisms.

During incubation, keep cap tight on plates to avoid any possible dehydration.

A dilution may be needed when the sample has a dark color.

When the sample is viscous (thick), pipetting the sample on several points on a plate or an additional dilution may be needed for an even suspension.

When the sample contains an enzyme, it may react with the enzyme substrate in the dry sheet and affect the color.

If the nature of sample does affect the reaction of the medium, inoculate only after the factor is eliminated by means of dilution and other techniques. (e.g. samples with high viscosity, colored, reactive with chromogenic substrate, and with a high or low pH).

It is recommended to use a stomacher and filter homogenized sample afterwards to eliminate carry over of tiny particles of foodstuff onto the surface of the medium.

Counting colonies may be difficult against a dark background. For best results, count colonies with the tray held against a white or illuminated background such as with the Scan® 100 colony counter (Cat. no. 435000).

If using a light box, the molded grid lines or colonies may be difficult to view due to excessive brightness. Diffuse the light using a sheet of white, gridded (1cm x 1cm) paper underneath the tray to facilitate colony counting.

Colonies are not distinguishable on trays if concentrations are above 100 CFU/ml, as high colony counts will result in the whole surface becoming colored. The sample should be diluted to a concentration of less than 100 CFU/ml for best use.

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 such as EnviroTrans™, applicator sticks, scoops, dilution buffers such as Dilu-Lok™ II, other culture media, Scan® 100 colony counter (Cat. no. 435000), incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

End users can anticipate the following typical performance characteristics when testing with CompactDry™.

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Salmonella enterica var. Typhimurium ATCC® 14028	J	24hr	41-43°C	Aerobic	Growth; yellow agar with green colonies
Salmonella enterica var. Enteritidis ATCC® 13076	J	24hr	41-43°C	Aerobic	Growth; yellow agar with green colonies
Escherichia coli ATCC® 6633	J	24hr	41-43°C	Aerobic	Inhibited
Staphylococcus aureus ATCC® 6538	J	24hr	41-43°C	Aerobic	Inhibited

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

Check for signs of contamination and deterioration. Users of commercially prepared culture media may be required to perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction (where applicable). See the following reference for more specific information. (1-5)

PHYSICAL APPEARANCE

Compact Dry™ SL should appear dry, free of particles, and blue-purple in color.

Salmonella enterica subsp. *enterica* serovar Typhimurium (ATCC® 14028) on Compact Dry SL, grown under aerobic conditions at 42°C for 24 hours.

REFERENCES

1. Association of Official Analytical Communities. *Official Methods of Analysis*. AOAC, Washington, D.C.

2. American Public Health Association. *Standard Methods for the Examination of Dairy Products.* APHA, Washington, D.C.

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

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

5. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater* APHA, Washington, D.C.

6. Ellis, P., G. Kirchhof, and R. Meldrum. 2003. Evaluation of the Compact Dry SL method for the detection of Salmonella in spiked food samples. *Poster presentation at HPA 1st Scientific Conference,* University of Warwick.

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

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