REF NGDS-ASY-0016

FilmArray®
Food & Water Panel v1.0
Instructions for Use

The Symbols Glossary is provided on page 30 of this booklet.

Not For Diagnostic Use

BIOFIRE DEFENSE

Manufactured by
BioFire Defense, LLC
79 West 4500 South, Suite 14
Salt Lake City, UT 84107 USA

Customer and Technical Support

Reach Us on the Web

http://www.BioFireDefense.com

Reach Us by Phone

8 a.m. to 5 p.m. - MST

1-801-262-3592 - US and Canada
IDD Prefix-1-801-262-3592 - Intl

Reach Us by E-mail

support@biofiredefense.com

Reach Us by Fax

1-801-447-6907 - US and Canada
IDD Prefix-1-801-447-6907 - Intl

BioFire Defense, LLC

79 West 4500 South, Suite 14
Salt Lake City, UT 84107 USA

FilmArray® Food & Water Panel Instructions for Use Booklet NGDS-PRT-0052-03, January 2025
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INTENDED USE

The FilmArray® Food & Water Panel is a qualitative multiplexed nucleic acid-based test intended for use in the screening of food and beverage samples on the FilmArray platform. Results from the FilmArray Food & Water Panel are meant to be used in conjunction with other laboratory data and are not intended to be used for diagnosis, treatment, or other patient management decisions. Positive results do not rule out the presence of organisms not included in the FilmArray Food & Water Panel. In addition, 'Not Detected' results do not preclude the presence of low levels of FilmArray Food & Water Panel analytes or any other interfering substances.

The following bacteria (including several diarrheagenic *E. coli*/*Shigella* pathotypes), parasites, and viruses are identified using the FilmArray Food & Water Panel:

- *Campylobacter* (*C. jejuni* / *C. coli* / *C. upsaliensis*)
- *Salmonella* spp.
- *Vibrio* (*V. parahaemolyticus* / *V. vulnificus* / *V. cholerae*), including specific identification of *Vibrio cholerae*
- *Yersinia enterocolitica*
- Enteroaggregative *Escherichia coli* (EAEC)
- Enteropathogenic *Escherichia coli* (EPEC)
- Enterotoxigenic *Escherichia coli* (ETEC) *lt/st*
- Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1/stx2* (including specific identification of the *E. coli* O157 serogroup within STEC)
- *Shigella* / Enteroinvasive *Escherichia coli* (EIEC)
- *Cryptosporidium parvum*
- *Cyclospora cayetanensis*
- *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*)
- Norovirus GI/GII

The FilmArray Food & Water Panel is not for diagnostic use.

Table 1. Target Organisms and Sample Types (Validated)

Target Organism		Sample Matrix										
		Tap Water	Chicken	Beef	Bagged Spinach	Sliced Ham	Weiner	Smoked Salmon Spread	Bagged Shredded Cheddar	Orange Juice - pulp free	Apple Juice	Oatmeal
Campylobacter	*jejuni*	X	X								X	
	jejuni subsp *doylei*	X	X								X	
	coli	X	X								X	
	upsaliensis	X	X								X	
Salmonella	*bongori*	X	X	X	X	X	X	X	X	X	X	X
	enterica ssp *enterica* serovar Typhimurium	X	X	X	X	X	X	X	X	X	X	X
Vibrio	*parahaemolyticus*	X						X				
	fluvalis	X						X				
	vulnificus	X						X				
	cholerae	X			X			X				
Yersinia	*Yersinia enterocolitica* O:3	X					X			X		
E. coli	Enteroaggregative (EAEC)	X										
	Enteropathogenic (EPEC)	X										
	Enterotoxigenic (lt/st) (ETEC)	X					X					
	Shiga-like toxin	X			X					X		
	Shiga-like toxin (O157)	X		X							X	
	Shigella/Enteroinvasive (EIEC)	X						X			X	
Norovirus	GI	X			X					X		
	GII	X			X					X		
Cyclospora	*cayetanensis*	X			X							
Cryptosporidum	*parvum*	X			X							
Giardia	*lamblia*	X			X							

SUMMARY AND EXPLANATION OF THE TEST

Despite advances in food safety, sanitation, and medical treatment, infectious gastroenteritis remains a significant problem in industrialized countries among all age groups. In the United States, around 76 million cases of foodborne disease, resulting in 325,000 hospitalizations and 5,000 deaths, are estimated to occur each year [1–3]. Potential food pathogens require a system of rapid detection and identification so an appropriate response to potential or confirmed acts of bioterrorism and spoilage may be initiated. Spoilage or deliberate contamination of food and drink items can cause widespread illness and impediment of operations. Rapidly identifying these pathogens from food samples is important in enacting an effective response to an act of bioterrorism or contamination with these agents.

Results from the FilmArray Food & Water Panel test are available within about one hour.

Table 2. Bacteria, Virus, Diarrheagenic *E. coli*/*Shigella*, and Parasites Detected by the FilmArray Food & Water Panel

Bacteria	**Viruses**
Campylobacter (*C. jejuni / C. coli / C. upsaliensis*) *Salmonella* spp. *Vibrio (V. parahaemolyticus / V. vulnificus / V. cholerae)* *V. cholerae* *Yersinia enterocolitica*	Norovirus GI/GII
Diarrheagenic *E. coli* / *Shigella*	**Parasites**
Enteroaggregative E. coli (EAEC) Enteropathogenic *E. coli* (EPEC) Enterotoxigenic *E. coli* (ETEC) *lt/st* Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2* *E. coli* O157 *Shigella* / Enteroinvasive *E. coli* (EIEC)	*Cryptosporidium parvum* *Cyclospora cayetanensis* *Giardia lamblia*

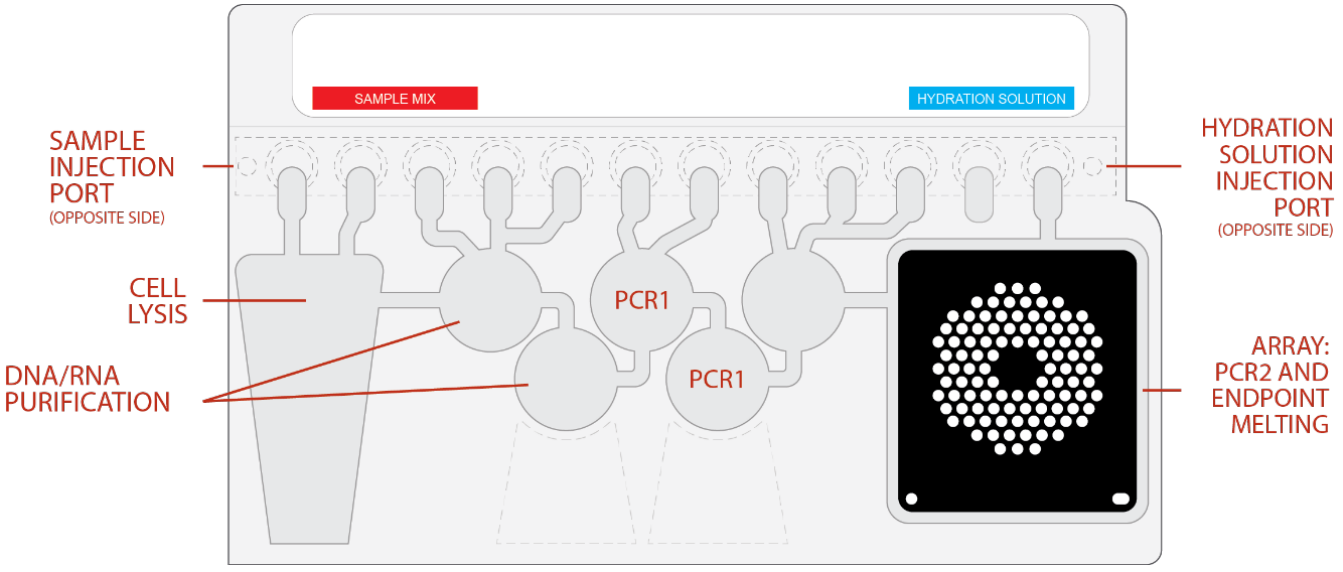
PRINCIPLE OF THE PROCEDURE

The FilmArray Food & Water pouch is a closed-system disposable that stores all the necessary reagents for sample preparation, reverse transcription, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple organisms and toxin-encoding genes within a single sample. A wide variety of environmental samples can be tested by the Food & Water Panel. After sample collection and preparation (refer to **Prepare Sample Mix** section), the operator injects hydration solution and sample combined with sample buffer into the pouch, places the pouch into a BIOFIRE® FILMARRAY® 2.0 instrument, and starts a run.

The entire run process takes about one hour. Additional detail can be found in the appropriate BIOFIRE® FILMARRAY® 2.0 Operator's Manual.

During a run, the FilmArray system:

- Lyses the sample by agitation (bead beating).
- Extracts and purifies all nucleic acids from the sample using magnetic bead technology.
- Performs nested multiplex PCR by:
  - First performing reverse transcription and a single, large volume, massively-multiplexed reaction (PCR1).
  - Then performing multiple, singleplex second-stage PCR reactions (PCR2) to amplify sequences within the PCR1 products.
- Uses endpoint melting curve data to detect and generate a result for each target on the FilmArray Food & Water array.



MATERIALS PROVIDED

Each kit contains sufficient reagents to test 30 samples. The different sample preparation accessories are sold separately. Refer to **Table 3** for the contents of the FilmArray Food & Water kit.

Table 3. Description of Materials

Kit Part Number	Description of Items in Kits	Quantity
NGDS-ASY-0016	Individually-packaged FilmArray Food & Water Panel Pouches	30
	Single-use (1.0mL) Sample Buffer Tubes	32
	Single-use pre-filled (1.5mL) Hydration Injection Vials (blue)	32
	Single-use Sample Injection Vials (red)	32
	Individually-packaged Transfer Pipettes	32
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MATERIALS NOT PROVIDED

Required

- FilmArray system including:
  - BIOFIRE® FILMARRAY® 2.0 instrument, computer, and software
  - BIOFIRE® FILMARRAY® Pouch Loading Station
- 10% bleach solution or a similar disinfectant

Optional

- Storage vessel for sample

WARNINGS AND PRECAUTIONS

General Precautions

1. This product is not for diagnostic use.
2. FilmArray Food & Water Panel pouches are only for use with BIOFIRE FILMARRAY 2.0 system.
3. Always check the expiration date on the pouch. Do not use a pouch after its expiration date.
4. FilmArray pouches are stored under vacuum in individually-wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, be sure that a FilmArray instrument/module will be available and operational before unwrapping any pouches for loading.
5. The performance of the Food & Water Panel has not been evaluated for all organisms and sample type combinations as described in the Intended Use section (refer to **Table 1**).
6. Bleach introduced in a sample may damage nucleic acids in the sample, which may lead to a false negative result.

Safety Precautions

1. Wear appropriate Personal Protective Equipment (PPE), including (but not limited to) disposable clean powder-free gloves, and lab coats. Protect skin, eyes, and mucus membranes. Change gloves often when handling reagents or samples.
2. Handle all samples and waste materials as if they were capable of transmitting infectious agents. Observe safety guidelines such as those outlined in:
   - *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories*[6]
   - CLSI document *M29 Protection of Laboratory Workers from Occupationally Acquired Infections*[7]
3. Follow your institution's safety procedures for handling biological samples.
4. Dispose of materials used in this assay, including reagents, samples, and used buffer vials, according to federal, state, and local regulations.
5. Sample Buffer is assigned the following classifications:
   - Acute toxicity (Category 4)
   - Serious eye damage (Category 1), and
   - Skin irritation (Category 2)
   - Please refer to the FilmArray Sample Buffer Safety Data Sheet (SDS) for more information.
6. Sample Buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants.

WARNING: Bleach should never be added to Sample Buffer or sample waste.

7. Bleach, a recommended disinfectant, is corrosive and may cause severe irritation or damage to eyes and skin. Vapor or mist may irritate the respiratory tract. Bleach is harmful if swallowed or inhaled.
   - Eye contact: Hold eye open and rinse with water for 15-20 minutes. Remove contact lenses after the first 5 minutes and continue rinsing eye. Seek medical attention.
   - Skin contact: Immediately flush skin with plenty of water for at least 15 minutes. If irritation develops, seek medical attention.
   - Ingestion: Do not induce vomiting. Drink a glassful of water. If irritation develops, seek medical attention.
   - Please refer to the appropriate SDS for more information.

Laboratory Precautions

1. Preventing Organism Contamination

Due to the sensitive nature of the FilmArray Food & Water Panel, it is important to guard against contamination of the sample and work area by carefully following the testing process outlined in this instruction document, including these guidelines:

- Samples should be processed in a biosafety cabinet (BSC). If a BSC is not used, a dead air box should be used when preparing samples for testing.

- A biosafety cabinet used for culturing biothreat organisms should not be used for sample preparation or pouch loading.
- Prior to processing samples, thoroughly clean both the work area and the Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach (one-part bleach to nine parts water) or a similar disinfectant. To avoid residue buildup and potential damage to the sample or interference from disinfectants, wipe disinfected surfaces with water.
- Samples and pouches should be handled and/or tested one at a time. Always change gloves and clean the work area between each pouch and sample.
- Use clean gloves to remove materials from bulk packaging bags, and reseal bulk packaging bags when not in use.

2. Preventing Amplicon Contamination

A common concern with PCR-based assays is false positive results caused by contamination of the work area with PCR amplicon. Because the FilmArray Food & Water Panel pouch is a closed system, the risk of amplicon contamination is low provided pouches remain intact after the test is completed. Adhere to the following guidelines, in addition to those above, to prevent amplicon contamination:

- Discard used pouches in a biohazard container immediately after the run has completed.
- Avoid excessive handling of pouches after test runs.
- Change gloves after handling a used pouch.
- Avoid exposing pouches to sharp edges or anything that might cause a puncture.

WARNING: If liquid is observed on the exterior of a pouch, the liquid and pouch should be immediately contained and discarded in a biohazard container. The instrument and workspace must be decontaminated as described in the appropriate BIOFIRE FILMARRAY **2.0 Operator's Manual.**

DO NOT PERFORM ADDITIONAL TESTING UNTIL THE AREA HAS BEEN DECONTAMINATED.

REAGENT STORAGE, HANDLING AND STABILITY

1. Store the test kit, including reagent pouches and buffers, at room temperature (15 to 25ºC). **DO NOT REFRIGERATE**.
2. Avoid storage of any materials near heating or cooling vents, or in direct sunlight.
3. All kit components should be stored and used together. Do not use components from one kit with those of another kit. Discard any extra components from the kit after all pouches have been consumed.
4. Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).
5. Once a pouch has been loaded, the test run should be started as soon as possible (within approximately 60 minutes). Do not expose a loaded pouch to temperatures above 40°C (104°F) prior to testing.

SAMPLE REQUIREMENTS

Minimum Sample Volume - 0.2mL (200µL) of sample is required for testing.

Transport and Storage - Specimens should be processed and tested as soon as possible, though they may be stored at room temperature or under refrigeration.

NOTE: Bleach can damage organisms/nucleic acids within the sample, potentially causing false negative results. Contact between bleach and samples during collection, disinfection, and testing procedures should be avoided.

PROCEDURE

Samples should be collected prior to opening a pouch. Clean gloves and other Personal Protective Equipment (PPE) should be used when handling pouches and samples. Only one FilmArray Food & Water pouch should be prepared at a time. Gloves should be changed between samples and pouches. Once the pouch is hydrated and the sample is added, promptly transfer it to the instrument to start the run. After the run is complete, the pouch should be discarded in a biohazard container.

Refer to the *FilmArray Food & Water Panel Quick Guide* or the appropriate *BIOFIRE FILMARRAY 2.0 Operator's Manual* for more details.

NOTE: Operators should follow the procedures as described in this *Instructions For Use* and the *Food & Water Panel Quick Guides*. Performance cannot be guaranteed if the operator deviates from these procedures.

Sample Pre-Processing (Non-Enriched Protocol)

Materials Required but Not Provided

- Biosafety Cabinet(s) (Optional)
- Stomacher® Mark II 400 110/120 V 60 Hz AC (NSN 6640-01-452-0670)
- Butterfield's Buffer (Sigma-Aldrich #Z699462 NSN 6640-01-494-8327)
- Stomacher® bags, sterile, 1,6247mL filtered. (B01318WA) Whirl-Pak®; Nasco® (NSN 6695-01-643-9096)
- Balance, electronic (NSN 6640-01-454-9198)
- Beaker 1,000mL (NSN 6640-00-982-1289) or Beaker 1,000mL, disposable, Cole-Parmer #EW-06020-11 (NSN TBD)
- Plastic sampling spoon, individually sterilized and bagged 1 Tbs (NSN 6640-01-485-6305) or sterile tongue depressor (NSN 6515-01-227-7037)
- Pad Isopropyl Alcohol (NSN 6510-00-786-3736)
- Scalpel stainless, sterile (NSN 6515-01-151-1833)
- Conical Tubes, sterile 50mL (NSN TBD)

Step 1: Prepare Sample Non-Enriched Protocol

For 25g Food Samples:

1. Take 225mL aliquot of sterile Butterfield's Buffer in a filtered Stomacher bag.
2. Aseptically add 25 +/- 1g (25 +/- 1mL, for liquid) samples using sterile tongue depressors or spoons to each 225mL media bag. If there is not enough initial sample, then prepare 10 +/- 1g (10 +/- 1mL, for liquid) samples for media bags containing 90mL of broth.
3. Homogenize the sample in a Stomacher bag for 30 seconds for liquids and 2 minutes for solid samples at 200 rpm. Alternatively, massage stomacher bag by hand for 30 seconds for liquids and 2 minutes for solid samples to homogenize sample.
4. Remove the bag from the Stomacher, place in beaker to keep upright and move into the BSC.
5. Check the inside of the Stomacher for any leaks and clean immediately; if any are found, follow proper decontamination procedures.
6. Remove the mesh insert from the bag and place in a secondary containment bag and dispose of in the biohazard waste. Change gloves.

For Liquid Samples:

No pre-processing is required.

NOTE: Sample matrix validation was carried out for tap water, apple juice and pulp-free orange juice only. This procedure has not been optimized for liquid samples containing pulp. It may be necessary to stomach or homogenize samples by hand prior to sample processing on the FilmArray.

Sample Pre-Processing (Enrichment Protocol)

DoD Veterinary Services Enrichment Protocol

Materials Required but Not Provided

- Biosafety Cabinet(s) (Optional)
- Buffered Peptone Water (BPW) (G127-4.5), Culture Media Concepts® (NSN TBD)
- 3M™ *Campylobacter* Enrichment Broth (CE250), 3M (NSN TBD)
- Alkaline Peptone Water (APW) (1.01800.0500), Sigma-Aldrich (NSN TBD)
- Stomacher® bags, sterile, 1,6247mL filtered. (B01318WA) Whirl-Pak®; Nasco® (NSN 6695-01-643-9096)
- Stomacher® bags, sterile, 710mL filtered. (B01348WA) Whirl-Pak®; Nasco® (NSN 6695-01-643-9096)
- Plastic sampling spoon, individually sterilized and bagged 1 Tbs (NSN 6640-01-485-6305) or sterile tongue depressor (NSN 6515-01-227-7037)
- Stomacher® Mark II 400 110/120 V 60 Hz AC. (NSN 6640-01-452-0670)
- Bacteriological Benchtop Incubator 0.8 cubic feet (Qty 2) (30-42°C), (NSN 6640-01-576-8119 or 6640-01-643-9945)
- Balance, electronic (NSN 6640-01-454-9198)
- Beaker 1,000mL (NSN 6640-00-982-1289) or Beaker 1,000mL, disposable, Cole-Parmer #EW-06020-11 (NSN TBD)

- pH Strips or pH Meter (NSN TBD)
- **Optional Broth Preparation**: Universal Pre-Enrichment Broth (UPE) (91366), Sigma-Aldrich (NSN TBD), Sodium chloride (Sigma-Aldrich, NSN 6505-01-330-6270) and Distilled Water

Procedure

For 25g food / 25mL liquid samples:

Take 225mL aliquot of sterile water in a filtered Stomacher bag (B01318WA Whirl-Pak®; Nasco®).

For 10g food /10mL liquid samples:

Take 90mL of sterile water in a smaller filtered Stomacher bag (B01348WA Whirl-Pak®; Nasco®)

1. To this, add either

   a) 1 sterile Buffered Peptone Water packet; G127 Culture Media Concepts) or,

   b) 8.5g Universal Pre-Enrichment Broth (UPE)

2. Placing these bags at 37 +/- 1ºC is advised in order to facilitate the dissolution of media.
3. Using aseptic technique, measure out the sample to be tested; 25 +/- 1g (food) or 25 +/- 1mL (liquid).
4. Liquid samples should be stomached for 30 seconds. Solid samples should be stomached for 1-2 minutes at 200 rpms.
5. Incubate the bag according to the table below.

Table 4. FilmArray Food & Water Assay Universal Pre-Enrichment (UPE) Media and Condition

Organism	Enrichment Media	Enrichment Conditions
*Campylobacter jejuni**	3M™ *Campylobacte*r Enrichment Broth	42 +/- 1°C for 48 +/- 1 hours Statically (Aerobic)
Salmonella	Buffered Peptone Water *or,* Universal Pre-Enrichment Broth	37 +/- 1°C for 24 +/- 1 hours Statically (Aerobic)
Escherichia coli, O157:H7, STEC, EAEC, EHEC, EIEC, EPEC	Buffered Peptone Water *or,* Universal Pre-Enrichment Broth	37 +/- 1°C for 24 +/- 1 hours Statically (Aerobic)
*Vibrio parahaemolyticus***	Alkaline Peptone Water pH 8.5 *or,* Universal Pre-Enrichment Broth + 3% Sodium chloride (UPE + 3% NaCl)	37 +/- 1°C for 24 +/- 1 hours Statically (Aerobic)
*Vibrio cholera***	Alkaline Peptone Water pH 8.5 *or,* Universal Pre-Enrichment Broth + 3% Sodium chloride (UPE + 3% NaCl)	37 +/- 1°C for 24 +/- 1 hours Statically (Aerobic)

Yersinia enterocolitica	Buffered Peptone Water *or,* Universal Pre-Enrichment Broth	30 +/- 1°C for 24 +/- 1 hours Statically (Aerobic)
Shigella	Buffered Peptone Water *or,* Universal Pre-Enrichment Broth	37 +/- 1°C for 24 +/- 1 hours Statically (Aerobic)

*__Campylobacter jejuni__ enrichment.** For enrichment of *C. jejuni*, specific enrichment media is required (3M *Campylobacter* Enrichment Broth; CE250). Sample prep/addition should be the same as that outlined above. *Campylobacter* samples should **not** be stomached/homogenized. Sample bags should be massaged by hand for 5-10 seconds. Incubate the bag at 42°C +/- 1 for 48 hours in a static, aerobic environment.

***Vibrio parahaemolyticus* and *Vibrio cholera* enrichment media preparation**: UPE+3% NaCl broth: 38.05g of UPE dehydrated media powder and 25g NaCl, dissolve in 1L distilled water. Autoclave 15min at 121°C. Final pH 6.3 ± 0.2. Store prepared media at 2 to 8°C.

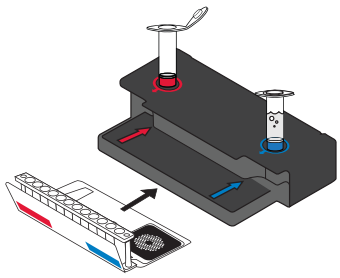
NOTE: The use of 3M™ *Campylobacter* media precludes the need for anaerobic incubation, however as much air as possible should be removed from the sample bag. It is recommended that this is done by grabbing the stomacher bag containing the sample at the water-air interface with both hand using thumb and index finger to flatten sides of the bag and squeezing the headspace (air) to the top. The bag sides should want to stick together; carefully roll down the top closure at least three turns to complete the seal.

Step 2: Prepare Pouch

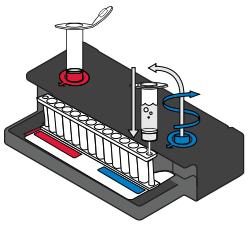
1. Thoroughly clean the work area and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by 2 water rinses.
2. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

   NOTE: The pouch may still be used even if the vacuum seal of the pouch is not intact. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.

3. Insert the pouch into the Pouch Loading Station, aligning the red and blue labels on the pouch with the red and blue arrows on the Pouch Loading Station.
4. Place a Sample Injection Vial (with red cover) into the red well of the Pouch Loading Station.
5. Place a Hydration Injection Vial (with blue cover) into the blue well of the Pouch Loading Station.



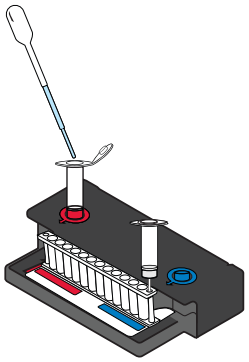
Step 3: Hydrate Pouch



1. Unscrew the Hydration Injection Vial from the blue cover.
2. Remove the Hydration Injection Vial, leaving the blue cover in the Pouch Loading Station.
3. Insert the Hydration Injection Vial into the pouch hydration port located directly below the blue arrow of the Pouch Loading Station.
4. Forcefully push down in a firm and quick motion to puncture seal until a faint “pop” is heard and there is an ease in resistance. Wait as the correct volume of Hydration Solution is pulled into the pouch by vacuum.
   - If the hydration solution is not automatically drawn into the pouch, repeat Step 2 to verify that the seal of the pouch hydration port was broken. If hydration solution is again not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from Step 1: Prepare Pouch.
5. Verify that the pouch has been hydrated.
   - Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen.
   - If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the pouch hydration port was broken or retrieve a new pouch and repeat from Step 2 of the *Prepare Pouch* section.

Step 4: Prepare Sample Mix

NOTE: Choose the sample mix pre-preparation directions appropriate to the sample type.



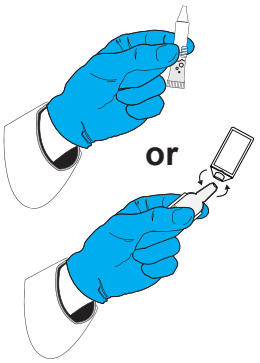
FOOD/BEVERAGE SAMPLE (use Transfer Pipette provided in Main Kit)

1. Add Liquid Sample:

   NOTE: Sample container should be mixed or vortexed prior to drawing sample.

   a. Using Transfer Pipette provided in the test kit, draw the Liquid Sample to the 2nd line (approximately 0.2mL) of the Transfer Pipette.
   b. Add the sample to Sample Injection Vial.
   c. Discard the Transfer Pipette in a biohazard waste container.

   NOTE: DO NOT use the Transfer Pipette to mix the sample once it is loaded into the Sample Injection Vial.



2. Add Sample Buffer to the Sample Injection Vial:

   NOTE: There are 2 possible designs of the Sample Buffer Ampoule.

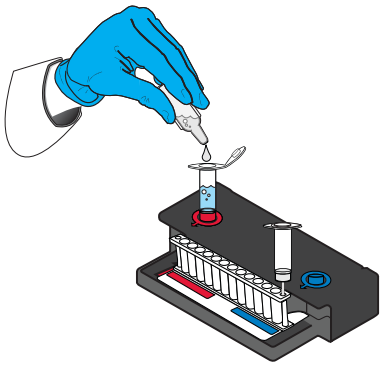
   - Hold the Sample Buffer Ampoule with the tip facing up.

   NOTE: Avoid touching the ampoule tip during handling, as this may introduce contamination.

   - If the ampoule has a textured tab on the side of it: firmly pinch the tab on the ampoule until the seal snaps.

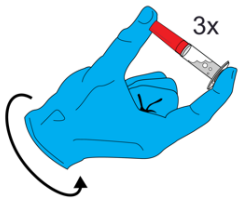
     or

   - If the ampoule has a plastic tab on the tip: gently twist and remove the tab at the tip of the ampoule.

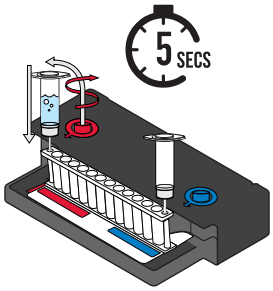


WARNING: Contact with sample buffer can cause serious eye damage and skin irritation and is harmful if swallowed.

3. Tightly close the lid of the Sample Injection Vial.
4. Remove the Sample Injection Vial from the Pouch Loading Station and gently invert the vial 3 times to mix.
5. Return the Sample Injection Vial to red well of Pouch Loading Station.



Step 5: Load Sample Mix



1. Slowly twist to unscrew the Sample Injection Vial from the red cover and wait for 5 seconds with the vial resting in the cover.

   NOTE: Waiting 5 seconds decreases the risk of dripping and contamination from the sample.

2. Lift the Sample Injection Vial, leaving the red cover in the well of the Pouch Loading Station, and insert the Sample Injection Vial into the pouch sample port located directly below the red arrow of the Pouch Loading Station.
3. Forcefully push down in a firm and quick motion to puncture seal (a faint "pop" is heard) and sample is pulled into the pouch by vacuum.
4. Verify that the sample has been loaded.
   - Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port.
   - If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from Step 1: Prepare Pouch.
5. Twist the Sample Injection Vial into its red plastic cover in the Pouch Loading Station. Twist the Hydration Injection Vial into its blue plastic cover in the Pouch Loading Station. Discard the Sample Injection Vial and the Hydration Injection Vial in a biohazard sharps container.
6. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

   NOTE: Optional added operator protection: Before removal from biosafety cabinet, run a bleach wipe, a paper towel with 10% bleach (one-part bleach to nine parts water), across the top of the pouch from the hydration port to the sample port, and follow with a water wipe. This reduces the potential for contact with small amounts of sample mixed with sample buffer that may be retained at the sample injection port.

Step 6: Run Pouch

The FilmArray Software includes step-by-step on-screen instructions that guide the operator through performing a run. Brief instructions for the FilmArray 2.0 system are given below. Refer to the appropriate FilmArray Operator's Manual for more detailed instructions.

1. Ensure that the FilmArray 2.0 system (instrument and computer) is powered on and the software is launched.
2. Follow on-screen instructions and procedures described in the BIOFIRE FILMARRAY 2.0 Operator's Manual to place the pouch in an instrument, enter pouch, sample, and operator information.
3. Pouch identification (Lot Number and Serial Number) and Pouch Type will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, and Pouch Type can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

   NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the FilmArray Food & Water pouch.

4. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
5. Enter an operator name and password in the Name and Password fields.

   NOTE: The font color of the operator's name is red until the operator's name is recognized by the software.

6. Review the entered run information on the screen. If correct, select Start Run.

   Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

   NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.

7. When the run is finished, follow the on-screen instructions to remove the pouch, then immediately discard it in a biohazard container.
8. The run file is automatically saved in the FilmArray database, and the test report can be viewed and/or saved as a PDF file.

QUALITY CONTROL

Process Controls

Two process controls are included in each pouch:

1. **RNA Process Control**

   The RNA Process Control assay targets an RNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, PCR1, dilution, PCR2, and DNA melting. A positive result indicates that all steps carried out in the FilmArray Food & Water Panel pouch were successful.

2. **PCR2 Control**

   The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that PCR2 was successful.

Both control assays must be positive for the FilmArray run to pass. If any of the controls fail, the sample should be retested using a new pouch. If any control fails, the Controls field of the test report (upper right-hand corner) will display 'Failed' and all results will be listed as 'Invalid'.

Monitoring Test System Performance

The FilmArray Software will automatically fail the run if the melting temperature (Tm) for either the RNA Process Control other PCR2 Control is outside of an acceptable range (80.3 to 84.3°C for the RNA Process Control, 73.8 to 77.8°C for the PCR2 Control). If required by local, state, or accrediting organization quality control requirements, operators can monitor the system by trending Tm values for the control assays and maintaining records according to standard laboratory quality control practices.[4,5] Refer to the appropriate FilmArray operator's manual for instructions on obtaining control assay Tm values.

Controls

Good laboratory practice recommends running positive and negative controls regularly. Molecular grade water can be used as a negative control. Previously characterized positive samples or negative samples spiked with well-characterized organisms can be used as positive controls Evaluation of positive controls is recommended prior to using a new shipment of Food & Water Panel pouches. Evaluation of controls is also recommended when there is a new operator and following replacement/repair of a BIOFIRE FILMARRAY 2.0 system. Controls should be used in accordance with the appropriate organization requirements, as applicable. It is ultimately the responsibility of each laboratory to determine the frequency of control testing with the FilmArray Food & Water Panel as part of the laboratory's Quality Control program.

INTERPRETATION OF RESULTS

Assay Interpretation

When PCR2 is complete, the FilmArray instrument performs a DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see appropriate BIOFIRE FILMARRAY 2.0 Operator's Manual). The FilmArray Software then performs several analyses and assigns a final assay result. The steps in the analyses are described below.

Analysis of melt curves. The FilmArray Software evaluates the DNA melt curve for each well of the PCR2 array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve and compares it against the expected Tm range for the assay. If the software determines that the Tm falls inside the assay-specific Tm range, the melt curve is called positive. If the software determines that the melt curve is not in the appropriate Tm range, the melt curve is called negative.

Analysis of Replicates

Organism Assays. Once melt curves have been identified, the software evaluates the three replicates for each organism assay to determine the assay result. For an assay to be called positive, two out of three melt curves must be called positive and the Tm for both positive melt curves must be similar (within 1.0°C). Assays that do not meet these criteria are called negative.

Control Assays.

- Once melt curves have been identified for the PCR2 and yeast RNA controls, the software evaluates the three replicates for each control to determine the result. For the PCR2 and yeast RNA controls to be called positive, at least two of the three associated melt curves must be called positive and the Tm for at least two of the three positive melt curves must be similar (within 1.0°C).
- Controls that do not meet these criteria will be reported as 'Failed' or 'Invalid' (see **Run Summary** section).

Organism Interpretation

The reported FilmArray Food & Water Panel organism interpretation or results ('Detected, 'Not Detected', N/A or 'Invalid') are based on the result of a single assay or on results from a combination of multiple assays (refer to **Table 5)**. In cases where any of the control assays have failed, all analyte results are reported as 'Invalid'. Refer to the **Run Summary** section for additional information on the Controls field.

Interpretation of *E. coli* O157

To aid in the identification of STEC of the O157 serotype, the FilmArray Food & Water Panel contains a single assay (E. coli O157) to detect a gene target that is specific to this serotype. Strains of *E. coli* O157 that do not carry the Shiga-like toxin genes have also been identified. However, as the pathogenicity of these non-STEC strains remains undefined, the *E. coli* O157 assay result is not reported unless a Shiga-like toxin gene is also detected (STEC detected).

Detection of STEC *stx1/stx2* and the *E. coli* O157 target results in a reporting of *E. coli* O157 as a qualifier to the positive STEC result. If STEC *stx1/stx2* is Not Detected, the result for *E. coli* O157 is indicated as N/A (Not Applicable). The FilmArray Food & Water Panel cannot distinguish between infections with a single toxigenic STEC O157 or rare co-infections of STEC (non-O157) with an *stx1/stx2*-negative *E. coli* O157 (see Table 5)

Table 5. Possible Assay Results and Corresponding Test Results for Enteropathogenic *E. coli* (EPEC) and Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2*

FilmArray Food & Water Results	EPEC (Ec eae) Assay	STEC *stx1/2* (STEC 1/ StEC 2) Assays	*E. coli* O157 (EC O157) Assay	Description
Enteropathogenic *E. coli* (EPEC): Not Detected **Shiga-like toxin producing *E. coli*** (STEC) *stx1/stx2*: Not Detected ***E. coli* O157**; N/A	Negative	Negative	Any Result	Enteropathogenic *E. coli* (EPEC) not detected and Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2* not detected *E. coli* O157 result is not applicable when STEC is not detected
Enteropathogenic *E. coli* (EPEC): Detected **Shiga-like toxin producing *E. coli*** (STEC) *stx1/stx2*: Not Detected ***E. coli* O157**; N/A	Positive	Negative	Any Result	Enteropathogenic *E. coli* (EPEC) detected Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2* not detected *E. coli* O157 result is not applicable when STEC is not detected
Enteropathogenic *E. coli* (EPEC): N/A **Shiga-like toxin producing *E. coli*** (STEC) *stx1/stx2*: Detected ***E. coli* O157**; Not Detected	Any Result	Positive [a]	Negative	EPC result is not applicable (detection cannot be differentiated from eae-containing STEC) Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2* detected, O157 serotype not detected
Enteropathogenic *E. coli* (EPEC): N/A **Shiga-like toxin producing *E. coli*** (STEC) *stx1/stx2:* Detected ***E. coli* O157**; Detected	Any Result	Positive [a]	Positive	EPEC result is not applicable (detection cannot be differentiated from eae-containing STEC) Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2* detected, O157 serotype detected [b]

[a] Positive results for the STEC assay(s) and the *Shigella* / Enteroinvasive *E. coli* (EIEC) assay may indicate the presence of *Shigella dysenteriae*.

[b] O157 determinant may be from the STEC or may be due to the rare possibility of a shiga-like toxin-negative *E. coli* O157 being in the same specimen with a non-O157 STEC.

The FilmArray software provides interpretation results in the Evaluator tab through the 'Summary' and 'Interpretation' subtabs (**Figures 1** and **2**). The 'Summary' subtab (**Figure 1**) contains the FilmArray software interpretations (e.g., 'Detected', 'Not Detected', 'Equivocal', and 'N/A') and this tab is not intended to be reviewed by the operator. The 'Interpretation' subtab (**Figure 2**) contains the Food & Water Software interpretations that is intended to be used by the operator along with the test report (**Figure 3**). The operator should review and report the results based upon the Food & Water Software 'Interpretation' subtab (**Figure 2**) which is also displayed on the test report (**Figure 3**).

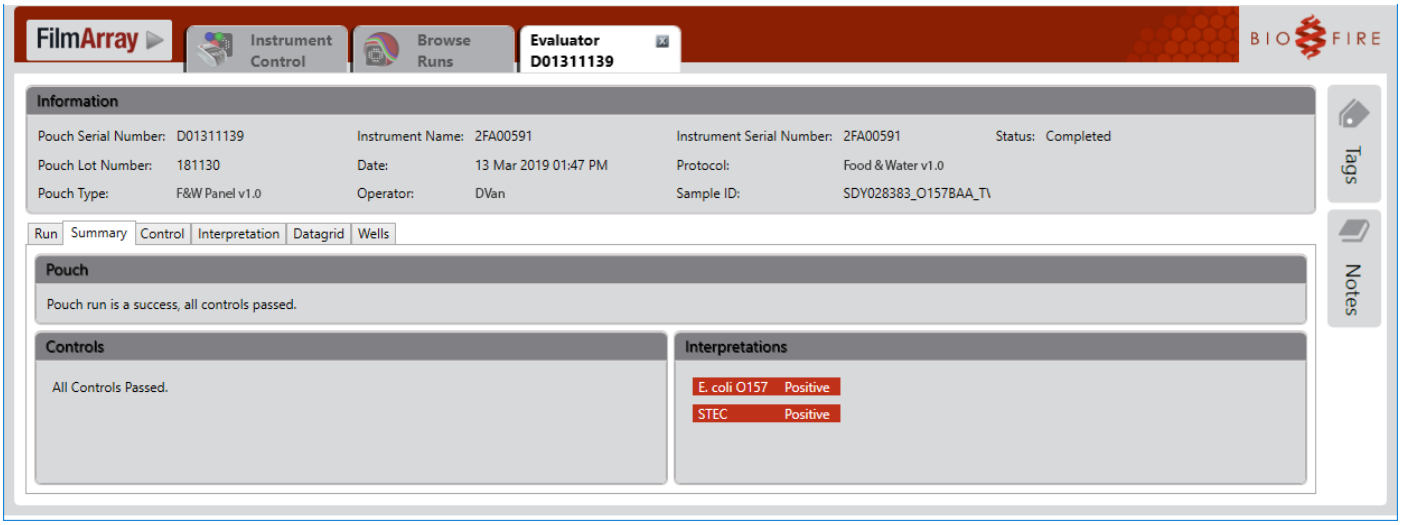


Figure 1. Summary Subtab (Initial Screen for FilmArray Base Software Interpretation)

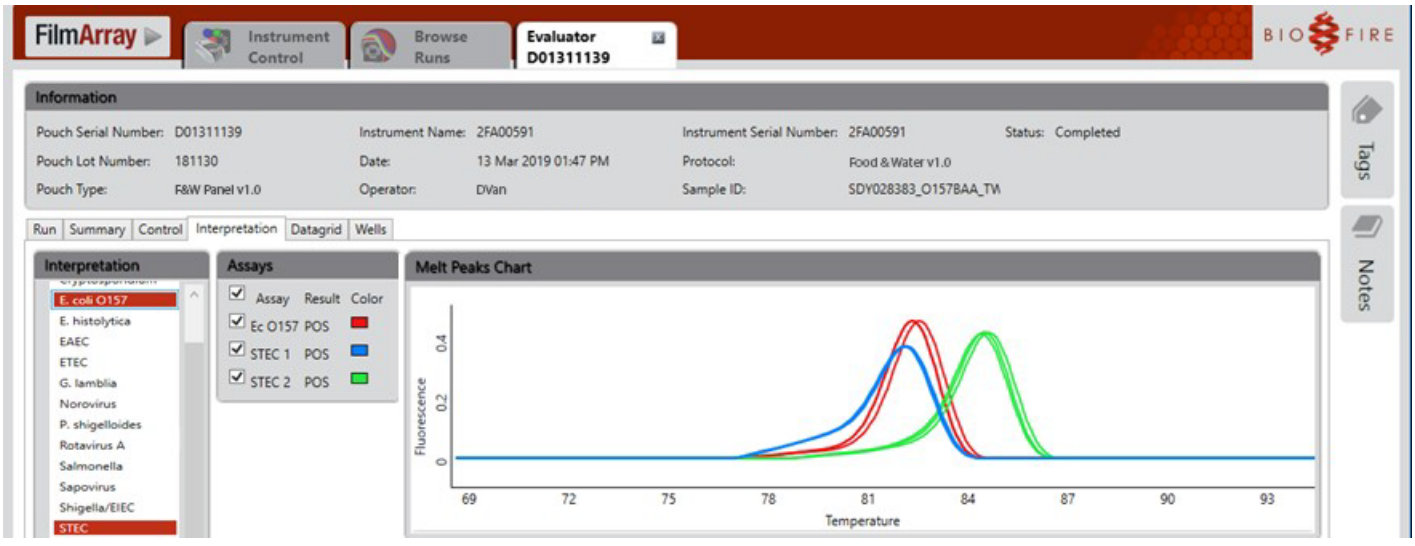


Figure 2. Interpretation Subtab (Operator Screen for Food & Water Panel Software Interpretation)

FilmArray Food & Water Panel Test Report

The FilmArray Food & Water Panel test report (**Figure 3**) is automatically displayed upon completion of a run and contains three sections: Run Summary, the Result Summary, and Run Details. The test report can be saved as a PDF file.

FilmArray®
Food & Water Panel - Not for Diagnostic Use
BIOFIRE
www.BioFireDefense.com

Run Summary			
Sample ID:	SAMPLE_01	**Run Date:**	07 May 2019 3:48 PM
Detected:	*Salmonella*	**Controls:**	Passed

Result Summary	
Bacteria	
Not Detected	*Campylobacter*
✓ Detected	*Salmonella*
Not Detected	*Vibrio*
Not Detected	*Vibrio cholerae*
Not Detected	*Yersinia enterocolitica*
Diarrheagenic *E. coli/Shigella*	
Not Detected	Enteroaggregative *E. coli* (EAEC)
Not Detected	Enteropathogenic *E. coli* (EPEC)
Not Detected	Enterotoxigenic *E. coli* (ETEC) *lt/st*
Not Detected	Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*
⊘ N/A	*E. coli* O157
Not Detected	*Shigella*/Enteroinvasive *E. coli* (EIEC)
Parasites	
Not Detected	*Cryptosporidium*
Not Detected	*Cyclospora cayetanensis*
Not Detected	*Giardia lamblia*
Viruses	
Not Detected	Norovirus GI/GII

Run Details			
Pouch:	F&W Panel v1.0	**Protocol:**	Food & Water v1.0
Run Status:	Completed	**Operator:**	Dan S Van (DVan)
Serial No.:	03587746	**Instrument:**	FA2132
Lot No.:	236515		

Figure 3. General Food & Water Panel Test Report Example

Run Summary

The **Run Summary** (**Figure 3**) section of the test report provides the sample ID, the result of a single assay or combination of multiple assays ('Detected 'Not Detected', 'N/A' or 'Invalid'), a list of organisms that were detected, the control results, and the time and date of the run. If all of the organism assays were negative, then 'None' will be displayed in the Detected field.

Result Summary

The **Result Summary** (**Figure 3**) section of the test report lists the result for each organism tested by the panel. The performance of the Food & Water Panel assays has not been evaluated for all organism and sample type combinations (refer to **Table 1**). Possible results for each organism are 'Detected', 'Not Detected', 'N/A' or 'Invalid'. **Table 6** provides an explanation for each result and any follow-up necessary to obtain a final result.

Table 6. Reporting of Results and Required Actions

Result	Explanation	Action
'Detected'	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organisms were POSITIVE (i.e., met the requirements for a positive result described in the Assay Interpretation section above.)	Report results.
'Not Detected'	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organisms or toxin-encoding genes were NEGATIVE (i.e., did not meet the requirements for a positive result described in the Assay Interpretation section above.)	Report results.
'N/A' **(applies to *E. coli* O157 and EPEC only)**	The run was successfully completed AND The pouch controls were successful (Passed) AND For *E. coli* O157: Shiga-like toxin-producing *E. coli* was Not Detected. For EPEC: Shiga-like toxin-producing *E. coli* was Detected.	Report results
'Invalid'	The pouch controls were not successful (Failed) OR The run was not successful (Run Status displayed as: Incomplete, Aborted, Instrument Error, or Software Error.)	See **Table 7**, *Interpretation of Controls Field on the FilmArray Food & Water Panel Test Report* for instruction.

Run Details

The **Run Details** (**Figure 3**) section provides additional information about the run including: pouch information (type, lot number, and serial number), Run Status ('Completed', 'Incomplete', 'Aborted', 'Instrument Error', or 'Software Error'), the sample type-specific protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

Change Summary

Once a run has completed, it is possible to edit the Sample ID. If this information has been changed, an additional section called **Change Summary** will be added to the test report. This Change Summary section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

Controls Field

The Controls field on the test report will display 'Passed', 'Failed', or 'Invalid'. The Controls field will display 'Passed' only if the run completed successfully (no instrument or software errors) and both of the pouch control assays (RNA Process Control and PCR2 Control) were successful. The Controls field will display 'Failed' if the run was completed successfully (no instrument or software errors) but one or both of the pouch control assays failed. If the control result is 'Failed', then the result for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch.

Table 7 provides a summary and explanation of the possible control results and follow-up actions.

Table 7. Interpretation of Controls Field on the FilmArray Food & Water Test Report

Controls Result	Explanation	Action Required	Outcome
'Passed'	The run was successfully completed AND Both pouch controls were successful	None	Report the results provided on the test report
'Failed'	The run was successfully completed BUT At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed	Repeat the test using a new pouch	Accept the results of the repeat testing. If the error persists, contact Technical Support for further instruction.
'Invalid'	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error)	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the appropriate FilmArray Operator's Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test or repeat the test using another instrument/Module.	Accept the valid results of the repeat testing. If the error persists, contact Technical Support for further instruction.

CLEANING MATERIALS

This list provides items that are necessary in a laboratory to keep contamination to a minimum.

- 10% bleach solution in a squeeze or spray bottle (1-part bleach to 9 parts water)
- Distilled water in a squeeze or spray bottle
- DNAZap™ or equivalent DNA degrading system
- Paper towels
- Bleach wipes

DECONTAMINATION PROCEDURES

The decontamination and cleaning procedures listed below are intended to limit spread of contaminants as a result of a Food & Water Panel detected pathogen, a suspected positive pouch, or a broken or leaked pouch. A suspected positive sample is one that the operator strongly suspects may be positive for an analyte on the Food & Water Panel.

NOTE: Use of distilled water is recommended for cleaning.

Pouch Loading Station Decontamination

Routine cleaning of the Pouch Loading Station includes a 10% bleach wipe followed by two water wipes before each new pouch is loaded.

In the event of work with a Food & Water Panel detected pathogen, a suspected positive sample, or contamination from a sample spill, or a pouch leak, perform the following decontamination procedures:

1. Put on clean PPE, such as lab coat, gloves, and eye protection.
2. Fill a sink or bin with water and add bleach to create a 10% bleach solution.
3. Submerge the Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.
4. Remove Pouch Loading Station from sink or bin. Replace bleach solution with water.
5. Rinse the Pouch Loading Station by completely submerging in water two additional times.

Decontamination Related to Food & Water Panel Detected Organism or a Suspected Positive Pouch or Pouch Leakage

If a pouch was loaded with a Food & Water Panel detected pathogen, a suspected positive sample, or if the pouch leaks, take the following precautions to avoid contamination:

1. Put on clean PPE, such as a lab coat, gloves, respirator, and eye protection.
2. Ensure no one uses the instrument or potentially contaminated areas until the decontamination is complete.
3. Decontaminate the instrument and work area and dispose of the pouch using the following steps:
   a. Dispose of potentially contaminated gloves and put on clean gloves.
   b. Dispose of the potentially contaminated lab coat and put on a clean lab coat.
   c. Discard leaking pouch in biohazard container.

d. Change gloves.

e. Clean the instrument and affected work areas per the guidelines below.

CAUTION: Use only 10% bleach solution, water, and/or DNAZap™ to decontaminate the instrument and Pouch Loading Station.

Instrument Decontamination

Pouch Loading Chamber Decontamination

1. Put on clean PPE, such as a lab coat, gloves, and eye protection.
2. Remove pouch from instrument and discard in biohazard waste container. Change gloves
3. Wet a paper towel with 10% bleach (one-part bleach to nine parts water), and wipe the inner chamber and under the lid. Change gloves.
4. Repeat Step 3 twice with fresh paper towels for a total of three bleach wipes.
5. Wet a paper towel with water and wipe the inner chamber.
6. Repeat Step 5 with fresh gloves and paper towel.

Instrument Exterior Decontamination

1. Put on clean PPE, such as a lab coat, gloves, and eye protection.
2. Wet a paper towel with the 10% bleach solution and wipe all exterior surfaces of the instrument, including the bottom and the bench top where the instrument had contact. Change gloves.
3. Repeat Step 2 twice with fresh paper towels and clean gloves, for a total of three bleach wipes.
4. Change gloves, then wet a new paper towel with water and wipe the surfaces of the inner chamber, including under the lid, and the entire exterior of the instrument, including the bottom and the bench top where the instrument had contact.
5. Repeat Step 4 with fresh gloves.

Decontamination of Bench Tops and Other Areas

1. Put on clean PPE, such as a lab coat and gloves.
2. Spray the 10% bleach solution on the area that may have been contaminated. Let it stand for at least three minutes to allow the bleach solution to react with any contaminants on the surface.
3. Wipe the area with a clean paper towel. Change gloves.
4. Repeat Steps 2 and 3 twice, for a total of three wipes.
5. Change gloves. Spray the area with water.
6. Wipe the area dry with a new paper towel. Change gloves
7. Spray the area with DNAZap™ or an equivalent product. Follow the product's instructions for correct use. Change gloves.
8. Rinse the area by spraying it with water and wiping it dry.

Check Function of Decontaminated Instrument

1. Test a negative sample by preparing a pouch, using water as the sample. Use distilled, sterile, or molecular grade water for the test.
2. If run is successful and all results are negative, continue using the instrument as normal.
3. If unexpected positive results are obtained or the run fails, please contact BioFire Defense Technical Support for further instructions.

Check for Environmental Contamination

After decontaminating instrument as described above, use environmental swabs to check for contamination by following the protocol below:

1. Prepare four aliquots of 0.2 mL of molecular grade water.
2. Place one environmental swab in each aliquot and let soak for five minutes.
3. Thoroughly swab exterior of instrument and accessories, including laptop, especially areas of operator contact.
4. Return each swab to its original aliquot and mix the sample well.
5. Dispose of swabs and combine the four aliquots into one.
6. Load pouch as described in Procedure section of this document.
    a. Load 0.2 mL of combined swabbing aliquot as the sample using Transfer Pipette, by drawing liquid up to the 2nd line.
    b. Add sample to Sample Injection Vial.
    c. Proceed with normal pouch loading procedure.
7. Run pouch using the Liquid protocol.
8. If positive result is found, repeat decontamination steps, and contamination testing until no contamination is detected.
9. If problems persist, contact BioFire Defense Technical Support for further instructions.

LIMITATIONS

1. Not for diagnostic use.
2. This test is a qualitative test and does not provide a quantitative value for the organism(s) in the sample.
3. False negative results may occur when the concentration of organism(s) in the sample is below the assay limit of detection.
4. The detection of nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive and false negative results caused by improperly collected, transported, or handled samples. The RNA process control and the PCR2 control will not indicate whether or not nucleic acid has been lost due to inadequate collection, transport, storage of samples, or improper sample preparation. See **Process Controls** section for the purpose of each control.
5. This test is intended only for use in biological surveillance activities as described in the Intended Use. The performance of the Food & Water Panel assays has not been evaluated for all organisms and sample type combinations (refer to **Table 1**).
6. The FilmArray Food & Water Panel performance has only been established on the BIOFIRE FILMARRAY 2.0 System.
7. Use only materials provided with or validated for the Food & Water Panel kit when testing samples.

Analytical Reactivity and Specificity

This testing evaluated 26 bacteria, and three protozoan isolates at high concentrations to check for the possibility of cross-reactivity with the Food & Water Panel assays. The organisms were selected for two reasons:

1. They are closely related to either organisms found on the panel, or organisms that are commonly found in matrices frequently tested with Food & Water pouches.
2. They are not targeted by the assays on the Food & Water Panel

Because Norovirus GIV virus was not available, synthetic RNA transcript specific to this viral target was ordered and evaluated. Additionally, the exclusivity testing also included a limited evaluation of the possibility of unexpected panel results due to cross-reactivity between the assays and non-targeted nucleic acids (on-panel exclusivity).

Table 8. Off-Panel Bacterial Analytes for Exclusivity Evaluation of the FilmArray Food & Water Panel

Bacterium	ID/source	Strain/Information
Yersinia kristensenii	33640 ATCC	CDC 1460-81 [IP 1475; La 547C]
Campylobacter jejuni subsp. *doylei*	NR-124 BEI	093
Carnobacterium piscicola	PTA-5314 ATCC	CB2
Clostridium perfringens	HM-310 BEI	WAL-14572, genomic DNA
E. coli EcoR 48	35367 ATCC	ECOR 48, replacing unavailable ECOR 51
Enterobacter cloacae	NR-48558 BEI	UCI 36
Grimontia hollisae	33564 ATCC	75-80, formerly *Vibrio*
Helicobacter pylori	NR-43639 BEI	CPY6081
Listeria grayi	25401 ATCC	F-9 [NCTC 10812]
Listeria monocytogenes	NR-105 BEI	53 XXIII
Micrococcus luteus	HM-114 BEI	SK58
Pantoae agglomerans	27155 ATCC	CDC 1461-67
Pseudomonas fluorescens	13525 ATCC	NCTC 10038
Rhodococcus equi	6939 ATCC	NCTC 1621
Staphylococcus aureus	NR-45869 BEI	HIP06854
Shigella flexneri	NR-517 BEI	24570
Vibrio alginolyticus	17749 ATCC	XII-53
Vibrio fluvialis	33809 ATCC	606 [NCTC 11327]
Vibrio mimicus	33653 ATCC	CDC 1721-77
STEC	NR-17638 BEI	O157:H45
STEC	NR-17639 BEI	O157:H39
EAEC	NR-9298 BEI	101-1

Table 9. Off-Panel Protozoan Analytes for Exclusivity Evaluation of the FilmArray Food & Water Panel

Protozoan	Source/Strain	Strain/Information
Acanthamoeba spp.	NR-33654 BEI	CDC: 12741:1
Entamoeba histolytica	NR-179 BEI	Rahman
Toxoplasma gondii	NR-44106 BEI	EGS

Table 10. Off-panel Viral Analyte for Exclusivity Evaluation of the FilmArray Food & Water Panel

Virus	Source/ID	Strain/Information
Norovirus GIV	BFDF	RNA transcript

Summary of Results: The Food & Water Panel demonstrated full exclusivity for the majority of the selected organisms, with the exception of two analytes, *Campylobacter jejuni* subsp. *doylei* and *Carnobacterium piscicola.* Although *Campylobacter jejuni* subsp. *doylei* had unexpected positive results, it is a desirable analyte for the Food & Water Panel and as such was considered for examination during All Organism Sensitivity testing (Table 11.) *Carnobacterium piscicola* showed unexpected positivity in 1/3 replicates for the EAEC and EPEC (ECeae) assays, however, when diluted an additional 10-fold in General Test Water the organism performed as expected resulting in all negative results. The following organisms were evaluated as part of on-panel exclusivity testing and gave expected positive results for their respective assays but were negative for all other assays on the panel: *Grimontia hollisae*, *Shigella flexneri*, STEC 17638, STEC 17639, *Vibrio alginolyticus*, *Vibrio fluvialis*, *Vibrio mimicus*, *Yersinia kristensenii* and *Entamoeba histolytica.*

Interference

Potentially interfering substances that could be present in samples, or introduced during sample collection and testing, were evaluated for their effect on the FilmArray Food & Water Panel performance. To obtain this information, contact Medical Countermeasures Systems - Joint Project Management Office (MCS-JPMO), Ft. Detrick, Maryland.

All Organism Sensitivity Testing

A total of 36 organisms (or purified recombinant virus) were evaluated to confirm the limit of detection (LoD) for the targets on the Food & Water Panel. Each organism was evaluated in the appropriate matrix.

Table 11. Confirmed LoDs for the Food & Water Panel

Organism	Species /serotype	Part ID #	Matrix										
			Tap Water	Chicken	Beef	Bagged Spinach	Sliced Ham	Weiner	Smoked Salmon Spread	Bagged Shredded Cheese	Orange Juice- pulp free	Apple Juice	Oatmeal
Campylobacter	*jejuni*	NR-403	2.00E+02	2.00E+03								2.00E+02	
	jejuni subsp doylei	NR-124	2.00E+04	4.00E+05								2.00E+04	
	coli	HM-296	4.00E+02	2.00E+04*								4.00E+02	
	upsaliensis	HM-297	4.00E+01	4.00E+02								4.00E+01	
Salmonella	b*ongori*	43975	2.00E+03	1.00E+04*	5.00E+04	1.00E+03	1.00E+03	5.00E+02	1.00E+04	2.00E+04	1.00E+03	1.00E+03	1.00E+03
	enterica ssp *enterica* serovar Typhimurium	NR-170	5.00E+03	5.00E+04*	2.50E+04	5.00E+02	5.00E+02	2.50E+03	2.50E+04*	5.00E+04*	2.50E+03	1.00E+03	5.00E+02*
Vibrio	*parahaemolyticus*	17802	8.00E+02						8.00E+03				
	fluvalis	33809	8.00E+01						8.00E+02				
	vulnificus	27562	8.00E+02						4.00E+03				
	cholerae Ogawa serotype O:1	14035	8.00E+00			8.00E-01			4.00E+01*				
Yersinia	*enterocolitica* O:3	700822	1.00E+02					2.50E+02*			1.00E+02		
	enterocolitica O:9	55075	1.00E+02*					5.00E+01			5.00E+01		
	enterocolitica O:8	NR-210	2.00E+02*					1.00E+02			2.50E+02		
E.*coli*	O157	BAA-1883	1.00E+03*		1.00E+04							5.00E+02	
	Enteroaggregative; O3	NR-102	1.00E+03*										
	Enteropathogenic; O127	NR-50518	5.00E+02										
	Enterotoxigenic (lt/st) O78:H11	35401	1.00E+02					5.00E+01					
	Shiga-like toxin O26:H11	BAA-2196	2.00E+02			1.00E+02					5.00E+02*		
	Shiga-like toxin O157:H7	NR-6	5.00E+02*			5.00E+02*					5.00E+02*		
	Enteroinvasive O29:NM	43892	5.00E+01						2.50E+02			5.00E+01	
	Enteroinvasive *S. sonnei*	NR-519	1.00E+02						5.00E+03			1.00E+02*	
	EPEC O111:NM	NR-9296	5.00E+02*										
	STEC O91:H21	NR-96	1.00E+02*			1.00E+02*					2.00E+02		
	STEC O111:H-	NR-17628	5.00E+02			2.00E+02					5.00E+02		
	O157:H7 EDL933	NR-11	1.00E+03*		5.00E+03							5.00E+02	
	EIEC O28a	NR-101	1.00E+02						1.00E+03			5.00E+01	
Norovirus[1]	GI	0810086CF	1.00E+01*			2.00E+00*					4.00E-01		
	GII	0810087CF	1.00E+01			1.00E+01					1.00E+01		
Cyclospora[2]	*cayetanensis*	PRA-3000SD	1.80E+02			9.00E+02*							
Giardia[3]	*lambia*	NR-9232	5.00E+00*			5.00E+00*							
Cryptosporidium[2]	*parvum*	PRA-67D	5.00E+02			2.50E+03							

All LoDs shown in this table are shown in CFU/mL with the exception of [1] PFU/mL (calculated from $TCID_{50}$), [2] GE/mL and [3] cells/mL, or unless otherwise stated.
*The LoD at these intersections was confirmed with reduced sensitivity compared with the Estimated LoD result

APPENDIX A

Symbols Glossary

The following symbols can be found on labeling for the BIOFIRE FILMARRAY 2.0, FilmArray Food & Water Panel kits, kit components, and throughout accompanying packaging.

ISO 7000 Graphical symbols for use on equipment – Registered Symbols					
3082 	Manufacturer	2607 	Use-By date (YYYY-MM-DD)	2492 	Batch Code (Lot Number)
2493 	Catalogue Number	2498 	Serial Number	2606 	Do Not Use if Package Is Damaged
0624 	Keep Away from Sunlight	0632 	Temperature Limit	1951 	Do Not Re-Use
1641 	Operator's Manual	0518 	Contains sufficient for <n> tests		
United Nations Globally Harmonized System of Classification and Labeling of chemicals (GHS) (ST/SG/AC. 10/30)					
	Corrosive (Skin Corrosion/ Burns, Eye Damage, Corrosive to Metals)		Exclamation Mark (Irritant, Acute Toxicity, Narcotic Effects, Respiratory Tract Irritant)		Hazardous to the aquatic environment, long-term hazard
Manufacturer Symbols (BioFire Defense, LLC)					
	BioFire Defense Logo		Food & Water Panel symbol		

APPENDIX B

References

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REVISION HISTORY

Version	Revision Date	Description of Revision(s)
01	09-12-2019	Initial Release
02	2020-12-14	Removed “Made for US Dept. of Defense” language. Added LOD and Reactivity and Specificity data
03	2025-01-27	Added the 2nd ampoule option to the prepare sample step. Updated branding to BIOFIRE FILMARRAY.

79 West 4500 South, Suite 14, Salt Lake City, Utah 84107 USA
1-801-262-3592 | www.BioFireDefense.com

For additional information regarding our products and applications, contact BioFire Defense Customer Support.