

# Visual Inspection of BIOFIRE Pouches

## 1. Introduction

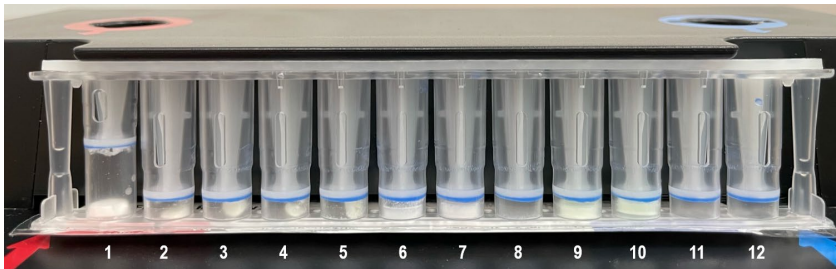
The purpose of this technical note is to provide guidance for pre-run and post-run visual inspection of the pouch and pouch chemistry for BIOFIRE panels.

FILMARRAY® is an automated in vitro diagnostic (IVD) system that utilizes nested multiplex PCR (nmPCR) and high-resolution melting analysis to detect and identify multiple nucleic acid targets from clinical specimens.

The BIOFIRE® 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 pathogens within a single specimen.

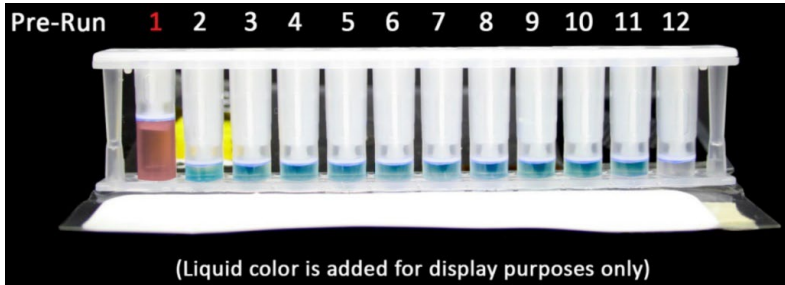
## 2. Pre-Run Visual Inspection

1. Check the expiration date on the kit. Do not use expired kit components or pouches.
2. Remove the pouch from its vacuum-sealed package and visually inspect for the presence of chemistry pellets of any size and shape. Chemistry pellets should be seen in all wells except 8, 11, and 12. If chemistry pellets are missing from any wells (other than 8, 11, and 12) discard the pouch and use a new pouch to test the sample.



**NOTE:** The pouch may still be used even if the vacuum seal of the pouch is not intact. In cases where there is no vacuum in the mylar bag, please attempt to hydrate the pouch. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.

- Hydrate the pouch. If hydration solution is not drawn into the pouch, discard the current pouch and retrieve a new pouch. Approximately 800µL of hydration solution should be dispersed equally in wells 2-11, filling each well completely. A small volume of bubbles may be present in a well but should not be greater than 10% of total well volume. Well 12 should not contain any liquid. Chemistry pellets may not fully dissolve at hydration.



- Continue with the pouch preparation steps listed in the respective Instructions for Use for the pouch being used.

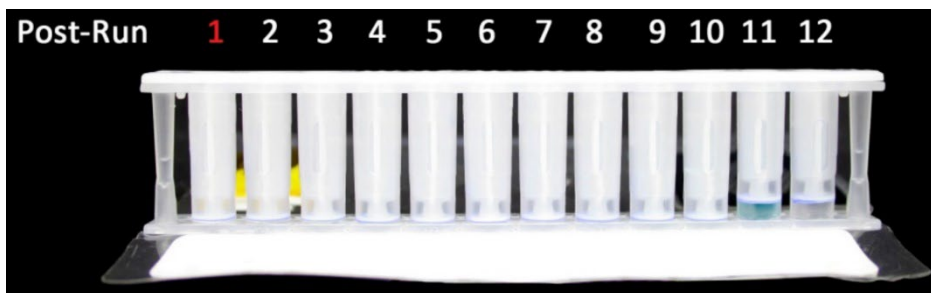
### 3. Variation in Pellet Size

While performing visual inspections of pouches prior to preparation, variation in pellet appearance may be seen. This variation is a natural occurrence due to the nature of the manufacturing process. There are several factors that can cause variation in appearance (shape and size). Each pouch passes through a visual inspection as part of the manufacturing process which includes a 16-point inspection. Variation of pellet appearance is written into the control plan limits and each lot is functionally tested prior to distribution. If any failure is observed during the inspection process, the failure is documented and the pouch is discarded. Pouches with variation in pellet size and shape should be utilized for these reasons. BioMérieux recommends continuing testing if there is variability seen in pellet size and shape.

### 4. Post-Run Visual Inspection

Once the run is complete, check the pouch for the following items:

- Wells 1-10 should have no liquid remaining with plungers fully plunged.
- Well 11 should be unchanged during the run. It should not be plunged and should contain the same amount of liquid as it did in its pre-run state.
- Well 12 should remain un-plunged and may contain liquid from the array.



## Technical Support Contact Information

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bioMérieux is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the BIOFIRE Technical Support team for assistance.

BIOFIRE Technical Support  
Email: [biofiresupport@biomerieux.com](mailto:biofiresupport@biomerieux.com)  
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