

# Guidelines for Laboratory Verification of Performance of the FilmArray® Injection Vials

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## Purpose

The FilmArray Respiratory Panel (RP) and the FilmArray Blood Culture Identification Panel (BCID) have been updated with an improved loading system. New devices, called FilmArray Injection Vials, will replace the syringes currently used for pouch hydration and sample loading. The FilmArray Injection Vial loading system improves usability and sample loading time but does not change any of the clinical or analytical performance characteristics of the tests. Clinical data that demonstrate FilmArray Injection Vial and syringe equivalence can be found in *The FilmArray Respiratory Panel Instruction Booklet* (RFIT-PRT-0435) and *The FilmArray Blood Culture Identification Panel Instruction Booklet* (RFIT-PRT-0369). The US Food and Drug Administration (FDA) has cleared the FilmArray Injection Vials for use with the FilmArray RP and BCID tests.

The Clinical Laboratory Improvement Amendments (CLIA), passed in 1988, establishes quality standards for all laboratory testing to ensure the accuracy and reliability of patient test results, regardless of where the test is performed. CLIA regulations require that performance specifications are verified when test systems have been modified with changes such as specimen and reagent volumes. The FilmArray Injection Vial loading system introduces minor changes in sample and sample buffer volumes as described in Table 1, requiring that laboratories perform a verification of performance using the FilmArray Injection Vials.

**Table 1.** Approximate volumes of sample (specimen) and loading buffer for syringe and FilmArray Injection Vial loading systems

	Syringe		FilmArray Injection Vial	
	Volume of Sample	Volume of Buffer	Volume of Sample	Volume of Buffer
RP	300 µl	500 µl	300 µl	800 µl
BCID	100 µl	500 µl	200 µl	800 µl

This verification is only intended for laboratories that are currently using syringes with FilmArray RP or BCID tests. This document provides guidelines to assist your laboratory in developing a protocol for the verification of FilmArray RP and BCID with the FilmArray Injection Vial loading system. As per the CLIA regulation, the Laboratory Director is ultimately responsible for ensuring that verification procedures meet the appropriate standards for CLIA and applicable laboratory accrediting agencies.

## FilmArray Intended Use

The complete intended use statement and additional information about the use of the FilmArray system can be found in the *FilmArray Respiratory Panel Instruction Booklet* and *FilmArray Blood Culture Identification Panel Instruction Booklet*.

## Performance Verification: Materials

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**Table 2.** Materials needed for RP procedures

Material	Part Number
FilmArray Respiratory Panel Kit with syringes (30 tests kit)	BioFire Diagnostics, LLC RFIT-ASY-0105
FilmArray Respiratory Panel Kit with FilmArray Injection Vials (30 tests kit)	BioFire Diagnostics, LLC RFIT-ASY-0124
Control Organism	ZeptoMetrix NATRVP-IDI <sup>a</sup>
Transport Medium (e.g. Remel M4 Viral Transport Media)	Various media are appropriate

<sup>a</sup> Any appropriate source of organism may be used for verification of any or all of the assays in the FilmArray RP.

**Table 3.** Materials needed for BCID procedures

Material	Part Number
FilmArray BCID Panel with syringes (30 tests kit)	BioFire Diagnostics, LLC, RFIT-ASY-0114
FilmArray BCID Panel with FilmArray Injection Vials (30 tests kit)	BioFire Diagnostics, LLC, RFIT-ASY-0126
BD BACTEC™ Plus Aerobic/F Medium with resin (or equivalent) <sup>a</sup>	BD, 442192
Human Whole Blood with EDTA (pathogen free)	Bioreclamation LLC, HMWBEDTA2 (or equivalent, with anticoagulant)
McFarland Turbidity Standard, 1.0	Fisher Scientific, R20411 (or equivalent)
Phosphate Buffered Saline, pH 7.4	Sigma, P3813 (or equivalent)
Polystyrene tube with cap (14 mL, 16 x 100 mm, round-bottom)	VWR, 82050-246 (or equivalent)
Polypropylene centrifuge tube with flat cap (50 mL, sterile)	VWR, 89004-364 (or equivalent)

<sup>a</sup> Charcoal-containing media should not be used with the FilmArray BCID Panel.

**Table 4.** Recommended organism strain and source for BCID procedures

Organism	Microbiologics Catalog Number <sup>a</sup>
<i>Acinetobacter baumannii</i> ATCC® 19606™ KWIK-STIK	0357P
<i>Candida albicans</i> ATCC® 10231™ Lab-Elite	0443-CRM
<i>Candida glabrata</i> ATCC® 15126™ KWIK-STIK	0737P
<i>Candida krusei</i> ATCC® 14243™ KWIK-STIK	0809P
<i>Candida parapsilosis</i> ATCC® 22019™ KWIK-STIK	0726P
<i>Candida tropicalis</i> ATCC® 1369™ KWIK-STIK	01036P
<i>Enterobacter cloacae</i> subsp. <i>cloacae</i> ATCC® 13047™ Lab-Elite	0323-CRM
<i>Enterococcus faecalis</i> ATCC® 51299™ KWIK-STIK	0959P <sup>b</sup>
<i>Escherichia coli</i> ATCC® 11229™ Lab-Elite	0681-CRM
<i>Haemophilus influenzae</i> ATCC® 10211™ KWIK-STIK	0441P
<i>Klebsiella oxytoca</i> ATCC® 13182™ KWIK-STIK	0530P
<i>Klebsiella pneumoniae</i> ATCC® BAA-1705™ KWIK-STIK	01005P <sup>c</sup>
<i>Listeria monocytogenes</i> ATCC® 19111™ KWIK-STIK	0277P
<i>Neisseria meningitidis</i> ATCC® 13077™ KWIK-STIK	0453P
<i>Proteus mirabilis</i> ATCC® 35659™ Lab-Elite	0944-CRM
<i>Pseudomonas aeruginosa</i> ATCC® 27853™ KWIK-STIK	0353P
<i>Serratia marcescens</i> ATCC® 13880™ KWIK-STIK	0247P
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC® 33591™ Lab-Elite	0496-CRM <sup>d</sup>
<i>Staphylococcus epidermidis</i> ATCC® 12228™ Lab-Elite	0371-CRM
<i>Streptococcus agalactiae</i> ATCC® 12386™ KWIK-STIK	0439P
<i>Streptococcus pneumoniae</i> ATCC® 10015™ KWIK-STIK	0865P
<i>Streptococcus pyogenes</i> ATCC® 19615™ Lab-Elite	0385-CRM

<sup>a</sup> Any appropriate source of organism may be used for verification of any or all of the assays in the FilmArray BCID Panel. Alternate organism strains may not provide the same results for antimicrobial resistance genes as those suggested here.

<sup>b</sup> This strain of *E. faecalis* (ATCC® 51299) carries the *vanB* gene (vancomycin resistance).

<sup>c</sup> This strain of *K. pneumoniae* (ATCC® BAA-1705) carries the *bla<sub>KPC</sub>* gene (carbapenems resistance).

<sup>d</sup> This strain of *S. aureus* subsp. *aureus* (ATCC® 33591) carries the *mecA* gene (methicillin resistance).

## Performance Verification: Procedures

### Example procedure using clinical specimens

Equivalency between the two loading systems can be demonstrated by testing well characterized positive patient specimens. Each specimen should be tested using the syringe loading system and the FilmArray Injection Vial loading system, and the results for both tests should be equivalent. It is recommended that approximately 10 individual patient specimens are tested (20 tests), and the samples should cover a variety of organisms. The number of samples and organisms tested in the study is ultimately at the discretion of the Laboratory Director.

**Note:** 3<sup>rd</sup> party reference materials are not needed if patient specimens are used for the verification procedures.

### Example procedure using surrogate material

Laboratories may choose to use surrogate material instead of or in addition to clinical specimens. In this case it is recommended that the laboratory uses the same material that was used for initial method verification. Refer to the *FilmArray Laboratory Verification Advisory Notice* for RP (FLM1-PRT-0060) or BCID (FLM1-PRT-0137) for pooling schemes. Equivalency between the two loading systems can be demonstrated by testing one or more of the organism pools. Each organism pool should be tested using the syringe loading system and the FilmArray Injection Vial loading system, and the results for both tests should be equivalent. It is recommended that each pool is tested with at least two replicates using the syringe loading system and two replicates using the FilmArray Injection Vial loading system (4 total tests for each pool). The total number of samples used in the study is ultimately at the discretion of the Laboratory Director.



BioFire Diagnostics is dedicated to providing you with the best customer support available. If you have any questions or concerns, please contact the FilmArray Technical Support team at 801-736-6354, option 5 or by email at [support@biofiredx.com](mailto:support@biofiredx.com)

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