Guidelines for Laboratory Verification of Performance of the FilmArray® RP System

Purpose

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. The CLIA regulations include a requirement for verifying the performance specifications of unmodified, moderate complexity tests cleared or approved by the FDA.

This document provides examples of verification procedures to assist your laboratory in developing a protocol for the verification of FilmArray RP system performance required by CLIA. Several possible verification schemes, compatible with the FilmArray RP system, have been designed. Each scheme provides positive and negative tests for each organism detected by the FilmArray RP system and may be easily modified or expanded to meet specific criteria. Each scheme was designed so that a trained laboratory technician could test at least 6 FilmArray pouches per day on each FilmArray instrument to be verified. Day-to-day variation is evaluated by testing each sample on two separate days. To evaluate user-to-user variation, multiple laboratory technicians may test the same sample. In addition, patient samples can be tested for verification or to evaluate matrix effects on the performance of the FilmArray RP 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

FilmArray Respiratory Panel (RP) is a multiplexed nucleic acid test intended for use with the FilmArray instrument for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following organisms and subtypes are identified using the FilmArray RP: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus, Bordetella pertussis, Chlamydia pneumoniae, and Mycoplasma pneumoniae.

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.
Performance Verification: Overview

Each procedure described below will generate multiple positive and negative results for each of the FilmArray RP assays. The procedures were developed using a Respiratory Verification Panel available from ZeptoMetrix Corporation, Buffalo, NY (part number NATRVP-IDI).

Four different examples of performance verification procedures are described: (1) a simple protocol for the verification of a single FilmArray instrument, (2A) expanded verification of a single instrument, (2B) an expanded protocol for the verification of 2 FilmArray instruments, and (3) a Viral Transport Media (VTM) protocol that evaluates the performance of each assay with a VTM sample matrix.

The Simple (1) and Expanded (2A, 2B) procedures have been designed to take advantage of the multiplex nature of the FilmArray RP system. Verification testing efficiency is maximized by evaluating multiple target organisms in a single test run.

In addition to, or in place of, verification schemes described here; a laboratory may chose to test clinical/patient samples to assess clinical sensitivity and sample matrix effects in its performance verification of the FilmArray RP system.

Table 1. Overview of Verification Protocols

<table>
<thead>
<tr>
<th>Verification Protocol</th>
<th>Organisms per Pool*</th>
<th>Number of Sample Pools</th>
<th>Replicates per Sample Pool</th>
<th>Pouches Required</th>
<th>Expected Positive Results</th>
<th>Expected Negative Results</th>
<th>Approximate Days of Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example 1: Simple protocol (one instrument)</td>
<td>2 or 3</td>
<td>7</td>
<td>4</td>
<td>28</td>
<td>4 per organism</td>
<td>24 per organism</td>
<td>6</td>
</tr>
<tr>
<td>Example 2A: Expanded protocol (one instrument)</td>
<td>2 or 3</td>
<td>7</td>
<td>8</td>
<td>56</td>
<td>8 per organism</td>
<td>48 per organism</td>
<td>12</td>
</tr>
<tr>
<td>Example 2B: Expanded protocol (two instruments)</td>
<td>2 or 3</td>
<td>7</td>
<td>4*</td>
<td>56</td>
<td>4 per organism*</td>
<td>24 per organism*</td>
<td>6</td>
</tr>
<tr>
<td>Example 3: Viral Transport Medium (VTM) protocol</td>
<td>1</td>
<td>19</td>
<td>4</td>
<td>76</td>
<td>4 per organism</td>
<td>72 per organism</td>
<td>14</td>
</tr>
</tbody>
</table>

* Depending on the material used for verification, pooling of organisms may not be appropriate and the values in the table may need to be modified.
Performance Verification: Materials

The following materials may be needed to perform verification procedures:

<table>
<thead>
<tr>
<th>Material</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>FilmArray Respiratory Panel Pouch Kit (30 tests)</td>
<td>BioFire Diagnostics, Inc. RFIT-ASY-0105</td>
</tr>
<tr>
<td>Control Organism</td>
<td>ZeptoMetrix NATRVP-IDI*</td>
</tr>
<tr>
<td>Transport Medium (i.e. Remel M4 Viral Transport Media)</td>
<td>Various media are appropriate</td>
</tr>
</tbody>
</table>

*Any appropriate source of organism may be used for verification of any or all of the assays in the FilmArray RP system. However, when alternate organism sources are used (i.e. not the ZeptoMetrix NATRVP-IDI material), the sample volumes or pooling schemes suggested in the examples below may need to be adjusted.

Performance Verification: Organism Pooling

The Simple and Expanded protocols described below (Examples 1, 2A and 2B) utilize samples prepared by pooling together either 2 or 3 different organisms (ZeptoMetrix NATRVP-IDI control organism).

The pooling scheme (Table 2) was designed so that both positive and negative target results can be obtained in a time and resource-efficient manner.

**Note:** To obtain the expected number of positive and negative results for each assay, it is important to avoid grouping organisms that share assays in the same sample (for example, Influenza A H1 and Influenza A H3). The organism pooling schemes presented were designed with this in mind.

**Note:** Dilution of ZeptoMetrix Respiratory Verification Panel organisms beyond levels proposed in these guidelines may lead to inconsistent results and is not recommended.

Table 2. Example Organism Pooling Scheme for Simple and Expanded Protocols

<table>
<thead>
<tr>
<th>Pool 1</th>
<th>Organism</th>
<th>Approximate volume</th>
<th>Approximate Final Volume of Pool</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adenovirus</td>
<td>0.6 mL</td>
<td>1.2 mL</td>
</tr>
<tr>
<td></td>
<td>Influenza A subtype H1</td>
<td>0.6 mL</td>
<td>1.2 mL</td>
</tr>
<tr>
<td>Pool 2</td>
<td>Influenza B</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Parainfluenza virus 4</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Coronavirus OC43</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td>Pool 3</td>
<td>Human Rhinovirus/Enterovirus</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Influenza A subtype H3</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Coronavirus 229E</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td>Pool 4</td>
<td>Parainfluenza virus 1</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Parainfluenza virus 2</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Mycoplasma pneumoniae</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td>Pool 5</td>
<td>Influenza A subtype H1-2009</td>
<td>0.6 mL</td>
<td>1.2 mL</td>
</tr>
<tr>
<td></td>
<td>Parainfluenza virus 3</td>
<td>0.6 mL</td>
<td>1.2 mL</td>
</tr>
<tr>
<td>Pool 6</td>
<td>Respiratory Syncytial Virus</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Coronavirus NL63</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Human Metapneumovirus</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td>Pool 7</td>
<td>Bordetella pertussis</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Chlamydophila pneumoniae</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
<tr>
<td></td>
<td>Coronavirus HKU1</td>
<td>0.6 mL</td>
<td>1.8 mL</td>
</tr>
</tbody>
</table>
Example 1: Simple protocol for verification of one instrument

In this example, a total of 28 pouches are tested, providing 4 positive results and 24 negative results per organism. This example assumes six tests can be completed per day on an instrument (about an hour per test). The actual number should be determined by the individual laboratory. The estimated total time to completion for this verification example is 6 days.

![Diagram of pooling workflow](image)

**Figure 1.** Simple protocol workflow. Each sample pool has enough material for four tests (A-D) to assess variability from day to day and user to user. Workflow can be repeated for each sample pool until all testing is complete.

**Note:** Pool volumes of 1.2 mL (pools 1 and 5) may not have sufficient volume to pipette exactly 0.3 mL per sample mix; however, these pools are of adequate volume for detection when the volume is split between the four samples.

**Day 1**

1. Prepare three sample pools (i.e. pools #1, #2, and #3) from ZeptoMetrix NATRVP-IDI control material. An example organism pooling scheme is presented above in Table 2.
   a. Use a transfer pipette to remove the entire contents of the ZeptoMetrix organism vial (approximately 0.6 mL) and transfer to a new vial or tube.
   b. Repeat with the second (and third) organism to combine the appropriate organisms into a single vial or tube (approximately 1.2 mL total volume for two organisms or 1.8 mL for three organisms).
   c. Ensure the pooled sample is effectively mixed by vortexing prior to removing a sample for testing.

**Note:** It is important to prepare only the number of sample pools that will be tested within 3 days of preparation. The suggestion to prepare 3 sample pools is based on an average workday, testing 6 pouches per day using one instrument. The number of samples prepared may be increased or decreased based on the laboratory’s work schedule.
Note: Store samples at refrigeration temperature (2–8°C) for up to 3 days for the evaluation of day-to-day variation.

2. Prepare and test two samples (i.e. A and B, see Figure 1) from a single sample pool (i.e. pool #1). The duplicate samples should be prepared consecutively and tested in a single day. For each sample:
   a. Follow instructions in the *FilmArray Respiratory Panel Instruction Booklet* for pouch preparation and pouch hydration.
   b. Prepare Sample Mix: Use the Transfer Pipette provided with the FilmArray RP kit and draw from sample pool to between the second and third line of the pipette (approximately 0.25–0.3 mL). Add sample to the red-capped Sample Buffer vial and gently pipette up and down to mix.
   c. Follow instructions in the *FilmArray Respiratory Panel Instruction Booklet* for sample loading and FilmArray RP testing.

3. Repeat Step 2 for the remaining sample pools (i.e. pools #2 and #3) to be tested that day.

**Day 2**
To evaluate day-to-day variation, test the remaining samples (i.e. samples C and D) from the same sample pools prepared on Day 1 by repeating Step 2 above.

**Day 3**
Prepare 3 new sample pools (i.e. pools #4, #5, and #6) as described in Step 1. Test samples according to Step 2 (i.e. samples A and B).

**Day 4**
To evaluate day-to-day variation, test the samples prepared on Day 3 by repeating Step 2 (i.e. samples C and D).

**Day 5-6**
Repeat Steps 1–2 as above for any remaining sample pools (i.e. pool #7) or test material from an alternate source (i.e. clinical sample).

Note: Please see Addendum 1 for a detailed day-to-day protocol for

**Example 2A and 2B: Expanded protocol for verification of one instrument (2A) or two instruments (2B)**

The Simple protocol testing scheme (Example 1 above) is easily expanded by preparing two pouches from each vial of Sample Mix. The following Expanded scheme can be used to double the number of verification samples tested on a single instrument or it can be used to verify two instruments simultaneously.

In this Expanded protocol, a total of 56 pouches are tested. When all pouches are tested on a single instrument, this scheme provides 8 positive results and 48 negative results per organism with an estimated total time to completion of 12 days. When this scheme is used to verify two instruments, the scheme provides 4 positive results and 24 negative results per organism per instrument. The estimated time to complete this verification scheme for two instruments is 6 days. An example of the workflow is shown in Figure 2.
*Volumes are approximate. Sample mix should be split between the two pouches.

**Figure 2.** Expanded protocol workflow. Each sample pool has enough material for eight tests, two tests for each sample (A-D), to assess variability from day to day and user to user. Workflow can be repeated for each sample pool until all testing is complete.

**Note:** Pool volumes of 1.2 mL (pools 1 and 5) may not have sufficient volume to pipette exactly 0.3 mL per sample mix; however, these pools are of adequate volume for detection when the volume is split between the four samples.

**Day 1**

1. Prepare three sample pools (i.e. pools #1, #2, and #3) from ZeptoMetrix NATRVP-IDI control material. An example organism pooling scheme is presented in Table 2.
   a. Use a transfer pipette to remove the entire contents of the ZeptoMetrix organism vial (approximately 0.6 mL) and transfer to a new vial or tube.
   b. Repeat with the second (and third) organism to combine the appropriate organisms into a single vial or tube (approximately 1.2 mL total volume for two organisms or 1.8 mL for three organisms).
   c. Ensure the pooled sample is effectively mixed by vortexing prior to removing a sample for testing.

**Note:** It is important to prepare only the number of sample pools that can be tested within 3 days of preparation. The suggestion to prepare 3 sample pools is based on an average workday, testing 6 pouches per day using one instrument. The number of samples prepared may be increased or decreased based on the laboratory’s work schedule.

**Note:** The sample pools can be tested in duplicate on the same day and refrigerated (2–8°C) for up to 3 days for the evaluation of day-to-day variation.
2. Prepare two samples (i.e. A and B in Figure 2) from a single sample pool (i.e. pool #1). The samples should be prepared consecutively and tested in a single day. To prepare each Sample Mix:
   a. Use the Transfer Pipette provided with the FilmArray RP kit and draw from sample pool to between the second and third line of the pipette (approximately 0.25–0.3 mL).
   b. Add sample to the red-capped Sample Buffer vial and gently pipette up and down to mix.

3. Load two pouches using one vial of Sample Mix.

   **Note:** The total volume of the Sample Mix will be approximately 0.75–0.80mL.

   **Note:** If you will be testing samples for the verification of two instruments (Example 2B), prepare two pouches from the same vial and proceed with testing. If you will be testing two samples from the same vial on the same instrument (Example 2A), prepare and test one pouch and store the remaining Sample Mix at refrigeration temperature (2–8°C) until ready to test the second pouch.

   a. Follow instructions in the *FilmArray Respiratory Panel Instruction Booklet* for pouch preparation, pouch hydration, and sample loading.
   b. Remove the sample syringe from the first pouch and carefully return any remaining volume to the Sample Buffer vial. (This step is critical to ensure adequate volume is available for testing the second pouch.)
   c. Follow instructions in the *FilmArray Respiratory Panel Instruction Booklet* for pouch preparation and pouch hydration of a second pouch.
   d. With a new Sample Loading Syringe, draw the remaining Sample Mix into the syringe (approximately 0.3 mL). Take care to avoid the formation of bubbles. If you notice bubbles at the base of the syringe, leave the tip of the cannula in the Sample Buffer vial and dislodge the bubbles by gently tapping the side of the syringe with your finger. The bubbles will float up to the plunger.
   e. Load sample into the second pouch.

4. Test pouch(es) in the FilmArray instrument following the procedure found in the *FilmArray Respiratory Panel Instruction Booklet* (i.e. pools #1, #2, and #3 with samples A and B).

**Day 2**
To examine day-to-day variation, test the samples prepared on Day 1 by repeating Steps 2–4 of the Expanded protocol (i.e. pools #1, #2, and #3 with samples C and D; 4 pouches per pool).

**Day 3–4**
Repeat Steps 1–4 for pooled samples #4, #5, and #6.

**Day 5-6**
Repeat Steps 1–4 of the Expanded protocol as above for any remaining sample pools (i.e. pool #7) or test material from an alternate source (i.e. clinical samples).

**Note:** Please see Addendum 2 for a detailed day-to-day protocol for Example 2B: Expanded protocol for the verification of two instruments.
Example 3: VTM protocol for verification of one instrument with VTM as a sample matrix

An example organism in VTM sample preparation scheme is presented in Table 3. These samples can be stored overnight (or up to 3 days) at refrigeration temperature (2–8°C) for subsequent testing to evaluate day-to-day variation. To evaluate user-to-user variation, multiple laboratory technicians may perform testing.

Table 3. Example VTM Protocol Sample Preparation Scheme

<table>
<thead>
<tr>
<th>VTM Sample</th>
<th>Approximate volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZeptoMetrix NATRVP IDI Control Organism</td>
<td>0.6 mL</td>
</tr>
<tr>
<td>VTM</td>
<td>0.8 mL</td>
</tr>
</tbody>
</table>

**Note:** Depending on the characteristics of the organism used, mixing with VTM may not be required (i.e. clinical specimens may already be in a VTM matrix). Similarly, the volume and ratio of organism to VTM in Table 3 may not be appropriate for organisms from other sources.

Using this example protocol, a total of 76 pouches are tested providing 4 positive calls and 72 negative calls per organism. The estimated total time to completion for this verification example is 14 days.

![Diagram of VTM protocol workflow](image)

**Figure 3.** VTM protocol workflow. Each VTM Sample has enough material for four tests (A-D) to assess variability from day-to-day and user-to-user. Workflow can be repeated for each sample until all testing is complete.

**Note:** VTM Sample volumes of 1.2 mL may not have sufficient volume to pipette exactly 0.3 mL per sample mix; however, these pools are of adequate volume for detection when the volume is split between the four samples.
Day 1
1. Prepare three VTM Samples (i.e. sample #1, #2, #3) by mixing ZeptoMetrix NATRVP-IDI control material with VTM as suggested in Table 3.
   a. Use a transfer pipette to remove the entire contents of the ZeptoMetrix organism vial (approximately 0.6 mL) and transfer to a new vial or tube.
   b. Combine with approximately 0.6 mL of VTM (approximately 1.2 mL total volume for one organism in VTM).
   c. Ensure the sample is effectively mixed by vortexing prior to removing a sample for testing.

Note: It is important to prepare only the number of VTM Samples that can be tested within 3 days of preparation. The suggestion to prepare 3 samples is based on an average workday, testing 6 pouches per day using one instrument. The number of samples prepared may be increased or decreased based on the laboratory's work schedule.

Note: Store samples at refrigeration temperature (2–8°C) for up to 3 days for the evaluation of day-to-day variation.

2. Prepare and test two samples from a single 1.2 mL VTM Sample (i.e. A and B in Figure 3). The duplicate samples should be prepared consecutively and tested in a single day. For each sample:
   a. Follow instructions in the FilmArray Respiratory Panel Instruction Booklet for pouch preparation and pouch hydration.
   b. Prepare Sample Mix: Use the Transfer Pipette provided with the FilmArray RP kit and draw from VTM Sample pool to between the second and third line of the pipette (approximately 0.25–0.3 mL). Add sample to the red-capped Sample Buffer vial and gently pipette up and down to mix.
   c. Follow instructions in the FilmArray Respiratory Panel Instruction Booklet for sample loading and FilmArray RP testing.

3. Repeat Step 2 for the remaining samples to be tested that day.

Day 2
To examine day-to-day variation, test the samples prepared on Day 1 by repeating Step 2.

Day 3–4
Repeat Steps 1–2 for 3 additional samples (i.e. #4, #5, and #6).

Day 5–6
Repeat Steps 1–2 for 3 additional samples (i.e. #7, #8, and #9).

Day 7–8
Repeat Steps 1–2 for 2 additional samples (i.e. #10, #11, and #12).

Day 9–10
Repeat steps 1–2 for the remaining samples (i.e. #13, #14 and #15).

Day 11–12
Repeat steps 1–2 for the remaining samples (i.e. #16, #17, and #18).
Day 13–14
Repeat steps 1–2 for the remaining samples (i.e. #19).

Note: Please see Addendum 3 for a detailed day-to-day protocol for Example 3: VTM protocol for verification of one instrument with VTM as a sample matrix.

Verification of loaner and repaired instruments

If it becomes necessary to verify the performance of a loaner or repaired instrument, the following protocol may serve as a guideline.

1. Select a few specimens and/or proficiency samples (any combination of positives and negatives) previously tested on the FilmArray RP system. The Laboratory Director should determine the appropriate number of samples to test. Three to six samples may be sufficient. Proficiency samples should not be pooled or diluted.

2. Test the selected specimens/samples on the loaner or repaired instrument and document the results.

For additional information on this technology and other BioFire Diagnostics products, please visit us at www.BioFireDX.com or call 1-801-736-6354.
Addendum 1:

Example 1. Simple protocol for verification of one instrument.
**Addendum 2:**

*Example 2B.* Expanded protocol for the verification of two instruments.

![Diagram of pooled testing protocol](image-url)
Addendum 3:

Example 3. VTM protocol for verification of one instrument with VTM as a sample matrix.
# FilmArray® Instrument Verification Record

Instrument Serial #: ________________________________
FilmArray Respiratory Panel Kit Part #: __________________ Lot #: __________
Organism/Sample Source and Lot #: ________________________________

<table>
<thead>
<tr>
<th>Organism</th>
<th>Was the Organism Detected?</th>
<th>No. Positive</th>
<th>No. Negative</th>
<th>No. Days Tested</th>
<th>No. Users</th>
<th>Patient Samples Tested?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus</td>
<td>[ ] Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bordetella pertussis</em></td>
<td>[ ] Yes</td>
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<tr>
<td><em>Chlamydia pneumoniae</em></td>
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<tr>
<td>Coronavirus 229E</td>
<td>[ ] Yes</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Coronavirus NL63</td>
<td>[ ] Yes</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Coronavirus OC43</td>
<td>[ ] Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronavirus HKU1</td>
<td>[ ] Yes</td>
<td></td>
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<td></td>
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<tr>
<td>Human Metapneumovirus</td>
<td>[ ] Yes</td>
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</tr>
<tr>
<td>Human Rhinovirus/Enterovirus</td>
<td>[ ] Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza A subtype H1</td>
<td>[ ] Yes</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Influenza A subtype H1-2009</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Influenza A subtype H3</td>
<td>[ ] Yes</td>
<td></td>
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<tr>
<td>Influenza B</td>
<td>[ ] Yes</td>
<td></td>
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<tr>
<td><em>Mycoplasma pneumoniae</em></td>
<td>[ ] Yes</td>
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<tr>
<td>Parainfluenza virus 1</td>
<td>[ ] Yes</td>
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<tr>
<td>Parainfluenza virus 2</td>
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<tr>
<td>Parainfluenza virus 3</td>
<td>[ ] Yes</td>
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<td>Parainfluenza virus 4</td>
<td>[ ] Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Syncytial Virus</td>
<td>[ ] Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reviewed by:

Signature __________________________ Date ____________