How Do You Revolutionize Infectious Disease Testing at the Point of Care?

BD Veritor™ System
Changing the Way You View Rapid Testing
Redefine Performance

**BD Veritor™ System Revolutionizes Testing at the Point of Care**

**Accurate**

*The first CLIA-waived Digital Immunoassay (DIA), a new category of diagnostic tests where the assay and instrument work together to combine advances in detection particles, optical image recognition, and interpretation algorithms to improve accuracy.*

**Advanced Particle Technology** enhances sensitivity by using a proprietary process to produce highly stable modified colloidal metal particles, helping improve test performance.

**Adaptive Read Technology** helps improve specificity to reduce false-positive results by compensating for background and non-specific binding.

**Simple**

*Streamlined Workflow – Requires minimal hands-on time*

- Color-coded unitized tubes
- Prefilled unitized tubes facilitate workflow
- Easy sample processing
- Swab is inserted into unitized tube, processed, and removed
- Ready in minutes
- Test device is ready to insert in reader 5-10 minutes after sample is added depending on the assay
- Insert and read
- Simple one-touch button reads the reader for test device insertion

**Fast**

*Objective digitally displayed test results are ready within minutes.*
Redefine Flu A+B Test Performance at the Point of Care

Influenza – Challenges of Clinical Diagnosis

- **Clinical diagnosis alone is unreliable:** In a peer-reviewed study of symptomatic pediatric patients, clinical diagnosis by pediatricians was 38% sensitive and 91% specific.¹
- **Testing better enables appropriate treatment:** Point of care (POC) testing significantly increased appropriate use of antivirals and antimicrobials by more than 2 times vs cases where POC tests were not used.²

BD Veritor System – The First CLIA-waived Flu A+B Test Referenced Against PCR,³ a Higher Sensitivity Standard Than Culture

**High performance – BD Veritor System vs PCR, CLIA-waiver swab study**

<table>
<thead>
<tr>
<th></th>
<th>Flu A</th>
<th>Flu B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Percent Agreement (PPA)</td>
<td>82% (95% C.I. 75.9%, 86.9%)</td>
<td>80% (95% C.I. 71.9%, 85.7%)</td>
</tr>
<tr>
<td>Negative Percent Agreement (NPA)</td>
<td>98% (95% C.I. 96.2%, 99.0%)</td>
<td>99% (95% C.I. 98.1%, 99.8%)</td>
</tr>
</tbody>
</table>

- Referenced vs polymerase chain reaction (PCR) the highest sensitivity standard available
- **Wide strain coverage:** Tested successfully against 73 strains including A/Switzerland H3N2, H5N1, H5N2, and H7N9
- Cleared for use with nasopharyngeal (NP) swabs and nasal swabs – please see Product Insert

Agreement of BD Veritor System and viral culture vs PCR in BD US clinical trials³,⁴

**BD Veritor™ System Positive**

**Culture Positive**

<table>
<thead>
<tr>
<th></th>
<th>POSITIVE AGREEMENT vs PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>100%</td>
</tr>
</tbody>
</table>

For nasal swab samples—Flu A + B combined

- Positive agreement vs PCR for current visual read rapid tests ranges from 10%-70%⁵

BD Veritor™ System

Changing the Way You View Rapid Testing
Redefine Flu A+B Test Performance at the Point of Care

BD Veritor System detected approximately 24% more Flu A+B positives than a leading visually read rapid test in a recent study.6

<table>
<thead>
<tr>
<th></th>
<th>BD Veritor System</th>
<th>Leading Rapid Flu Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPA</td>
<td>89.6% 104 TP</td>
<td>72.4% 84 TP</td>
</tr>
<tr>
<td>NPA</td>
<td>98.8% 83 TN</td>
<td>100% 84 TN</td>
</tr>
</tbody>
</table>

TP = true positive
TN = true negative

• PCR yielded 116 true positives

Streamlined Workflow — Provides a digital result in <11 minutes—with <50 seconds of hands-on time

Easy sample processing
Unitized tube containing the correct volume of process reagent facilitates workflow

Ready in minutes
Test device is ready to insert into reader 10 minutes after sample is added

Insert and read
Simple one-touch button reads the reader for test device insertion

Results delivered
Once the test device is inserted in the reader, an objective, digital test result is displayed in 10 seconds


BD Diagnostics
www.bd.com/ds

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Redefine Group A Strep Test Performance at the Point of Care

Group A Strep (GAS) – A Common Bacterial Cause of Illness

- Most common bacterial cause: GAS is responsible for 5%–15% of sore throat visits in adults and 20%–30% in children.
- Clinical diagnosis alone is unreliable: Signs and symptoms of GAS and non-streptococcal pharyngitis overlap so broadly that accurate diagnosis based on clinical grounds alone is usually impossible.
- Testing better enables antimicrobial stewardship: As many as 10 million antibiotic prescriptions per year are directed toward respiratory conditions for which they are unlikely to provide benefits.

The BD Veritor™ System – The First CLIA-waived Digital Immunoassay (DIA) for the Rapid Detection of Group A Strep (GAS) With an Instrumented Result

- This digital, rather than visual, test result provides greater consistency regardless of the user’s experience.
- Reliable results available in minutes.
- High sensitivity and specificity performance was established vs bacterial culture in a multicenter clinical trial (N=692)

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Sensitivity*</th>
<th>Specificity*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Throat swab sample</td>
<td>95.4% (95% CI: 90.3%, 97.9%)</td>
<td>95.7% (95% CI: 93.7%, 97.1%)</td>
</tr>
</tbody>
</table>

*Reference method: bacterial culture; data from package insert

BD Veritor™ System
Changing the Way You View Rapid Testing
Redefine Group A Strep Test Performance at the Point of Care

Streamlined Workflow — Provides a digital result in minutes

Easy sample processing
Unitized tube containing the correct volume of process reagent facilitates workflow. Processing requires addition of 3 drops of Reagent 1 and 1-2 minutes incubation

Ready in minutes
Test device is ready to insert into reader 5 minutes after sample is added

Insert and read
Simple one-touch button reads the reader for test device insertion

Results delivered
Once the test device is inserted in the reader, an objective, digital test result is displayed in 10 seconds

Ordering Information

<table>
<thead>
<tr>
<th>Description</th>
<th>Cat. No.</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Veritor® System Reader</td>
<td>256055</td>
<td>1</td>
</tr>
<tr>
<td>BD Veritor® System Group A Strep CLIA-waived Kit</td>
<td>256040</td>
<td>30</td>
</tr>
</tbody>
</table>

References:
Redefine RSV Test Performance at the Point of Care

RSV – Challenges of Clinical Diagnosis

- Respiratory Syncytial Virus (RSV) is a virus that causes infections of the lungs and respiratory tract. It’s so common that most children have been infected with the virus by age 2
- RSV causes a substantially greater burden in young children and their families than influenza²
- Clinical diagnosis alone is unreliable: Data suggests that it is often clinically difficult to distinguish between infections from influenza A and RSV and other respiratory viruses³

BD Veritor System – The First CLIA-waived RSV Test Referenced Against a Higher Sensitivity Standard Than Culture

Agreement of BD Veritor System and viral culture vs PCR in BD US clinical trials⁴

<table>
<thead>
<tr>
<th>BD Veritor™ System Positive</th>
<th>Culture Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>POSITIVE AGREEMENT vs PCR</td>
<td></td>
</tr>
<tr>
<td>For NP swab samples—RSV</td>
<td></td>
</tr>
</tbody>
</table>

- High sensitivity and specificity performance was established vs PCR in a multicenter clinical trial (N=523)

High performance – BD Veritor System vs PCR, NP swab results⁴

<table>
<thead>
<tr>
<th>BD Veritor RSV Compared to PCR</th>
<th>Positive Percent Agreement (PPA)</th>
<th>Negative Percent Agreement (NPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP Swab Sample</td>
<td>81.6% (95% C.I: 75.2%, 86.6%)</td>
<td>99.1% (95% C.I: 97.5%, 99.7%)</td>
</tr>
</tbody>
</table>
Redefine RSV Test Performance at the Point of Care

Streamlined Workflow – Provides a digital result in less than 11 minutes with <50 seconds of hands-on time

Easy sample processing
Unitized tube containing the correct volume of process reagent facilitates workflow

Ready in minutes
Test device is ready to insert into reader 10 minutes after sample is added

Insert and read
Simple one-touch button reads the reader for test device insertion

Results delivered
Once the test device is inserted in the reader, an objective, digital test result is displayed in 10 seconds

3 results with 1 processed sample
- The same sample processed for RSV can also be used for Flu A+B

References:

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Redefine Performance

Accurate
The first Digital Immunoassay (DIA), a new category of diagnostic tests that combines advances in detection particles, optical image recognition, and interpretation algorithms to improve accuracy.

Simple
Requires minimal hands-on time with an objective, digitally displayed result.

Fast
Digital test result is delivered in minutes.

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