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


BD

Helping all people live healthy lives

# BD Veritor™ System

Changing the Way You View Rapid Testing

CLIA WAIVED

# 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

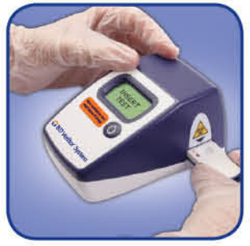
### Simple

**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 readies the reader for test device insertion

### Fast


Objective digitally displayed test results are ready within minutes.

**BD Veritor™ System**

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# 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]

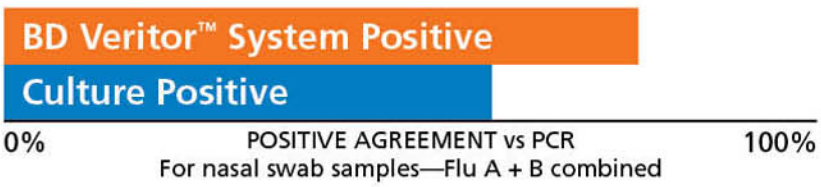
## BD Veritor System – The First CLIA-waived Flu A+B Test Referenced Against PCR,[3] a Higher Sensitivity Standard Than Culture

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

| | Flu A | Flu B |
|---|---|---|
| **Positive Percent Agreement (PPA)** | **82%** (95% C.I: 75.9%, 86.9%) | **80%** (95% C.I: 71.9%, 85.7%) |
| **Negative Percent Agreement (NPA)** | **98%** (95% C.I. 96.2%, 99.0%) | **99%** (95% C.I. 98.1%, 99.8%) |

- 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 trials[3,4]




- Positive agreement vs PCR for current visual read rapid tests ranges from 10%-70%[5]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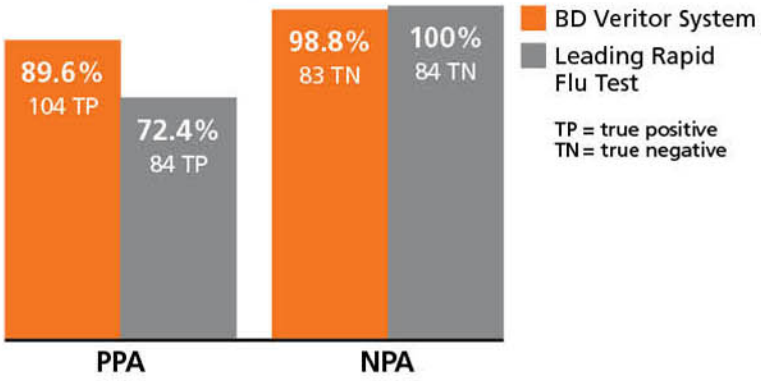
# Redefine Flu A+B Test Performance at the Point of Care

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




- PCR yielded 116 true positives

**Ordering Information**

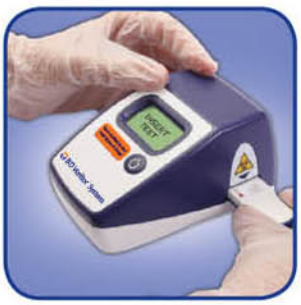
| Description | Cat. No. | Qty. |
|---|---|---|
| BD Veritor™ System Reader | 256055 | 1 |

| Description | Cat. No. | Qty. |
|---|---|---|
| BD Veritor™ System Flu A+B CLIA-waived Kit | 256045 | 30 |

## 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 readies 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

**References: 1.** Peltola V, Reunanen T, Ziegler T, Silvennoinen H, Heikkinen T. Accuracy of clinical diagnosis of influenza in outpatient children. *Clin Inf Dis.* 2005;41(8)1198-2000. **2.** Blaschke AJ, et al. A national study of the impact of rapid influenza testing on clinical care in the emergency department. *J Ped Inf Dis Soc.* 2013. **3.** BD Veritor System [package insert]. Sparks, MD: Becton, Dickinson and Company; 2012. **4.** Data on file. Becton, Dickinson and Company; 2012. **5.** Centers for Disease Control and Prevention. Guidance for clinicians on the use of rapid diagnostic tests. http://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm. Accessed February 1, 2014. **6.** Hassan F, Nguyen A, Formanek A, Bell J, Selvarangan R. Comparison of the BD Veritor™ System Flu A+B with the Alere BinaxNOW® Influenza A+B Card for detection of influenza A and B in respiratory specimens from pediatric patients. *J Clin Microbiol.* Mar 2014; 52(3): 906-910.

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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[1]
- **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[1]
- **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[2]

## 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)

| Sample Type | Sensitivity* | Specificity* |
|---|---|---|
| **Throat swab sample** | **95.4%** (95% CI: 90.3%, 97.9%) | **95.7%** (95% CI: 93.7%, 97.1%) |

*Reference method: bacterial culture; data from package insert


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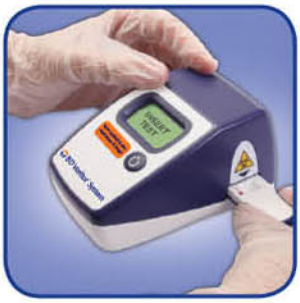
# Redefine Group A Strep Test Performance at the Point of Care

## 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 readies 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**

| Description | Cat. No. | Qty. |
|---|---|---|
| BD Veritor™ System Reader | 256055 | 1 |

| Description | Cat. No. | Qty. |
|---|---|---|
| BD Veritor™ System Group A Strep CLIA-waived Kit | 256040 | 30 |

**References: 1.** Infectious Diseases Society of America. Clinical Practice Guidelines for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America. *Clin Infect Dis.*2012. doi:10.1093/cid/cis629. **2.** Hersh AL, et al. Principles of judicious antibiotic prescribing for bacterial upper respiratory tract infections in pediatrics. *Pediatrics.*doi:10.1542/peds.2013-3260.

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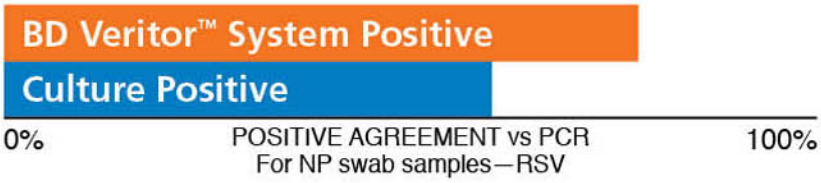
# Redefine RSV Test Performance at the Point of Care

## 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[1]
- RSV causes a substantially greater burden in young children and their families than influenza[2]
- **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 viruses[3]

## 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 trials[4]




- 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 results[4]

| BD Veritor RSV Compared to PCR | Positive Percent Agreement (PPA) | Negative Percent Agreement (NPA) |
|---|---|---|
| NP Swab Sample | **81.6%** (95% C.I: 75.2%, 86.6%) | **99.1%** (95% C.I: 97.5%, 99.7%) |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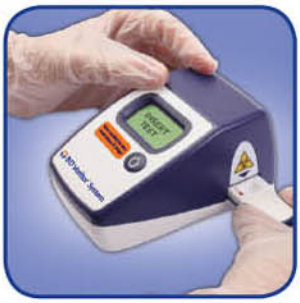
## **Streamlined Workflow** – Provides a digital result in less than 11 minutes with < 50 seconds of hands-on time

**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



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**Results delivered**
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## 3 results with 1 processed sample


- The same sample processed for RSV can also be used for Flu A+B

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| Description | Cat. No. | Qty. |
|---|---|---|
| BD Veritor™ System Reader | 256055 | 1 |

| Description | Cat. No. | Qty. |
|---|---|---|
| BD Veritor™ System RSV Kit | 256038 | 30 |

**References: 1.** Mayo Clinic staff. Respiratory syncytial virus (RSV). http://www.mayoclinic.com/health/respiratory-syncytial-virus/DS00414. Accessed February 1, 2014. **2.** Bourgeois FT, Valim C, McAdam AJ, Mandl KD. Relative impact of influenza and respiratory syncytial virus in young children. *Pediatrics*. 2009;124:e1072. **3.** Friedman MJ, Attia MW. Influenza A in young children with suspected respiratory syncytial virus infection. *Acad Emerg Med*. 2003;10(12):1400-1403. **4.** Data on file. Becton, Dickinson, and Company.

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### Simple

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


### Fast

Digital test result is delivered in minutes

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