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

BD

Helping all people live healthy lives

BD Veritor™ System

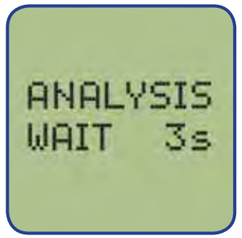
Changing the Way You View Rapid Testing

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

Changing the Way You View Rapid Testing

Redefine Flu A+B Test Performance at the Point of Care

FLU

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]

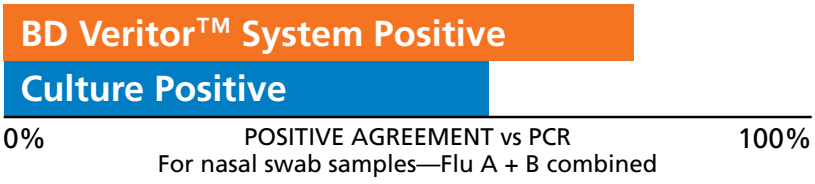
BD Veritor System – The First CLIA-waived Flu A+B Test Referenced Against PCR,[3] a Higher Sensitivity Standard Than Culture

High Performance – BD Veritor System vs PCR, nasal swab results

	Flu A	Flu B
Positive Percent Agreement (PPA)	82.1%	74.6%
Negative Percent Agreement (NPA)	98.6%	99.6%

- Referenced vs polymerase chain reaction (PCR) the highest sensitivity standard available
- **Wide strain coverage:** Tested successfully against 59 strains including multiple strains of H3N2v and the novel H7N9[3]
  - Also cleared for use with nasopharyngeal (NP) swabs – please see Product Insert

Agreement of BD Veritor System and viral culture vs PCR in BD US clinical trials[3]



- Positive agreement vs PCR for current visual read rapid tests ranges from 10%-70%[4]

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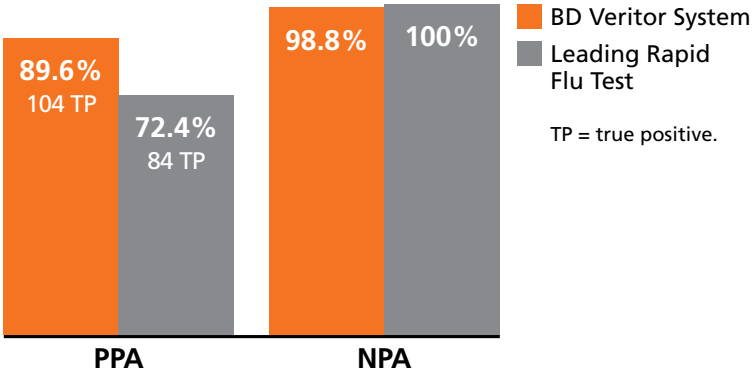
Redefine Flu A+B Test Performance at the Point of Care

BD Veritor System detects over 24% more Flu A+B positives than a leading visually read rapid test[5]



- 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.** 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. **5.** 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.* 2014: epub ahead of print.

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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

GROUP A STREP

BD Veritor™ System

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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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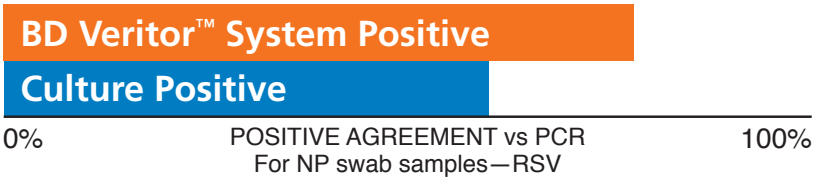
Redefine RSV Test Performance at the Point of Care

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 (PPA)
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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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 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

3 results with 1 processed sample

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

Ordering Information

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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Redefine Performance

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

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Fast
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