

BD Veritor™ Plus System Frequently Asked Questions for Pharmacies

A. What is the BD Veritor™ Plus System?

The BD Veritor™ Plus System is a digital immunoassay (DIA), which is a category of testing that provides lab-quality test results for point-of-care testing within minutes.

B. What tests can be performed on the BD Veritor™ Plus System?

1. Influenza (FLU) A + B
2. Group A Strep (GAS)
3. Respiratory Syncytial Virus (RSV)

Note: some states may have requirements regarding who can order diagnostic laboratory tests which should be taken into consideration before adopting the BD Veritor™ Plus System in your pharmacy.

C. What type of documentation is required for HIPAA?

Pharmacies can develop their own patient log and tracking system for test results. Pharmacies should already have policies and procedures established to protect the confidentiality of patient information. Any new documentation log or tracking system should be compliant with the site's HIPAA policies and procedures. Remember that some states may have laws that require more stringent privacy protection for patients that may exceed the requirements under HIPAA.



Log Sheet Example:

BD Veritor™ Plus System

for Rapid Detection of Flu A&B

Lab Name:

Log Sheet

For Recording Patient Results

	DATE	PATIENT NAME	TEST RESULTS (@ 10 Minutes)	Kit Lot Number & Expiration Date	Technician
1					
2					
3					
4					

D. What type of training is available for new customers?

BD offers online instructional training videos for the Veritor™ Plus System, and a customer support hotline.

BD Veritor™ Plus System website:

bd.com/ds/VeritorSystem

Customer Support Hotline:

800.638.8663

E. How does a pharmacy obtain a CLIA waiver?

The rules for this certification vary by state, and each state has its own agency that pharmacies must work with to get CLIA-certified.

The links below provide information on how to become CLIA - certified. At the bottom of the page, under downloads (CLIA state agency contacts) is a list of agencies that provide the certification in each state. All questions need to be directed to these state agencies.

How to become CLIA waived:

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

Agencies that provide CLIA certification in each state:

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.PDF

Once the pharmacy receives their CLIA waiver number, it must include it on any payment request submitted to insurance companies, Medicare or Medicaid for reimbursement.

F. Can a pharmacy perform mobile testing if they are CLIA-waived?

Yes, a CLIA waiver can be granted to vehicles used for mobile testing purposes. Please check the CMS website for specific information about the state requirements where the pharmacy is located for additional information:

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html

G. How much can a pharmacy charge to perform a test on the BD Veritor™ Plus System?

There are two ways that pharmacies can generate revenue by performing tests on the BD Veritor™ Plus System.

1. Pharmacies can charge cash for the tests performed.

- a. We have seen pharmacies charge anywhere from \$15 to \$66 per test. Each pharmacy will need to determine the appropriate cash price for their location.

2. Pharmacies can bill insurance companies and Medicare for tests performed.

- a. BD does not provide coding or reimbursement guidance or recommendations regarding its products due to the complexities involved and autonomy of more than 1,000 payer entities in the U.S. Accordingly, BD strongly recommends that you consult with your payers, reimbursement specialist(s) and/or legal counsel regarding coding, coverage, and payment for the BD Veritor™ System. CPT® codes which may be applicable to billing for INFLUENZA, RSV, and GROUP A STREP immunoassay tests, such as the BD Veritor™ Plus System, include:

CPT Code	Description	Modifiers
87804	Infectious agent antigen detection by immunoassay with direct optical observation; influenza	-QW -59
87807	Infectious agent antigen detection by immunoassay with direct optical observation; RSV	-QW
87880	Infectious agent antigen detection by immunoassay with direct optical observation; Group A Strep	-QW

- b. The tests listed above with the modifiers are FDA cleared CLIA waived tests. In order to bill a CLIA item, a pharmacy must be CLIA certified.

- c. To bill a test, each pharmacy bills insurance, Medicaid or Medicare to other tests such as blood glucose strips (medical benefit). On the payment submission form, they need to include the CPT code with the modifier and their CLIA certification # for payment.
- d. BD Veritor FLU A+B, RSV, and Group A STREP tests may be covered by Medicare, Medicaid and a majority of commercial insurance plans using the CPT billing codes.
- e. The 2018 National Medicare average reimbursement for Flu A, Flu B with immunoassay is \$16.55, and Strep A with immunoassay is \$16.53. Please check with your individual state for actual reimbursement rates.

H. How many tests (on average) are performed per store in the retail clinics where BD Veritor™ Plus System is available today?

The average number of tests performed can vary depending on the following:

- How active the respiratory season is
- If pediatric patients are routinely seen in the retail clinic
- The location of the individual retail clinic

I. If a pharmacy is CLIA-waived, can anyone in the pharmacy perform the test?

Applicable state and local personnel regulations must be met. Training on the BD Veritor™ Plus System is available online via the BD instructional videos or in-person by a BD representative.

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bd.com/ds/VeritorSystem

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