**PRINCIPLE**

The BD Veritor System Reader is an optoelectronic instrument that used a reflectance-based measurement method to evaluate the signal intensities on the assay test strip, and a specific algorithm to determine the presence or absence of any target analyte(s).

The reader determines the line intensity at each of the spatially-defined test and control line positions, interprets the results using a scoring algorithm, and reports a positive, negative, or invalid result based on pre-set thresholds.

**READER EXPIRATION**

The reader is designed to have a finite lifetime. The expiration date is determined by one of the following:

* Number of tests performed = 3000 tests maximum
* Number of months from first use = a minimum of 22 months upto a maximum of 24 months
* Maximum shelf-life from the date of manufacture = 34 months

**MATERIALS AND EQUIPMENT**

**Materials:** BD Veritor System for Rapid Detection of Flu A&B

Flocked Swabs

 Transport tubes

**Equipment:** BD Veritor System Reader

 Two AA 1.5V non-rechargeable LR6 alkaline batteries

**STORAGE**

The BD Veritor Reader should be stored at 15-30ºC.

**CALIBRATION**

A Verification Cartridge is supplied to allow the user to perform a functional test on the reader. A verification test counts as one test on the reader’s maximum allowed number of tests.

The Verification Test is performed each day of use

Performing verification test

1. Place BD Veritor System Reader on a flat, dry, stable surface.
2. Press the front panel power button. The BD Veritor Reader must complete a 5 second self-test before it is ready to use.
3. When the display window reads **INSERT TEST**, remove the BD Veritor System Verification cartridge from the pouch and insert into the slot on the right side of the reader, aligning the insertion arrow on the cartridge with the insertion arrow on the reader. Insert the cartridge all the way in until it stops and “clicks”.
4. The display will show remaining read time (10 seconds) as the read is performed. Do not remove or touch the cartridge during this time.
5. When the read is complete, the test result will be displayed as one of the two following messages:

**QC PASS**

**QC FAIL**

1. If the message **QC PASS** appears, the reader may be used to test specimens.

If the message **QC FAIL** appears, the reader may not be used to test specimens and must be replaced.

**Contact BD Technical Services at (800) 638-8663 for assistance**.

1. Return the BD Veritor System Verification Cartridge to the resealable pouch for the next use.

**TEST PROCEDURE**

1. Place the BD Veritor Reader on a flat, dry, stable surface.
2. Ensure that the Reader is not in direct sunlight or exposed to a bright light.
3. Press the front panel power button. The Reader must complete a 5 second self-test before it is ready to use.
4. When the display window reads **INSERT TEST**, insert the BD Vertitor System device into the slot on the right side of the reader, aligning the insertion arrow on the device with the insertion arrow on the reader. Insert the device all the way in until it stops and “clicks”.
5. The display will show the remaining read time as the read is performed. **Do not touch** the BD Veritor System Reader or remove the BD Veritor test kit device during this time.
6. When the read is complete, the test result will be displayed with the name of the test and a “+” or “-“ symbol to indicate a positive or negative test.
7. Remove the device by pulling it out. The display will change to **INSERT TEST** to indicate the reader is ready to perform another read.
8. After the tests are read, turn off the power by pressing the front panel power button. If the reader is left unattended for 5 minutes, the power will turn off automatically and the test result will not be retained.

**MAINTENANCE**

 **Battery Installation –** Requirestwo AA 1.5V non-rechargeable LR6 alkaline batteries

1. Using slight thumb pressure, slide the battery door, located on the bottom of the reader, toward the front. Remove the door.
2. Remove the existing batteries and discard.
3. Install the new batteries. Ensure that the polarity orientation is correct.
4. Reinstall the battery door.

 **Cleaning**

 The outer case and display may be wiped with clean towel lightly moistened with 70% isopropyl alcohol,

 Sani-Cloth,10% bleach solution, or mild soap solution. Do not use a saturated towel which may introduce liquid

 into the case oer display seams.

**WARNINGS AND PRECAUTIONS**

* **Do not use** after expiration date.
* Dispose of used BD Veritor System Test Kit Devices as biohazardous waste.
* Dispose of expired BD Veritor System Readers as biohazardous waste and according to local environmental electronic waste disposal regulations.
* “Standard Precautions” for the handling of biohazardous materials should be followed in handling all items contaminated with blood and other body fluids.
* Wear laboratory coats, gloves, and eye protection when specimens are processed. FLU tests should be processed in a Biological Safety Cabinet if available.
* Humidity and temperature can adversely affect results; therefore, operate the BD Veritor system Reader indoors at room temperature (15-30ºC)
* Ensure that the BD Veritor System Reader is not in direct sunlight or exposed to a bright light.
* The BD Veritor System Reader is designed for use only with BD Veritor System Test Kit Devices. Do not insert any foreign materials into the BD Veritor Reader.

**REFERENCES**

Package Insert, “BD Veritor System Reader” L010108(01) 2011/11, Becton, Dickinson and Company, Sparks MD 21152

800-638-8663

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| **Date:** | **Author:** | **Date:** | **Validated by:** | **Date:** | **Approved by:** |
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| **Annual Review** |
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