

Quick Reference Guide for BD Veritor™ Strep A CLIA waived kit cat no. 256040

# BD Veritor™ System for Rapid Detection of Group A Strep

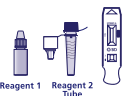
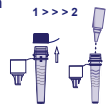

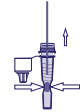

## Throat Swab Test Procedure R<sub>x</sub> Only

Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test.

**For Questions and Technical Support call 1-800-638-8663.**

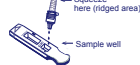


A Certificate of Waiver is required to perform this test in a CLIA waived setting. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived category.

### I. Sample preparation steps 1-5 are shared by all instrument configurations:




- 1** Gather materials and label with specimen ID.  

- 2** Remove caps from GAS Reagents 1 and 2. Add 3 drops of Reagent 1 to Reagent 2 tube. Mix.  

- 3** Incubate swab in Reagent 2 tube for 1-2 min. Then plunge and scrub up and down for at least 15 sec. Avoid splashing.  

- 4** Remove swab while squeezing tube to extract liquid.  

- 5** Press the dispensing tip on the tube firmly.  


### II. Before continuing to step 6, choose from the instrument and work flow configurations below:

#### A Reader or Analyzer in Analyze Now mode

- 6** Add 3 drops of the processed sample to the device.  

- 7** Time test development for 5 minutes.  

- 8** Power on instrument with a **single click** and insert device when prompted.  

- 9** Record result and remove device.

#### B Analyzer in Walk Away mode

- 6** Click once to power on, wait for prompt then **double-click** to start WalkAway mode.  

- 7** Add 3 drops of the processed sample to the device.  

- 8** Insert device to start timing and analysis. **Do not touch/keep level.**  

- 9** Record result and remove device - Analyzer returns to Analyze Now mode.

### INTERPRETATION OF RESULTS

**Test results must NOT be read visually.** The BD Veritor Instrument (purchased separately) must be used for all interpretation of test results. Refer to table at right.

**Positive Test Results** – Strep A antigen present; does not rule out co-infection with other pathogens.

**Negative Test Results** – Negative results are presumptive and it is recommended that these results be confirmed by culture or an FDA-cleared Strep A molecular test. If outside the U.S., a molecular test assay cleared for diagnostic use in the country of use may be utilized. Negative test results do not preclude Group A *Streptococcus* infection and should not be used as the sole basis for treatment or other patient management decisions.

**Invalid Test** – If the test is invalid, the BD Veritor System Instrument will display a “CONTROL INVALID” result and the test or control must then be repeated.

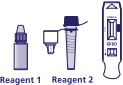




Display	Interpretation
STREP: +	Positive Test for Strep A (Strep A antigen present)
STREP: -	Negative Test for Strep A (no antigen detected)
CONTROL INVALID	Test Invalid. Repeat the test.

# BD Veritor™ System for Rapid Detection of Group A Strep

Throat Swab Test Procedure R<sub>x</sub> Only


With the Addition of an Optional InfoScan or InfoSync module

## I. Sample preparation steps 1-5 are shared by all instrument configurations:

- 1** Gather materials and label with specimen ID. 
- 2** Remove caps from GAS Reagents 1 and 2. Add 3 drops of Reagent 1 to Reagent 2 tube. Mix. 
- 3** Incubate swab in Reagent 2 tube for 1-2 min. Then plunge and scrub up and down for at least 15 sec. Avoid splashing. 
- 4** Remove swab while squeezing tube to extract liquid. 
- 5** Press the dispensing tip on the tube firmly. 

## II. Before continuing to step 6, choose from the work flow configurations below:

### C Analyzer in **Analyze Now** mode + InfoScan/Sync

- 6** Add 3 drops of the processed sample to the device. 

- 7** Time test development for 5 minutes. 

- 8** Power on with **single click** and insert device when prompted. 


- 9** Scan required bar codes to start analysis. 

- 10** Record result and remove device.

### D Analyzer in **Walk Away** mode + InfoScan/Sync

- 6** Click once to power on, wait for prompt then **double-click** to start WalkAway mode. 

- 7** Scan required bar codes. 

- 8** Add 3 drops of the processed sample to the device. 

- 9** Insert device to start timing and analysis. **Do not touch/keep level.** 

- 10** Record result and remove device - Analyzer returns to Analyze Now mode.

**QUICK REFERENCE GUIDE:** This test is CLIA-waived for direct testing of throat swab specimens. A Certificate of Waiver is required to perform this test in a CLIA waived setting. Follow manufacturer's instructions. Any modifications to the test procedure instructions will result in the test no longer meeting the requirements for waived category and will be subject to all applicable CLIA requirements. See reverse side of this card for interpretation of results.

#### SPECIMEN COLLECTION AND HANDLING:

1. For *in vitro* Diagnostic use.
2. Proper specimen collection and handling is required to ensure accurate results (see enclosed specimen collection guide). Specimens should be tested within 8 hours of collection if stored at room temperature or 72 hours if stored at 2-8 °C. Additional training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Handle all specimens and materials as if capable of transmitting infectious agents.
3. Dispose of used materials as biohazardous waste according to federal, state and local requirements.
4. Ensure ALL components are at room temperature (15-30 °C) when running the test.



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2016-04

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