Procedure* BD Veritor™ System For Rapid Detection of Group A Strep
For use with throat swab specimens.

Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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***Any modifications to this document are the sole responsibility of the facility. This "Sample Procedure" is not intended as a substitute for your facility procedure manual, instrument manual, or reagent labeling/package insert. This "Sample Procedure" is intended as a model for use by your facility to meet the needs of your laboratory.**

BD Veritor™ System

8087675(08)

CLSI For Rapid Detection of Group A Strep

INTENDED USE

The **BD Veritor** System for Rapid Detection of Group A Strep is a rapid chromatographic immunoassay for the direct and qualitative detection of Group A Streptococcus antigen from throat swabs of symptomatic patients. It is intended to be used in conjunction with the **BD Veritor** System Reader as an aid in the diagnosis of Group A Strep. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment.

The **BD Veritor** System for Rapid Detection of Group A Strep test is intended for use in point-of-care or laboratory settings.

SUMMARY AND EXPLANATION

Streptococcus pyogenes is a gram-positive coccus, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] Traditional identification procedures for group A streptococcal infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3]

Rapid diagnosis and early antibiotic therapy of group A streptococcal infection appear to be the best means of preventing medical complications and reducing the spread of the disease.[4] The **BD Veritor** System for Rapid Detection of Group A Strep is a digital immunoassay to qualitatively detect the presence of Strep A antigen in throat swab specimens from symptomatic patients, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield group A *Streptococcus* to selectively detect Strep A antigen.

All **BD Veritor** System Strep A test devices are interpreted by a **BD Veritor** System Instrument, either a **BD Veritor** Reader or **BD Veritor** Plus Analyzer (the "Analyzer"). When using an Analyzer, procedures to evaluate test devices depend on the workflow configuration chosen. In **Analyze Now mode**, the instrument evaluates assay devices after manual timing of their development. In **Walk Away mode**, devices are inserted immediately after application of the specimen, and timing of assay development and analysis is automated. Additionally, connection of an Analyzer to a printer or IT system is possible if desired. Additional result documentation capabilities are possible with the integration of a **BD Veritor** InfoScan ("InfoScan") or **BD Veritor** InfoSync ("InfoSync") module. Please refer to the Analyzer *Instructions for Use* for details on how to implement these features. InfoSync is not available in all regions.

PRINCIPLES OF THE PROCEDURE

The **BD Veritor** System for Rapid Detection of Group A Strep is a qualitative, digital immunoassay for the detection of Strep A antigen in a throat swab. In this test, antibody specific to Strep A antigen is coated on the test line region of the Assay device. During testing, the processed throat swab specimen reacts with an antibody to Strep A that is conjugated onto detector particles. The mixture migrates up the membrane and is captured by the line of antibody on the membrane. A positive result for Strep A is determined by the **BD Veritor** System Instrument when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the **BD Veritor** System Strep A assay device. The instrument analyzes and corrects for non-specific binding and detects positives not recognized by the unaided eye to provide an objective digital result.

REAGENTS

The following components are included in the **BD Veritor** System for Rapid Detection of Group A Strep (GAS) kit:

BD Veritor System Group A Strep Devices	30 devices	Foil pouched device containing one reactive strip. Each strip has one test line of polyclonal antibody specific to Strep A antigen and a positive control line containing purified Strep A antigen.
BD GAS Reagent 1	Bottle with 4 mL reagent	Dilute acetic acid solution
BD GAS Reagent 2	30 tubes with 200 µL reagent	Sodium nitrite and EDTA
Individually packaged swabs, sterile	30 each	Swab for throat specimen collection
Positive Control Swab	1 each	Strep A Positive Control Swab (purified Strep A antigen) with < 0.1% sodium azide (preservative)
Negative Control Swab	1 each	Strep A Negative Control Swab with < 0.1% sodium azide (preservative)

Materials Required But Not Provided: BD Veritor™ System Reader (Cat. No. 256055) or **BD Veritor™** Plus Analyzer (Cat. No. 256066), Timer, Tube Rack for specimen testing

Optional Equipment: BD Veritor™ InfoScan Module (Cat. No. 256068), **BD Veritor™** InfoSync Module (Cat. No. 256067), USB Printer Cable for **BD Veritor™** Analyzer (Cat. No. 443907), Epson Printer model TM-T20 II.

Warnings and Precautions:

Warning

H302 Harmful if swallowed. **H401** Toxic to aquatic life. **H315** Causes skin irritation.

P270 Do not eat, drink or smoke when using this product. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P302+P352** IF ON SKIN: Wash with plenty of soap and water. **P403** Store in a well-ventilated place. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

1. For *in vitro* Diagnostic Use.
2. Test results are not meant to be visually determined. **All test results must be determined using the BD Veritor System Instrument**.
3. Pathogenic microorganisms, including hepatitis viruses, and Human Immunodeficiency Virus may be present in clinical specimens.[5] "Standard Precautions"[5-8] and institutional guidelines should be followed in handling, storing and disposing of all specimens and all items contaminated with blood and other body fluids.
4. Dispose of used **BD Veritor** System test devices as biohazardous waste in accordance with federal, state and local requirements.
5. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. Contact with acids produces very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
6. Only use the reagents provided with the kit for preparation. Do not mix components from different kit lots.
7. Other than the swabs that are used for specimen collection, kit components should not make contact with the patient.
8. Do not use kit components beyond the expiration date.
9. Do not reuse the device.
10. Do not use the kit if the Positive Control Swab and Negative Control Swab do not yield appropriate results.
11. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
12. To avoid erroneous results, swab specimens must be processed as indicated in the assay procedure section.
13. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

Caution: GAS Reagent 1 may cause skin, eye and respiratory tract irritation. **GAS Reagent 1** contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water. The combination of **GAS Reagent 1** and **Gas Reagent 2** generates nitrous acid which may cause skin, eye and respiratory tract irritation. If this solution contacts the skin or eye, flush with large volumes of water.

Storage and Handling: Kits may be stored at 2–30 °C. DO NOT FREEZE. **Reagents and devices must be at room temperature (15–30 °C) when used for testing.**

SPECIMEN COLLECTION AND HANDLING

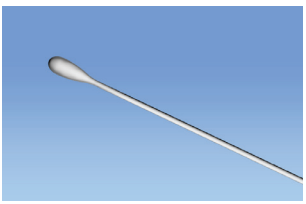
Specimen Collection:

For optimal performance, collect the throat swab with the swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Excess blood or mucus on the swab specimen may interfere with test performance. Avoid touching the tongue, cheeks and teeth[9] and any bleeding areas of the mouth with the swab when collecting specimens.

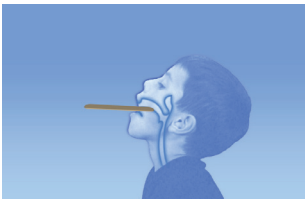
Specimen Transport and Storage:

Testing should ideally be performed immediately after the specimens have been collected. Swab specimens may be stored in clean, dry plastic tubes for up to 8 hours at room temperature or 48 hours at 2–8 °C. Supplied kit swabs can be transported in Stuart's or Modified Amies Liquid Medium and stored for up to 48 hours. Nylon swabs can be transported in **BD™** ESwab transport medium and be stored up to 48 hours. If a culture is desired, lightly roll the swab tip onto a blood agar plate **before** using the swab in the **BD Veritor** System for Rapid Detection of Group A Strep.

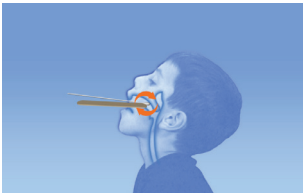
1. The **BD Veritor** System Group A Strep Kit includes sterile swabs with a rayon tip for throat specimen collection.



2. Have the patient open his or her mouth. Depress the tongue completely with a tongue depressor.



3. Swab the posterior pharynx,tonsils, and other infl amed areas. Avoid touching the tongue, cheeks, and teeth with the swab.



4. Withdraw the swab from the mouth. The sample is now ready for processing using the **BD Veritor** System Group A Strep Kit.

DOs and DON'Ts of Sample Collection

- Do collect sample as soon as possible after onset of symptoms
- Do test sample immediately
- BD recommends flocked swabs which are provided in the **BD Veritor** System Flu A+B Kit
- Do not use swabs with cotton tips and wood shafts
- Do not use calcium alginate swabs

PROCEDURE

Throat Swab Test Procedure

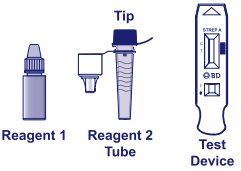
NOTE: Reagents, specimens and devices must be at room temperature (15–30 °C) for testing. The **BD Veritor** System instrument should be powered-on prior to use and will indicate when it is ready for insertion of the **BD Veritor** System Group A Strep device.

Prepare for testing

The following steps assume that users of a BD Veritor Plus Analyzer have chosen and set all configuration options, and that the Analyzer is ready to use. To choose or change these settings, see the BD Veritor Plus Analyzer *Instructions for Use*, section 4.7. A printer is not necessary to display results. However, if your facility has chosen to connect the BD Veritor Plus Analyzer to a printer, check that the printer is plugged into a power source, paper supply is adequate and any necessary network connections are enabled before testing.

Step 1 – Prepare for testing

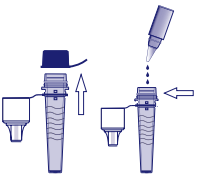
- Immediately before testing, for each control swab or patient specimen, take the bottle of **GAS Reagent 1** and one **GAS Reagent 2** tube/tip and one **BD Veritor** Group A Strep device from its foil pouch.
- Label one **BD Veritor** System device and one **GAS Reagent 2** tube for each control or specimen to be tested.
- Place the labeled **GAS Reagent 2** tube(s) in the designated area of the workstation or rack.



Prepare the Sample

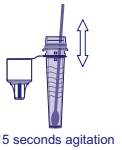
Step 2

- Remove the cap from the **GAS Reagent 2** tube corresponding to the sample to be tested.
- Remove the cap from the **GAS Reagent 1** bottle and add **3 drops** from the **GAS Reagent 1** bottle to the **GAS Reagent 2** tube. **GAS Reagent 2** contains a pH sensitive dye which turns from blue to yellow to confirm the addition of **GAS Reagent 1**. A uniform yellow color indicates complete mixing of the reagent. If any blue color remains, mix the solution by gently swirling the tube.



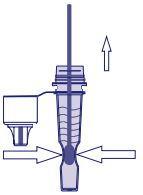
Step 3

- Insert the specimen or control swab and incubate for **1–2** minutes, then plunge the swab up and down for a minimum of **15** seconds, scrubbing inside the tube with the swab. Avoid splashing.



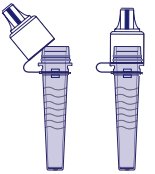
Step 4

- Remove the swab while squeezing the sides of the tube to extract the liquid.



Step 5

- Snap fit the tip onto the tube containing the processed specimen or control (threading/twisting not required).
- Note: Do not use tips from any other product, including other products from BD or other manufacturers.



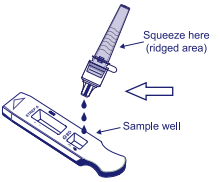
After step 5, choose from the model and workflow option below before continuing to step 6:				
	BD Veritor Reader or Analyzer in **Analyze Now** mode	**BD Veritor** Plus Analyzer in **Walk Away** mode	**BD Veritor** Plus Analyzer with either InfoScan or InfoSync module In **Analyze now** mode---or---**Walk Away** mode	
Instructions in section:	**A**	**B**	**C**	**D**

A Using a BD Veritor Reader or Analyzer in "*Analyze Now*" mode:

Step 6A: Adding the specimen

- Invert the tube and hold the tube vertically (approximately one inch above the labeled **BD Veritor** System Strep A device sample well).
- Gently squeeze the ridged body of the tube, dispensing three **(3) drops** of the processed specimen into the sample well of a labeled **BD Veritor** System Strep A device.

NOTE: Squeezing the tube too close to the tip may cause leakage.

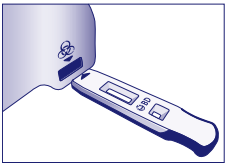


Step 7A: Timing development

- After adding the sample, allow the test to run for **5** minutes before inserting into the **BD Veritor** Instrument.
- **NOTE**: If running test under laminar flow hood or in an area with heavy ventilation, cover test device to avoid inconsistent flow.

Step 8A: Using the BD Veritor Instrument

- During incubation time, turn the **BD Veritor** Instrument on by pressing the power button once.
- Insert assay device when 5 minute assay development time is complete.
- Follow the on-screen prompts to complete the procedure. The status of the assay analysis process appears in the display window.



Step 9A: Record the Result

- When analysis is complete, the test result appears in the display window.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 60 minutes (if the AC power adapter is connected).

B

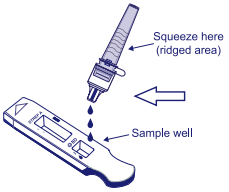
Using a BD Veritor Plus Analyzer in *"Walk Away" mode:* (with no optional module installed)

To use **Walk Away mode** – connect the AC power adapter to the Analyzer and a power source

Step 6B: **Starting Walk Away mode**

- Turn the Analyzer on by pressing the blue power button once.
- When the display window reads:
  "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE,"
  – **Double-click** the blue power button.

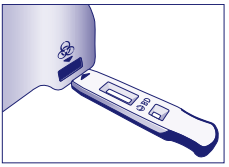
Step 7B: Add the specimen to the test device



- When the display window reads "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY":
  – Invert the tube, holding it vertically (approximately one inch above the **BD Veritor** System Strep A device sample well).
  – Gently squeeze the ridged portion of the tube, allowing three **(3) drops** of the processed specimen to dispense into the sample well of a labeled **BD Veritor** System Strep A device.

NOTE: Squeezing the tube close to the tip may cause leakage.

Step 8B: Start the development and reading sequence



- Immediately insert the test device into the slot on the right side of the Analyzer.
  The test device must remain horizontal to prevent spilling the specimen out of the sample well.
- "DO NOT DISTURB TEST IN PROGRESS" appears in the display window. Automatic timing of the assay development, image processing and result analysis begins.
- A countdown timer in the display window shows the remaining analysis time.
- **Do not touch the Analyzer or remove the test device during this process. Doing so will abort the assay analysis.**

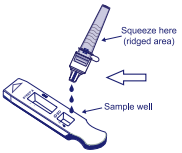
Step 9B: Record the Result

- When analysis is complete, the test result appears in the display window.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 60 minutes (if the AC power adapter is connected).

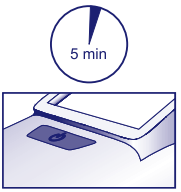
C Using an Analyzer In "*Analyze Now*" mode: with InfoScan or InfoSync module installed

Step 6C: Add the specimen to the test device



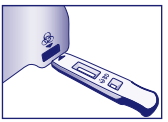
- Invert the tube, holding it vertically (approximately one inch above the **BD Veritor** System Group A Strep device sample well).
- Gently squeeze the ridged body of the tube, dispensing three **(3) drops** of the processed specimen into the sample well of a labeled **BD Veritor** System Group A Strep A device. **NOTE: Squeezing the tube close to the tip may cause leakage.**

Step 7C: **Timing development**



- Allow the test to develop for **5** minutes. BD recommends the use of a digital timer or stopwatch.
- If running the test in a laminar flow hood or in an area with heavy ventilation, cover test device to avoid inconsistent flow.

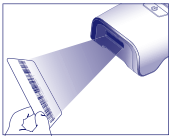
Step 8C: Using the BD Veritor Plus Analyzer



During the incubation time, turn the BD Veritor Plus Analyzer on by pressing the blue button once.

- The display window will briefly display "SCAN CONFIG BARCODE." This is an opportunity to change the configuration of the Analyzer. Please refer to the Analyzer *Instructions for Use* for configuration instructions. Ignore this message and postpone this process when an assay is awaiting analysis.
- When assay development time is complete and the Analyzer display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE":
  - Insert the **BD Veritor** System Group A Strep device into the **BD Veritor** Plus Analyzer.

Step 9C: Using the Bar Code scanner



- Follow the prompts on the display window to complete any required barcode scans of:
  - OPERATOR ID
  - SPECIMEN ID and/or
  - KIT LOT NUMBER

According to site requirements and Analyzer setting

- **Prompts for each scanning step appear in the display window for only 10 seconds. Failure to complete scans during that time will cause the Analyzer to default to the beginning of step 8C. To restart this step, remove and reinsert the test device to initiate a new sequence.**
- **Move the barcode slowly toward the window until a confirmation tone sounds. The scanned barcode value appears in the next display window.**
- **The Analyzer can record the kit Lot Number in the test record but does not restrict the use of expired or inappropriate reagents. Management of expired materials is the responsibility of the user. BD recommends against the use of expired materials.**

After required scans are completed, the Analyzer displays a countdown timer and test analysis begins.

- **Do not touch the Analyzer or remove the test device during this process. Doing so will abort the assay analysis.**
- When analysis is complete, a result appears in the display window. If configured to display, the specimen ID barcode value also appears. If a printer is connected, specimen ID and result are automatically printed.

If a printer is not connected, record the result before removing the assay device.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 15 minutes (60 minutes if the AC power adapter is connected).

Step 10C: Remove the test device

- Pull the device out. The display will show INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE to indicate the Analyzer is ready to perform another test. Note that the Analyzer returns to Analyze Now mode at the conclusion of each read sequence.

If an InfoSync module is installed the ENVELOPE symbol will appear to indicate that results are transmitting.

- In the event that the **BD Veritor** Plus Analyzer does not detect adequate cellular network strength while the ENVELOPE symbol is still displayed, it will queue all results to be transmitted and continuously attempt to transmit them. If it is powered off during this time, it will attempt to transmit as soon as power is restored.

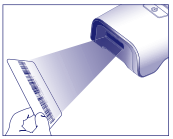
D Using an Analyzer In "*Walk Away*" mode: with InfoScan or InfoSync module installed

To use Walk Away mode - connect the AC power adapter to the Analyzer and a power source

Step 6D: **Starting Walk Away mode**

- Turn the Analyzer on by pressing the blue power button once.
- The display window will briefly display "SCAN CONFIG BARCODE." This is an opportunity to change the configuration of the Analyzer. Please refer to the Analyzer *Instructions for Use* for configuration instructions. Ignore this message and postpone this process when an assay is awaiting analysis.
- When the display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE"
  - **Double-click** the blue power button.

Step 7D: Using the Bar Code scanner

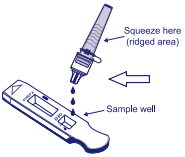


- Follow the prompts on the display window to complete any required barcode scans of:
  - OPERATOR ID
  - SPECIMEN ID and/or
  - KIT LOT NUMBER

According to site requirements and Analyzer setting

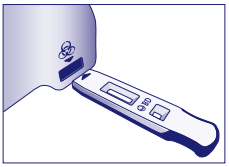
- **Prompts for each scanning step appear in the display window for only 10 seconds. Failure to complete scans during that time will cause the Analyzer to default to the beginning of step 6D. To restart this step, double-click the power button.**
- **Move the barcode slowly toward the window until a confirmation tone sounds. The scanned barcode value appears in the next display window.**
- **The Analyzer can record the kit Lot Number in the test record but does not restrict the use of expired or inappropriate reagents. Management of expired materials is the responsibility of the user. BD recommends against the use of expired materials.**

Step 8D: Add the specimen to the test device:



- When the display window reads: "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY":
  - Invert the tube, holding it vertically (approximately one inch above the **BD Veritor** System Group A Strep device sample well).
  - Gently squeeze the ridged portion of the tube, allowing three **(3) drops** of the processed specimen to dispense into the sample well of a labeled **BD Veritor** System Group A Strep A device. **NOTE: Squeezing the tube close to the tip may cause leakage.**

Step 9D: Start the development and reading sequence



- Immediately insert the test device into the slot on the right side of the Analyzer. **The test device must remain horizontal to prevent spilling the specimen out of the sample well.**
- DO NOT DISTURB TEST IN PROGRESS appears in the display window. Automatic timing of the assay development, image processing and result analysis begins.
- A countdown timer in the display window shows the remaining analysis time.

Do not touch the Analyzer or remove the test device during this process. Doing so will abort the assay analysis.

- When analysis is complete, a result appears in the display window. If configured to display, the specimen ID barcode value also appears. If a printer is connected, specimen ID and result are automatically printed. **IF a printer is not connected, note the result before removing the assay device.**

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 60 minutes (if the AC power adapter is connected).

Step 10D: Remove the test device

- Pull the device out. The display will show INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE to indicate the Analyzer is ready to perform another test. Note that the Analyzer returns to Analyze Now mode at the conclusion of each read sequence.

If an InfoSync module is installed the ENVELOPE symbol will appear to indicate that results are transmitting.

- In the event that the **BD Veritor** Plus Analyzer does not detect adequate cellular network strength while the ENVELOPE symbol is still displayed, it will queue all results to be transmitted and continuously attempt to transmit

them. If it is powered off during this time, it will attempt to transmit as soon as power is restored.

INTERPRETATION OF RESULTS

Due to the technologies incorporated in the **BD Veritor** System, operators should not attempt to interpret assay results visually from the test strip contained within the **BD Veritor** System Strep A assay device. The **BD Veritor** System Instrument must perform interpretation of results of all **BD Veritor** Assays.

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

Invalid Test If the test is invalid, the **BD Veritor** System Instrument will display "CONTROL INVALID" and the test or control must then be repeated. If "CONTROL INVALID" reading results, contact BD.

REPORTING OF RESULTS

Positive Test Positive for the presence of Strep A antigen. A positive result may occur in the absence of viable bacteria.

Negative Test Negative for the presence of Strep A antigen. Infection due to Strep A cannot be ruled-out because the antigen present in the sample may be below the detection limit of the test. **Culture confirmation of negative samples is recommended.**

Invalid Test Test result is inconclusive. Do not report results.

QUALITY CONTROL:

ATTENTION: To document kit quality control procedures (QC) using the BD Veritor Plus Analyzer

To utilize the Analyzer's QC documentation capability, specimen barcode scanning must be enabled on an Analyzer equipped with either an InfoScan or InfoSync module. Please refer to the Analyzer *Instructions for Use*, section 4, to choose or change this configuration.

Each **BD Veritor** System Group A Strep device contains both positive and negative internal/procedural controls:

1. The internal positive control validates the immunological integrity of the device, proper reagent function, and verifies correct test procedure.
2. The membrane area surrounding the test lines functions as a background check on the assay device.

The BD Veritor System Instrument evaluates the positive and negative internal/procedural controls after insertion of the BD Veritor System test device. The BD Veritor System Instrument will prompt the operator should a quality issue occur. Failure of the internal/procedural controls will generate an invalid test result. NOTE: The internal controls do not assess proper sample collection.

External Positive and Negative Controls:

Strep A Positive and Strep A Negative control swabs are supplied with each kit to ensure that the test reagents work properly and that the test procedure is performed correctly. **Prepare and test kit control swabs using the same workflow procedure as used for patient specimen swabs.**

Your laboratory's standard Quality Control procedures and applicable local, state and/or federal regulations or accreditation requirements dictate the performance of external quality control procedures.

BD recommends controls be run once for:

- each new kit lot,
- each new operator,
- each new shipment of test kits,
- and at periodic intervals as required by your facility.

If the kit controls do not perform as expected, do not report patient results. Contact BD Technical Services at 1.800.638.8663.

LIMITATIONS OF THE PROCEDURE

1. This test will indicate the presence of Strep A antigen in the throat swab specimen from both viable and non-viable group A *Streptococcus* bacteria. It does not determine the qualitative concentration of Strep A antigen.
2. Respiratory infections can be caused by Streptococci of serogroups other than A as well as other pathogens. This test does not differentiate between carriers and infected individuals.
3. Excess blood or mucus on the swab specimen may interfere with test performance.
4. Avoid touching the tongue, cheeks, and teeth[9] and any bleeding areas of the mouth with the swab when collecting specimens.
5. False negative results can occur from inadequate or improper specimen collection, or from antigen levels that are below the limit of detection for this test.

6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. As recommended by the American Academy of Pediatrics, patients with symptoms and an antigen negative test should have a follow-up culture.[10]
8. The use of antibiotics or over-the-counter medications may suppress the growth of Group A *Streptococcus* in culture despite the presence of organisms detectable by rapid antigen tests.

EXPECTED VALUES

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by group A beta-hemolytic *Streptococcus*.[11] In school-aged children and adults, the incidence of Strep throat infection is about 40%.[12] This disease usually occurs in the winter and early spring in temperate climates.[3]

Analytical Studies

Analytical Sensitivity (Limit of Detection)

The limit of detection for *Streptococcus pyogenes* was established with the **BD Veritor** System for Rapid Detection of Group A Strep test. The limit of detection (LOD) is defined as the lowest concentration that produces an approximate 95% positive reaction when tested with 60 replicates.

Strain	LOD (CFU/mL)	Results	% Positivity
12384	1×10^5	57/60 Positive	95.0%
19615	5×10^4	58/60 Positive	96.7%
25663	2×10^5	57/60 Positive	95.0%

Analytical Specificity (Cross Reactivity)

The reactivity of various Streptococcal strains was determined with the **BD Veritor** System for Rapid Detection of Group A Strep test. Lancefield Groups B, C, D, F and G were tested at 1×10^9 CFU/mL in triplicate and yielded negative results.

Various microorganisms (including bacteria and yeasts) that might be found in specimens were evaluated for potential cross reactivity with the **BD Veritor** System for Rapid Detection of Group A Strep test. Of the microorganisms tested, none demonstrated cross-reactivity with the **BD Veritor** System for Rapid Detection of Group A Strep test.

Microorganism Name	Concentration Tested
Arcanobacterium haemolyticum	1×10^9 CFU/mL
Bordetella pertussis	5×10^8 CFU/mL
Candida albicans	1×10^9 CFU/mL
Corynebacterium diphtherium sp. *(Corynebacterium* sp.*)*	1×10^9 CFU/mL
Enterococcus faecalis	1×10^9 CFU/mL
Enterococcus faecium	1×10^9 CFU/mL
Escherichia coli	1.5×10^9 CFU/mL
Fusobacterium necrophorum	1×10^9 CFU/mL
Haemophilus influenzae	1×10^9 CFU/mL
Haemophilus parahemolyticus	1.2×10^5 CFU/mL
Haemophilus parainfluenzae	1×10^9 CFU/mL
Klebsiella pneumoniae	1.5×10^9 CFU/mL
Lactobacillus sp. *(Lactobacillus casei)*	1×10^9 CFU/mL
Moraxella catarrhalis	1×10^9 CFU/mL
Moraxella lacunata	1×10^9 CFU/mL
Mycobacterium tuberculosis avirulent	5×10^6 CFU/mL
Neisseria gonorrhoeae	1×10^9 CFU/mL
Neisseria lactamica	1×10^9 CFU/mL

Microorganism Name	Concentration Tested
Staphylococcus haemolyticus	1×10^9 CFU/mL
Staphylococcus oralis	1×10^9 CFU/mL
Staphylococcus sanguis	1×10^9 CFU/mL
Streptococcus anginosus	1×10^9 CFU/mL
Streptococcus mitis	1×10^9 CFU/mL
Streptococcus mutans ATCC 25173	3×10^9 CFU/mL
Streptococcus pneumoniae	1×10^9 CFU/mL
Streptococcus salivarius	1×10^9 CFU/mL
Streptococcus sp. Group B	1×10^9 CFU/mL
Streptococcus sp. Group C	1×10^9 CFU/mL
Streptococcus sp. *(bovis* II*)* Group D	1×10^9 CFU/mL
Streptococcus sp. Group F	1×10^9 CFU/mL
Streptococcus sp. Group G	1×10^9 CFU/mL
Yersinia enterocolitica	1×10^9 CFU/mL
Adenovirus Type 1	1.6×10^6 $TCID_{50}$/mL
Adenovirus Type 7	2.81×10^5 $TCID_{50}$/mL
Cytomegalovirus	8.9×10^3 $TCID_{50}$/mL
Enterovirus (VR-28 Human Coxsackievirus)	8.9×10^6 $TCID_{50}$/mL

Microorganism Name	Concentration Tested
Neisseria meningitidis	1 x 10^9 CFU/mL
Neisseria mucosa	1 x 10^6 CFU/mL
Neisseria sicca	1 x 10^9 CFU/mL
Neisseria subflava	1 x 10^9 CFU/mL
Proteus vulgaris	1 x 10^9 CFU/mL
Pseudomonas aeruginosa	1 x 10^9 CFU/mL
Serratia marcescens	1 x 10^9 CFU/mL
Staphylococcus aureus	1 x 10^9 CFU/mL
Staphylococcus epidermidis	1 x 10^9 CFU/mL

Microorganism Name	Concentration Tested
Epstein Barr Virus	N/A
HSV Type 1 (HF)	8.89 x 10^6 $TCID_{50}$/mL
Human coronavirus OC43	2.81 x 10^4 $TCID_{50}$/mL
Human metapneumovirus (HMPV-27 A2)	2.8 x 10^6 $TCID_{50}$/mL
Human parainfluenza	2.8 x 10^6 $TCID_{50}$/mL
Measles	1.6 x 10^4 $TCID_{50}$/mL
Mumps virus	1.6 x 10^5 $TCID_{50}$/mL
Respiratory syncytial virus VR-26	1.6 x 10^7 $TCID_{50}$/mL
Rhinovirus	2.8 x 10^6 $TCID_{50}$/mL

Interfering Substances

Various substances were evaluated for potential interference with the **BD Veritor** System for Rapid Detection of Group A Strep test at concentrations comparable to or greater than levels that may be present in patient respiratory samples. Of the substances tested in this study, none exhibited interference when either Group A positive or Group A negative samples were tested with the **BD Veritor** System for Rapid Detection of Group A Strep test.

Substance	Concentration Tested
4-Acetamidophenol	10 mg/mL
Acetylsalicylic acid	20 mg/mL
Albuterol	0.083 mg/mL
Amantadine	500 ng/mL
Ascorbic acid chewable tablets	5% by weight
Beclomethasone	500 ng/mL
Benzocaine throat spray (Cepacol)	5% by volume
Blood, type A	2% (v/v)
Blood, type B	2% (v/v)
Blood, type AB	2% (v/v)
Blood, type O	2% (v/v)
Budesonide	500 ng/mL
Chlorpheniramine maleate	5 mg/mL
Dexamethasone	10 mg/mL
Dextromethorphan	10 mg/mL
Dyclonine HCl lozenges (Sucrets)	5% w/v
Diphenhydramine HCl	5 mg/mL
Fexofenadine	500 ng/mL
FluMist™	1% v/v
Fluticasone	500 ng/mL
Guaiacol Glyceryl Ether	20 mg/mL
Ibuprofen	10 mg/mL
Loratidine	100 ng/mL

Substance	Concentration Tested
Menthol Throat Lozenges	5% w/v
Mometasone	500 ng/mL
Mouthwash Listerine	5% (v/v)
Mouthwash Scope	5% v/v
Mouthwash CVS	5% v/v
Mucin, salivary protein, purified	1 mg/mL
Nasal Spray	5% v/v
Nasal Spray	5% v/v
Nasal Spray	5% v/v
Oseltamivir	500 ng/mL
Oxymetazoline	0.05 mg/mL
Phenol throat spray (Chloraseptic)	5% v/v
Phenylephrine	1 mg/mL
Pseudoephedrine HCl	20 mg/mL
Throat drops: CVS	5% w/v
Throat drops: Pedia Care	5% w/v
Throat drops: Triaminic	5% w/v
Tobramycin	500 ng/mL
Triamcinolone	500 ng/mL
Zanamivir	1 mg/mL
Zicam throat spray (Zn / benzalkonium chloride)	5% v/v
Zinc Lozenges	5% w/v

Using risk analysis as a guide, analytical flex studies were conducted. The studies demonstrated that the test is insensitive to stresses of environmental conditions and potential user errors.

Technical Support

Technical Information: In the United States, contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com. Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800 FDA-1088; fax: 1-800 FDA-1078: or http://www.fda.gov/medwatch).

AVAILABILITY

Cat. No.	Description
256040	**BD Veritor™** System for Rapid Detection of Group A Strep, 30 tests
220093	**BD BBL™ CultureSwab™** Liquid Amies, 50 Single Swabs
220099	**BD BBL™ CultureSwab™** Liquid Stuart, 50 Single Swabs
220105	**BD BBL™ CultureSwab™** Liquid Amies, 50 Double Swabs
220109	**BD BBL™ CultureSwab™** Liquid Stuart, 50 Double Swabs
256049	**BD Veritor™** System Group A Strep Control Swab Set, 10 pairs of swabs
220245	**BD™** ESwab Regular Collection Kit – White polypropylene screw-cap tube filled with 1 mL of Liquid Amies Medium and one regular size flocked applicator swab, 50 units
220246	**BD™** ESwab Minitip Collection Kit – Green polypropylene screw-cap tube filled with 1 mL of Liquid Amies Medium and one minitip flocked applicator swab, 50 units
220532	**BD™** ESwab Flexible Minitip Collection Kit – Blue polypropylene screw-cap tube filled with 1 mL of Liquid Amies Medium and one flexible minitip flocked applicator swab, 50 units
256055	**BD Veritor™** System Reader
256066	**BD Veritor™** Plus Analyzer,
256067	**BD Veritor™** InfoSync Module
256068	**BD Veritor™** InfoScan Module
443907	USB Printer Cable for **BD Veritor™** Analyzer

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Technical Information: In the United States, contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.