Strep A Rapid Test
Package Insert

REF VIST-702/VIST-701	English

INTENDED USE

The VivaDiag™ Strep A Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Strep A antigen in human throat swab samples. It is intended to be for auxiliary diagnosis of group A hemolytic streptococcus infection. For *in vitro* diagnostic use only.

SUMMARY

Streptococcus pyogenes is non-motile gram-positive cocci, 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 Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3,4]

The VivaDiag™ Strep A Rapid Test is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

PRINCIPLE

The VivaDiag™ Strep A Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. The test device/strip consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-Group A Streptococcus monoclonal antibody conjugated with colloid gold (Strep A Ab conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with another anti-Group A Streptococcus monoclonal antibody, and the C line is pre-coated with a goat anti-rabbit IgG.
When an adequate volume of test specimen is dispensed into the sample well of the device/strip, the specimen migrates by capillary action across the device/strip. The Strep A Antigen, if present in the specimen will bind to the Strep A Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-Group A Streptococcus monoclonal antibody reagent, forming a burgundy colored T band, indicating a Strep A positive test result.
The test contains an internal control (C line) which should exhibit a burgundy colored band of the immunocomplex of the control antibodies regardless of the color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device/strip.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- All specimens should be considered capable of transmitting disease. Take appropriate precautions when collecting, handling, storing, and disposing of patient samples and used kit contents. And follow biosafety guidelines.
- Wear appropriate personal protective equipment (e.g. gown, gloves, goggles) when handling the contents of this kit.
- Proper sample collection, storage, and transportation are critical to the performance of this test.
- Discard after first use. This test cannot be used multiple times.
- Do not touch the reaction area of the test device/strip.
- Do not use expired kits.
- Do not use the kit if the bag is punctured or poorly sealed.
- Reagent 2 contains an acidic solution. If the solution comes into contact with skin or eyes, flush with plenty of water.
- Do not interchange Reagent bottle caps.
- Do not interchange external control solution caps.
- Do not smoke, eat or drink in the testing area.
- Testing should be performed by professionally trained personnel working in an accredited laboratory or clinic and samples should be collected by qualified medical personnel.
- Test results should be interpreted by a physician along with clinical findings and other laboratory test results.
- Disposal of diagnostic reagents: All specimens and used kits carry a risk of infection. Disposal of diagnostic reagents must comply with local infectious disease disposal laws or laboratory regulations.

COMPOSITION

Materials provided
1. Test device/strip in foil bags
2. Sterile Swab
3. Test tube
4. Tube tip
5. Tube stand
6. Reagent 1
7. Reagent 2
8. Package insert

Materials required but not provided
1. Timer
2. Personal protective equipment, such as protective gloves, medical masks, lab coats, etc.
3. Appropriate biohazardous waste containers and disinfectants.

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 2-30°C. Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 15-30°C.
- Do not use beyond the expiration date. (printed on the foil pouch and box).

Note: *All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.*

SPECIMEN COLLECTION AND HANDLING

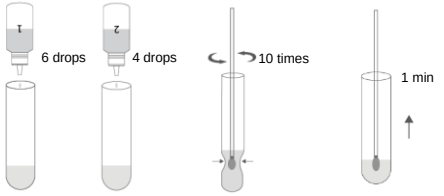
1) Specimen collection
- Collect a throat swab sample using the sterile swab provided in the kit. Use a sterile swab to wipe the posterior pharynx, tonsils, and other surrounding inflamed areas, avoiding contact with the tongue, inner cheeks, and teeth. Transport swabs containing modified Stuart or Amies medium can also be used for sample collection.

2) Specimen handling
- Testing is recommended when taking a throat swab sample. If testing cannot be performed immediately, throat swab samples should be stored in a clean, dry, airtight container for 8 hours at room temperature and 72 hours at 2-8°C.
- If culture is required, throat swab samples should be transferred to Group A Selective (GAS) blood agar plates for culture.

TEST PROCEDURE

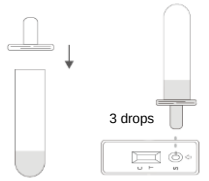
Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

1. Remove the test device/strip from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Holding the Reagent 1 bottle vertically, add 6 full drops (approximately 240 µL) of Reagent 1 to the test tube. Holding the bottle of Reagent 2 vertically, add 4 full drops (approximately 160 µL) to the tube..
3. Collect specimen refer to **Specimen Collection**.
4. Immediately add the throat swab to the solution test tube. Agitate the throat swab in the tube 10 times, then leave it in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.



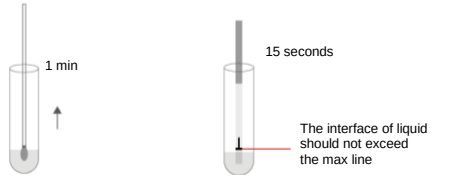
5. **For Device:**

- Install the tube tip on top of the test tube. Place the test device on a clean and level surface. Add 3 full drops of solution (approx. 100 µL) to the specimen well (S) and then start the timer.



6. **For Strip:**

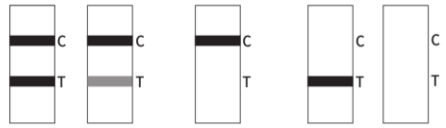
- Put the end of the test strip print with arrow into the sample, the interface of liquid should not exceed the max line, take it out and place the test strip on a clean and level surface after 15 seconds.



7. Wait for the red line(s) to appear. Read the result **at 5 minutes**. Do not read the results after 10 minutes.

Note:
- *Handle buffer with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.*
- *Please follow local regulations to handle the used materials.*

INTERPRETATION OF TEST RESULTS



Positive Negative Invalid

Positive*; Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

**Note: The intensity of the color in the test line region (T) may vary depending on the concentration of Strep A Antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.*

Negative: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

Invalid; Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control
- Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control
- In addition to your laboratory's standard quality control procedures, it is recommended that a positive external control be tested at least once within each test kit and by each operator performing testing within a kit. This will verify that the reagents and test devices/strips are working properly and the operator is able to correctly perform the test procedure. External positive controls are supplied in the kit.

LIMITATIONS

- The VivaDiag™ Strep A Rapid Test is intended for professional in vitro diagnostic use only for the qualitative detection of Strep A antigen in throat swab samples.
- A positive VivaDiag™ Strep A Rapid Test only indicates the presence of Strep A antigen in the sample and should not be used as the sole criterion for diagnosing Group A hemolytic streptococcus infection.
- Negative results should be confirmed by culture. A negative result may be obtained if the concentration of Strep A antigen present in the throat swab is insufficient or below the detectable level of the test.
- Excessive blood or mucus on the swab sample may interfere with test performance and may produce false positive results.
- As with all diagnostic tests, a doctor can only make a definitive diagnosis after evaluating all clinical and laboratory findings.

PERFORMANCE

1. Accuracy

The VivaDiag™ Strep A Rapid Test compared to Culture Method using 247 specimens was shown as below:

VivaDiag™ Strep A Rapid Test	Culture Method		
	Positive	Negative	Total
Positive	48	3	51
Negative	2	197	199
Total	50	200	250
Sensitivity	96.00% (48/50,95% CI: 96.29%-99.51%)		
Specificity	98.50% (197/200,95% CI: 95.68%-99.69%		
Accuracy	98.00% (245/250,95% CI: 95.39%-99.35%)		

2. Cross-Reactivity

There was no cross-reaction with potential cross-reactive substances. The following organisms were tested at 1 × 10^7 organisms/swab and showed negative results.

Potential cross-reactive substances	Potential cross-reactive substances	Potential cross-reactive substances
Bordetella pertussis	*Group G Streptococcus*	*Serratia marcescens*

Branhamella catarrhalis	*Hemophilus influenza*	*Staphylococcus aureus*
Candida albicans	*Klebsiella pneumoniae*	*Staphylococcus epidermidis*
Corynebacterium diphtheria	*Neisseria sicca*	*Streptococcus mutans*
Enterococcus faecalis	*Neisseria gonorrhea*	*Streptococcus pneumoniae*
Group B Streptococcus	*Neisseria meningitidis*	*Streptococcus sanguis*
Group C Streptococcus	*Neisseria subflava*	/
Group F Streptococcus	*Pseudomonas aeruginosa*	/

3. Interfering Substances

There was no interference for potential interfering substances listed below.

Interfering substance	Concentration in specimen	Interfering substance	Concentration in specimen
4-Acetamidophenol	10 mg/mL	Benzocaine throat spray (Cepacol)	5% by volume
Menthol Throat Lozenges	5% w/v	Blood, type A	2% (v/v)
Acetylsalicylic acid	20 mg/mL	Blood, type B	2% (v/v)
Albuterol	0.083 mg/mL	Blood, type AB	2% (v/v)
Amantadine	500 ng/mL	Blood, type O	2% (v/v)
Mometasone	500 ng/mL	Dexamethasone	10 mg/mL
Mouthwash Listerine	5% (v/v)	Dextromethorphan	10 mg/mL
Mouthwash Lion	5% (v/v)	Diphenhydramine HCl	5 mg/mL
Ascorbic acid chewable tablets	5% by weight	Ibuprofen	10 mg/mL
Beclomethasone	500 ng/mL	Mucin	1 mg/mL
Nasal Spray	5% v/v	Oseltamivir	500 ng/mL
Oxymetazoline	0.05 mg/mL	Phenylephrine	1 mg/mL
Zanamivir	1 mg/mL	Tobramycin	500 ng/mL

4. Reproducibility

The reproducibility study is performed by two Production Technicians in production technology lab, two QC Technicians in QC lab and one R&D Technician in R&D lab respectively for four concentration levels with each concentration of sample repeated 5 times on each lot totally three lots of test devices/strips used, and tested once a day for five days. The intra-assay agreements were 100%. The inter-site agreement was 100%.

5. Hook Effect

Sample containing as high as 5×10^6 organisms/mL of Strep A can still test positive. The tests do not show a Hook or Prozone Effect up to the maximal observed physiological concentration (5×10^8 organisms/mL).

REFERENCES

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2. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574-83.
3. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
4. Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
5. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta haemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Paediatrics (June 1999), 38: 357-360.,.
6. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

INDEX OF SYMBOLS

	Consult instructions for use		Use by		Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

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CE
IVD

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