

Lab Name:

Procedure #:

Procedure: CLIA Complexity: Waived

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2.

Quidel Corporation provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

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INTENDED USE

The QuickVue Dipstick Strep A is intended for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. The test is to be used to aid in the diagnosis of Group A Streptococcal infection. For use by healthcare professionals.

SUMMARY AND EXPLANATION

Group A *Streptococcus* is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and serious complications such as rheumatic fever and glomerulonephritis.¹ Conventional identification procedures for Group A *Streptococcus* from throat swabs involve the isolation and subsequent identification of viable pathogen techniques that require 24 to 48 hours or longer for results.²

PRINCIPLE OF THE TEST

The QuickVue Dipstick Strep A is a lateral-flow immunoassay utilizing Quidel's patented antibody-labeled particles. The test detects either viable or nonviable organisms directly from throat swabs or culture colonies within 5 minutes.

To perform the test, a throat swab specimen is collected. Antigen is extracted from the swab specimen with Reagents A and B. The Dipstick is then added to the extracted sample.

If the sample contains Strep A antigen, a pink-to-purple Test Line along with a blue procedural Control Line will appear on the Dipstick, indicating a positive result. If Strep A antigen is not present, or present at very low levels, only a blue procedural Control Line will appear.

REAGENTS AND MATERIALS SUPPLIED

Each kit contains:

- Individually packaged Dipsticks (25 or 50): Dipsticks coated with rabbit polyclonal anti-Group A Streptococcus
- Extraction Reagent A (1): Contains 4 M sodium nitrite

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- Extraction Reagent B (1): Contains 0.2 M acetic acid
- Sterile Throat Swabs (25 or 50)
- Tubes (25 or 50)
- Positive Control (1): Heat-inactivated Group A *Streptococcus* with 0.2% sodium azide
- Negative Control (1): Heat-inactivated Group C *Streptococcus* with 0.2% sodium azide
- Package Insert (1)
- Procedure Card (1)

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use beyond the expiration date printed on the outside of the box.
- Dispose of containers and used contents in accordance with Federal, State and Local requirements.
- The Dipstick must remain sealed in the protective foil pouch until just prior to use.
- Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- Use of nitrile or latex gloves is recommended when handling the extraction reagents within this kit.^{3,4}
- Do not interchange reagent bottle caps.
- If Reagent B is green prior to mixing with Reagent A in the Tube, do not use and contact Technical Support.
- To obtain accurate results, you must follow the package insert instructions.

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KIT STORAGE AND STABILITY

Store the kit at room temperature 59–86°F (15–30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

SPECIMEN COLLECTION AND STORAGE

Collect throat swab specimens by standard clinical methods. Consult standard reference procedures such as the collection method described by Miller and Holmes.⁵ Depress the tongue with a tongue blade or spoon. When swabbing the throat, be careful not to touch the tongue, sides or top of the mouth with the swab. Rub the swab on the back of the throat, on the tonsils and in any other area where there is redness, inflammation or pus.

Use rayon tipped swabs to collect throat specimens. Do not use calcium alginate, cotton tipped or wooden shaft swabs.

It is recommended that swab specimens be processed as soon as possible after collection. Swabs can be held in any clean, dry plastic tube or sleeve up to 72 hours at room temperature (15–30°C), or refrigerated (2–8°C) before processing. The use of charcoal or agar medium is not recommended.

If a culture is desired, lightly streak the swab on a 5% sheep blood agar plate before using the swab in the QuickVue Dipstick Strep A test. Do not perform the QuickVue Dipstick Strep A test before streaking the swab, as the Extraction Solution will destroy the bacteria on the swab, thereby rendering the organism incapable of successful culturing. Alternatively, throat swab specimens can be obtained by dual swabs or by two sequential swabs for the culture procedure.

CULTURE CONFIRMATION

The QuickVue test can be used to confirm the identification of Group A Streptococcus on blood agar plates. Lightly touch a colony using a sterile swab. Do not sweep the plate. Follow the instructions in the TEST PROCEDURE section to test the swabs.

QUALITY CONTROL

Built-in Control Features

The QuickVue Dipstick Strep A provides three levels of internal procedural controls with each test run. For daily quality control, Quidel recommends documenting that these internal controls were checked for the first sample tested each day.

- The color of the Extraction Reagent changes from clear to green as the reagents are mixed together. The color change is an internal extraction reagent control and is an indication that the reagents were mixed and functioning properly.

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- The appearance of a blue Control Line is an internal control. The Dipstick must absorb the proper amount of sample and the Dipstick must be working properly for the blue Control Line to appear. Additionally, the appearance of the Control Line indicates that capillary flow occurred.
- A clear background is an internal background negative control. If no interfering substances are in the sample and the Dipstick is working properly, the background in the Result area should be white to light pink within 5 minutes and not interfere with the reading of the test result.

External Quality Control Testing

External controls may also be used to demonstrate that the reagents and assay procedure perform properly.

Quidel recommends that positive and negative controls be run once for each untrained operator, once for each new shipment of kits - provided that each different lot received in the shipment is tested - and as deemed additionally necessary by your internal quality control procedures, and in accordance with local, state, and federal regulations or accreditation requirements.

If the controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens.

ASSAY PROCEDURE

- Do not remove Dipsticks from the foil pouch until ready to perform the assay.
- To avoid cross contamination, do not allow the tip of the reagent bottles to come in contact with sample swabs.

TEST PROCEDURE

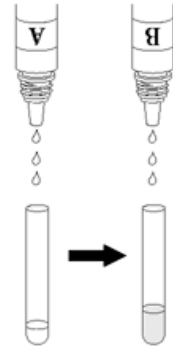
Important:

- *Gloves should be worn when handling samples.*
- *Do not use Reagent B if the solution is green prior to mixing with Reagent A in the Tube. If this occurs, contact Technical Support.*

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1. Just before testing, add **three (3) DROPS** of Reagent A and **three (3) DROPS** of Reagent B into a clean tube. This solution should turn **green**.

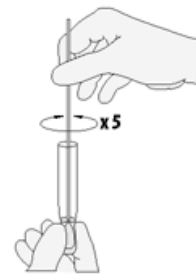
When adding drops, hold bottle vertically so that a complete drop forms.



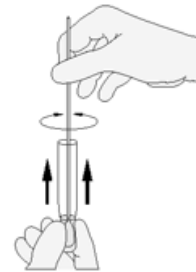
2. Immediately add the patient swab sample to the tube. **Squeeze** the bottom of the tube so the swab head is compressed. Rotate the swab a **minimum of five (5) times**.



Keep swab in tube for one (1) minute.



3. Express **all** liquid from the swab against the inside of the tube. **Squeeze** the swab firmly as it is removed from the tube. Discard the swab.



4. Remove the Dipstick from the foil pouch. Place the Dipstick into the tube with the arrows of the Dipstick pointing down. Do not handle or move the Dipstick until the test is complete and ready for reading.



5. Read result at five (5) minutes. Some positive results may appear sooner.



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INTERPRETATION OF RESULTS

POSITIVE RESULT:

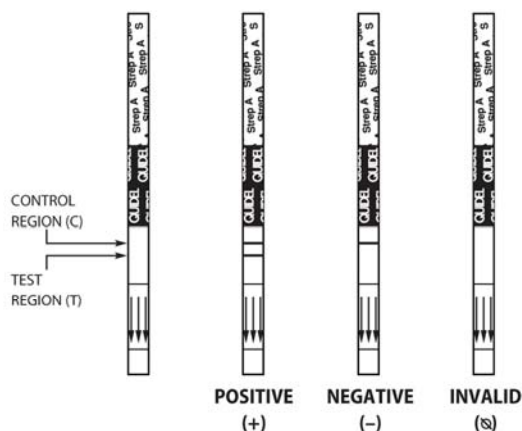
Any pink to purple Test Line along with any shade of a blue procedural Control Line is a positive result for the detection of Group A *Streptococcus* antigen.

NEGATIVE RESULT:

A blue procedural Control Line and no pink Test Line is a presumptive negative result.

INVALID RESULT:

The test result is invalid if a blue Control Line is not visible at 5 minutes. If this occurs, retest using a new sample and a new Dipstick or contact Technical Support.



QC TESTING PROCEDURE

- Follow the instruction procedures in the TEST PROCEDURE to dispense the Extraction Reagents into the tube (step 1).
- Vigorously mix the Control Bottles. Add one (1) drop of the Negative or Positive Control into the tube.
- Place a clean swab into the tube and follow the instructions for testing the patient swab.

LIMITATIONS

The contents of this kit are for use in the **qualitative** detection of Group A Streptococcal antigen from throat swab specimens and culture colonies only. Failure to follow the test procedure and interpretation of test results may adversely affect performance and/or produce invalid results.

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The test detects both viable and nonviable Group A *Streptococci* and may yield a positive result in the absence of living organisms.

Respiratory infections, including pharyngitis, can be caused by *Streptococcus* from serogroups other than Group A as well as other pathogens. The QuickVue Dipstick Strep A will not differentiate asymptomatic carriers of Group A *Streptococcus* from those exhibiting Streptococcal infection.⁶

Some commercial controls may contain interfering additives and are not recommended for use in the QuickVue test.

Test results must always be evaluated with other data available to the physician. A negative test result might occur if the level of extracted antigen in a sample is below the sensitivity of the test or if a poor quality specimen is obtained. Additional follow-up testing using the culture method is recommended if the QuickVue test result is negative.

EXPECTED RESULTS

It is believed that approximately 19% of all upper respiratory tract infections are caused by Group A *Streptococci*.⁷ Infection is most prevalent in winter and early spring, with most cases arising in patients living in highly populated areas.

PERFORMANCE CHARACTERISTICS

Field Study

In a multi-center field evaluation, a total of 329 throat swab specimens were collected from patients presenting with pharyngitis. Each swab was inoculated onto a sheep blood agar plate, then tested by the QuickVue Dipstick Strep A test. Plates were incubated for 24–48 hours at 37°C with a Bacitracin disk. Presumptive GAS colonies were confirmed with commercially available Strep A testing kits.

Of the 329 total specimens, 192 were negative and 137 were positive by culture. The QuickVue test identified 188 of the culture negative and 126 of the culture positive for a specificity of 98% and a sensitivity of 92%. The 95% confidence intervals were calculated to be 95%–99% for specificity and 86%–96% for sensitivity. Overall agreement between culture and the QuickVue Dipstick Strep A test was 95%. These study results demonstrate that no statistical differences were observed between the QuickVue test and standard culture techniques.

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	Culture +	Culture -
QuickVue +	126	4
QuickVue -	11	188
Total	137	192

Sensitivity: 126/137 = 92%

Specificity: 188/192 = 98%

Agreement: 314/329 = 95%

Culture Classification	QuickVue Results
Total Negative Specificity	188/192 (98%)
Rare	1/3 (33%)
1+(≤ 10 colonies)	16/20 (80%)
2+(11-50 colonies)	46/49 (94%)
3+(> 50 colonies)	28/30 (93%)
4+ (predominant growth)	35/35 (100%)
Total Positive Sensitivity	126/137 (92%)
Total Agreement	314/329 (95%)

In addition, the QuickVue test was used to confirm the identification of Group A *Streptococcus* on blood agar plates. As a culture confirmation, the test was 100% sensitive.

Cross-Reactivity

The following organisms tested at levels of approximately 1×10^7 organisms/test and greater were all found to be negative when tested in the QuickVue test.

- | | |
|-----------------------------------|-----------------------------------|
| <i>Streptococcus</i> Group B | <i>Enterococcus faecalis</i> |
| <i>Streptococcus</i> Group C | <i>E. coli</i> |
| <i>Streptococcus</i> Group F | <i>Hemophilus influenza</i> |
| <i>Streptococcus</i> Group G | <i>Klebsiella pneumoniae</i> |
| <i>Streptococcus pneumoniae</i> | <i>Neisseria gonorrhoea</i> |
| <i>Streptococcus mutans</i> | <i>Neisseria meningitidis</i> |
| <i>Streptococcus sanguis</i> | <i>Neisseria sicca</i> |
| <i>Streptococcus ungrouped</i> | <i>Neisseria subflava</i> |
| <i>Branhamella catarrhalis</i> | <i>Pseudomonas aeruginosa</i> |
| <i>Bordetella pertussis</i> | <i>Staphylococcus aureus</i> |
| <i>Candida albicans</i> | <i>Staphylococcus epidermidis</i> |
| <i>Corynebacterium diphtheria</i> | <i>Serratia marcescens</i> |

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POL Studies

An evaluation of the QuickVue test was conducted at three Physicians' Offices using a panel of coded specimens. Testing was performed by physician office personnel with diverse educational backgrounds and work experiences at three different locations. The proficiency panel contained negative, low positive and moderate positive specimens. Each specimen level was tested at each site in replicates of at least five over a period of three days. No significant differences were observed within run, between runs or between sites.

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support Number, (800) 874-1517 (toll-free in the U.S.A.) or (858) 552-1100, Monday through Friday, between 7:00 a.m. and 5:00 p.m., Pacific Time, U.S.A. If outside the United States, contact your local distributor or technicalsupport@quidel.com.

REFERENCES

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Covered by U.S. Patent Nos. 4,943,522, 5,766,961 and 5,770,460; European Patent Nos. 0 296 724 and 0 566 695.

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REF

20108 – QuickVue Dipstick Strep A 50-Test

20125 – QuickVue Dipstick Strep A 25-Test
(Not available for sale in the U.S.)

IVD



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Authorized Representative



Manufacturer

Lab Name:

IVD

For *In Vitro* Diagnostic Use



Temperature Limit

Lab Name:

LOG SHEET



Record Built-in Procedural Controls on the first patient tested each day.

	Date	Patient Name	Extraction Reagent Control (A+B turns green)	Positive Procedural Control (C = Blue Line)	Negative Procedural Control (Background = no interference)	Test Results At 5 minutes	Lot Number and Exp. Date	Technician
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

Lab Name:

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	Date/Date Received	External Positive Control	External Negative Control	Lot Number and Exp. Date	Technician
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

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