QUIDEL | QuickVue+®

Strep A Test

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the QuickVue+ Strep A Test?
The suggested CPT code is 87880.* For the Medicare National Limit amount** click here.

What is the CLIA complexity of the kit?
The test is moderately complex.

How often should external controls be run on the kit?
Quidel recommends positive and negative controls be run with each shipment of a new kit lot number, and as otherwise required by your laboratory's standard quality control procedures.

What is the shelf life and kit storage of the QuickVue+ Strep A kit?
The shelf life is 18 months from date of manufacture. The kit should be stored at room temperature (59°F to 86°F, 15°C to 30°C).

How should specimens be transported when using the QuickVue+ Strep A kit?
Swab specimens should be processed as soon as possible after collection. However, swabs can be stored in a clean, dry, sealable plastic tube or in 1 mL or less liquid media, such as Modified Liquid Stuart's, for up to eight hours at room temperature (15°C to 30°C) or 72 hours refrigerated (2°C to 8°C). Do not use charcoal agar or semi-solid transport media. (For more information see "Can I use culturette swabs or culture swab transport systems with this kit?").

What swabs can be used with this kit?
Use rayon-tip or Dacron®-tip swabs with plastic shafts to collect throat samples. In order to guarantee the performance claims described in the Package Insert, we recommend using the sterile rayon-tipped swabs provided in the QuickVue+ Strep A kit. To order additional swabs, use Quidel Cat. #20227. Do not use calcium alginate, cotton-tip or wooden-shaft swabs. For more information on using culturette swabs or culture swab transport systems, see the next question and answer below.

Can I use culturette swabs or culture swab transport media systems with this kit?
Rayon-tipped culturette swabs on plastic shafts and Dacron-tipped culturette swabs on plastic shafts may be used with the QuickVue+ Strep A kit. Additionally, the following culture swab transport media systems are recommended for use with this kit:

- BD® BBL® CultureSwab® Liquid Stuart (Cat. #220109)
- Remel® Liquid Amies Dual Swab Pack (Cat. #R723090 and R723095)

NOTE: The Remel BactiSwab™ II and Remel BactiSwab are NOT compatible swab systems with this test.

Do I have to do Proficiency Testing?
Usually, facilities that perform moderately complex tests have been mandated to perform Proficiency Testing.

Can the test be read after the designated read time?
The QuickVue+ Strep A Test must be read within 10 minutes of adding the sample. Some positive results may appear as early as 5 minutes after adding the sample, but negative results must be confirmed negative at 10 minutes.

Is it okay if I accidentally touch the inside cheeks or tongue with the collection swab?
No, this may cause an interference with our test chemistry. The sample should be re-collected.

Is the Positive Control Swab infectious?
No. The swab has been inoculated with heat-inactivated Group A *Streptococcal* antigen and is not infectious.

Do I have to do a culture if the test is negative?
Quidel recommends additional follow-up testing using the culture method if the QuickVue+ Strep A test result is negative.
The FDA states, "Since no rapid test has been cleared, approved, or waived through the regulatory process as a stand-alone test in the face of locally suppurative disease, lack of a backup method for a negative rapid GAS test result constitutes off label use." Below is the link for reference:
https://wayback.archive-it.org/7993/20170112085448/http:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109407.htm

How long after antibiotic treatment will the patient show positive?
This test detects the presence of the antigen. Depending on the individual, and their compliance with antibiotic therapy, the antigen may remain present for 2-3 weeks after the initiation of antibiotic treatment, even though the patient's signs and symptoms of pharyngitis are gone.

Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service.
Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.

**For state by state fee schedule go to www.cms.gov.

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