QUIDEL | QuickVue®

Dipstick Strep A Test

Frequently Asked Questions

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

What is the CLIA complexity of this kit?
The test is CLIA waived.

How often should external controls be run on the kit?
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.

What is the shelf life and kit storage of the QuickVue Dipstick Strep A kit?
The shelf life is 24 months from date of manufacture. All kits 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 Dipstick Strep A Test?
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°C to 30°C) or refrigerated (2°C to 8°C) before processing. The use of charcoal or agar medium is not recommended.

What swabs can be used with this kit?
In order to guarantee the performance claims described in the Package Insert, we recommend using the sterile rayon-tipped swabs provided in the 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 may be used with the QuickVue Dipstick Strep A kit. Additionally, the following culture swab transport media systems are recommended for use with the kit:

- BD® BBL® CultureSwab® Liquid Stuart (Cat. #220109/220099)
- Remel® Liquid Amies Dual Swab Pack (Cat. #R723090 and R723095)
- Remel BactiSwab® II (Cat. #R12200)/Remel BactiSwab (Cat. #R12100)

Do I have to do Proficiency Testing?
Usually, facilities that perform Moderately Complex tests have been mandated to perform Proficiency Testing. Waived tests do not require Proficiency Testing unless the governing agencies, or your internal quality control requirements, have their specific guidelines that supersede federal guidelines.

Can the tests be read after the designated read time?
Results should be read at 5 minutes. Some positive results may appear sooner.

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 Dipstick 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. "QW" modifier is added to report use of CLIA-Waived test system(s) for Medicare/Medicaid claims.

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