



## Frequently Asked Questions

### **What is the CMS suggested CPT code and National Limit Amount for the QuickVue® Strep A kits?**

The Medicare National Limit Amount\* is \$17.52. The suggested\*\*\* CPT codes are:

- QuickVue Dipstick and In-Line® Strep A kits: 87880QW\*\*
- QuickVue+® Strep A kit: 87880

### **What is the CLIA status of our kits?**

- QuickVue In-Line Strep A: CLIA Waived
- QuickVue Dipstick Strep A: CLIA Waived
- QuickVue+ Strep A: Moderately Complex

### **What is the ICD-9 code for this test?**

This is **NOT** to be suggested by Quidel or representatives on behalf of Quidel. This is determined by the clinician's diagnosis.

### **How often should external controls be run on the kit?**

For QuickVue Dipstick Strep A and QuickVue In-Line Strep A, 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. For QuickVue+ Strep A, 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 our Strep A kits?**

- QuickVue+ Strep A = 18 months from date of manufacture
- QuickVue Dipstick Strep A = 18 months from date of manufacture
- QuickVue In-Line Strep A = 14 months from date of manufacture

All kits should be stored at room temperature (59-86°F, 15-30°C).

### **Can transport media be used with these kits?**

1 mL or less of liquid media, such as Stuart's Transport Media, may be used with the QuickVue+ Strep A kit. Additionally, there are two culture swab transport media systems recommended for use with the QuickVue Dipstick and QuickVue+ Strep A kits (for more information, see the "Can I use culturette swabs or culture swab transport media

systems with these kits?" question and answer below). Transport media cannot be used with QuickVue In-Line Strep A kit.

**Can I use other swabs with these kits?**

The QuickVue In-Line Strep A test swabs are specifically engineered with larger tips to fit snugly into the testing device well. Other swabs (including proficiency samples) will not perform consistently with the QuickVue In-Line Strep A test, and discrepant results can occur. In order to guarantee the performance claims described in the package inserts, we recommend using the sterile rayon-tipped swabs provided in the QuickVue Dipstick Strep A and QuickVue+ Strep A kits. Dacron-tipped swabs on plastic shafts can also be used with the QuickVue+ Strep A kit. Do not use calcium alginate, cotton-tip or wooden-shaft swabs with any of the kits. 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 these kits?**

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

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

**Why is the Proficiency Testing procedure for the QuickVue In-Line Strep A test different from the regular procedure?**

The sample swab provided for Proficiency Surveys has a smaller tip that will not be compatible with the QuickVue In-Line Strep A test device; results will not be consistent. Please refer to the QuickVue In-Line Package Insert Proficiency Testing Survey Procedure section for instructions on proficiency testing.

**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?**

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. The QuickVue In-Line and QuickVue Dipstick Strep A tests should be read at 5 minutes. Some positive results may appear sooner.

**What is the amount of liquid from the dropper in the Proficiency Test kit provided in the QuickVue In-Line Strep A kit?**

Approximately 350 µL.

**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?**

Yes, the FDA requires negative rapid diagnostic Strep A results to be backed-up with culture. Here is the link for your reference:

<http://www.fda.gov/cdrh/oivd/laboratory.html#tip7>.

**How long after breaking the QuickVue In-Line Strep A test Extraction Reagent Delivery Device is it still good?**

The ERDD should not be activated (by crushing) until the test is ready to be performed. It should be used immediately.

**Why is the QuickVue In-Line Strep A test sample not flowing?**

The swab may be plugging the aperture from the chamber to the test strip. If you still observe no flow after 1 minute, take out the swab and reinsert it into the chamber. Do not re-set timer.

**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.

\*For state by state fee schedule go to [www.cms.gov](http://www.cms.gov).

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

\*\*\**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.



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