



QuickVue®

Chlamydia Test

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the QuickVue Chlamydia kit?

The suggested CPT code is 87810.* For the current Medicare National Limit amount** [click here](#).

What is the CLIA complexity of this test?

The test is moderately complex.

What is the shelf life and kit storage?

The shelf life is 9 months from the date of manufacture. Store kit at room temperature (59°F to 86°F, 15°C to 30°C).

Is it essential to obtain a sample with the swabs provided in the kit?

Only the sterile swabs provided in the kit or cytology brushes (not provided in the kit) may be used. To order additional swabs, use Quidel Cat. #20228.

How soon after exposure to the infection can a patient be tested for Chlamydia?

The incubation period is 6-14 days. However, it often goes undetected because it is often asymptomatic.¹

How long after treatment can an infected patient be tested to determine if the patient was cured?

Therapeutic failure or success cannot be determined because antigen may persist following appropriate antimicrobial therapy. Since the test detects Chlamydia **antigen**, testing prior to three weeks may yield positive results due to non-viable organisms being present, which have not been cleared from the body. This clearance is dependent upon the treatment used, and the test used.²

Is it possible to obtain a positive result on the QuickVue Chlamydia Test and a negative culture from the same patient?

Antigen detection tests, such as the QuickVue Chlamydia Test, do not require viable organisms. Therefore, they may yield positive results when a duplicate swab may yield a negative culture if no viable organisms have survived to be cultured. Sensitivity of the culture is estimated to be only 70%-85% compared with DNA amplification.

What may be the cause of insufficient sample extract (3 drops) to perform the test?

Assuming the correct amount of extraction solution was used, an insufficient amount of extract is usually caused by **not expressing the liquid out of the swab strongly enough**.

¹ Sweet, R.L., M.D., Gibbs, R., M.D. Infectious Diseases of the Female Genital Tract, Fourth Ed., Lippincott, Williams & Wilkins, Phila., Chapter 5, p. 61.

² Black, C.M., Current Methods of Laboratory Diagnosis of C. Trachomatis Infection, Clinical Microbiology Reviews, Jan. 1997, p. 177.

Can vaginal samples from children be used?

No. The QuickVue Chlamydia Test has not been validated for use with this type of specimen, usually taken as part of an investigation into child abuse. Standard chlamydia cell culture methods should be used in the evaluation of suspected sexual abuse and for other medical legal cases where diagnosis could lead to adverse psychosocial impact.

Can the test be used on men?

No. The test has not been validated for use on male patients.

What is the volume of the dropper to dispense Reagent B?

½ mL.

What is the volume of the positive external control?

2 drops = approximately 120 microliters.

What is the concentration level in the positive external control?

Approximately 350 IFU (Infectious Units)/test.

What is the analytical sensitivity of the test?

Analytical sensitivity was determined by testing serial dilutions of cultures of known infectivity. The detection limit of the Chlamydia trachomatis serovars A, B, Ba, C, D, E, F, G, I, K, L1, and L3 ranged from ≤ 200 to 2,000 IFU/test; serovars H, L2, and J ranged from 2,000 to 20,000 IFU per test. In addition, C. pneumonia strain TWAR tested positive at 300 IFU per test.

Why are two swabs provided in the kit for each test?

Two swabs should be used for sample collection. The first swab is to remove excess mucus from the exocervix. The second swab should be inserted into the endocervical canal, past the squamocolumnar junction, until most of the swab is no longer visible. Firmly rotate the swab for 15-20 seconds. The swab should be withdrawn without contamination with exocervical or vaginal cells.

Can transport media be used?

No. Transport medium interferes with the assay and may cause erroneous results.

How often should external Controls be run on this test?

The QuickVue Positive and Negative Control solutions should be tested with each new lot or shipment of test materials once for each 25-test kit and as otherwise required by your laboratory's standard quality control procedures.

**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 recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels.*

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

FQ0B006002EN00 (09/21)