



QuickVue[®] Adenoviral conjunctivitis TEST

CLIA Complexity: Waived for tear fluid samples.

Store between 39°F to 77°F (4°C to 25°C)

QUICK REFERENCE INSTRUCTIONS

QuickVue Adenoviral conjunctivitis Test is a CLIA-waived test for the visual, qualitative *in vitro* detection of Adenoviral antigens (hexon protein) directly from eye fluid. A CLIA Certificate of Waiver is required to perform the test in a waived setting. Laboratories with a CLIA Certificate of Waiver must follow the manufacturer's instructions for performing the test. To obtain a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA or from your state health department. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

Test Contents



QuickVue Adenoviral conjunctivitis Test



Sample Collector



Test Cassette



Buffer Vial

Note: An unused QuickVue Adenoviral conjunctivitis Test device has two faint orange lines in the result window.



Test Procedure

1 Sample Prep

Gently dab and drag the sampling fleece in multiple locations along the inside of the patient's lower eyelid (palpebral conjunctiva) 6 to 8 times, and then allow it to rest against the conjunctiva for an additional 5 seconds. Upon saturation with tear fluid, the fleece will glisten.



2 Assembly

Assemble the test by gently placing the sampling fleece of the Sample Collector into the sample transfer window of the Test Cassette body.



3 Snap Together

Press firmly where indicated until the test feels secure. A double click means the test is properly assembled.

4 Buffer Step

Open the buffer vial and immerse the absorbent tip for a minimum of **20 seconds**.



5 Running the Test

Remove the absorbent tip from the buffer vial, replace the protective cap, and lay the test flat on a horizontal surface for 10 minutes.

External Control Procedure

- QuickVue Adenoviral conjunctivitis Test external controls are available directly through Quidel. QuickVue Adenoviral conjunctivitis Test external controls consist of two (2) vials (a positive control containing detergent and recombinant Adenovirus hexon protein as well as additional proteins to simulate biological matrix and a negative control). It is recommended that both a positive and negative external control be tested once with each new lot number of QuickVue Adenoviral conjunctivitis Test, once with each new shipment received, and once by each new untrained operator before he/she tests patient samples.
- Only one (1) control may be run on each QuickVue Adenoviral conjunctivitis Test Cassette. To run the other control, use another Test kit.
- Open the selected control vial.
- Open the Sample Collector pouch from an unused QuickVue Adenoviral conjunctivitis Test.
- Dip the sampling fleece into the selected control vial to moisten the fleece.
- Follow the instructions provided in the QuickVue Adenoviral conjunctivitis Test Package Insert to run the test and read the results.
- A positive control should show a positive result. A negative control should show a negative result.
- When the correct control results are not obtained, repeat the test control or contact Quidel Technical Support at 800.874.1517 before testing patients.

Interpretation of Results

Once the background within the result window is white and 10 minutes have elapsed, the test may be read.

NOTE: Do not interpret the test results before completing 10 minutes of development time. A purple fluid wave may be observed moving across the result window while the test is running.

The results of the test are indicated through two (2) lines which appear in the result window: the control line and the result line. The control line appears as a BLUE line in the control zone. It indicates the correct application and performance of the test, and must appear for the test to be valid.

POSITIVE RESULT

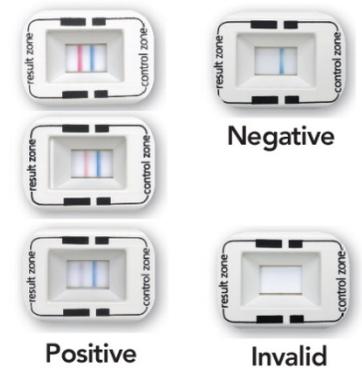
The presence of both a BLUE line in the control zone and a RED line in the result zone indicates a positive result. Even if the RED line is faint in color, incomplete over the width of the test strip, or uneven in color, it must be interpreted as a positive. A positive result indicates the presence of Adenovirus antigens.

NEGATIVE RESULT

The presence of only a BLUE line in the control zone indicates a negative result. A negative result is indicative of an absence of Adenovirus antigens.

INVALID RESULT

If a BLUE line does not appear, the test is invalid. Re-immers the absorbent tip into the Buffer Vial for an additional 10 seconds. If a BLUE line still does not appear, the test must be discarded and the subject retested by resampling the eye using a new QuickVue Adenoviral conjunctivitis Test.



Warnings and Precautions

- For *in vitro* diagnostic use only. For prescription use.
- Keep the Test Cassette and Sample Collector in their foil pouches until just before use.
- The Dacron® material used in the sampling fleece may cause allergic reactions for some people.
- Do not use QuickVue Adenoviral conjunctivitis Test past the expiration date.
- Follow Universal Precautions when handling patient samples.
- Wear disposable gloves while handling samples and wash hands after the test is complete.
- Both QuickVue Adenoviral conjunctivitis Test and the Buffer Vial are single-use items. Do not reuse with multiple specimens.
- QuickVue Adenoviral conjunctivitis Test requires a visual readout. Do not interpret the test result if you have color-impaired vision.
- Result interpretation requires a brightly lit environment.
- Do not use the same QuickVue Adenoviral conjunctivitis Test on more than one patient.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Allow 5 minutes after administering ocular anesthetic before collecting the specimen.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

ASSISTANCE

If the QuickVue Adenoviral conjunctivitis Test does not perform as expected, contact Quidel Technical Support 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.), technicalsupport@quidel.com, or your local distributor.

Refer to the Package Insert for *Warnings and Precautions, Specimen Collection and Handling, and Quality Control.*



Study the Package Insert thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.



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