



QUIDEL

QuickVue® Adenoviral conjunctivitis Control Set *Positive Control and Negative Control*

For *in vitro* diagnostic use.

R_x ONLY



INTENDED USE

QuickVue Adenoviral conjunctivitis external controls are to be used with the QuickVue Adenoviral conjunctivitis Test only and are intended to verify that the test reagents are working and that the test is performed correctly.

QuickVue Adenoviral conjunctivitis Test is a rapid immunoassay test for the visual, qualitative *in vitro* detection of Adenoviral antigens (hexon protein) directly from human eye fluid. The test is intended for professional use as an aid in the rapid differential diagnosis of acute conjunctivitis.

REAGENTS AND MATERIALS

- Positive Control (1)
- Negative Control (1)
- Package Insert (1)

Contents

Positive Control

- Buffered solution containing detergent and recombinant Adenovirus hexon protein as well as additional proteins to simulate biological matrix.

Negative Control

- Buffered solution containing detergent and proteins to simulate biological matrix.

MATERIALS NOT PROVIDED

- QuickVue Adenoviral conjunctivitis Test kit
- Gloves
- Timer

EXTERNAL CONTROLS STORAGE AND STABILITY

The unopened controls are to be stored at room temperature not to exceed 86°F/30°C until the expiration date noted on the outer packaging.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Directions in the QuickVue Adenoviral conjunctivitis Test kit Package Insert must be followed for optimal results.

- Controls should be clear and colorless. Controls should not be used if there is flocculation or discoloration.
- The unopened controls are to be stored at room temperature not to exceed 86°F/30°C.
- Unopened controls may be used until the expiration date noted on the outer packaging. Do not use the controls past their expiration date.
- Controls are designed for a maximum of three (3) uses.
- Do not dilute the controls.
- Follow Universal Precautions when handling these controls.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- 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.

PROCEDURE

1. Choose either the Positive or Negative Control vial. The QuickVue Adenoviral conjunctivitis Test Sample Collector, Test Cassette and Buffer can only be used once.
2. Open the selected control vial.
3. Obtain an unused QuickVue Adenoviral conjunctivitis Test kit and open the Sample Collector pouch.
4. Dip the Sample Collector's sampling fleece into the selected control vial to moisten the fleece.
5. 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.

Note: The Test Cassette may only be used once. The controls may be used up to a maximum of three (3) times within the expiration date on the control vial.

DAILY QUALITY CONTROL

QuickVue Adenoviral conjunctivitis Test has built-in procedural controls (see Procedural Controls section of the QuickVue Adenoviral conjunctivitis Test Package Insert). For daily quality control, Quidel recommends documenting that these internal procedural controls were checked for the first sample tested each day.

PROCEDURAL CONTROLS

An unused QuickVue Adenoviral conjunctivitis Test device has a purple flow indicator on the test strip in the sample transfer window. The unused device also has faint orange lines in the result window.

If the test runs and the reagents work, a blue line will appear in the control zone. This is indicative of the functionality of the test. The appearance of the control line indicates the correct application and performance of the test. The control line must appear in all valid tests. If the control line does not appear, the test must be interpreted as invalid and should be repeated by resampling the eye using a new QuickVue Adenoviral conjunctivitis Test kit.

A purple fluid wave is observed moving across the result window while the test is running. Once the background within the result window is white and 10 minutes have elapsed; the test may be accurately read. If there is a streaky-fluid wave in the background after 10 minutes, allow an additional 5-10 minutes of running time prior to interpretation. The clearing of the background color from the result window is a negative background control.

External Positive and Negative Controls

In addition to your facility's standard quality control procedures, 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
- once with each new untrained operator before he/she tests patient samples

Additional controls may be tested according to the requirements of Local, State and Federal regulations or accrediting organizations.

TEST LIMITATIONS

As with all diagnostic tests, QuickVue Adenoviral conjunctivitis Test results should be interpreted along with clinical findings and results from other diagnostic methods.

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support number, 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.), Monday through Friday, from 7:00 a.m. to 5:00 p.m. Pacific Time. If outside the United States, contact your local distributor or technicalsupport@quidel.com.

REF

RPS-ADSTD – QuickVue Adenoviral conjunctivitis External Controls

IVD



Quidel Corporation
10165 McKellar Court
San Diego, CA 92121
quidel.com

1337702EN00 (01/19)

REF

Catalogue number

LOT

Batch code



Use by



Manufacturer



Temperature limitation



Intended use

R_x ONLY

Prescription use only



Consult instructions for use

IVD

For *In Vitro* diagnostic use

CONT

Contents/Contains

CONTROL +

Positive control

CONTROL -

Negative control
