IMPORTANT
See package insert, including QC section, for complete instructions for use, precautions, and study results. For questions and technical support, call +1.941.556.1850.

INTENDED USE
AdenoPlus 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. Negative results do not preclude Adenovirus infection nor are they intended to rule out other microbial-caused infections of the conjunctiva, and should not be used as the sole basis for treatment or other management decisions.

EXTERNAL QUALITY CONTROL
Positive and negative controls are available directly from RPS. Please refer to the AdenoPlus external controls package insert for more information.

TEST CONTENTS
AdenoPlus®
Sample Collector
Test Cassette
Buffer Vial

Note: An unused AdenoPlus device has two faint orange lines in the result window.

1. Gently dab and drag the sampling fleece in multiple locations along the inside of the patient’s lower eyelid (palpebral conjunctiva) 6-8 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. Assemble the test by gently placing the sampling fleece of the sample collector into the sample transfer window of the test cassette body.

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

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

5. Remove the absorbent tip from the buffer vial, replace the protective cap, and place the test horizontally on a flat surface for 10 minutes.
Once the background within the result window is white and 10 minutes have elapsed, the test may be accurately 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 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 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 may be invalid. Reimmerse 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 AdenoPlus test kit.

**WARNINGS AND PRECAUTIONS**

1. For *in vitro* diagnostic use only.
2. Keep the test cassette and sample collector in their foil pouches until just before use.
3. The Dacron material used in the sampling fleece may cause allergic reactions for some people.
4. Do not use AdenoPlus past the expiration date.
5. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. Proper handling and disposal methods should be established according to local, state, and federal regulations.
6. Wear disposable gloves while handling samples and wash hands after the test is complete.
7. Both AdenoPlus and the buffer vial are single use items. Do not reuse with multiple specimens.
8. AdenoPlus requires a visual readout. Do not interpret the test result if you have color-impaired vision.
9. Result interpretation requires a brightly lit environment.
10. Do not use the same AdenoPlus test kit on more than one patient.

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