



## PACKAGE INSERT

### AdenoPlus® External Controls

#### Intended Use

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

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.

#### Package Components (materials supplied)

- 1 vial labeled positive control
- 1 vial labeled negative control

#### 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

#### Procedure

1. Choose either the positive or negative control vial. Only one control may be run on each AdenoPlus test kit.
2. Open the selected control vial.
3. Obtain an unused AdenoPlus 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 AdenoPlus 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

AdenoPlus has built-in procedural controls (see procedural controls section). For daily quality control, RPS recommends documenting that these internal procedural controls were checked for the first sample tested each day.

#### Procedural Controls

An unused AdenoPlus 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 has to be repeated by resampling the eye using a new AdenoPlus 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 AdenoPlus
- 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.

#### Warnings and Precautions

- Directions in the AdenoPlus test kit's 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, and must be recapped immediately upon completion of the test.
- Do not dilute the controls.
- Once used, control vials should be discarded in accordance with the rules of the facility, and in accordance with local, state, and Federal regulations.
- A material safety data sheet (MSDS) for this product is available on the RPS website.

#### Materials Not Provided

AdenoPlus test kit (Part Number: RPS-AD)

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. The controls are for a maximum of three (3) uses.

#### Test Limitations

As with all diagnostic tests, AdenoPlus results should be interpreted along with clinical findings and results from other diagnostic methods.

#### Ordering Information

**RPS-ADSTD** – AdenoPlus External Controls

**RPS-AD** – AdenoPlus (box of 10 test kits)

#### Contact Information and Technical Support

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