HealthPartners/GHI

AdenoPlus™ Test Procedure	**Attachments** ☐ Yes ☒ No
Key words AdenoPlus™, Adenovirus	**Number** **GHP-PC-CLINIC LAB-Procedures-AdenoPlus™** v. 05-2014
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APPROVAL(S) Director, Laboratory Services	

AdenoPlus™ Procedure
Clinic Lab Procedure (Pages 1-6)
Specimen collection procedure (Pages 2-3)
Computer Entry (Page 7)

I. PURPOSE/PRINCIPLE

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.

AdenoPlus™ utilizes Direct Sampling Micro Filtration technology. Adenoviral antigen, the conserved Adenovirus hexon protein, when present in the patient sample is captured between two antigen specific monoclonal antibodies. One antibody is immobilized in the detection zone of the device. The second antibody is labeled with colloidal gold. The detector is a disposable, rapid test requiring 10 minutes for a result.

II. POLICY

Laboratory Staff will follow the approved techniques outlined in this procedure.

Storage Requirements:

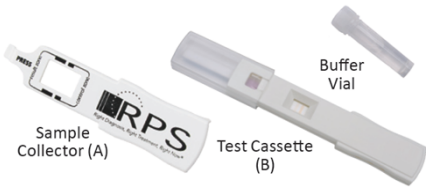
- Store kits in dry location at room temperature 4-25 °C (39-77°F)
- Kits may be used until printed expiration date on the outer packaging and containers.

- Test cassette and sample collector must remain in their foil pouches until just before use

Reagents and Equipment:

AdenoPlus™ test kit includes two foil pouches containing the following materials and a buffer vial

- The Sample collector (A) is a separately packaged sterile component that can be assembled easily onto the test cassette (B). The test cassette (B) guarantees correct sample transfer onto the lateral flow assay strip

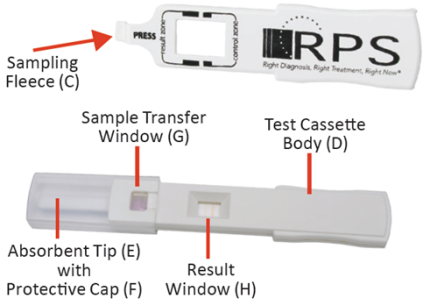


- Timer
- Gloves
- Quality control materials

Specimen:

Collection Procedure (Care unit provider/nurse):
NOTE: Check the expiration date on all packaging. Do not use if foil pouches are damaged. Always test the most affected eye.

- Obtain the two foil pouches containing the Sample collector (A) and the test cassette (B) from the lab. The accompanying buffer vial must remain in the lab.
- Identify patient according to patient identification policy.
- Tear open each foil pouch at the indicated perforation and remove the contents. Remove the protective cap (F) from the test cassette body (D). Do not touch the sterile sampling fleece (C) prior to collecting the patient sample.



- Locate the sampling fleece (C) on the underside of the sample collector (A).
- If ocular anesthetic is applied to the eye, wait at least 5 minutes prior to collecting a sample.
- Gently lower the patient's eyelid to expose the inside of the lower lid (palpebral conjunctiva).
- Gently dab and drag the sampling fleece(C) in multiple locations along the palpebral conjunctiva 6-8 times and then allow it to rest against the conjunctiva for an additional 5 seconds. This will moisten the sampling fleece.
- Upon saturation with tear fluid the fleece will glisten. Based on tear volume and composition, the fleece may appear white or patchy pink in color. If the fleece is not saturated and glistening, gently dab and drag the sampling fleece(C) along the palpebral conjunctiva an additional 4-6 times.

Assembling the test:

- Locate the test cassette (B) with the test cassette body (D) and the protective cap (F).
- Assemble the test by gently placing the sampling fleece(C) of the sample collector (A) into the sample

transfer window (G) of the test cassette body (D).

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

- Replace the protective cap (F) over the absorbent tip (E).
- Label with a patient label by wrapping and flagging the label around the test cassette body (D).. Do not cover the test result window (H) with the patient label.
- Deliver the cassette to the laboratory technician.

NOTE: The opened test cassette should be used within one (1) hour of collection.

SPECIAL SAFETY PRECAUTIONS

Use Universal Blood and Body fluid Precautions.

QUALITY CONTROL

Positive and negative external controls must be run and documented on the AdenoPlus™ QC worksheet for each new box. Controls must perform as expected prior to reporting patient results. Internal controls must be verified and documented on the patient worksheet for each test performed.

Internal Controls

- AdenoPlus™ has built-in procedural controls.
- An unused AdenoPlus™ device has a purple flow indicator on the test strip in the sample transfer window (G). The unused device also has faint orange lines in the result window (H).

- If the test flows correctly and the reagents work, a blue line will appear in the control zone. 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.
- If the background does not clear the test must be interpreted as invalid and has to be repeated by resampling the eye using a new AdenoPlus™ test kit.

External Controls:

External quality controls are intended to verify that the test reagents are working and that the test is performed correctly.

- External Positive Control: Buffered solution containing detergent and recombinant Adenovirus hexon protein as well as additional proteins to simulate biological matrix
- External Negative Control: Buffered solution containing detergent and proteins to simulate biological matrix.

- Store controls at room temperature until the expiration date noted on the outer packaging.
- Each control vial may be used up to a maximum of three (3) times within the expiration date on the control vial. After each use, place a check mark on the vial and dispose of the vial after the third use.

Quality Control Procedure:

1. Obtain an unused AdenoPlus™ test kit and open the sample collector pouch
2. Dip the sample collector's sampling fleece into the selected control vial to moisten the fleece.
3. Follow the procedure for assembling, performing and interpreting the test. A positive control should show a positive result and a negative control should show a negative result.

III. PROCEDURE

NOTE: The test should be run within 24 hours of obtaining a sample and assembling the test.

On the Care Unit:

1. Obtain the two foil pouches containing the Sample collector (A) and the test cassette (B) from the lab. **The accompanying buffer vial must remain in the lab.**
2. Care Unit staff: After specimen collection and assembling the test (see above), deliver the labeled cassette to the laboratory technician for testing.

In the lab:

3. Lab tech: Open the buffer vial. Do NOT allow any portion of the test cassette besides the absorbent tip (E) to touch the buffer vial.
4. Immerse the absorbent tip into the buffer vial for a minimum of 20 seconds and until you see the purple fluid wave line appear in the result window.

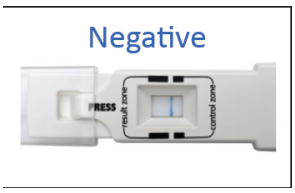
5. Remove the absorbent tip from the buffer vial, replace the protective cap (F) and place the test horizontally on a flat surface for 10 minutes.
6. A positive result may be read as soon as there is a white background and a BLUE line in the control zone. A negative result must be confirmed by waiting the required 10 minutes. 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 test should be read within 12 hours of test completion.
7. The BLUE line in the control zone indicates the correct application and performance of the test and must appear for the test to be valid. Accurate visual interpretation requires examination under brightly lit conditions.

a. 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. An uneven or incomplete RED line is due to an uneven distribution of eye fluid on the sampling fleece. 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 in the tear fluid. A positive test may be resulted as positive as soon as both the Blue control line and the Red result line are visible.

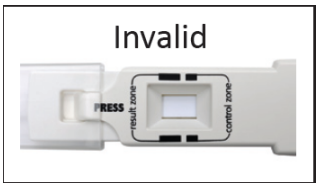
b. Negative Result

Only a BLUE line appears in the control zone and the background is white. A negative result is indicative of an absence of Adenovirus antigens present in the tear fluid. A negative result must be given the full 10 minute incubation time.



c. Invalid Results

If a BLUE line does not appear, the test may be invalid. Re-immerse the absorbent tip (E) into the buffer vial for an additional 10 seconds. If a BLUE line still does not appear after 10 minutes, the test must be discarded and the subject retested by resampling the eye using a new AdenoPlus™ test kit.



Although the test requires only 10µl of fluid, if a second sampling is needed, repeat swabs may reveal reduced eye fluid available for collecting an adequate sample. Each additional sampling may reduce the Adenoviral antigen load transferred to the test. The test should always be performed on the eye that is more severely affected. If both eyes are equally affected, it is recommended that the second sample be taken from the other eye. If only one eye is affected, the sample may be repeated 30 minutes later.

CALCULATIONS

NA

EXPECTED VALUES/REFERENCE RANGE

Negative

The prevalence of Adenovirus varies during the year and from region to region, with outbreaks typically occurring during spring and early summer. The true incidence of Adenoviral conjunctivitis is dependent on many factors including the method of specimen collection and the test method used. In previous studies, the prevalence of Adenovirus infections varied between 20% and 75% of all cases of infectious conjunctivitis. In the AdenoPlus™ clinical study the Adenoviral incidence was found to be 24%

LIMITATIONS OF THE PROCEDURE

- The test is best used within seven days of developing a red eye consistent with infectious conjunctivitis. Always test the most affected eye.

- AdenoPlus™ tests for both infectious and noninfectious Adenoviral antigens. Test performance depends on the antigen load in the specimen zone and may not correlate with a cell culture performed on the same specimen.

- Inadequate specimen collection or low levels of virus shedding may result in suboptimal performance and may yield false negative results.

- Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.

- The performance of this test has not been evaluated for sample types other than human eye fluid specimens.

- The positive and negative predictive values are dependent on the prevalence of the disease in a given populations.

- A negative result does 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.

- Limits of detection: All human Adenovirus serotypes contain the hexon protein that is detected by the AdenoPlus™. The detection limit was measured by serial dilutions of the Adenovirus hexon protein and found to be 6 ng/ml or 60 pg per test and this is estimated to be equivalent to 40-50 Adenoviruses.

Interfering Substances

- Refer to package insert for various eye medications that were tested for interference. Neither false positives nor false negative at the cutoff level were found.

PROCEDURE NOTES
NA

REFERENCES
AdenoPlus™ package insert, 05/2012; RPS- Rapid Pathogen Screening, Inc.

RELATED DOCUMENTS
NA

APPENDIXES
NA

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KNOlson

IV. DEFINITIONS

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS

VII. OTHER RESOURCES

VIII. ENDORSEMENT

Laboratory Administration

ADENOPLUS TEST
Order Codes:
ADPOC

ADPOC Adenovirus POC EPIC5283

RESULTING:
WORKSHEET:
Function MEM Worksheet _ _ KIT (BL,CO,HS,WE)

RESPONSE:
NOTE: If results are invalid (control line not visible), re-collect specimen and re-test per procedure instructions.

	(A battery which includes the ADPOC test for the result and QA tests to document your kit quality tests.)	
Code	**Name**	**Response**
PSS	Source/Site	Answered by provider when ordered in EPIC Right eye = RT-EYE Left eye = LEFT-EYE
ADN	Adenovirus Result	POS = positive NEG = negative P or N will not be accepted as a viable result.
IQC	Internal QC	Internal QC line present or absent? Y = yes for present N = no for absent. If IQC is NO, reject test and recollect specimen.
ADKIT	ADPOC Kit Lot Number	Enter the lot number (12345) from the kit box. If there is a letter in the kit lot number, put a **;** in front of the lot number (;A1234)

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