AdenoPlus™

Right Diagnosis, Right Treatment, Right Now™

Results in 10 Minutes

CLIA-waived

A Certificate of Waiver is required to perform this test in a CLIA-waived setting. 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, from your state health department, or by contacting RPS at +1-941-556-1850.

Read this package insert completely before using the product. Follow the instructions carefully when performing a test. 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.

RPS
Right Diagnosis, Right Treatment, Right Now®

NOTE: Do not discard this package insert. There is only one package insert per dispenser box. Additional copies of the package insert can be found at: RPSdetectors.com

STERILE R IVD 25°C 4°C CE

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.

Store between 77ºF/25ºC and 39ºF/4ºC. For *in vitro* diagnostic use. Not to be taken internally. Keep out of reach of children.

SUMMARY AND EXPLANATION OF THE TEST

Morphologically, Adenoviruses are non-enveloped DNA viruses with an icosahedral structure about 80 nm in diameter.[1]

Adenovirus has been implicated in diseases affecting the respiratory, ocular and gastrointestinal systems.[2-4]

Adenovirus is a frequent cause of infectious conjunctivitis. Human Adenoviruses are classified into 6 subgenera and 53 serotypes.[5-7] Approximately one third of the human Adenovirus serotypes have been associated with common forms of Adenovirus related eye infections[8] but the most common causes of acute conjunctivitis are related to serotypes 3, 4, 8, 11, 19 and 37.[9] The serotypes have the following associations: serotypes 8, 19 and 37 are most responsible for epidemic keratoconjunctivitis;[10-13] serotypes 3, 4, 5 and 7 tend to cause pharyngeal-conjunctival fever, which usually affects children;[10] serotypes 1–11 and 19 are the primary cause of nonspecific follicular conjunctivitis.[10] However, the other serotypes can also produce clinically indistinguishable episodes of acute follicular conjunctivitis.[1, 11, 14]

Cell culture in combination with immunofluorescence is the historical "gold standard" for identifying Adenovirus in conjunctival specimens.[15] Virus isolation requires an intensive process, technical expertise and may take up to 3 weeks to complete. The polymerase chain reaction (PCR) is increasingly used in place of cell culture to detect Adenovirus.[1, 16] In addition, the differential diagnosis of various forms of conjunctivitis (viral, bacterial, allergic) is often difficult because they manifest similar symptoms.

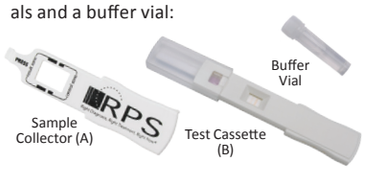
PRINCIPLES OF THE PROCEDURE

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.

REAGENTS AND MATERIALS

Materials Provided

The 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). Additionally, the test cassette (B) guarantees correct sample transfer onto the lateral flow assay strip.

Materials Recommended but Not Provided:

- Timer
- Gloves
- Quality Control materials (see section on external controls)

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.

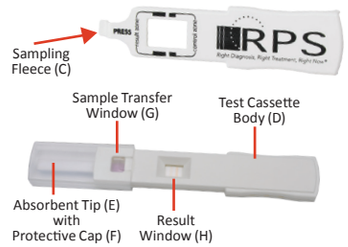
STORAGE AND STABILITY

Store AdenoPlus between 77ºF/25ºC and 39ºF/4ºC. Both AdenoPlus and the buffer are stable until the expiration dates marked on their outer packaging and containers.

TEST PROCEDURE

I. PREPARING THE TEST

1. Check the expiration date on all packaging. Make sure there is no damage to the foil pouches. Do not use if foil pouches are damaged.
2. 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.



II. TAKING A SAMPLE

1. Locate the sampling fleece (C) on the underside of the sample collector (A).
2. 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.

III. ASSEMBLING THE TEST

1. Locate the test cassette (B) with the test cassette body (D) and the protective cap (F). The opened test cassette should be used within one (1) hour.
2. 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).
3. Press firmly where indicated until the test feels secure. A double-click means the test is properly assembled.

IV. RUNNING THE TEST

NOTE: The test should be run within 24 hours of taking a sample and assembling the test. After this period of time, it is possible that the results may change.

1. Open the buffer vial. Do not allow any portion of the test besides the absorbent tip (E) to touch the buffer vial.
2. Immerse the absorbent tip (E) into the buffer vial for a minimum of 20 seconds.

3. Remove the absorbent tip (E) from the buffer vial, replace the protective cap (F) and place the test horizontally on a flat surface for 10 minutes.

V. READING AND INTERPRETING THE RESULTS

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 (H) while the test is running.

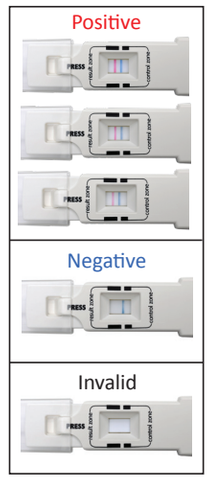
The cut-off of the AdenoPlus assay was determined by serial dilutions of the Adenovirus hexon protein and found to be 6 ng/ml or 60 pg per test and this is estimated to be equivalent to 40-50 Adenoviruses.

Once the background within the result window (H) 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 test should be read within 12 hours of test completion. After this period of time, it is possible that the results may change. Accurate visual interpretation requires examination under brightly lit conditions.

The results of the test are indicated through two lines, which appear in the result window (H): 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. An uneven or incomplete RED line is due to an uneven distribution of eye fluid on the sampling fleece (C). 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.



NEGATIVE RESULT

Only a BLUE line appears in the control zone. A negative result is indicative of an absence of Adenovirus antigens present in the tear fluid.

INVALID RESULT

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. Do not report an invalid test result to your patient. Although the test requires only 10 µl 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.

QUALITY CONTROL

AdenoPlus has built-in procedural controls (see below). 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 (G).

The unused device also has faint orange lines in the result window (H).

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 (H) while the test is running. Once the background within the result window (H) 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 (H) is a negative background control.

External Controls
Positive external controls containing purified Adenovirus hexon protein at the lower detection limit of AdenoPlus are available directly from RPS.

AdenoPlus external controls require the sample collector's sampling fleece to be dipped into the control vial. Once the control specimen is collected, the test is assembled, activated, and read in an identical manner as the clinical setting.

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 by each new untrained operator before he/she tests patient samples

For ordering external controls, please refer to the "Ordering and Contact Information" section of this package insert.

Please refer to the external controls package insert for instructions on how to run the external controls. External controls will have an individual expiration date printed on each package.

Additional controls may be tested according to the requirements of local, state and federal regulations or accrediting organizations. For guidance on proper QC testing refer to CLSI document EP12-A and 42 CFR 493.1202c.

When the correct control results are not obtained, repeat the test control or contact RPS at 1.941.556.1850 before testing patients.

Any problems with the device should be reported to RPS at 1.941.556.1850 or via email at info@RPSdetectors.com or directly to the FDA online at www.fda.gov/medwatch.

LIMITATIONS

1. The test is best used within seven (7) days of developing a red eye consistent with infectious conjunctivitis. Always test the most affected eye.

2. 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.

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

4. 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.

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

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

EXPECTED VALUES

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.[7] In the AdenoPlus clinical study the Adenoviral incidence was found to be 24%.

PERFORMANCE CHARACTERISTICS

A prospective, multicenter, masked, sequential, clinical trial was performed at a combination of private ophthalmology practices and academic centers. The study enrolled 128 patients presenting with a clinical diagnosis of acute viral conjunctivitis. Thirty-one (31) patients were confirmed positive for Adenovirus by viral cell culture. The AdenoPlus clinical performance data is summarized in the following table:

N=128		Cell Culture	
		+	-
AdenoPlus	+	28	4
	-	3	93
Sensitivity		90% (28/31) 95% CI [74.2-98.0]	
Specificity		96% (93/97) 95% CI [89.8-98.9]	
Negative Predictive Value		97% (93/96) 95% CI [91.1-99.3]	
Positive Predictive Value		88% (28/32) 95% CI [71.0-96.5]	

LIMITS OF DETECTION

All human Adenovirus serotypes contain the hexon protein that is detected by AdenoPlus. The antibodies target a conserved region of the hexon protein universal to all Adenovirus serotypes.[17-18] In the laboratory, RPS tested serotypes 1, 3, 4, 5, 7, 8, 11, 14, 19, 31, 37 and demonstrated a positive antigen-antibody reaction. The AdenoPlus 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.

CROSS REACTIVITIES

Various infectious pathogens generated in cell culture and important for conjunctivitis were applied in the laboratory to determine potential cross-reactivities with AdenoPlus:

- Echovirus Type 6 Culture Fluid
- Parainfluenza Type 2
- Parainfluenza Type 3
- Haemophilus influenzae
- Pseudomonas aeruginosa
- Streptococcus pneumoniae
- Staphylococcus aureus
- Parainfluenza Type 1
- Moraxella catarrhalis
- Echovirus Type 11
- Rhinovirus Type 1A
- Herpes Simplex Virus 2 Strain G
- Herpes Simplex Virus 1 Strain F
- Herpes Simplex Virus 1 Strain HF
- Coxsackievirus B1
- Echovirus Type 7
- Staphylococcus epidermis (3 strains)
- Chlamydia trachomatis, Serovar H
- Chlamydia trachomatis, Serovar I

All isolates were cultured from human specimen. The concentrations of the suspensions were between 500,000 and 1,500,000 microorganisms (virus, bacteria) per ml. No positive test lines developed, and no cross-reactivities to these microorganisms occurred when 10 µl of the culture suspension was tested.

INTERFERING SUBSTANCES

The following eye medications were tested for interferences with AdenoPlus. To check for specificity, 10% of each medication was applied to the sampling fleece. Sensitivity was checked with 1:1 mixtures of purified Adenoviral hexon protein in human tears at twice the cutoff level and 20% of the respective medication. Neither false positives nor false negatives at the cutoff level were found.

Alcon - *Alcaine*
Alcon - *Azopt*
Alcon - *Econopred*
Alcon - *Nevanac*
Alcon - *Pataday*
Alcon - *Systane*
Alcon - *Tobradex*
Alcon - *Travatan*
Alcon - *Vigamox*
Allergan - *Acular LS*
Allergan - *Alphagan*
Allergan - *Combigan*
Allergan - *Elastat*
Allergan - *FML*
Allergan - *Lumigan*
Allergan - *Optive*
Allergan - *Pred Forte*
Allergan - *Refresh Liquigel*
Allergan - *Refresh Tears*
Allergan - *Zymar*
AMO - *Blink Tears*
AVS - *Thera Tears*
Bausch + Lomb - *Alrex*
Bausch + Lomb - *Lotemax*
Bausch + Lomb - *Zylet*
Falcon - *Gentamicin Sulfate*
Falcon - *Polymyxin B Sulfate*
Falcon - *Timolol*
Inspire - *AzaSite*
Ista - *Xibrom*
MedPointe - *Optivar*
Merck - *Trusopt*
Novartis - *GenTeal*
Novartis - *Voltaren*
Novartis - *Zaditor*
Pfizer - *Visine*
Pfizer - *Xalatan*
SigmaAldrich - *Human IgA (1 mg/ml)*
SigmaAldrich - *Human lactoferrin (1 mg/ml)*
SigmaAldrich - *Transferrin (1 mg/ml)*
Triad Disposables - *Povidone*
Vistakon - *Betimol*
Vistakon - *Iquix*
Vistakon - *Quixin*
Wilson - *Proparacaine*

PRECISION AND REPRODUCIBILITY STUDY

Precision: Samples were prepared in stabilizing buffer with purified Adenovirus hexon protein. Eight samples containing weak positive, weak negative, positive and negative controls were tested. At one site, 160 additional tests consisting of eight samples containing weak positive, weak negative, positive and negative controls were tested over 20 operating days. The inter-assay precision to detect positive and negative samples was 100% although the strength of the signal varied for the weak positive samples.

Reproducibility: Samples were prepared in stabilizing buffer with purified Adenovirus hexon protein. Eight samples containing weak positive, weak negative, positive and negative controls were tested. A total of 162 tests were performed at 3 sites over 3 consecutive days. The inter-assay precision to detect positive and negative samples was 100% although the strength of the signal varied for the weak positive samples.

Batch to batch reproducibility was tested with three different AdenoPlus batches. There was no variability among the three batches as assessed by testing in triplicates with seven different concentrations of hexon ranging from 0 to 48 ng/ml.

CLIA WAIVER PERFORMANCE

The following studies were conducted to evaluate the accuracy of AdenoPlus when used by operators in CLIA-waived settings.

The prospective clinical study described in the Performance Section above was conducted with 26 intended users at 8 CLIA-waived (intended use) sites. The study enrolled 128 patients presenting with a clinical diagnosis of acute viral conjunctivitis. The following agreement was observed between AdenoPlus and viral cell culture.

Sensitivity: 90% (28/31) 95% CI [74.2-98.0]

Specificity: 96% (93/97) 95% CI [89.8-98.9]

PCR was found to be negative for 1 of the 3 sensitivity discordants and positive for 2 of the 4 specificity discordant samples.

There were no invalid results.

An additional prospective study was conducted at 3 CLIA-waived ophthalmology/optometry clinical sites on patients with ocular ailments. Seventy patients were tested with AdenoPlus by 9 untrained operators at 3 clinical sites. The table below depicts the agreement of the AdenoPlus results in the hands of untrained operators, when compared to cell culture results.

N=70		Cell Culture	
		+	-
AdenoPlus	+	1	5
	-	0	64
Sensitivity		100% (1/1) 95% CI [20.1-100.0]	
Specificity		93% (64/69) 95% CI [84.1-96.9]	

There was one invalid result:
1.4% (1/71) 95% CI [0.3-7.6]

To further evaluate the performance of AdenoPlus in the hands of the intended users, contrived samples prepared in human tear matrix, at concentrations ranging from 1 to 5 times the LOD reflecting the dynamic range of the assay. A total of 189 masked and randomized samples, consisting of 108 positive and 81 negative samples were tested at 3 clinical sites by 3 untrained operators at each site, over a period of 10 operating days. The positive contrived samples consisted of inactivated Adenovirus in human tears and the negative samples consisted of AdenoPlus negative external controls.

The table below depicts the positive and negative agreement of AdenoPlus with known positive and negative contrived samples, when tested by untrained operators at 3 clinical sites combined.

N=189		Contrived Samples	
		+	-
AdenoPlus	+	105	1
	-	3	80
Positive Percent Agreement		97% (105/108) 95% CI [92.2-99.1]	
Negative Percent Agreement		99% (80/81) 95% CI [93.3-99.8]	

There were no invalid results.

Study Near the Assay Cut-off: This study evaluated the performance of the AdenoPlus test with weakly reactive samples when used by untrained operators at 3 CLIA-waived sites. Twelve (12) untrained intended users were required to assemble, initiate and interpret test results from 120 unknown samples. The samples were contrived in tear matrix spiked with purified Adenovirus hexon protein and consisted of 60 weak positives (at the limit of detection {LOD} or assay cutoff) and 60 weak negatives (0.2x LOD). On a single day at each clinical site, the samples were blinded, randomized and tested. The agreement of the AdenoPlus test with the expected results when tested by untrained users is presented below.

Sample	Agreement with expected result
Weak Positive* (at LOD)	97% (58/60) [88.7-99.0]
Weak Negative* (below LOD)	100% (60/60) [94.1-99.9]

**The expected results for "Weak Positive" samples are "Positive," while the expected results for "Weak Negative" samples are "Negative."*

There were no invalid results.

Flex studies: Using risk analysis as a guide, analytical flex studies were conducted. The studies demonstrated that the test is insensitive to stresses of environmental conditions and potential user errors.

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ORDERING AND CONTACT INFORMATION

Ordering Information

REF RPS-AD – AdenoPlus

REF RPS-ADSTD – AdenoPlus External Controls

STERILE R IVD

Contact Information and Technical Support

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