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IMAGEN Adenovirus

REF K610011-2.....50 Tests **EN**

1. INTENDED USE

The IMAGEN™ Adenovirus test is a qualitative direct immunofluorescence test for the detection of adenovirus antigen in clinical specimens and the confirmation of adenovirus in cell cultures.

2. SUMMARY

Adenoviruses are non-enveloped DNA viruses of icosahedral symmetry. The family Adenoviridae comprise 2 genera, mammalian adenoviruses (Mastadenoviruses) and avian adenoviruses (Aviadenoviruses).[1] At least 47 known serotypes of human adenovirus have been identified and characterised by haemagglutination, neutralisation, DNA-hybridization and restriction endonuclease analysis of adenoviral DNA.[1,2,3,4]

Human adenoviruses are associated with a wide range of clinical disease in both immunocompetent and immunocompromised individuals which include infections of the respiratory tract, conjunctiva and gastro-intestinal tract.[3,5] Infections are common in children and can occur sporadically or in outbreaks.

Approximately 5% of acute respiratory disease in children and 10% of febrile illnesses and childhood pneumonias have been associated with adenovirus infection.[3,6,7]

Adenovirus infections of the eye may lead to pharyngo-conjunctival fever, follicular conjunctivitis or epidemic keratoconjunctivitis.[3,8]

Adenovirus serotypes 40 and 41 are commonly associated with viral gastroenteritis in infants and are reported to be responsible for 4-15% of nosocomial infections in paediatric wards.[3,9,10] In immunocompromised patients (eg transplant or AIDS patients) severe systemic infections can occur which can be life threatening.[3]

The laboratory diagnosis of adenovirus infection plays an important role in patient management and enables effective management and control of outbreaks. Diagnostic methods include direct detection of virus or viral proteins in clinical specimens (eg nasopharyngeal aspirates), isolation of viable virus in cell culture monolayers inoculated with respiratory, conjunctival or faecal specimens, and detection of adenovirus specific immunoglobulins.[3,5]

Isolation of adenoviruses from clinical specimens can be accomplished in continuous cell lines of mainly epithelial origin including HeLa, HEp-2, KB and 293 cell lines, in which adenoviruses may exhibit characteristic cytopathic effect.[3,5]

A range of techniques have been used to confirm the identification of adenovirus isolates including neutralisation tests, radioimmunoassay, DNA hybridisation, electron microscopy and DNA electrophoretyping.[11,12,13,14,15] These techniques can be complex, laborious and often inappropriate for routine use.

Recently indirect immunofluorescence tests or enzyme-immunoassays (eg IDEIA™ Adenovirus) using genus specific monoclonal or polyclonal antibodies have been described for the direct detection of adenovirus in clinical specimens or cell culture monolayers.[15,16,17]

Direct immunofluorescence tests utilising specific monoclonal antibodies offer a rapid sensitive and specific method for the direct detection of adenoviruses in clinical specimens such as nasopharyngeal aspirates and conjunctival smears or for the confirmation of adenovirus isolates in cell culture monolayers.

IMAGEN Adenovirus is a direct immunofluorescence test for the detection and identification of human adenovirus serotypes in clinical specimens or cell cultures. The test utilises a genus specific monoclonal antibody to detect an epitope of adenovirus hexon proteins which is expressed in all known human adenovirus serotypes.[18]

3. PRINCIPLE OF THE TEST

The IMAGEN Adenovirus test contains monoclonal antibody conjugated to fluorescein isothiocyanate (FITC). The conjugated reagent binds specifically to an epitope common to the hexon protein found in all serotypes of human adenovirus. The reagent is used in a one step direct immunofluorescence technique. Specimens are incubated with the FITC conjugated antibody reagent for 15 minutes, then excess reagent is washed off with phosphate buffered saline (PBS). The stained areas are mounted and viewed microscopically using epifluorescent illumination. If adenovirus is present, characteristic bright apple green fluorescence is seen within the cytoplasm and/or nucleus of infected cells, contrasting with the red background staining of uninfected cells.

Acknowledgements

The monoclonal antibody used in this test was originated by the Division of Microbiological Reagents and Quality Control, Central Public Health Laboratory, Colindale, London, United Kingdom.

4. DEFINITIONS

The following symbols and definitions have been used in the product information.

REF Catalogue number

Consult the instructions for use

Σ N Contains sufficient for <N> tests

Manufacturer

IVD *In vitro* diagnostic medical device

Use by

LOT Batch Code

Storage temperature limitations

5. REAGENTS PROVIDED

Σ 50 - Each kit contains sufficient materials for 50 direct specimens or cell culture preparations.

- The shelf life of the kit is as indicated on the outer box label.

5.1. IMAGEN ADENOVIRUS REAGENT

Instructions for Use

POSITIVE CONTROL SLIDE 2 x 1 well positive control slide containing acetone fixed human epithelial cells (HEp 2) infected with adenovirus.

One bottle of each of the following:

MOUNTING FLUID 3mL of mounting fluid. The mounting fluid contains a photobleaching inhibitor in a glycerol solution (pH 10.0).

REAGENT 1.4mL of IMAGEN Adenovirus reagent. The reagent contains purified murine monoclonal antibody, specific to a common epitope on the adenovirus hexon protein, conjugated to FITC. The conjugate is prepared in a protein stabilised buffer solution (pH 7.5) containing evans blue dye as counterstain and 15mmol/L sodium azide as preservative.

5.2. PREPARATION, STORAGE AND RE USE OF KIT COMPONENTS

In order to ensure optimal kit performance it is important that unused kit components are stored according to the following instructions:

5.2.1. POSITIVE CONTROL SLIDES -

POSITIVE CONTROL SLIDE Positive control slides are provided individually in sealed foil pouches filled with nitrogen. Store unused slides at 2-8°C. The slide should be left for 5 minutes at room temperature (15-30°C) before opening.

Stain the slide immediately after opening.

5.2.2. MOUNTING FLUID -

MOUNTING FLUID Ready to use. Store mounting fluid at 2-8°C. The mounting fluid should be left at room temperature (15-30°C) for 5 minutes before use.

5.2.3 REAGENT -

REAGENT Ready to use. Store unused reagent 2-8°C. The reagent should be stored in the dark at 2-8°C and left at room temperature (15-30°C) for 5 minutes before use.

6. ADDITIONAL REAGENTS

6.1. REAGENTS

Fresh acetone (for fixation).

Phosphate buffered saline (PBS) pH 7.5 for washing stained specimens and for specimen preparation.

6.2. ACCESSORIES

The following products are intended for use in conjunction with IMAGEN Adenovirus. Contact your local distributor for further information.

Teflon coated glass microscope slides with single 6mm diameter well (100 slides per box) available from your local distributor, (REF S611430-6).

Positive Control Slide (REF S611330-2).

7. EQUIPMENT

The following equipment is required:

Precision pipette and disposable tips to deliver 25µL.

Wash bath.

Coverslips suitable to cover 6mm diameter well.

Non fluorescing immersion oil.

Epifluorescence microscope with filter system for FITC (maximum excitation wavelength 490nm, mean emission wavelength 520nm) and x200 x500 magnification.

Incubator at 37°C.

Low speed centrifuge.

For Direct Specimens

Sterile swabs.

Mucus extractor (nasopharyngeal specimens only).

For Culture Confirmation

Sterile swabs, viral transport medium (VTM) and container suitable for collection, transportation and culture of Adenoviruses.

Cell lines recommended for culture and isolation of Adenoviruses.

8. PRECAUTIONS

IVD - For *in vitro* diagnostic use. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.

8.1. SAFETY PRECAUTIONS

8.1.1 The IMAGEN Adenovirus test contains <0.1% sodium azide, which is a poison. Sodium azide may react with copper and lead plumbing systems to form explosive metal azides. Always dispose of materials containing azide by flushing with large quantities of water.

8.1.2 Adenovirus on the positive control slide has been shown to be non infectious in cell culture, however, the slide should be handled and disposed of as though potentially infectious.

8.1.3 Evans blue dye is present in the Reagent. Although present below the concentration for the product to be classified as carcinogenic, contact with the skin should be avoided.

8.1.4 Care should be taken when using the mounting fluid as it may cause skin irritation. Skin should be flushed with water if contact occurs.

8.1.5 Do not eat, drink, smoke, store or prepare foods, or apply cosmetics within the designated work area.

8.1.6 Do not pipette materials by mouth.

8.1.7 Wear disposable gloves while handling clinical specimens and infected cells, always wash hands after working with infectious materials.

8.1.8 Dispose of all clinical specimens in accordance with local legislation.

8.1.9 Safety data sheet available for professional user on request.

8.2. TECHNICAL PRECAUTIONS

8.2.1 Components must not be used after the expiry date printed on the labels. Do not mix or interchange different batches/lots of reagents.

8.2.2 The reagents are provided at fixed working concentrations. Test performance will be adversely affected if the reagents are modified or stored under conditions other than those detailed in Section 5.

8.2.3 Prepare fresh Phosphate Buffered Saline (PBS) as required on the day of use.

8.2.4 Washing in PBS is necessary. Use of other wash solutions such as tap water or distilled water will compromise test results.

8.2.5 Avoid microbial contamination of reagents.

8.2.6 The reagents must not be frozen.

9. COLLECTION AND PREPARATION OF SPECIMENS[19]

The collection and preparation of specimens is of fundamental importance in the diagnosis of adenovirus by direct immunofluorescence and cell culture methods.

Specimens must be collected from the site of infection during the time of peak viral shedding so that they contain as much infected material as possible and prepared in such a way as to preserve either intact cells which are free from adherent mucus etc for direct microscopy of specimens or the viability of viruses in specimens to be cultured.

9.1. CLINICAL SPECIMENS

9.1.1 Ophthalmic Specimens

Collection

Apply local anaesthetic to the eye, then expose upper and lower conjunctiva. Using a cotton or Dacron™ tipped swab vigorously wipe both upper and lower conjunctival surfaces, rotating the swab during the sampling process to ensure that the entire conjunctival surface is sampled.

Preparation of Slides

Roll the specimen swab, using slight pressure, within the 6mm well area on the microscope slide. Ensure that the whole swab tip is used to prepare the slide. Allow the specimen to air dry thoroughly at room temperature (15-30°C) and then fix in fresh acetone for 10 minutes. Allow the slide to air dry. If the specimen is not stained immediately store at 4°C overnight.

9.1.2 Nasopharyngeal aspirates/secretions

Collection

Collect specimens from the nasopharyngeal region into a mucus extractor through a size 8 feeding tube. The mucus extractor and tubing should be maintained at 2-8°C and sent to the laboratory as soon as possible for processing.

Cell Separation

If necessary add 2mL phosphate buffered saline (PBS) to the sample prior to centrifugation to reduce the viscosity and dilute the mucus. Centrifuge the mucus extractor at room temperature (15-30°C) for 10 minutes at 380g. Remove the supernatant which can be used for cell culture. Resuspend the cell deposit in 2mL PBS and gently pipette the cells up and down with a wide bore pipette, or vortex gently, until the mucus is broken up and cellular material released. Avoid vigorous pipetting/vortexing to prevent damage to the cells. When a smooth suspension has been obtained add further PBS as required, pipetting or vortexing after addition of the extra PBS to wash the cells further. Remove and discard any visible flecks of mucus remaining at this point.

Excess mucus must be removed as it will prevent adequate penetration of the reagent and may result in non specific fluorescence.

If all secretions remain in the feeding tube and none reach the mucus extractor, wash all secretions out of the tube into PBS. This is best achieved by inserting a pasteur pipette into the end of the tube which was attached to the mucus extractor. Suck up the appropriate fluid into the tube and expel it repeatedly until the secretions adhering to the wall of the tube have been dislodged. Pipette the suspension up and down until the mucus has been adequately broken up.

Preparation of Slides

After completing the cell separation process, centrifuge the resultant cell suspension at room temperature (15-30°C) for 10 minutes at 380g and discard the supernatant. Resuspend the cell deposit in sufficient PBS to dilute any remaining mucus, while at the same time maintaining a high cell density. Place 25µL of the resuspended cell deposit into the well area on the slide

Allow the specimen to air dry thoroughly at room temperature (15-30°C) and fix in fresh acetone at room temperature (15-30°C) for 10 minutes. If the specimen is not stained immediately store at 4°C overnight or freeze at –20°C for longer storage periods.

9.2. CELL CULTURE

Inoculation of Cell Cultures

Specimens collected for the diagnosis of adenovirus infections should be inoculated into the cell lines routinely used in the laboratory according to established laboratory methods. Cell cultures should be examined regularly for the appearance of cytopathic effect (CPE) and haemadsorption tests carried out at regular intervals. Any haemadsorption positive cultures or cell cultures showing CPE, can be harvested and tested for the presence of Adenovirus.

Preparation of Slides

If a haemadsorption or CPE consistent with adenovirus infection is observed then the cell culture monolayer should be harvested when at least 50% of the cells are affected.

Scrape the cell sheet into the liquid culture medium using a sterile pipette. Deposit the cells by Centrifuge at 200g for 10 minutes at room temperature (15-30°C) and remove the supernatant.

Wash the cells by resuspending the cell deposit in PBS (see Section 8.2) and repeat the centrifugation. Remove the supernatant and resuspend the cell deposit in a small volume of fresh PBS to maintain a high cell density.

Place 25µL aliquots of the cell suspension on to individuals wells on the slides. Allow to air dry thoroughly and fix in fresh acetone at room temperature (15-30°C) for 10 minutes. If the specimen is not stained immediately store at 4°C overnight or freeze at –20°C for longer storage periods.

10. TEST PROCEDURE

PLEASE REFER TO SECTION 8.2 TECHNICAL PRECAUTIONS BEFORE PERFORMING TEST PROCEDURE.

10.1. ADDITION OF REAGENT

Add 25µL of Reagent to each 6mm well. Ensure that the reagent covers the entire well area.

10.2. FIRST INCUBATION

Incubate the slides with reagent in **a moist chamber** for **15 minutes** at **37°C**. **Do not** allow the reagent to dry on the specimen, as this will cause the appearance of non-specific staining.

10.3. WASHING THE SLIDE

Wash off excess reagent with Phosphate Buffered Saline (PBS) then gently wash the slide in an agitating bath containing PBS for 5 minutes. Drain off PBS and allow the slide to air dry at room temperature (15-30°C).

10.4. ADDITION OF MOUNTING FLUID

Add one drop of IMAGEN Adenovirus mounting fluid to the centre of each well and place a coverslip over the mounting fluid and specimen ensuring that no air bubbles are trapped.

10.5. READING THE SLIDE

Examine the entire well area containing the stained specimen using an epifluorescence microscope. Fluorescence, as described in Section 11, should be visible at x200-x500 magnification. (For best results slides should be examined immediately after staining, but may be stored at 2-8°C, in the dark, for up to 24 hours).

11. INTERPRETATION OF TEST RESULTS

11.1. CONTROLS

11.1.1 Positive Control Slide

When stained and viewed as described in Section 10, the positive control slide should show cells with intracellular nuclear and/or cytoplasmic apple-green fluorescence contrasting against a background of red counterstained material. These cells are slightly larger than respiratory or conjunctival epithelial cells but show similar intracellular, nuclear and/or cytoplasmic fluorescence when infected with adenovirus. Positive control slides should be used to check that the staining procedure has been satisfactorily performed.

11.1.2 Negative Control

If a negative control is required, uninfected intact cells of the type used for the culture and isolation of adenovirus are recommended. The cells should be prepared and fixed as described in Section 9.2 and stained as described in Section 10.

11.2. CLINICAL SPECIMENS

11.2.1 Appearance of Adenovirus Infected Cells

Intracellular, nuclear and/or cytoplasmic granular apple-green fluorescence is seen in respiratory or conjunctival epithelial cells infected with adenovirus.

Uninfected cells stain red with the evans blue counterstain.

11.2.2 Interpretation of Results

A positive diagnosis is made when one or more cells in the fixed, stained specimen show the typical fluorescence pattern described in Section 11.2.1.

A negative diagnosis is made when fixed, stained specimens do not exhibit fluorescence with the reagent.

For directly stained nasopharyngeal aspirate or ophthalmic specimens, at least 20 uninfected respiratory or conjunctival epithelial cells must be observed before a negative result is reported. See Section 11.2.3 if insufficient cells are present.

11.2.3 Insufficient Cells

If insufficient cells are present on the slide, the remainder of the clinical specimen should be centrifuged at 380g for 10 minutes at room temperature (15-30°C). Resuspend the cells in a smaller volume of PBS before re distribution (25µL) on the well area. Alternatively, a repeat clinical specimen should be requested.

11.3. CELL CULTURE CONFIRMATION

11.3.1 Appearance of Adenovirus Infected Cells

Infected cells will demonstrate intracellular, nuclear and/or cytoplasmic apple green fluorescence and should be recorded as positive for Adenovirus.

Uninfected cells will be counterstained red, with the evans blue counterstain.

11.3.2 Interpretation of Results

A positive diagnosis is made when at least one fixed, stained cell shows the fluorescence pattern described in Section 11.3.1 after staining.

At least 50 uninfected cells of the cell culture being tested must be observed in the slide well before a negative result is reported. See Section 11.3.3. if insufficient cells are present.

11.3.3 Insufficient Cells

If insufficient cells are present in the slide preparation, the remainder of the cell culture specimen should be centrifuged at 200g for 10 minutes at room temperature (15-30°C). Resuspend in a smaller volume of PBS before re distribution (25µL) on the well area.Alternatively, a repeat specimen should be re inoculated on to fresh cell monolayers and the cell culture repeated.

12. PERFORMANCE LIMITATIONS

12.1. Use only the mounting fluid provided with the IMAGEN Adenovirus test.

12.2. The visual appearance of the fluorescence image obtained may vary due to the type of microscope and light source used.

12.3. It is recommended that 25µL of reagent is used to cover a 6mm diameter well area. A reduction in this volume may lead to difficulties in covering the specimen area and may reduce sensitivity.

12.4. All reagents are provided at fixed working concentrations. Test performance may be affected if the reagents are modified in any way or not stored under recommended conditions as outlined in Section 5.

12.5. Failure to detect adenovirus may be a result of factors such as inappropriate collection, improper sampling and/or handling of specimen, failure of cell culture etc. A negative result does not exclude the possibility of adenovirus infection.

12.6. The presence of adenovirus in nasopharyngeal secretions does not necessarily exclude the possibility of concomitant infection with other pathogens. All positive results must be interpreted with caution since adenovirus is capable of latency and recrudescence. Asymptomatic shedding may occur up to 18 months after infection.[20] Test results should be interpreted in conjunction with information available from epidemiological studies, clinical diagnosis of the patient and other diagnostic procedures.

12.7. Test results should be interpreted in conjunction with information available from epidemiological studies, clinical assessment of the patient and other diagnostic procedures.

13. EXPECTED VALUES

Members of different adenovirus subgenera show distinctly different organ tropisms. However, illnesses are primarily manifested as respiratory, ocular and enteric infections.

The positive isolation rate will vary, depending on the test employed, the adequacy of the specimen collection, age of the population being tested and whether the populations studied are subject to overcrowding.

Isolation frequency is influenced by the severity of virus associated diseases and also by the tendency of virus strains to cause persistent infections with shedding of infectious virus over extended periods.

Adenoviruses are responsible for 5% of the acute respiratory infections in children under 4 years of age and they account for 10% of the hospitalised respiratory infections in this age group.[3,6,7] Acute haemorrhagic cystitis in children may be caused by adenoviruses. Enteric adenoviruses have been implicated in 4% to 15% of all hospitalised children with viral gastroenteritis and are most prevalent in children under 3 years of age.[3,11,12]

Ocular infections with adenoviruses (epidemic keratoconjunctivitis and swimming pool conjunctivitis) may occur in any age group as may adenovirus infection in immunosuppressed patients.[3,8]

In adults, adenoviruses have been isolated from the cervix and penile lesions and from acute respiratory infection, especially in military personnel.

14. SPECIFIC PERFORMANCE CHARACTERISTICS

14.1. SPECIFICITY OF THE MONOCLONAL ANTIBODY WITH ADENOVIRUS SEROTYPES

The monoclonal antibody utilised in this test has been shown to react with a genus specific epitope of adenovirus hexon protein which is present in all human serotypes.

14.2. CLINICAL STUDIES

The IMAGEN Adenovirus test was evaluated for direct use at two clinical trial centres on nasopharyngeal secretions collected from children and adults hospitalised with symptoms of respiratory infection. The test was also evaluated at a leading ophthalmic centre on conjunctival specimens from patients presenting with conjunctivitis. Three trial centres evaluated the IMAGEN Adenovirus test for the detection of adenovirus in cell culture.

The trial centres tested 474 clinical respiratory specimens and 179 conjunctival specimens directly, plus 296 specimens for culture confirmation. The standard tests for direct specimens were cell culture with or without indirect immunofluorescence and for culture confirmation the standard tests were indirect polyclonal antibody fluorescence or specific neutralisation.

All calculations assume that the standard tests were 100% sensitive and specific. Sensitivity, specificity and predictive values were calculated as previously described.[21]

14.3. CLINICAL PERFORMANCE

14.3.1 Direct Specimens

Nasopharyngeal Secretions

Fresh clinical specimens were tested during the winter of 1988/89 and stored (frozen) specimens which had been collected between 1978 and 1988 were also tested. The two centres compared IMAGEN Adenovirus test with reference methods. A result by the reference method was considered positive if either the cell culture or indirect immunofluorescence was positive. This allowed for the presence of non-viable virus to be detected by fluorescence or cell-free virus to be detected by cell culture. A specimen was scored positive in the IMAGEN Adenovirus test when one or more fluorescing epithelial cells were seen (see Section 11.2).

Table 14.1 shows the results of the IMAGEN Adenovirus test reagent. The overall incidence of adenovirus in these populations was 9.1% (43/474). The results correlated with the standard tests in 468 cases (98.7%). The IMAGEN Adenovirus test sensitivity was 86.0% (37/43) and specificity was 100% (431/431). The predictive values for positive and negative results were 100% (37/37) and 98.6% (431/437) respectively.

Table 14.1 Comparison of test results by the IMAGEN Adenovirus test and cell culture onnasopharyngeal specimens at 2 trial centres

TEST	RESULT			
Reference method	Neg	Pos	Pos	Neg
IMAGEN Adenovirus	Neg	Pos	Neg	Pos
No. of Specimens (474)	431	37	6*	0

*1) 4/6 specimens took greater than 10 days to produce CPE in culture. This may indicate a very low level of virus initially present in the sample.

2) 2/6 specimens were negative by indirect IF.

Ophthalmic Specimens

The IMAGEN Adenovirus test was evaluated against an established cell culture system. Conjunctival swabs were collected from 179 patients with conjunctivitis attending an eye hospital. The incidence of adenovirus infection in the population group studied was 19.6% (35/179). Smears were prepared from specimen swabs at the clinic and the swabs were then placed in a transport medium for cell culture evaluation. A specimen was scored positive in the IMAGEN Adenovirus test when one or more fluorescing epithelial cells were observed (see Section 11.2). A specimen was scored positive in the cell culture test when characteristic cytopathic effect was confirmed by indirect immunofluorescence. The results from this trial are shown in Table 14.2. Of 179 specimens tested, the same result was obtained by both methods in 174 specimens after repeat testing, giving a correlation of 97.2%. The sensitivity and specificity of the IMAGEN Adenovirus test was 91.4% (32/35) and 98.6% (142/144) respectively.

The predictive values for positive and negative tests were 94.1% (32/34) and 97.9% (142/145) respectively.

Table 14.2 Comparison of test results by the IMAGEN Adenovirus test and cell culture on humanophthalmic specimens

TEST	RESULT			
Reference method	Neg	Pos	Pos	Neg
IMAGEN Adenovirus	Neg	Pos	Neg	Pos
No. of Specimens (179)	142	32	3*	2**

*Insufficient material available for retesting of one specimen.

**Both specimens were cultured for only 2 days.

14.3.2 Cell Culture Confirmation

Three trial centres tested the IMAGEN Adenovirus test on cell cultures from clinical specimens. This was compared against indirect immunofluorescence and/or neutralisation tests for culture confirmation. Isolations were made in routine cell lines used for adenovirus culture. Cell cultures were washed in PBS before being removed and spotted on to slides. The slides were fixed in acetone and then tested using the IMAGEN Adenovirus test reagents. Both fresh clinical isolates and previously frozen specimens were used for this evaluation. A total of 296 cultures were evaluated. Cell culture positive isolates were confirmed by either immunofluorescence or neutralisation tests.

The results (Table 14.3) indicate that the IMAGEN Adenovirus test detected all positive adenovirus isolates giving a sensitivity of 100% (162/162). The specificity of the reagent was 100% (134/134).

Table 14.3 Comparison of test results by the IMAGEN Adenovirus test and standard methods for culture confirmation at 3 trial centres

TEST	RESULT			
Standard confirmation	Neg	Pos	Pos	Neg
IMAGEN Adenovirus	Neg	Pos	Neg	Pos
No. of Specimens (296)	134	162	0	0

14.4. CROSS REACTIVITY

The IMAGEN Adenovirus test was performed against preparations of other viruses and organisms likely to be present in respiratory or ophthalmic specimens or cell cultures. All organisms tested (Table 14.4) were negative with the IMAGEN Adenovirus test.

Table 14.4 Organisms tested in the IMAGEN Adenovirus test and found to be non-reactive

Acholeplasma laidlawii
Branhamella catarrhalis
Candida albicans
Chlamydia psittaci
Chlamydia trachomatis
Coxsackie virus
Cytomegalovirus
Echovirus
Epstein-Barr virus
Haemophilus influenzae
Herpes simplex virus
Influenza virus A & B
Legionella pneumophila
Measles virus
Mumps virus
Mycobacterium avium
Mycobacterium intracellulare
Mycobacterium tuberculosis
Mycoplasma arginini
Mycoplasma hominis
Mycoplasma hyorhinus
Mycoplasma orale
Mycoplasma pneumoniae
Mycoplasma salivarium
Neisseria cinerea
Neisseria flavescens
Neisseria gonorrhoea
Neisseria lactamica
Neisseria meningitidis A, B, C & D
Neisseria mucosa
Neisseria perflava
Neisseria pharyngis
Parainfluenza virus types 1,2,3 & 4b
Pneumocystis carinii
Polio virus types 1 & 2
Respiratory syncytial virus
Rhinovirus
Staphylococcus aureus
Streptococcus gps A,B,C,D,F,G
Varicella zoster virus

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