**IMAGEN Parainfluenza virus Types 1, 2 and 3**

**INTENDED USE**

IMAGEN Parainfluenza virus test kits are qualitative direct immunofluorescence test kits for the detection of Parainfluenza virus types 1, 2 and 3 in nasopharyngeal aspirates or in cell cultures. The test is intended for the confirmation of the presence of Parainfluenza virus antigens directly in nasopharyngeal aspirates and in cell culture preparations.

**A negative result obtained following direct staining of nasopharyngeal aspirates should be considered presumptive until confirmed by culture.**

**2. SUMMARY**

Parainfluenza virus types are members of the genus Parainfluenza classified within the family Paramyxoviridae. There are 6 species of Paramyxovirus known to infect man which include Parainfluenza virus types 1, 2, 3, 4 and 5 (Mumps virus and Newcastle disease virus). Of the 6 species of Paramyxovirus, Parainfluenza virus types 1, 2 and 3 have been recognized as a major cause of acute respiratory illness in infants and children.

**Rapid diagnosis is important in the management of patients infected with either Parainfluenza virus type 1, 2 or 3 (strain CDC V6-004, CDC V7-003 and CDC V7-008 respectively).**

**3. CLINICAL SPECIMENS**

- Nasopharyngeal aspirates/secretions
- Collection
- Specimens collected for the diagnosis of parainfluenza virus infections should be processed within 3 days of collection. Nasopharyngeal aspirates/secretions should be collected from the nasopharyngeal region into a mucus collection vial. Secretions should then be transferred to a PBS vial and centrifuged. The supernatant is decanted and the pellet air dried. The pellet is then suspended in 1mL of IMAGEN Parainfluenza virus Types 1, 2 and 3 reagent and 3mL of mounting fluid. The mounting fluid contains 0.1% sodium azide, which is a poison. Sodium azide may react with copper and copper leaf printing systems to form toxic metal complexes. SDS-PAGE gel studies have indicated that the main haemagglutinin protein and the nuclear and/or cytoplasmic granular apple-green fluorescence is seen in respiratory epithelial cells infected with Parainfluenza virus types 1, 2 and 3.

**4. REAGENTS PROVIDED**

- Each kit contains sufficient materials for testing 50 cell culture specimens.
- All reagents are stored at room temperature (15-30°C) between 2°C and 30°C.

**5. COLLECTION AND PREPARATION OF SPECIMENS**

The collection and preparation of specimens is of fundamental importance in the diagnosis of Parainfluenza virus infection. Specimens must be collected from the site of infection during the peak of viral shedding so that they contain as much infectious material as possible. In general, Nasopharyngeal aspirates/secretions collected in a PBS vial should be stored refrigerated until processed. The aspirates/secretions are centrifuged to recover the cell deposit which is then resuspended in IMAGEN Parainfluenza virus Types 1, 2 and 3 reagent. This reagent consists of a purified murine monoclonal antibody specific to Parainfluenza virus types 1, 2 and 3 reagent. This reagent consists of a mixture of 3 purified murine monoclonal antibodies specific to Parainfluenza virus types 1, 2 and 3 conjugated to FITC, diluted in a protein stabilised phosphate buffered saline solution containing 0.1% sodium azide as a preservative. One kit contains 1mL of IMAGEN Parainfluenza virus Types 1, 2 and 3 reagent.

**8.2.3 Typing reagents should not be pooled, or used together for typing purposes.**

**11.1.2 Negative Control**

When stained and viewed as described in Section 10, the negative control slides provided serve as a suitable control to which the test results can be compared and should be evaluated as not positive. Positive control slides should be used to check that the staining protocol is working correctly. The negative control slides provided are tested for the presence of Parainfluenza virus antigens only, and will only provide positive control for the test procedure and not the specimen processing steps. Staining negative control procedures should be controlled using positive clinical material.

**11.3.2 Interpretation of Results**

Inoculation of cells culture

**11.2. CLINICAL SPECIMENS**

**11.1. INTRODUCTION OF TEST RESULTS**

A positive diagnosis is made when either one or more of the cells in the fixed cell preparation displays intracytoplasmic, perinuclear and/or cytoplasmic green fluorescence. When viewed under the appropriate control slides. Enriched nasal cells and stained as described in Section 10. The cells on the negative control slides should not show green fluorescence. Slides prepared in this way will only provide adequate control for the test procedure and not the specimen processing steps. Staining negative control procedures should be controlled using positive clinical material.
Parainfluenza virus in the overall population as specimens were taken for Parainfluenza virus type 2 and 14.3% (24/168) for Parainfluenza virus type 3. During the winter of 1994-1995, the overall incidence of Parainfluenza virus at one trial centre based on viral isolation results was 12.5%.

Infections or reinfections in older children and adults are usually caused by Parainfluenza viruses.

Over 90% of infants will experience a primary infection with a Parainfluenza virus type during the first two years of life, and more than 80% will have been infected by the age of five.

9.2. Culture confirmation

The IMAGEN Parainfluenza virus Group test and the IMAGEN Parainfluenza virus 1, 2 and 3 Typing test were tested in clinical trials in the United Kingdom and the United States. Clinical trials were undertaken during July-October 1991. During this period, a total of 157 patient samples were collected and processed as outlined in Section 9.1.2.

9.2.1. Clinical performance

A total of 222 samples from patients with suspected respiratory virus were tested in the IMAGEN Parainfluenza virus Group test and the IMAGEN Parainfluenza virus Types 1, 2, and 3 test. At a centre in the Northeast of the United Kingdom, during the winter of 1995-1996, a total of 164 samples were collected from a population of 60 patients likely to be present in routine clinical samples (see Section 14.3).

The IMAGEN Parainfluenza virus Group test and the IMAGEN Parainfluenza virus Type 1, 2 and 3 Typing test were tested in clinical trials at 4 centres within the UK. Parainfluenza virus 1, 2 and 3 Typing test were tested in clinical trials at 2 UK Centres.

The IMAGEN Parainfluenza virus Group (Types 1, 2 and 3) test showed a correlation, sensitivity and specificity of 100% when compared with viral isolation and the reference indirect immunofluorescence test. The IMAGEN Parainfluenza virus Type 1, 2 and 3 Typing test were 97.9% and 97.5% respectively against the reference indirect immunofluorescence test. The sensitivity was 98.4% against the reference indirect immunofluorescence test. The specificity was 96.2% and 99.0% respectively.

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9.2.2. Culture confirmation

Results from one of the four trial centres include a proportion of frozen samples.

For all enquiries please contact your local distributor.