**Anti-Parainfluenza virus types 1-4 IFA (IgA, IgG or IgM)**

**BIOCHIP Mosaic™ Test System**

**Test instruction**

For In Vitro Diagnostic Use

CLIA Complexity: High

<table>
<thead>
<tr>
<th>ORDER NO.</th>
<th>ANTIBODIES</th>
<th>SUBSTRATE</th>
<th>SPECIES</th>
<th>FORMAT SLIDES x FIELDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FL 2721-1003-1 A, G or M</td>
<td>Parainfluenza virus</td>
<td>Infected cells</td>
<td>EU 18/9</td>
<td>10 x 03 (030)</td>
</tr>
<tr>
<td>FL 2721-1005-1 A, G or M</td>
<td>type 1</td>
<td>(4 BIOCHIPS per field)</td>
<td>EU 18/9</td>
<td>10 x 05 (050)</td>
</tr>
<tr>
<td>FL 2721-1010-1 A, G or M</td>
<td>type 2</td>
<td></td>
<td>EU 18/9</td>
<td>10 x 10 (100)</td>
</tr>
<tr>
<td>FL 2721-2005-1 A, G or M</td>
<td>type 3</td>
<td></td>
<td>EU 18/9</td>
<td>20 x 05 (100)</td>
</tr>
<tr>
<td>FL 2721-2010-1 A, G or M</td>
<td>type 4</td>
<td></td>
<td>EU 18/9</td>
<td>20 x 10 (200)</td>
</tr>
</tbody>
</table>

**Intended use:** These kits are intended for the qualitative or semi-quantitative determination of antibodies against Parainfluenza virus types 1-4 in human serum and plasma. They are used as an aid in the diagnosis of infections of the respiratory tract and pseudocroup, in conjunction with other laboratory and clinical findings.

**Summary and explanation**

**Clinical significance:** Parainfluenza viruses (PIV) with 4 human pathogenic serotypes (RNA viruses) belong to the Paramyxovirus family and occur worldwide. The Sendai virus, also known as murine parainfluenza virus 1 because it mainly infects rodents, was the first human parainfluenza virus (HPIV) to be discovered in 1952 in Japan [1, 2, 3]. It was followed by the HPIV type 2 (HPIV-2) in 1955, isolated from children with acute laryngotracheo-bronchitis, by the HPIV type 3 (HPIV-3) in 1985, isolated from children with respiratory disease, and finally by the HPIV type 4 (HPIV-4) in 1998, detected in children with partly mild infections of the respiratory tract [4]. The latter has two known subtypes: HPIV-4a and HPIV-4b [5]. According to the current classification there are 2 genera of human parainfluenza viruses: respiroviruses (HPIV-1, HPIV-3) and rubulaviruses (HPIV-2, HPIV-4).

Human parainfluenza viruses are transmitted through aerosols or directly by contaminated hands. The incubation period is 2 to 6 days. HPIV may occur endemically [6]. The pathogens HPIV-1 and HPIV-2 cause respiratory infections particularly in autumn, HPIV-3 is active in spring and during the first months in summer [7, 8, 9]. HPIV-4 does not show any seasonal preferences [10]. The four HPIV subtypes have the following prevalence: type 1 approx. 37%, type 2 approx. 10.5%, type 3 approx. 3913.5% and type 4 approx. 13.5% [4]

HPIV are responsible for around 30 to 40% of infections of the upper and lower respiratory tract in children and infants [9]. They are at the origin of a quarter of all pseudocroup cases in children under the age of 4 and are the second most frequently causative agent of bronchiolitis and pneumonia in children under the age of 1 after respiratory syncytial viruses. HPIV infections with symptoms of a common cold accompanied by fever, pharyngitis and fits of coughing (pseudocroup) are mainly caused by HPIV-1; bronchitis, bronchiolitis and pneumonia result from infections with HPIV-3 and HPIV-4a [10]. Reinfections may occur but generally have a mild course [11]. 90 to 100% of children under the age of 5 exhibit antibodies against HPIV-3 and around 75% against HPIV-1 and HPIV-2.
HPIV infections play a particular role in infections of the lower respiratory tract in adults. Approx. 45% of type-1 positive patients show double and multiple infections. It is difficult to determine the significance of HPIV-1 for diseases of the lower respiratory tract. An infection with type 1 might cause a disposition for further infections. In around 85% of type-3 positive patients no other pathogen was found, which is why the disease can be exclusively associated to HPIV-3 with respect to infections of the lower respiratory tract [7, 12]. HPIV-3 may also cause asthma in adults [13].

In contrast to diseases showing characteristic clinical symptoms such as measles, mumps or rubella, parainfluenza infections have a varying, unspecific clinical picture, which can be caused by various pathogens. Therefore, laboratory diagnostics play a significant role [14].

Due to the fact that there is no approved gold standard, a combination of tests should be performed, e.g. IIFT and ELISA for antibody determination in the serum. A common method is the direct determination of the agent in secretion. Growing the virus is very difficult and only performed in a few special laboratories. It is known from literature that the detectability of antibodies does not necessarily correlate with the presence of the pathogen [15]. Another frequently used method is complement binding reaction (CBR). It is however increasingly criticised for its insufficient sensitivity and its inability to differentiate between different antibody classes [16]. Today, the detection of virus RNA using RT-PCR is considered as a fast and reliable determination method but is so far only carried out in special laboratories [14]. Thus in contrast, IIFT and ELISA for the serological determination of antibodies allow a simple and reliable diagnosis [18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28]. However, it must be taken into account that clinical diagnosis can only be established on the basis of two serum samples taken and investigated in an interval of two to three weeks in addition to the clinical symptoms. The information gathered by investigating only one serum sample is considered to be insufficient [16, 17] Therefore, monitoring the disease course by repetitive testing is indispensable. Antibody testing serves for the verification of suspected cases of HPIV infection in addition to prevalence analysis. Diagnosis can be established based on the titer increase or serum conversion of specific IgA and IgM as well as the investigation of IgM.

During the acute phase two thirds of patients show a high serum titer of specific HPIV IgM antibodies or a significant increase in these antibodies. IgM antibodies may persist 2 to 11 weeks [7]. In 70 to 80% of patients cases an increase in specific IgG antibodies, at least fourfold within approx. ten days, is found during primary infection with HPIV-1, -2 or 3 using ELISA [21, 22, 23]. The individual parainfluenza virus types are known to cross-react. They may be differentiated by comparing the antibody titers [18, 19, 20, 21].

**Antigen:** For the detection of antibodies against Parainfluenza virus types 1-4 by indirect immunofluorescence infected cells (species EU 18/9) are used as standard substrate.

**Principles of the test:** Mosaics with Parainfluenza virus infected cells are incubated with diluted patient sample. If the reaction is positive, specific antibodies of classes IgA, IgG and IgM attach to the viral antigens. In a second step, the attached antibodies are stained with fluorescein-labelled anti-human antibodies and made visible with a fluorescence microscope.
Materials

Contents of a test kit for 50 determinations (FI 2721-1005-1 G):

<table>
<thead>
<tr>
<th>Description</th>
<th>Format</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Slides, each containing 5x4 BIOCHIPS coated with Parainfluenza virus infected cells (PIV types 1-4)</td>
<td>10 slides</td>
<td>SLIDE</td>
</tr>
<tr>
<td>2. Fluorescein-labelled anti-human IgG (goat), ready for use</td>
<td>1 x 1.5 ml</td>
<td>CONJUGATE</td>
</tr>
<tr>
<td>3. Positive control: antibodies against Parainfluenza virus (IgG), human, ready for use</td>
<td>1 x 0.1 ml</td>
<td>POS CONTROL</td>
</tr>
<tr>
<td>4. Negative control: anti-Parainfluenza virus negative, human, ready for use</td>
<td>1 x 0.1 ml</td>
<td>NEG CONTROL</td>
</tr>
<tr>
<td>5. Salt for PBS pH 7.2</td>
<td>2 packs</td>
<td>PBS</td>
</tr>
<tr>
<td>6. Tween 20</td>
<td>2 x 2.0 ml</td>
<td>TWEEN 20</td>
</tr>
<tr>
<td>7. Embedding medium, ready for use</td>
<td>1 x 3.0 ml</td>
<td>GLYCEROL</td>
</tr>
<tr>
<td>8. Cover glasses (62 mm x 23 mm)</td>
<td>12 pieces</td>
<td>COVERGLASS</td>
</tr>
<tr>
<td>9. Instruction booklet</td>
<td>1 booklet</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LOT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IVD</td>
<td></td>
</tr>
</tbody>
</table>

Additional materials and equipment (not supplied):

- Performance of the test with TITERPLANE technology requires reagent trays TRAY, which are not provided in the test kits. These reagent trays are reusable. They are available from EUROIMMUN under the following order number:
  - ZZ 9999-0110 Reagent trays for slides containing up to 10 fields (5x5 mm)
- Single slides (e.g., EUROIMMUN order no. FK 2721-1005-1) are provided together with cover glasses.
- Additional positive control (e.g., order no. CI 2720-0101 G) and negative control (e.g., order no. CI 2720-0101 Z) can be ordered.
- Fluorescent Microscope: Equipped with a 488 nm excitation filter; 510 nm color separator; & 520 nm blocking filter with a 100 W mercury vapour lamp light source or LED bluelight.
- Distilled or de-ionized water for wash buffer production
- Pipettes with a range of 10µl to 200µl
- Cuvettes or wash/staining dishes for PBS wash step
- Lint free towelling

Warnings and precautions

For in vitro diagnostic use.

Warning: Potentially biohazardous material. The BIOCHIPS coated with antigen substrates have been treated with a disinfecting fixing agent. Neither HBsAg nor antibodies against HIV-1, HIV-2, and HCV could be detected in the control sera using FDA-cleared or European CE-approved test systems. Nevertheless, all test system components should be handled as potentially infectious materials. Patient samples, controls and slides are to be handled as potentially infectious materials. All reagents are to be disposed of in accordance with official disposal regulations.

Some of the reagents contain sodium azide at a concentration of ≤ 0.09%. Sodium azide has been reported to form lead or copper azides in laboratory plumbing which may cause explosions. Rinse sink thoroughly with water after disposing of solutions containing azide. Avoid skin contact.

The individual reagents of one lot are matched with one another and should not generally be swapped with reagents of another lot or with reagents from another manufacturer.
Preparation and stability of the reagents

**Storage and stability:** The slides and the reagents should be stored at a temperature of between +2°C and +8°C. The test system is stable for a period of 18 months from the date of manufacture if stored properly. Do not use beyond the expiration date noted on the kit label. After initial opening, the reagents are stable until the expiry date when stored between +2°C and 8°C and protected from contamination, unless stated otherwise below. Protect from exposure to heat and light.

**Indications of instability:** Do not use if reagents appear cloudy.

- **Slides:** Ready for use. Remove the protective cover only when the slides have reached room temperature (condensed water can damage the substrate). Mark with a felt-tip pen. Do not touch the BIOCHIPS. After the protective cover has been opened, the slide should be incubated within 15 minutes. If the protective cover is damaged, the slide must not be used for diagnostics.

- **Fluorescein-labelled secondary antibody (FITC):** Ready for use. Before using for the first time, mix thoroughly. The conjugate is sensitive to light. Protect from sunlight ☀.

- **Positive and negative controls:** Ready for use. Before using for the first time, mix thoroughly.

- **PBS-Tween:** 1 pack of “Salt for PBS” should be dissolved in 1 liter of distilled water and mixed with 2 ml of Tween 20 (stir for 20 min until homogeneous). The prepared PBS-Tween can be stored at +2°C to +8°C, generally for 1 week. PBS-Tween should not be used if the solution becomes cloudy or contamination appears.

- **Embedding medium:** Ready for use.

- **Reagent trays:** Reaction fields of the reagent tray must be hydrophilic and surrounding area hydrophobic. If necessary, wipe with Extran MA 01 (Merck) and rinse generously with water. To disinfect: Immers in Sekusept Extra (Henkel) (3% in water) for 1 hour. After disinfection rinse generously with water and dry with absorbent paper.

Preparation and stability of the patient samples

**Samples:** Human sera or EDTA, heparin or citrate plasma.

**Stability:** CLSI (formerly NCCLS) Document H18-A2 recommends the following storage conditions for samples: Samples should be stored at room temperature no longer than 8 hours. If the assay will not be completed within 8 hours, the samples should be refrigerated at 2-8°C. If the assay will not be completed within 48 hours, or for shipment of the sample, samples should be frozen at -20°C or lower. Frozen samples must be mixed well after thawing and prior to testing. Diluted samples should be incubated within 8 hours. Do not use bacterially contaminated samples.

**Antibodies of class IgM:** Before determining specific antibodies of class IgM, antibodies of class IgG should be removed from the patient samples by immunoabsorption (e.g., EUROSORB: EUROIMMUN Order No.: ZF 1270-0145). This prevents rheumatoid factors of class IgM present in the sample from reacting with specifically bound IgG and giving false IgM positive results, or specific IgG displacing IgM from the antigen (false IgM negative results). With immunoabsorption rheumatoid factors are removed at the same time (RF absorbent).
Recommended sample dilution for qualitative evaluation: Determination of antibodies of classes IgA and IgG: The sample to be investigated is diluted 1:10 in PBS-Tween. For example, dilute 11.1 µl sample in 100 µl PBS-Tween and mix thoroughly, e.g., vortex for 4 seconds.

Determination of antibodies of class IgM: For immunoabsorption, dilute patient samples 1:10 with EUROSORB (for example, add 11.1 µl sample to 100 µl EUROSORB and mix thoroughly, e.g. by vortexing for 4 seconds). Incubate the mixture for 15 minutes at room temperature. Do not stir the pellet, which might have formed. Alternatively, centrifuge the mixture (5 minutes, 2000 rpm, room temperature).

Recommended sample dilution for semi-quantitative evaluation: The dilution of samples to be investigated is performed using PBS-Tween (for special considerations for the determination of class IgM antibodies, see above). For each add 100 µl of PBS-Tween to the tube and mix with 11.1 µl of the next highest concentration, e.g. vortex for 2 seconds. EUROIMMUN recommends incubating samples from a dilution of 1:10.

<table>
<thead>
<tr>
<th>Dilution</th>
<th>Dilution scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:10</td>
<td>100 µl PBS-Tween + 11.1 µl undiluted sample</td>
</tr>
<tr>
<td>1:100</td>
<td>100 µl PBS-Tween + 11.1 µl 1:10 diluted sample</td>
</tr>
<tr>
<td>1:1000</td>
<td>100 µl PBS-Tween + 11.1 µl 1:100 diluted sample</td>
</tr>
<tr>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

After every two dilution steps, a new pipette tip should be used to prevent carryover.
Procedure

The TITERPLANE Technique was developed by EUROIMMUN as an aid in standardizing immunological analyses: Patient samples, controls and in separate steps conjugate and embedding medium are applied to the reaction fields of a reagent tray. The BIOCHIP Slides are then placed into the recesses of the reagent tray, where all BIOCHIPs of the slide come into contact with the fluids, and the individual reactions commence simultaneously. The fluids are confined to the recessed wells eliminating the need to use a conventional “humidity chamber”.

*Reaction fields of the reagent tray must be hydrophilic and surrounding area hydrophobic. The reagent tray may be used repeatedly as long as the hydrophilic and hydrophobic properties are maintained. Clean with mild laboratory glassware detergent and rinse thoroughly with DI water. The tray can be checked for these properties by adding a defined amount of PBS (25µl) to each well to be sure it is restricted to the well.

Prepare: The preparation of the reagents and of the serum and plasma samples is described in this test instruction.

Pipette: Apply 30 µl of diluted sample to each reaction field of the reagent tray, avoiding air bubbles. Transfer all samples to be tested before starting the test to a reagent tray.

Incubate: Start reactions by fitting the BIOCHIP Slides into the corresponding recesses of the reagent tray. Ensure that each sample makes contact with its BIOCHIP and that the individual samples do not come into contact with each other. Incubate for 30 min at room temperature (+18°C to +25°C).

Wash: Rinse the BIOCHIP Slides with a gentle flush of PBS–Tween using a beaker and immerse them immediately afterwards in a cuvette containing PBS–Tween for 5 min. Shake with a rotary shaker if available. Wash max. 16 slides then replace PBS–Tween with new buffer.

Pipette: Apply 25 µl of fluorescein-labelled anti-human globulin to each reaction field of a clean reagent tray. Fill all the fields needed before continuing incubation. The labelled anti-human serum should be mixed before use.

Incubate: Remove one BIOCHIP Slide from cuvette. Within five seconds blot only the back and the sides with a lint free paper towel and immediately fit the BIOCHIP Slide into the recesses of the reagent tray. Do not dry the areas between the reaction fields on the slide. Check for correct contact between the BIOCHIPs and liquids. Then continue with the next BIOCHIP Slide. Protect the slides from direct sunlight. Incubate for 30 min at room temperature (+18°C to +25°C).

Wash: Fill cuvette with new PBS-Tween. Rinse the BIOCHIP Slides with a gentle flush of PBS–Tween using a beaker and place them into the cuvette filled with the new PBS-Tween for 5 min. Optional: shake with a rotary shaker if available. 10 drops of Evans Blue for each 150 ml phosphate buffer can be added for counterstaining. Wash max. 16 slides then replace PBS-Tween with new buffer.

Embed: Place embedding medium onto a cover glass – drops of max. 10 µl per reaction field. Use a reagent tray. Remove one BIOCHIP Slide from PBS–Tween and dry the back, all four sides, as well as the surface around, but not between the reaction fields with a lint free paper towel. Put the BIOCHIP Slide, with the BIOCHIPs facing downwards, onto the prepared cover glass. Check immediately that the cover glass is properly fitted into the recesses of the slide. Gently correct the position if necessary.

Evaluate: Read the fluorescence with the microscope.
General recommendation: Objective ’20x (tissue sections, infected and transfected cells), 40x (cell substrates).
Light source: mercury vapor lamp, 100 W, EUROIMMUN LED, EUROStar Bluelight.
TITERPLANE Technique

Pipette: 30 µl per field
Incubate: 30 min
Wash: 1 s flush
5 min cuvette

Pipette: 25 µl per field
Incubate: 30 min
Wash: 1 s flush
5 min cuvette

Embed: max. 10 µl per field
Evaluate: fluorescence microscopy
Interpretation of results

Fluorescence pattern (positive reaction): Antibodies against Parainfluenza virus react with the infected cells on the test substrates. They cause a fine to coarsely granular fluorescence, the cell nuclei are only very weakly stained. Some of the cells in the field of view are not infected and show no fluorescence.

If a patient samples contains antibodies against Parainfluenza virus, essentially the same pattern must be obtained as for the positive control.

If the cell nuclei or the cytoplasm of all cells are stained, i.e. also those of non-infected cells, antinuclear antibodies or antibodies against mitochondria and other cell antigens are present.

If the positive control shows no specific fluorescence pattern or the negative control shows a clear specific fluorescence, the results are not to be used and the test is to be repeated.

A large range of fluorescence images can be found on the EUROIMMUN website (www.euroimmun.com).

Qualitative evaluation:

<table>
<thead>
<tr>
<th>IgG reactivity</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No reaction at 1:10</td>
<td>Negative. No IgG class antibodies against Parainfluenza viruses detected in the patient sample. Infection cannot be excluded.</td>
</tr>
<tr>
<td>Positive reaction at 1:10</td>
<td>Positive. Former or acute infection.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IgA and IgM reactivity</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No reaction at 1:10</td>
<td>Negative. No IgA or IgM class antibodies against Parainfluenza viruses detected. Infection cannot be excluded.</td>
</tr>
<tr>
<td>Positive reaction at 1:10</td>
<td>Positive. Indication of an acute infection.</td>
</tr>
</tbody>
</table>

Semi-quantitative evaluation: The titer is defined as the sample dilution factor for which specific fluorescence is just identifiable. This should be compared to the reaction obtained with an equivalently diluted negative serum.

Antibody titers can be determined according to the following table from the fluorescence of the different sample dilutions.

<table>
<thead>
<tr>
<th>Fluorescence at 1:10</th>
<th>1:100</th>
<th>1:1000</th>
<th>1:10000</th>
</tr>
</thead>
<tbody>
<tr>
<td>weak</td>
<td>negative</td>
<td>negative</td>
<td>negative</td>
</tr>
<tr>
<td>moderate</td>
<td>negative</td>
<td>negative</td>
<td>negative</td>
</tr>
<tr>
<td>strong</td>
<td>weak</td>
<td>negative</td>
<td>negative</td>
</tr>
<tr>
<td>strong</td>
<td>moderate</td>
<td>negative</td>
<td>negative</td>
</tr>
<tr>
<td>strong</td>
<td>strong</td>
<td>weak</td>
<td>negative</td>
</tr>
<tr>
<td>strong</td>
<td>strong</td>
<td>strong</td>
<td>weak</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antibody titer</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1:10</td>
<td></td>
</tr>
<tr>
<td>1:32</td>
<td></td>
</tr>
<tr>
<td>1:100</td>
<td></td>
</tr>
<tr>
<td>1:320</td>
<td></td>
</tr>
<tr>
<td>1:1000</td>
<td></td>
</tr>
<tr>
<td>1:3200</td>
<td></td>
</tr>
<tr>
<td>1:10000</td>
<td></td>
</tr>
</tbody>
</table>

IgG antibody titers of 1:320 or higher are evaluated as an indicator for an acute infection.

For diagnosis the clinical symptoms of the patient should always be taken into account along with the serological results.
Limitations of the procedure

1. A diagnosis should not be made on a single test result. The clinical symptoms of the patient should always be taken into account along with the serological results by the physician.

2. In the case of positive and questionable immunofluorescence reactions, an enzyme immunoassay with defined target antigens should be performed subsequently for the verification and differentiation of the results.

3. Adaptation of this assay for use with automated sample processors and other liquid handling devices, in whole or in part, may yield differences in test results from those obtained using the manual procedure. It is the responsibility of each laboratory to validate that their automated procedure yields test results within acceptable limits.

4. Mishandling of slides during the staining procedure, especially allowing slides to dry between steps, may result in a "washed out" pattern appearance and/or a high level of background staining.

5. Coplin jars used for slide washing should be free from all dye residues. Use of coplin jars containing dye residue may cause staining artifacts.

6. The light source, filters and optical equipment of the fluorescence microscope can influence the sensitivity of the assay. Using traditional mercury vapour lamp systems, the performance of the microscope is significantly influenced by correct maintenance, especially alignment of the lamp and replacement of the lamp after the recommended period of time. The EUROIMMUN EUROStar fluorescence microscope with LED-Bluelight as the light source offers many advantages. Contact EUROIMMUN for details.

7. Cross reactivity: Cross reactivities among Paramyxoviridae cannot be ruled out.

8. Interference: Hemolytic, lipaemic or icteric samples were not found to affect the test results with concentrations up to 500 mg/dl for hemoglobin, 2000 mg/dl for triglyceride and 40 mg/dl for bilirubin.

Expected values

Sensitivity: The sensitivity of this test system for antibodies of the class IgG is 100%. Reference: CFT (n = 18, origin: Belgium).

Reference range: Titer 1: < 10 (IgA, IgG, IgM)
The following antibody prevalences (titer of 1:10 or higher) were determined using a panel of samples (origin: Germany) from healthy blood donors:

<table>
<thead>
<tr>
<th>antibody preferences</th>
<th>IgA (no. of samples)</th>
<th>IgG (no. of samples)</th>
<th>IgM (no. of samples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIV-1</td>
<td>24% (n = 200)</td>
<td>100% (n = 200)</td>
<td>0% (n = 146)</td>
</tr>
<tr>
<td>PIV-2</td>
<td>32% (n = 200)</td>
<td>100% (n = 200)</td>
<td>0% (n = 146)</td>
</tr>
<tr>
<td>PIV-3</td>
<td>42% (n = 200)</td>
<td>100% (n = 200)</td>
<td>0% (n = 146)</td>
</tr>
<tr>
<td>PIV-4</td>
<td>32.5% (n = 200)</td>
<td>100% (n = 200)</td>
<td>0% (n = 146)</td>
</tr>
</tbody>
</table>

Note: It is recommended that each laboratory determine its own normal range based on the population and equipment used.
**Performance characteristics**

**Measurement range:** The dilution starting point for this measurement system is 1:10. Samples can be further diluted by a factor of 10 so that the dilution series is 1:100, 1:1000, 1:10000 etc. There is no upper limit to the measurement range.

**Reproducibility:** Reproducibility was tested with more than 10 different lots. In semi-quantitative evaluation of results, the deviation amounted to no more than ±1 fluorescence intensity level for all samples. The intensity of the specific fluorescence as a numeric value is called fluorescence intensity level by EUROIMMUN. These values can reach from “0” (no specific fluorescence) to “5” (extremely strong specific fluorescence).

**Literature references**


2. Gorman WL, Gill DS, Scroggs RA, Portner A. **The hemagglutinin-neuraminidase glycoproteins of human parainfluenza virus type 1 and Sendai virus have high structure-function similarity with limited antigenic cross-reactivity.** Virology 175 (1990) 211-221.


17. Laborlexikon. laborlexikon.de/Lexikon/Inf frame/p/Parainfluenza-Antikoerper.htm


25. EUROIMMUN AG. Morrin M. Vorrichtung und Verfahren zur automatischen Fokussierung für die Mikroskopie schwach leuchtender Substrate. Deutsche Patentanmeldung DE 10 2010 053 104.0 (2010).


29. Parainfluenza-Virus 1, 2. Serologie. Hygiene-Institut Heidelberg.
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