

# PASTOREX™ STREP

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REF 61721

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Agglutination test for the grouping streptococci  
belonging to groups A, B, C, D, F, G

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## 1- INTENDED USE

Pastorex™ Strep assay is a rapid agglutination test for grouping streptococci according to Lancefield classification. The test involves use of latex suspensions specific for groups A, B, C, D, F, and G. Identification of group-specific antigens by homologous antisera requires a prior enzymatic extraction.

## 2. SUMMARY AND EXPLANATION OF THE TEST

The identification of streptococci rests on evaluation of the type of hemolysis surrounding colonies grown on Columbia blood agar ( $\beta$ ,  $\alpha$ ) and on the detection of group-specific polysaccharide antigens in the cell wall (Lancefield grouping [1]). The main serogroups following Lancefield classification are A, B, C, D, F and G. Strains belonging to these serogroups are mostly  $\beta$ -hemolytic but some may be  $\alpha$ -hemolytic or non-hemolytic. Notably, *Enterococcus* and *Streptococcus bovis* belonging to group D are not  $\beta$ -hemolytic.

Some groups of streptococci (A, C, or G groups) are consistently associated with clinical disease [2, 3, 4], whereas other streptococci (B, D, or F groups) are commensal of oral, genital or intestinal mucosa and are pathogenic only when found outside their natural habitat [5, 6]. Streptococci are responsible for a number of infections, including pharyngitis with or without septic complications [11, 12], skin infections, puerperal sepsis [2], and endocarditis. Some diseases are caused by a specific group, such as rheumatic fever and acute glomerulonephritis (group A); neonatal infections (septicemia, meningitis) and invasive infection in adults (group B) [5, 6, 14]; postsurgical infections (group F); and septicemia associated with intravenous substance abuse (group G) [4]. Group C streptococci, which are highly pathogenic in animals, can produce severe infections in pediatric patients (endocarditis, meningitis) [3] and acute bacterial arthritis in patients without risk factors [15]. Group D streptococci are responsible for urinary tract infections and endocarditis [13].

Identification of streptococci belonging to groups A, B, C, D, F or G, on the basis of group-specific polysaccharide antigens (Lancefield grouping [1]) can be difficult for a number of reasons:

- Some strains have two group antigens (D and G) [7, 8, 9];
- Some  $\alpha$ -hemolytic strains exhibit the group C antigen [10];
- Some atypical strains produce hemolytic microcolonies exhibiting A, C, or G antigens [11].

However, in most instances, prompt identification of streptococci following Lancefield grouping allows to establish a presumptive diagnosis of streptococcal infections. Pastorex™ Strep assay is a simple test, requiring basic laboratory equipment and easy to perform, allowing this identification.

### 3. PRINCIPLES OF THE PROCEDURE

Pastorex™ Strep assay uses a simple enzymatic extraction. The antigen contained in the extract is identified using latex particles coated with group-specific homologous antibodies. In the presence of the homologous antigen, the latex particles agglutinate. In the absence of antigen, they remain in homogenous suspension.

### 4. REAGENTS

#### 4.1. DESCRIPTION

##### A) Pastorex™ Strep, code 61721 (60 tests):

Identification		Description	Presentation
A	<b>Pastorex™ Strep A</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group A <i>Streptococcus</i> Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 red cap</b> dropper bottle, <b>ready to use</b>
B	<b>Pastorex™ Strep B</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group B <i>Streptococcus</i> Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 yellow cap</b> dropper bottle, <b>ready to use</b>
C	<b>Pastorex™ Strep C</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group C <i>Streptococcus</i> Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 blue cap</b> dropper bottle, <b>ready to use</b>
D	<b>Pastorex™ Strep D</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group D <i>Streptococcus</i> Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 orange cap</b> dropper bottle, <b>ready to use</b>
F	<b>Pastorex™ Strep F</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group F <i>Streptococcus</i> Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 plum cap</b> dropper bottle, <b>ready to use</b>

Identification		Description	Presentation
G	<b>Pastorex™ Strep G</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group G <i>Streptococcus</i> Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 green cap</b> dropper bottle, <b>ready to use</b>
-	<b>Pastorex™ Strep Positive control</b>	Polyvalent positive control antigen, containing the polysaccharide antigens of groups A, B, C, D, F2, and G streptococci Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 x 1.5 ml (q.s. for 5 tests using each latex suspension)
-	<b>Pastorex™ Strep Extraction enzyme</b>	Extraction enzyme in TRIS (35.8%) Preservative: 1.43% Bronidox	<b>2 bottles of lyophilized extraction enzyme</b> to be reconstituted with 10 ml sterile water (Volume sufficient for <b>30 reactions</b> )
-	<b>Cards</b>	Disposable agglutination cards (8 circles)	<b>4 x 15 agglutination cards</b>
-	<b>Sticks</b>	Disposable mixing sticks	<b>3 x 125 units</b>

### B) Pastorex™ Strep, Individual latex tests (60 tests each):

Product code	Identification		Description	Presentation
61726	<b>A</b>	<b>Pastorex™ Strep A</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group A <i>Streptococcus</i> Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 red cap</b> dropper bottle, <b>ready to use</b>
61727	<b>B</b>	<b>Pastorex™ Strep B</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group B <i>Streptococcus</i> Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 yellow cap</b> dropper bottle, <b>ready to use</b>

Product code	Identification		Description	Presentation
61732	<b>C</b>	<b>Pastorex™ Strep C</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group C Streptococcus Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 blue cap</b> dropper bottle, <b>ready to use</b>
61728	<b>D</b>	<b>Pastorex™ Strep D</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group D Streptococcus Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 orange cap</b> dropper bottle, <b>ready to use</b>
61733	<b>F</b>	<b>Pastorex™ Strep F</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group F Streptococcus Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 plum cap</b> dropper bottle, <b>ready to use</b>
61734	<b>G</b>	<b>Pastorex™ Strep G</b> Latex	Red latex suspension sensitized with rabbit immunoglobulins specific for group G Streptococcus Preservative: 0.3% ProClin™ 300 and 0.005% Gentamicin sulfate	1 ml <b>1 green cap</b> dropper bottle, <b>ready to use</b>
61729	<b>Pastorex™ Strep Extraction enzyme</b>		<b>Extraction enzyme</b> in TRIS (35.8%) Preservative: 1.43% Bronidox	<b>2 bottles of lyophilized</b> extraction enzyme to be reconstituted with 10 ml distilled water (Volume sufficient for <b>30 reactions</b> )
61723	<b>Agglutination Cards</b>		Disposable agglutination cards (8 circles)	<b>4 x 15 agglutination cards</b>

## 4.2. STORAGE AND HANDLING REQUIREMENTS

- Reagents can be used until the expiry date stated on the package if stored at +2-8°C and in the absence of microbial contamination (even once open).
- THE LATEX REAGENTS SHOULD NOT BE FROZEN.
- Ensure that the caps of the dropper bottles are firmly tightened to avoid contamination or drying of the reagents.
- Store the latex reagent bottles upright (inside the original foam provided in the kit).

Identification	Preservation (after first opening)
A, B, C, D, F, G, Positive control	After first opening: until the expiry date mentioned on the package at +2-8°C
Extraction enzyme	After reconstitution: 4 months at +2-8°C

## 5. WARNING AND PRECAUTIONS

For *in vitro* diagnostic use by laboratory professional user only, in laboratory environment:

### 5.1. HEALTH AND SAFETY PRECAUTIONS

- This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
- Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or biohazardous wastes must be handled and discarded in accordance with all local, regional and national regulations.
- For hazard and precaution recommendations related to some chemical components in this test kit, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instruction for use. The Safety Data Sheet is available on [www.biorad.com](http://www.biorad.com).

## 5.2. PRECAUTIONS RELATIVE TO THE PROCEDURE

### 5.2.1. Preparing

- Before use, wait for 10 minutes for the reagents dropper bottle to reach room temperature (18-30°C).
- Do not touch the reaction surface of the agglutination cards.
- The extraction enzyme solution should be reconstituted with distilled sterile water avoiding any contamination.
- It is recommended to identify the circles of the card with the latex group(s) before to start the grouping procedure.
- Use the plastic mixing sticks supplied in the kit for mixing the reagents with bacterial colonies.
- Do not use expired reagents.
- DO NOT USE the kit if the packaging of components is damaged.

### 5.2.2. Processing

- Perform the test at room temperature (between 18-30°C), avoiding to be placed under an air-conditioning flow.
- Shake gently the reagents before each use. Then check that the latex suspension remains homogenous before use.
- To ensure proper drop delivery, always hold the reagent dropper bottles in a vertical position.
- Wipe the tip of the reagent dropper bottle in order to obtain well calibrated drops.
- Change the mixing stick for each reaction.
- Discard all disposable material used in an autoclavable waste bin or disinfectant bath.

## 6. SPECIMENS

The Pastorex™ Strep assay must be performed with **fresh** and **well isolated** streptococci colonies on Columbia Blood agar (e.g. Bio-Rad, codes 63804, 63784) or Columbia CNA agar (e.g. Bio-Rad, code 63954) (Gram-positive, catalase negative cocci colonies).

Pastorex™ Strep B latex can also be performed with **fresh** and **well isolated** suspected Group B streptococci colonies on **StrepBSelect™** (Bio-Rad, code 63750) [16].

## 7. PROCEDURE

### 7.1. MATERIAL REQUIRED

- All materials listed under “Reagents” and their controls
- Pastorex™ Strep Extraction enzyme (code 61729)



- Disposable agglutination cards (code 61723)
- 37°C dry incubator (optional for extraction enzyme preparation)

## 7.2. MATERIAL REQUIRED BUT NOT PROVIDED

- Standard micropipettes for distributing 40 µl and 300 µl
- Standard pipettes for distributing 10 ml
- Loop for collection of bacterial colonies
- Sterile distilled water
- Sterile physiological water
- Hemolysis tubes or micro-tubes (1 per strain to be tested)
- Timer
- Disinfectant bath

## 7.3. ASSAY PROCEDURE

### Extract Preparation:

*Note: Internal studies show that Pastorex™ Strep B latex (61727) gives correct specificity and sensitivity results when used to test suspected group B colonies grown on StrepBSelect™ medium, without prior enzymatic extraction.*

Place 300 µl of extraction enzyme suspension in a hemolysis tube for each strain isolated to be tested.

- Using a loop, carefully emulsify 5 to 10 colonies of a fresh Streptococci culture in the enzyme solution in such a way in order to obtain a homogeneous suspension. If the diameter of the colonies is less than 0.5 mm, increase the size of the inoculum until cloudiness is visible with the naked eye.
- Incubate either 15 to 45 minutes at room temperature (18-30°C) or 10 to 30 minutes at 37°C.

### Grouping Procedure from Columbia Blood agar or Columbia CNA agar:

- Place 40 µl of the extract suspension in each circle of the agglutination card.
- Gently shake the reagents. Holding the dropper bottles upright, place one drop of each A, B, C, D, F and G reagents at the periphery of the extract suspension on the agglutination card.
- Mix the drop of latex and the extract suspension using a stick on the whole circle surface, changing the stick between each latex reagent.
- Rotate the card gently, horizontally, **for 1 minute maximum**.
- Observe for any agglutination visible to the naked eye within a **maximum of 1 minute**. The size and speed of development of the clumps varies with the concentration of the antigen in the extract solution.

### **Grouping Procedure from StrepBSelect™ agar:**

Based on internal studies, it is recommended to perform the grouping of suspected Group B streptococci (GBS) on **StrepBSelect™** with latex B reagent directly from colonies without the prior enzymatic extraction used in standard procedure:

- Gently shake the latex B reagent. Holding the dropper bottle upright, place one drop of latex B reagent at the periphery of the agglutination card.
- Using a loop, pick 1 blue colored suspected GBS colony on **StrepBSelect™**.
- Using the loop, carefully emulsify the colonies in the drop of latex in such a way in order to obtain a homogeneous suspension. Then, spread the suspension to the whole circle surface.
- Rotate the card gently, horizontally, **for 1 minute maximum**.
- Observe for any agglutination visible to the naked eye within a **maximum of 1 minute**. The size and speed of development of the clumps varies with the concentration of the antigen in the extract solution.

### **7.4. QUALITY CONTROL**

The latex reagents should be completely homogenous after shaking.

#### **Latex suspensions control:**

- Dispense 1 drop of the Positive control in each circle on the disposable card.
- Gently shake the latex reagents. Holding the dropper bottles upright, place one drop of each latex reagent on the disposable card following your distribution pattern.
- Mix the latex reagents and the Positive control using a stick, changing the stick between each latex reagent.
- Rotate the card gently **for 1 minute** and observe for the appearance of any agglutination.
- A sterile physiological water controls the absence of unspecific agglutination of each latex reagent. To perform this quality-control test, sterile physiological water is used according to the protocol for the Positive control aforementioned.
- The latex reagents should not be used when they do not agglutinate with the Positive control, or when they non-specifically agglutinate with sterile physiological water (this could be due to incorrect storage conditions of the kit or a latex reagent contamination).

### **Enzyme extract control:**

The activity of the enzyme solution can be controlled using a *Streptococcus* strain whose group is known. The antigen extracted from this strain should promptly agglutinate the corresponding latex suspension.

## **7.5. INTERPRETATION OF RESULTS**

### **Positive reaction**

A positive reaction is indicated by red clumps on a green background, visible to the naked eye. Agglutination intensity and time of appearance depends upon the strain tested.

Only marked, rapid agglutination with only one of the six latex suspensions convincingly establishes the group of the strain tested.

### **Negative reaction**

A negative reaction is indicated by a homogenous brown suspension, without clumps, after 1 minute of agitation. Do not conclude a negative result before 1 minute.

### **Non-interpretable results**

A reaction is un-interpretable if small clumps appear on a brown background, or if agglutination appears with more than one latex reagent in the kit. When a doubtful reaction of this type occurs, it is recommended to repeat the isolation procedure.

## **8. TEST LIMITATION**

- a) Erroneous results can occur if an incorrect number of colonies are used for the extraction.
- b) Some strains of *Streptococcus dysgalactiae* may agglutinate with Strep A latex (code 61721).
- c) Rare strains of *Corynebacterium* may agglutinate with Strep B latex (code 61727). Colony size and type R morphology enable the differentiation from typical streptococci colonies.
- d) Some strains of *Streptococcus pneumoniae* may agglutinate with Strep C latex (code 61732). This cross-reaction is due to a similarity with the pneumococcal F antigen [10].
- e) Some strains of *Enterococcus* (*E. durans*, *E. avium*, *E. faecium* and *E. gallinarium*) may not agglutinate with Strep D latex (code 61728).
- f) The final diagnosis, as for all laboratory diagnoses, cannot be based on the results of one single test, but on an overview of the clinical data and the biochemical, cytological and immunological results.

## 9. PERFORMANCES CHARACTERISTICS

### 9.1. PRECISION MEASUREMENT

A panel of 2 specimens was used for determining the reproducibility and precision of the Pastorex™ Strep assay. The 2-member reproducibility panel included 1 negative (*Streptococcus pneumoniae* non-reactive with all latex reagents) and 1 positive consisting of groups A, B, C, F, G *Streptococcus* or *Enterococcus* colonies defined according to each latex reagent. For each sample to test with the different latex A to G, an enzymatic extraction must be performed on the corresponding *Streptococcus* colonies.

#### 9.1.1. Repeatability

Reproducibility panel (N = 2) as described above was tested in replicates of 10 on the same day on one lot of Pastorex™ Strep assay and read by one operator. As shown on table I, negative and positive panel members gave the same expected results with all the 10 replicates.

**Table I: Repeatability results**

Repeatability with Pastorex™ Strep assay		Negative Panel member			Positive Panel member		
Pastorex™ Strep Latex Reagent	Strain detection	Total reps	Non-reactive	Reactive	Total reps	Non-reactive	Reactive
A	Group A <i>Streptococcus</i>	10	10	0	10	0	10
B	Group B <i>Streptococcus</i>	10	10	0	10	0	10
C	Group C <i>Streptococcus</i>	10	10	0	10	0	10
D	Group D <i>Streptococcus</i>	10	10	0	10	0	10
F	Group F <i>Streptococcus</i>	10	10	0	10	0	10
G	Group G <i>Streptococcus</i>	10	10	0	10	0	10

### 9.1.2. Intermediate Precision

Reproducibility panel (N=2) as described above was tested in replicates of 20 by two independent operators in 2 replicates per day during 5 days. As shown on table II, negative and positive panel members gave the same expected results with all the 20 replicates.

**Table II: Run-to-run, day-to-day and inter-operator Precision results**

Run-to-run, day-to-day and inter-operator Precision		Negative Panel member			Positive Panel member		
Pastorex™ Strep Latex Reagent	Strain detection	Total reps	Non- reactive	Reactive	Total reps	Non- reactive	Reactive
<b>A</b>	Group A <i>Streptococcus</i>	20	20	0	20	0	20
<b>B</b>	Group B <i>Streptococcus</i>	20	20	0	20	0	20
<b>C</b>	Group C <i>Streptococcus</i>	20	20	0	20	0	20
<b>D</b>	Group D <i>Streptococcus</i>	20	20	0	20	0	20
<b>F</b>	Group F <i>Streptococcus</i>	20	20	0	20	0	20
<b>G</b>	Group G <i>Streptococcus</i>	20	20	0	20	0	20

### 9.1.3. Inter-lot Precision

Inter-lot precision was examined through QC results (sensitivity and specificity) of three manufacturing lots. Streptococci and *Enterococcus* strains panels were used to compare sensitivity and specificity characteristics of latex reagents.

Batch-to-batch consistency of latex sensitivity is evidenced by very near agglutination intensity levels obtained on the three lots with strains positive panels (see table III). Batch-to-batch consistency of latex specificity is evidenced by absence of agglutination obtained on the three lots with non-intended strains (see table IV).

**Table III: Between-Lot Precision with positive panels**

Inter-lot Precision with Pastorex™ Strep assay		Strains panel (agglutination intensity)		
Latex Reagent	Strain detection	Lot A	Lot B	Lot C
A	Group A <i>Streptococcus</i> (strain 1)	3	3	3
	Group A <i>Streptococcus</i> (strain 2)	3	2.5	3
B	Group B <i>Streptococcus</i> (strain 1)	3	3	3
	Group B <i>Streptococcus</i> (strain 2)	3	3	3
C	Group C <i>Streptococcus</i> (strain 1)	2.5	2.5	2.5
	Group C <i>Streptococcus</i> (strain 2)	2.5	3	3
D	Group D <i>Enterococcus</i> (strain 1)	3	2.5	2.5
	Group D <i>Enterococcus</i> (strain 2)	< 0.5	0.5	0.5
	Group D <i>Enterococcus</i> (strain 3)	3	3	2.5
F	Group F <i>Streptococcus</i> (strain 1)	3	3	3
	Group F <i>Streptococcus</i> (strain 2)	3	3	2.5
G	Group G <i>Streptococcus</i> (strain 1)	2.5	3	3
	Group G <i>Streptococcus</i> (strain 2)	2.5	3	2.5

Notes: Agglutination Intensity was quoted between 0 and 3 (“0” = negative homogeneous reaction; “1” = fine red clumps on green background; “2” = small clumps but clearly visible on green background; “3” = numerous and visible clumps on green background; e.g 2.5 is comprised between 2 and 3)

**Table IV: Between-Lot Precision with negative panels**

Between-lot Precision with Pastorex™ Strep assay		Strains panel (agglutination intensity)		
Latex Reagent	Strain detection	Lot A	Lot B	Lot C
B, C, D, F, G	Group A <i>Streptococcus</i> (strain 1)	0	0	0
	Group A <i>Streptococcus</i> (strain 2)	0	0	0
A, C, D, F, G	Group B <i>Streptococcus</i> (strain 1)	0	0	0
	Group B <i>Streptococcus</i> (strain 2)	0	0	0
A, B, D, F, G	Group C <i>Streptococcus</i> (strain 1)	0	0	0
	Group C <i>Streptococcus</i> (strain 2)	0	0	0
A, B, C, F, G	Group D <i>Streptococcus</i> (strain 1)	0	0	0
	Group D <i>Streptococcus</i> (strain 2)	0	0	0
	Group D <i>Streptococcus</i> (strain 3)	0	0	0
A, B, C, D, G	Group F <i>Streptococcus</i> (strain 1)	0	0	0
	Group F <i>Streptococcus</i> (strain 2)	0	0	0
A, B, C, D, F	Group G <i>Streptococcus</i> (strain 1)	0	0	0
	Group G <i>Streptococcus</i> (strain 2)	0	0	0

## 9.2. CLINICAL PERFORMANCES

### 9.2.1. Diagnostic Specificity

Specificity performance tested on 55 strains as *Streptococcus mitis* (N=1); *Streptococcus pneumoniae* (N=7); *Streptococcus viridans* (N=6); oral streptococci (N=16); *Aerococcus viridans* (N=1); *Listeria monocytogenes* (N=2); *Gardnerella vaginalis* (N=1) and *Corynebacterium* (N=21) was 100% (55/55) with Strep A, D, F and G latex, 98.2% with Strep B latex and 90.9% with Strep C latex, showing non-specific reactivity. One false positive result was obtained with Strep B latex and *Corynebacterium* strain (but colony size/aspect was different from streptococci) and five false positive results were obtained with Strep C latex and *Streptococcus pneumoniae* strains (due to common cross-reaction with pneumococcal antigen F).

**Table V: Specificity on colonies from bacterial culture**

Pastorex™ Strep Latex Reagent	Strain detection	Number tested	Number found Non-Reactive	Specificity (%)
<b>A</b>	Group A <i>Streptococcus</i>	55	55	<b>100</b>
<b>B</b>	Group B <i>Streptococcus</i>	55	54 (**)	<b>98.2</b>
<b>C</b>	Group C <i>Streptococcus</i>	55	50 (*)	<b>90.9</b>
<b>D</b>	Group D <i>Streptococcus</i>	55	55	<b>100</b>
<b>F</b>	Group F <i>Streptococcus</i>	55	55	<b>100</b>
<b>G</b>	Group G <i>Streptococcus</i>	55	55	<b>100</b>

Notes: (\*) 5 *S. pneumoniae* strains over 7 false reactivity with latex C reagent, due to common cross-reaction with pneumococcal antigen F [10].

(\*\*) 1 *Corynebacterium* strain over 21 tested false reactivity with latex B, but colony size/aspect was different from streptococci.

### 9.2.2. Diagnostic Sensitivity

As shown in table VI, sensitivity performance tested on 162 strains (2 strains were excluded) is 100% with latex A, B, C, F and G and 88.9% (24/27) with latex D, due to non-reactivity with three enterococci strains (*E. durans*, *E. avium* and *E. gallinarium*). Each streptococci strain was tested with the 6 latex reagents and did not show any cross-reactivity with non-specific latex reagents.

164 strains tested on Pastorex™ Strep assay were group A streptococci (N=67); group B streptococci (N=41); group C streptococci (N=9); group D streptococci (N=29) including *Enterococcus durans*, *Enterococcus casseliflavus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Enterococcus avium*, *Enterococcus gallinarium* and *Streptococcus bovis*; group F streptococci (N=4) and group G streptococci (N=14).

**Table VI: Sensitivity on colonies from bacterial culture**

Pastorex™ Strep Latex Reagent	Strain detection	Number tested	Number found Reactive	Sensitivity (%)
<b>A</b>	Group A <i>Streptococcus</i>	67	67	<b>100</b>
<b>B</b>	Group B <i>Streptococcus</i>	41	41	<b>100</b>
<b>C</b>	Group C <i>Streptococcus</i>	9	9	<b>100</b>
<b>D</b>	Group D <i>Streptococcus</i>	27	24 (*)	<b>88.9</b>
<b>F</b>	Group F <i>Streptococcus</i>	4	4	<b>100</b>
<b>G</b>	Group G <i>Streptococcus</i>	14	14	<b>100</b>

Notes: (\*) Five strains (1 *E. durans*; 1 *E. avium*; 1 *E. gallinarium*; 1 *S. bovis* and 1 *E. faecium*) over 29 tested were found non-reactive with latex D reagent. The two last strains (*S. bovis* and *E. faecium*) were excluded because also non-reactive with the reference comparator assay for giving at final 3 false negative over 27 tested strains (specificity 88.9%).

### 9.3. CROSS REACTIVITY STUDY

See §9.2.1 Diagnostic specificity on colonies from bacterial culture.

### 9.4. HOOK EFFECT

The number of colonies to be handled cannot be more than 10-15 units (giving accurate results according to the robustness study), thus making Hook effect not relevant with Pastorex™ Strep assay.

## 10. BIBLIOGRAPHY REFERENCES

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- (BG)** • Този продукт съдържа човешки или животински компоненти. Бъдете внимателни при работа с него.
- (CZ)** • Tento výrobek obsahuje lidské nebo zvířecí komponenty. Zacházejte s ním opatrně.
- (DE)** • Dieses Produkt enthält Bestandteile menschlichen oder tierischen Ursprungs. Vorsichtig handhaben.
- (DK)** • Dette produkt indeholder humane og animalske komponenter. Skal behandles med forsigtighed.
- (EE)** • Käesolev toode sisaldab inim-või loomseid komponente. Käsitseta ettevaatlikult.
- (EN)** • This product contains human or animal components. Handle with care.
- (ES)** • Este producto contiene componentes humanos o animales. Manejar con cuidado.
- (FI)** • Tässä tuotteessa on ihmisestä tai eläimistä peräisin olevia osia. Käsittele varovasti.
- (FR)** • Ce produit contient des composants d'origine humaine ou animale. Manipuler avec précaution.
- (GR)** • Αυτό το προϊόν περιέχει ανθρώπινα ή ζωικά στοιχεία. Χειριστείτε το με προσοχή.
- (HR)** • Ovaj proizvod sadrži ljudske ili životinjske sastojke. Pažljivo rukovati.
- (HU)** • A készítmény emberi vagy állati eredetű összetevőket tartalmaz. Óvatosan kezelendő.
- (IT)** • Questo prodotto contiene componenti umane o animali. Maneggiare con cura.
- (LT)** • Šiame produkto yra žmogiškosios arba gyvūninės kilmės sudėtinųjų dalių. Elgtis atsargiai.
- (NL)** • Dit product bevat menselijke of dierlijke bestanddelen. Breekbaar.
- (NO)** • Dette produktet inneholder humane eller animalske komponenter. Håndteres med forsiktighet.
- (PL)** • Niniejszy produkt zawiera składniki pochodzenia ludzkiego lub zwierzęcego. Należy obchodzić się z nim ostrożnie.
- (PT)** • Este medicamento contém componentes de origem humana ou animal. Manuseie com cuidado.
- (RO)** • Acest produs conține materiale de origine umană sau animală. Manevrati-l cu grijă.
- (SE)** • Denna produkt innehåller beståndsdelar från människa eller djur. Hantera produkten varsamt.
- (SI)** • Izdelek vsebuje človeške ali živalske sestavine. Rokujte previdno.
- (SK)** • Tento výrobok obsahuje ľudské alebo zvieracie zložky. Narábajte s ním opatrne.



**H315-H319-H335-H317**  
**P261-P280-P302+P352-**  
**P333+P313-P305+P351+P338-**  
**P304+P340-P501**

## (BG)

### внимание

Предизвиква дразнене на кожата. Предизвиква сериозно дразнене на очите. Може да предизвика дразнене на дихателните пътища. Може да причини алергична кожна реакция.

Избягвайте вдишване на прах/пушек/газ/дим/изпарения/аерозоли Използвайте предпазни ръкавици/предпазно облекло/предпазни очила/предпазна маска за лице. ПРИ КОНТАКТ С КОЖАТА: Измийте обилно със сапун и вода. При поява на кожно дразнене или обрив на кожата: Потърсете медицински съвет/помощ. ПРИ КОНТАКТ С ОЧИТЕ: Промийте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако има такива и докопкото това е възможно. Продължавайте да промивате. ПРИ ВДИШВАНЕ: Изведете пострадалия на чист въздух и го поставете в позиция, улесняваща дишането. Изхвърлете съдържанието/контейнера в съответствие с местните/регионалните/националните/международните разпоредби.

## (CZ)

### Varování

Dráždí kůži. Způsobuje vážné podráždění očí. Může způsobit podráždění dýchacích cest. Může vyvolat alergickou kožní reakci.  
Zamezte vdechování prachu/dýmu/plynu/mlhy/par/aerosolů. Používejte ochranné rukavice/ochranný oděv/ochranné brýle/obličejový štít. PŘI STYKU S KŮŽÍ: Omyjte velkým množstvím vody a mýdla. Při podráždění kůže nebo výrazce: Vyhleďte lékařskou pomoc/ošetření. PŘI ZASAŽENÍ OČÍ: Několik minut opatrně vyplachujte vodou. Vyjměte kontaktní čočky, jsou-li nasazeny a pokud je lze vyjmout snadno. Pokračujte ve vyplachování. PŘI VDECHNUTÍ: Přenešte postiženého na čerstvý vzduch a ponechte jej v klidu v poloze usnadňující dýchání. Obsah/nádobu likvidujte v souladu s místními/regionálními/národními/mezinárodními předpisy.

## (DE)

### Achtung

Verursacht Hautreizungen. Verursacht schwere Augenreizung. Kann die Atemwege reizen. Kann allergische Hautreaktionen verursachen.  
Einatmen von Staub/Rauch/Gas/Nebel/Dampf/Aerosol vermeiden. Schutzhandschuh/e/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.  
BEI KONTAKT MIT DER HAUT: Mit viel Wasser und Seife waschen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.  
BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter

spülen. BEI EINATMEN: An die frische Luft bringen und in einer Position ruhigstellen, die das Atmen erleichtert. Entsorgung des Inhalts / des Behälters gemäß den örtlichen / regionalen / nationalen / internationalen Vorschriften.

## (DK)

### Advarsel

Forårsager hudirritation. Forårsager alvorlig øjenirritation. Kan forårsage irritation af luftvejene. Kan forårsage allergisk hudreaktion.  
Undgå indånding af pulver/røg/gas/tåge/damp/spray. Bær beskyttelsehandsker/beskyttelsestøj/øjenskyttelse/ansigtsbeskyttelse VED KONTAKT MED HUDEN: Vask med rigeligt sæbe og vand. Ved hudirritation eller udslæt: Søg lægehjælp. VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning. VED INDÅNDING: Flyt personen til et sted med frisk luft og sørg for, at vedkommende hviler i en stilling, som letter vejrtrækningen. Bortskaftelse af indholdet/holderen i henhold til de lokale/regionale/nationale/internationale forskrifter.

## (EE)

### Hoiatus

Põhjustab nahaärritust. Põhjustab tugevat silmade ärritust. Võib põhjustada hingamisteede ärritust. Võib põhjustada allergilist nahareaktsiooni.  
Vältida tolm/suitsu/gaasi/udu/auru/pihustatud aine sissehingamist. Kanda kaitsekindaid/kaitserõivastust/kaitsepille/kaitsemaski. NAHALE SATTUMISE KORRAL: pesta rohke vee ja seebiga. Nahaärrituse või \_obe korral: pööruda arsti poole. SILMA SATTUMISE KORRAL: loputada mitme minuti jooksul ettevaatlikult veega. Eemaldada kontaktiläätsed, kui neid kasutatakse ja kui neid on kerge eemaldada. Loputada veel kord. SISSEHINGAMISE KORRAL: toimetada kannatanu värske õhu kätte ja asetada mugavasse puhkeasendisse, mis võimaldab kergesti hingata. Sisu/konteineri kaitlus vastavuses kohalike/regionaalsete/rahvuslike/rahvusvaheliste nõuetega.

## (EN)

### Warning

Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May cause an allergic skin reaction.  
Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Dispose of contents/container in accordance with local/regional/national/international regulations.

**(ES)****Atención**

Provoca irritación cutánea. Provoca irritación ocular grave. Puede irritar las vías respiratorias. Puede provocar una reacción alérgica en la piel.  
Evitar respirar el polvo/el humo/el gas/la niebla/los vapores/el aerosol. Llevar guantes/prendas/gafas/máscara de protección. EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes. En caso de irritación o erupción cutánea: Consultar a un médico. EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. EN CASO DE INHALACIÓN: Transportar a la víctima al exterior y mantenerla en reposo en una posición confortable para respirar. Eliminar el contenido o el recipiente conforme a la reglamentación local/regional/nacional/internacional.

**(FI)****Varoitukset**

Ärsyttää ihoa. Ärsyttää voimakkaasti silmiä. Saattaa aiheuttaa hengitysteiden ärsytystä. Voi aiheuttaa allergisen ihoreaktion.  
Vältä pölyn/savun/kaasun/sumun/höyryn/suihkeen hengittämistä. Käytä suojakäsineitä/suojavaatetusta/silmien suojausta/kasvosuojainta. JOS KEMIKAALIA JOUTUU IHOLLE: Pese runsaalla vedellä ja saippualla. Jos ilmenee ihoärsytystä tai ihottumaa: Hakeudu lääkäriin. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhto huolellisesti vedellä usean minuutin ajan. Poista piilolinssit, edical voi tehdä hengittä. Jatka huuhtomista. JOS KEMIKAALIA ON HENGITETTY: Siirrä henkilö raittiiseen ilmaan ja jädä lepoasennossa, jossa on helppo hengittää. Säilytä säiliö(t) noudattaen paikallisia/alueellisia/kansallisia/kansainvälisiä määräyksiä.

**(FR)****Attention**

Provoque une irritation cutanée. Provoque une sévère irritation des yeux. Peut irriter les voies respiratoires. Peut provoquer une allergie cutanée. Éviter de respirer les poussières/fumées/gaz/brouillards/vapeurs/aérosols. Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon. En cas d'irritation ou d'éruption cutanée: consulter un médecin. EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. EN CAS D'INHALATION: transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer. Éliminer le contenu/réceptacle conformément à la réglementation locale/régionale/nationale/internationale.

**(GR)****Προσοχή**

Προκαλεί ερεθισμό του δέρματος. Προκαλεί σοβαρό οφθαλμικό ερεθισμό. Μπορεί να προκαλέσει ερεθισμό της αναπνευστικής οδού. Μπορεί να προκαλέσει αλλεργική δερματική αντίδραση. Αποφεύγετε να αναπνεύετε σκόνη/αναθυμιάσεις/αέρια/σταγονίδια/ατμούς/εκνεφώματα. Να φοράτε προστατευτικά γάντια/προστατευτικά ενδύματα/μέσα ατομικής προστασίας για ταμάρτια/πρόσωπο. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΟ ΔΕΡΜΑ: Πλύνετε με άφθονο νερό και σαπούνι. Εάν παρατηρηθεί ερεθισμός του δέρματος ή εμφανιστεί εξάνθημα: Συμβουλευθείτε/Επισκεφθείτε γιατρό. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΑ ΜΑΤΙΑ: Ξεπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχουν φακοί επαφής, αφαιρέστε τους, εφόσον είναι εύκολο. Συνεχίστε να ξεπλένετε. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΙΣΠΝΟΗΣ: Μεταφέρετε τον παθόντα στον καθαρό αέρα και αφήστε τον να ξεκουραστεί σε στάση που διευκολύνει την αναπνοή. Απορρίψτε τα περιεχόμενα/δοχείο σύμφωνα με τους τοπικούς/εθνικούς/διεθνείς κανονισμούς.

**(HR)****UPOZORENJE**

Nadražuje kožu. Uzrokuje jako nadraživanje oka. Može nadražiti dišni sustav. Može izazvati alergijsku reakciju na koži. Izbjegavati udisanje prašine/dima/plina/magle/pare/aerosola. Nositi zaštitne rukavice/zaštitnu odijelo/zaštitu za oči/zaštitu za lice. U SLUČAJU DODIRA S KOŽOM: oprati velikom količinom sapuna i vode. U slučaju nadražaja ili osipa na koži: zatražiti savjet/pomoć liječnika. U SLUČAJU DODIRA S OČIMA: oprezno ispirati vodom nekoliko minuta. Ukloniti kontaktne leće ukoliko ih nosite i ako se one lako uklanjaju. Nastaviti ispiranje. AKO SE UDIŠE: premjestiti unesrećenog na svjež zrak, umiriti ga i postaviti u položaj koji olakšava disanje. Odložite sadržaje /spremnike u skladu s lokalnim/regionalnim/nacionalnim/međunarodnim odredbama.

**(HU)****Figyelem**

Bőrirritáló hatású. Súlyos szemirritációt okoz. Légúti irritációt okozhat. Allergiás bőrreakciót válthat ki. Kerülje a por/füst/gáz/köd/gőzök/permet belélegzését. Védőkesztyű/védőruha/szemvédő/arcvédő használatát kötelező. HA BŐRRE KERÜL: Lemosás bő szappanos vízzel. Bőrirritáció vagy kiütések megjelenése esetén: orvosi ellátást kell kérni. SZEMBE KERÜLÉS esetén: Több percig tartó óvatos öblítés vízzel. Adott esetben a kontaktlencsék eltávolítása, ha könnyen megoldható. Az öblítés folytatása. BELÉLEGZÉS ESETÉN: Az érintett személyt friss levegőre kell vinni és olyan nyugalmi testhelyzetre kell helyezni, hogy könnyen tudjon lélegezni. Az edény tartalmát / a tartályt a helyi/regionális/nemzeti/nemzetközi szabályozásoknak megfelelően kell hulladékként elhelyezni.

**(IT)****Attenzione**

Provoca irritazione cutanea. Provoca grave irritazione oculare. Può irritare le vie respiratorie. Può provocare una reazione allergica cutanea.

Evitare di respirare la polvere/i fumi/i gas/la nebbia/i vapori/gli aerosol. Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso. IN CASO DI CONTATTO CON LA PELLE: lavare abbondantemente con acqua e sapone. In caso di irritazione o eruzione della pelle: consultare un medico. IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. IN CASO DI INALAZIONE: trasportare l'infortunato all'aria aperta e mantenerlo a riposo in posizione che favorisca la respirazione. Smaltire il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

**(LT)****Atsargiai**

Dirgina odą. Sukelia smarkų akių dirginimą. Gali dirginti kvėpavimo takus. Gali sukelti alerginę odos reakciją.

Stengtis neįkvėpti dulkių/dūmų/dujų/rūko/garų/aerozolio. Mūvėti apsaugines pirštines/dėvėti apsauginius drabužius/naudoti akių (veido) apsaugos priemonės. PATEKUS ANT ODOŠ: Nuplauti dideliu kiekiu muilo ir vandens. Jeigu sudirginama oda arba ją išberia: kreiptis į gydytoją. PATEKUS Į AKIS: Kelias minutes atsargiai plauti vandeniu. Išimti kontaktinius lęšius, jeigu jie yra ir jeigu lengvai galima tai padaryti. Toliau plauti akis. ĮKVĖPUS: Išnešti nukentėjusį į gryną orą; jam būtina ramybė ir padėtis, leidžianti laisvai kvėpuoti. Turinį/talpą išplinti (išmesti) - šalinti pagal vietines / regionines / nacionalines / tarptautines taisykles.

**(NL)****Waarschuwing**

Veroorzakt huidirritatie. Veroorzaakt ernstige oogirritatie. Kan irritatie van de luchtwegen veroorzaken. Kan een allergische huidreactie veroorzaken.

Inademing van stof/rook/gas/nevel/damp/sputnevel vermijden. Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. BIJ CONTACT MET DE HUID: met veel water en zeep wassen. Bij huidirritatie of uitslag: een arts raadplegen. BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen. NA INADEMING: het slachtoffer in de frisse lucht brengen en laten rusten in een houding die het ademen vergemakkelijkt. De inhoud en de verpakking verwerken volgens de plaatselijke/regionale/nationale/internationale voorschriften.

**(NO)****Advarsel**

Irriterer huden. Forårsaker alvorlige øyeirritasjoner. Kan irritere luftveiene. Kan forårsake allergiske hudreaksjoner.

Unngå innånding av støv/røyk/gass/sprøytetåke/damp/aerosol. Bruk vernehansker/vermekåpe/vernebriller/ansiktsskjerm. VED HUDKONTAKT: Vask med store mengder vann og såpe. Ved hudirritasjon eller -utslett: Kontakt / tilkall lege. VED KONTAKT MED ØYENENE: Skyll forsiktig med vann i opptil flere minutter. Fjern evt. kontaktlinser såfremt dette er lett mulig. Fortsett skyllingen. VED INNÅNDING: Bring den skadelidende ut i frisk luft og hold i ro i en stilling som letter pustingene. Innholdet / emballasjen skal avhendes i henhold til de lokale / regionale / nasjonale / internasjonale forskrifter.

**(PL)****Uwaga**

Działa drażniąco na skórę. Działa drażniąco na oczy. Może powodować podrażnienie dróg oddechowych. Może powodować reakcję alergiczną skóry. Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy. Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody z mydłem. W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie. Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi.

**(PT)****Atenção**

Provoca irritação cutânea. Provoca irritação ocular grave. Pode provocar irritação das vias respiratórias. Pode provocar uma reacção alérgica cutânea. Evitar respirar as poeiras/fumos/gases/névoas/vapores/aerosóis. Usar luvas de protecção/vestuário de protecção/protecção ocular/protecção facial. SE ENTRAR EM CONTACTO COM A PELE: lavar com sabonete e água abundantes. Em caso de irritação ou erupção cutânea: consulte um médico. SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continuar a enxaguar. EM CASO DE INALAÇÃO: retirar a vítima para uma zona ao ar livre e mantê-la em repouso numa posição que não dificulte a respiração. Eliminar o conteúdo/recipiente de acordo com a legislação local/regional/nacional/internacional.

**(RO)****Atenție**

Provoacă iritarea pielii. Provoacă o iritare gravă a ochilor. Poate provoca iritarea căilor respiratorii. Poate provoca o reacție alergică a pielii.

Evitați să inspirați praful/fumul/gazul/ceață/vaporii/spray-ul. Purtați mănuși de protecție/îmbrăcăminte de protecție/echipament de protecție a ochilor/ chipament de protecție a feței. ÎN CAZ DE CONTACT CU PIELEA: spălați cu multă apă și săpun. În caz de iritare a pielii sau de erupție cutanată: consultați medicul. ÎN CAZ DE CONTACT CU OCHII: clătiți cu atenție cu apă timp de mai multe minute. Scoateți lentilele de contact, dacă este cazul și dacă acest lucru se poate face cu ușurință. Continuați să clătiți. ÎN CAZ DE INHALARE: transportați victima la aer liber și mențineți-o în stare de repaus, într-o poziție confortabilă pentru respirație. Aruncați conținutul/containerul în acord cu regulamentele locale/regionale/naționale/internaționale.

**(SE)****Warning**

Irriterar huden. Orsakar allvarlig ögonirritation. Kan orsaka irritation i luftvägarna. Kan orsaka allergisk hudreaktion.

Undvik att inandas damm/rök/gaser/dimma/ångor/sprej. Använd skyddshandskar/skyddskläder/ögonskydd/ansiktsskydd. VID HUDKONTAKT: Tvätta med mycket tvål och vatten. Vid hudirritation eller utslag: Sök läkarhjälp. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Försätt att skölja. VID INANDNING: Flytta personen till frisk luft och se till att han eller hon vilar i en ställning som underlättar andningen. Innehållet / behållaren avfallshanteras enligt lokala / regionala / nationella / internationella föreskrifter.

**(SI)****Pozor**

Povzročá draženje kože. Povzročá hudo draženje oči. Lahko povzroči draženje dihalnih poti. Lahko povzroči alergijski odziv kože. Ne vdihavati prahu/dima/plina/meglice/hlapov/ razpršila. Nositi zaščitne rokavice/zaščitno obleko/ zaščitno za oči/zaščitno za obraz. PRI STIKU S KOŽO: umiti z veliko mila in vode. Če nastopi draženje kože ali se pojavi izpuščaj: poiščite zdravniško pomoč/ oskrbo. PRI STIKU Z OČMI: previdno izpirajte z vodo nekaj minut. Odstranite kontaktne leče, če jih imate in če to lahko storite brez težav. Nadaljujte z izpiranjem. PRI VDIHAVANJU: prenesi žrtev na svež zrak in jo pustiti počivati v položaju, ki olajša dihanje. Vsebinsko/vsebnik odstranite v skladu z lokalnimi/regionalnimi/narodnimi/mednarodnimi predpisi.

**(SK)****Pozor**

Dráždí kožu. Spôsobuje vážne podráždenie očí. Môže spôsobiť podráždenie dýchacích ciest. Môže vyvolať alergickú kožnú reakciu. Zabráňte vdychovaniu prachu/dymu/plynu/hmly/pár/ aerosólov. Noste ochranné rukavice/ochranný odev/ ochranné okuliare/ochranu tváre. PRI KONTAKTE S POKOŽKOU: Umyte veľkým množstvom vody a mydla. Ak sa prejaví podráždenie pokožky alebo sa vytvoria vyrážky: vyhľadajte lekársku pomoc/ starostlivosť. PO ZASIAHNUTÍ OČÍ: Niekoľko minút ich opatrne vyplachujte vodou. Ak používate kontaktné šošovky a ak je to možné, odstráňte ich. Pokračujte vo vyplachovaní. PO VDÝCHNUTÍ: Presuňte postihnutého na čerstvý vzduch a nechajte ho oddychovať v polohe, ktorá mu umožní pohodlné dýchanie. Zneškodnenie obsahu/obalu v súlade s miestnymi/oblastnými/národnými/medzinárodnými nariadeniami.

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