

Pastorex™ Staph-Plus

Σ 5 x 50

Σ 1 x 50

REF 56353

REF 56356

Latex agglutination test for the identification of *Staphylococcus aureus*



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1. INTENDED USE

Pastorex™ Staph-Plus is a rapid agglutination test for the simultaneous detection of the fibrinogen affinity (clumping factor), protein A, and capsular polysaccharides of *Staphylococcus aureus*.

2. SUMMARY AND EXPLANATION OF THE TEST

Staphylococcus aureus is one of the most frequently encountered pathogens in clinical specimens. The rapid distinction between this species and other less virulent staphylococci is of great importance for an appropriate patient management. The test for the detection of free coagulase production (tube coagulase test) is generally considered as the standard test for differentiating *S. aureus* from coagulase-negative staphylococcus (CoNS) [1, 2]. However, this test takes 4 to 24 hours and plasma may have lot-to-lot variation that can affect the reaction [3].

Through the years, agglutination reagents have been developed, giving a more rapid and reliable detection of *S. aureus* [4]. The earliest of these tests consisted of erythrocytes sensitized with fibrinogen for the detection of clumping factor [5]. Thereafter, a second generation of products was developed, which employed coated latex particles and/or sensitized sheep erythrocytes to identify *S. aureus* by the simultaneous detection of clumping factor and protein A, which are biochemical characteristics of *S. aureus* [3, 6]. Initially, these tests were reported to be very accurate, but later studies reported that certain strains of *S. aureus* (essentially the methicillin-resistant (MRSA) strains) were not agglutinated by these agglutination tests [7, 8, 9]. A study of these strains has shown that they all possess capsular polysaccharides [8]. It was hypothesized that the polysaccharide capsule which envelopes all the bacteria under certain conditions (direct specimens, culture isolation, and bacterial clone) masks protein A and clumping factor, thereby preventing agglutination of the latex particles only sensitized for clumping factor and Protein A detection. After investigations, it was demonstrated that capsular polysaccharides Type 5 and Type 8 were specific antigens present on the surface of up to 80% of *S. aureus* strains [10].

Therefore third-generation latex agglutination tests were developed, which incorporated antibodies against capsular polysaccharides or antibodies against group-specific antigens of the *S. aureus* cell surface [8, 11, 6] and allowed simultaneous detection of the fibrinogen affinity factor, Protein A, and capsular polysaccharides of *S. aureus*. The combination of fibrinogen, IgG and anti-capsular antibodies in the same reagent allows the recognition of highly encapsulated strains of *S. aureus* as well as poorly encapsulated strains. For highly encapsulated strains, anti-capsular polysaccharide antibodies agglutinate the bacteria. For strains that have lost their polysaccharide capsule, the bacteria are agglutinated by fibrinogen and IgG.

3. PRINCIPLES OF THE PROCEDURE

The Pastorex™ Staph-Plus assay was designed to allow simultaneous detection of the following three components specific to *Staphylococcus aureus*:

- 1) the fibrinogen affinity factor, also referred to as bound coagulase or "clumping factor";
- 2) the protein A, which possesses an affinity for the crystallisable fragment (Fc) of gamma immunoglobulins (IgG);
- 3) the capsular polysaccharides of *S. aureus*.

The reagent is made of latex particles sensitized by fibrinogen and IgG as well as specific monoclonal antibodies (Pasteur Institute patent) raised against capsular polysaccharides of *S. aureus* [12, 13, 14, 15].

Culture isolates of *S. aureus* are mixed with the latex reagent on a slide. Following complete mixing, the slide is evaluated visually for the presence of agglutination, which indicates the presence of *S. aureus* organisms.

4. REAGENTS

4.1. Description

A) Pastorex™ Staph-Plus, code 56356 (50 tests):

Identification	Description	Presentation
Pastorex™ Staph-Plus Latex test	Red latex sensitized with bovine albumin solution, fibrinogen, IgG, and monoclonal antibodies directed against capsular polysaccharides of <i>S. aureus</i> . Preservative: <1.5% ProClin™ 300	1 ml 1 red cap dropper bottle, ready to use
Pastorex™ Staph-Plus Negative control	Negative control reagent of red latex sensitized by bovine albumin solution Preservative: <1.5% ProClin™ 300	1 ml 1 white cap dropper bottle, ready to use
Cards	Disposable agglutination cards (8 circles)	16 disposable agglutination cards
Sticks	Disposable mixing sticks	2 x 100 units

B) Pastorex™ Staph-Plus code 56353 (5 x 50 tests):

Identification	Description	Presentation
Pastorex™ Staph-Plus Latex test	Red latex sensitized with bovine albumin solution, fibrinogen, IgG, and monoclonal antibodies directed against capsular polysaccharides of <i>S. aureus</i> . Preservative: <1.5% ProClin™ 300	5 x 1 ml 1 red cap dropper bottle, ready to use
Pastorex™ Staph-Plus Negative control	Negative control reagent of red latex sensitized by bovine albumin solution Preservative: <1.5% ProClin™ 300	5 x 1 ml 1 white cap dropper bottle, ready to use
Cards	Disposable agglutination cards (8 circles)	4 x 16 disposable agglutination cards
Sticks	Disposable mixing sticks	3 x 100 units

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)
Latex test	After first opening: until the expiry date mentioned on the package at +2-8°C
Negative control	

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.bio-rad.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.
- It is recommended to identify the circles of the card with the reagent tests before starting the identification procedure.
- Only use the plastic mixing sticks supplied in the kit or a loop 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 or loop for each reaction.
- Discard all disposable material used in an autoclavable waste bin or disinfectant bath.

6. SPECIMENS

The Pastorex™ Staph-Plus assay must be performed with **fresh** and **well isolated** suspected staphylococci colonies (Gram-positive, catalase positive) on the following recommended isolation agar culture media:

- Tryptone-Casein-Soy agar (e.g. Bio-Rad, code 63884)
- Columbia Blood agar (e.g. Bio-Rad, codes 63804, 63784)
- Baird Parker agar
- Mannitol Salt agar (Chapman) (e.g. Bio-Rad, code 63844)
- **MRSASelect™II** (Bio-Rad, codes 63757, 63758, 63759, 63763)
- **SASelect™** (Bio-Rad, code 63748)

7. PROCEDURE

7.1. Material required

- All materials listed in under “Reagents” and their controls
- Disposable agglutination cards (Bio-Rad, code 61723)

7.2. Material required but not provided

- Loop for collection of bacterial colonies
- Timer
- Disinfectant bath

7.3. Assay procedure

Each suspected staphylococci bacterial strain must be tested with both Latex test and Negative control in dedicated circles.

- Gently shake the latex reagent. Holding the dropper bottle upright, place **one drop** of latex reagent in a circle on the agglutination card.
- Using a loop or a mixing stick provided with the kit, pick 1 to 3 suspected staphylococci colonies (Gram positive, catalase positive) on the agar plate.
- Using the loop or the mixing stick, carefully emulsify the colonies in the drop of latex for 10 seconds 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, **from 30 seconds to 1 minute maximum**.
- Observe for any agglutination visible to the naked eye within a **maximum of 1 minute**.

Note: On **MRSASelect™II**, pick pink colored colonies; on **SASelect™** pick pink to orange colored colonies. Refer to the corresponding package insert for more information.

7.4. Quality control

- The latex reagents should be completely homogenous after shaking.
- Evaluate the Latex test reagent **at each use** by verifying the absence of any unspecific agglutination when depositing the latex on the card. The latex should be periodically tested (according to the laboratory procedures) with previously identified strains of *Staphylococcus aureus* and *Staphylococcus epidermidis*. The Latex test reagent must agglutinate with *Staphylococcus aureus* and must show absence of agglutination with *Staphylococcus epidermidis*, within a **maximum of 1 minute**.
- The Negative control must show an absence of agglutination with both aforementioned microorganisms.

7.5. Interpretation of results

Positive reaction

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

The aggregates of latex particles may be of varying sizes with a more or less cloudy, pinkish background.

A slow and weak agglutination could signify a non-specific agglutination. In case of doubt, perform the assay again with more colonies than previously used.

Negative reaction

A negative reaction is indicated by a homogenous milky appearance suspension, without clumps, after 30 seconds of agitation. Do not conclude a negative result before 1 minute.

Result interpretation

Interpretation	Criteria	
	Latex test	Negative control
Positive result	Positive reaction	Negative reaction
Negative result	Negative reaction	Negative reaction
Non-interpretable result	Positive or negative reaction	Positive reaction

Non-interpretable result

A reaction is un-interpretable if clumps appear with Negative control. In this case, identify using another method such as testing for the presence of free coagulase and heat-stable DNase.

8. TEST LIMITATION

- False positive results have been reported with some strains of Staphylococci.
 - S. lugdunensis* and *S. schleiferi* have been reported to possess a fibrinogen affinity factor [16, 17] and may react with the Pastorex™ Staph-Plus, depending on the strains and the isolation medium [11, 18, 6, 19, 20, 21].
 - Some strains of *S. haemolyticus* are recognized by antibodies directed to capsular polysaccharide type 5 [22] and may result in false positive results with the Pastorex™ Staph-Plus [11, 18].
 - Some strains of *S. epidermidis* are described as possessing capsular polysaccharide type 8 [23] and may give false-positive results with Pastorex™ Staph-Plus [24, 18].
 - Other staphylococci as *S. cohnii*, *S. capitis* and *S. hominis* have been reported to give very rarely false positive result [6, 20, 25, 18, 19].
- Some strains of Staphylococci (*S. saprophyticus*, *S. epidermidis*) and *Micrococcus luteus* may cause non-specific aggregation, leading to invalid results [6, 20, 26].
- S. intermedius* which is essentially found in animal pathology but is very rarely isolated in human, may present a positive reaction with the classical coagulase tests and may therefore also react with fibrinogen affinity factor detection tests [21, 17].
- Certain streptococci possess a protein with an affinity for the Fc fragments of immunoglobulins and may therefore react with the latex [27].
- Non-specific reactions have also been reported for *Candida albicans* [27, 28, 29]. It is recommended to perform a Gram stain and catalase test on the colonies to be tested prior to the latex test.
- False negative reactions can occur if the isolated *S. aureus* does not produce the fibrinogen affinity factor (clumping factor), protein A, or capsular polysaccharides against which the specific monoclonal antibodies were raised [30, 20].
- False negative results can occur with an insufficient inoculum.
- 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 3 specimens was used for determining the reproducibility and precision of the Pastorex™ Staph-Plus assay. The 3-member reproducibility panel included 1 negative (*S. epidermidis* colonies) and 2 positive consisting of two different strains of *S. aureus* colonies (strain 1 used for fibrinogen activity factor detection and strain 2 used for capsular polysaccharides detection).

9.1.1 Repeatability

Reproducibility panel (N=3) was tested in replicates of 10 on the same day, on one lot of Pastorex™ Staph-Plus assay and read by one operator. Negative and positive panel members gave the same expected results with all the 10 replicates.

Table I: Repeatability results

Repeatability with Pastorex™ Staph-Plus assay	Negative control			Latex test		
Strain panel member	Total replicates	Non- reactive	Reactive	Total replicates	Non- reactive	Reactive
Negative (<i>S. epidermidis</i>)	10	10	0	10	10	0
Positive (<i>S. aureus</i> , strain 1)	10	10	0	10	0	10
Positive (<i>S. aureus</i> , strain 2)	10	10	0	10	0	10

9.1.2 Intermediate Precision

Reproducibility panel (N=3) 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

Repeatability with Pastorex™ Staph-Plus assay	Negative control			Latex test		
Strain panel member	Total replicates	Non- reactive	Reactive	Total replicates	Non- reactive	Reactive
Negative (<i>S. epidermidis</i>)	20	20	0	20	20	0
Positive (<i>S. aureus</i> , strain 1)	20	20	0	20	0	20
Positive (<i>S. aureus</i> , strain 2)	20	20	0	20	0	20

9.1.3 Inter-lot Precision

Inter-lot precision panel including reactive and non-reactive strain colonies, was tested on three lots of Pastorex™ Staph-Plus assay. As shown on table III of agglutination results, negative and positive panel members gave the same expected results with the three lots.

Table III: Inter-lot Precision results

Inter-lot Precision with Pastorex™ Staph-Plus assay		Agglutination Intensity (from 0 to 3)*					
		Latex test			Negative control		
Strain panel member		Lot A	Lot B	Lot C	Lot A	Lot B	Lot C
Positive	<i>Staphylococcus aureus</i> (a)	2	3	2,5-	0	0	0
	<i>Staphylococcus aureus</i> (b)	2,5	3	2,5	0	0	0
	<i>Staphylococcus aureus</i> (c)	3	3	3	0	0	0
	<i>Staphylococcus aureus</i> (d)	3	3	3-	0	0	0
	<i>Staphylococcus aureus</i> (e)	3	3	3-	0	0	0
	<i>Staphylococcus aureus</i> (f)	2,5	3	2,5	0	0	0
Negative	<i>Staphylococcus epidermidis</i> (g)	0	0	0	0	0	0
	<i>Staphylococcus saprophyticus</i> (h)	0	0	0	0	0	0
	<i>Staphylococcus kloosii</i> (i)	0	0	0	0	0	0
	<i>Staphylococcus haemolyticus</i> (j)	0	0	0	0	0	0
	<i>Staphylococcus warneri</i> (k)	0	0	0	0	0	0
	<i>Staphylococcus haemolyticus</i> (l)	0	0	0	0	0	0
Negative	Physiological sterile water	0	0	0	0	0	0

Note: (*) Agglutination intensity quotation was fine-tuned with .5 and + or - suffix (e.g. 2.5- is comprised between 2 and 3, with slightly less intensity than 2.5)

9.2 Diagnostic Performances

9.2.1 Diagnostic Specificity

Specificity with colonies from bacterial culture

Specificity performance tested in three laboratories [31, 9, 32] with Pastorex™ Staph-Plus assay on 138 strains other than *Staphylococcus aureus* is 99.3% (137/138) with CI95 [96.03-99.98%] and 1 false reactive (*S. lugdunensis*).

Site 1: Thirty (30) strains tested negative with reference assays including PCR testing.

Site 2: Twelve (12) Coagulase-Negative Staphylococci (CNS) clinical isolates grown on Columbia Blood agar (BA), Mannitol Salt agar (MSA) and Baird-Parker agar (BP).

Site 3: Coagulase-Negative Staphylococci (CNS, N=96) grown on Columbia agar as *Staphylococcus epidermidis* (n=64); *Staphylococcus haemolyticus* (n=7); *Staphylococcus warnerii* (n=6); *Staphylococcus hominis* (n=5); *Staphylococcus capitis* (n=3); *Staphylococcus lentus* (n=3); *Staphylococcus saprophyticus* (n=3); *Staphylococcus lugdunensis* (n=2); *Staphylococcus simulans* (n=2) and *Staphylococcus carnosus* (n=1).

Table IV: Specificity with colonies from bacterial culture

Specificity on colonies	Number tested	Number found Non-Reactive	Number found Reactive	Specificity (%)
Site 1	30	30	0	100%
Site 2	12	12	0	100%
Site 3	96	95	1(*)	99.0%
Total	138	137	1	99.3%

Note: (*) Cross-Reactivity with strains: One false positive result was obtained with *Staphylococcus lugdunensis* strain (over 2 tested).

9.2.2 Diagnostic Sensitivity

Sensitivity with colonies from bacterial culture

Sensitivity performance tested in three laboratories [31, 9, 32] with Pastorex™ Staph-Plus assay on 439 staphylococci strains is 100% (439/439) with CI95 [96.2-100.0%].

Staphylococcus aureus strains were also checked for their susceptibility to methicillin.

Site 1: Methicillin susceptible *Staphylococcus aureus* strains (MSSA, N=222) and Methicillin resistant *Staphylococcus aureus* strains (MRSA, N=78).

Site 2: MRSA strains (N=40) grown on Columbia blood agar, Mannitol Salt agar and Baird-Parker agar medium.

Site 3: MRSA strains (N=99) after exclusion of one non-interpretable result. The one hundred strains grown on Columbia Blood agar came from Belgium (N=9); Denmark (N=1); Germany (N=18); France (N=12); The Netherlands (N=9); Italy (N=6); Austria (N=9); East European countries (N=9); Switzerland (N=18) and Spain (N=9).

Table V: Sensitivity with colonies from bacterial culture

Sensitivity on colonies	Number MRSA tested	Number MSSA tested	Number found Reactive	Number found Non-Reactive	Sensitivity (%)
Site 1	78	222	300	0	100%
Site 2	40	/	40	0	100%
Site 3	99	/	99	0	100%
Total	217	222	439	0	100%

9.3 Analytical Specificity/Cross Reactivity

See §9.2.1 Diagnostic specificity with colonies from bacterial culture.

10. BIBLIOGRAPHY REFERENCES

1. Kloos W.E. and Lambe D.W. (1991). *Staphylococcus* Manual of Clinical Microbiology, 5th Ed. Edited by Balows A., Hausler W.J., Herrmann K.L., Isenberg H.D., and Shadomy J.J. American Society for Microbiology, Washington, D.C., 222-237.
2. Kloos W.E., and Schleifer K.H. *Staphylococcus* Bergey's manual of systematic bacteriology. 1986, vol. 2, 1013-1035.
3. Selepack S.T., and Witebsky F.G. Inoculum size and lot-to-lot variation as significant variables in the tube coagulase test for *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1985, 22:835-837.
4. Esserts I., and Radebold K. Rapid and reliable identification of *Staphylococcus aureus* by a latex agglutination test. *J. Clin. Microbiol.*, 1980, 12:641-643.
5. Pennels D.R., Rott-Petri J.A., Kurzynski T.A. Evaluation of Three Commercial Agglutination Tests for the Identification of *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1984, 20:614-617.

6. Personne P., Bes M., Lina G., Vandernes F., Brun Y., Etienne J. Comparative Performances of Six Agglutination Kits Assessed by Using Typical and Atypical Strains of *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1997, 35:1138-1140.
7. Ruane P.J., Morgan M.A., Citron D.M., and Mulligan M.E. Failure of rapid agglutination methods to detect oxacillin-resistant *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1986, 24:490-492.
8. Fournier J.M., Boutonnier A., and Bouvet A. *Staphylococcus aureus* strains which are not identified by rapid agglutination methods are of capsular serotype 5. *J. Clin. Microbiol.*, 1989, 27:1372-1374.
9. Luijendijk A.D., Alex van Belkum, Verbrugh H., and Kluytmans J. Comparison of Five Tests for Identification of *Staphylococcus aureus* from Clinical Samples. *J. Clin. Microbiol.*, 1996, 34:2267-2269.
10. Verdier I., Durand G., Bes M., Taylor K.L., Lina G., Vandenesch F., Fattom A.I., Etienne J. Identification of the Capsular Polysaccharides in *Staphylococcus aureus* Clinical Isolates by PCR and Agglutination Tests. *J. Clin. Microbiol.*, 2007, 45:725-729.
11. Fournier J.M., Bouvet A., Mathieu D., Nato F., Boutonnier A., Gerbal R., Brunengo P., Saulnier C., Sagot N., Slizewicz B., Mazie J.C. New Latex Reagent Using Monoclonal Antibodies to Capsular Polysaccharide for Reliable Identification of Both Oxacillin-Susceptible and Oxacillin-Resistant *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1993, 31:1342-1344.
12. Boutonnier A., Nato F., Bouvet A., Lebrun L., Audurier A., Mazie J.C., and Fournier J.M. Direct testing of blood cultures for detection of the serotype 5 and 8 capsular polysaccharides of *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1989, 27:989-993.
13. Fournier J.M., Bouvet A., Boutonnier A., Audurier A., Goldstein F., Pierre J., Bure A., Lebrun L., and Hochkeppel H.K. Predominance of capsular polysaccharide type 5 among oxacillin-resistant *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1987, 25:1932-1934.
14. Hochkeppel H.K., Braun D.G., Vischer W., Imm A., Sutter S., Staeubli U., Guggenheim R., Kaplan E.L., Boutonnier A., and Fournier J.M. Serotyping and electron microscopy studies of *Staphylococcus aureus* clinical isolates with monoclonal antibodies to capsular polysaccharide types 5 and 8. *J. Clin. Microbiol.*, 1987, 25:526-530.
15. Karakawa W.W., Fournier J.M., Vann W.F., Arbeit R., Schneerson, R.S. and Robbins. J.B. Method for the serological typing of the capsular polysaccharides of *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1985, 22:445-447.
16. Hébert G.A. Hemolysins and Other Characteristics That Help Differentiate and Biotype *Staphylococcus lugdunensis* and *Staphylococcus schleiferi*. *J. Clin. Microbiol.*, 1990, 28:2425-2431.
17. Wilkerson M., McAllister S., Miller M., Heiter B.J., Bourbeau P.P. Comparison of Five Agglutination Tests for Identification of *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1997, 35:148-151.
18. Van Griethuysen A., Bes M., Etienne J., Zbinden R., Kluytmans J. International Multicenter Evaluation of Latex Agglutination tests for Identification of *Staphylococcus aureus*. *J. Clin. Microbiol.*, 2001, 39:86-89.
19. Andriesse G.I., Elberts S., Vrolijk A., Verhulst C., Kluytmans J.A.J.W. Evaluation of a fourth-generation latex agglutination test for the identification of *Staphylococcus aureus*. *Eur. J. Clin. Microbiol. Infect. Dis.*, 2011, 30:259-264.
20. Idelevitch E.A., Walther T., Molinaro S., Li X., Xia G., Wieser A., Peters G., Peschel A., Becker K. Bacteriophage-Based Latex Agglutination Test for Rapid Identification of *Staphylococcus aureus*. *J. Clin. Microbiol.*, 2014, 52:3394-3398.
21. Carricajo A., Treny A., Fonsale N., Bes M., Reverdy M.E., Gille Y., Aubert G., Freydiere A.M. Performance of the Chromogenic Medium CHROMagar Staph Aureus and the Staphychrom Coagulase Test in the Detection and Identification of *Staphylococcus aureus* in Clinical Specimens. *J. Clin. Microbiol.*, 2001, 39:2581-2583
22. Poutrel B., Mendolia C., Sutra I., Fournier J.M. Reactivity of Coagulase-Negative Staphylococci Isolated from Cow and Goat Milk with Monoclonal Antibodies to *Staphylococcus aureus* Capsular Polysaccharide Types 5 and 8. *J. Clin. Microbiol.*, 1990, 28:358-360.
23. Blake J.E., Metcalfe M.A. A Shared Noncapsular Antigen Is Responsible for False-Positive Reactions by *Staphylococcus epidermidis* in Commercial Agglutination Tests for *Staphylococcus aureus*. *J. Clin. Microbiol.*, 2001, 39:544-550.
24. Hollyday M.G., Ford M., Perry J.D., Gould F.K. Rapid Identification of *Staphylococcus aureus* by Using Fluorescent Staphylocoagulase Assays. *J. Clin. Microbiol.*, 1999, 37:1190-1192.
25. Tveten Y. Evaluation of New Agglutination Test for Identification of Oxacillin-Susceptible and Oxacillin-Resistant *Staphylococcus aureus*. *J. Clin. Microbiol.*, 1995, 33:1333-1334.
26. Gregson D.B., Low D.E., Skulnick M., Simor A.E. Problems with Rapid Agglutination Methods for Identification of *Staphylococcus aureus* When *Staphylococcus saprophyticus* Is Being Tested. *J. Clin. Microbiol.*, 1988, 26:1398-1399.
27. Kronvall G. A Surface Component in Group A, C, and G Streptococci with Non-Immune Reactivity for Immunoglobulin G. *J. Immunology.*, 1973, 11:1401-1406.
28. Becker K., Almasri A.S., von Eiff C., Peters G., Heilmann C. Fegeler W. Systematic Survey of Nonspecific Agglutination by *Candida* spp. in Latex Assays. *J. Clin. Microbiol.*, 2007, 45:1315-1318.
29. Goncalves Rodrigues A., Pina-Vas C., Costa-de-Oliveira S., Tavares C. Expression of Plasma Coagulase among Pathogenic *Candida* Species. *J. Clin. Microbiol.*, 2003, 41:5792-5793.

30. Compennolle V., Verschaege G., Claeys G. Combined Use of Pastorex Staph-Plus and Either of Two New Chromogenic Agars, MRSA ID and CHROMagar MRSA, for Detection of Methicillin-Resistant *Staphylococcus aureus*. *J. Clin. Microbiol.*, 2007, 45:154-158.
31. Davies S. Detection of methicillin-resistant *Staphylococcus aureus*: the evaluation of rapid agglutination methods, *Br. J. Biomed. Sci.*, 1997, 54:13-15.
32. Neher C., Allerberger F., Prodinger W. Dierich M.P., Evaluation of commercially available agglutination tests for methicillin-resistant. 8th ECCMID Congress, Lausanne, 1997.

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- (IT)** • Questo prodotto contiene componenti umane o animali. Maneggiare con cura.
- (LT)** • Šiame produkto yra žmogiškosios arba gyvūninės kilmės sudėtiniai dalių. Elgtis atsargiai.
- (LV)** • Šis produkts satur cilvēkiem vai dzīvniekiem paredzētas sastāvdaļas. Apieties uzmanīgi.
- (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. Manevrați-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.



H317
P280+P302+P352-
P333+P313-P501

(BG)

ВНИМАНИЕ

Може да причини алергична кожна реакция.

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. Изхвърлете съдържанието/контейнера в съответствие с местните/регионалните/националните/международните разпоредби.

(CZ)

Varování

Může vyvolat alergickou kožní reakci.

Používejte ochranné rukavice/ochranný oděv/ochranné brýle/obličejový štít. PŘI STYKU S KŮŽÍ: Omyjte velkým množstvím vody a mýdla. Při podráždění kůže nebo vyrážce: Vyhledejte lékařskou pomoc/ ošetření. Obsah nádobu likvidujte v souladu s místními/regionálními/národními/mezinárodními předpisy.

(DE)

Achtung

Kann allergische Hautreaktionen verursachen.

Schutzhandschuhe/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. Entsorgung des Inhalts / des Behälters gemäß den örtlichen / regionalen / nationalen/ internationalen Vorschriften.

(DK)

Advarsel

Kan forårsage allergisk hudreaktion.

Bær beskyttelseshandsker/beskyttelsestøj/øjebeskyttelse/ansigtsbeskyttelse VED KONTAKT MED HUDEN: Vask med rigeligt sæbe og vand. Ved hudirritation eller udslæt: Søg lægehjælp. Bortskaffelse af indholdet/beholderen i henhold til de lokale/regionale/nationale/internationale forskrifter.

(EE)

Hoiatus

Võib põhjustada allergilist nahareaktsiooni.

Kanda kaitsekindaid/kaitserõivastusi/kaitseprille/kaitsemaski. NAHALE SATTUMISE KORRAL: pesta rohke vee ja seebiga. Nahaärrituse või _õbe korral: pööruda arsti poole. Sisukonteineri kõrvaldamine vastavalt kohalike/regionaalsete/rahvuslike/rahvusvaheliste nõuetele.

(EN)

Warning

May cause an allergic skin reaction.

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. Dispose of contents/ container in accordance with local/regional/national/international regulations.

(ES)

Atención

Puede provocar una reacción alérgica en la piel.

Llevar guantes que aislen del frío/gafas/máscara. EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido o el recipiente conforme a la legislación local/regional/nacional/internacional.

(FI)

Varoitus

Voi aiheuttaa allergisen ihoreaktion.

Käytä suojakäsineitä/suojavaateitusta/silmiensuojainta/kasvosuojainta. JOS KEMIKAALIA JOUTUU IHOLLE: Pese runsaalla vedellä ja saippualla. Jos ilmenee ihoärsytystä tai ihottumaa: Hakeudu lääkäriin. Säilytä säiliö(t) noudattaen paikallisia/alueellisia/kansallisia/kansainvälisiä määräyksiä.

(FR)

Attention

Peut provoquer une allergie cutanée.

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. Éliminer le contenu/réceptacle conformément à la réglementation locale/régionale/nationale/internationale.

(GR)

Προσοχή

Μπορεί να προκαλέσει αλλεργική δερματική αντίδραση.

Να φοράτε προστατευτικά γάντια/προστατευτικά ενδύματα/μέσα ατομικής προστασίας για τα μάτια/ πρόσωπο. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΙΦΩΣ ΜΕ ΤΟ ΔΕΡΜΑ: Πλύνετε με άφθονο νερό και σαπούνι. Εάν παρατηρήσετε ερεθισμό του δέρματος ή εμφανιστεί εξάνθημα: Συμβουλευθείτε/Επισκεφθείτε/επιστρέψτε. Απορρίψτε τα περιεχόμενα/δοχεία σύμφωνα με τους τοπικούς/εθνικούς/διεθνείς κανονισμούς.

(HR)

Upozorenje

Može izazvati alergijsku reakciju na koži.

Nositi zaštitne rukavice/zaštitnu odjeću/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. Odložite sadržaje /spremnike u skladu s lokalnim/regionalnim/nacionalnim/međunarodnim odredbama.

(HU)

Figyelem

Allergiás bőreakciót válthat ki.

Védőkesztyű/védőruha/szemvédő/arcvédő használatra kötelező. HA BŐRRE KERÜL: Lemosás bő szappanos vízzel. Bőrirritáció vagy kiütések megjelenése esetén: orvosi ellátást kell kérni. Az oldény tartalmát / a tartályt a helyi/regionális/nemzeti/nemzetközi szabályozásoknak megfelelően kell hulladékként elhelyezni.

(IT)

Attenzione

Può provocare una reazione allergica cutanea.

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. Smaltire il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

(LT)

Atsargiai

Gali sukelti alerginę odos reakciją.

Mūvėti apsauginės pirštines/dėvėti apsauginius drabužius/naudoti akių (veido) apsaugos priemones. PATEKUS ANT ODOŠ: Nuplauti dideliu kiekiu muilo ir vandens. Jeigu sudirginama oda arba ją išberia: kreiptis į gydytoją. Turinį/talpą išpliti (išmesti) - šalinoti pagal vietines / regionines / nacionalines / tarptautines taisykles.

(LV)

Uzmanību / Brīdinājums

Gali sukelti alerģiņģ odos reakcijā.

Mūvēti apsaugīnes pīrstīnes/dēvēti apsaugīnīus drabuzīus/naudoti akių (veido) apsaugos priemones. PATEKUS ANT ODOŠ: Nuplauti dideliu kieku muilo ir vandens. Jeigu sudirginama oda arba ją īšberia: kreiptis į gydytoją. Turinį/talpą īšplītī (īšmestī) - šalīntī pagal vietīnes / regionīnes / nacionalīnes / tarptautīnes taisyklēs.

(NL)

Waarschuwing

Kan een allergische huidreactie veroorzaken.

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. De inhoud en de verpakking verwerken volgens de plaatselijke/regionale/nationale/ internationale voorschriften.

(NO)

Advarsel

Kan forårsake allergiske hudreaksjoner.

Bruk vernehansker/verneklær/vernebriller/ansiktsskjerm. VED HUDKONTAKT: Vask med store mengder vann og såpe. Ved hudirritasjon eller -utslett: Kontakt / tilkall lege. Innholdet / emballasjen skal avhendes i henhold til de lokale / regionale / nasjonale / internasjonale forskrifter.

(PL)

Uwaga

Może powodować reakcję alergiczną skóry.

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. Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi.

(PT)

Atenção

Pode provocar uma reacção alérgica cutânea.

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. Eliminar o conteúdo/recipiente de acordo com a legislação local/regional/ nacional/internacional.

(RO)

Atenție

Poste provocă o reacție alergică a pielii.

Purtajți 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 întare a pielii sau de erupție cutanată: consultați medicul. Anunțați conținutul/containerul în acord cu regulamentele locale/regionale/naționale/internationale.

(SE)

Varning

Kan orsaka allergisk hudreaktion.

Använd skyddshandskar/skyddskläder/ögonskydd/ansiktsskydd. VID HUDKONTAKT: Tvätta med mycket tvål och vatten. Vid hudirritation eller utslag: Sök läkarhjälp. Innehållet / behållaren avfalls hanteras enligt lokala / regionala / nationella / internationella föreskrifter.

(SI)

Pozor

Lahko povzroči alergijski odziv kože.

Nositi zaščitne rokavice/zaščitno obleko/zaščito za oči/zaščito za obraz. PRI STIKU S KOŽO: umiti z veliko mila in vode. Če nastopi draženje kože ali se pojavi izpuščaj: poiščite zdravniško pomoč/oskrbo. Vsebino/vsebnik odstranite v skladu z lokalnimi/regionalnimi/narodnimi/međnarodnimi predpisi.

(SK)

Pozor

Môže vyvolať alergickú kožnú reakciu.

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. Zneškodnenie obsahu/obalu v súlade s miestnymi/oblastnými/národnými/mezinárodnými nariadeniami.

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