PROLEX™ STAPH XTRA LATEX KIT

For Identification of *Staphylococcus aureus*
(for *in vitro* diagnostic use)

PRODUCT CODE PL.1080 (100 Tests)
PL.1081 (300 Tests)

CE

PRO-LAB DIAGNOSTICS

INTENDED USE

Prolex™ Staph Xtra Latex Kit provides a rapid method to distinguish staphylococci (particularly *Staphylococcus aureus*) and methicillin-resistant *S. aureus* (MRSA) from other species of staphylococci in cultured specimens.

SUMMARY AND EXPLANATION

Although most *Staphylococcus* species are common inhabitants of the skin and mucous membranes, certain species have been found frequently as etiological agents of a variety of human and animal infections.
Superficial suppurative infections caused by *S. aureus* are the most common human staphylococcal infections.[1] Food poisoning and toxic shock syndrome also have been attributed to infection with *S. aureus*[2].
Essers and Radebold[3] described a rapid slide agglutination test which has been shown to be a reliable method for identification of *S. aureus* in the routine bacteriological laboratory. These types of tests perform well but may yield false negative results with certain MRSA, a phenomenon believed to be due to expression of capsular type 5 and 8 antigens[4, 5]. The performance of the latex reagents containing fibrinogen and IgG is improved by addition of IgG that is specific for capsular types 5 and 8 of *S. aureus*.

PRINCIPLE OF THE TEST

The Prolex™ Staph Xtra Latex Kit utilizes polystyrene latex particles which have been sensitized with fibrinogen and IgG that are specific for capsular types 5 and 8 of *S. aureus*. When Staphylococcal colonies which possess at least one of clumping factor, protein A and / or capsular 5 or 8 antigens are mixed with the latex reagent, the latex particles agglutinate strongly within 20 seconds.

REAGENTS

Staph Xtra Latex Reagent (PL.1083 / PL.1084): Two vials each containing 2.5 ml (100 test/kit - PL.1080) or 7.5 ml (300 test/kit - PL.1081) of latex particles coated with rabbit IgG recognizing *S. aureus* expressing capsular antigen 5 and 8 and human fibrinogen. The latex particles are suspended in buffer containing 0.098% sodium azide as preservative.
Negative Control Latex Reagent (PL.1085 / PL.1086): One vial containing 2.5 ml (PL.1080) or 7.5 ml (PL.1081) of unsensitized latex particles suspended in buffer containing 0.098% sodium azide as preservative.

PRECAUTIONS

1. Do not use reagents after expiry date shown on product label.
2. Reagents contain sodium azide. Sodium azide is toxic and can react explosively with copper or lead plumbing if allowed to accumulate. Although the amount of sodium azide in the reagents is minimal, large quantities of water should be used to flush plumbing immediately after waste disposal.
3. Safety precautions should be taken in handling, processing and discarding all clinical specimens as a pathogenic organism may be present.
4. Human source materials used in the manufacture of the reagent have been tested and found negative for antibody to HIV and HBsAg. Although the concentration of human source materials in the reagent is very low, the device may transmit infectious agents and should be handled with extreme caution. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, test latex reagent should be handled using the same safety precautions employed as when handling any potentially infectious material.
5. Latex reagents contain materials of animal origin and should be handled as a potential carrier and transmitter of disease.
6. The kit is intended for *in vitro* diagnostic use only.
7. Do not freeze the latex reagents.
8. The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid test results.

STABILITY AND STORAGE

Shelf life of kit is 12 months from the date of manufacture. The expiration date is stated on the outer label and the vial labels. All kit components should be stored at 2-8°C. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION OF CULTURES

For specific procedures regarding specimen collection and preparation of primary cultures refer to a standard microbiology textbook. In general, a fresh (18-36 hour incubation) Gram positive isolate grown on non-selective media such as blood agar should be used.

MATERIALS SUPPLIED

Staph Xtra Latex Reagent
Negative Control Latex Reagent
Disposable cards with ten test circles labeled 1 through 10.
Disposable mixing sticks.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer
2. The following ATCC strains are recommended for use in quality control;
   Positive Control: *Staphylococcus aureus* ATCC # 25923
   Negative Control: *Staphylococcus epidermidis* ATCC # 12228

TEST PROTOCOL

1. Bring the reagents to room temperature (22-28°C) for about 10 minutes prior to use.
2. Resuspend the latex reagent by shaking prior to use.
3. Dispense 1 drop of Staph Xtra Latex Reagent into separate circles on the test card.
4. Take a mixing stick and transfer two suspect colonies into a circle. Mix this into the test latex reagent and spread to cover the complete area of the circle.
5. Gently rock the card allowing the mixture to flow slowly over the entire test ring area.
6. At 20 seconds, under normal lighting conditions, observe for agglutination.
7. If the result is positive, repeat steps 2 to 6 in the same way, using the negative control latex reagent.

QUALITY CONTROL PROCEDURES

The following procedures are recommended to check the performance of the reagents:

1. Test a known positive strain, such as *S. aureus* ATCC # 25923, according to the Test Protocol. The organism must agglutinate the Staph Xtra Latex Reagent within 20 seconds. There must be no agglutination with the Negative Control Latex Reagent.
2. Test a known negative strain, such as *S. epidermidis* ATCC # 12228, according to the Test Protocol. There must be no visible agglutination of the Staph Xtra Latex Reagent and Negative Control Latex Reagent within 20 seconds.

Do not use the kit if the reactions with the control organisms are incorrect.

INTERPRETATION OF RESULTS

Positive results: A significantly rapid strong clumping (within 20 seconds) with the Staph Xtra Latex Reagent and no agglutination with Negative Control Latex Reagent. Reaction occurring after the 20 seconds should be ignored.
Negative results: No visible agglutination of the latex particles.
Uninterpretable results: If an organism agglutinates both the Staph Xtra Latex Reagent and the Negative Control Latex Reagent, the test is uninterpretable. This indicates the culture causes autoagglutination.

LIMITATION OF THE PROCEDURE

1. False negative or false positive results can occur if inadequate amounts of culture or reagent are used.
2. Some rare isolates of staphylococci, notably *S. hyicus* and *S. intermedius*, may agglutinate the latex reagent[6].
3. Some streptococci and possibly other organisms that possess immunoglobulin binding factors and some species such as *Escherichia coli* may also agglutinate latex reagents non-specifically[7].

PERFORMANCE CHARACTERISTICS

The Prolex™ Staph Xtra Latex Kit (PL.1080) was evaluated using 50 *S. aureus* reference strains, including 5 each of capsular types 5 and 8 that are not recognized by Staph latex reagents that identify organisms expressing only clumping factor and / or Protein A, and 9 coagulase negative *Staphylococcus* reference strains. The Prolex™ Staph Xtra Latex Kit correctly identified all strains in the study indicating the kit had a sensitivity of 100% and specificity of 100%. In a separate study, the Prolex™ Staph Xtra Latex Kit was evaluated using 50 MRSA and 50 methicillin-sensitive *S. aureus*. The Prolex™ Staph Xtra Latex Kit correctly identified all strains in the study indicating that it had a sensitivity of 100% and specificity of 100%.

REFERENCES

1. Schleifer, K.H., and Kloos, W.E. (1975). Int. J. Syst. Bacteriol. **25:** 50-61.
2. Schlievert, P.M., Shands, K.N., Dan, B.B., Schmid, G.P. and Nishimura, R.D. (1981). J. Infect. Dis. **143:** 509-516.
3. Essers, L. and Radebold, K. (1980). J. Clin. Microbiol. **12:** 641-643.
4. Fournier J M, Boutonnier A, and Bouvet A. (1989). J Clin Microbiol.; **27:** 1372–1374.
5. Fournier, J.M., Bouvet, A. et al. (1987). J Clin Microbiol. **25:** 1932-1933.
6. Phillips, W. and Kloos, W. (1981). J. Clin. Microbiol. **14:** 671-673.
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	= Use by
LOT	= Lot number
REF	= Catalogue number
	= Manufacturer
EC REP	= Authorized Representative in the European Community
Σ	= Contains sufficient for <n> tests
IVD	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use

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