

INTENDED USE

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

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 infections¹. Food poisoning, septicemia, toxic shock syndrome and many other conditions have also been attributed to infection with *S. aureus*².

Rapid slide agglutination tests have been shown to be a reliable method for the identification of *S. aureus* in the routine bacteriological laboratory³. 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 blue polystyrene latex particles which have been sensitized with fibrinogen and IgG that is 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 will agglutinate strongly within 20 seconds.

MATERIALS PROVIDED

Staph Xtra Latex Reagent (PL.1083 / PL.1084):

- Two dropper bottles each containing 2.5 ml (PL.1080) or 7.5 ml (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 a buffer containing 0.098% sodium azide as a preservative.

Negative Control Latex Reagent (PL.1085 / PL.1086):

- One dropper bottle containing 5.0 ml (PL.1080) or two dropper bottles containing 7.5 ml each (PL.1081) of unsensitized latex particles suspended in a buffer containing 0.098% sodium azide as a preservative.
- Test cards
- Mixing sticks
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Inoculating loop or needle
- Timer

STABILITY AND STORAGE

All kit components should be stored at 2-8°C. Reagents stored under these conditions will be stable until the expiration date shown on the product labels. **Do not freeze.**

PRECAUTIONS

1. Do not use the reagents after the expiration date shown on the product label.
2. The reagents contain a very small amount of sodium azide. Sodium azide 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 if the reagents are flushed down

a sink.

3. Universal precautions should be taken in handling, processing and discarding all of the materials used to perform the test.
4. The kit is intended for *in vitro* diagnostic use only.
5. The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid test results.
6. These reagents contain materials of human or animal origin and should be handled as a potential carrier and transmitter of disease.

PREPARATION OF CULTURES

A fresh isolate (18-24 hours incubation) grown on blood agar or a commercially available chromogenic agar should be used for testing.

TEST PROTOCOL

All components should be brought to room temperature prior to use.

1. Re-suspend the test latexes by gently inverting the dropper bottle several times. Examine the dropper bottles to ensure that the latex particles are properly suspended before use. Do not use if the latex fails to re-suspend.
2. Dispense 1 drop of the Prolex™ Staph Xtra Latex Reagent into a circle on the test card.
3. Using a sterile loop or needle transfer two suspect colonies into the circle. Mix this into the test latex reagent and spread to cover the complete area of the circle.
4. Gently rock the card allowing the mixture to flow slowly over the entire test ring area.
5. Observe for agglutination for up to 20 seconds.
6. Negative Control Latex Reagent is included in the kit to be used in accordance with the customer's requirements. If a positive result is obtained, it is recommended that steps 1 to 5 be repeated 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 or equivalent according to the test protocol. The organism must agglutinate with the Prolex™ Staph Xtra Latex Reagent within 20 seconds. There must be no agglutination with the Prolex™ Negative Control Latex Reagent.
2. Test a known negative strain, such as *S. epidermidis* ATCC # 12228 or equivalent according to the test protocol. There must be no agglutination of the Prolex™ Staph Xtra Latex Reagent and Prolex™ Negative Control Latex Reagent within 20 seconds.
3. Do not use the kit if the reactions with the control organisms are incorrect.

INTERPRETATION OF RESULTS

Positive result: Strong agglutination within 20 seconds with the Prolex™ Staph Xtra Latex Reagent. If you have performed a negative control there should be no agglutination with the Prolex™ Negative Control Latex. Reactions occurring after 20 seconds should be ignored.

Negative result: No visible agglutination of the Prolex™ Staph Xtra Latex Reagent particles. If traces of granulation are seen this should also be regarded as negative.

Inconclusive result: If weak clumping or a non-specific reaction (stringiness) is present in the test circle at 20 seconds, the test should be repeated using a fresh subculture. If the same result is seen after retesting, biochemical testing should be used to identify the isolate.

Uninterpretable result: If the test isolate agglutinates with both the Prolex™ Staph Xtra Latex and the Prolex™ Negative Control Latex, the test is uninterpretable.

LIMITATION OF THE PROCEDURE

1. Ensure that all isolates tested are staphylococci as non-specific false positive results may occur with other bacteria which include certain strains of streptococci, *Escherichia coli* and other species of *Enterobacteriaceae*⁷.
2. False negative reactions may occur if an insufficient amount of the test isolate is used.
3. Positive or non-specific reactions may occur with other less frequently isolated Staphylococcal species that possess clumping factor, coagulase and/or presence of capsular polysaccharides of *S. aureus*. These organisms will include some isolates of *S. lugdenensis*, *S. schleiferi*, *S. hyicus*, *S. delphini* and *S. intermedius*⁶. If necessary these organisms can be identified by biochemical tests.

PERFORMANCE CHARACTERISTICS

1. 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%.
2. 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%.
3. The Prolex™ Staph Xtra Latex Kit and a number of commercially available kits were evaluated to determine if testing isolates picked directly from four of the most commonly used Selective Chromogenic Culture Media would affect their performance. The results show that with the 70 strains of MRSA in the study the Prolex™ Staph Xtra Latex Kit was able to correctly identify 100% of the isolates from three of the four media. All kits were unable to agglutinate two isolates on the fourth medium. The authors noted that in general the Prolex™ Staph Xtra Latex Kit gave quicker and stronger reactions with the test isolates.
4. A study performed at a major teaching hospital in Canada compared the Prolex™ Staph Xtra Latex Kit with two other commercially available kits. A total of 392 clinical isolates composed of 136 Methicillin-Susceptible *S. aureus*, 114 Methicillin-Resistant *S. aureus* and 142 coagulase-negative staphylococci. The results of the study showed that the Prolex™ Staph Xtra Latex Kit demonstrated 100% sensitivity in detecting all of the *S. aureus* and isolates as did the two other kits. Full data is on file at Pro-Lab Diagnostics and is available on request.

REFERENCES

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	= Use by
	= Lot number
	= Catalogue number
	= Manufacturer
	= Authorized Representative in the European Community
	= Contains sufficient for <n> tests
	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use