PROLEX™ STAPH LATEX KIT

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

PRODUCT CODE PL.080B Σ 100

PRODUCT CODE PL.081B Σ 300

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INTENDED USE

The Prolex™ Staph Latex Kit provides a rapid platform for the identification of Staphylococcal isolates particularly *Staphylococcus aureus* which possess bound coagulase (clumping factor) and / or protein A 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 infections.[1] Food poisoning, septicemia, toxic shock syndrome and many other conditions also have been attributed to *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 laboratory.[3,6]

PRINCIPLE OF THE TEST

The Prolex™ Staph Latex Kit utilizes blue polystyrene latex particles that have been sensitized with fibrinogen and IgG. When Staphylococcal colonies which possess bound coagulase (clumping factor) and / or protein A are mixed with the latex reagent, the latex particles will agglutinate strongly within 20 seconds.

MATERIALS PROVIDED

- Staph Test Latex Reagent (PL.083B / PL.084B): Two dropper bottles each containing 2.5 ml (100 test/kit - PL.080B) or 7.5 ml (300 test/kit - PL.081B) of latex particles coated with IgG and human fibrinogen. The latex particles are suspended in a buffer containing 0.098% sodium azide as a preservative.
- Negative Control Latex Reagent (PL.085B / PL.086B): One dropper bottle containing 2.5 ml (PL.080B) or 7.5 ml (PL.081B) 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°C to 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 the 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

For specific procedures regarding specimen collection and preparation of primary cultures refer to a standard microbiology textbook. In general, a fresh (18-24 hours incubation) isolate grown on non-selective media such as blood agar is prefered for testing. However, clinical studies have shown that this test will work if the isolate is taken from Chromogenic media. The user should always confirm that the test performs as expected if they are using a culture medium other than blood agar for the initial culture of the specimen.

TEST PROTOCOL

1. Remove the test kit from the refrigerator 10 minutes prior to use and allow the latex reagents to reach room temperature.
2. Resuspend the latex reagent by inverting the dropper bottle several times.
3. Dispense 1 drop of Staph Test Latex Reagent into a circle on the test card.
4. Using a sterile loop or needle transfer two colonies of the test isolate into the 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. Observe for agglutination for up to 20 seconds.
7. Negative Control Latex Reagent is included in the kit to be used in accordance with the customer's requirements.

QUALITY CONTROL PROCEDURES

A. 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 Staph Test 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 or equivalent according to the test protocol. There must be no agglutination of the Staph Test Latex and Negative Control Latex Reagents within 20 seconds.
3. Do not use the kit if the reactions with the control organisms are incorrect.

B. Additional QC Procedure (Optional)
Staph Positive Control (PL.089B / 1 ml volume) is available for sale and can be used with the Prolex™ Staph Latex Kit. The following procedure is used in conjunction with this reagent:

1. Label two circles on the test card (one as positive and one as negative).
2. Dispense one drop of the Staph Test Latex Reagent into the circle labelled as positive.
3. Dispense one drop of the Staph Negative Control Latex Reagent into the circle labelled as negative.
4. Dispense one drop of the Positive Control into both the positive and negative circles and mix to cover the complete circles.
5. Examine for agglutination within 20 seconds.
6. The Positive Control must agglutinate with the Staph Test Latex Reagent within 20 seconds. There must be no agglutination with the Negative Control Latex Reagent. Do not use the reagents if the results with the controls are incorrect.

INTERPRETATION OF RESULTS

- Positive result: Strong agglutination within 20 seconds with the Staph Test Latex Reagent. If you have performed a negative control there should be no agglutination with the Negative Control Latex Reagent. Clumping occurring after the 20 seconds should be ignored.
- Negative result: No visible agglutination of the Staph Test Latex Reagent particles.
- Inconclusive result: If weak clumping or a non-specific reaction (stringiness) is present in the test circle after 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 Latex and Negative Control Latex, the test is uninterpretable.

LIMITATIONS 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.[4]
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.[5]

PERFORMANCE CHARACTERISTICS

The Prolex™ Staph Latex Kit (PL.080B/PL.081B) was evaluated in the Clinical Microbiology Department of a hospital in the United Kingdom. A total of 100 known strains were tested (50 MSSA, 30 MRSA and 20 CNS). Strains were grown on Chromogenic agar. Coagulase and DNase testing was used to confirm *Staphylococcus* and methicillin strips on nutrient agar was used to confirm MRSA. CNS were identified by multipoint or API. The PL.080B/PL.081B correctly identified all *Staphylococcus aureus* strains as positive and all CNS gave a negative result. In this study, the Prolex™ Staph Latex Kit was found to have a sensitivity of 100% and specificity of 100%.

REFERENCES

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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
i	= Consult instructions for use

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Canada ☎ 800 268 2341 Fax 905 731 0206
20 Mural Street, Unit #4, Richmond Hill, ON, L4B 1K3

U.S.A. ☎ 512 832 9145 Fax 512 832 6424
21 Cypress Blvd., Suite 1155, Round Rock, Texas, 78665-1046

U.K. ☎ 0151 353 1613 Fax 0151 353 1614
3 Bassendale Road, Bromborough, Wirral, Merseyside, CH62 3QL

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta