PRO-LAB DIAGNOSTICS

PROLEX™ STAPH LATEX KIT

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

PRODUCT CODE PL.080B (100 Tests)
PRODUCT CODE PL.081B (300 Tests)

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INTENDED USE

Prolex™ Staph Latex Kit provides a rapid method to distinguish staphylococci (particularly *Staphylococcus aureus*) which possess coagulase (clumping factor) and / or protein A 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 supportive 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.

PRINCIPLE OF THE TEST

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

REAGENTS

Staph Test Latex Reagent: Two vials 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 buffer containing 0.098% sodium azide as preservative.
Negative Control Latex Reagent: One vial containing 2.5 ml (PL.080B) or 7.5 ml (PL.081B) 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 can react explosively with copper or lead if allowed to accumulate. Although the amount of sodium azide in the reagents is minimal, large quantities of water should be used when flushing used reagents down the sink.
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 are 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. The kit is intended for *in vitro* diagnostic use only.
6. Do not freeze the latex reagents.
7. 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.

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 Test Latex Reagent
Negative Control Latex Reagent
Disposable cards with ten test circles labelled 1 through 10.
Disposable mixing sticks.

TEST PROTOCOL

1. Bring the latex reagent 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 Test 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.

INTERPRETATION OF RESULTS

Positive results: A significantly rapid strong clumping (within 20 seconds) with the Latex Test 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.

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[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

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. Phillips, W. and Kloos, W. (1981). J. Clin. Microbiol. **14**: 671-673.
5. Myhre, E.B. and Kuusela, P. (1983). Inf. Imm. **40**: 29-34.

	= 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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