

Pastorex[®] Strep/Kit

(Latex for grouping *Streptococci* groups A, B, C, D, F, G)

356-1721
356-1726
356-1727
356-1728 / 356-1729

PRESENTATION

• Pastorex[®] Strep A, B, C, D, F, G

code 356-1721

Each pack of 50-60 tests contains:

- 6 bottles of 1 ml of latex suspension of each group A, B, C, D, F, G: Latex particles covered with rabbit Immunoglobulin specific to each group, in suspension in a glycine buffer at pH 8.2 containing 0.01% of thimerosal and 0.1% sodium azide as preservatives.
- 2 bottles of freeze-dried extraction enzyme in TRIS buffer, NaCl, pH 8 containing 0.01% thimerosal. The contents of the bottle are reconstituted with 10 ml of distilled water. The solution obtained can be kept for 4 months at + 2°C to 8°C.
- 1 bottle of 1.5 ml of polyvalent positive control antigen containing a mixture of Lancefield extracts of each of Group A, B, C, D, F, G, and 0.02% thimerosal as preservative (quantity sufficient for 5 tests on each latex suspension).
- 2 x 125 rods
- 60 disposable agglutination cards.

• Individual latex (50-60 tests)

Pastorex[®] Strep latex A code 356-1726
Pastorex[®] Strep latex B code 356-1727
Pastorex[®] Strep latex D code 356-1728

• PASTOREX[®] Strep

Extraction enzyme code 356-1729

PRINCIPE

Pastorex[®] Strep is a rapid and sensitive agglutination test for β -hemolytic *Streptococci* belonging to the main Lancefield groups. It contains latex suspensions enabling identification of Groups A, B, C, D, F et G.

Identification of β -hemolytic *Streptococci* on the basis of group-specific polysaccharides necessitates previous extraction of these antigens from colonies isolated in primary culture on blood agar. The PASTOREX[®] Strep Kit performs this extraction in 15 minutes at room temperature or in 10 minutes at 37°C, using an active enzyme that lyses the cell walls and makes it possible to put polyoside C in solution.

In the presence of the antigen, latex particles covered in homologous antibodies agglutinate very rapidly.

The speed which agglutinations appear depend on the sensitivity of the various latex suspensions; this is due to the quality of the antisera obtained from rabbits by the Lancefield immunisation protocol and to the optimal quantities of purified immunoglobulins absorbed by the latex particles.

STORAGE

- Pack: + 2°C to 8°C.
- Expiration date and batch number are shown on the package.
In-vitro use.

EQUIPMENT REQUIRED

(non-exhaustive)

- Pipettes in 0.3 ml aliquot parts
- Hemolysis tubes (1 per strain)

PROTOCOL

• Preparation of specimens

The Pastorex[®] Strep Kit is for use with colonies isolated on blood agar and surrounded with a zone of β -hemolysis.

Microscope observation of Gram-positive cocci and detection of negative catalase make it possible to pursue identification by direct grouping if a sufficient number of colonies isolated on primary culture is available.

• Preparation of extraction

Place 0.3 ml of extraction enzyme solution in a hemolysis tube for each isolated strain.

Collect at least 5 β -hemolytic colonies and dissociate them in the enzyme. When colonies are less than 0.5 mm in size, increase the inoculum until turbidity visible to the naked eye is obtained.

Incubate:

- either for 15-45 minutes at room temperature
- or for 10-30 minutes at 37°C

• Identification of extract group

Give the bottles containing latex particles a vigorous shake for a few seconds in order to replace them in suspension.

Deposit 1 drop of each latex in circles on the agglutination card (holding the bottle upright).

Using a pipette, place 1 drop of extract in each of the circles of the agglutination card.

Homogenize the contents of each circle using a

rod. Use a different rod for each circle and throw it away after use in a container for contaminated material.

Using circular movements, agitate the card for a maximum of 1 minute.

Take a reading. A positive reaction is revealed by agglutination of latex particles within a maximum of 1 minute. The size of clumps and the rapidity of their appearance depend on the antigenic concentration of the extract. This varies according to the number of colonies collected from the agar and their size.

READING AND INTERPRETATION

Positive reaction: appearance of red agglutinations on a green background.

Only distinct and rapid agglutination with a single one of the 6 latex makes it possible to identify the group of the test strain.

Negative reaction: homogenous brown suspension.

Aspecific reactions:

- Weak agglutinations against a brown background.
- Any multiple agglutinations that could be due to other bacteria collected from the agar at the same time as the β -hemolytic colonies (mixture of streptococci of various groups or of other bacteria possessing antigens giving a crossed reaction). This type of doubtful reaction necessitates re-isolation of the test strain. Biochemical identification will permit confirmation of the identification of certain strains possessing antigens to both Group C and G, for example.

PRECAUTIONS

- Return each reagent to suspension before use.
- Close bottles with the appropriate stopper.
- Avoid all contact with eyes, skin and mucous tissues.
- Sodium azide can react with the lead or copper in drainage pipes and produce explosive metallic azides. When eliminating it, rinse abundantly to prevent formation of azide deposits.

PERFORMANCES / QUALITY CONTROL OF THE TEST

• Latex suspension

The sensitivity of reagents is measured by their reactivity compared to the positive antigen control, which should provoke distinct agglutination of each latex suspension within 1 minute.

• Enzyme

The activity of the enzymatic solution can be tested in relation to a strain of a known group, the antigen of which should be extracted and should be able to rapidly agglutinate the homogenous latex suspension.

• Specificity

Negative control carried out during each test by the reaction of the enzymatic extract with heterologous latex suspensions: in addition, the latex suspensions should remain in the presence of a drop of extraction enzyme.

QUALITY CONTROL OF MANUFACTURER

Every product manufactured and marketed by Bio-Rad is subject to a quality-assurance procedure at all stages, from the reception of raw materials to the marketing of the end-product. Each batch of finished product undergoes quality control and is marketed only if it satisfies the acceptability criteria.

Documentation relative to the production and control of each batch is kept on file.

BIBLIOGRAPHY

- **ARDITI M., SHULMAN S.T., TODD DAVIS A., YOGEV R. (1989):** Group C hemolytic streptococcal infections in children. Nine pediatric cases and review. *Review of Infections Diseases*, **11**: 34-35.
- **CIMOLAI N., ELFORD R.W., BRYAN L., ANAND C., BERGER P. (1988):** Do the β -hemolytic Non-group A Streptococci cause Pharyngitis. *Reviews of Infections Diseases*, **10**: 587-601.
- **KAVIT J., WISER (1988):** Group A-hemolytic *Streptococcus* causing disseminated intra vascular coagulation and maternal death. *Lancet*, **I**: 993-994.
- **Mc MEEKLING A.A., HOLZMAN R.S. (1988):** Group G Streptococcal Bacteremia and Parental Drug Abusers. *The Journal of Infectious Diseases*, **157**: 612-613.