PRO-LAB DIAGNOSTICS

PROLEX™ STREPTOCOCCAL XTRA SELECT KIT

(for *in vitro* diagnostic use)

PRODUCT CODE PL.1042

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INTENDED USE

The Prolex™ Streptococcal Xtra Select Kit provides a rapid platform for the serological identification of beta-haemolytic streptococci belonging to Lancefield groups A and B.

SUMMARY AND EXPLANATION

Clinical, epidemiological and microbiological studies have conclusively shown the need for a more rapid identification method for streptococci primarily groups A and B due to the high prevalence and association with human disease. The diagnosis of streptococcal infections based on clinical symptoms always requires microbiological verification (4). Beta-haemolytic streptococci are the most frequently isolated human pathogens among the representatives of the genus *Streptococcus*. Nearly all the beta-haemolytic streptococci possess specific carbohydrate antigens (streptococcal group antigens). Lancefield showed that these antigens can be extracted in soluble form and identified by precipitation reactions with homologous antisera. Different procedures for extraction of streptococcal antigens are currently in use (1,2,6,7,10,11,12). The Prolex™ Streptococcal Xtra Select Kit is based on liberation of specific antigen from bacteria cell walls by the action of lytic enzymes. The extracted antigen in conjunction with latex agglutination offers a rapid, sensitive and specific method for identification of streptococcal groups A and B from primary culture plates.

PRINCIPLE OF THE TEST

The Prolex™ Streptococcal Xtra Select Kit grouping method involves enzymatic extraction of group specific carbohydrate antigens using specially selected lytic enzymes. The Streptococcal Xtra Extraction Reagent provided in the kit contains a proprietary formulation of lytic enzymes able to extract streptococcal group specific antigens at room temperature. Extracts can be easily identified using blue polystyrene latex particles sensitized with purified group specific rabbit immunoglobulins. These blue latex particles agglutinate strongly in the presence of homologous antigen and will not agglutinate when homologous antigen is absent.

MATERIALS PROVIDED

Each kit is sufficient for 120 tests. Materials are supplied ready for use.

- Latex Reagents: The customer selects which two vials of Blue Latex Grouping Reagents that they want in the kit. Each dropper bottle contains 3.0 ml of blue latex particles coated with purified rabbit antibodies to Lancefield groups A or B. The blue latex particles are suspended in buffer pH 7.4 containing 0.098% sodium azide as a preservative. The latex reagents available are:

Reagent	Catalogue Number
Group A Latex Reagent	PL.1031
Group B Latex Reagent	PL.1032

- Streptococcal Xtra Extraction Reagent (PL.1037): Two dropper bottles containing 6.0 ml of extraction reagent with preservative.
- Polyvalent Positive Control (PL.1040): One dropper bottle containing 2 ml of ready-to-use polyvalent antigens extracted from inactivated streptococci of Lancefield groups A, B, C, D, F and G.
- Plastic Mixing Sticks
- Test Cards
- Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Inoculating loops or needles
- Pasteur pipettes
- 12 mm x 75 mm test tubes
- 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 label. Do not freeze.

PRECAUTIONS

1. Do not use the reagents after the expiration date shown on the product label.
2. Some reagents contain a 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 clinical specimens. All test materials should be considered potentially infectious during and after use and should be handled and disposed of appropriately.
4. The reagents are 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. Reagents contain material of animal origin and should be handled as a potential carrier and transmitter of disease.

SPECIMEN COLLECTION AND PREPARATION OF CULTURES

For specific procedures regarding specimen collection and preparation of primary cultures refer to a standard microbiology textbook. A fresh (18-24 hour) culture on blood agar should be used.

TEST PROCEDURE

All components should be at room temperature (18-22°C) prior to use.

1. Re-suspend the latex reagent by gently inverting the dropper bottle several times. Examine the dropper bottle to ensure that the latex particles are properly suspended before use. Do not use if the latex fails to re-suspend.
2. Label one test tube for each isolate to be tested.
3. Add 2 drops of Streptococcal Xtra Extraction Reagent to each tube.
4. Select one beta-haemolytic colony using a disposable loop or needle and suspend it in the Streptococcal Xtra Extraction Reagent. In all cases the streptococcal colony should be picked from an area which will afford the lowest probability of contamination with another organism.
5. Mix the reaction by tapping the tube and develop for 60 seconds.
6. Dispense one drop of each group latex reagent onto separate circles on the test card.
7. Using a Pasteur pipette, place one drop of extract beside each drop of latex reagent.
8. Mix the latex and the extract with the sticks provided, using the complete area of the circle. A new stick should be used for each test.
9. Gently rock the card allowing the mixture to flow slowly over the entire test ring area.
10. Observe for agglutination for up to 30 seconds.

QUALITY CONTROL PROCEDURES

The routine quality control procedure for each Prolex™ lot involves testing blue latex reagents and Streptococcal Xtra Extraction Reagent with each streptococcal group A and B using the ATCC strains or equivalent as listed in this section. The extract from these strains will agglutinate with the homologous latex reagent. The Polyvalent Positive Control is used to test the individual latex reagents.

Organism	Lancefield Group	Reference
Streptococcus pyogenes	Group A	ATCC #19615
Streptococcus agalactiae	Group B	ATCC #12386

INTERPRETATION OF RESULTS

Positive results: Rapid strong agglutination of the blue latex particles within 30 seconds with one of the latex reagents indicates the specific identification of the streptococcal isolate.

Negative results: No agglutination of the blue latex particles.

LIMITATIONS OF THE PROCEDURE

1. False negative or false positive results can occur if the kit is not used as directed and if an inadequate amount of culture is used for extraction.
2. The kit is intended for use in identification of beta-haemolytic streptococci only. If alpha or non-haemolytic streptococci are tested, the identification should be confirmed by biochemical tests (5,9).
3. False positive reactions have been known to occur with organisms from unrelated genera, e.g. *Escherichia coli*, *Klebsiella* or *Pseudomonas* (3,8). These are likely to non-specifically agglutinate all of the latex reagents.
4. *Listeria monocytogenes* may cross react with the Group B Streptococcal latex reagents, since *L. monocytogenes* exhibits similar antigenicity to Group B streptococci. The catalase test may be performed to distinguish between *Listeria*, which are catalase-positive, and streptococci, which are catalase-negative. Gram staining and motility testing may be performed as further aids to differentiation.
5. Some strains of *Streptococcus milleri* (*Streptococcus anginosus*) typically non-haemolytic possess A, C, F or G antigens and can give positive reaction with Strep A, C, F or G latex reagents. Morphology on blood agar and biochemical testing should be used to identify these organisms.

PERFORMANCE CHARACTERISTICS

The Prolex™ Streptococcal Xtra Select Kit was tested for performance at hospitals in the United Kingdom using 293 isolates of beta-haemolytic streptococci. The isolates included 61 *Streptococcus pyogenes* (Lancefield group A Strep) 91 *Streptococcus agalactiae* (Lancefield group B Strep), 19 *Streptococus* sp. group C, 65 *Enterococcus faecalis* group D, 4 *Streptococcus* sp. group F and 53 Streptococcus group G . The kit demonstrated 100% sensitivity and specificity for both latex reagents when tested against the isolates. The average time for a positive reaction with the Group A and Group B reagents was 13 seconds and 12 seconds, respectively.

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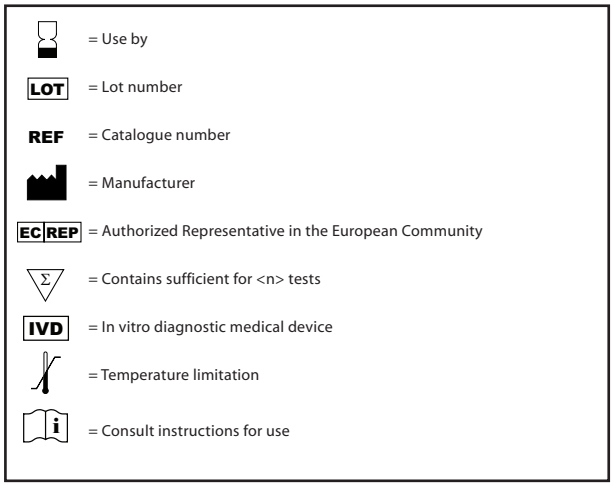

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