Six dropper bottles, one specific for each of extracted streptococci antigens of representative strains of Lancefield Groups A, B, C, D, F, and G. The solution contains 0.05% sodium azide as preservative. Store uptight and tightly capped; stable at 2 to 8°C until the expiration date indicated on the label.

**Reagent 1 (0.070%)**
- One bottle containing 4.0 ml of a blue solution (acidic solution) and a purple indicator.
- Store uptight and tightly capped; stable at 2 to 30°C until the expiration date indicated on the label.

**Reagent 2 (0.070%)**
- One bottle containing 4.0 ml of a milky solution (acidic solution) and a purple indicator.
- Store uptight and tightly capped; stable at 2 to 30°C until the expiration date indicated on the label.

**Reagent 3 (0.070%)**
- Two bottles containing 10 ml of a cloudy neutralising solution (Tris buffer solution) with 0.05% sodium azide as preservative. Store uptight and tightly capped; stable at 2 to 7°C until the expiration date indicated on the label.

**PRECAUTIONS**
- The reagents are for in vitro diagnostic use only.
- Please refer to the Safety Data Sheet (SDS) and product labeling for information on potentially hazardous components.

**HEALTH AND SAFETY INFORMATION**
- In accordance with the principles of Good Laboratory Practice it is strongly recommended that at any stage of preparation potentially infectious material is treated as potentially infectious and handled with all necessary precautions.
- The concentration of the latex is maintained between 0.3% and 0.5% which is classified as a Class IIB hazard according to European Community (EC) Regulation as a sensitizer. The following are the appropriate hazard (H) and precautionary (P) statements.

**SYMPTOMS**
- May cause an allergic skin reaction.
- Eyes: Immediate irritation and redness.
- Respiratory tract: Immediate irritation and coughing.
- Other: Immediate irritation, vomiting, etc.

**DISPOSAL**
- May be disposed of as clinical waste in accordance with local requirements.
- If skin irritation or rash occurs: Get medical advice immediately.
- If skin contact occurs: Wash with plenty of soap and water.
- If eye contact occurs: Wash with plenty of water for at least 15 minutes.
- If swallowed: Do not induce vomiting, call a Poison Centre immediately. Do not give anything by mouth to an unconscious person.

**ALLERGIC SENSITISATION**
- For professional use only. This product may cause an allergic skin reaction. The possibility of cross reactions with latex is known. It is advisable to perform skin testing before use.

**SPECIMENS**
- The test is to be used on specimens collected (as described in test procedure on solid media) from a patient suspected of having a streptococcal infection. It is not possible to provide a general list of these specimens. The specimens are generally considered to be clinical specimens and include:
  - Wound swabs and clots from skin and soft tissue infection.
  - Tissue swabs and clots from gas and soft tissue infection.
  - Nasal and throat swabs and clots from nasopharyngeal infection.
  - Urine clots from urinary tract infection.
  - Other clinical specimens, such as effusion, synovial fluid, and so forth.

**SAFETY AND STABILITY OF THE TEST**
- Do not add any other reagents to the broth. The broth should be prepared (as described in test procedure on solid media) from a patient suspected of having an active streptococcal infection.

**EQUIPMENT**
- A Colonies On Solid Media:
  - Label 12×17 mm test tubes for each specimen.
  - Add free flowing drop of Reagent 1 to the solid media by squeezing the bottle gently in a vertical position.
  - Place 1 to 4 isolated Staphylococcus haemolyticus colonies with a disposable applicator and cover with Reagent 1.

**INTERPRETATION**
- A positive reaction occurs when there is visible agglutination of the latex microparticles with a clearening of the background within 60 seconds. The Positive control lot should be used as a positive test control. A negative reaction with the addition of latex microparticles is a common occurrence with the direct testing procedure. To avoid any false positive reactions, the test must be stopped after an initial positive reaction is seen.
blood agar plates and serologic reaction are the only criteria used for characterization of S. anginosus at the Centers for Disease Control\(^2\). Biochemical differentiation may be done using a scheme such as that described by Lawrence et al\(^2\).

### 12 PERFORMANCE CHARACTERISTICS

The performance of the PathoDxtra Streptococcal Grouping Kit was evaluated at a hospital laboratory in Paris, France. A total of 419 isolates were tested, including 311 Lancefield grouped streptococci, 79 non-groupable streptococci/enterococci and 29 non-streptococci. The results obtained were compared to a commercially available nitrous acid extraction kit.

The sensitivity and specificity of the kits examined was calculated from the trial data, as follows:

<table>
<thead>
<tr>
<th></th>
<th>PathoDxtra Streptococcal Grouping Kit</th>
<th>Predicate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean sensitivity</td>
<td>89.1%</td>
<td>85.2%</td>
</tr>
<tr>
<td>Mean specificity</td>
<td>97.0%</td>
<td>97.5%</td>
</tr>
</tbody>
</table>

### 13 BIBLIOGRAPHY