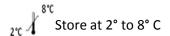


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# STREPTOCOCCAL GROUPING SLIDE LATEX TEST

A qualitative latex agglutination test for the Detection of Streptococcal groups A, B, C, D, F and G

IVD For In-Vitro diagnostic and professional use only



#### **INTENDED USE**

For the qualitative detection of streptococcal groups A, B, C, D, F and G based on latex agglutination.

## **INTRODUCTION & PRINCIPLES**

ATLAS Streptococcal test uses an enzyme extraction procedure to release Carbohydrate antigen from Streptococcal cell walls.

The antigens are detected using specific antibodies to groups A, B, C, D, F and G Lancefield. These antibodies are coated on latex particles. When the antigen extract is mixed with the latex reagent, agglutination will occur. The agglutination appears as a visible clumping and can be seen macroscopically.

## **MATERIALS**

#### **MATERIALS PROVIDED**

- Group A, B, C, D, F and G latex reagents.
- Extraction Enzyme dried.
- Positive control.
- Test slide.
- Stirring Sticks.
- Package Insert.

#### MATERIALS NEEDED BUT NOT PROVIDED

- Water bath.
- Pipette to deliver 50ul.
- Timer and test tubes.

#### PRECAUTIONS:

- 1. Prior to use, the Latex reagent should be mixed well to obtain a uniform suspension of the Latex.
- 2. This kit should be stored in an upright position and refrigerated between 2 to 8°C. Never Freeze.
- 3. Use a fresh disposable slide and mixer for each test.
- 4. Always ensure an acceptable performance of the kit by performing the test on the negative and the Positive controls before using the kit.
- 5. The extraction procedure may not kill all organisms; therefore carefully dispose the materials into disinfectant or by autoclaving.

#### PREPARING THE EXTRACTION ENZYME

The Extract enzyme in this kit comes in two vials dried. Reconstitute with 10ml distilled or deionized water. Once reconstituted store at 2-8°C for a maximum of 3 months or a liquot in 0.4ml volumes and store at -20°C for up to a year.

#### SAMPLE PREPARATION

#### Cultures

Note colonial characteristics, hemolysis, and cell morphology before starting the test. Ensure that the organisms to be tested are Gram-positive and catalase-negative. Any blood agar plate culture yielding 2-6 well-separated colonies maybe used, they should have been inoculated from a pure culture of the organism.

#### **PROCEDURES**

- Using a sterile bacteriological loop, pick no more than 6 colonies of streptococci (avoiding other types of colony on the plate) and emulsify them in 0.4 ml extraction enzyme. (If a broth culture is to be grouped, pipette 0.1ml of an overnight culture into 0.4ml extraction enzyme).
- Incubate the mixture in a water bath at 37ºC for 10 minutes. Shake the tubes vigorously after 5 minutes incubation. Longer incubation period may lead to false positive results.
- 3. Re-suspend the latex reagents by gentle agitation.
- 4. Dispense 1 drop of each latex into the appropriate labeled circle on the test slide.

- 5. Using a pipette, place 50ul of the extract to each drop of latex reagent, and mix the contents of each circle with a separate mixing stick.
- 6. Gently rock the slide for one minute.
- Read the result in normal light and observe for any agglutination.

#### READING THE RESULT

POSITIVE: If Agglutination appears within one minute. NEGATIVE: If Agglutination does not appear within one minute.

# PROCEDURE LIMITATION

- This test provides a presumptive diagnosis. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- Faint granularity may be seen in some negative patterns, this should be disregarded.

#### PERFORMANCE CHARACTERISTICS

		Test reagent	
		+	-
Reference method	+	607	55
	-	0	24

Sensitivity 607/662 = 92% Specificity 24/24 = 100%

#### INTERNAL QUALITY CONTROL

A positive control is provided and should be used to verify that the latex reagents are working satisfactorily under test conditions.

Periodically check the following:

- 1. The test reagents agglutinate with a known reference Streptococcus strain
- 2. The test reagents do not auto agglutinate in normal saline solution.

#### REFERENCES

1. Lancefield, R.c., (1938)Proc. Soc.Exp. Bio. Med. 38, 473

- 2. Harvey,C.L.,Mcillmurray, M.B. (1984) Eur.J. Clin. Microbiol, 3.6,526
- Facklam,R.R., (1980) "Manual of Clinical Microbiology"
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REF	Catalogue Number	1	Store at
IVD	For In-Vitro Diagnostic use	Ţ	Caution
Σ	Number of tests in the pack	(i	Read product insert before use
LOT	Lot (batch) number		Manufacturer
Ţ	Fragile, handle with care	X	Expiry date
	Manufacturer fax number		Do not use if
<b>_</b>	Manufacturer telephone number		