Atlas Medical CE

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*

Store at 2° to 8° C

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

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- 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:

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Location: Moldova

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 8ºC. 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

1. 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).
2. 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.
7. 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
3. Facklam,R.R., (1980) “Manual of Clinical Microbiology” 3 Edn., American Society for Microbiology, Washington, DC, pp 88-110.

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REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if
	Manufacturer telephone number		