Key Code TSMX4001F
www.oxoid.com/ifu

Europe + 800 135 79 135
CA 1 855 805 8539
US 1 855 236 0910
ROW +31 20 794 7071

Oxoid Streptococcal Grouping Reagents EN

REF

DR0586G .....Latex Grouping Reagent A
DR0587G .....Latex Grouping Reagent B
DR0588G .....Latex Grouping Reagent C
DR0589G .....Latex Grouping Reagent D
DR0590G .....Latex Grouping Reagent F
DR0591G .....Latex Grouping Reagent G
DR0592G .....Polyvalent Positive Control
DR0593G .....Extraction Enzyme
DR0500G .....Disposable reaction cards

1. INTENDED USE

A latex agglutination test for the identification of streptococcal groups A, B, C, D, F, and G.

2. DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

See also Warnings and Precautions.

Store at 2 to 8°C, protected from light. Use on or before the expiration date marked on the label. All components must be at room temperature (15 to 28°C) before use; mix thoroughly by inversion.

Components of this kit are interchangeable with components of other lots of the same catalog number.

3. WARNINGS AND PRECAUTIONS

IVD

The reagents are for *in vitro* diagnostic use only.

Do not freeze the latex grouping reagents

For professional use only.

Please refer to the Safety Data Sheet (SDS) and the product labeling for information on potentially hazardous components.

Working Reagents

Each latex reagent is ready for use after reaching room temperature.

It is essential that the latex reagent is vigorously shaken to obtain a homogenous suspension before use.

When required for use, the enzyme reagent should be reconstituted with distilled water to the amount shown on the label.

HEALTH AND SAFETY INFORMATION

Preservatives

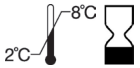
1. Each latex reagent contains 0.1% sodium azide.
2. The extraction enzyme contains 1.7% thiomersal and achromopeptidase at 7.32% which is classified per applicable European Econimic Community (EEC) directives as toxic and a sensitiser. The following are the appropriate Hazard (H) and Precautionary (P) statements:

DANGER

H332	Harmful if inhaled.
H311	Toxic in contact with skin.
H301	Toxic if swallowed.
H373	May cause damage to organs through prolonged or repeated exposure.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P280	Wear protective gloves/ protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P285	In case of inadequate ventilation wear respiratory protection.
P260	Do not breathe dust/fume/ gas/mist/vapours/spray.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

STORAGE

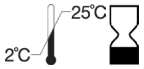
A. Latex Reagents



The latex reagent bottles should be stored in an upright position at 2-8°C.

Under these conditions they will retain their activity until the date shown on the bottle label.

B. Extraction enzyme



The freeze dried extraction enzyme should be stored at 2-25°C. Under these conditions it will retain its activity until the date shown on the bottle.

After reconstitution with distilled water, store the solution at 2-8°C. Under these conditions it will retain its activity for four months.

4. PREPARATION OF CULTURES

Samples for identification should be grown on a blood agar plate overnight at 37°C. Note the haemolytic reaction of suspect colonies. It is also advisable to carry out a Gram-stain and catalase test to confirm the presence of Gram-positive, catalase-negative cocci. For further details please consult standard texts.

For each culture to be grouped:

1. Reconstitute a bottle of Oxoid Streptococcus Extraction Enzyme (DR593) with sterile distilled water to the amount shown on the label. Label test tubes appropriately and dispense 0.4 ml of enzyme into each test tube.
2. Select 2-5 test colonies equivalent to 2-3mm of growth with a bacterial loop and emulsify in the enzyme preparation. If the culture is mixed, avoid obvious contamination.
3. Incubate for 10 minutes at 37°C in a water bath. After 5 minutes it is important to remove each tube and shake vigorously for 2-3 seconds, then continue the incubation. Remove and allow to cool to room temperature.

The extract is now ready for use.

For further information, please refer to instruction leaflet in the Streptococcal Grouping Kit (DR0585A).

5. TEST PROCEDURE

Test Method

1. Bring the latex reagents to room temperature by warming the bottles by hand.Make sure the latex suspensions are mixed by vigorously shaking.Expel any latex from the dropper pipette for complete mixing.
2. Dispense 1 drop from each latex reagent into the circular rings on the reaction card (DR500)
3. Using a Pasteur pipette, add one drop of extract to each of the 6 rings.
4. With the mixing sticks provided, spread the mixture over the entire area of the ring using a separate stick for each ring.
5. Gently rock the card. Agglutination in 1 or more of the rings will normally take place within 30 seconds. Do not rock the card for more than 1 minute. Do not use a magnifying glass to aid reading.
7. Dispose of the reaction card safely into a suitable disinfectant.

6. QUALITY CONTROL

Quality control testing should be run with each shipment and new kit lot number received. Each laboratory should follow their state and local requirements.

The following procedures can be used to check the performance of the latex reagents:

a) Test for the reactivity of the latex suspensions (Positive Control Procedure)

For one test: Dispense one drop (40µl) of Positive Control Antigen onto the test card and mix with the latex suspension. Mix the contents of the circle with a fresh mixing stick. After rocking the card gently for one minute, definite agglutination should occur with all the test latexes.

b) Test for specificity of agglutination (negative control procedure)

In cases of very weak agglutination the positive tests should be repeated in parallel against one drop of an extraction enzyme with an uninoculated mixing stick or inoculating loop. The latex suspension should not show significant agglutination and the result serves as a control for direct comparison of the test performed with bacterial extract.

c) Carry out the complete test procedure on stock cultures of known groups.

7. INTERPRETATIONS

Interpretation of Results

The test should be considered positive when agglutination occurs with one grouping reagent or when one grouping agent gives a substantially stronger reaction than the other five. The test should be considered negative when no agglutination occurs.Faint traces of granular material may be observed in negative reactions and should be ignored.

8. LIMITATIONS

Limitations of the Test

False negative results can occur if an inadequate amount of the culture is used for extraction. Nearly all beta-haemolytic streptococci isolated from the human infections possess specific carbohydrate antigens which can be recognised by serological reactions.

Attempts to extend these procedures to non-beta haemolytic streptococci have been unsuccessful except for groups B, D and N. Group N streptococci are not found in human infections.[2]

It should be noted that the Group D reagent may fail to react with some *S bovis* strains and these strains would require further tests for identification.When carrying out a serological identification for streptococci the following initial observations should be made, (i) note haemolysisa,[c], (ii) note cell morphologyb,[c], (iii) assess colonial growth for purity and quantity.[d]

(a) Rule out *Strep pneumoniae*. This streptococcus is α-haemolytic, bile soluble and optochin susceptible. Other streptococci are not bile soluble and are optochin resistant[2].

(b) Aerococci are non-ß-haemolytic, grow in 6.5% NaCl broth and give variable reactions in the bile-aesculin test. They can be differentiated from enterococci by their arrangement in tetrads or as single cells, whereas enterococci are arranged as diplococci or short chains[2].

(c) Staphlococci and Listeria monocytogenes are haemolytic and can be distinguished from streptococci by their cellular morphology and catalase reaction[3,4].

(d) Subculture if the suspected organism is overgrown or insufficient.

(e) Strains have been found which appear to have both D and G antigens.[1]

9. REFERENCES

1. Birch B.R., Keaney M.G.L. and Ganguli L.A.(1984) Lancet, I, 856-857.
2. Facklam R.R. and Carey R.B. (1985) in 'Manual of Clinical Microbiology',4th Edition. Eds. Lennette E.H., Balows A., Hausler W.J., Shadomy H.J., Amer. Soc. for Microbiol., Washington, D.C.,pp. 154-175.
3. Kloos W.E. and Jorgensen J.H. (1985) in 'Manual of Clinical Microbiology',4th Edition, pp. 143-153.
4. Bortolussi R., Schlech W.F. and Albritton W.L. (1985) in 'Manual of Clinical Microbiology', 4th Edition, pp. 205-208.

SYMBOL LEGEND

REF	Catalogue Number
IVD	*In Vitro* Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
	Contains sufficient for <N> tests
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

CE

Oxoid Ltd, Wade Road, Basingstoke,
Hants RG24 8PW, UK

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