LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
Strep Test kit	860050

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 24 March 2016.

Eddy Velthuis
Technical Director

File No A12241;
ISO 13485:2003; ISO 9001:2008

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LORNE LABORATORIES LTD.
GREAT BRITAIN

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BACTERIAL IDENTIFICATION
DIRECTIONS FOR USE

Jno7 171

Strep-Check Kit: For Identification Of Streptococci, Lancefield's Groups A, B, C, D, F And G.

SUMMARY

Streptococci carry group specific carbohydrate antigens in their cell walls and after extraction using a specially developed enzyme preparation these antigens will agglutinate latex particles coated with the corresponding antibody.

PRINCIPLE

When used by the recommended techniques, latex particles in the reagent will agglutinate (clump) in the presence of the corresponding streptococci antigen. No agglutination generally indicates absence of the corresponding streptococci antigen (see **Limitations**).

KIT DESCRIPTION

Lorne Strep-Check is for identification of streptococci, Lancefield's groups A, B, C, D, F and G. The different reagents are coated with the specific antibody and will agglutinate in the presence of enzymatically-extracted antigen. All the reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Keep all vials clean, well sealed and store upright at 2-8°C during storage and transportation. Do not freeze the latex reagents; storage outside recommended temperature range may result in accelerated loss of reagent reactivity. The reconstituted extraction enzyme will maintain activity for 3 months or until the date shown on the original bottle when stored at 2-8°C. Alternatively enzyme may be stored in aliquots and frozen at –20°C, where it will remain active for 6 months or until date shown on the bottle, whichever is sooner. **Do not freeze and thaw extraction enzyme more than once.**

SPECIMEN COLLECTION

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

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagents contain less than 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
5. No known tests can guarantee products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended the Positive Control be tested in parallel with each batch of tests. Tests must be considered invalid if control does not show expected results.
2. All the reagents must be allowed to reach 18-25°C before use.
3. Shake the reagents well before use to ensure homogeneity.
4. Do not interchange components between different kits.
5. Use of kit and interpretation of results must carried out by properly trained and qualified personnel in accordance with the requirements of the country where the kit is in use.
6. User must determine suitability of kit for use in other techniques

KIT COMPONENTS SUPPLIED

- Streptococcal A Test Reagent (Yellow label).
- Streptococcal B Test Reagent (Yellow label).
- Streptococcal C Test Reagent (Yellow label).
- Streptococcal D Test Reagent (Yellow label).
- Streptococcal F Test Reagent (Yellow label).
- Streptococcal G Test Reagent (Yellow label).
- Polyvalent Positive Control (Red label).
- Extraction Enzyme (2 bottles) (Green label).
- Disposable Agglutination Slides.
- Stirrers.

MATERIALS AND EQUIPMENT REQUIRED

- Glass Test Tubes (10 x 75 mm or 12 x 75 mm).
- 37°C Water Bath.
- Sterile Bacteriological Loops.
- Pasteur and Graduated Pipettes.

RECONSTITUTION OF EXTRACTION ENZYME

To one bottle of Extraction Enzyme add 10 ml of deionised water. Shake the bottle's contents thoroughly and then allow the contents to stand for 5 minutes. The Extraction Enzyme is now reconstituted and ready for use.

RECOMMENDED TECHNIQUE

1. Using a sterile loop pick 2-6 colonies of streptococci making sure to avoid other types of colony on the plate.
2. Emulsify the colonies in 0.4 ml of the Extraction Enzyme. (If a broth culture is to be grouped, pipette 0.1 ml of an overnight culture into 0.4 ml of the Extraction Enzyme).
3. Incubate the mixture in a water bath at 37°C (± 1°C) for 10 minutes, shaking tubes vigorously after 5 minutes incubation.
4. Dispense 1 drop of each latex reagent into the appropriate labelled circle on the test slide.
5. Add one drop of the extract to each drop of latex reagent, and mix the contents of each circle with a separate mixing stick.
6. Rock the slide for not longer than 1 minute and then observe for agglutination.
7. Record the results.

INTERPRETATION OF RESULTS

1. **Positive:** Strong agglutination of specimen with **ONE** latex reagent, normally within a few seconds of mixing constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of that specific Streptococci group, either A, B, C, D, F or G.
2. **Negative:** No visible agglutination of latex particles in a milky liquid constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of Streptococci groups A, B, C, D, F and G.
3. **Equivocal:** If agglutination occurs in all groups then either the enzyme has been over-inoculated in which case repeat the test using a lighter innoculum, or a mixed culture was tested, in which case check for purity and retest.

LIMITATIONS

1. False positive reactions have been known to occur with organisms from unrelated genera, e.g. Escherichia, Klebsiella or Pseudomonas. These are likely to non-specifically agglutinate all latex reagents.
2. Group D antigen is common to organisms of group Q, R and S.
3. False negative results can occur if an inadequate amount of culture is used for extraction.
4. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper storage of test materials or omission of reagents
   - Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne Strep-Check Kit is tested by the **Recommended Techniques** to ensure suitable reactivity.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. Lancefield RC. (1938). Proc, Soc, Exp, Bio. Med. 38, 473.
2. Harvey CL, McIlmurry MB. (1984). Eur. J. Clin. Microbiol. 3.6, 526.
3. Facklam RR. (1980). "Manual of Clinical Microbiology" 3rd Ed. American Society for Microbiology, Washington, DC. Pp 88-110.

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
6 X 50 Tests Per Kit	860050

For the availability of other sizes, please contact:

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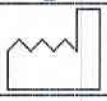
TABLE OF SYMBOLS

LOT	Batch Number	IVD	*in-vitro* Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		