LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

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

Product name	Catalogue numbers
Staph Test kit	870050 870100

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.

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ISO 13485:2003; ISO 9001:2008

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LORNE LABORATORIES LTD.
GREAT BRITAIN

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BACTERIAL IDENTIFICATION
DIRECTIONS FOR USE

pot 169

Staph-Check Kit: For Identification Of Species Possessing Clumping Factor And/Or Protein A.

SUMMARY:
Over 95% of pathogenic stains of *Staphylococcus aureus* produce protein A, either with or without clumping factor. Protein A has a high affinity for the Fc moiety of IgG.

PRINCIPLE:
When used by the recommended techniques, latex particles in the reagent will agglutinate (clump) in the presence of either clumping factor and/or protein A. No agglutination generally indicates the absence of either clumping factor and/or protein A (see **Limitations**)

KIT DESCRIPTION:
Lorne Staph-Check kit is for identification of Staphylococcus species possessing clumping factor and/or protein A. The *Aureus* reagent consists of latex particles coated with human fibrinogen and IgG and the control reagent consists of latex particles that are not coated with fibrinogen and IgG. All the reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. Lot reference number and expiry dates are printed on the kit box and individual vial labels.

STORAGE CONDITIONS, TRANSPORTATION & HANDLING:
Keep all vials clean, well sealed and store upright at 2-8°C during storage and transportation. Do not freeze or expose to elevated temperatures. Prolonged storage outside the recommended temperature range may result in accelerated loss of reagent reactivity. Protective clothing should be worn when handling the kit components, such as disposable gloves and a laboratory coat.

SPECIMEN COLLECTION:
Cultures should be fresh 24-hour growths, and may be tested directly from the plate. If there is insufficient growth, sub culture to blood or nutrient agar and incubate overnight at 37°C. Organisms grown on high salt media such as mannitol salt agar may show stringiness when mixed with reagents. Testing control latex reagent in parallel can eliminate any discrepancies. Alternatively, sub culturing to blood agar base or nutrient agar should be sufficient.

PRECAUTIONS:
1. The kit for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. 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.
4. Materials used to produce the kit were tested at source and found to be negative for HIV 1+2 and HBsAg using approved microbiological tests. However, no known tests can guarantee that 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 a positive control specimen 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 country where the kit is in use.
6. The user must determine the suitability of the kit for use in other techniques.

MATERIALS REQUIRED:

A. Kit Components Supplied:
1. Latex Test Reagent (Yellow label).
2. Latex Control Reagent (Red label).
3. Disposable Agglutination Slides.
4. Mixing Sticks.

B. Materials And Equipment Not Supplied:
1. Glass Test Tubes (10 x 75 mm or 12 x 75 mm).
2. 37°C Water Bath or Dry Heat Incubator.
3. Sterile Inoculation Loops.
4. Pasteur and Graduated Pipettes.
5. Known Staphylococcus Positive Specimen.

RECOMMENDED TECHNIQUE:
1. Place one drop of Test Reagent in the centre of a test circle on a disposable agglutination slide.
2. Using a sterile loop, pick off 2-4 colonies from a fresh overnight culture plate of the organism to be investigated, and emulsify in the drop of reagent on the slide.
3. Rotate the slide gently for one minute and then observe for agglutination. Do not use magnifiers or bench lights.
4. In the case of rough or stringy samples, carry out the above procedure using Control Latex and the same specimen culture.

INTERPRETATION OF RESULTS:
1. **Positive:** Agglutination of latex particles, normally within a few seconds of mixing constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of either coagulase and/or protein A.
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 either coagulase and/or protein A.
3. **Equivocal:** In some cases, a culture specimen may cause the test latex to appear stringy or speckly, whilst not seeming to be a definite positive reaction. In these instances, the control latex should be used. If the control latex remains smooth i.e. completely milky background, then the specimen is likely to be positive for coagulase or protein A. If the control latex gives a rough or stringy appearance, then further biochemical tests may be necessary.

STABILITY OF THE REACTIONS:
Slide tests should be interpreted straight after the 1-minute rotation period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS:
1. Some species of Staphylococcus, other than *S. aureus*, notably *S. intermedius* and *S. hyicus* may give positive results in conventional coagulase tests and may also agglutinate latex reagents.
2. Rare species such as *S. lugdunensis* and *S. schleiferi* have been reported as clumping factor positive.
3. Novobiocin-resistant species may also give false positive results using latex based tests.
4. Several species such as *E. coli* and *C. albicans* are capable of agglutinating latex particles non-specifically.
5. Organisms that possess immunoglobulin-binding factors may also agglutinate latex based reagents.
6. 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. A blind trial was undertaken at the Leicester P.H.L.S. Two hundred and fourteen reference strains were tested. These represented a number of species commonly isolated and some rare species. The reagents used in the trial were 12 months old and at the end of the recommended shelf life. All strains of S. aureus examined gave the expected positive results.
3. Lorne Staph-Check Kit was considered to be easy to use and the provision of a control was a beneficial feature. The Lorne kit was judged to provide a rapid accurate, easy to read method for detecting *S. aureus* in a routine clinical laboratory and was comparable with other rapid slide latex methods commercially available.

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. Philips W, Kloos W. (1981). J. Clin. Microbiol; **14**: 671.
2. Freney J, Brun Y, Bes M. (1988). Int. J. Syst. Bacteriol; **38**: 168.
3. Stevens M, Geary C. (1989). Eur. J. Clin. Mic. Inf. Dis: **8**: 153-156.
4. Berke A, Tilton R.C. (1986). J. Clin. Mic; **23**: 916-919.
5. Gregson D.B, Low D.E, Skulnick M, Simor A.E. (1988). J. Clin. Mic; **26**: 1398-1399.

AVAILABLE KIT SIZES:

Kit Size	Catalogue Number
50 Test Kit	870050
100 Test Kit	870100

For the availability of other sizes, please contact:

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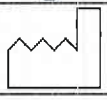
TABLE OF SYMBOLS

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