Instruction for Use

Microgen *Staph* Latex Kit

Cat. No. M43

GOLD STANDARD DIAGNOSTICS

MICROGEN BIOPRODUCTS

Contents

1 INTRODUCTION

Microgen Staph is a rapid latex slide agglutination test for the confirmatory identification of presumptive *Staphylococcus aureus* colonies from primary plate culture. The kit is intended for professional use only, to be used for industrial diagnostics only and not for use in clinical testing

2 PRINCIPLE

Latex particles are coated with fibrinogen (to which coagulase binds) and IgG (which binds with Protein A). When mixed with a suspension of *S. aureus*, the latex particles rapidly agglutinate to form visible clumps. No obvious agglutination occurs in the absence of coagulase/Protein A-positive *Staphylococci*.

3 REAGENTS

Kit Contents (100 tests)

- Staph Latex Reagent: **M43a** / 5ml / blue cap
  Latex particles coated with human fibrinogen and IgG. Preserved with 0.099% sodium azide.
- Positive Control: **M43b** / 1ml / black cap
  Inactivated preparation of *S. aureus* preserved with 0.099% sodium azide.
- Disposable agglutination slides (25 pcs)
- Disposable mixing sticks (4x25pcs)

Additional Materials Required (not supplied in the kit)

- Bacteriological loops

4 STORAGE

Microgen Staph should be stored at 2-8°C when not in use. The kit should not be used after the expiry date printed on the carton label.

5 TEST STEPS

Before using this product, refer to Precautions and Limitations. The controls specified in Section 8 should be performed each time the kit is used.

SPECIMENS

Select 1-2 isolated colonies grown for 18-24 hours at 35-37°C on primary isolation medium such as 5% blood agar. The morphology of the colonies tested should resemble that of *S. aureus*. Pure single colonies should be tested to minimise the possibility of erroneous results. If necessary, isolate by streaking on to a new agar plate. Colonies with atypical morphologies can be tested for Gram-positive staining to maximise the probability that *Staphylococci* have been selected for testing.

TEST PROCEDURE:

1. Mix the Microgen Staph latex by gentle inversion and add 1 drop to a circle of a clean dry, test slide.
2. Using a sterile loop, pick one colony of the organism to be tested and emulsify in the drop of latex reagent on the slide. Spread over the area of the circle with a mixing stick.
3. Gently rock the slide for up to 2 minutes and observe for agglutination.
4. After reading, discard used slides and mixing sticks into suitable disinfectant.

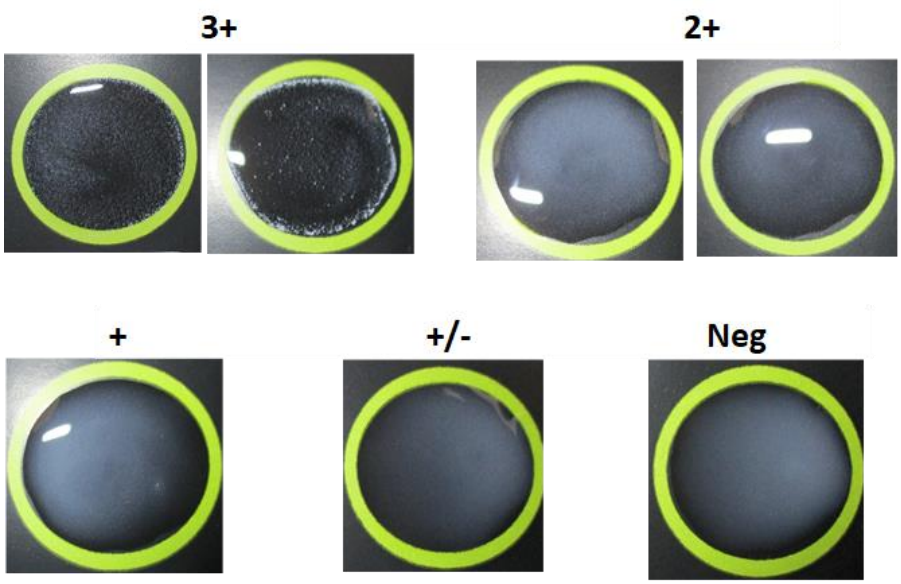
INTERPRETATION

Agglutination within 2 minutes is a positive result and indicates the presence of *S. aureus*. No agglutination indicates the absence of *S. aureus* and of other coagulase/Protein A-positive strains of *Staphylococcus*.

REACTION GRADE PATTERNS

Reaction grade	Description
3+	Large, agglutinated particles, which may form a ring of white precipitation. Background is clear.
2+	Visible agglutination, but background appears milky.
+	Fine agglutination where the particles are seen only when rocking. Background appears milky.
Trace (Tr +/-)	Very fine agglutination only seen when rocking with a milky background. A middle ground between + reaction and a negative reaction.
Negative (-)	No agglutination appears as a milky liquid.

Figure 1 – Reaction grade pattern examples



6 PRECAUTIONS

Safety

1. The kit and its reagents supplied are intended for professional use only, to be used for industrial diagnostics only and not for use in clinical testing.
2. Sodium azide, which is used as a preservative in the kit reagents can react with lead or copper plumbing to form potentially explosive metal azides. Dispose by flushing with a large volume of water to prevent azide build-up.
3. The IgG and fibrinogen used to sensitise the latex reagent are derived from human plasma which has been tested and found negative for the presence of antibodies to HIV-1, HIV-2 and HCV, and HbsAg. It should nevertheless be handled as though potentially infectious.
4. Appropriate precautions should be taken when handling or disposing of potential pathogens. Decontamination of infectious material can be achieved with sodium hypochlorite at a final concentration of 3% for 30 minutes. Liquid waste containing acid must be neutralised before treatment.
5. The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.

Procedural

1. Microgen Staph should be used according to the kit instructions.
2. Allow all reagents to reach room temperature before use.
3. Do not dilute any of the kit reagents.
4. Do not intermix reagents from different batches of kits.
5. Do not freeze any of the kit reagents.
6. Do not allow the latex reagent dropper to touch the positive control or bacterial samples.
7. Be careful only to record agglutination. Reactions that are “curdy” or “stringy” may not be true agglutination.
8. Ensure the slide is clean and dry prior to use.

7 LIMITATIONS

1. Results should be interpreted in the context of all available clinical and laboratory information.
2. Test only pure, single colonies since mixed colonies may give erroneous results.
3. Cultures older than 30 hours may auto agglutinate.
4. Media with a high salt content, such as Mannitol Salt Agar, inhibit Protein A production and this may lead to false negative results.
5. Rough strains of *Staphylococcus* may cause false positive reactions. These strains are rare and distinguishable from smooth strains by their colonial morphology. If suspected, these can be confirmed by emulsifying in a drop of saline and examining carefully for a smooth suspension.
6. Stringy reactions on the slide may not be true positive reactions and further biochemical tests are required.
7. Some yeasts may cause false positive results.

8. All coagulase positive strains of *Staphylococcus* will react with Microgen Staph and *S. aureus* will therefore not be distinguishable from *S. intermedius* and *S. hyicus*. However, the latter two strains are infrequently isolated from human sources and are more commonly found in animals or as saprophytes.
9. Microgen Staph is intended for the identification of presumptive *S. aureus*. Colonies giving positive results should be confirmed as *S. aureus* by biochemical tests.

8 QUALITY CONTROL

The following controls should be performed each time the kit is used.

1. **Positive Control**: Add one drop of positive control (M43b) to one circle on the test slide. Mix the Microgen Staph latex by gentle inversion and add 1 drop to the same circle and mix with a mixing stick. Do not allow the dropper to touch the positive control. Rock the slide gently. Within 2 minutes, agglutination, indicating a positive result, should be visible. If no agglutination is seen, a fresh kit should be used.
2. **Negative Control**: Mix the Microgen Staph latex by gentle inversion and add 1 drop to a circle on the test slide. Using a known coagulase/Protein A-negative *Staphylococcus*, e.g., *S. epidermidis*, take one fresh colony of 18-24 hour growth and emulsify in the drop of latex reagent on the slide. Gently rock the slide for 2 minutes. No agglutination should occur.

9 WASTE DISPOSAL

Dispose of according to any local, national, or regional regulations.

10 PRODUCT WARRANTIES, SATISFACTION GUARANTEE

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