Instruction for Use

Microgen *Salmonella* Latex Kit

Cat. No. F42

GOLD STANDARD DIAGNOSTICS

Microgen Salmonella Latex Kit

Cat. No. F42

v2.0

25 APR 2025

Contents

1 INTRODUCTION

Microgen Salmonella is a latex slide agglutination test for the confirmatory identification of presumptive *Salmonella* colonies from selective agar plates. The kit is intended for professional use only.

2 PRINCIPLE

Latex particles are coated with polyvalent antisera raised against a wide range of *Salmonella* antigens. When mixed with a suspension of *Salmonella* organisms, the latex particles rapidly agglutinate to form visible clumps. Microgen Salmonella detects >99% of motile *Salmonella* species and early investigations have indicated that specific non-motile species may also be detected.

3 REAGENTS

Kit Contents (50 tests)

- Salmonella Latex Reagent: **F42a** / 2.5ml / blue cap
  Latex particles coated with rabbit antiserum against Salmonella antigens.
  Preserved with 0.099% sodium azide.
- Positive Control: **F42b** / 0.5ml / black cap
  Inactivated preparation of Salmonella antigens preserved with 0.099% sodium azide.
- 0.85% Isotonic Saline: **M40** / 5.0ml / white cap
  Preserved with 0.099% sodium azide.
- Disposable agglutination slides (25pcs)
- Disposable mixing sticks (2x25)

Additional Materials Required (not supplied in the kit)

- Bacteriological loops

4 STORAGE

Microgen Salmonella should be stored at 2-8^{o}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

Colonies grown on selective agar plates can be tested with Microgen Salmonella.

TEST PROCEDURE

1. Dispense 1 drop of M40 isotonic saline into a circle of a Microgen agglutination slide.
2. Using an inoculating loop, remove a colony from the selective agar plate and emulsify the colony in the drop of saline to produce a heavy smooth suspension. Suspensions should only be made from colonies with morphologies resembling *Salmonella spp.*
3. Rock the slide gently for up to 2 minutes and observe for auto agglutination or clumping. If the suspension remains smooth, proceed to Step 4 (see Limitations of Use Note 1).
4. Mix the Microgen Salmonella latex by gently inverting and add one drop next to the bacterial suspension. **Do not allow the dropper to touch the suspension.**
5. Mix the latex reagent and the bacterial suspension with a clean mixing stick and rock the slide gently two or three times. Excessive rocking of the slide is not necessary. Examine for agglutination within a maximum of 2 minutes.
6. After reading, discard the used mixing sticks and slides accordingly.

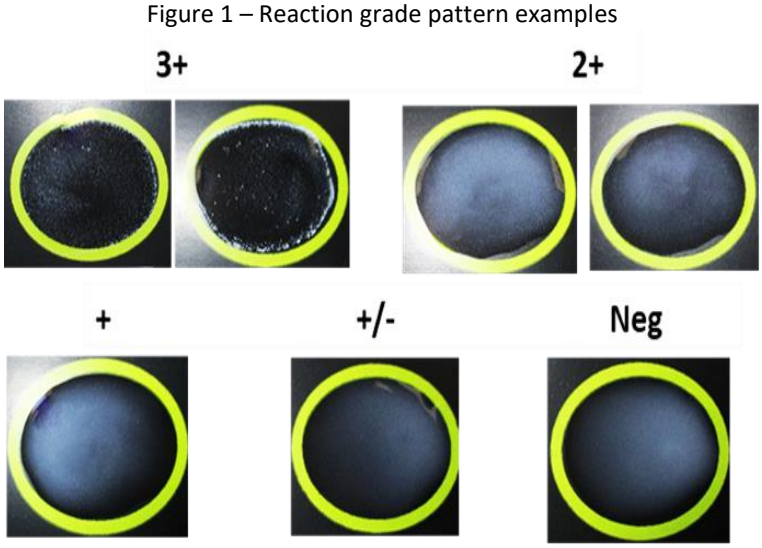
INTERPRETATION

Agglutination within 2 minutes is a positive result and indicates the presence of *Salmonella* in the sample. Absence of agglutination indicates that Salmonella is not present in the test culture.

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.

1. 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.
2. 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 30minutes. Liquid waste containing acid must be neutralised before treatment.
3. The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.

Procedural:

1. Microgen Salmonella 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 laboratory information.
2. Rough strains of *Salmonella* are known to cause non-specific autoagglutination in saline alone and therefore cannot be tested with Microgen Salmonella.
3. Some non-motile strains may not be detected by Microgen Salmonella.
4. Some oxidase-positive organisms may give false positive reactions.
5. Old stock cultures of *Enterobacteriaceae* on nutrient agar slopes may cause non-specific agglutination whereas old stocks of *Salmonella* may give false negative results. Fresh sub-cultures should be prepared for testing.
6. Identification with Microgen Salmonella is presumptive and all positive results should be confirmed by further identification tests and serotyping of pure cultures.

8 QUALITY CONTROL

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

1. **Reagent Control**: Add one drop of Microgen Salmonella latex (F42a) to one drop of M40 saline solution in the same circle on a slide. Mix and spread the liquid over the entire area of the circle with a mixing stick. Rock the slide gently for 2 minutes and observe for agglutination. If any agglutination is seen, either the latex or the saline is contaminated and should be discarded.

2. **Positive Control**: Add one drop of positive control (F42b) to one circle on the test slide. Add one drop of Microgen Salmonella latex to the same circle and mix. **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.

9 WASTE DISPOSAL

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

10 PRODUCT WARRANTIES, SATISFACTION GUARANTEE

Gold Standard Diagnostics Budapest ("GSDB") warrants that the products manufactured by it will be free of defects in materials and workmanship, when used in accordance with the applicable instructions before the expiration date marked on the product packaging, and when stored under the storage conditions recommended in the instructions and/or on the package.

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A copy of the terms and conditions can be obtained on request and is also provided in our price lists.

TECHNICAL SUPPORT SERVICE

For technical assistance and more information please contact Gold Standard Diagnostics Budapest's Customer Service or your local distributor.

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LIST OF MODIFICATIONS		
VERSION	DESCRIPTION OF THE CHANGE	ISSUE DATE
1.0	First issue	12 SEP 2023
2.0	Second issue: Removal of the Microgen logo	25 APR 2025