INSTRUCTIONS FOR USE

SALMONELLA RAPID LATEX TEST

LATEX SLIDE AGGLUTINATION TEST FOR THE CONFIRMATORY IDENTIFICATION OF PRESUMPTIVE *SALMONELLA* COLONIES

1 – INTRODUCTION

Salmonella Rapid Latex Test is a manual, rapid latex slide agglutination test for the confirmatory identification of presumptive Salmonella colonies from selective 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 OF THE METHOD

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. Salmonella Rapid Latex Test detects >99% of motile *Salmonella* species and early investigations have indicated that specific non-motile species may also be detected.

3 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
SALMONELLA RAPID LATEX TEST	Latex agglutination test	**271030U** (50 tests)	1 glass bottles containing Salmonella Latex Reagent (REAG TEST S1). Latex particles coated with rabbit antiserum against Salmonella antigens. Preserved with 0.099% sodium azide. (2,5 mL = 50 tests – blue cap) 1 glass bottle containing Positive Control (CONTROL +): Inactivated preparation of *Salmonella's* antigens preserved with 0.099% sodium azide. (1.0 mL – black cap) 1 glass bottle containing SAMPLE DILUENT, isotonic saline solution. Containing Sodium azide 0.099% as preservatives. (5.0 mL – white cap) Slide, 6 test areas: waterproof sheets for reaction (25 items) Sticks: plastic sticks for mixing (50 items) Secondary packaging: cardboard box.

4 - MATERIALS REQUIRED BUT NOT PROVIDED

Bacteriological loops.

5 - PRECAUTIONS AND WARNINGS

- SALMONELLA RAPID LATEX TEST is for professional use only, to be used for industrial diagnostics only and not for use in clinical testing.
- The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.
- 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.
- Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state, provincial or national regulations. 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.
- The sensitivity of the test may be reduced at low temperatures. Allow the reagents and samples to reach room temperature (15-30ºC/59-86ºF) before use.
- Do not use after expiration date or if the packaging is damaged. The quality of the reagent cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.
- Do not dilute any of the kit reagents.
- Do not allow the latex reagent dropper to touch the positive control or bacterial samples.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices and according to the Instruction for use of the kit.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Be careful only to record agglutination. Reactions that are "curdy" or "stringy" may not be true agglutination.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.masciabrunelli.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

6 - STORAGE CONDITIONS AND SHELF LIFE

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

7 – SPECIMENS COLLECTION

The sample consists of presumptive colonies of *Salmonella* isolated on a selective agar medium.

8 - TEST PROCEDURE

Allow the components of the kit to reach to room temperature (15-30ºC/59-86ºF) prior to testing.

Quality Control

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

1. **Reagent Control**: Add one drop of REAG TEST S1 to one drop of SAMPLE DILUENT (using pipette) 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 to one circle on the test slide. Mix the REAG TEST S1 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.

Test Procedure

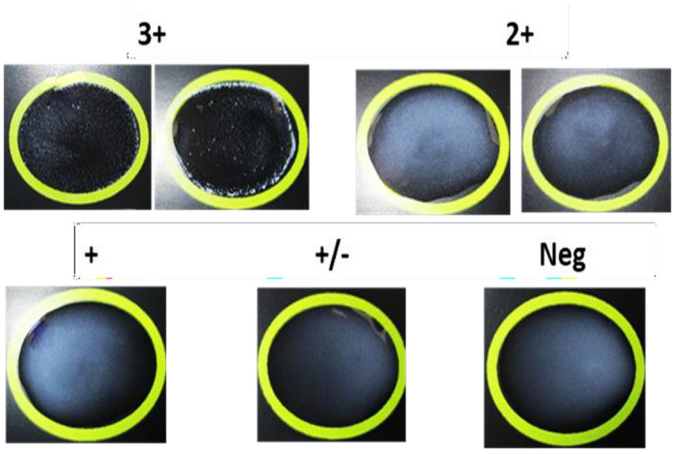
1. Dispense 1 drop **SAMPLE DILUENT** (using pipette) into a circle of an agglutination slide.
2. Using an inoculating loop, remove a colony from the selective agar plate and emulsify the colony in the drop of SAMPLE DILUENT to produce a heavy smooth suspension. Suspensions should only be made from colonies with morphologies resembling *Salmonella spp.*
3. Rock the slide gently for up to 2 minutes and observe for autoagglutination or clumping. If the suspension remains smooth, proceed to Step 4 (see Limitations of Use Note 1).
4. Mix the **REAG TEST S1** by gently inverting and add one drop near 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 used slides and mixing sticks into suitable disinfectant

9 – READING, INTERPRETATION

Agglutination within 2 minutes is a positive result and indicates the presence of *Salmonella* in the sample. No agglutination indicates the absence of *Salmonella* in the culture cell.

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



10 – LIMITATIONS OF THE METHOD

- The results should be interpreted in the context of all available laboratory information.
- Rough strains of *Salmonella* are known to cause non-specific autoagglutination in saline alone and therefore cannot be tested with Salmonella Rapid Latex Test.
- Some non-motile strains may not be detected by Salmonella Rapid Latex Test.

- Some oxidase-positive organisms may give false positive reactions.
- Old stock cultures of *Enterobacteriaceae* on nutrient agar slopes may cause non-specific agglutination whereas old stocks of *Salmonella* may give false negative results.
- Identification with Salmonella Rapid Latex Test is presumptive and all positive results should be confirmed by further identification tests and serotyping of pure cultures.
- The components of this product were always tested together without compatibility with components from other manufacturers. While not excluding the possibility that these components can be used with components of the same formulation but produced by other companies, there is no experimental evidence of such compatibility.

TABLE OF APPLICABLE SYMBOLS

	Temperature limitation	LOT	Batch code (DXXX)		Keep away from heat		Manufacturer		Keep dry
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care

REVISION HISTORY

Version	Description of changes	Date

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.