SSI DIAGNOSTICA

Instructions for use

# *SALMONELLA* SERO-QUICK GROUP KIT


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# *SALMONELLA* ANTISERA SERO-QUICK GROUP KIT

For *in vitro* diagnostic use

## Intended use

The *Salmonella* Sero-Quick Group Kit is a screening kit for identifying *Salmonella* isolates to the serogroup level. Sero-Quick Group Kit is used as an *in vitro* diagnostic aid for qualitative manual complete or partial bacterial serotyping by slide agglutination It is important to use pure culture isolates for determination of bacterial antigens.

## Description

The *Salmonella* Sero-Quick Group Kit from SSI Diagnostica contains eight vials (see table 1). The content of the kit is sufficient for 150 tests. *Salmonella* O group antisera and Vi monoclonal antibody are for screening of live cultures from a non- selective agar plate.

| | Serogroup | Antisera | Volume |
|---|---|---|---|
| **O antisera** | A | O:2 | 3 mL |
| | B | O:4 | 3 mL |
| | C | O:7,8 | 3 mL |
| | D | O:9 | 3 mL |
| | E | O:3,10,15 | 3 mL |
| | F | O:11 | 3 mL |
| | G | O:13,22,23 | 3 mL |
| **Monoclonal Vi** | - | Vi | 3 mL |

Table 1. Content of *Salmonella* Sero-Quick Group Kit.

All of the included *Salmonella* antisera are absorbed free of cross-reactions.

The antisera are polyclonal, prepared in rabbits using reference strains according to the methods recommended by the Pasteur Institute[1] and absorbed to eliminate cross-reacting antibodies.

This kit includes antisera against the most common serogroups of *Salmonella* (serogroup A-G) and the capsule antigen Vi. Serogroups B and D are the most frequently occurring serogroups, as they include *S.*

Typhimurium and *S*. Enteritidis, respectively. The serogroup A and the Vi antigen are not common but expressed by the clinically important serotypes *S*. Typhi (9,12,[Vi]:d:-) and *S*. Paratyphi (1,2,12:a:-).

SSI Diagnostica antisera are for use by laboratory professionals and/or healthcare professionals only.

## Principle

The *Salmonella* Sero-Quick Group Kit contains antisera intended for slide agglutination.

Antigen-antibody complexes are formed (agglutination) when a bacterial culture is mixed with a specific antiserum directed against bacterial surface components. The complexes are usually visible to the naked eye which allows for easy determination of the O serotype by slide agglutination. The nomenclature of the serotype can be determined by using the Kauffmann-White Scheme[3].

## Precautions

- Before using SSI Diagnostica *Salmonella* antisera, confirm that the strain is a *Salmonella*, e.g. by using a biochemical method.

- Rough cultures/strains will self-agglutinate and cause false positive reactions.

- Excessive amount of culture compared to antisera might cause false positive reactions.

- For the antisera for slide agglutination, please make sure that result is read within 10 seconds.

- Turbidity due to lipoprotein precipitation can occur after prolonged storage. If you experience precipitation and/or contamination, it can be removed by centrifugation (10,000 g) followed by sterile filtration (0.22 µM).

- The antisera have only been validated for serotyping by the below described methods.

- Antisera that have accidentally been frozen should not be used.

- The strain to be tested must be grown on a non-selective agar plate. Be sure that the strain is a pure culture.

- Do not mix the components of the lot with components from other lots.

- Do not use the antisera after the expiry date.

- Inspect the vials before use to ensure they are intact. Any damaged vials should be discarded.

**Materials provided**

The *Salmonella* Sero-Quick Group Kit from SSI Diagnostica contains seven vials of ready-to-use O Group antisera and one vial of ready-to-use monoclonal Vi antibody (see table 1).

The antisera are supplied in dropper bottles containing 3 mL ready-to-use antisera.

## Materials required but not provided

- Non-selective agar medium (e.g. beef extract agar)
- Physiological saline pH 7.4
- Inoculating loop or toothpick
- Glass slides
- Incubator (35-37 °C)

## Storage and stability

Expiry date is printed on the labels.

*Salmonella* antisera must be stored at 2-8 °C in a dark place. Do not freeze. Stored under these conditions the antisera may be used up to the date of expiry shown on the product label.

The in-use stability is not affected by working with the antiserum on the bench throughout the day if it is stored at 2-8 °C when not in-use, for no longer than 4 years from date of production.

*Salmonella* antisera have been tested after being stored at 37 °C for up to four weeks. The antisera were still fully functional.

## Preservative

The *Salmonella* antisera contains less than 0.1% sodium azide ($NaN_3$) as preservative.

## Sample collection and storage

For sample storage please follow your local standard procedure.

## Quality control

Before use, check the vials to ensure that there is no damage and/or leaks. In case of damage or leaks discard the vial.

Saline is used as negative control to confirm that the strain is not self-agglutinating.

## Procedure

The *Salmonella* Sero-Quick Group Kit is intended for slide agglutination of *Salmonella* cultures after overnight growth on a suitable culture medium, e.g. beef extract agar.

Use the *Salmonella* Sero-Quick Group Kit in the following order: Saline, D, B, C, E, G, F, A. Strains that are positive in D may be tested with the Vi antibody (see figure 1).

When a positive reaction appears, the result is the serogroup indicated on the label and no further testing is necessary. Example: the test of D, B and C is negative but the test of E is positive. The *Salmonella* strain then belongs to serogroup E. The test of G, F and A should not be performed.

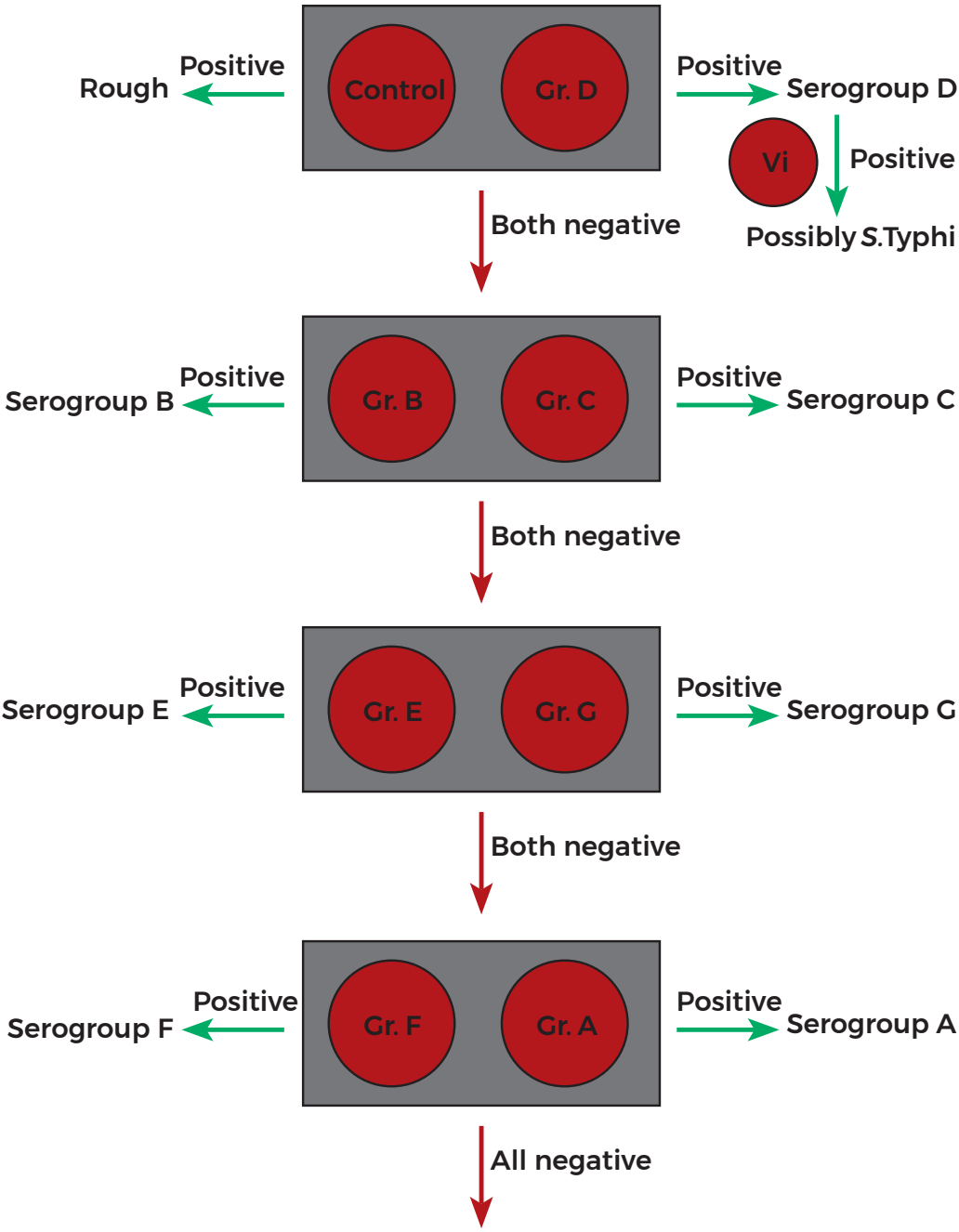


Figure 1: Flow chart of *Salmonella* Sero-Quick group Kit

**Slide agglutination with O antisera**

1. The *Salmonella* strain is grown over night at 35-37 °C on a non-selective agar medium.

2. Apply a small drop of antiserum (approx. 20 µL) on the glass slide.

3. Transfer culture from 3 to 5 colonies to the drop of antiserum and mix well. The amount of culture should be sufficient to give a distinct milky turbidity. Use an inoculating loop or a toothpick.

4. Tilt the slide for 5-10 seconds.

5. The reaction is read with the naked eye by holding the slide in front of a light source against a black background (indirect illumination).

6. A positive reaction is seen as a visible agglutination (see figure 2 reaction A). A negative reaction is persistence of the homogeneous milky turbidity (see figure 2 reaction B). A late or weak agglutination (after 10 seconds) should be considered negative.

Absence of reactions may be due to a strain expressing the Vi antigen, to a strain not covered by the antisera used or to a strain not being *Salmonella*.

The presence of the Vi antigen may interfere with or prevent agglutination in O antisera. Negative isolates must therefore be examined for Vi antigen. Due to form variation in the Vi antigen, it is important to select single colonies, as colony forms expressing the Vi antigen are more opaque than Vi negative colonies.

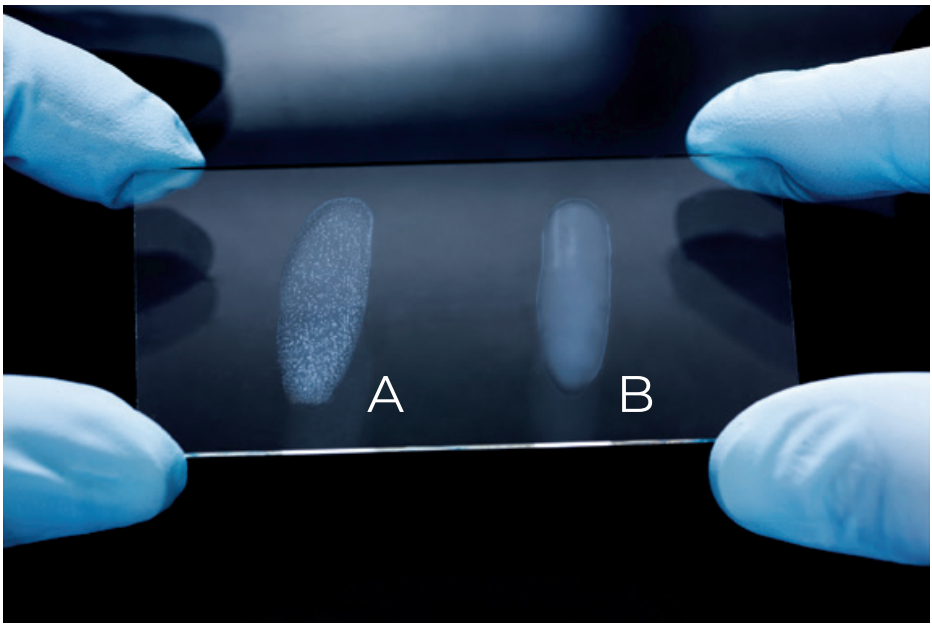


Figure 2. Sample A is a positive reaction and sample B is a negative reaction.

## Interpretation of results

### Slide agglutination:

A positive reaction is seen as a visible agglutination, whereas a negative reaction is seen as homogeneous milky turbidity (figure 2).

Do not interpret the results after 10 seconds as any reaction seen after 10 seconds cannot be considered a true positive result.

## Disposal

Follow your local procedures and/or national guidelines for disposal of biological materials.

## Limitations

The culture must be confirmed *Salmonella* before serotyping using antisera from SSI Diagnostica.

## Performance

### Sensitivity, specificity and repeatability

| *Salmonella* antiserum overall results | | |
|---|---|---|
| | Percent (number positive/actual positive) | 95% confidence interval |
| Sensitivity | 98% (143/146) | 94-99 |
| Specificity | 100% (140/140) | 97-100 |
| Repeatability | 99% (425/429) | 98-100 |

Table 2: Sensitivity, specificity and repeatability for *Salmonella* antisera included in the *Salmonella* Sero-Quick Group Kit

### Reproducibility

The reproducibility within the different groups of antisera and all antisera combined is 100% (99%-100%). Therefore, all produced antisera have a high level of reproducibility throughout time and lots.

## Incident reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

## Quality certificate

SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 13485[2].

Certificate of analysis can be downloaded from our website: ssidiagnostica.com

Presafe
Presafe Denmark A/S

Quality System
DS/EN
ISO 13485

REF
18349

IVD

CE

## References


1. Grimont, P.A.D. and Weill, F.-X. Antigenic formulae of the *Salmonella* serovars, WHO Collaborating Centre for Reference and Research on *Salmonella*, Institut Pasteur, Paris, France, 9th ed., 2007.

2. ISO/TR 6579-3:2014 Guideline "Microbiology of food and animal feed – Horizontal method for the detection, enumeration and serotyping of *Salmonella*"

3. Michel Y. Popoff and L. Le Minor. Antigenic formulas of the *Salmonella* serovars, 8. Ed. (2001 with supplements). WHO Collaborating Centre for Reference and Research on *Salmonella*. Institut Pasteur, Paris, France.

## Information and ordering

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