

 **BD Difco™ Salmonella O Antisera**
Difco™ Salmonella H Antisera
Difco™ Salmonella Vi Antiserum

R_x Only  

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English

INTENDED USE

BD Difco™ Salmonella O Antisera are used in slide agglutination tests for the identification of *Salmonella* by somatic (O) antigens. BD Difco Salmonella H Antisera are used in tube agglutination tests for the identification of *Salmonella* by flagellar (H) antigens. BD Difco Salmonella Vi Antiserum is used in slide agglutination tests for the identification of *Salmonella* Vi.

SUMMARY AND EXPLANATION

Salmonella species cause a variety of human diseases called salmonellosis. The range of disease is from mild self-limiting gastroenteritis to more severe forms, possibly with bacteremia or typhoid fever, which can be life threatening. Severe disease and bacteremia are associated primarily with three serovars of *S. enterica* subsp. *enterica* (Choleraesuis, Paratyphi A and Typhi), while most of the other 2,300 or more strains are associated with gastroenteritis. The severity of the diarrheal disease depends upon the virulence of the strain and the condition of the human host.

Salmonella is found in nature and occurs in the intestinal tract of many animals, both wild and domestic. The microorganism can spread to man from contact with the environment or from eating meat or vegetable food products.

All *Salmonella* serovars belong to two species: *S. bongori*, which contains 18 serovars, and *S. enterica*, which contains the remaining 2,300 or more serovars divided among six subspecies.^{1,2}

The six subspecies of *S. enterica* are:

<i>S. enterica</i> subsp. <i>enterica</i> (I or 1)	<i>S. enterica</i> subsp. <i>diarizonae</i> (IIIb or 3b)
<i>S. enterica</i> subsp. <i>salamae</i> (II or 2)	<i>S. enterica</i> subsp. <i>houtenae</i> (IV or 4)
<i>S. enterica</i> subsp. <i>arizonae</i> (IIIa or 3a)	<i>S. enterica</i> subsp. <i>indica</i> (VI or 6)

Nomenclature and classification of these bacteria are constantly changing.³ *Salmonella* and the former *Arizona* should be considered a single genus, *Salmonella*.⁴ It is recommended that laboratories report the names of *Salmonella* serovars for the subspecies *enterica*. The serovar names are no longer italicized and the first letter is capitalized. For example, the strain that used to be identified as *Salmonella typhimurium* is now known as *Salmonella Typhimurium*.

Serovars of other subspecies of *S. enterica* (except some in the subspecies *salamae* and *houtenae*) and those of *S. bongori* are not named and are designated by their antigenic formula. For the most recent information on nomenclature, consult appropriate references.¹⁻¹⁰

PRINCIPLES OF THE PROCEDURE

Salmonella O antigens are somatic (O) heat-stable antigens and are identified first. The Vi antigen is a heat-labile envelope antigen that may surround a cell wall and mask somatic antigen activity. Microorganisms having the Vi Antigen will not agglutinate in O antisera. In order to determine the O antigen of these cultures, a suspension of the organism must be boiled to destroy the heat-labile envelope antigen and then tested with O antisera. The flagellar (H) antigens are heat labile and are usually associated with motility.

Complete serological characterization of *Salmonella* is not required for successful detection of the microorganism when it occurs as a pathogen. The use of adequate isolation procedures and differential biochemical tests is of primary importance. Because antigenic relationships exist between genera of the family *Enterobacteriaceae*, it is recommended that the isolate be biochemically identified as *Salmonella* prior to Serology testing. Possible *Salmonella* isolates can be presumptively identified with a minimum of serological identification. Isolates can be sent to laboratories that perform the level of testing necessary to completely identify the microorganism.

For a further discussion of the serological identification of *Salmonella*, consult appropriate references.^{1-3,9,11-14}

Identification of *Salmonella* species includes both biochemical and serological identification. Serological confirmation involves the procedure in which the microorganism (antigen) reacts with its corresponding antibody. This *in vitro* reaction produces macroscopic clumping called agglutination. The desired homologous reaction is rapid, does not dissociate (high avidity) and bonds strongly (high affinity).

Because a microorganism (antigen) may agglutinate with an antibody produced in response to another species, heterologous reactions are possible. Such unexpected and perhaps unpredictable reactions may lead to some confusion in serological identification. Therefore, a positive homologous agglutination reaction should support the morphological and biochemical identification of the microorganism.

Agglutination of the somatic antigen in the slide test appears as a firm granular clumping. Homologous reactions are rapid and strong (3+). Heterologous reactions are slow and weak.

Agglutination of flagellar antigens in the tube test appears as a loose flocculation that can easily be resuspended.

REAGENTS

BD Difco Salmonella O, H and Vi Antisera are lyophilized, polyclonal rabbit antisera containing approximately 0.2% sodium azide as a preservative.

BD Difco Salmonella O Poly Antisera are polyvalent antisera. Each antiserum is specific for certain serogroup antigens. When properly rehydrated and used as recommended, each vial of BD Difco Salmonella O or Vi Antisera contains sufficient reagent for 60 tests. BD Difco Salmonella O Antiserum Poly A-I & Vi are prepared with representative strains of these serogroups and are not absorbed. They may cross-react because of shared common O antigens.

BD Difco Salmonella O Group Antisera are specific for the major factors present in the serogroup. BD Difco Salmonella O Factor Antisera are specific for the factors of the individual serogroups. When using BD Difco Salmonella O Group Antisera, cross-reactions are possible because serogroups may share non-major group antigens. BD Difco Salmonella O Factor Antisera are absorbed as necessary to render each antiserum as specific as practical without reducing the homologous reactions to an unsatisfactory level.

BD Difco Salmonella H Poly Antisera are polyvalent antisera specific for certain flagellar antigens. Each vial of BD Difco Salmonella H Antisera contains sufficient reagent to perform between 150–1500 tests, depending on the antiserum used. BD Difco Salmonella H Antisera are either absorbed or unabsorbed specifically for either phase 1 or phase 2 antigens. BD Difco Salmonella H Antisera Spicer-Edwards are pooled, polyvalent antisera and additional adjunctive antisera to identify the more commonly occurring H antigens.

Warnings and Precautions

For *in vitro* Diagnostic Use.

This product contains dry natural rubber.

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, specimens, containers, slides, tubes and other contaminated material must be sterilized by autoclaving. Directions for use should be followed carefully.

WARNING: This product contains sodium azide. Sodium azide is toxic by inhalation, by skin contact, and if swallowed. Contact with acid liberates very toxic gas. After contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Warning



H302 Harmful if swallowed.

P264 Wash thoroughly after handling. **P270** Do not eat, drink or smoke when using this product. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P330** Rinse mouth. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

Storage: Store lyophilized and rehydrated BD Difco Salmonella O, H and Vi Antisera at 2–8 °C.

Expiration date applies to the product in its intact container when stored as directed.

Prolonged exposure of reagents to temperatures other than those specified is detrimental to the products.

Discard any antiserum that is cloudy or has a precipitate after rehydration or storage unless it can be clarified by centrifugation or filtration and demonstrates proper reactivity with validated positive and negative controls. Gross turbidity indicates contamination and such antisera should be discarded.

SPECIMEN COLLECTION AND PREPARATION

Clinical specimens: *Salmonella* can be recovered from selective differential media such as Hektoen Enteric Agar or XLD agar. For specific recommendations, consult appropriate references.^{11,12} Determine that a pure culture of the microorganism has been obtained and that biochemical test reactions are consistent with the identification of the organism as a *Salmonella* species. After these criteria are met, serological identification can be performed.

Food samples: *Salmonella* can be recovered when samples are processed to recover injured microorganisms and prevent overgrowth of competing microorganisms. Consult appropriate references for recommended procedures for isolation of *Salmonella* from foods.^{13,14} Determine that a pure culture of the microorganism has been obtained and that biochemical test reactions are consistent with the identification of the organism as a *Salmonella* species. After these criteria have been met, serological identification can be performed.

The isolate for serological testing should be subcultured from selective media to a nonselective agar.

PROCEDURE

Materials Provided: BD Difco Salmonella O Antisera; BD Difco Salmonella H Antisera; or BD Difco Salmonella Vi Antiserum.

Materials Required But Not Provided: Slide Test: 0.85% NaCl solution, sterile; agglutination slides with 1 inch squares; applicator sticks; boiling water bath; centrifuge.

Tube Test: 0.85% NaCl solution, sterile; culture tubes, 12 x 75 mm, and rack; water bath, 50 ± 2 °C; serological pipettes, 1 mL; formaldehyde.

Reagent Preparation: Equilibrate all materials to room temperature prior to performing the tests. Ensure that all glassware and pipettes are clean and free of residues such as detergents.

To reconstitute, add 3 mL of sterile 0.85% NaCl solution and rotate gently to completely dissolve the contents. Reconstituted antisera are considered a 1:2 dilution.

Test Isolate for Autoagglutination

1. From the test culture on nonselective media, transfer a loopful of growth to a drop of sterile 0.85% saline on a clean slide and emulsify the organism.
2. Rotate the slide for 1 min, then observe for agglutination.
3. If agglutination (autoagglutination) occurs, the culture is rough and cannot be tested. Subculture to nonselective agar, incubate and test the organism again as described in steps 1 and 2.
4. If no agglutination occurs, proceed with testing the organism.

Choice of Antisera

Salmonella O Antisera: This serological identification Scheme I (See Table 1 below) begins with BD Difco Salmonella O Antisera Poly A through Poly G, which contain the following:

Salmonella Group Antisera	Somatic Groups Present
Salmonella O Antiserum Poly A	A,B,D,E ₁ (E ₂ ,E ₃) *, E ₄ ,L
Salmonella O Antiserum Poly B	C ₁ ,C ₂ ,F,G,H
Salmonella O Antiserum Poly C	I,J,K,M,N,O
Salmonella O Antiserum Poly D	P,Q,R,S,T,U
Salmonella O Antiserum Poly E	V,W,X,Y,Z
Salmonella O Antiserum Poly F	51–55
Salmonella O Antiserum Poly G	56–61

*Strains of groups E₂ and E₃ are lysogenized by phage 15, then by phage 34. These strains are now classified into group E₁.²

If agglutination occurs, use individual BD Difco Salmonella O Group Antisera to determine the specific serogroup to which the isolate belongs. For efficiency, test first with individual BD Difco Salmonella O Group Antisera B, D and C₁ (the most common serogroups).

If agglutination does not occur with Poly A or B, test the isolate with BD Difco Salmonella Vi Antiserum. If positive, heat and retest with BD Difco Salmonella Vi Antiserum. If agglutination occurs after boiling with BD Difco Salmonella Vi Antiserum, the isolate is not likely to be *Salmonella*. If agglutination does not occur with BD Difco Salmonella Vi Antiserum after boiling, test boiled culture with individual BD Difco Salmonella O Antisera. If test results are indeterminate, isolate should be sent to a reference laboratory for additional testing.

If agglutination does not occur with Poly C, D, E, F and G, the isolate is not likely to be *Salmonella*.

Table 1. – Scheme I for using Salmonella O Antisera Poly Groups A, B, C, D, E, F and G.

Test with	Salmonella O Antisera Poly Groups A, B, C, D, E, F and G				
Test Result	+	– with Poly A or B			– with Poly C, D, E, F and G
Test with	Individual Salmonella O Antisera	Salmonella Vi Antiserum			↓
Test Result	+ with one Salmonella O Antiserum (required)	+	–		
Test with	↓	Heat and retest with Salmonella Vi Antiserum			↓
Test Result		+	–		
Test Conclusion or Next Action	Determine the Salmonella H Antigen	Test isolate is not a <i>Salmonella</i>	Test boiled culture with individual Salmonella O Antisera	Test isolate is not a <i>Salmonella</i>	Test isolate is not a <i>Salmonella</i>

Salmonella O Antiserum Poly A-I & Vi Scheme II (See Table 2 below): This antiserum detects factors 1-16, 19, 22-25, 34 and Vi. This combination of factors represents the most frequently isolated Groups A-I and the Vi antigens and is used to screen possible *Salmonella* isolates.

A positive reaction indicates that further serological testing is needed to identify the isolate using BD Difco Salmonella O Group Antisera. The most common serogroups are B, D and C₁. For efficiency, first use the BD Difco Salmonella O Group Antisera for these serogroups.

If the isolate is positive with BD Difco Salmonella O Antiserum Poly A-I & Vi but negative with the specific somatic antisera, test the isolate with BD Difco Salmonella Vi Antiserum. If positive with BD Difco Salmonella Vi Antiserum, heat and retest with BD Difco Salmonella Vi Antiserum. If positive with BD Difco Salmonella Vi Antiserum after boiling, the isolate is not likely to be *Salmonella*. If agglutination does not occur with BD Difco Salmonella Vi Antiserum after boiling, test boiled culture with individual BD Difco Salmonella O Antisera. If test results are indeterminate, isolate should be sent to a reference laboratory for additional testing.

A negative reaction with BD Difco Salmonella O Antiserum Poly A-I & Vi indicates the isolate is not in serogroups A-I. If the biochemical reactions are consistent with *Salmonella*, a serogroup other than A-I is possible. Further testing with antisera for other serogroup antigens is necessary.

Table 2. – Scheme II for using Salmonella O Antiserum Poly A-I & Vi.

Test with	Salmonella O Antiserum Poly A-I & Vi				
Test Result	+				-
Test with	Individual Salmonella O Antisera				↓
Test Result	+	-			
Test with	↓	Salmonella Vi Antiserum			↓
Test Result		+		-	
Test with	↓	Heat and retest with Salmonella Vi Antiserum		↓	
Test Result		+	-		
Test Conclusion or Next Action	Determine the Salmonella H Antigen	Test isolate is not a <i>Salmonella</i>	Test boiled culture with individual Salmonella O Antisera	Test isolate is not a <i>Salmonella</i>	May be a <i>Salmonella</i> detectable by use of Salmonella O Antisera Poly C, D, E, F or G

Salmonella O Group Factor and Single Factor Antisera: Use selected BD Difco Salmonella O Group Antisera for further identification of isolates. Cross-reactions may occur between serogroups that share O antigens. Consider this partial list of BD Difco Salmonella O Group Antisera as an example:

Salmonella O Antiserum Group A Factors 1, 2, 12; Salmonella O Antiserum Group B Factors 1, 4, 5, 12; Salmonella O Antiserum Group B Factors 1, 4, 12, 27

Factors 1 and 12 occur in combination with other antigens and may cause cross-reactions. The strength of the reactions will help in interpretation. Rapidly forming 3+ or greater agglutination indicates a homologous reaction.

Use selected BD Difco Salmonella O Factor Antisera. Absorbed antisera specific for an identifiable antigen in a given serogroup is used to identify the isolate further. In the example above, BD Difco Salmonella O Factor Antisera could be used:

Salmonella O Antiserum Factor 2; Salmonella O Antiserum Factor 4; Salmonella O Antiserum Factors 4, 5; Salmonella O Antiserum Factor 5

Polyvalent Salmonella H Antisera: Further identification of a *Salmonella* isolate includes characterization of the flagellar antigens. Serogrouping with the following BD Difco Polyvalent H Antisera can be done:

Salmonella H Poly Group Antisera	Flagellar Antigens Present
Salmonella H Antiserum Poly a-z	Groups EN,G,L,Z ₄ , 1 complexes and a-k,r-z,Z ₆ ,Z ₁₀ ,Z ₂₉
Salmonella H Antiserum Poly A	Groups a,b,c,d,i,Z ₁₀ ,Z ₂₉
Salmonella H Antiserum Poly B	Groups eh,en,ex,enZ ₁₅ , G complex
Salmonella H Antiserum Poly C	Groups k,l,r,y,z,Z ₄
Salmonella H Antiserum Poly D	Groups Z ₃₅ ,Z ₃₆ ,Z ₃₇ ,Z ₃₈ ,Z ₃₉ ,Z ₄₁ ,Z ₄₂
Salmonella H Antiserum Poly E	1 complex, Z ₆

Absorbed H antisera specific for single antigens or a complex of antigens can be used to identify the isolate further.

Unabsorbed and Absorbed Salmonella H Antisera: Complete identification of a *Salmonella* isolate involves analysis of phase 1 and phase 2 antigens using H antisera. For the complex pattern of analysis and procedures, consult appropriate references.⁹

Salmonella H Antisera Spicer-Edwards: BD Difco Salmonella H Antisera Spicer-Edwards is used for screening and identifying the most commonly encountered *Salmonella* using a combination of polyvalent and single complex antisera.

Table 3. – Identification of *Salmonella* H using Salmonella H Antisera Spicer-Edwards.

H Antigen(s)	Salmonella H Antisera Spicer-Edwards				H Antigen(s)	Salmonella H Antisera Spicer-Edwards			
	1	2	3	4		1	2	3	4
a	+	+	+	-	k	-	+	+	+
b	+	+	-	+	r	-	+	-	+
c	+	+	-	-	y	-	+	-	-
d	+	-	+	+	z	-	-	+	+
e, h	+	-	+	-	Z ₄ Complex**	-	-	+	-
G Complex*	+	-	-	+	Z ₁₀	-	-	-	+
i	+	-	-	-	Z ₂₉	-	+	+	-

*The G complex component of Salmonella H Antisera Spicer-Edwards 1 and 4 reacts with antigens f,g; f,g,s; f,g,t; g,m; g,m,q; g,m,s; g,m,s,t; g,m,t; g,p; g,p,s; g,p,u; g,q; g,s,t; g,t; m,p,t,u and m,t.

**The Z₄ Complex component reacts with Z₄,Z₂₃; Z₄,Z₂₄ and Z₄,Z₃₂.

Note that no antigen is positive with all four Salmonella H Antisera Spicer-Edwards. Any antigen that reacts with all four sera should be checked for smoothness.

Slide Test Procedure

Salmonella O and Vi Antisera

Use this procedure to test the isolate with each selected antiserum.

1. Dispense 1 drop (35 μ L) of each antiserum to be tested on an agglutination slide.
2. **Negative control:** Dispense 1 drop of 0.85% sterile NaCl solution on an agglutination slide.
3. From a solid agar medium, transfer a portion of a loopful of an isolated colony to each reaction area above and mix thoroughly.
4. **Positive control:** Dispense 1 drop of each BD Difco Salmonella O Antiserum to be tested on an agglutination slide. Add 1 drop of an appropriate BD Difco QC Antigen Salmonella or stock cultures of known serological identification.
5. Rotate the slides for 1 min and read for agglutination. Results must be read within 1 min.

Tube Test Preparation

1. **0.6% Formalized Saline:** Prepare by adding 6 mL formaldehyde per 1000 mL of sterile 0.85% NaCl solution.
2. **Test organism:** It is often necessary to increase the motility of the test organism. To accomplish this, make several consecutive transfers in Motility GI Medium.
 - Inoculate the tube slightly below the surface of the medium using the stab method.
 - Incubate at 35–37 °C for 18–20 h.
 - Transfer only those organisms that have migrated to the bottom of the tube.
 - When the organism successfully travels 50–60 mm through the medium in 18–20 h, it is ready for use.
 - An infusion broth such as Veal Infusion Broth is recommended for cultivating motile *Salmonella* prior to testing. It should be inoculated and incubated at 35 °C for 24 h. Brain Heart Infusion Broth may be used with incubation at 35 °C for 4–6 h. If Tryptic Soy Broth is used, incubate at 35 °C for 24 h.
 - Prepare the test organism suspension by using equal volumes of broth culture and 0.6% formalized saline. The final density of this test suspension should be that of a McFarland Turbidity Standard No. 3.
3. **Positive control:** Commercially prepared QC Salmonella H antigens are not available. The user must maintain stock cultures of known serological identification for use in quality control. Prepare the antigen by using known serotypes and following the procedure described above. (See **Test organism**, above.)
4. **Salmonella H Antisera:** Reconstituted antisera are considered a 1:2 working dilution. Prepare dilutions as follows and use on the day prepared. Discard any unused portion.
 - Most **Salmonella H Antisera:** Prepare a 1:250 dilution by adding 0.1 mL reconstituted antiserum to 24.9 mL of 0.85% NaCl solution. After mixing equal amounts (0.5 mL) of diluted antiserum and test isolate, the final dilution is 1:1,000.
 - **Salmonella H Antisera x, z₁₅ and z₂₈:** Prepare a 1:125 dilution by adding 0.1 mL reconstituted antiserum to 12.4 mL of 0.85% NaCl solution. After mixing equal amounts (0.5 mL) of diluted antiserum and test isolate, the final dilution is 1:500.
 - **Salmonella H Antiserum Poly a-z:** Prepare a 1:25 dilution by adding 0.1 mL reconstituted antiserum to 2.4 mL of 0.85% NaCl solution. After mixing equal amounts (0.5 mL) of diluted antiserum and test isolate, the final dilution is 1:100.

Tube Test Procedure

Salmonella H Antisera

1. Prepare a 12 x 75 mm culture tube for each organism to be tested.
2. **Diluted antiserum:** Dispense 0.5 mL in each tube.
3. **Test isolate:** Add 0.5 mL to the appropriate tube.
4. **Positive control:** Add 0.5 mL of antigen positive control to a tube containing 0.5 mL of antiserum.
5. **Negative control:** Add 0.5 mL of 0.85% NaCl solution to a tube containing 0.5 mL of test isolate.
6. Incubate all tubes in a water bath at 50 \pm 2 °C for 1 h.
7. Read for flocculation (agglutination).
8. Repeat the Tube Test using a phase-reversed test organism. (See the procedure for **Phase Reversal** below.)

Phase Reversal

1. Prepare Motility GI Medium phase reversal medium according to directions.
2. Prepare the antiserum opposite to the phase desired. For example, incubating *Salmonella Typhimurium* phase 1[i] in GI Motility Medium containing i antiserum allows growth and spread of *S. Typhimurium* phase 2 [1,2].
3. Add 1 mL of a 1:10 dilution of antiserum to 25 mL of sterile GI Motility Medium and mix well. Pour into a sterile Petri dish and allow to solidify.
4. Inoculate by punching the edge of the solidified medium.
5. Incubate at 35–37 °C for 24 h.
6. Transfer growth from the spreading edge opposite the inoculation site to a liquid medium for testing according to steps under **Tube Test Procedure – Salmonella H Antisera**.
7. If motility is not acceptable, pass through Motility GI Medium again.

Salmonella H Antiserum Spicer-Edwards

1. Prepare the test organism and the 1:2 antiserum dilution as described above in **Tube Test Preparation**.
2. **Final 1:1,000 dilution of antiserum:** Prepare by adding 0.1 mL of reconstituted antiserum (1:2 working dilution) to 24.9 mL of 0.85% NaCl solution.

- Prepare 4 culture tubes (12 x 75 mm) for each test organism.
- Salmonella H Antisera Spicer-Edwards 1-4:** Add 0.5 mL of the diluted antiserum to the culture tubes.
- Test organism:** Add 0.5 mL to each tube.
- Incubate tubes in water bath at 50 ± 2 °C for 1 h.
- Remove from the water bath. Avoid excessive shaking when the tubes are in the water bath or when removing them from the water bath prior to reading the reactions.
- Read for flocculation (agglutination).

User Quality Control: At the time of use, apply both homologous and heterologous controls to check performance of the antiserum, techniques and methodology. BD Difco QC Antigens Salmonella may be used as a homologous control. Refer to the BD Difco QC Antigens Salmonella package insert for further instructions.

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS

Slide Test

- Read and record results as follows:

4+	100% agglutination, background is clear to slightly hazy.	1+	25% agglutination, background is cloudy.
3+	75% agglutination, background is slightly cloudy.	–	No agglutination.
2+	50% agglutination, background is moderately cloudy.		

- The positive control should show 3+ or greater agglutination.
- The negative control should show no agglutination.
- For test isolates, a 3+ or greater agglutination is a positive result.
- A partial (less than 3+) or delayed agglutination reaction should be considered negative.
- If an H antigen identification is required, proceed to the next section.

Tube Test

- Read and record results as follows:

4+	100% agglutination, background is clear to slightly hazy.	1+	25% agglutination, background is cloudy.
3+	75% agglutination, background is slightly cloudy.	–	No agglutination.
2+	50% agglutination, background is moderately cloudy.		

- The positive control should show 3+ or greater agglutination at the routine test dilution (RTD).
- The negative control should show no agglutination.

When using BD Difco Salmonella H Spicer-Edwards, compare results with the flocculation (agglutination) patterns for the Spicer-Edwards schema (See Table 3, above).

LIMITATIONS OF THE PROCEDURE

- Complete O and H antigen characterization of a *Salmonella* isolate is required for final identification. Due to the complexity of the laboratory procedures, identification with polyvalent antisera may be sufficient for most laboratories.
- Possible *Salmonella* isolates having inconsistencies in biochemical reactions and O and H antigen tests should be referred to a reference laboratory for further testing.
- Excessive heat from external sources (hot bacteriological loop, burner flame, light source, etc.) may prevent making a smooth suspension of the microorganism or cause evaporation or precipitation of the test mixture. False-positive reactions may occur.
- Rough culture isolates do occur and will agglutinate spontaneously, causing agglutination of the negative control reaction (autoagglutination). Smooth colonies must be selected and tested in serological procedures.
- In the slide agglutination procedure for O antigen testing, it is recommended that several colonies be tested and that unabsorbed polyvalent antisera be used followed by absorbed single factor antisera. For example, colonies of a 1,2,12 culture on an agar plate will have varying degrees of each antigen. A 1,2,12 antiserum absorbed of 1 and 12 antibodies will be highly specific but will show weak or no agglutination with colonies that have less of antigen 2 and more of antigens 1 and 12. Using unabsorbed BD Difco Salmonella O Antiserum Group A Factors 1,2,12 to test several suspicious colonies on a plate followed by testing with absorbed BD Difco Salmonella O Antiserum Factor 2 gives the needed balance of sensitivity and specificity.
- Agglutination reactions of 3+ or greater are interpreted as positive reactions. Cross-reactions resulting in a 1+ or 2+ agglutination are likely since there are somatic antigens shared among different groups as non-major group antigens.
- There may exist common antigens between various "O" serogroups of *Salmonella*. As an example, BD Difco Salmonella O Antiserum Poly A contains, among others, agglutinins for factor 1, since cultures possessing factor 1 were used in immunization. It may be expected that this polyvalent antiserum will react with cultures other than those contained in "O" serogroups A, B, D, E and L due to the common 1 antigen (those organisms in Group G₁, G₂, H, R, T, etc., which contain factor 1).
- BD Difco Salmonella O Antiserum Poly A-I & Vi has been prepared with representative members of those somatic groups and has not been absorbed. It is obvious that this serum may and will react with higher O groups of *Salmonella*.

9. The tube agglutination technique is recommended for H antigen testing because cross-reactions with somatic antigens may occur at the dilutions used in the slide technique.
10. In the tube test, make certain that the proper dilution is prepared for a given antiserum. Various dilutions are used for various antisera. Refer to the **Tube Test Preparation** section for details.

PERFORMANCE CHARACTERISTICS

Salmonella O Antisera and Salmonella Vi Antiserum: Sensitivity of BD Difco Salmonella O Antisera and Salmonella Vi Antiserum are determined by demonstrating appropriate reactivity, as defined in the Results, Slide Test section, against a battery of homologous *Salmonella* cultures (See Table 4). Specificity is determined by demonstrating non-reactivity against non-related (heterologous) *Salmonella* groups.

Salmonella H Antisera

Sensitivity of BD Difco Salmonella H Antisera is determined by demonstrating appropriate reactivity, as defined in the Results, Tube Test section, against a battery of homologous *Salmonella* cultures (See Table 5). Specificity is determined by demonstrating non-reactivity against non-related (heterologous) *Salmonella* groups.

AVAILABILITY

Cat. No.	Description	Cat. No.	Description
228201	BD Difco™ Salmonella H Antiserum a, 3 mL	225401	BD Difco™ Salmonella H Antiserum Poly B, 3 mL
228211	BD Difco™ Salmonella H Antiserum b, 3 mL	225411	BD Difco™ Salmonella H Antiserum Poly C, 3 mL
228221	BD Difco™ Salmonella H Antiserum c, 3 mL	225421	BD Difco™ Salmonella H Antiserum Poly D, 3 mL
228231	BD Difco™ Salmonella H Antiserum d, 3 mL	225431	BD Difco™ Salmonella H Antiserum Poly E, 3 mL
222731	BD Difco™ Salmonella H Antiserum eh, 3 mL	224741	BD Difco™ Salmonella H Antiserum Single Factor 2, 3 mL
225441	BD Difco™ Salmonella H Antiserum Single Factor f, 3 mL	224751	BD Difco™ Salmonella H Antiserum Single Factor 5, 3 mL
225451	BD Difco™ Salmonella H Antiserum Single Factor h, 3 mL	224761	BD Difco™ Salmonella H Antiserum Single Factor 6, 3 mL
228241	BD Difco™ Salmonella H Antiserum i, 3 mL	224771	BD Difco™ Salmonella H Antiserum Single Factor 7, 3 mL
222741	BD Difco™ Salmonella H Antiserum k, 3 mL	222651	BD Difco™ Salmonella H Antiserum Spicer-Edwards 1, 3 mL
225461	BD Difco™ Salmonella H Antiserum Single Factor m, 3 mL	222661	BD Difco™ Salmonella H Antiserum Spicer-Edwards 2, 3 mL
225481	BD Difco™ Salmonella H Antiserum Single Factor p, 3 mL	222671	BD Difco™ Salmonella H Antiserum Spicer-Edwards 3, 3 mL
222751	BD Difco™ Salmonella H Antiserum r, 3 mL	222681	BD Difco™ Salmonella H Antiserum Spicer-Edwards 4, 3 mL
225501	BD Difco™ Salmonella H Antiserum Single Factor s, 3 mL	222721	BD Difco™ Salmonella H Antiserum 1 Complex, 3 mL
225511	BD Difco™ Salmonella H Antiserum Single Factor t, 3 mL	228141	BD Difco™ Salmonella O Antiserum Factor 2, 3 mL
225541	BD Difco™ Salmonella H Antiserum Single Factor w, 3 mL	226591	BD Difco™ Salmonella O Antiserum Factor 4, 3 mL
225551	BD Difco™ Salmonella H Antiserum Single Factor x, 3 mL	228151	BD Difco™ Salmonella O Antiserum Factors 4,5, 3 mL
222761	BD Difco™ Salmonella H Antiserum y, 3 mL	226601	BD Difco™ Salmonella O Antiserum Factor 5, 3 mL
222771	BD Difco™ Salmonella H Antiserum z, 3 mL	228161	BD Difco™ Salmonella O Antiserum Factor 7, 3 mL
224731	BD Difco™ Salmonella H Antiserum z ₆ , 3 mL	228171	BD Difco™ Salmonella O Antiserum Factor 8, 3 mL
222791	BD Difco™ Salmonella H Antiserum z ₁₀ , 3 mL	228181	BD Difco™ Salmonella O Antiserum Factor 9, 3 mL
225571	BD Difco™ Salmonella H Antiserum Single Factor z ₁₅ , 3 mL	222571	BD Difco™ Salmonella O Antiserum Factor 10, 3 mL
225581	BD Difco™ Salmonella H Antiserum Single Factor z ₂₃ , 3 mL	227791	BD Difco™ Salmonella O Antiserum Factor 12, 3 mL
225611	BD Difco™ Salmonella H Antiserum Single Factor z ₂₈ , 3 mL	226611	BD Difco™ Salmonella O Antiserum Factor 14, 3 mL
222801	BD Difco™ Salmonella H Antiserum z ₂₉ , 3 mL	222581	BD Difco™ Salmonella O Antiserum Factor 15, 3 mL
225621	BD Difco™ Salmonella H Antiserum Single Factor z ₃₂ , 3 mL	222591	BD Difco™ Salmonella O Antiserum Factor 19, 3 mL
222701	BD Difco™ Salmonella H Antiserum EN Complex, 3 mL	226621	BD Difco™ Salmonella O Antiserum Factor 20, 3 mL
222691	BD Difco™ Salmonella H Antiserum G Complex, 3 mL	226631	BD Difco™ Salmonella O Antiserum Factor 22, 3 mL
222711	BD Difco™ Salmonella H Antiserum L Complex, 3 mL	226641	BD Difco™ Salmonella O Antiserum Factor 23, 3 mL
222781	BD Difco™ Salmonella H Antiserum Z ₄ Complex, 3 mL	226661	BD Difco™ Salmonella O Antiserum Factor 25, 3 mL
224061	BD Difco™ Salmonella H Antiserum Poly a-z, 3 mL	226671	BD Difco™ Salmonella O Antiserum Factor 27, 3 mL
225391	BD Difco™ Salmonella H Antiserum Poly A, 3 mL	211778	BD Difco™ Salmonella O Antiserum Factor 34, 3 mL
		229471	BD Difco™ Salmonella O Antiserum Group A Factors 1, 2, 12, 3 mL
		229481	BD Difco™ Salmonella O Antiserum Group B Factors 1, 4, 5, 12, 3 mL

229731	BD Difco™ Salmonella O Antiserum Group B Factors 1, 4, 12, 27, 3 mL	222621	BD Difco™ Salmonella O Antiserum Group H Factors 1, 6, 14, 24, 25, 3 mL
229491	BD Difco™ Salmonella O Antiserum Group C1 Factors 6, 7, 3 mL	222631	BD Difco™ Salmonella O Antiserum Group I Factor 16, 3 mL
229501	BD Difco™ Salmonella O Antiserum Group C2 Factors 6, 8, 3 mL	211780	BD Difco™ Salmonella O Antiserum Group J Factor 17, 3 mL
230161	BD Difco™ Salmonella O Antiserum Group C3 Factors (8), 20, 3 mL	225181	BD Difco™ Salmonella O Antiserum Group K Factor 18, 3 mL
229511	BD Difco™ Salmonella O Antiserum Group D1 Factors 1, 9, 12, 3 mL	225191	BD Difco™ Salmonella O Antiserum Group L Factor 21, 3 mL
230171	BD Difco™ Salmonella O Antiserum Group D2 Factors (9), 46, 3 mL	211781	BD Difco™ Salmonella O Antiserum Group M Factor 28, 3 mL
228191	BD Difco™ Salmonella O Antiserum Group E Factors 1, 3, 10, 15, 19, 34, 3 mL	211783	BD Difco™ Salmonella O Antiserum Group N Factor 30, 3 mL
229521	BD Difco™ Salmonella O Antiserum Group E1 Factors 3, 10, 3 mL	225221	BD Difco™ Salmonella O Antiserum Group O Factor 35, 3 mL
229541	BD Difco™ Salmonella O Antiserum Group E2 Factors 3, 15, 3 mL	222641	BD Difco™ Salmonella O Antiserum Poly A-I & Vi, 3 mL
230181	BD Difco™ Salmonella O Antiserum Group E3 Factors (3), (15), 34, 3 mL	225341	BD Difco™ Salmonella O Antiserum Poly A, 3 mL
230191	BD Difco™ Salmonella O Antiserum Group E4 Factors 1, 3, 19, 3 mL	225351	BD Difco™ Salmonella O Antiserum Poly B, 3 mL
222601	BD Difco™ Salmonella O Antiserum Group F Factor 11, 3 mL	225361	BD Difco™ Salmonella O Antiserum Poly C, 3 mL
230291	BD Difco™ Salmonella O Antiserum Group G Factors 13, 22, 23, (36), (37), 3 mL	225371	BD Difco™ Salmonella O Antiserum Poly D, 3 mL
222611	BD Difco™ Salmonella O Antiserum Group G1 Factors 13, 22, (36), 3 mL	225381	BD Difco™ Salmonella O Antiserum Poly E, 3 mL
230201	BD Difco™ Salmonella O Antiserum Group G2 Factors 1, 13, 23, (37), 3 mL	226451	BD Difco™ Salmonella O Antiserum Poly F, 3 mL
		226461	BD Difco™ Salmonella O Antiserum Poly G, 3 mL
		228271	BD Difco™ Salmonella Vi Antiserum, 3 mL

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Table 4

REF	Product	Homologous Cultures Tested	
		Antigen Group	Serovar
229471	Salmonella O Antiserum Group A Factors 1, 2, 12	A	Paratyphi A <u>1,2,12</u> Paratyphi A 2,12 var. Durazzo
228141	Salmonella O Antiserum Factor 2		
227791	Salmonella O Antiserum Factor 12		
229481	Salmonella O Antiserum Group B Factors 1,4,5,12	B	Paratyphi B <u>1,4,(5),12</u> Essen 4,12 Schleissheim 4,12, <u>27</u> Typhimurium <u>1,4,(5),12</u>
229731	Salmonella O Antiserum Group B Factors 1,4,12, 27		
226591	Salmonella O Antiserum Factor 4		
226601	Salmonella O Antiserum Factor 5		
227791	Salmonella O Antiserum Factor 12		
228151	Salmonella O Antiserum Factors 4, 5		
226671	Salmonella O Antiserum Factor 27		
229491	Salmonella O Antiserum Group C1 Factors 6,7	C	Kentucky 8, <u>20</u> Thompson 6,7, <u>14</u> Newport 6,8 Virginia 8
229501	Salmonella O Antiserum Group C2 Factors 6,8		
230161	Salmonella O Antiserum Group C3 Factors (8), 20		
226621	Salmonella O Antiserum Factor 20		
228161	Salmonella O Antiserum Factor 7		
228171	Salmonella O Antiserum Factor 8	D	Enteritidis <u>1,9,12</u> Typhi 9,12,(Vi) Pullorum <u>1,9,12</u> Haarlem (9),46
229511	Salmonella O Antiserum Group D1 Factors 1,9,12		
227791	Salmonella O Antiserum Factor 12		
230171	Salmonella O Antiserum Group D2 Factors (9), 46		
228181	Salmonella O Antiserum Factor 9	E	Illinois 3, <u>15,34</u> Anatum 3,10 London 3,10,26 Newington 3, <u>15</u> Senftenberg 1,3,19
228191	Salmonella O Antiserum Group E Factors 1,3,10,15,19,34		
229521	Salmonella O Antiserum Group E1 Factors 3,10		
229541	Salmonella O Antiserum Group E2 Factors 3,15		
230181	Salmonella O Antiserum Group E3 Factors (3),(15),34		
230191	Salmonella O Antiserum Group E4 Factors 1,3,19		
222571	Salmonella O Antiserum Factor 10		
222581	Salmonella O Antiserum Factor 15		
222591	Salmonella O Antiserum Factor 19		
211778	Salmonella O Antiserum Factor 34		
222601	Salmonella O Antiserum Group F Factor 11	G	Poona <u>1,13,22,(36)</u> Worthington 1,13,23,(37)
230291	Salmonella O Antiserum Group G Factors 13,22,23, (36), (37)		
222611	Salmonella O Antiserum Group G1 Factors 13, 22, (36)		
230201	Salmonella O Antiserum Group G2 Factors 1,13,23,(37)		
226631	Salmonella O Antiserum Factor 22		
226641	Salmonella O Antiserum Factor 23	H	Florida (1),6,14,(25)
222621	Salmonella O Antiserum Group H Factors 1,6,14,24,25		
226611	Salmonella O Antiserum Factor 14		
226661	Salmonella O Antiserum Factor 25	I	Gaminara 16
222631	Salmonella O Antiserum Group I Factor 16	J	Kirkee 17
211780	Salmonella O Antiserum Group J Factor 17	K	Cerro <u>6,14, 18</u>
225181	Salmonella O Antiserum Group K Factor 18	L	Minnesota 21,26
225191	Salmonella O Antiserum Group L Factor 21	M	Telaviv 28ab Dakar 28ac
211781	Salmonella O Antiserum Group M Factor 28		
211783	Salmonella O Antiserum Group N Factor 30	N	Urbana 30ab
225221	Salmonella O Antiserum Group O Factor 35	O	Adelaide 35

REF 225341 Salmonella O Antiserum Poly A (Groups A,B,D,E1,E2,E3,E4 and L) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
A	Paratyphi A <u>1,2,12</u> ; Paratyphi A var Durazzo 2,12	D	Enteritidis 1,9,12; Typhi 9,12,(Vi); Pullorum 9,12; Haarlem (9),46
B	Paratyphi B <u>1,4,(5),12</u> ; Essen 4,12; Schleissheim 4,12, <u>27</u>	E	Anatum 3,10; London 3,10,26; Newington 3,15; Illinois 3, <u>15,34</u> ; Senftenberg 1,3,19
		L	Minnesota 21,26

REF 225351 Salmonella O Antiserum Poly B (Groups C1,C2,F,G and H) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
C1	Thompson 6,7,14	G1	Poona 1,13,22,(36)
C2	Newport 6,8	G2	Worthington 1,13,23,(37); Grumpensis 13,23
F	Rubislaw 11	H	Carrau 6,14,(24); Florida (1),6,14,(25); Boecker (1),6,14,(25)

REF 225361 Salmonella O Antiserum Poly C (Groups I,J,K,M,N and O) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
I	Gaminara 16	M	Telaviv 28ab; Dakar 28ac
J	Kirkee 17	N	Urbana 30
K	Cerro 6,14,18	O	Adelaide 35

REF 225371 Salmonella O Antiserum Poly D (Groups P,Q,R,S,T and U) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
P	Inverness 38	S	Waycross 41
Q	Champaign 39	T	Weslaco 42; Loenga 1,42ab
R	Riogrande 40ab; Bulawayo 1,40ac	U	Milwaukee 43abc, Bunnik 43acd

REF 225381 Salmonella O Antiserum Poly E (Groups V,W,X,Y and Z) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
V	Niareme 44	Y	Dahlem 48ab; Djakarta 48abc
W	Devesoir 45ab; Dugbe 45ac	Z	Wassenaar 50abc; Greenside 50abd
X	Bergen 47ab; Kaolack 47ac		

REF 226451 Salmonella O Antiserum Poly F (Groups 51–55) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
51	Treforest 1,51	54	Uccle 3,54
52	Utrecht 52	55	Tranoroa 55
53	Humber 53		

REF 226461 Salmonella O Antiserum Poly G (Groups 56–61) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
56	Artis 56	59	Betioky 59
57	Locarno 57	60	Luton 60
58	Basel 58	61	Eilbek 61

REF 228271 Salmonella Vi Antiserum Homologous Cultures Tested

Antigen Group	Serovar
Vi	Typhi (felix) 9,12,Vi; Ballerup Vi

Parentheses enclosing the designation for an antigen indicate that the antigen may be weakly agglutinable or absent.

Table 5

REF	Product	Antigen Group	Serovar		
222691	Salmonella H Antiserum G Complex	G Complex	Derby f,g; Berta f,g,t; Enteritidis g,m; Blegdam g,m,q; Montevideo g,m,(p),s; Dublin g,p; Rostock g,p,u; Senftenberg g,(s),t; Budapest g,t; Oranienburg m,t		
225441	Salmonella H Antiserum f				
225461	Salmonella H Antiserum m				
225481	Salmonella H Antiserum p				
225501	Salmonella H Antiserum s				
225511	Salmonella H Antiserum t				
222711	Salmonella H Antiserum L Complex	L Complex	Bredeney l,v; London l,v; Worthington l,w; Livingstone l,w; Morocco l,z ₁₃ ,z ₂₈ ; Javiana l,z ₂₈ ; Rutgers l,z ₄₀ ; lz ₁₉ , lz ₁₃ lz ₁₃		
225541	Salmonella H Antiserum w				
225611	Salmonella H Antiserum z ₂₈				
222721	Salmonella H Antiserum 1 Complex	1 Complex	Newport var. Puerto Rico 1,2; Thompson var. Berlin 1,5; 3,10:-:1,6 1,6; Madelia 1,7		
224741	Salmonella H Antiserum Single Factor 2				
224751	Salmonella H Antiserum Single Factor 5				
224761	Salmonella H Antiserum Single Factor 6				
224771	Salmonella H Antiserum Single Factor 7				
222701	Salmonella H Antiserum EN Complex	EN Complex	Abortusequi e,n,x; Salinatis e,n,z ₁₅		
225551	Salmonella H Antiserum x				
225571	Salmonella H Antiserum z ₁₅				
222781	Salmonella H Antiserum Z ₄ Complex	Z ₄ Complex	Cerro z ₄ ,z ₂₃ ; Duesseldorf z ₄ ,z ₂₄ ; Tallahassee z ₄ ,z ₃₂		
225621	Salmonella H Antiserum z ₃₂				
225581	Salmonella H Antiserum z ₂₃				
225451	Salmonella H Antiserum h	h	Reading e,h		
222731	Salmonella H Antiserum eh				
222651	Salmonella H Antiserum Spicer-Edwards 1	Spicer-Edwards	Paratyphi A a Paratyphi B b	Budapest g,t Typhimurium i Thompson k	
222661	Salmonella H Antiserum Spicer-Edwards 2				
222671	Salmonella H Antiserum Spicer-Edwards 3				
222681	Salmonella H Antiserum Spicer-Edwards 4		Choleraesuis c Paratyphi C c S. typhi d Reading e,h Derby f,g	Oranienburg m,t Rubislaw r Madelia y Atlanta-Worthington z Taksony z ₆ Cerro z ₄ ,z ₂₃ Duesseldorf z ₄ ,z ₂₄ Tallahassee z ₄ ,z ₃₂ Tennessee z ₂₉ Illinois z ₁₀	
228201	Salmonella H Antiserum a				
228211	Salmonella H Antiserum b				
228221	Salmonella H Antiserum c				
228231	Salmonella H Antiserum d				
228241	Salmonella H Antiserum i				
222741	Salmonella H Antiserum k				
222751	Salmonella H Antiserum r				
222761	Salmonella H Antiserum y				
222771	Salmonella H Antiserum z				
222791	Salmonella H Antiserum z ₁₀				
222801	Salmonella H Antiserum z ₂₉				
224731	Salmonella H Antiserum z ₆				Senftenberg g,(s),t

REF 225391 Salmonella H Antiserum Poly A (Groups a, b, c, d, i, z₁₀ and z₂₉) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
a	Paratyphi A	i	Typhimurium
b	Paratyphi B	z ₁₀	Illinois
c	Paratyphi C	z ₂₉	Tennessee
d	Typhi		

REF 225401 Salmonella H Antiserum Poly B (Groups eh, en, enx, enz15 and G complex) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
e,h	Reading	g,m,(p),s	Montevideo
e,n,x	Abortusequi	g,p	Dublin
e,n,z ₁₅	Salinatis	g,p,u	Rostock
f,g	Derby	g,(s),t	Senftenberg
f,g,t	Berta	g,t	Budapest
g,m	Enteritidis	m,t	Oranienburg
g,m,q	Blegdam		

REF 225411 Salmonella H Antiserum Poly C (Groups k, l, r, y, z and z₄) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
k	Thompson	r	Rubislaw
l,v	Bredeney	y	Madelia
l,w	Worthington	z	Atlanta-Worthington
l,z ₁₃	lz ₁₉ , lz ₁₃	z ₄ ,z ₂₃	Cerro
l,z ₂₈	Javiana	z ₄ ,z ₂₄	Duesseldorf
l,z ₄₀	Rutgers	z ₄ ,z ₃₂	Tallahassee

REF 225421 Salmonella H Antiserum Poly D (Groups z₃₅, z₃₆, z₃₇, z₃₈, z₃₉, z₄₁ and z₄₂) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
z ₃₅	Chittagong	z ₃₉	Quimbamba
z ₃₆	Weslaco	z ₄₁	Karamoja
z ₃₇	Wichita	z ₄₂	Locarno
z ₃₈	Lille		

REF 225431 Salmonella H Antiserum Poly E (Groups 1 Complex, z₆) Homologous Cultures Tested

Antigen Group	Serovar	Antigen Group	Serovar
z ₆	Taksony	1,6	3,10:-:1,6
1,2	Newport var. Puerto Rico	1,7	Madelia
1,5	Thompson var. Berlin		

Parentheses enclosing the designation for an antigen indicate that the antigen may be weakly agglutinable or absent.

Change History

Revision/Date	Section	Change Summary
(04) 2018-12	All p1 Warnings and Precautions p12-15 p16	Updated BD branding. Updated Technical Information Statement. Updated revision and date Updated the "Warnings and Precautions" section with new GHS requirements for P codes. Revised Tables 4 and 5. Updated Trademark line
Revision	Date	Change Summary
(05)	2019-09	Converted printed instructions for use to electronic format and added access information to obtain the document from BD.com/e-labeling. Corrected product name throughout from Salmonella Antiserum Vi to Salmonella Vi Antiserum where applicable.

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary



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RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = slutning af måned)
JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα)
AAAA-MM-DD / AAAA-MM (MM = fin del mes)
AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese)
ЖОЖОЖ-АА-КК / ЖОЖОЖ-АА / (АА = айдың соны)
YYYY-MM-DD/YYYY-MM (MM = 월말)
MMMM-MM-DD / MMMM-MM (MM = mēnesio pabaiga)
GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
AAAA-MM-DD / AAAA-MM (MM = slutten av månaden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês)
AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
AAAA-MM-DD / AAAA-MM (MM = slutet av månaden)
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PPPP-MM-DD / PPPP-MM (MM = кінець місяця)
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In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostik medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro biyowotik iatirik suukeu / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsiiniparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnosztikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisai / Medicinas ierces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostik medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispozitiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicinska rombicka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknik produkt för in vitro-diagnostik / In Vitro Diagnostik Tibbi Cihaz / Медицинский прибор для диагностики in vitro / 体外诊断医疗设备



Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrensning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температуры шектеу / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturlimit / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenje teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制



Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotta) / Топтама коды / 배치 코드(코트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serie / Partinummer (Lot) / Parti Kodu (Lot) / Код партии / 批号 (亚批)



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Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Limite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі рұқсат шегі / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrænse / Dolna granica temperatury / Limite minimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限

CONTROL

Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolé / Kontrolle / Controle / Controllo / Контроль / 对照

CONTROL+

Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitiv kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitivná kontrol / Positivne controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂

CONTROL-

Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negativ kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negativná kontrol / Negativne controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂

STERILE/EO

Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismetode: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Sterilizacija: etilēns oksīds – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksis / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringmetode: etylenoksid / Metoda sterilizacji: tienek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metodá sterilizácie: etylenoxid / Metoda sterilizacije: etilen oksid / Steriliseringmetode: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилизації: этиленоксидом / 灭菌方法: 环氧乙烷

STERILE R

Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismetode: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Sterilizacija: radiacija – Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringmetode: bestråling / Metoda sterilizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metodá sterilizácie: ožiarenie / Metoda sterilizacije: ozračevanje / Steriliseringmetode: strålning / Sterilizasyon yöntemi: ırradyasyon / Метод стерилизації: опромінення / 灭菌方法: 辐射



Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Biologilised riskid / Risques biologiques / Biološki rizik / Biológiai veszélyes / Rischio biologico / Биологические тәуекелдер / 생물학적 위험 / Biologinis pavojus / Biologiskie riski / Biologisch risico / Biologiskie risiko / Zagrożenia biologiczne / Perigo biológico / Riscu biologico / Biologiskie / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Біологічна небезпека / 生物学风险



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Keep dry / Пазете сухо / Skladujte v suchém prostředi / Opbevares tørt / Trockklager / Φυλάξτε το στεγνό / Mantener seco / Conservar au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávaťe v suchu / Držite na suvom mestu / Förvaras tørt / Kur bir çekilde muhafaza edin / Беретти від вологи / 请保持干燥



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Perforation / Перфорация / Perforace / Perforering / Διάτρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесик тесу / 찢히술 / Perforacija / Perforácia / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔



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Cut / Срежете / Odsfihňete / Klip / Schneiden / Κόψτε / Cortar / Lőigata / Découper / Reži / Vágja ki / Tagliare / Keciңiz / 잘라내기 / Kirpti / Noghriet / Knippen / Kutt / Odciąć / Cortar / Decupați / Отрезать / Odsřihnite / Iseći / Klipp / Kesme / Pozpizati / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuurpäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаған тізбекүні / 수집 날짜 / Paémimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Dátum odberu / Datum prikupljanja / Uppsamlingsdatum / Toplama tarihi / Дата забору / 采集日期



µL/test / µL/тест / µL/Test / µL/εξέταση / µL/prueba / µL/teszt / µL/테스트 / мкл/тест / µL/tyrims / µL/pårbaude / µL/teste / мкл/анализ / µL/检测



Keep away from light / Пазете от светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svjetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródła światła / Manter ao abrigo da luz / Feriți de lumină / Хранить в темноте / Uchovávať mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / İşıktan uzak tutun / Беретти від дії світла / 请远离光线



Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrží hydrogen vodík / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтөктес сүтері пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdeņradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Osloбаda se vodonik / Genererad vätagas / Açığa çıkan hidrojen gazı / Реакция з виділенням водню / 会产生氢气



Patient ID number / ИД номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID / No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациенттін идентификациялық нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacienta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Идентифікатор пацієнта / 患者标识号



Fragile. Handle with Care / Чупливо. Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Εύθραστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Öm, käsitsese ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынғыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Traru, elkités atsargiai. / Trausls; rīkoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålígg, håndter forsigtig. / Kruha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Frágil, manipulați cu atenție. / Хрупкое! Обращаться с осторожностью. / Křehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşın. / Тендітна, звертається з обережністю / 易碎, 小心轻放

Rx Only

This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / S'applique uniquement aux États-Unis: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Vale solo per gli Stati Uniti: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Gilt nur für die USA: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Sólo se aplica a los EE.UU.: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."



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