

INTENDED USE

Polyvalent *Shigella* antisera are prepared for use in serological identification of organisms belonging to the genus *Shigella*, for use by appropriately qualified personnel.

SUMMARY AND EXPLANATION

Organisms of the genus *Shigella* are Gram-negative, aerobic, non-motile, non-sporulating rods. Most species are pathogenic to man, giving rise to dysentery or acute gastro-enteritis. They ferment glucose without production of gas but do not ferment lactose. (*S. sonnei* may ferment lactose, without production of gas, after prolonged incubation). Complete identification of *Shigella* requires culture isolation, biochemical characterization and serological identification (serotyping).

Pro-Lab Polyvalent *Shigella* antisera are intended to aid initial serogrouping. The principle of the serological identification of *Shigella* involves mixing the suspected colony with antiserum containing specific *Shigella* antibodies. The bacteria will agglutinate (clump) in the presence of homologous antiserum. Antisera are prepared in rabbits using reference strains according to recognised guidelines, and absorbed to remove cross-reactions. Pro-Lab *Shigella* antisera are supplied in dropper bottles containing 2.0 ml of ready-to-use sera.

PRECAUTIONS

1. Do not use antisera after expiry date shown on the product label.
2. The antisera contain sodium azide as preservative, appropriate safety precautions should be observed in handling, processing and discarding the reagent.
3. Avoid contamination of the reagent bottle.
4. The test specimens may contain organisms pathogenic to man and should be handled and discarded as infectious material.
5. The reagents are for *in vitro* diagnostic use only.
6. Reagents must be used in accordance with good laboratory practice and good standards of occupational hygiene. Procedures, storage conditions, precautions and limitations specified must be adhered to in order to obtain valid test results.
7. Do not mouth pipette the reagent, wear disposable gloves and observe all standard laboratory safety precautions when handling specimens and performing the test.

SPECIMEN COLLECTION AND PREPARATION OF CULTURES

For specific procedures regarding specimen collection and preparation of primary cultures refer to a standard microbiology textbook. Colonies isolated on enteric differential media and suspected of being *Shigella* should be confirmed with conventional biochemical tests.

	<i>Sh. dysenteriae</i> <i>shigae</i>	<i>schmitzii</i>	<i>Sh. boydii &</i> <i>Sh. flexneri</i>	<i>Sh. sonnei</i>
Lactose	-	-	-	A*
Glucose	A	A	A~	A
Mannitol	-	-	(A)	A
Sucrose	-	-	-	A*
Dulcitol	-	-	-	-
Adonitol	-	-	-	-
Urea	-	-	-	-
Salicin	-	-	-	-
Citrate	-	-	-	-
VP	-	-	-	-
Indole	-	+	(+)	-
Gluconate	-	-	-	-
Malonate	-	-	-	-
Phenylalanine -	-	-	-	-
Gelatin	NL	NL	NL	NL
Hydrogen sulphide	-	-	-	-
Trimethylamine oxide reduction	-	-	-	-

A=acid. () = variable reaction. * = after prolonged incubation.
 NL = not liquified. ~ = aerogenic variants of *Sh. flexneri* 6 exist.

STABILITY AND STORAGE

Shigella antisera should be stored at 2-8°C. Do not freeze. Stored under these conditions the antisera may be used up to the date of expiry shown on the product label. On storage, some antisera may become slightly turbid; this does not necessarily indicate deterioration and the antisera may be clarified by centrifugation or filtration before use. Gross turbidity indicates contamination and such antisera should be discarded.

MATERIAL REQUIRED BUT NOT SUPPLIED

Glass Slides.
 Normal Saline (0.85% NaCl Solution).
 Disposable wire loops.

RECOMMENDED PROCEDURE

1. Place two separate drops of saline on a clean glass slide.
2. Using a sterile loop, emulsify the same colony of the suspected culture with both drops of saline to obtain a smooth suspension.
3. To one suspension, as a control for auto-agglutination, add one drop or a loop-full of saline and mix.
4. To the other suspension add one drop or a loop-full of undiluted antiserum and mix.
5. Rock the slide gently back and forth for up to one minute and observe for agglutination under normal lighting conditions. A low-power objective can be used to facilitate reading fine agglutination reactions.

INTERPRETATION OF RESULTS

A distinct agglutination (granular clumping) within 60 seconds, without agglutination in the saline control (auto-agglutination) is regarded as a positive result.

LIMITATIONS








1. Serological tests used alone provide no more than presumptive identification and established practice requires confirmatory biochemical tests to be performed. Polyvalent *Shigella* antisera should only be used for identification of cultures which have been previously characterised biochemically as *Shigella*. The presence of similar antigens on the surface of bacteria other than *Shigella* may give false results
2. Some species of *Shigella* do not agglutinate due to the presence of K (capsular) antigens. These capsular antigens can be removed by heating at 100°C for 2 hours; slide serology testing can then be performed.
3. It is recommended that the potency of *Shigella* antisera is checked with stock reference cultures of known origin and antigenic structure.
4. A normal saline control for auto-agglutination should be included in every test to ensure the specificity of the reaction.

PRODUCTS AVAILABLE

PL6900 - *Sh. sonnei* Phase 1&2
 PL6901 - *Sh. flexneri* 1-6, X&Y
 PL6902 - *Sh. dysenteriae* 1-10
 PL6903 - *Sh. boydii* 1-15

REFERENCES

1. Ewing, W.H. Edwards & Ewing's Identification of Enterobacteriaceae. 4th edition.
2. Carpenter K.P. (1968) Association of Clinical Pathologists Broadsheet 60.

	= Use by
	= Lot number
	= Catalogue number
	= Manufacturer
	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use

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