Shigella Agglutination Sera

(for *In Vitro* Diagnostic use only)

PRODUCT CODE: PL.6900, PL.6901, PL.6902, PL.6903

INTENDED USE

Polyvalent Shigella Agglutination Sera 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, nonsporulating rods. Most species are pathogenic to man, giving rise to dysentery or acute gastroenteritis. 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 characterisation and serological identification (serotyping).

PRINCIPLE OF THE TEST

Polyvalent Shigella Agglutination Sera 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. Agglutination Sera are prepared in rabbits using reference strains according to recognised guidelines, and absorbed to remove cross-reactions. Shigella Agglutination Sera are supplied in dropper bottles containing 2.0 ml of ready-to-use diluted Agglutination Sera with sodium azide as a preservative.

MATERIALS PROVIDED

- PL.6900 – *Shigella sonnei* Phase 1&2
- PL.6901 – *Shigella flexneri* 1-6, X&Y
- PL.6902 – *Shigella dysenteriae* 1-10
- PL.6903 – *Shigella boydii* 1-15

MATERIALS REQUIRED BUT NOT PROVIDED

- Glass slides
- Normal Saline (0.85% NaCl solution)
- Disposable wire loops

STABILITY AND STORAGE

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

PRECAUTIONS

- Do not use Sera after the expiry date shown on the product label.
  The Sera contain sodium azide, which is highly toxic. Although the amount of sodium azide in the Sera is minimal, safety precautions should be taken in handling, processing and discarding the reagent.
- Avoid contamination of the reagent bottle.
- The test specimen may contain organisms pathogenic to man and should be handled and discarded as infectious material.
- The reagent is intended for *in vitro* diagnostic use only.
- The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid test results.
- Product contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

SAMPLE STORAGE AND COLLECTION

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

TEST PROCEDURE

1. Place two separate loopfuls of normal saline (0.85% sodium chloride) on a clean glass slide.
2. Emulsify a small part of a suspect Shigella colony from an overnight culture plate into each of the drops of saline. Mix thoroughly to obtain a smooth bacterial suspension. Discard the slide and repeat if auto-agglutination (clumping) occurs.
3. Add one loopful of Sera to one of the bacterial suspension drops. Add one loopful of saline to the other; this will act as a control.
4. Mix the Agglutination Sera with the bacterial suspension using a sterile loop.
5. Gently tilt the slide back and forth for one minute. Under normal lighting conditions, observe for agglutination (clumping) of the suspension with Sera, and clearing of the saline suspension.

QUALITY CONTROL PROCEDURE

Refer to lot specific Certificate of Analysis.

INTERPRETATION OF RESULTS

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

LIMITATIONS OF THE PROCEDURE

- Serological tests used alone provide no more than presumptive identification and established practice requires confirmatory biochemical tests to be performed. Polyvalent Shigella Agglutination Sera 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.
- 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.
- It is recommended that the potency of Shigella Agglutination Sera is checked with stock reference cultures of known origin and antigenic structure.
- A normal saline control for auto-agglutination should be included in every test to ensure the specificity of the reaction.

REFERENCES

- Carpenter, K.P. (1968) Association of Clinical Pathologists Broadsheet 60.
- Ewing, W.H. Edwards & Ewing's Identification of Enterobacteriaceae. 4th edition. *Eisevier Science Publishing Co*., New York.

	= Use by
LOT	= Lot number
REF	= Catalogue number
	= Manufacturer
EC REP	= Authorized Representative in the European Community
Σ	= Contains sufficient for <n> tests
IVD	= In vitro diagnostic medical device
	= Temperature limitation
i	= Consult instructions for use

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