Shigella Antisera

(for *In Vitro* Diagnostic use only)

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

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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, 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 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. Shigella antisera are supplied in dropper bottles containing 2.0 ml of ready-to-use sera.

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
- Low power objective

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.

PRECAUTIONS

- Do not use antisera after the expiry date shown on the product label.
- The antisera contain thimerosal, which is a highly toxic mercury-based compound. Although the amount of thimerosal in the antisera 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 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 loopful 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.

QUALITY CONTROL PROCEDURE

Refer to lot specific Certificate of Analysis.

INTERPRETATION OF RESULTS

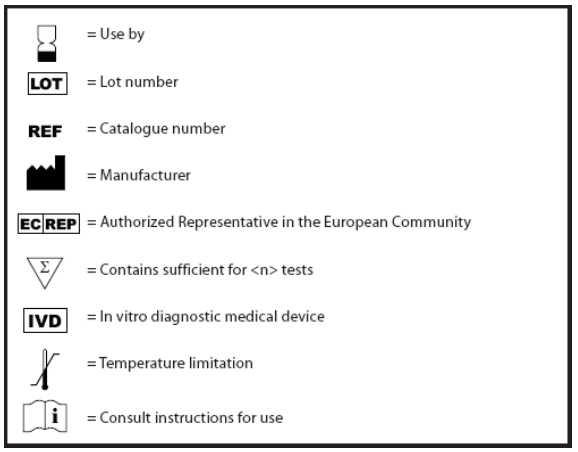
A distinct agglutination (granular clumping) within 60 seconds, without agglutination in the saline control (auto-agglutination) is regarded as a positive result.

LIMITATIONS 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 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.
- 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 antisera 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

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



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