

Shigella

RAPID TEST



*Rapid one step coloured chromatographic immunoassay for the qualitative detection of **Shigella spp. antigen** in stool samples.*



1. What is SHIGELLA?

Shigella is a genus of Gram-negative, non-spore forming rod-shaped bacteria closely related to *Escherichia coli* and *Salmonella*.

Shigella species are classified by serogroups:

* **Serogroup A:** *S. dysenteriae* (12 serotypes)

* **Serogroup C:** *S. boydii* (23 serotypes)

* **Serogroup B:** *S. flexneri* (6 serotypes)

* **Serogroup D:** *S. sonnei* (1 serotype)

Shigella infection is typically via ingestion (fecal–oral contamination); depending on age and condition of the host as few as 100 bacterial cells can be enough to cause an infection.

The most common symptoms are diarrhea, fever, nausea, vomiting, stomach cramps and flatulence. The stool may contain blood, mucus, or pus. Symptoms can take as long as a week to show up, but most often begin two to four days after ingestion. Symptoms usually last for several days but can last for weeks. *Shigella* is implicated as one of the pathogenic causes of reactive arthritis worldwide.

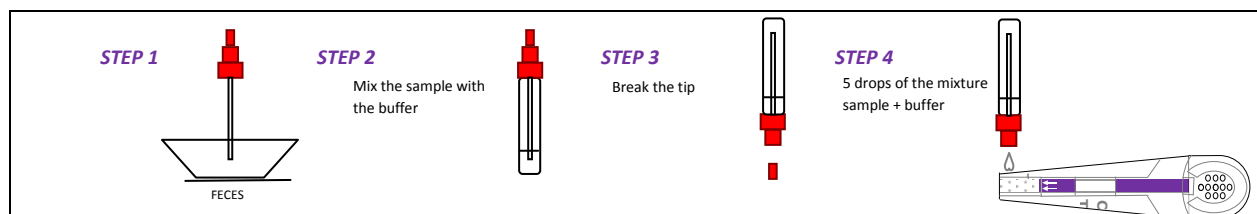
2. What is H&R *Shigella* test?

It is a rapid, colored chromatographic immunoassay for **professional *in vitro* diagnostic use only**, for the qualitative detection of *Shigella spp.* antigens in stool samples in order to detect shigellosis in infected humans.



3. How is H&R *Shigella* test performed?

- Collect sufficient quantity of faeces.
- Unscrew the cap of the vial and introduce the stick into different parts of the faecal specimen to pick up enough sample.
- Introduce the stick with the sample into the vial and shake it in order to assure good sample dispersion.
- Break off the tip of the vial and open the poche to take the H&R *Shigella* test device.
- Dispense exactly 5 drops or 150 µL into the cassette and wait 10 minutes for the result.



3. Interpretation of results

a. POSITIVE



b. NEGATIVE



c. INVALID



d. INVALID



4. Performance Data

It was performed an evaluation using H&R *Shigella*. It was studied some stool samples and the results were confirmed by culture H&R *Shigella* showed >99% of sensitivity and >99% of specificity

It was performed an evaluation to determine the cross reactivity of H&R *Shigella*. There is no cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in faeces: *H. pylori*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Campylobacter spp.*, *Salmonella spp.*