VITASSAY

Salmonella typhi

Rapid test for the qualitative detection of *Salmonella typhi* in human stool samples.

IUE-7355030 Ed01 August 2023

CE IVD EN

Vitassay

EN

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay Salmonella typhi is a rapid, immunochromatographic, one step assay for the qualitative detection of *Salmonella typhi* in human stool samples.

Simple, non-invasive and highly sensitive screening assay to make a presumptive diagnosis of *Salmonella typhi* infection.

INTRODUCTION

Typhoid fever is a systemic infection caused by the enteric gram-negative bacterium *Salmonella enteric serovar typhi* (*S. typhi*). This food and waterborne disease are strongly correlated with poor hygiene as well as overpopulated areas with poor sanitation. Typhoid fever continues to be a serious global public health problem and is a major cause of morbidity and mortality in the developing world.

Typhoid fever is a severe and life-threatening systemic illness transmitted via the fecal-oral route and is a major cause of morbidity and mortality worldwide. It affects only humans (who are the reservoir) and is spread through consumption of contaminated food and drink handled by people who shed the organism from stool or, less commonly, urine or water contaminated with sewage.

PRINCIPLE

Vitassay Salmonella typhi is a qualitative immunochromatographic assay for the detection of *Salmonella typhi* in human stool samples.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against *Salmonella typhi*.

During the process, the sample reacts with the antibodies against *Salmonella typhi*, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears.

The presence of this green line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Read the instructions for use carefully before using the test.
- Do not use the kit if the label sealing the outer carton is torn or if the bags are open or damaged upon arrival.
- Do not use the tests if the desiccant material is missing or broken inside the foil pouch.
- Do not use the test if the primary packaging is damaged.
- Specimens should be considered potentially hazardous and should be handled in the same manner as an infectious agent, following local/national regulations. A new test should be used for each specimen to avoid contamination errors.
- Used material should be discarded in an appropriate biohazard container after testing.
- The reagents contain preservatives. Any contact with skin or mucous membranes should be avoided. See safety data sheets, available on request.
- Tests after use should be disposed of as medical waste (medical waste container).
- The components supplied with the kit are approved for use with **Vitassay Salmonella typhi.** They should not be used with components from other commercially available kits.
- Follow Good Laboratory Practices. These practices should include, but are not limited to, personal protective equipment (PPE), such as lab coat, surgical or appropriate mask or face shield, disposable gloves and eye protection. Take the necessary precautions during sample collection, transport, storage, handling and disposal. Each sample must be correctly and unequivocally identified to ensure proper traceability of samples.
- In case of spillage, clean thoroughly with a suitable disinfectant.
- Do not eat, drink or smoke in the workplace.
- The presence of yellow lines in the result window (control line area and test line area), before using the test, is completely normal and does not imply a failure in the functionality of the test.
- The visual interpretation of the results is done by coloured lines, the interpretation of the results should be done by a professional user without problems of visualisation and colour interpretation.
- A certificate of analysis can be provided on request (not included).

STORAGE AND STABILITY

The storage temperature of the kits should be 2-30ºC.

Do not freeze.

Under these conditions, they can be used until the expiry date indicated on the kit label.

All kit components are for single use only and must remain in their primary packaging until use. The test must remain in the sealed pouch until use.

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MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ **25** tests/kit **Vitassay Salmonella typhi** ▪ Instructions for use. ▪ **25** vials with diluent for the sample dilution.	▪ PPE, such as disposable gloves ▪ Specimen collection container ▪ Timer ▪ Micropipette (in case of liquid stool)

SPECIMEN COLLECTION

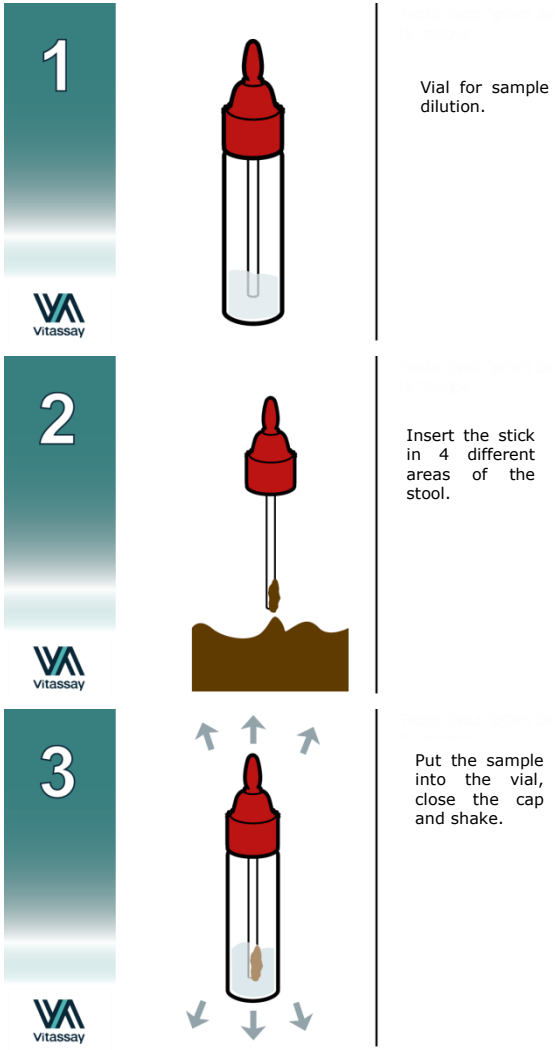
Collect sufficient quantity of feces: 1-2g or mL for liquid samples. Stool samples should be collected in clean containers.

Samples can be stored in the refrigerator (2-8ºC) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20ºC. Samples must be brought to room temperature before testing.

Freezing and defrosting cycles are not recommended, so ensure that only the amount needed is thawed. Homogenize stool samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick in 4 different areas of the stool sample, taken approx. 125mg, (figure 2) and add it into the vial with diluent for the sample dilution. For liquid stool, take 125µL of the sample using a micropipette and transfer it into the vial with diluent for the sample dilution.
2. Close the vial with the diluent and stool sample. Shake vigorously the vial in order to assure good sample dispersion (figure 3).

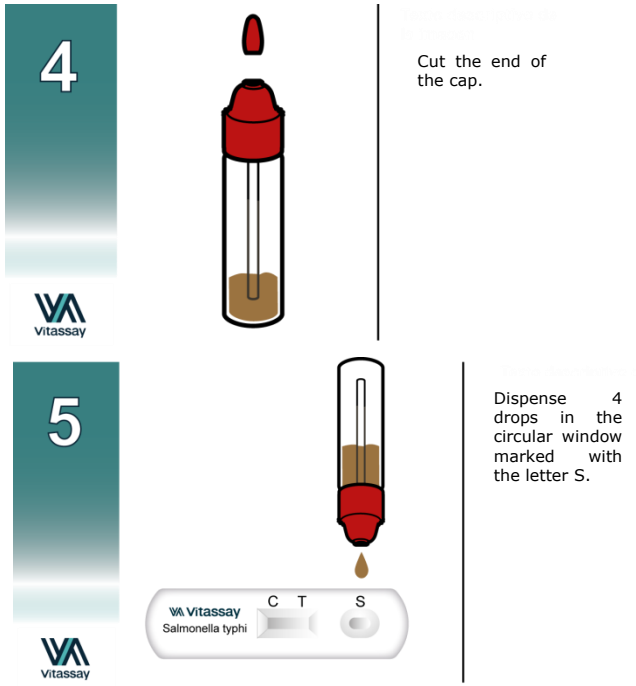


PROCEDURE

Allow the test, stool sample, controls and diluent to reach room temperature (15-30ºC) prior to testing. Do not open pouches until the performance of the assay.

1. Shake the vial with the sample to obtain a good sample dilution.
2. Remove the **Vitassay Salmonella typhi** from its sealed bag just before using it.
3. Take the vial containing the diluted sample, cut the end of the cap (figure 4) and dispense 4 drops in the circular window marked with the letter S (figure 5).
4. Read the results at **10 minutes**. Do not read the results later than 10 minutes.

If the test does not run due to solid particles, stir the sample added in the sample window (S) with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.



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INTERPRETATION OF THE RESULTS

	**NEGATIVE** Only one green line in the control zone ©.	There is no *Salmonella typhi* presence. No infection caused by *Salmonella typhi.*
	**POSITIVE** In addition to the green line (**control line C**), a red line appears, (**test line T**)	There is presence *of Salmonella typhi.* Possible *Salmonella typhi* infection, which might mean include high fever, weakness, lethargy, muscle pain, headache, loss of appetite or constipation. Pink spots appear on the chest; examination will usually reveal enlargement of the liver and spleen. In severe cases, symptoms of altered mental status and meningitis (fever, stiff neck, seizures) have been reported.
ANY OTHER RESULTS		Invalid result, we recommend repeating the assay using the sample with another test. **Note:** Wrong procedural techniques, deterioration of the reagents or insufficient specimen volume are mostly the main reasons for control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor.

Notes: The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

QUALITY CONTROL

Internal procedural control is included in **Vitassay Salmonella typhi**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.
- The quality of **Vitassay Salmonella typhi** depends on the quality of the sample, so proper sampling must be performed.
- The intensity of test line may vary depending on the concentration of antigens.
- The use of other samples different from human samples has not been established.
- Positive results determine the presence of Salmonella typhi in stool samples, however, this may be due to various causes and/or species. A positive result should be contrasted with other laboratory techniques (biochemical and serological methods or PCR) to determine the results. Infection should be confirmed by a qualified specialist or physician, after evaluation of the clinical evidence and laboratory findings, taking into account the correlation that may exist with all clinical observations.
- A negative result should not be considered as conclusive, it may be that the concentration of antigens in the stool sample is below the limit of detection value. If symptoms or the situation persists, for the determination of Salmonella typhi the test should be performed with the sample previously subjected to enrichment.
- **Bloody stool samples** and/or **mucous** stool samples can cause non-specific reactions in the test. Such positive samples should be followed up with other diagnostic techniques to confirm the result.

EXPECTED VALUES

According to the World Health Organization, it is estimated that the yearly incidence of typhoid fever exceeds 22 million cases with over 200000 deaths. In the United States, 200-300 new cases are reported annually, most of which occur in travelers returning from endemic countries.

It occurs worldwide, primarily in developing nations whose sanitary conditions are poor. Typhoid fever is endemic in Asia, Africa, Latin America, the Caribbean, and Oceania, but 80% of cases come from Bangladesh, China, India, Indonesia, Laos, Nepal, Pakistan, or Vietnam.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation was performed using **Vitassay Salmonella typhi** and these results were confirmed with a commercially available immunochromatographic test (Singlepath®Salmonella, Merck).

Results were as follows:

		Singlepath®Salmonella		
		Positive	**Negative**	**Total**
Vitassay Salmonella typhi	**Positive**	10	0	10
	Negative	0	25	25
	Total	10	25	35

Table 1. Results of **Vitassay Salmonella typhi** compared to a commercially available immunochromatographic test (Singlepath®Salmonella, Merck).

Vitassay Salmonella typhi vs Singlepath®Salmonella			
Sensitivity	**Specificity**	**PPV**	**NPV**
>99%	>99%	>99%	>99%

Table 2. Sensitivity, specificity, positive predictive values and negative predictive values of the **Vitassay Salmonella typhi** kit compared to a commercial test.

Vitassay Salmonella typhi shows high sensitivity (>99%) and specificity (>99%) for detecting *Salmonella typhi* antigens.

The results showed that **Vitassay Salmonella typhi** has a high sensitivity and specificity to detect *Salmonella typhi.*

Analytical sensitivity

The limit of detection (LoD) of **Vitassay Salmonella typhi** is $1.25x10^7$ CFU/mL.

Cross reactivity

No cross reactivity was detected against gastrointestinal pathogens that are occasionally present in faeces:

Campylobacter coli	*Helicobacter pylori*	*Shigella flexneri*
Campylobacter jejuni	*Listeria monocytogenes*	*Shigella sonnei*
Clostridium difficile	*Shigella boydii*	*Staphylococcus aureus*
Escherichia coli O157:H7	*Shigella dysenteriae*	*Yersinia enterocolitica*

REFERENCES

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SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number
CE	CE Marking		

Changes control		
Nº Version	**changes**	**Date**
IUE-7355030 Ed01 August 2023	The format has been updated. Analytical sensitivity section has been added. Limitations section has been updated. Grammatical and editorial changes have been made to Precautions, Limitations, Sample Collection, Storage and Stability. Material required but not included updated with minor changes. Transcription error in interpretation of results has been corrected.	25/08/2023

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