VITASSAY

Salmonella typhi

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

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CE IVD EN

Vitassay

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 is strongly correlated with poor hygiene as well as over populated 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.
- Do not use the test if its pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Salmonella typhi**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF).

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

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.	▪ Specimen collection container. ▪ Disposable gloves. ▪ Timer.

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/35.6-46.4ºF) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20ºC/-4ºF. 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.

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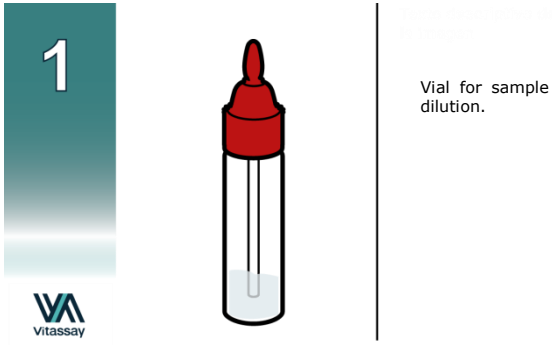
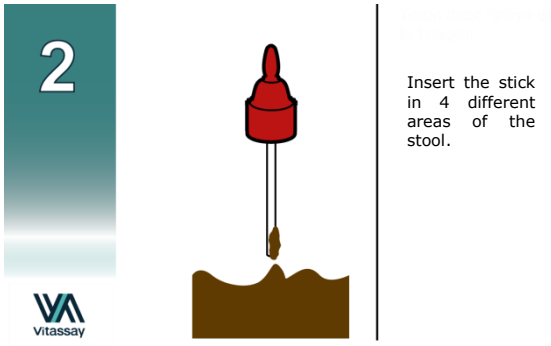
SPECIMEN PREPARATION

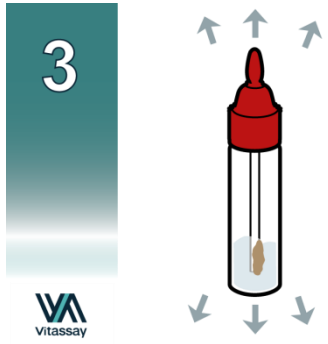
1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick in 4 different areas of the stool sample, taken approx. 125mg, (figure 2) and add it into the vial with diluent for the sample dilution. 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).



Vial for sample dilution.



Insert the stick in 4 different areas of the stool.



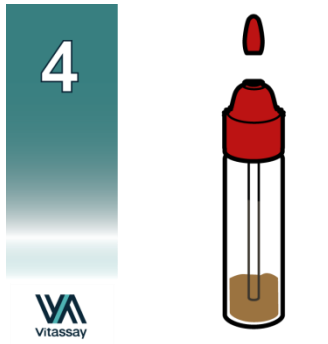
Put the sample into the vial, close the cap and shake.

PROCEDURE

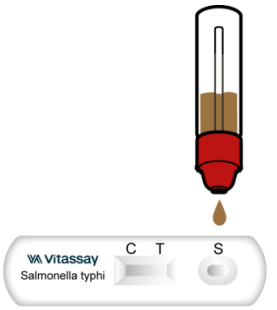
Allow the test, stool sample, controls and diluent to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until the performance of the assay.

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.



Cut the end of the cap.



Dispense 4 drops in the circular window marked with the letter S.

INTERPRETATION OF THE RESULTS

	**NEGATIVE** Only one green line in the control zone (**C**).	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. 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.

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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

- **Vitassay Salmonella typhi** must be carried out within 2 hours of opening the sealed bag.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.
- 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.
- The quality of **Vitassay Salmonella typhi** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of Salmonella typhi in fecal samples; nevertheless, a positive result should be followed up with additional laboratory techniques (biochemical and serological methods or by PCR) to confirm the results. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been evaluated and must be based in the correlation of the results with further clinical observations.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigens is lower than the detection limit. If symptoms or situation still persist, a Salmonella typhi determination should be carried out, on a sample from an enrichment culture.

EXPECTED VALUES

According to the World Health Organization, it is estimated that the yearly incidence of typhoid fever exceeds 21 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 commercial 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

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

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

Cross reactivity

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

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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2. MOHAMMAD ATIQUR RAHMAN. "Antimicrobial Resistance Patterns of Salmonella Typhi isolated from stool culture". Chattagram Maa-o-Shishu Hospital Medical College Journal, Vol 14, Issue 1, January 2015.

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

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