VITASSAY

Salmonella

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

IUE-7355029 Ed00 November 2016

CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

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

Simple, non-invasive and highly sensitive screening assay to make a presumptive diagnosis of Salmonella infection (salmonellosis).

INTRODUCTION

Salmonella spp. and Campylobacter spp. (Campylobacter coli and Campylobacter jejuni) are recognized as the leading causes of bacterial gastroenteritis followed by Shigella spp. and Shiga toxin-encoding Escherichia coli (STEC).

Foodborne diarrheal outbreaks represent an important global health problem.

Salmonella is an enteroinvasive pathogen that most commonly causes self-limiting gastroenteritis.

Approximately 5% of all patients develop septicemia and the effect on children, elderly, and immunocompromised patients can lead to more serious complications, including death.

Salmonella enteritidis is considered the most common serovar in human infections, and most of these infections are associated with poultry products.

PRINCIPLE

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

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

During the process, the sample reacts with the antibodies against Salmonella, 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**. 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** ▪ 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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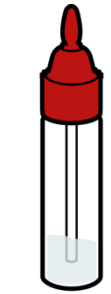
SPECIMEN PREPARATION

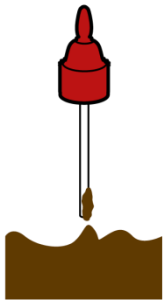
1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick in 4 different areas of the stool sample, taken approx. 125mg, (figure 2) and add it into the vial with diluent for the sample dilution.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

1



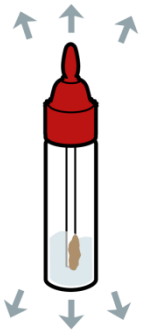
Vial for sample dilution.

2



Insert the stick in 4 different areas of the stool.

3



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

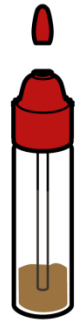
PROCEDURE

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** 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.

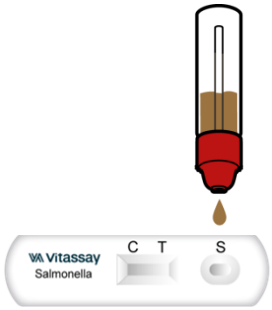
If the test does not run due to solid particles, stir the sample added in the sample window (S) with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.

4



Cut the end of the cap.

5



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 presence. No infection caused by Salmonella.
	**POSITIVE** In addition to the green line (**control line C**), a red line appears, (**test line T**)	There is presence of Salmonella. Salmonella infection, which might mean abdominal pain, diarrhea, mild fever, chills, headache, nausea and vomiting, develops 12-72 hours (but occasionally as long as 7 days) after infection.
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**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

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LIMITATIONS

- **Vitassay Salmonella** 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** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of Salmonella 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 determination should be carried out, on a sample from an enrichment culture.

EXPECTED VALUES

Food-borne illness in the United States accounts for an stimated 9.4 million cases of gastroenteritis, ≥50,000 hospitalizations, and 1,351 deaths each year.

Recent studies estimate that there are 80.3 million annual cases of Salmnella related diseases wordwide.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation was performed using **Vitassay Salmonella** 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	Positive	10	1	11
	Negative	0	33	33
	Total	10	34	44

Vitassay Salmonella vs Singlepath®Salmonella			
Sensitivity	Specificity	PPV	NPV
>99%	>97%	91%	>99%

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

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*	*Staphylcoccus aureus*
Escherichia coli O157:H7	*Shigella dysenteriae*	*Yersinia enterocolitica*

REFERENCES

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2. MARIA REGINA PIRES CARNEIRO; PEDRO HERNAN CABELLO; RICARDO LUIZ CAVALCANTI ALBUQUERQUE-JUNIOR; SONA JAIN; ALEXANDRE LUNA CANDIDO. "Characterization of a foodborne outbreak caused by Salmonella Enteritidis in Aracaju, State of Sergipe, Brazil". Revista da Sociedade Brasileira de Medicina Tropical 48(3):334-337, May-Jun, 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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