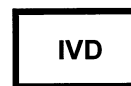




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Rapid-VIDITEST

Yersinia enterocolitica O:9

One step Yersinia enterocolitica O:9 Card test

Instruction manual

INTENDED USE:

The *Yersinia enterocolitica* O:9 Card is a rapid chromatographic immunoassay for the qualitative detection of *Yersinia enterocolitica* O:9 in human feces specimens in order to detect *Yersinia enterocolitica* O:9. Only for laboratory use.

INTRODUCTION:

This bacterium is a gram negative, coccoid shaped, non spore-forming bacillus of the genus *Yersinia*, family *Enterocateriaceae*. It is a facultative anaerobe and is motile at room temperature but non-motile at 37°C. Strains are usually 0.5-0.8 µm by 1-3µm in size. There are 6 biotypes (1A, 1B, 2, 3, 4 and 5 based on their genomic sequence) containing 50 different serogroups of *Yersinia enterocolitica*; however only certain serogroups are pathogenic for humans.

The principal animal reservoirs of non-human *Yersinia enterocolitica* infection include domestic animals such as swine, goats, cattle and horses, rodents and household pets such as dogs and cats. Man is an accidental host and is not necessary in the ongoing maintenance of transmission in nature.

The majority of human pathogenic strains are found in distinct serogroups (e.g. O:3, O:5.27, O:8 and O:9). In addition to colonizing the above-mentioned animal reservoirs as for *Yersinia enterocolitica*, *Yersinia pseudotuberculosis* resides in a number of avian species, including pigeons, turkeys, ducks, geese and canaries. Yersiniosis is found more commonly in countries with temperature climates rather than in tropical and subtropical regions. In colder climates, *Yersinia* infections occur especially during winter months.

The infection presents as an invasive diarrhea characterized by fever, abdominal pain, mucus- and blood-containing stool cultures. The incubation period for intestinal yersiniosis is about 3 to 7 days, and patients shed organisms in feces and remain infectious during the symptomatic period of about 2 to 3 weeks. Convalescent carriage of *Yersinia* in stool of untreated individuals may uncommonly extend for weeks to months in a small percentage of patients.

In addition, intestinal yersiniosis may mimic acute appendicitis.

PRINCIPLE OF THE TEST:

The *Yersinia enterocolitica* O:9 Card is a qualitative lateral flow immunoassay for the detection of *Yersinia enterocolitica* O:9 antigens in human feces samples. The membrane is pre-coated with monoclonal antibodies against *Yersinia enterocolitica* O:9 antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*Yersinia enterocolitica* O:9 antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured line always appears in the control line and serves as verification that sufficient volume is added, that proper flow was obtained and as an internal control for the reagents.

MATERIALS PROVIDED:

- Card tests
- Instructions for use
- Specimen collection vials with buffer

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Disposable gloves
- Timer

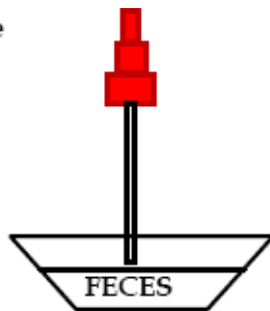
SPECIMEN COLLECTION AND PREPARATION:

Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C/36-46.4°F) for 1-2 days prior to testing. For longer storage (maximum 1 year) the specimen must be kept frozen at -20°C/-4°F. In this case, the sample will be totally thawed, and brought to room temperature before testing.

TEST PROCEDURE:

Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick four times into the fecal specimen to pick up the sample (approx. 125mg). Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add 125µL into the vial with buffer.

Pick up the sample



Mix the sample with the buffer

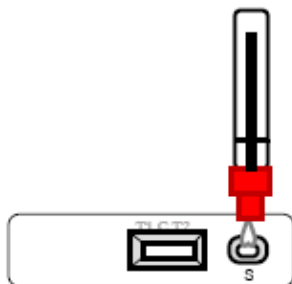


Break the cap



Allow the tests, stool samples and buffer to reach room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the *Yersinia enterocolitica* O:9 Card from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate card for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.



4 drops of the mixture "sample + buffer"

INTERPRETATION OF RESULTS



POSITIVE: Two lines appear across the central window, a **red** test line marked with the letter T and a **green** control line marked with the letter C.

NEGATIVE: Only one **green** line appears across the control line region marked with the letter C (control line).

INVALID: Total absence of the green control coloured band regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the red coloured test line in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL:

Internal procedural controls are included in the test:

- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:

1. *Yersinia enterocolitica* O:9 Card will only indicate the presence of *Yersinia enterocolitica* O:9 in the specimen (qualitative detection) and should be used for the detection of *Yersinia enterocolitica* O:9 antigens in feces specimens only. Neither the quantitative value nor the rate of increase in *Yersinia enterocolitica* O:9 antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown lines appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control green line.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *Yersinia enterocolitica* O:9 infection.
5. This test provides a presumptive diagnosis of *Yersinia enterocolitica* O:9 infection. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

The gastrointestinal tract is the portal of entry for most cases of yersiniosis. An inoculum of 10⁹ organisms is typically required to cause clinical infection. Routes of transmission of *Yersinia enterocolitica* and *Yersinia pseudotuberculosis* include fecal-oral spread via ingestion of contaminated food as the most common route. Erythrocyte and platelet transfusions contaminated with *Yersinia enterocolitica* have also been described in the USA and Europe, Australia and New Zealand. Over the last decade, *Yersinia enterocolitica* has emerged as an increasingly important agent of foodborne gastrointestinal outbreaks in the USA and elsewhere. In addition, several hospital outbreaks of *Yersinia enterocolitica* gastroenteritis have been reported.

PERFORMANCE

Sensitivity and specificity

It was performed an evaluation using *Yersinia enterocolitica* O:9 Card. The results were confirmed by an agglutination test (*Yersinia enterocolitica* Agglutination Kit, Progen). Sensitivity >99% and specificity >99%.

Cross-reactivity

It was performed an evaluation to determine the cross reactivity of *Yersinia enterocolitica* O:9 Card. There is not cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in feces:

- | | | |
|--------------------------------|---------------------------------|--------------------------------------|
| - <i>Campylobacter</i> | - <i>H. pylori</i> | - <i>Shigella</i> |
| - <i>Clostridium difficile</i> | - <i>Listeria monocytogenes</i> | - <i>Staphylococcus aureus</i> |
| - <i>E. coli</i> | - <i>Salmonella</i> | - <i>Yersinia enterocolitica</i> O:9 |

STORAGE AND STABILITY:

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.










PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

REFERENCES:

- R.A. Smego, J. Frean, H. J. Koornho. "Yersiniosis I: Microbiological and Clinicoepidemiological Aspects of Plague and Non-Plague *Yersinia* Infections". Eur J Clin Microbiol Infect Dis (1999) 18:1-15 Q Springer-Verlag 1999.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

 IVD	<i>In vitro</i> diagnostic device	 LOT	Batch code
	Use by		Manufacturer
	Consult instruction for use		Number of tests
	Keep dry	 REF	Catalogue Code
	Temperature limitation	DIL	Buffer (sample diluent)

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