



MEGACOR FASTest E.coli-K99 Strip Instructions

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MEGACOR FASTest E.coli-K99 Strip










INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit FASTest® E.coli-K99 Strip contains

- 2 or 10 dipsticks coated with monoclonal antibodies
- 2 or 10 sample tubes with 2.0 ml buffer diluent each
- 1 instructions for use

STABILITY AND STORAGE	
 15–25°C	Store at 15–25 °C
	Expiry date – see label
APPLICATION AND ABBREVIATIONS	
	For veterinary use only
	<i>In vitro</i> diagnosticum
	Follow instructions for use precisely
	Lot number
	Do not use test-kit components from different kits, lot numbers or beyond stated expiry date.
TL – TEST line, CL – CONTROL line, LF – Lateral flow	

LIABILITY

The entire risk due to the performance of this product is assumed by the purchaser. The manufacturer shall not be liable for indirect, special or consequential damages of any kind resulting from the use of this product.

ACCURACY

- **Sensitivity:** 96 %
- **Specificity:** 97 %
- **(Comparison Method:** E.M., ELISA)

INTRODUCTION

The diarrhoea pathogen *Escherichia coli* (E. coli) K99 (F5) is a highly infectious bacterium occurring worldwide. Normally, the bacteria appear together with other pathogens of the Neonatal Calf Diarrhoea Complex, leading to severe diarrhoea in calves. The prevalences differ, depending on the stock, between 3 and 54 %. Mostly, calves of the age between 1 and 5 days are affected. The different virulence factors (haemolysins, adhesins, enterotoxins (in ETEC) and Shiga toxins) of E. coli lead to various clinical symptoms of diarrhoea. E. coli K99 (F5) belongs to the enterotoxin-producing E. coli bacteria. These show specific surface structures, so-called fimbria (F5 antigens) attaching to enterocytes of the intestinal mucosa, thus leading to massive diarrhoea, partially with lethal consequences. The faecal-orally transmitted bacteria colonize in the distal small and large intestines. In young calves, small amounts of hydrochloric acid secretion in the abomasum prevent mortification of the E. coli bacteria, leading to a bacterial E. coli invasion of the intestine, together with secretory diarrhoea.

Caused by the high infectiveness, often a population problem arises. Here, next to aetiological diagnostics of all animals, especially older ones (asymptomatic chronic carriers!), the management of keeping and feeding shall be examined, too. The FASTest® E.coli-K99 Strip offers the veterinarian a fast and reliable on-site proof of E. coli K99 (F5) for a fast and targeted initiation of suitable therapy and prophylaxis measures and therefore a reduction of the calf loss rate.

INFORMATION ON THE SPECIMEN MATERIAL

Due to the normally inhomogeneous or nest-like dissemination of antigens in the faeces, the specimen material has to be mixed up homogeneously (spatula, vortex-mixer) before sampling. For the test, the required amount of faeces as described in point 4b / Specimen collection and preparation, is needed. The amount depends on the consistency of the sample. Use the attached spoon. Non-cooled (15–25 °C), the sample should be tested within 4 hours! At 2–8 °C, the sample can be stored up to 4 days, permanently at a minimum –20 °C.

Keep in mind that the sample material, as well as all used test-kit components, should have reached room temperature at the time of application. Endogenous and exogenous interfering substances of the sample (e. g. proteases, mucosa components, blood, but also viscosity, pH-value as well as grass and cat litter) can cause interferences (matrix effects) that can influence the target measurement. These can lead to an impaired LF and/or unspecific reactions on the TL and CL.

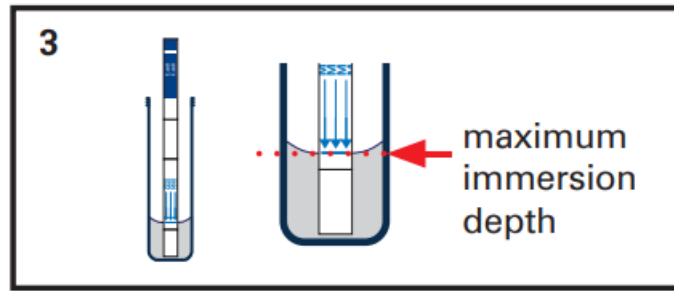
SPECIMEN COLLECTION AND PREPARATION



- Open the sample tube with the buffer diluent.
- Mix the faeces sample homogeneously (applicator, vortexer). Then mix the required sample volume (compact: 1 level spoon, pulpy: 2 level spoons, fluid-watery: 3 level spoons of faeces) steadily into the buffer diluent (fig.1).
- Close sample tube tightly and rotate it easily to get the mixture as homogeneous as possible (fig.2).
- For sedimentation of gross faeces particles place the sample tube on a flat and horizontal surface for 1–5 minutes.

TEST PROCEDURE

1. Remove the dipstick from its foil pouch shortly before use.



2. Introduce the dipstick vertically and with the arrows pointing downwards into the sample tube for at least 1 minute. The liquid level (meniscus!) must not exceed the blue horizontal line below the blue arrowheads (fig.3).
3. Remove the dipstick from the sample tube as soon as the sample-buffer mixture (SBM) has reached the CL. If so, the pink-purple CL will appear slowly but surely (fig.4 / 5). If the CL does not appear after 5–10 minutes, a new SBM must be prepared and sedimented for at least 5 minutes. The dipstick must be held only in the supernatant until the LF has reached the CL (see also 7. Precautions for users*).
4. Place the dipstick on a flat and horizontal surface for incubation.

READING OF THE TEST RESULT



Read the test result after 5 (max. 10) minutes. Positive test results may be observed earlier, depending on the concentration of antigen in the sample.

POSITIVE TEST RESULT

fig.4
POSITIVE TEST RESULT



- A pink-purple TEST line of any intensity (varying from very weak to strongly intensive) and a pink-purple CONTROL line appear.

NEGATIVE TEST RESULT

fig.5
NEGATIVE TEST RESULT



Only a pink-purple CONTROL line appears. This line indicates, irrespective of its intensity, that the test has been performed properly.

INVALID TEST RESULT

- No CONTROL line visible. The test should be repeated using a new dipstick.

PRECAUTIONS FOR USERS

- The guidelines for working in medical laboratories must be observed. It is recommended to wear disposable gloves and other personal protective equipment (protective clothing, possibly a face mask). Wash and disinfect hands after completing the test.
- Label sample material and associated sample tube to ensure a precise assignment.
- Use a new sample tube and a new dipstick for each sample.
- The buffer diluent contains low concentrations of toxic sodium azide as a preservative, therefore avoid skin / eye contact and/or ingestion.
- The sample material must be seen as potentially infectious and disposed of accordingly, together with the used test-kit components.

To avoid an application error / external influence (e. g. too much sample material, too short sedimentation time, components in the faeces that clog the pores of the suction pad), the test can be repeated. Use a new dipstick and carefully observe the sample preparation. It is advisable to only hold the dipstick in the supernatant when repeating the test until the LF has reached the CL.

TEST PRINCIPLE

The FASTest® E.coli-K99 Strip is based on latest rapid immunochromatographic technique. The Escherichia coli (E. coli) antigens in the faeces sample will react at the conjugate pad with mobile monoclonal antibodies bound to gold particles. Migrating ("lateral flow", LF) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed monoclonal anti-E.coli antibodies (mAbs) producing a pink-purple TEST line (TL). These mAbs guarantee a high level of specificity for the aetiological detection of E. coli. A correct test procedure will be indicated by a second, pink purple CONTROL line (CL). Please note the two light-green quality control lines on TL and CL. They indicate that the test membrane is of good quality and can be used.

INFORMATION FOR THE INTERPRETATION


- The interpretation of the test result should always be based on anamnestic and clinical data as well as the therapy and prophylaxis possibilities.
- Any non-described colour or contour variation of TL and CL within the indicated incubation time or after more than 10 minutes (e. g. greyish, shadow-like lines) has to be considered as an unspecific reaction and therefore as negative test result.
- TL can vary both in intensity (from weak to intense pink-purple) and width. Therefore, any pink-purple line appearing within the required incubation time is to be interpreted as a positive test result.
- Because of intermittent antigen shedding, with ongoing diarrhoea, a single negative test result should be confirmed by testing a serial faeces sample (individual testing of at least three consecutive faeces samples).

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- Veterinary Market By Vetlab Supplies Ltd
- Visit Our Website: www.vetlabsupplies.co.uk
- Telephone: 01798 874567
- email us: info@vetlabsupplies.co.uk

- **Manufacturer:** 6912 Hörbranz – AUSTRIA
- www.megacor.com

Documents / Resources

	MEGACOR FASTest E.coli-K99 Strip [pdf] Instructions FASTest E.coli-K99 Strip, FASTest, E.coli-K99 Strip, Strip
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References

-  [MEGACOR Diagnostik GmbH – Veterinary in vitro diagnostics](#)
-  [Wholesale Vet Supplies & Products for Practices & Labs | Vet Supplies Online UK](#)

Manuals+.