

tamaVet®

# Multi 2TD Test (Giardia, Cryptosporidium parvum) (test cassette)

REF. 1172067N-05 / REF. 1172667N-01



For veterinary use only

<b>DE</b>	Gebrauchsanweisung	2	<b>CZ</b>	Návod k použití	14
<b>EN</b>	Instructions for use	5		Symbols	19
<b>FR</b>	Instructions d'utilisation	8		Our Teams	20
<b>PL</b>	Sposób użycia	11			

This package insert contains information on the following tamaVet® Multi 2TD Tests:

Ref. Nr.:	Number of test cassettes	Packaging
1172067-N05	5	Test cassettes, individually sealed
1172667-N01	1	Test cassettes, individually sealed

### 1. Intended Use

The tamaVet® Multi 2TD Test is for use in the detection of specific antigens of the parasites *Giardia lamblia* (*syn. intestinalis/ duodenalis*) and *Cryptosporidium parvum* in **dog or cat faeces**. The test is intended for use as an aid in the diagnosis of a single or mixed infection of *Giardia lamblia* and *Cryptosporidium parvum*.

### 2. Introduction and Clinical Significance

*Giardia* (*Giardia lamblia*) and *Cryptosporidia* (*Cryptosporidium parvum*) are microscopic small intestinal parasites which have a worldwide distribution.

*Giardia* is one of the most common intestinal parasites in dogs and cats, although cats are more commonly affected than dogs. Clinical symptoms, such as diarrhea and weight loss, usually occur in juvenile or immunosuppressed animals, but in many cases an infection is asymptomatic. Giardiasis is diagnosed by the detection of versatile *Giardia* trophozoites or cysts in fresh faeces. Considering that the excretion of *Giardia* trophozoites and cysts is irregular and can also stop intermittently, repeated testing is recommended. At least three examinations of faecal samples over a period of approximately seven to ten days should be carried out before giardiasis may be excluded or diagnosed.

*Cryptosporidia* infections occur in both dogs and cats and are transmitted by oocysts. They often remain asymptomatic. In immunocompromised puppies, more severe symptoms such as small bowel diarrhea may occur. In cases of manifest diarrheal diseases, there is often a mixed infection with *giardia*, *cryptosporidia* or coronavirus.

With the help of the tamaVet® Multi 2TD, two of the foremost intestinal parasites in dogs and cats can be detected.

### 3. Test Principle

The tamaVet® Multi 2TD Test is a rapid **sandwich immunoassay**. The assay employs specific antibodies which capture either *Giardia* or *Cryptosporidium parvum* antigens from the sample and thus visualise the agent. The tamaVet® Multi 2TD Test is a highly sensitive immunoassay and comprises two test strips housed in a practical test cassette.

The tamaVet® Multi 2TD Test strips consist of a sample pad, a conjugate pad, a reaction membrane and an absorption pad. The conjugate pad contains specific latex-labeled anti-*Giardia* antibodies or gold-labeled anti-*Cryptosporidium parvum* antibodies. The reaction membrane is precoated with additional *Giardia* or *Cryptosporidium parvum* -specific antibodies immobilised in the test line region and, as an internal control, suitable antibodies immobilised in the control

line region. The absorption pad located at the end of the test strip takes up the fluid applied to the test cassette.

Following the application of the sample onto the test strips, the *Giardia* or *Cryptosporidium parvum* antigens present in the sample material react with the latex- or gold-labeled antibodies to form a complex in the conjugate pad. The fluid then migrates along the strips by capillary action. In the test line region, the formed complexes are detected by the immobilised capture reagent, causing the formation of a blue (*Giardia*) or red (*Cryptosporidium parvum*) line. The presence of a blue or red line in the test line region indicates a positive result. If the sample does not contain *Giardia* or *Cryptosporidium parvum* antigens, then no line will form in the test line region. Additionally, a blue/red line must form in the control line region, irrespective of the presence of *Giardia* or *Cryptosporidium parvum* antigens in the sample. This control line serves as an internal control and indicates that sufficient sample fluid has been applied to the test strip and that proper membrane wicking has occurred.

### 4. Reagents and Materials Supplied

Depending on the packaging unit, the tamaVet® Multi 2TD test kit contains:

- 1/5 tamaVet® Multi 2TD test cassette/s
- 1/5 sample tubes with 1 mL buffer solution
- 1/5 cotton swabs
- 1 package insert

### 5. Additional Materials Required

Timer

### 6. Storage & Stability

Test kits should be stored at room temperature (15-30°C) until the expiry date printed on the packaging. The test cassette should remain in the sealed foil pouch until use. Do not freeze tests. Care should be taken to protect the components of the test kit from contamination. Do not use test cassettes if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, specimen collection containers or reagents can lead to inaccurate results.

### 7. Warnings and Precautions

- For veterinary use only.
- Carefully read through the test procedure prior to testing.
- For single use only.
- Store tests between 15-30°C. Do not to freeze tests.
- Do not use tests beyond the expiry date.
- Do not use tests with damaged pouches.
- Perform the test within 60 minutes of removing the test cassette from the pouch.
- Test results interpreted after more than 10 minutes should be considered invalid.
- Please use the indicated amount of sample. An incorrect number of drops can lead to a false result.
- Place the test cassette on a smooth, flat surface whilst performing the test.
- Do not touch the reaction fields.

- Use only the test components included in the kit. Do not mix or replace the test components with components from a different kit.
- Avoid cross contamination by using a new sample tube and a new swab for each sample.
- Sample materials are potentially infectious. During the test procedure, adhere to standard guidelines for the handling of potentially infectious material and chemical reagents. The use of protective clothing (laboratory coat, gloves, eye protection) is recommended. Materials that have come into contact with the sample material should be disposed of in accordance with local regulations.

**8. Specimen Collection and Preparation**

The tamaVet® Multi 2TD Test was developed for the examination of **fresh dog or cat faeces**.

**General comments:**

- Pooled faecal samples are also suitable for testing.
- If testing is not to be carried out on the day of sample collection, the faecal sample can be stored for a maximum of 6 days at 2°C to 8°C.
- The faecal sample must be brought to room temperature (15-30°C) before performing the test.
- As the cysts are spread irregularly throughout the faeces, use the swab to thoroughly stir the faecal sample.
- Avoid picking up cat litter or other coarse particles during sample collection.
- Use the cotton swab to collect the faeces. It is sufficient when the cotton tip of the swab is covered with faeces.

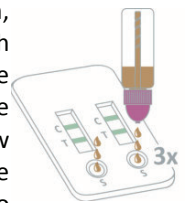


**9. Test Procedure**

1. Sample and kit components must be brought to room temperature (15-30°C) before performing the test.
2. Remove the test cassette from the sealed foil pouch and place it on a clean, level surface.
3. Open the sample tube and put the cotton swab with the faecal sample into the sample tube containing the reagent. Stir the fluid well with the cotton swab so that the sample material dissolves. For an optimal test result, it is recommended to wring the swab into the sample tube by squeezing the tube with the swab in the middle a couple of times to dissolve the sample. As a control measure, you should be able to observe the discoloration of the reagent.
4. Remove the swab and screw the sample tube closed. Shake the sample tube well, so that the reagent can react with the sample. Break off the tip of the sample tube by pressing it firmly.



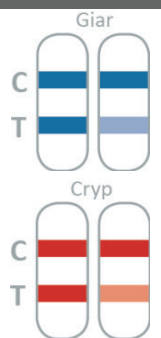
5. Holding the tube vertically with the lid open, dispense **3 drops** of sample solution to each sample well of the test cassette. Start the timer. If the liquid does not migrate sufficiently along the test strip within a few seconds, add another drop to the sample well until the liquid starts running. If too much faeces is in the sample well you can also touch the tip of the cotton swab into the sample well to reactivate the test run.
6. Read the results 10 minutes after starting the timer. **Do not interpret the result after more than 10 minutes.** The test and the result are considered as invalid after this period.



**10. Result Interpretation**

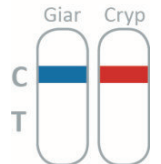
**Positive result**

The test is positive when a blue/red control line (C) and a blue/red test line (T) are visible in the reaction area. *Giardia- or Cryprosporidium parvum* antigens have been detected in the sample material. When a weakly defined test line appears, the test result is nevertheless positive.



**Negative result**

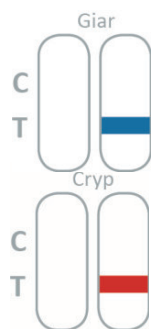
The test is negative when only a blue/red control line (C) is visible in the reaction area. No *Giardia or Cryprosporidium parvum* antigens have been detected in the sample material.



**Invalid result**

If no control (C) line is visible after the test was performed, the test is invalid. All results that show no control line after the denoted time must be rejected. Review the test procedure and repeat the test with a new test cassette.

If problems continue, discontinue using the test kit and contact your distributor.



**Possible test results:**

- Both tests are positive (C- and T-Line appear on both reaction fields).
- Both tests are negative (only the C-lines appear).
- One test is positive (in addition to both C-lines, a T-line appears in only one reaction field).

**11. Quality Control**

An internal procedural control is included in the test cassette:

A blue/red line forming in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

In addition, a green/blue line can be observed in the reaction fields of both the control and test line region before starting the test. The lines are considered to be a quality control method and will be washed away by the sample liquid during the test.

**12. Limitations**

- Test results must be interpreted in the light of all medical findings and never individually. All test results which do not correlate with the clinical picture must be repeated. Positive results detected with the tamaVet® veterinary rapid tests must be approved with another analytical method.
- There is a possibility that the test result will be falsified by technical errors, errors in the experiment, or by substances or factors that influence the test and have not been mentioned here.

**13. Performance Characteristics**

	Sensitivity	Specificity	PPV/ NPV	OA
<b>Giar</b>	96.0%	97.2%	98.0% 94.6%	96.5%
<b>Cryp</b>	99.9 %	95.9%	96.3% 99.9%	98.0%

PPV = Positive predictive value

NPV = Negative predictive value

OA = Overall agreement











Comparison method: ELISA, Study (2013 and 2014)











**14. References**

1. Krankheiten der Katze (Hrsg.: M. Chr. Horzinek, Vera Schmidt, Hans Lutz) Enke, 4. Auflage, 2005, S. 199 – 200
2. Innere Medizin der Kleintiere (von Richard W. Nelson – C. Guillermo Couto) Elsevier, 2006, S. 47
3. Praktikum der Hundeklinik (Hrsg.: H. G. Niemand, P. F. Suter) Parey, 9. Auflage, 2001, S. 350ff, S. 364
4. ESCCAP (Adaption der ESCCAP-Empfehlung für die Schweiz) Nr. 6, Mai 2013, S. 14 ff



Rev. 1, 2019-03-26 HM/RR

Symbol	Deutsch	English	Français	Español	Italiano	Polski
	CE Konformitätszeichen	CE marking of conformity	Conforme aux normes européennes	Conformidad europea	Conformità europea	Znak zgodności CE
	Gebrauchsanweisung beachten	Consult instructions for use	Consulter la notice d'utilisation	Consúltense las instrucciones de uso	Consultare le istruzioni per l'uso	Przestrzegać instrukcji obsługi
	<i>in-vitro</i> -Diagnostika	<i>in-vitro</i> diagnostic medical device	Dispositif médical de diagnostic <i>in-vitro</i>	Producto sanitario para diagnóstico <i>in-vitro</i>	Dispositivo medico- diagnostico <i>in-vitro</i>	Tylko do diagnostyki <i>in-vitro</i>
	Temperaturbegrenzung	Temperature limitation	Limites de température	Límite de temperatura	Limiti di temperatura	Temperatura przechowywania
	Chargenbezeichnung	Batch code	Numéro de lot	Código de lote	Codice lotto	Numer serii
	Nicht zur Wiederverwendung	Do not reuse	Ne pas réutiliser	No reutilizar	Non riutilizzare	Tylko do jednorazowego użytku
	Verwendbar bis	Use by	Utiliser jusqu'au	Fecha de caducidad	Utilizzare entro	Data ważności
	Bestellnummer	Catalogue Number	Référence du catalogue	Número de catálogo	Riferimento di Catalogo	Numer katalogowy
	Hersteller	Manufacturer	Fabricant	Fabricante	Fabbricante	Producent
	Ausreichend für <n> Ansätze	Sufficient for <n> tests	Suffisant pour "n" tests	Suficiente para <n> utilizaciones	Sufficiente per "n" saggi	Wystarczający na <n> Powtórzeń

Symbol	Português	Český	Suomi	Svenskt	Nederlands	Dansk	Norsk
	Conformidade com as normas europeias	CE certifikát	CE-merkitty	CE-märkning	CE-markering	CE-mærkning	CE standardisert
	Consultar as instruções de utilização	Viz návod k použití	Katso käyttöohjetta	Läs bruksanvisningen	Raadpleeg de gebruiksaanwijzing	Se brugsanvisningen	Les bruksanvisning nøye
	Dispositivo médico para diagnóstico <i>in-vitro</i>	Diagnostický zdravotnický prostředek <i>in-vitro</i>	<i>in-vitro</i> - diagnostiikkaan tarkoitettu lääkinnällinen laite	Medicinteknisk produkt avsedd för <i>in-vitro</i> -diagnostik	Medisch hulpmiddel voor <i>in-vitro</i> diagnostiek	Medicinsk udstyr til <i>in-vitro</i> -diagnostik	<i>in-vitro</i> diagnostic medisinsk enhet
	Limites de temperatura	Teplotní omezení	Lämpötilarajat	Temperatur- begränsning	Temperatuurlimiet	Temperatur- begrænsning	Temperatur begrænsning
	Código do lote	Kód šarže	Eräkoodi	Satsnummer	Code van de partij	Batchkode	Merking
	Não reutilizar	Pro jednorázové použití	Kertakäyttöinen	Får inte återanvändas	Niet opnieuw gebruiken	Må ikke genbruges	Må ikke brukes om igjen
	Prazo de validade	Spotřebujte do	Käytettävä viimeistään	Används före	Houdbaar tot	Udløbsdato	Tidtaking
	Número de catálogo	Katalogov číslo	Luettelnumero	Listnummer	Catalogus nummer	Best il l ingsnummer	Katalog nummer
	Fabricante	Výrobce	Valmistaja	Tillverkare	Fabrikant	Fabrikant	Produsent
	Suficiente para <n> test	Dostačuje pro <n> testů	Lukumäärä <n> test	Räcker till <n> test	Voldoende voor <n> test	Tilstrækkeligt til <n> test	Tilstrækkelig for<n> tester

## Our Teams

### Germany:

#### Regensburg

Tel: +49 941 290 10-0

Fax: +49 941 290 10-50

#### Moers

Tel: +49 2841 99820-0

Fax: +49 2841 99820-1

### Austria:

Tel: +49 941 290 10-29

Free Tel: 0800 291 565

Fax: +49 290 10-50

Free Fax: 0800 298 197

### UK & Ireland:

Tel: +49 941 290 10-18

Free Tel –UK: 0808 234 1237

Free Tel – IRE: 1800 555 080

Fax: +49 290 10-50

### France:

France Tel: 0800 915 240

France Fax: 0800 909 493

### Switzerland

Swiss Tel: 0800 564 720

Swiss Fax: 0800 837 476

### Belgium

Belgium Tel: 0800 718 82

Belgium Fax: 0800 747 07

### Luxembourg

Lux. Tel: 800 211 16

Lux. Fax: 800 261 79

### Spain:

Tel: +49 941 290 10-759

Free Tel: 900 938 315

Fax: +49 941 290 10-50

Free Fax: 900 984 992

### Italy:

Tel: +49 941 290 10-34

Fax: +49 941 290 10-50

### Poland:

Tel: +49 941 290 10-44

Free Tel: 00 800 491 15 95

Fax: +49 941 290 10-50

Free Fax: 00 800 491 15 94

### Portugal:

Tel: +49 941 290 10-735

Tel. Verde: 800 849 230

Fax: +49 941 290 10-50

Fax Verde: 800 849 229

### Netherlands:

Tel: +31 30 75 600

Free Tel: 0800 0222 890

Fax: +31 70 30 30 775

Free Fax: 0800 024 9519

### Nordic countries (Finland, Norway, Sweden, Denmark):

Tel: +31 703075 607

Free Tel: +45 80 88 87 53

Tax: +31 703030 775

### Laboratory Diagnostics Team:

Tel: +49 941 290 10-40

Fax: +49 941 290 10-50



nal von minden GmbH

Carl-Zeiss-Strasse 12 • 47445 Moers • Germany

www.nal-vonminden.com • info@nal-vonminden.com

Fon: +49 2841 99820-0 • Fax: +49 2841 99820-1