User´s Manual

Camelid Ig One-Step

For the detection of Camelid Ig in serum or plasma samples of newborn calves to confirm colostrum intake.

REF **K1005-AB01**

Σ **6**

Effective, januari 2011

Please use only the valid version of the package insert provided with the kit.
Verwenden Sie nur die jeweils gültige, im Testkit enthaltene, Arbeitsanleitung.
Si prega di usare la versione valida dell'inserto del pacco a disposizione con il kit.
Por favor, se usa solo la version valida de la metodico técnico incluido aqui en el kit.

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1 INTRODUCTION

New-born camelid calves are born with a naïve immune system meaning the calf has essentially no ability to mount an immune response to infection. Therefore the importance of the first feed of colostrum to the newborn calf cannot be underestimated.

Colostrum contains three different types of immunoglobulins, IgG, IgA and IgM. As immunoglobulins do not pass through the cow's placenta to her foetus, the only way a cow can pass on adequate immunity to her calf is through colostrum. These maternal antibodies allow the calf to obtain a passive immunity until its own immune system can produce antibodies.

Maternal immunoglobulins (Ig, antibodies) derived from colostrum are the single most important factor in protecting a neonatal calf from disease. Calves must rely on adequate intake and absorption of colostral Ig for resistance to infectious diseases during the first few weeks of life. Ingestion of colostrum must occur soon after birth since the ability of the gut to absorb Ig can only be efficiently absorbed through the calve's intestinal wall during the first 12 – 24 hours of life.

Inadequate colostrum intake can result in reduced immunity and lead to bacterial infections, arthritis, pneumonia and enteritis.

Low Ig concentration occurs when Ig from cow's blood does not reach protective levels in calf's blood within a certain period of time. Level of IgG considered to be protective depends on many factors relating to the calf's environment, management, etc.

Generally it is accepted that IgG level of serum of normal, healthy calve is > 8 mg/mL within 24 hours after birth. The calve has insufficient Ig if the serum concentration is < 5 mg/mL

This Camelid Ig One-Step test allows the veterinarian to determine practically, rapidly and accurately the Ig levels of the calf.

2 INTENDED USE OF THE TESTKIT

This One- Step Test is intended to use as practical/routine screening test that can be done in a few minutes. This test kit is designed to detect Camelid Ig by use of a Rapid Immunochromatic Assay.

3 PRINCIPLE OF THE TEST KIT

The Camelid Ig One-Step Test is based on the blocking principle for the detection of Camelid Ig. The specific immunoglobulin's directed to Camelid immunoglobulin's are immobilized to the capture zone "T". Camelid Ig in a sample that is applied to the strip at the sample zone "S" will bind to the gold particles which then migrate to zone "T". No colour change in zone "T" indicates a positive test. Specific immunoglobulin reactive with colloid gold is immobilized in the control zone "C", which binds the gold conjugate to indicate that the test is working properly.

4 CONTENTS

- 6 x pouches, each containing 1 test strip and 1 pipette
- 6 x vials containing 2000µL buffer
- 1x protocol

5 HANDLING AND STORAGE OF SPECIMENS.

The One-Step should be stored at room temperature (± 21 ˚C). An unopened package can be used until the expiry date. An opened package must be used immediately. If the conditions are no longer fulfilled the test can no longer be used. Avoid freezing and heating as this will contribute to destruction of the test. Samples may be used fresh or may be kept frozen below -20˚C before use.

6 SAMPLE MATERIAL

It is advised to test serum or plasma samples, tissue culture samples can also be tested. Do not use hemolytic or lipaemic serum.

7 TEST PROTOCOL

1. Unpack the test strip and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Add 1 drop of serum/ plasma to the sample vial using the pipette (fig 1).
3. Mix well using the pipette
4. Add 3 drops of the mixture to the sample zone using the pipette (fig 2).
5. Read the results after 20-25 minutes (* see IX; Validation of the test).

Figure 1

Figure 2

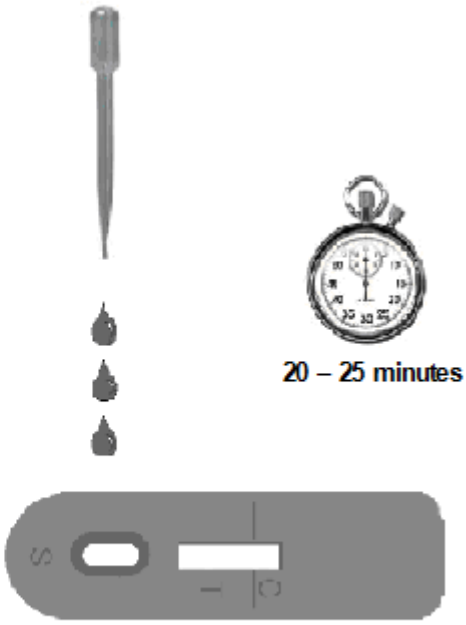


Figure 3

8 PRECAUTIONS

- Handle all biological materials as though capable of transmitting infectious diseases.
- Do not pipette by mouth.
- Do not eat, drink, smoke, prepare foods or apply cosmetics within the designated work area.
- Do not use components which passed the expiry date and do not mix components from different serial lots together.
- Optimal results will be obtained by strict adherence to this protocol. Careful pipetting and sampling throughout this procedure are necessary to maintain precision and accuracy.
- Each test strip is ultimately used as an optical reference. Therefore, do not touch the surface of the test strip and protect it from damage and dirt.

9 VALIDATION OF THE TEST

To validate an EVL One-Step a control line should always be visible at control zone “C”. If no control line is visible the test should be considered invalid. * Results should be read in the given time. Results read after the given time should be considered invalid. Invalid tests should be repeated with a new test.

10 INTERPRETATION OF TEST RESULTS

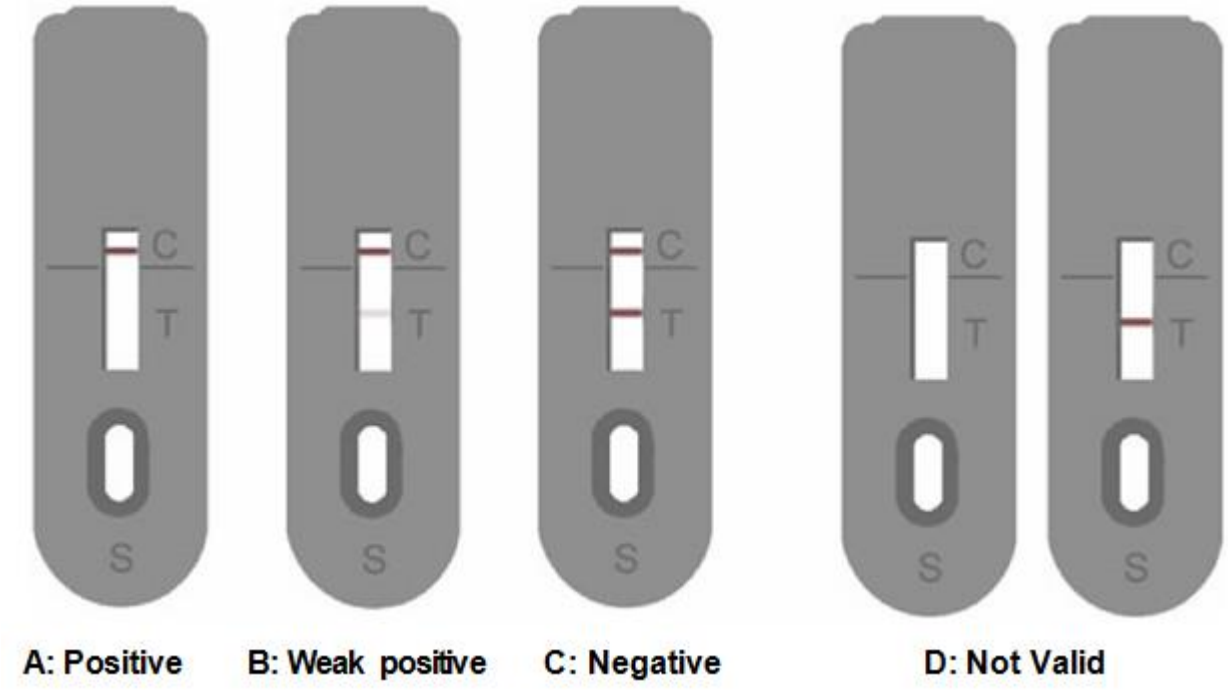
Positive:
Only one line is visible in zone “C” (fig. A). The sample contains Camelid Ig concentration >4 mg/mL.

Weak Positive:
Two lines are visible, a weak line in zone “T” and a line in zone “C” (fig. B) which is equal or stronger than the line in zone “T”. The sample contains Camelid Ig concentration 2 - 4 mg/mL.
Positive results may vary in optical density due to variations in Camelid Ig concentrations in the sample.

Negative:
Two lines are visible in zone “T” and zone “C” (fig. C). The sample contains Camelid Ig concentration < 0.5 mg/ml.
Negative results may vary in optical density due to variations in Camelid Ig concentrations in the sample.

Not valid:
No line is visible in zone “C” (fig. D). Repeat the test procedure.

Important:
A positive result should be confirmed by ELISA . Diseased, but negative tested patients should be retested within 2-3 weeks.



SYMBOLS USED WITH EVL ASSAYS

Symbol	English	Deutsch	Français	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità

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In case of problems or questions contact EVL.