

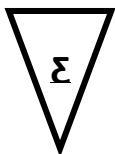
User's Manual

Bovine Ig One-Step

For the detection of Bovine Ig in serum or plasma samples of new-born calves to confirm colostrum intake



B1005-AB01



24

January 2022

Please use only the valid version of the package insert provided with the kit.

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2. Introduction

New-born 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 new-born calf cannot be underestimated.

Colostrum contains three different types of immunoglobulins; IgG, IgA and IgM. As immunoglobulins do not pass through the cows 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 colostrum 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 calves 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 occur when Ig from cows blood does not reach protective levels in calves blood with a certain period of time. Level of Ig considered to be protective depends on many factors relating to the calves environment, management, etc.

Generally it is accepted that IgG level of serum of a normal, healthy calf is > 8 mg/ml within 24 hours after birth. The calf has insufficient Ig if the serum concentration is < 5 mg/ml. This Bovine Ig One-Step test allows the veterinarian to determine practically, rapidly and accurately the Ig levels of the calf.

3. Intended use of the test kit

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 Bovine Ig by use of a rapid immunochromatic assay.

4. Principle of the test kit

The Bovine Ig One-Step is a blocking test for the detection of Bovine Ig in serum or plasma samples of new-born calves. The specific immunoglobulins directed to Bovine immunoglobulins are immobilized to the test zone "T". Bovine Ig in a sample that is applied to the strip at the samples zone "S" will bind to the gold particles which then migrate to zone "T". **No colour change** in zone "T" indicates a positive test. Labelled colloidal gold particles are also immobilized on the test strip in the control zone "C", to indicate that the test is working properly.

5. Contents

- 24 x Pouches, each containing 1 test strip and 1 pipette
- 24 x Buffer vials
- 1 x Protocol

6. Handling and storage of specimens

The One-Step should be stored at room temperature ($\pm 21^{\circ}\text{C}$). 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.

7. Sample material

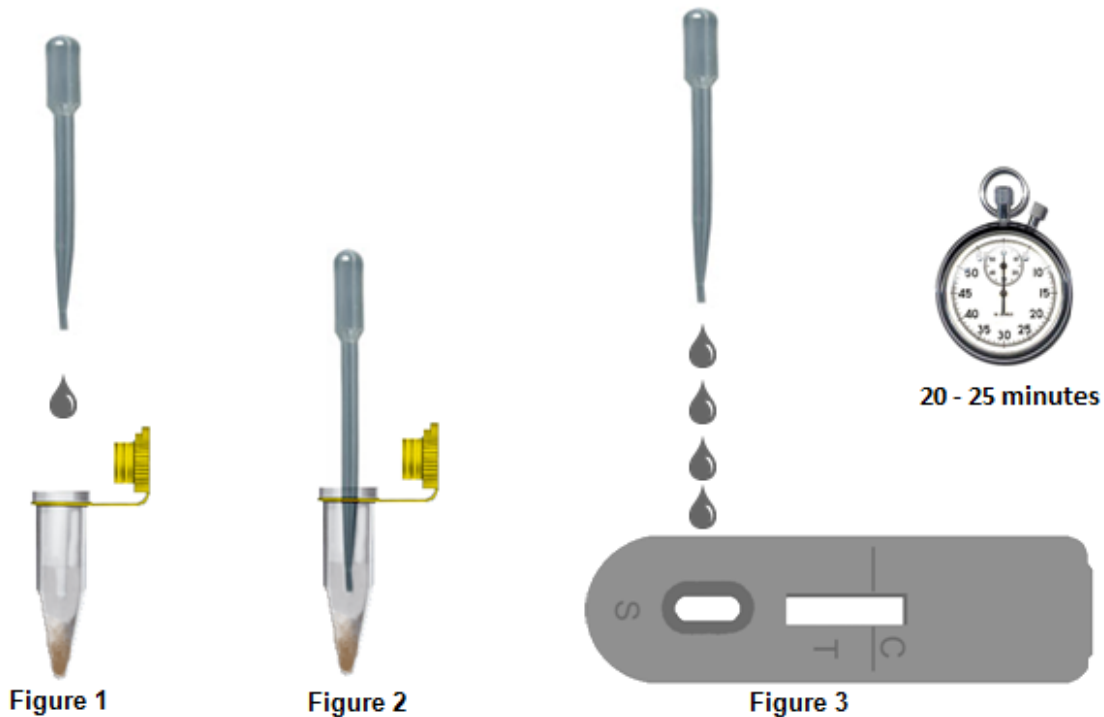
It is advised to test fresh serum or plasma samples. Do not use haemolytic or lipemic serum.

8. Precautions

- Handle all biologicals 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 serials 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. 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 buffer vial using the pipette (Figure 1).
3. Mix well by using the pipette (Figure 2).
4. Add **4 drops** of the buffer vial containing the sample, with the included pipette **slowly** to the sample zone "S" (Figure 3).
5. Read the result after 20 – 25 minutes (for the interpretation of the test result see chapter 10 and chapter 11).



10. 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.

11. Interpretation of the test results

Positive:

One line is visible in zone "C" (Figure A). The sample contains Bovine Ig concentrations > 4 mg/ml.

Weak positive:

Two lines are visible, a weak line in zone "T" and a line in zone "C" (Figure B). The sample contains Bovine Ig concentrations of 2 – 4 mg/ml.

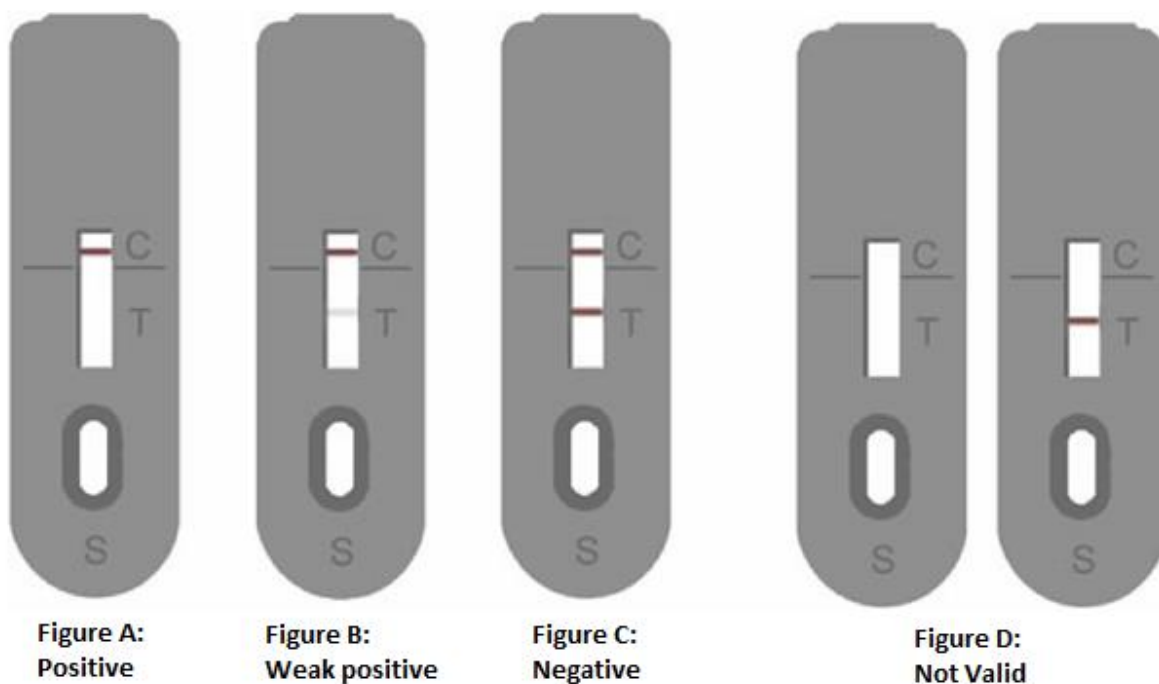
Positive results may vary in optical density due to variations in Bovine Ig concentrations in the sample.

Negative:

Two lines are visible in zone "T" and zone "C" (Figure C). The sample contains Bovine Ig concentration of $< 0,5$ mg/ml.

Not valid:

No line is visible in zone "C" (Figure D). Repeat the test procedure, with a new test cassette.





12. Symbols used with EVL ASSAYS

<u>Symbol</u>	<u>English</u>
	Consult instructions for use
	European Conformity
	In vitro diagnostic device
	For research use only
	Catalogue number
	Lot/ No. / Batch code
	Contains sufficient for <n> tests
	Storage Temperature
	Expiration Date
	Legal Manufacturer
Distributed by	Distributor
Content	Content
Volume/No.	Volume / No.

The entire risk as to the performance of these products is assumed by the purchaser. EVL shall not be liable for indirect, special or consequential damages of any kind resulting from use of the products. In case of problems or questions contact EVL.