

User's Manual

Horse Ig One-Step

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

REF E1001-AB01

Σ 6

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

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2. Introduction

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

Colostrum contains three different types of immunoglobulins, IgG, IgA and IgM. As immunoglobulins do not pass through the mare's placenta to her foetus, the only way a mare can pass on adequate immunity to her foal is through colostrum. These maternal antibodies allow the foal 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 foal from disease. Foals 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 foal'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 mare's blood does not reach protective levels in foal's blood within a certain period of time. Level of IgG considered to be protective depends on many factors relating to the foaling environment, management, etc.

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

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

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 Horse Ig by use of a rapid immunochromatographic assay.

4. Principle of the test kit

The Horse Ig One-Step test is based on the blocking principle for the detection of Horse Ig. The purified horse specific immunoglobulins are conjugated to colloidal gold particles and the horse specific immunoglobulin is immobilized on the strip in the test zone "T".

Horse 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. 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

- 6 x Pouches, each containing 1 test strip and 1 pipette
- 6 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 unopened 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

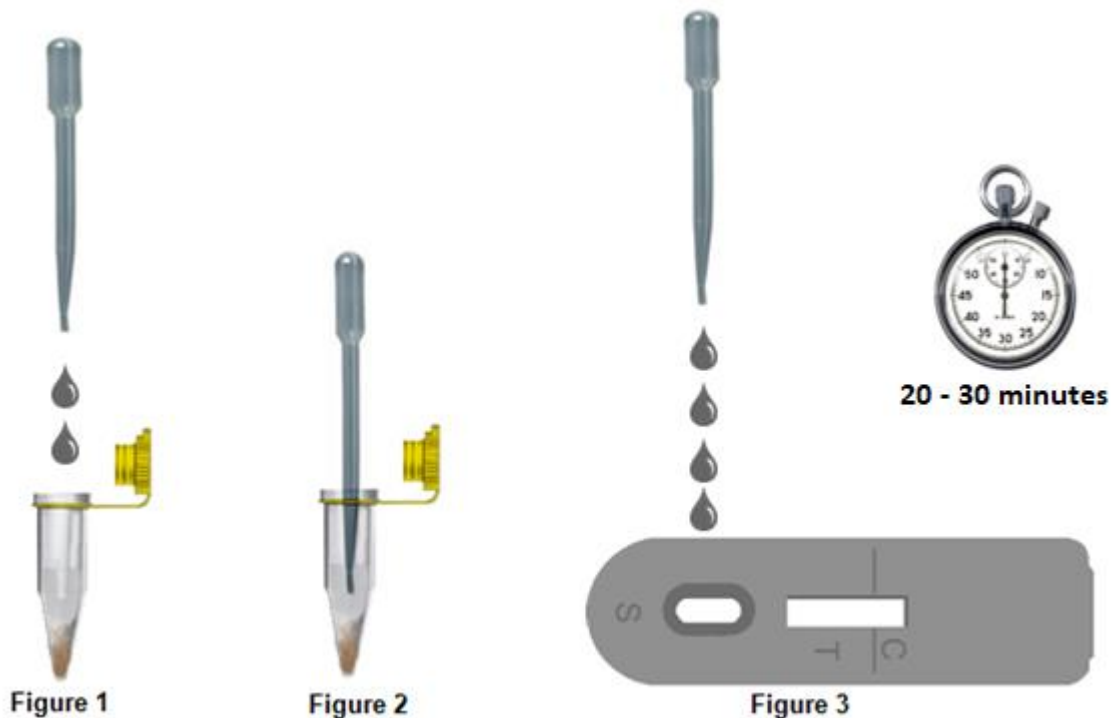
It is advised to test serum or plasma. Do not use haemolytic or lipemic serum.

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 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, swab and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Add **2 drops** 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 – 30 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:

Only one line is visible in zone "C" (Figure A). The sample contains Horse Ig concentration > 8 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 Horse Ig concentration 5 – 8 mg/ml.

The intensity of line "T" will vary depending on the concentration of Horse Ig in de sample.

Negative:

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

Not valid:

No line is visible in zone "C" (Figure D). Repeat the test procedure.

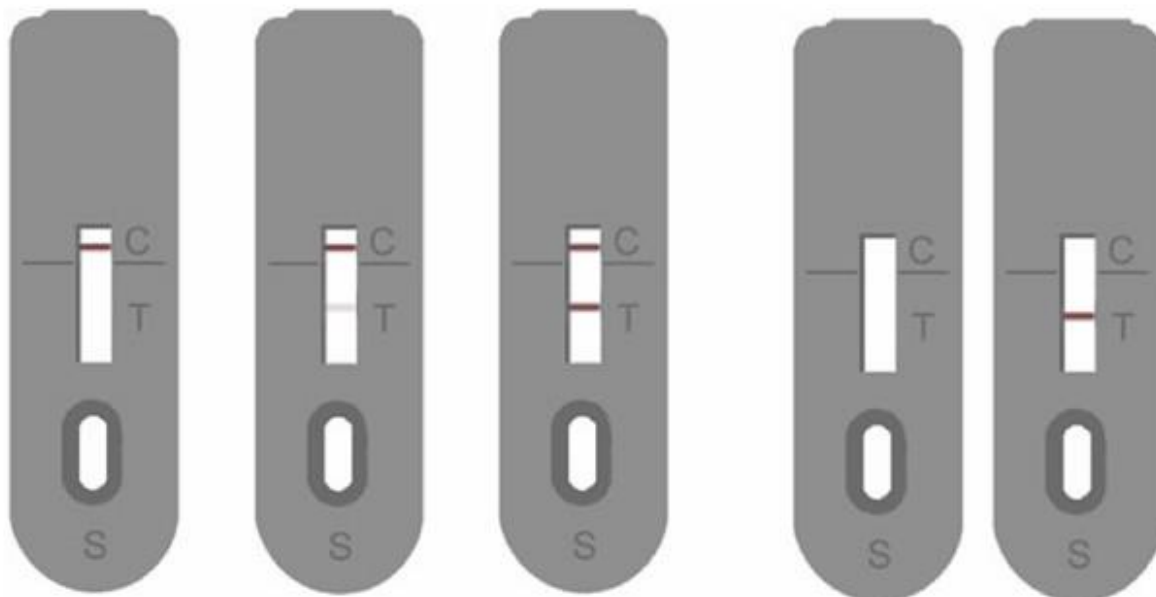


Figure A:
Positive

Figure B:
Weak positive

Figure C:
Negative

Figure D:
Not Valid

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. |

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