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LOMINA ASFV Ab P30/P54/P72 Test

Instructions for Use (IFU)

[PRODUCT NAME]

LOMINA ASFV Antibody Test

[PACKING SPECIFICATION]

Variant	1 piece in a package - box	1 piece in a package - pouch	5 pieces in a package - box	50 pieces in a package - box
Catalogue Nr.	LaV-ASFV--Ab/1B	LaV-ASFV--Ab/1P	LaV-ASFV--Ab/5B	LaV-ASFV--Ab/25B

[INTRODUCTION]

African swine fever virus (ASFV) is a highly contagious viral disease in domestic pigs and wild boars. (ASFV) is a large double-stranded DNA virus (the only member of the Ascarviridae family) with a complex molecular structure. Its large genome, which encodes multiple virulence factors, allows efficient replication, which occurs predominantly in the cytoplasm of monocytes and macrophages. ASFV also has the ability to interfere with cellular signalling pathways, leading to various modulations in the interferon synthesis profiles and other cytokines. ASFV infects domestic pigs, wild boars (Sus scrofa), (also warthogs and bush pigs) as well as soft ticks (Ornithodoros erraticus), which probably act as transmitters. The incubation period is reported to be 4 to 19 days in naturally-acquired cases. The morbidity rate for African swine fever can approach 100% in naïve herds of domesticated pigs. Cumulative mortality depends on the virulence of the isolate, and can range from < 5% to 100%. It is usually 30- 70% in subacute cases.

[INTENDED USE]

The LOMINA ASFV Antibody Test (P30/P54/P72) is a Lateral Flow chromatographic immunoassay for the qualitative detection of P30 antibody, P54 antibody and P72 antibody proteins of the African swine fever virus (ASFV) in veterinary serum or plasma samples in vitro.

P30 protein, P54 protein and P72 protein are expressed in the early, middle and late stage of the ASFV infection. The detection of corresponding antibodies helps in diagnosis and monitoring the complete infection cycle.

[TEST PRINCIPLE]

The LOMINA ASFV Antibody Test (P30/P54/P72) is a Lateral Flow chromatographic immunoassay based on double antigen sandwich format for the qualitative detection of P30 antibody, P54 antibody and P72 antibody to African Swine Fever Virus in veterinary serum or plasma In Vitro. The test cassette has three testing windows. Each testing window has T (test) region and C (control) region. The membrane is pre-coated with ASFV antigens. During testing, antibody to ASFV, if present in matrix specimen, will react with ASFV antigen coated colloidal gold particles in the test strip. The mixture then migrates due capillary effect trough the membrane while causing chromatographic reaction of ASFV antigens on the membrane in the test line region. If the specimen contains antibodies of African Swine Fever Virus, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain African Swine Fever Virus antibodies, a colored line will not appear in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[CONTENT OF PRESENTATION]

1. DETECTION CARD composed of:
   - P30 strip containing P30 specific antigens labeled by colloidal gold particles.
   - P54 strip containing P54 specific antigens labeled by colloidal gold particles.
   - P72 strip containing P72 specific antigens labeled by colloidal gold particles.
2. Humidity absorbing pad.
3. Stabilization fluid - bottle containing 300 ul (+/-5%) of buffer that are being used as bixing tubes.
4. Dripping lid for safe sample (matrix) mixing (50ul).
5. Sterile Lancet for blood collection.
6. Dropper (1drop 25ul).
7. Instruction for Use.

[MATERIALS NOT PROVIDED]

Stopwatch / a clock for measuring the time duration of the test.

[STORAGE CONDITIONS]

1. The test package shall be stored at 2°C to 30°C.
2. The components of different batches must not be mixed.
3. Each component is stable under the specified conditions, and can reach the specified validity period of the kit.
4. Kit contents are stable until the expiration dates marked on its outer packaging and containers, its validity period is set to 24 months (based on stability study).
5. Prolonged exposure to heat and humidity will make the reagent useless.

[TRANSPORT CONDITIONS]

The test package may be temporarily transported at -10°C.

[SPECIMEN COLLECTION AND QUALITY]

Specimen Collection:

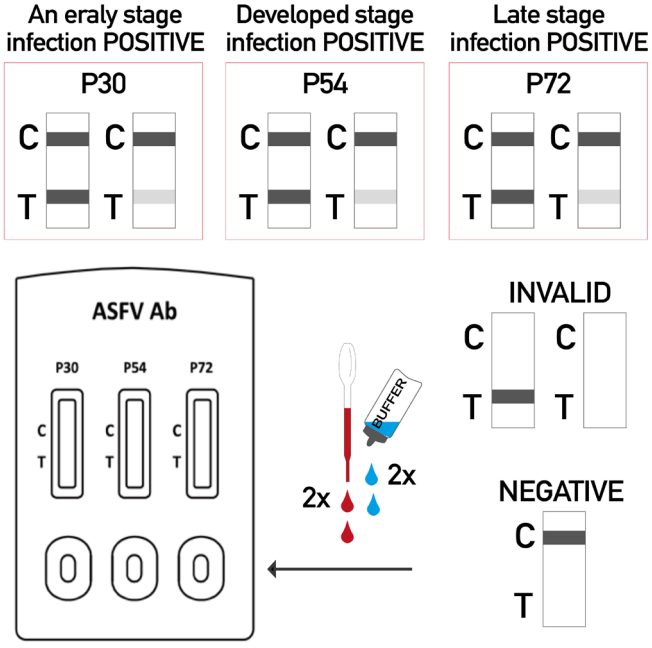
- Use only clear, non-hemolyzed blood specimens.
- Do not use specimens that are obviously contaminated.
- Use freshly collected samples for best test results.
- After sampling, the appropriate buffer provided in the kit shall be used as soon as possible. No other type of solution should be used to store the sample!
- Long-term storage of the samples is not recommended.
- If necessary, Serum specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept below -20 °C/-80 °C.

[OPERATING STEPS]

1. Allow the test cassette, specimen, buffer, and/or controls to equilibrate best at temperature of (10-30 °C) prior to testing.
2. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening.
3. Separate serum from blood as soon as possible to avoid hemolysis or apply blood amd mix it well with the buffer immediately after collection.
4. If using lancet, press the lancet, on the side from where the cap was extracted; the tip retracts automatically and safely after use.
5. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 2 drops of serum or blood (approximately 50 µl) to the specimen well (S) of the test cassette, then quickly add 2 drops of buffer and start the timer.
6. Wait for the colored line(s) to appear. Read results at 10 minutes.
7. Do not interpret the result after 20 minutes.

[INTERPRETATION OF TEST RESULTS]

1. Positive: The presence of both C line and T line (any testing window), regardless of T line being strong or faint.
2. Negative: Only clear C line appears.
3. Invalid: No colored line appears in C region, regardless of T line's appearance.



[PRECAUTIONS !]

- Please read all the information in this package insert before performing the test.
- For veterinary in vitro diagnostic use only.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Store in a dry place at 2-30°C (36-86°F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with a veterinary doctor or similar professional.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Keep out of the reach of children.
- The used test should be discarded according to local regulations.
- Use safety protective equipment (gloves, glasses etc.)

[OPERATING STEPS]

1. The LOMINA ASFV Antibody Test (P30/P54/P72) has been intended for veterinary in vitro diagnostic use only. This test should be used for the detection of antibodies to ASFV in serum or full blood specimens. Neither the quantitative value nor the rate of increase in ASFV antibody concentration can be determined by this qualitative test.
2. The test will only indicate the presence of antibodies to ASFV in the specimen and should not be used as the sole criterion for the diagnosis of ASFV infection or immune state.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA or PCR etc.
4. If the test result is negative and clinical symptoms persist, or visible post mortem signs are present additional follow up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of ASFV infection or immune state.
5. Carefully observe National veterinary Burreaus for instructions.

[INTERPRETATION OF TEST RESULTS]

1 Correia S., Ventura S., Parkhouse R.M. 2013. Identification and utility of innate immune system evasion mechanisms of ASFV. Virus Research 173: 87-100

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3 Cubillos C., G.mez-Sebastian S., Moreno N., Nu.ez M.C., Mulumba-Mfumu L.K., Quembo C.J., Heath L., Etter E.M.C., Jori F., Escribano J.M., Blanco E. 2013. African swine fever virus serodiagnosis: a general review with a focus on the analyses of African serum samples. Virus Research 173: 159-167

4 G.mez-Puertas P., Rodr.guez F., Oviedo J.M., Ramiro-Ib..ez F., Ruiz-Gonzalvo F., Alonso C., Escribano J.M. 1996. Neutralizing
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5 G.mez-Puertas P., Rodr.guez F., Oviedo J.M., Brun A., Alonso C., Escribano J.M. 1998. The African swine fever virus proteins p54 and p30 are involved in two distinct steps of virus attachment and both contribute to the antibody-mediated protective immune response. Virology 243: 461-471

6 Gallardo C., Blanco E., Rodr.guez J.M., Carrascosa A.L., Sanchez-Vizcaino J.M. 2006. Antigenic properties and diagnostic potential of African swine fever virus protein pp62 expressed in insect cells. Journal of Clinical Microbiology 44: 950-956

7 Kollnberger S.D., Gutierrez-Casta.eda B., Foster-Cuevas M., Corteyn A., Parkhouse R. M.E. 2002. Identification of the principal
serological immunodeterminants of African swine fever virus by screening a virus cDNA library with antibody. Journal of General Virology 83: 1331-1342.

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REF L-D-PRO

IVD VETERINARY

2°C 30°C

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