Swine Acute Diarrhoea Syndrome (SADS) Antigen Rapid Test

REF KINER5064

Ver 1.0

IVT For In-Vitro Test Only

Σ 40 test/kit

Purchase does not include or carry the right to resell or transfer this product either as a stand-alone product or as a component of another product. Any use of this product other than the permitted use without the express written authorization of KINETIC BIOTECH FZCO is strictly prohibited.

KINETIC BIOTECH FZCO

Building A1,
Dubai Digital Park,
Dubai Silicon Oasis, Dubai,
UAE
Tel: +44-186-5522721
Email: info@kineticbiotech.ae

Ste#619,
606 S Hill Street,
Los Angeles, CA 90014.
USA

Introduction:

Swine Acute Diarrhoea Syndrome (SADS) is a highly contagious viral enteric disease of pigs, primarily affecting neonatal piglets and characterised by acute watery diarrhoea, vomiting, dehydration, and high mortality rates.

The causative agent, Swine Acute Diarrhoea Syndrome Coronavirus (SADS-CoV), is an enveloped, single-stranded, positive-sense RNA virus belonging to the genus Alphacoronavirus within the family *Coronaviridae*. The virus is mainly transmitted via the faecal–oral route through contaminated faeces, feed and water. The disease results in rapid weight loss and severe economic losses in affected herds due to increased piglet mortality and reduced productivity.

Intended Use:

The Swine Acute Diarrhoea Syndrome (SADS) Antigen Rapid Test is used for the qualitative detection of Swine Acute Diarrhoea Syndrome Coronavirus (SADS-CoV) antigen in faecal/rectal swabs and intestinal tissue homogenates.

Principle:

This Rapid Test is an immuno-chromatographic test, using colloidal gold immunoassay method to detect the indicated antigen/antibody. After the addition of the sample, as per the instruction for use (IFU), the sample moves along with the colloidal gold labeling protein. If the relevant protein is present, it will develop a reddish color line near the space marked as “T”. This indicates the sample is Positive and if a line is not developed or seen, it indicates the sample is Negative for the tested antigen/antibody.

Materials Provided:

1. Cassette: with a pad in the device.
2. Sample Diluent - 3 ml

Materials to be provided by the End-User:

1. Adjustable pipettes and multichannel pipettor to measure volumes ranging from 25 ul to 1000 ul
2. Alcohol prep-pad
3. Clock or timer
4. Specimen collection container
5. Centrifuge
6. Biohazard waste container
7. Sterile gauze or cotton

Handling / Storage:

1. All reagents should be stored at 2ºC to 8ºC for stability.
2. All the reagents and wash solutions should be used within 12 months from manufacturing date.
3. Before using, bring all components to room temperature (18-25ºC). Upon assay completion ensure all components of the kit are returned to appropriate storage conditions.

Health Hazard Warnings:

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin.

2. For Research Use Only.

Sample Preparation and Storage:

Faecal samples: Collect the sample from faeces using a sterile swab. Insert the swab into the specimen tube containing 1 ml of sample diluent. Mix the swab samples well with the sample diluent to ensure proper extraction of the faecal sample. Faecal samples may be stored at room temperature for 24 hours or at 2-7ºC for 7 days. If longer storage is required, the samples may be frozen. Avoid sample deterioration by multiple freeze-thaw cycles.

Rectal swab sample: Collect the rectal sample using a sterile swab by gently inserting it into the rectum and rotating to absorb the material. Place the swab into the specimen tube containing 1 ml of sample diluent. Mix the swab samples well with the sample diluent to ensure proper extraction of the sample. Rectal swab samples may be stored at room temperature for 24 hours or at 2-7ºC for 7 days. If longer storage is required, the samples may be frozen. Avoid sample deterioration by multiple freeze-thaw cycles.

Intestinal Tissue homogenate: Collect tissue samples aseptically and cut approximately 0.1 g (100 mg) of tissue and place it into a sterile tube containing 1.0 mL of sample diluent. Homogenize thoroughly to obtain a uniform suspension. Allow large debris to settle or clarify by brief centrifugation if necessary, and use the clear supernatant for testing. Prepared samples should be tested immediately. If testing is delayed, store at 2–8°C for up to 24 hours or at –20°C or below for long-term storage. Avoid repeated freeze–thaw cycles.

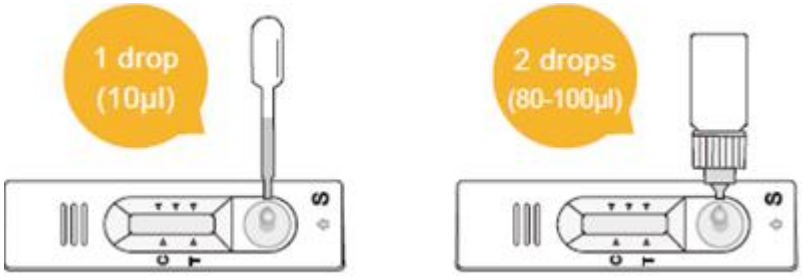
Preparation Before Use:

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20ºC - 30ºC) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (humidity ≤ 60%, temp: 20ºC - 30ºC). Please use immediately when the humidity＞60%.

Assay Procedure:

For Faecal/Rectal/Intestinal Tissue samples

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add one (1) full drop of prepared sample (10 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

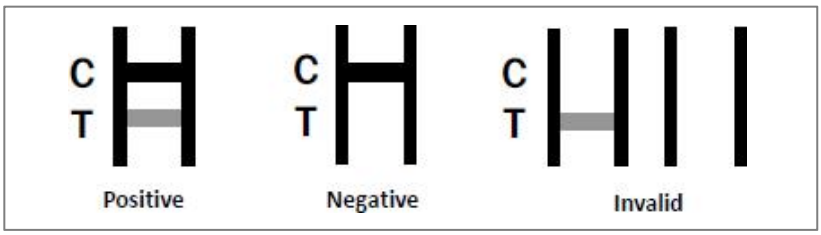


Interpretation of Results:

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Quality Control:

It is recommended that for each laboratory assay appropriate quality control samples in each run to be used to ensure that all reagents and procedures are correct.

Performance Characteristics of the Kit:

Sensitivity:
Negative coincident rate with Molecular testing: ≥ 97%, Positive coincident rate with Molecular testing: ≥ 75%.

Limitations of Method

Any diagnosis should not be based on the results of in vitro methods alone. Veterinarians are suggested to consider all clinical and laboratory findings possible to state a diagnosis. This reagent is designed for the qualitative screening test.

Safety Precautions:

- Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.
- Avoid time shift during pipetting of reagents.
- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide (< 0.1 % w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Since the kit contains potentially hazardous materials, the following precautions should be observed
  - Do not smoke, eat or drink while handling kit material
  - Always use protective gloves
  - Never pipette material by mouth
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

Symbols


Use by

Lot/Batch

Catalog number


Temperature limitation


Caution, consult accompanying documents


Manufacturer

LIMITED WARRANTY

KINETIC BIOTECH FZCO does not warrant against damages or defects arising in shipping or handling, or out of accident or improper or abnormal use of the product; against defects in products or components not manufactured by KINETIC BIOTECH FZCO, or against damages resulting from such non-KINETIC BIOTECH FZCO made products or components. KINETIC BIOTECH FZCO passes on to customer the warranty it received (if any) from the maker thereof of such non-KINETIC BIOTECH FZCO made products or components. This warranty also does not apply to product to which changes or modifications have been made or attempted by persons other than pursuant to written authorization by KINETIC BIOTECH FZCO.

THIS WARRANTY IS EXCLUSIVE. The sole and exclusive obligation of KINETIC BIOTECH FZCO shall be to repair or replace the defective product in the manner and for the period provided above. KINETIC BIOTECH FZCO shall not have any other obligation with respect to the products or any part thereof, whether based on contract, tort, strict liability or otherwise. Under no circumstances, whether based on this Limited Warranty or otherwise, shall KINETIC BIOTECH FZCO be liable for incidental, special, or consequential damages.

This Limited Warranty states the entire obligation of KINETIC BIOTECH FZCO with respect to the product. If any part of this Limited Warranty is determined to be void or illegal, the remainder shall remain in full force and effect.

KINETIC BIOTECH FZCO. 2026

THANK YOU FOR USING KINETIC BIOTECH PRODUCT!