

PORCINE Rapid Test Kit

PRODUCT NAME
PORCINE Rapid Test Kit
PACKAGE SPECIFICATION
25 tests/kit
INTENDED USE

Consumption and handling of the materials of porcine origin is strictly prohibited by some religious confessions. Porcine components may be also used for adulteration of foods. The kit is based on principle of immunochromatographic rapid test (lateral flow) and may be used for qualitative determination of porcine meat antigen in food. The kit is intended for users concerned about detecting porcine components adulterated into food.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

A pig (*Sus scrofa domesticus*) belongs to the genus *Sus*, within Suidae family. The wild ancestor of domestic pig is wild boar (*Sus scrofa*), other related species from the same family are peccary and warthog.

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Frenovo PORCINE Rapid Test Kit is based on principle of immunochromatographic rapid test (lateral flow) and may be used for qualitative determination of porcine meat antigen in food such as Raw meat, Processed meat, Canned Food Meat Based, Animal Feed in Can, Biscuit Meat Based, Gelatin Product, Frozen Food Meat Based, Snacks, Stock Liquid, Fat and oil, etc. In immunochromatographic method, the target antigen (a thermostable antigen of porcine) bound by highly specific antibodies attached to the test line and colored microparticles. This two-site binding results in formation of immune complex visible as the colored line. A red band will appear in the quality control area (C) regardless of whether porcine meat antigen is present in the sample or not. The red band in the quality control area (C) is the standard to determine whether there are enough samples and whether the chromatographic process is normal, and it is also the internal control standard of reagents.

KIT COMPONENTS

Each kit contains:

1. Test devices: 25 pieces test devices individually pouched.
2. Droppers: 25 pieces droppers of 25 ul.
3. Instructions For Use: 1 copy attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves.

WARNINGS

1. Read the Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. FRENOVO PORCINE Rapid Test is for detection use only.
3. Perform test at room temperature.

PRECAUTIONS

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not use the kit past the expiration date (this date is printed on the kit box).
5. Dispose used components according to regulatory and /or organizational requirements.
6. The result should be read immediately after the end of the 10 minutes incubation time following the addition of collected specimen. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SPECIMEN HANDLING

Specimen such as Raw meat, Processed meat, Canned Food Meat Based, Animal Feed in Can, Biscuit Meat Based, Gelatin Product, Frozen Food Meat Based, Snacks, Stock Liquid, Condiment, Bakery, Fat and oil, etc, should be brought to temperature range 15-30°C before use; The solid food should be broken up into small pieces as much as possible before testing. Testing of colder specimens diminishes the sensitivity of the assay; testing of hot specimens is NOT possible!

For solid specimen :

1. Weigh a piece of tested material (0,1-0,5 g) and record the actual weight in grams, Then use a clean tool (preferably disposable) to break up the solid material into small pieces and put them into specimen collection tube.
2. weigh required tap water as 5x actual weight (for example, if the weight is 0,25 g, add 1.25g of water or 1.25ml of water). Then screw the cap securely onto the tube and shake vigorously for 15 - 30 seconds or use the vortex mixer. Allow to settle for 2 minutes.

For liquid specimen :

1. Collect 1 ml of liquid specimen into a specimen collection tube (by first marker on the tube wall or using a pipette).
2. Add an equal volume of tap water, screw the cap securely onto the tube and shake vigorously for 15 – 30 seconds or use the vortex mixer. Allow to settle for 2 minutes.

NOTE: If the liquid is thick and cloudy, it may not penetrate into the test device, and testing fails. To avoid it, allow to settle for longer period (up to 6 hours). The extract may be also filtered by textile material or centrifuged.

TEST PROCEDURE

1. Determine the total number of the following elements that are in this

INTERPRETATION OF RESULTS

Positive result: if both the quality control line C and the detection line

Invalid result: if the quality control line C is not observed, it will be

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

FRENOVO DOBGINE Rapid Test Kit shows negative result in each

IMPORTANT NOTE: the test gives FALSE NEGATIVE result in most

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Address: Room 401, Building 26, Room 401&301, Building

District, Hangzhou City, Zhejiang Province, China.

Tel: +86-571-89170657

Email: business@frenovo.com

— **THE UNIVERSITY OF CHICAGO**

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