Rapid African Swine Fever Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ ASFV Ag Test Kit

[CAT No. LGM-PAG-11]

Introduction

African swine fever virus (ASFV), a large double stranded DNA virus, genus *Asfivirus* in the only member of the Asfarviridae family[1], is known as not infectious to humans and not directly affect public health[2].
African swine fever (ASF) is a lethal hemorrhagic fever of pigs with high mortality and morbidity rates approaching 100 percent[3]. ASF was first reported in Southeast African countries, including Kenya, in the 1920s[3].
The spread of ASF outside Africa where was first described is persistent in Europe, the Russian Federation, China, Mongolia and Vietnam. It also has posed a serious threat of animal health, pig production and global food security. Since its introduction to and dramatic spread in 2018 in China, which has half of the world's pig population, current epidemiological situation keeps impact on the pig industry[5].
Apparent symptoms of disease are eruptions, in which the skin turns pinkish and nearly purple marks on the skin of the extremities, ears, chest, abdomen and perineum. Moreover, abortion can frequently occur in gestating females and be sometimes the first clinical sign of an outbreak[2].
At present, there are no treatment or vaccines available to prevent ASF so the control strategy mainly relies on strict administration of sanitary measures and slaughtering of infected and exposed animals. Therefore, rapid and accurate diagnosis of the infections is essential for prevention, control, and extermination of the disease in affected various countries[6].
Point-of-care rapid and sensitive detection of ASFV is key to the timely implementation of control[7].

Principle

The RIDX™ ASFV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of ASFV in porcine blood.
This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the ASFV antigen exists in the sample, it binds to the gold-conjugated anti-ASFV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the secondary anti-ASFV antibody on the test line, resulting in a red line. The control line indicates that the test is performed correctly and should appear when the test is complete.
Two different monoclonal antibodies to the conservative phosphoprotein p30 protein[8] of ASFV are used as a capture and detector in the kit. The RIDX™ ASFV Ag Test Kit can detect ASFV in porcine blood with high accuracy.

Performance

1. Sensitivity & Specificity

		PCR		
		+	−	Total
RIDX™ ASFV Ag Test	+	10	0	10
	−	2	435	437
	Total	12	435	447

Sensitivity: 83.33% (10/12, 95% CI*: 55.20% ~ 95.30%)
Specificity: 100% (435/435, 95% CI: 99.12% ~ 100%)
Diagnostic Agreement: 99.55% (445/447, 95% CI: 98.38% ~ 99.88%)

* CI: Confidence Interval

2. Limit of Detection: 5 x 10^4 $TCID_{50}$/mL, 7.5 HAD_{50}/mL

3. Cross-Reactivity
Below potential cross-reactivity substances do not affect the performance of the RIDX™ ASFV Ag Test Kit.

Pathogen	Titer ($TCID_{50}$/mL)
Classical swine fever virus (CSFV)	1 x 10^5
Japanese encephalitis virus (JEV)	1 x 10^5
Porcine circovirus type 2 (PCV2)	1 x 10^4
Porcine reproductive and respiratory syndrome virus (PRRSV)	1 x 10^3
Porcine epidemic diarrhea virus (PEDV)	1 x 10^4
Transmissible gastroenteritis virus (TGEV)	1 x 10^3

Kit Components

	Component	Number/Kit
1	ASFV Ag Test device	10
2	Dilution buffer (4mL)	1
3	Disposable capillary tube	10
4	Instructions for use	1

Storage & Stability

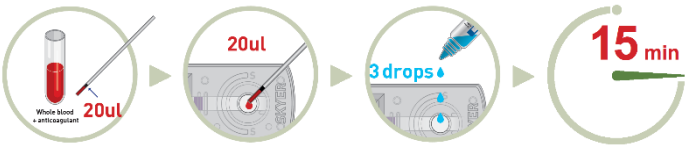
1. Store the test kit at 2~30℃ (35.6~86℉). Do NOT freeze.
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Preparation

1. Use swine whole blood as a specimen.
2. An anticoagulant (EDTA, heparin, or citrate) is treated immediately after the whole blood sample collecting (anticoagulant is not provided).
3. For the best performance, the blood samples should be tested within 24 hours after collection.
4. When using stored blood, use only blood that has been stored for up to 3 days (72 hours) at 2~8°C (35.6~46.4°F), a refrigerated condition. Do NOT use frozen samples.

Test Procedure

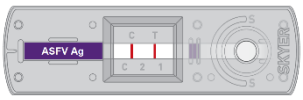
1. All samples and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Take 20μL of sample (anticoagulated whole blood) to the black line of the capillary tube.
3. Add the sample into the sample hole (S).
4. After 1~3 minutes, add 3 drops (~100μL) of the dilution buffer into the sample hole (S).
5. Read test results at 15 minutes.



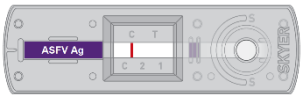
[Summary of Test Procedure]

Interpretation of Results

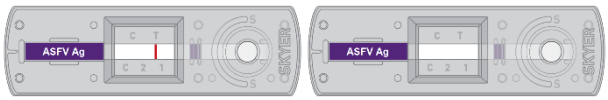
1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of African swine fever virus antigens.



2. Negative result
Only control (C) line appears in the result window.



3. Invalid results
If the control (C) line does not appear, the result might be considered invalid. The sample should be retested.



4. **Precautions** for interpretation of the results
• If the result is positive, be sure to conduct a retest with a new device to reconfirm. Occasionally, if the sample is too viscous or hemolytic, the flow along the membrane may be impeded, resulting in a non-specific reaction.
• This kit is for screening, and the final confirmation must be made according to the results of the detailed examination stipulated by the quarantine authorities.

Precautions

1. This test kit is for veterinary *in vitro* diagnosis only especially swine. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the membrane in the sample hole on the device.
4. Do not use the test device if the foil pouch is damaged or the seal is open.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the test components (device, capillary tube).
7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials following national and local regulations.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

1. International Committee on Taxonomy of Viruses (ICTV). *Virus Taxonomy: 2020 Release*. Email Ratification March 2021 (MSL # 36).
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4. Penrith ML, Thomson GR, Bastos ADS. African swine fever. *Infectious diseases of livestock* (Eds: Coetzer JAW, Tustin RC). 2004; vol 2: 1088-1119. Oxford University Press, Oxford, UK.
5. Dixon LK, Sun H, Roberts H. African swine fever. *Antiviral Res.* 2019; 165: 34-41.
6. Sastre P, Gallardo C, Monedero A, Ruiz T, Arias M, Sanz A, Rueda P. Development of a novel lateral flow assay for detection of African swine fever in blood. *BMC Vet Res*. 2016; 12: 206.
7. Wang X, Ji P, Fan H, Dang L, Wan W, Liu S, Li Y, Yu W, Li X, Ma X, Ma X, Zhao Q, Huang X, Liao M. CRISPR/Cas12a technology combined with immunochromatographic strips for portable detection of African swine fever virus. *Comm Biol*. 2020; 3: 62.
8. Afonso CL, Alcaraz C, Brun A, Sussman MD, Onisk DV, Escribano JM, Rock DL. Characterization of P30, a Highly Antigenic Membrane and Secreted Protein of African Swine Fever Virus. *Virol*. 1992; 189: 368-373.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σn	Contains sufficient for ⟨n⟩ tests
	Do not reuse
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not use, if the package is damaged
	Upper side
	Manufacturer

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