

GUIDANCE ON THE USE OF RAPID DIAGNOSTIC TEST STRIPS



COMPANY



Shenzhen Zhenrui Biotech Co.,Ltd. was established in 2013 as a National High-tech Enterprise, focusing on product research and development in the field of disease diagnosis. It mainly provides immunology and molecular biology in vitro detection reagents and related services.

Since the establishment of the company, it never give up pursuing “professional and experienced technical capabilities”, “focusing on research and development continuously”, “realizing the production capacity of high-quality products”. Zhenrui has been committed to transforming advanced technology and corporate experience into high-quality products and enices, providing users with a full range of solutions to help users improve the level and ability of disease diagnosis and prevention.



INTRODUCTION

Shenzhen Zhenrui Biotechnology Co.,Ltd. is a high-tech enterprise focusing on the research, development, production, and sales of biomedical in vitro diagnostics, food safety testing, and supporting equipment.

The company is committed to providing more accurate and efficient infectious disease detection reagents for the public health field; committed to providing complete and convenient animal husbandry disease diagnosis and epidemic prevention detection reagents for the animal husbandry industry; providing reliable infectious disease diagnostic reagents for companion animals; for food safety testing provides high-quality and rapid testing reagents.



The company operates in strict accordance with GMP standards and ISO9001 quality management system and has departments for research and development, production, quality control, finance, domestic sales, foreign sales, procurement, and warehouses.



The products are well received by users at the domestic and overseas market and established friendly cooperation models with distributors in Southeast Asia, Europe, Japan, South Korea, Southeast Asia, and the rest of the world market.

“ Professional ”



Zhenrui provides our customers with high-quality products and services with its "professional and experienced technical capabilities", "continuous focused research and development" and "realizing the production capacity of high-quality products".



The company has established technology platforms for enzyme-linked immunoassay, nanoparticle chromatography and molecular biology detection.

The products cover the three major product lines of ELISA, colloidal gold, and PCR, which also cover the antigen and antibody detection products of various animal diseases such as pigs, poultry, ruminants, pets, aquatic animals, etc., which is the most complete product line in the industry One of the companies that can meet the needs of customers for different diagnostic reagents.

As one of the companies own most complete product line in industry, Zhenrui can meet the needs of customers for different diagnostic reagents. The product performance has been comprehensively evaluated by a number of high-level experiments and has been unanimously affirmed.

CERTIFICATE

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA

兽药GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR ANIMAL DRUGS

证书号: (2020) 兽药GMP证字 19016号
Certificate NO.: (2020) Veterinary Drug GMP License No. 19016

企业名称: 深圳真瑞生物科技有限公司
Manufacturer: Shenzhen Zhenrui Biotech Co., Ltd

生产地址: 深圳市龙华区清澜村富安娜公司B栋501
Address: 5F, Building B, Fuanna Industrial Park, No. 1, Qinglan Road, Longhua District, Shenzhen, China.

验收范围: 免疫学类诊断制品(B类)、分子生物学类诊断制品(B类)
Scope Of Inspection: Immunological diagnostic products (Class B), Molecular biological diagnostic products (Class B)

经审核, 符合中华人民共和国《兽药生产质量管理规范》要求, 特发此证。
This is to certify that the above manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Animal Drugs.

有效期: 2020年7月30日至2025年7月29日
Valid: 30/07/2020 - 29/07/2025

发证机关: 广东省农业农村厅
Administrative Unit: Department of Agriculture and Rural Affairs of Guangdong Province
发证日期: 2020年7月30日
Issued Date: 30/07/2020

Certificate CN2142559

The management system of

Shenzhen Zhenrui Biotech Co., Ltd.
501, Building B, Fuanna Industrial Park, Qinghu Community, Longhua Street, Longhua District, Shenzhen, Guangdong, 518109, P.R. China
has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design, development, manufacture and distribution of sample solution and in-vitro diagnostic test kits for detection of infectious disease-related (including COVID-19 rapid test kits)

This certificate is valid from 27 July 2021 until 26 July 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 1. Certified since 27 July 2021

Automated by

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2110 13485 2016 3031
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SGS

中华人民共和国
兽药生产许可证

证书号: (2020) 兽药生产证字 19147号

企业名称: 深圳真瑞生物科技有限公司
生产范围: 免疫学类诊断制品(B类)、分子生物学类诊断制品(B类)

注册地址: 深圳市龙华区清澜村富安娜公司B栋501

法定代表人: 张杰

住 址: 深圳市南山区东滨路汇智大厦A座附楼605室

企业负责人: 丁杰

生产地址: 深圳市龙华区清澜村富安娜公司B栋501

有效期: 2020年7月30日至2025年7月29日

发证机关: 广东省农业农村厅
发证日期: 2020年7月30日

高新技术企业证书

企业名称: 深圳真瑞生物科技有限公司
证书编号: GR202044201608

发证时间: 二〇二〇年十二月十一日
有效期: 三年

批准机关: 广东省科技厅

中华人民共和国
新兽药注册证书

证书号: (2019) 兽药注册证字 41号

新兽药名称: 非洲猪瘟病毒荧光PCR检测试剂盒
注册类别: 二类

研制单位: 中国动物疫病预防控制中心, 北京森康生物技术开发有限公司, 沈阳美普生信息科技有限公司, 深圳真瑞生物科技有限公司

根据《兽药管理条例》, 该兽药符合规定, 准予注册, 特发此证。

发证日期: 二〇一九年七月二十三日

中华人民共和国农业农村部
兽药产品批准文号批件

批件号: 0194000001010-001

企业名称: 深圳真瑞生物科技有限公司
生产地址: 深圳市龙华区清澜村富安娜公司B栋501
通用名称: 非洲猪瘟病毒荧光PCR检测试剂盒

商品名称: 无

兽药产品批准文号: 兽药生字(19)43880

有效期至: 2021-04-16至2023-04-15

发证日期: 2021-04-15

THREE TECHNOLOGY PLATFORM REAGENTS

▶ ELISA test kit ◀

We have developed more than 50 ELISA test kits, covering almost all common animal diseases. According to different applications, we use indirect method, sandwich method, competition method, blocking method and other modes, especially the blocking method kit established by monoclonal antibodies, which effectively solves the problem of multiple interference factors and specificity in the detection of animal disease antibodies.



ZR-96C
ELISA analyzer



ZR-310
Automatic Washer

▶ Colloidal gold chromatography rapid test card ◀

We have developed more than 50 types of rapid detection cards for colloidal gold chromatography. In particular, the antibody rapid test card used for the evaluation of the immune effect of economic animals and the antigen test card used for rapid diagnosis have been recognized and welcomed by different groups of customers due to their convenient, rapid and accurate characteristics.



Antibody Titer Colorimetric Chart

▶ Real-time PCR ◀

We have developed more than 60 kinds of fluorescent quantitative PCR detection reagents. This series of reagents uses high-efficiency A-MLV reverse transcriptase and hot-start Taq DNA polymerase to prepare a one-step RT-PCR amplification system, which can quickly check for the presence of animal disease pathogens within 2 hours.



RealTime
PCR System



Nucleic Acid
Extractor

GUIDANCE ON THE USE OF RAPID DIAGNOSTIC TEST STRIPS (DOG)



▶ Gastrointestinal tract

Main clinical symptoms

- Vomiting, diarrhea

Optional test strips

- CPV Ag
- CCV Ag
- GIA Ag
- RV Ag
- Lyme Ab



▶ Heart

Main clinical symptoms

- Cardiac hypertrophy, myocarditis, heart failure

Optional test strips

- CHW Ag
- To Ab



▶ Ear

Main clinical symptoms

- Redness of the auricle

Optional test strips

- IgE Canine allergen testing



▶ Face

Main clinical symptoms

- Redness

Optional test strips

- IgE Canine allergen testing



▶ Eye

Main clinical symptoms

- Increased eye feces
- Conjunctival redness
- Blue cornea, edema
- Visible pale or yellowish mucosa

Optional test strips

- CDV Ag
- IgE Canine allergen testing
- To Ab



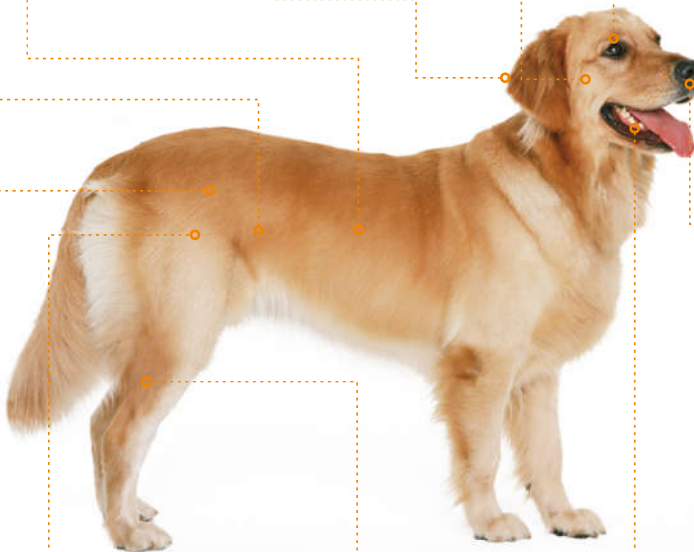
▶ Body surface

Main clinical symptoms

- High fever

Optional test strips

- CDV Ag
- CIV Ag
- CAV Ag
- To Ab
- Lep Ab



▶ Nose

Main clinical symptoms

- Runny nose

Optional test strips

- CIV Ag
- CAV Ag
- To Ab



▶ Skin

Main clinical symptoms

- Pale skin, that is, anemia

Optional test strips

- CPV Ag
- CHW Ag
- To Ab



Main clinical symptoms

- Coat is rough, even falling off, skin thickening lesions

Optional test strips

- LSH Ab



▶ Limbs

Main clinical symptoms

- Redness and swelling, especially on the feet

Optional test strips

- IgE Canine allergen testing



Main clinical symptoms

- Lameness, inflammation and swelling of joints

Optional test strips

- Lyme Ab



▶ Oral cavity

Main clinical symptoms

- Difficulty breathing

Optional test strips

- CIV Ag
- CAV Ag
- CHW Ag
- To Ab

GUIDANCE ON THE USE OF RAPID DIAGNOSTIC TEST STRIPS (CAT)



▶ Oral cavity

Main clinical symptoms

- Stomatitis, gingivitis

Optional test strips

- FIV Ab



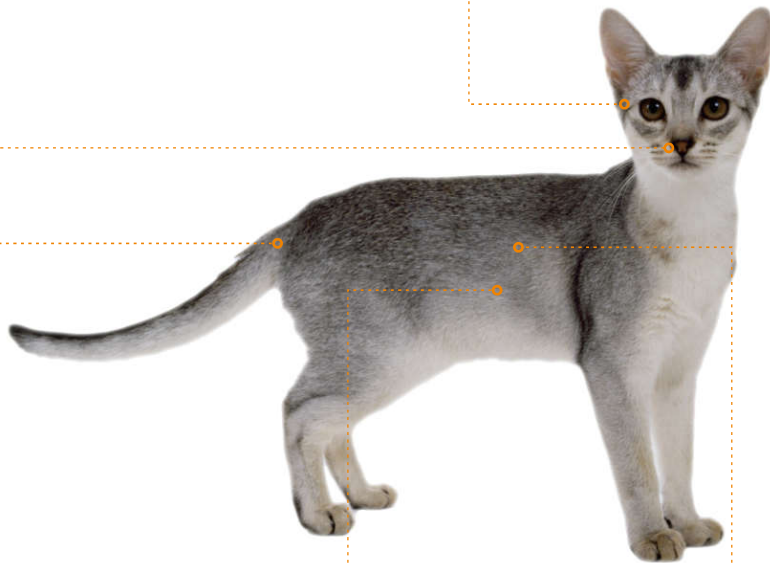
▶ Eye

Main clinical symptoms

- Eye disease

Optional test strips

- FIP Ab



▶ Body surface

Main clinical symptoms

- Increased body temperature

Optional test strips

- FPV Ag
- FIP Ab



▶ Gastrointestinal tract

Main clinical symptoms

- Vomiting, diarrhea

Optional test strips

- FPV Ag



▶ Skin

Main clinical symptoms

- Pale skin, that is, anemia

Optional test strips

- FeLV Ag
- FCV Ag
- FIV Ab
- FIP Ab

PHYSICAL EXAMINATION



Total IgE Canine Allergen Test

Allergic dermatitis is the most common canine allergies. Elevated IgE in serum is the most effective indicator of allergic diseases. Canine total IgE antibody rapid detection card adopts immunochromatographic detection technology to detect IgE immunoglobulin in canine serum and plasma.

Provide materials: Test Device、Dilution Buffer、Capillary sampling tube、Dropper、Instruction.

Features: Fully equipped, simple operation, fast presentation

Cat and dog Toxoplasma antibody detection

Toxoplasma gondii is a zoonotic parasitic disease, and its pathogen is Toxoplasma gondii (Toxoplasma gondii), which can be transmitted to humans by cats, dogs and other animals that carry the worm. It often causes eye and brain damage. Infecting pregnant women (animals) may also cause teratogenesis or even abortion.

Cat and dog Toxoplasma antibody gold-labeled rapid detection card uses rapid immunochromatographic detection technology to detect Toxoplasma antibody (total antibody) in whole blood and serum of cats and dogs, which can assist in the diagnosis of Toxoplasma gondii infection and help early Protection.

Test sample: cat, dog whole blood, serum

Features: one-step detection, convenient and fast; high sensitivity and specificity

Evaluation of Rabies Immunity

The rabies virus antibody rapid test card can detect the level of rabies virus antibodies in dogs, thereby helping to determine whether the rabies disease vaccinated by the dog has produced protection.

Test sample: serum, plasma

Provide Materials: Test Device、Neutralization Reaction Tube、Dilution Buffer

Features: Simple operation and quick results; Monoclonal antibody blocking method, higher accuracy



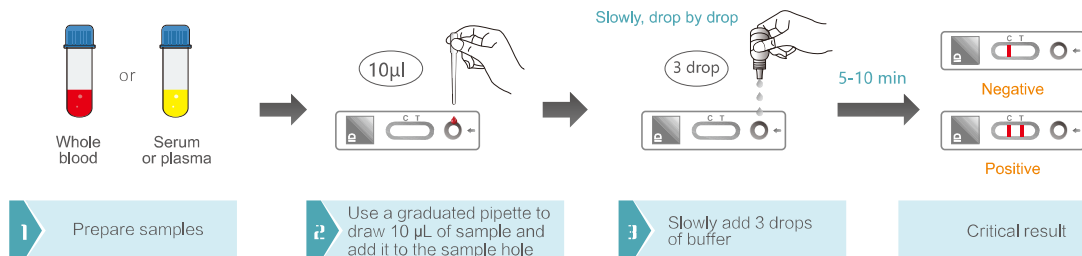
INSECT VECTOR PRODUCTS

Test sample: Whole blood, serum or plasma

Provide Materials: Test Device, Dropper, Dilution Buffer

Catalog Number	Product Name	Test purpose	Sensitivity	Specificity
FZCC023-10	Rapid Anaplasma Ab test kit	Anaplasma Ab	97.0%	96.0%
FZCC024-10	Rapid Lyme Ab test kit	Lyme Ab	97.1%	97.0%
FZCC018-10	Rapid CHW Ag Test Kit	CHW Ag	98.6%	97.4%
FZCC017-10	Rapid Leishmania Ab Test Kit	Leishmania Ab	98.7%	97.3%
FZCC026-E10	Rapid Babesia Ab test kit	Babesia Ab	99.0%	98.0%
FZCC027-E10	Heartworm/Ehrlichia/Anaplasma Combined Test kit	Heartworm/Ehrlichia/Anaplasma Combined	97.5%	96.3%
FZCC028-E10	Heartworm/Ehrlichia/Leishmania/Anaplasma Combined Test kit	Heartworm/Ehrlichia/Leishmania/Anaplasma Combined	97.4%	98.0%

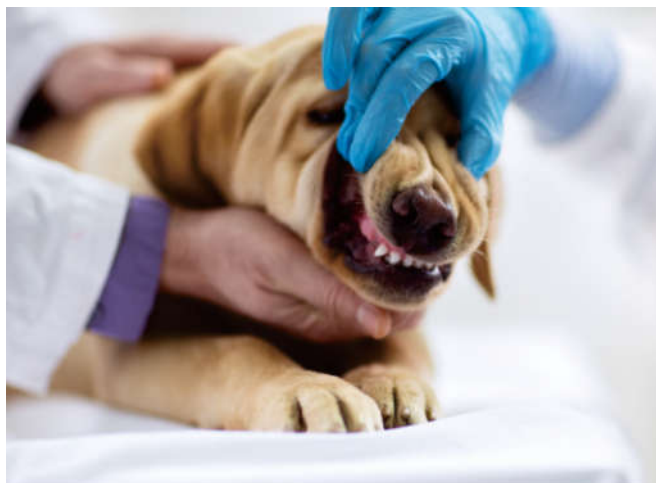
Test steps :



- **Note:** For the sample volume specified in the instruction manual, the black line on the capillary represents 10µL.
(addition of too much or too little sample will produce wrong results, so strictly follow the specified sample volume (10µL).)



RESPIRATORY PRODUCTS



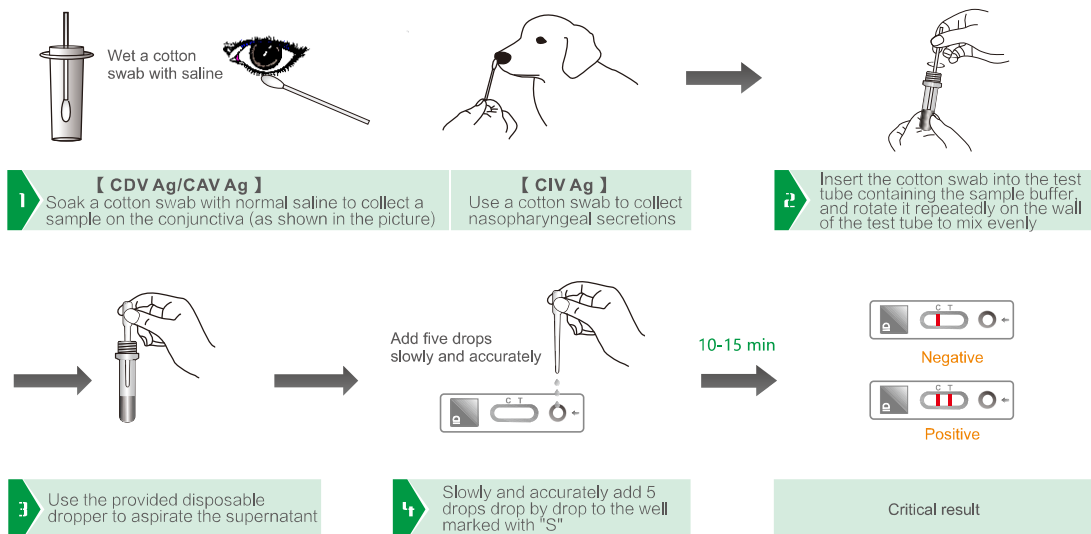
Test sample: Conjunctiva (CDV Ag、CAV Ag) , Nasopharyngeal fraction exosomes (CIV Ag)

Provide Materials: Test Device、Sterile cotton swab、Disposable dropper、Dilution Buffer

Features: simple operation, quick results

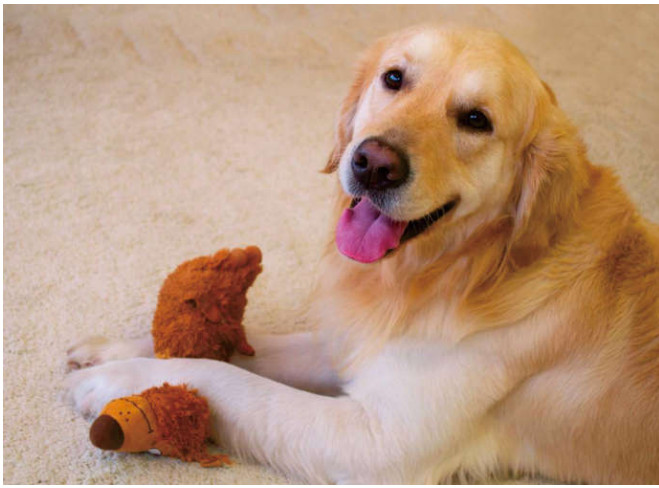
Catalog Number	Product Name	Test purpose	Sensitivity	Specificity
FZCC001-10	Rapid CDV Ag Test Kit	CDV Ag	98%	99%
FZCC009-10	Rapid CAV Ag Test Kit	CAV Ag	97%	99.5%
FZCC013-10	Rapid CDV/CAV Combined Ag Test Kit	CDV Ag + CAV Ag	97%	99%
FZCC003-10	Rapid CIV Ag Test Kit	CIV Ag	98.5%	98%

Test steps:



1、Line C is not displayed as an invalid board;

2、Look at the results within 10–15 minutes, the results will not be used for reference after 15 minutes.



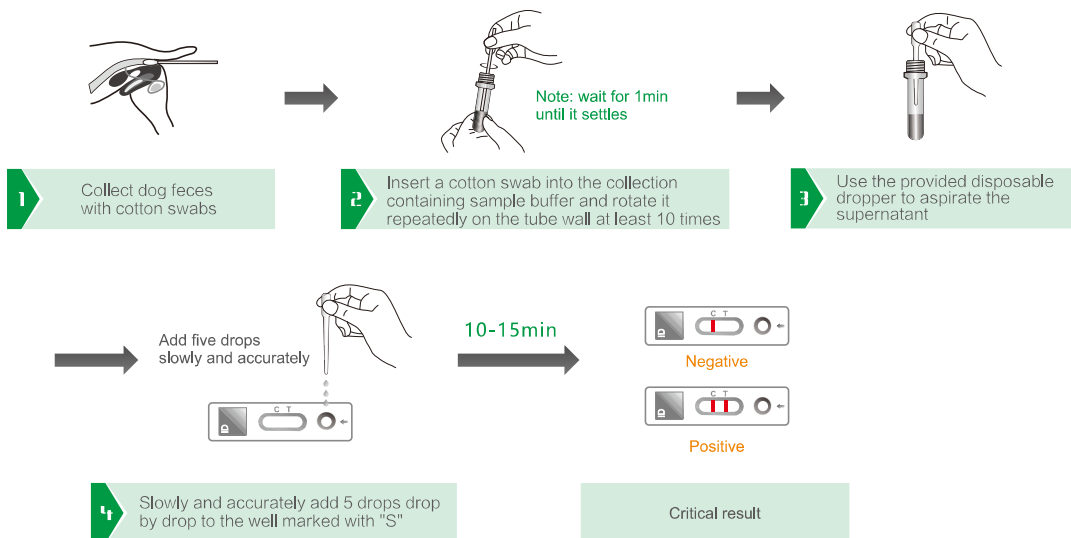
INTESEINAL DIAGNOSIS

Test sample: Stool 、 Rectal swab

Provide Materials: Test Device、 Sterile cotton swab、 Disposable dropper、 Dilution Buffer

Catalog Number	Product Name	Test purpose	Sensitivity	Specificity
FZCC002-10	Rapid CPV Ag Test Kit	CPV Ag	98.0%	97.0%
FZCC010-10	Rapid CCV Ag Test Kit	CCV Ag	98.2%	98.0%
FZCC014-10	Rapid CPV/CCV Ag Test Kit	CPV/CCV Ag	98.0%	97.0%
FZCC019-10	Rapid Giardia Ag Test Kit	Giardia Ag	97.4%	98.0%

Test steps:



1、 Line C is not displayed as an invalid board;

2、 Look at the results within 10–15 minutes, the results will not be used for reference after 15 minutes.

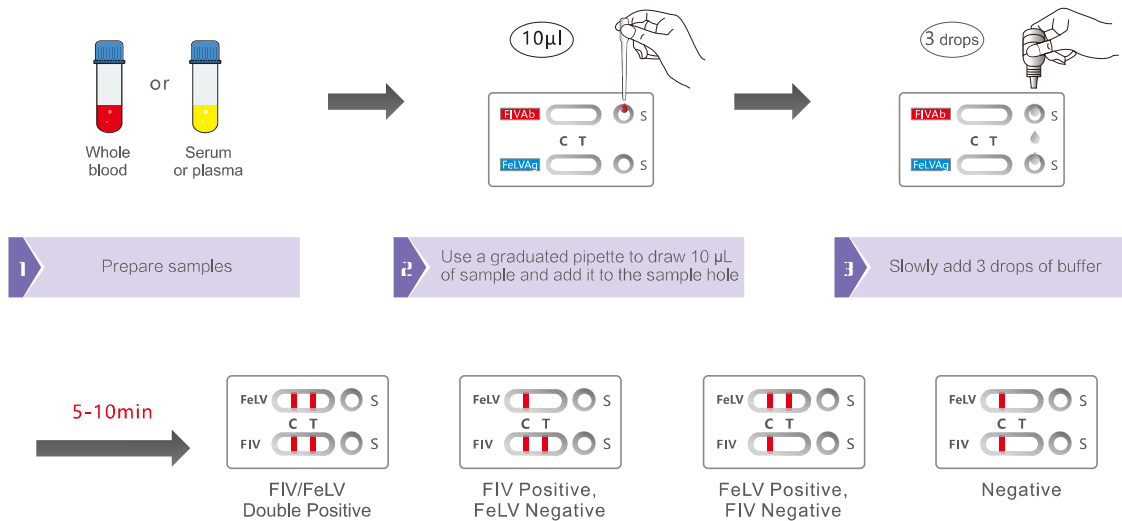
CAT DISEASE PRODUCT INTRODUCTION



Rapid FIV Ab+FeLV Ag Combined Ag Test Kit

Objective: To detect the antibody of feline immunodeficiency virus and feline leukemia virus antigen at the same time
Test sample: Whole blood, serum, or plasma
Provide Materials: Test Device、Sterile cotton swab、Dropper、Dilution Buffer
Features: One-step detection, efficient and convenient; High accuracy; Economical inspection cost

Test steps:



► **Note:** For the sample volume specified in the instruction manual, the black line on the capillary represents 10 μL . (addition of too much or too little sample will produce wrong results, so strictly follow the specified sample volume (10 μL)).





PRODUCT CATALOG

ELISA KIT

Catalog Number	Product Name	Spec	Method
FZEC001-192	Rabies virus Ab Elisa kit	96T/192T	CELISA
FZEC002-96	Echinococcus granulosus Ag Elisa kit	96T	DAS-ELISA

RAPID TEST KIT

Catalog Number	Product Name	Spec	Test Sample
FZCC001-10	Rapid CDV Ag Test Kit	10T	Eye, nose swabs
FZCC002-10	Rapid CPV Ag Test Kit	10T	Stool or rectal swab
FZCC003-10	Rapid CIV Ag Test Kit	10T	Nasal or throat swab
FZCC004-E10	Rapid Rabies Ag Test Kit	10T	Saliva
FZCC005-E10	Rapid Rabies Ab Test Kit	10T	Serum
FZCC006-E10	Rapid FPV Ag Test Kit	10T	Stool or rectal swab
FZCC007-10	Rapid Canine Brucella Ag Test Kit	10T	Swab, Tissue
FZCC008-10	Rapid Canine Brucella Ab Test Kit	10T	Serum
FZCC009-10	Rapid CAV Ag Test Kit	10T	Conjunctiva
FZCC010-10	Rapid CCV Ag Test Kit	10T	Stool or rectal swab
FZCC011-10	Rapid FCV Ag Test Kit	10T	Stool or rectal swab

PRODUCT CATALOG



RAPID TEST KIT

Catalog Number	Product Name	Spec	Test Sample
FZCC012-10	Rapid Toxoplasma Ab Test Kit	10T	Serum
FZCC013-10	Rapid CDV/CAV Ag Test Kit	10T	Conjunctiva
FZCC014-10	Rapid CPV/CCV Ag Test Kit	10T	Stool or rectal swab
FZCC015-10	Rapid FIV Ab/FelV Ag Test Kit	10T	Serum or plasma
FZCC016-10	Canine Total IgE Ab Test Kit	10T	Blood or serum
FZCC017-10	Rapid Leishmania Ab Test Kit	10T	Serum
FZCC018-10	Rapid CHW Ag Test Kit	10T	Serum
FZCC019-10	Rapid Giardia Ag Test Kit	10T	Serum
FZCC020-10	Rapid FIP Ag Test Kit	10T	Serum
FZCC021-10	Rapid E.Canis Ab Test Kit	10T	Serum
FZCC022-10	Rapid Leptospira IgM Ab Test kit	10T	Serum
FZCC023-10	Rapid Anaplasma Ab test kit	10T	Serum
FZCC024-10	Rapid Lyme Ab test kit	10T	Serum
FZCC026-E10	Rapid Babesia Ab test kit	10T	Serum
FZCC027-E10	Heartworm/Ehrlichia/Anaplasma Combined Test kit	10T	Serum
FZCC028-E10	Heartworm/Ehrlichia/Leishmania/Anaplasma Combined Test kit	10T	Serum
FZCC029-E10	Rapid CPV/CCV/Giardia Ag Test Kit	10T	Stool or rectal swab
FZCC030-E10	Rapid Heartworw/E.canis/Leishmania/Anaplasma Combined test kit	10T	Serum
FZCC035-E10	Feline Calicivirus (FCV) Ag Rapid Test Kit	10T	Mouth, eye and nose swab
FZCC036-E10	Feline Herpes Virus (FHV) Ag Rapid Test Kit	10T	Mouth, eye and nose swab



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Website



Wechat PublicAccount