伊仕生物
EGENS

Enterprise through
ISO9001、ISO14001
ISO45001、ISO13485
System authentication

Product Manual

2023 Edition II

Immune Chromatography

http:// www.egens-bio.com
http://ntys.en.alibaba.com

伊仕生物
EGENS

南通伊仕生物技术股份有限公司
NanTong Egens Biotechnology Co.,Ltd

Nantong Egens Biotechnology Co.,LTd

Egens Biotechnology Co.,Ltd was founded in 1999. It's a collection of biological raw materials development, diagnostic reagent manufacturing, domestic and foreign trade in one of the comprehensive biotechnology company. Early pregnancy multi-function detection reagent, COVID-19 antigen detection kit and other products are mainly used in home self-examination, drug detection, clinical detection and other fields.

Nantong Egens Biotechnology Co.,Ltd has more than 600 employees ,30000 square meters spare standby plants in Nantong Free Trade Zone, 25000 square meters purification production workshop and more than 200 sets of automatic flow production line and has more than one hundred products sFDA licensed .

Nantong Egens Biotechnology Co.,Ltd is capable of complete supply chain, perfect quality management system, strong production capacity and excellent global marketing team.

Nantong Egens Biotechnology Co.,Ltd obtained 13 national invention patents of HCG multi-function detection reagent, LH quantitative detection system, dual-channel automatic quantitative detector and other, 12 utility model patents and dozens of patents under review.

Beijing Kewei Clinical Diagnostic Reagents

Beijing Kewei Clinical Diagnostic Reagents Manufacturer was established with the technology and resource advantages of 302 Hospital of the P.L.A.in 1990 ,it is one of the earliest companies specialized in producing diagnostic reagents. 302 Hospital of P.L.A. is one of the largest domestic infectious hospitals with many famous clinical and diagnostic experts. At present, Kewei has obtained GMP certificate and has a 3000 square meter clean room meeting GMP requirements that laid the reliable foundation for good product quality.

Kewei has a professional and experienced sales team. The Domestic and International market sales volume increases rapidly each year, is the superior positions in blood screening tests for infectious diseases in China. Our marketing efforts extend to the fields of clinical testing, disease control and prevention, blood screening etc.
Since the year 2013, Beijing Kewei Clinical Diagnostic Reagent Co.,Ltd has been a wholly -owned subsidiary of Nantong Egens Biotechnology Co.,Ltd.

Enterprise through ISO13485 ISO9001 ISO14001 ISO45001 ISO13485 System authentication

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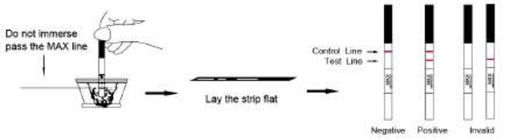
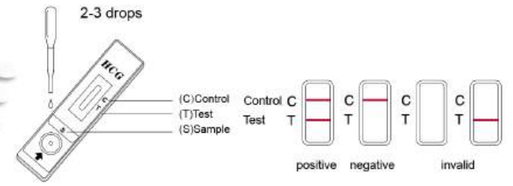
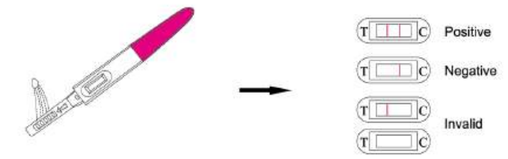
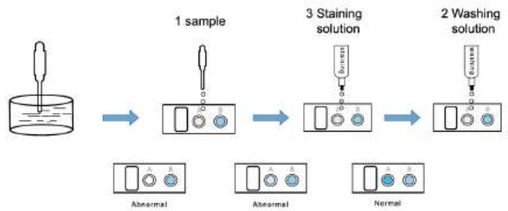




- Over 99% accuracy
- One-step urine test
- Results in 5 minutes
- Easy and convenient



Sperm Concentration Test Kit



- Qualitative Testing of Sperm counts
- Self-Testing of Male Fertility
- Well A color<Well B color, Low sperm counts
- Well A color>Well B color, Normal or high sperm counts
- Results in 5 minutes

Compare the colour of test well A to reference Well B.

Abnormal: The colour of test well A is lighter than the standard colour of reference Well B, and that means the count of sperm is less than 15million/ml, and sperm count is low. This is known as oligospermia (a range that is normally between 5million/ml and 15million/ml)

Normal: The colour of test well A is darker than the standard colour of reference Well B, and that means the sperm count is greater than 15million/ml and sperm count is normal or high.

NOTE: If well A is colourless this means the sperm count is less than 5million/ml or zero and this is known as azoospermia. Where you are unsure of the result or you feel the result is Abnormal you should repeat the test using the second test that is included in the pack but make sure you do not partake in any sexual activity for 6 days before carrying out the second test. If the second test is also Abnormal you should discuss the results with your doctor or medical professional.

Fertility&Eugenic Test

Product Name	Format	Specimen	Sensitivity	Reg.
Pregnancy(HCG) Test	Strip/Cassette/Midstream	Urine	25/20/10mIU/ml	K123050* CE0123 FSC Anvisa EFDA
Pregnancy(HCG) Test	Strip/Cassette	Urine/Serum	25mIU/ml	FSC
Ovulation(LH) Test	Strip/Cassette/Midstream	Urine	25mIU/ml	D163970 CE0123 FSC
FSH Test	Strip/Cassette/Midstream	Urine	25mIU/ml	CE0123 FSC
SPERM Concentration Test	Cassette	Seminal fluid	$15x10^6$/ml	CE0123 FSC
Digital Pregnancy Test	Midstream	Urine	25mIU/ml	FSC
FFN(Fetal Fibronectin) Test	Strip/Cassette	Cervical Mucus	50ng/ml	FSC
HSVI/HSVII antibody Test	Strip/Cassette	Serum/Plasma	N/A	FSC
TOXO antibody Test	Strip/Cassette	Serum/Plasma	N/A	FSC
Rubella Virus antibody	Strip/Cassette	Serum/Plasma	N/A	FSC
Cytomegalovrus antibody	Strip/Cassette	Serum/Plasma	N/A	FSC
TORCH-IgM(COMB-5) Test	Cassette	Serum/Plasma	N/A	FSC

*K123050 only sensitivity 25mIU/ml approved

Electrical midstream for gestational weeks

Show the number of weeks pregnant
Double confirmation

Accurate resluts from the estimated period of menstruation
Get the resluts four days in advance

Requirements for Sample

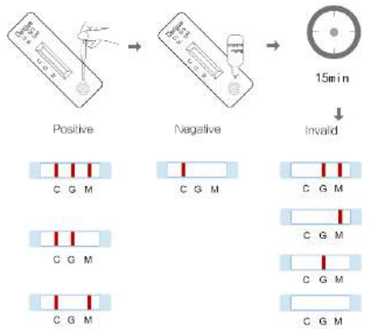
1. Use disposable urine cups or dry, clean plastic or glass containers. Urine can be collected at any time, morning urine is recommended at the beginning.
2. It is recommended to use a fresh urine sample. If it cannot be detected in time within 3 hours, then it can be frozen and stored at -18℃～-20℃ for no more than 3 months. The sample can only be frozen and thawed once.
3. Specimens after abortion and natural termination of pregnancy are not applicable to this product.
4. Patients with menopause and gestational trophoblastic disease are not suitable for this reagent.
5. HOOK effect: When the concentration of hCG exceeds 200000mIU/ml, a hook effect may occur.

Infectious Disease Test

Dengue IgM/IgG

Dengue NS1

Dengue Combo



Dengue IgM and/or IgG Rapid Test

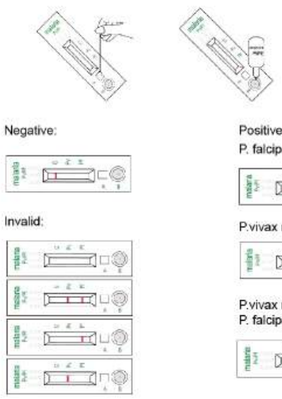
Format:Cassette
Specimen:Serum(Plasma)/Whole Blood
Dengue IgM and/or IgG Rapid Test Cassette is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgM and IgG anti-dengue in human serum (or plasma). The kit is a diagnostic device for qualitative detection .

Pf/pv

Pf

Pan/Pf

HIV1+2



TP

HCV

Format:Cassette
Specimen:Whole Blood
For the rapid qualitative determination of Malaria P.falciparum specific histidine rich protein-2(Pf HRP-2)and malaria P.vivax specific lactate dehydrogenase (pLDH) in human blood as an aid in the diagnosis of Malaria infection.

Infectious Disease Test

Tropics Infectious Disease Rapid Test Kits

Product Name	Format	Specimen	Reg.
Malaria Pf	Cassette	WB	CFDA FSC EFDA
Malaria Pv+Pf	Cassette	WB	CFDA FSC EFDA
Malaria Pan+Pf	Cassette	WB	FSC EFDA
Dengue IgG/IgM	Cassette	S/P/WB	FSC
Dengue NS1 antigen	Cassette	S/P/WB	FSC
Dengue IgG/IgM NS1 combo	Cassette	S/P/WB	FSC
Typhoid IgG/IgM	Cassette	S/P/WB	FSC

Infectious Disease Rapid Test Kits

Product Name	Format	Specimen	China Reg.No
HAV IgM	Cassette	S/P/WB	CFDA FSC
HEV IgM	Cassette	S/P/WB	CFDA FSC
HAV IGM HEV IGM COMBO	Cassette	S/P/WB	CFDA FSC
HBsAg	Strip/Cassette	S/P/WB	CFDA FSC EFDA
HBsAb	Strip/Cassette	S/P/WB	CFDA FSC EFDA
HbeAg	Strip/Cassette	S/P/WB	FSC EFDA
HBeAb	Strip/Cassette	S/P/WB	FSC EFDA
HBcAb	Strip/Cassette	S/P/WB	FSC EFDA
HBcAb IgM	Strip/Cassette	S/P/WB	FSC EFDA
HBV COMBO	Cassette	S/P/WB	FSC EFDA
HCV	Strip/Cassette	S/P/WB	CFDA FSC EFDA
TB	Cassette	S/P/WB	FSC
SYPHILIS	Strip/Cassette	S/P/WB	CFDA FSC EFDA
HIV 1+2	Strip/Cassette	S/P/WB	CFDA FSC
HIV 1+2 TRILINES	Cassette	S/P/WB	FSC
HIV 1+2+O	Cassette	S/P/WB	FSC
TOX-IgM	Cassette	S/P/WB	FSC
RV-IgM	Cassette	S/P/WB	FSC
CMV-IgM	Cassette	S/P/WB	FSC
HSV- Ⅰ -IgM	Cassette	S/P/WB	FSC
HSV- Ⅱ -IgM	Cassette	S/P/WB	FSC
TOX-IgG	Cassette	S/P/WB	FSC
RV-IgG	Cassette	S/P/WB	FSC
CMV-IgG	Cassette	S/P/WB	FSC
HSV- Ⅰ -IgG	Cassette	S/P/WB	FSC
HSV- Ⅱ -IgG	Cassette	S/P/WB	FSC
TORCH-IgM(COMBO-5)	Cassette	S/P/WB	FSC
TORCH-IgG(COMBO-5)	Cassette	S/P/WB	FSC
H.pylori Antigen	Strip/Cassette	Feces	FSC EFDA
H.pylori Antibody	Strip/Cassette	S/P/WB	CE CFDA FSC EFDA

*CFDA: Registered in China
*EFDA: Registered in Ethiopia

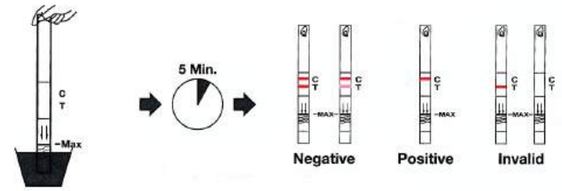
Drug Of Abuse Test

Features & Benefits

- Easy to use
- Results in 5 minutes
- Visually interpreted
- Multiple formats: dipcard, cassette, urine cup, saliva device
- High accuracy
- Cost effective

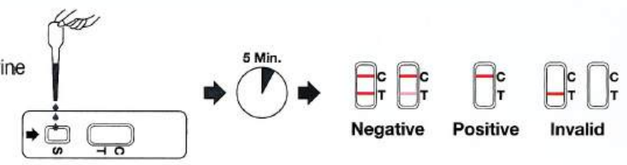
Strip

- Immerse the strip into urine
- Read results at 5 minutes



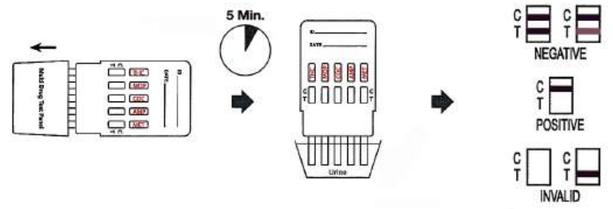
Cassette

- Add 2-3 full drops (approx.100uL) of urine
- Read results at 5 minutes



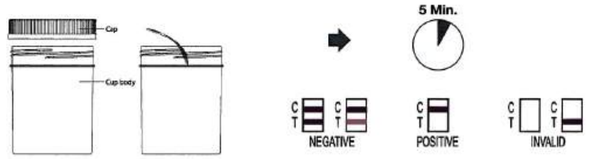
Panel

- Immerse the strip into urine
- Read results at 5 minutes



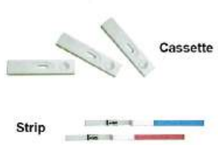
Cup

- Collect the fresh urine sample in the cup
- Read results at 5 minutes



Drug Of Abuse Test

Product	Method	Specimen	Sensitivity	Certificate
Morphine（MOP、OPI）	Colloidal Gold	Urine	300ng/ml	K151557 FSC CE
Methyl amphetamine（MET）	Colloidal Gold	Urine	1000ng/ml	K151557 FSC CE
Amphetamine(AMP)	Colloidal Gold	Urine	1000ng/ml	FSC CE
Cocaine（COC）	Colloidal Gold	Urine	300ng/ml	FSC CE
Ketamine（KET）	Colloidal Gold	Urine	1000ng/ml	FSC CE
Methadone（MTD）	Colloidal Gold	Urine	300ng/ml	FSC CE
Marijuana(THC)	Colloidal Gold	Urine	50ng/ml	K152643 FSC CE
Barbital（BAR）	Colloidal Gold	Urine	300ng/ml	FSC CE
MDMA	Colloidal Gold	Urine	500ng/ml	K152643 FSC CE
Benzodiazepines（BZO）	Colloidal Gold	Urine	300ng/ml	FSC CE
Bupivacaine（BUP）	Colloidal Gold	Urine	10ng/ml	FSC CE
Phencyclidine (PCP)	Colloidal Gold	Urine	25 ng/ml	FSC CE
Oxycodone(OXY)	Colloidal Gold	Urine	100 ng/ml	FSC CE
TCA	Colloidal Gold	Urine	1000 ng/ml	FSC CE
Tramadol(TRA)	Colloidal Gold	Urine	100 ng/ml	FSC CE
EDDP	Colloidal Gold	Urine	100 ng/ml	FSC CE
Propoxyphen(PPX)	Colloidal Gold	Urine	300 ng/ml	FSC CE
Caffeine(CAF)	Colloidal Gold	Urine	8ug/ml	FSC CE
Methaqualone(MQL)	Colloidal Gold	Urine	300 ng/ml	FSC CE
Fentanyl(FYL)	Colloidal Gold	Urine	200 ng/ml	FSC CE
Synthetic Cannabis(K2)	Colloidal Gold	Urine	50 ng/ml	FSC CE
Carisoprodol/Somadril(SOMA)	Colloidal Gold	Urine	1000 ng/ml	FSC CE
Morphine（MOP、OPI）	Colloidal Gold	Saliva	15 ng/ml	FSC CE
Methyl amphetamine（MET）	Colloidal Gold	Saliva	50 ng/ml	FSC CE
Ketamine（KET）	Colloidal Gold	Saliva	100 ng/ml	FSC CE
Multi-Drug 2-12 Test Panel	Colloidal Gold	Urine	--	FSC CE
Multi-Drug 2-15 Test Cup	Colloidal Gold	Urine	--	FSC CE




Panel

Cup

SARS-CoV-2 Rapid Test Kit

SARS-CoV-2 Antigen Rapid Test for Self-testing

Product Features

- Specimen type:Nasal Aspirate Fluid/Nasal Swab
- Easy to collect samples,simple operation, without professional equipment and laboratory
- Testing time:15-20 minutes
- convenient transportation
- Applicable to self- testing at home

Sensitivity And Specificity

SARS-CoV-2 Antigen Rapid Test	RT-PCR		TOTAL
	Positive	Negative	
Positive	205	1	206
Negative	14	599	613
Total	219	600	819

Sensitivity=205/219×100%=93.61%
(Wilson 95%CI: 89.51% - 96.46%)

Specificity=599/600×100%=99.83%
(Wilson 95%CI: 99.07% - 100.00%)

Total accuracy=(205+599)/819×100%=98.17%
(Wilson 95%CI: 97.00% - 98.97%)

Kit Components

1 Test/Box	5 Tests/Box	25 Tests/Box
1 Test Cassette	5 Test Cassettes	25 Test Cassettes
1 Sterilized swab	5 Sterilized swabs	25 Sterilized swabs
1 Extraction Tube	5 Extraction	25 Extraction Tubes
with Buffer	Tubes with Buffer	with Buffer
1 Biosafety bag	5 Biosafety bags	25 Biosafety bags
1 Instructions for use	1 Instructions for use	1 Instructions for use
1 cardboard rack	1 cardboard rack	1 cardboard rack

Packing information

Product Code Format	D0101TE 1 Test/box,400 Box/Ctn	D0501EE 5 Test/box,200 Box/Ctn	D2501AT 25 Test/box,40 Box/Ctn
Box Size	13.5*7*2CM	15*7*4CM	19.5*13.2*8.5CM
Carton Size	57*38*43CM	63*38*43CM	55.5*41*45.5CM
G.W.	12.0KGS	16.0KGS	14.0KGS

SARS-CoV-2 Rapid Test Kit

Covid-19 IgG/IgM Test kit

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and dierential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma.

Features & Benets

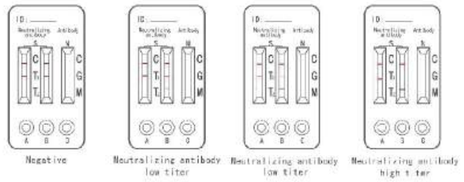
- Specimen type:Whole Blood/Serum/Plasma
- Facilitates patient treatment decisions quickly
- Little specimens, only 5 μL of serum/plasma or 5 μL of whole blood specimens
- All necessary reagents provided & no professional equipment needed
- Relative Sensitivity:96.88% Relative Specificity:100%

Overall Agreement:99%

SARS-CoV-2 Multiplex Antibody Rapid Test Kit

Intend Use

The Test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG, IgM and neutralizing antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma.



SARS-CoV-2 Rapid Test Kit

Product	Specimen	Packing	Reg.
SARS-CoV-2 Antigen	Oropharyngeal Nasopharyngeal	1pcs/Box.5pcs/Box,25pcs/Box	CE,Anvisa,Bfarm,EFDA
SARS-CoV-2 Antigen(saliva)	Saliva	1pcs/Box.5pcs/Box,25pcs/Box	CE,Bfarm
FluA/FluB/SARS-Cov-2 Antigens Multiplex	Oropharyngeal Nasopharyngeal	1pcs/Box.25pcs/Box	CE,Anvisa
SARS-CoV-2 IGG/IgM	WB/S/P	1pcs/Box,25pcs/Box	CE,Anvisa
SARS-CoV-2 Multiplex Antibody	WB/S/P	25pcs/Box	CE
SARS-CoV-2 Neutralizing Antibody	WB/S/P	25pcs/Box	CE

YS-qPCR-1

Real-time Fluorescence Quantitative PCR

Overview

YS-qPCR-1 is based on fluorescent polymerase chain reaction (PCR) and requires use with a companion nucleic acid detection reagents. It can be used clinically for quantitative and qualitative detection of nucleic acid samples (RNA/DNA) from humans, including pathogens and human genetic engineering.

Structure and Composition

YS-qPCR-1 is mainly composed of a control assembly, a photoelectric assembly, a thermal cycling assembly, a heated lid assembly, housing components and system software.

YS-qPCR-1 Basic Parameters and Performance Indicators

Sample size	2 × 8, 16 test wells, 0.2mL tube (30-100 ul), 8-strip tube with 8-strip cap is recommended
Reaction system	10-10^{1}Copies
Fluorescent dye	F1:FAM, SYBR Greenl etc. F2: HEX, VIC, JOE etc. F3: ROX, TEXAS RED etc. F4: Cy5 etc.
Full-plate fluorescence detection time	within 2S
Temperature range	10-100℃
Temperature uniformity	±0.1℃ (@58℃)
Temperature accuracy	±0.1℃ (@58℃)
Heating rate (average)	≥8.0℃/s
Heating rate(maximum)	≥10.5℃/s
Cooling rate (average)	≥5.0℃/s
Cooling rate (maximum)	≥7.5℃/s
Hot lid temperature range	30-120℃
Repeatability of fluorescence intensity test	CV≤0.5%
Sample test repeatability	CV≤1%
Sample linearity	Linear regression coefficient R ≥ 0.98
Fluorescence linearity	Linear regression coefficient R ≥ 0.99
Instrument communication interface	Network port / serial port
Input power	100-240VAC 50/60Hz Max 800VA
Dimensions	380×300×185mm(Outer box size: 520×410×360mm)
Net weight	9.8kg

Operation Process

YS-qPCR-1

- CLINICAL TRIAL in China, good Coincidence rate with over 500 clinical samples, CE mark approved
- UNIQUE TECHNOLOGY, inactivate virus and preserve RNA at room temperature
- EASY TO USE, mix sample and lysis buffer, then do PCR amplification in machine
- TIME SAVING, from sample to result in 30 minutes
- QUALITY TRUST, Internal control inside to monitor the False Negative

■ Inactivating Virus during sample collection - safety and efficiency

The virus can be inactivated directly after the sample is placed into the preservation solution at room temperature without RNA degradation.

Step 1: Throat swabs, Sputum, alveolar lavage fluid were all taken with a swab.

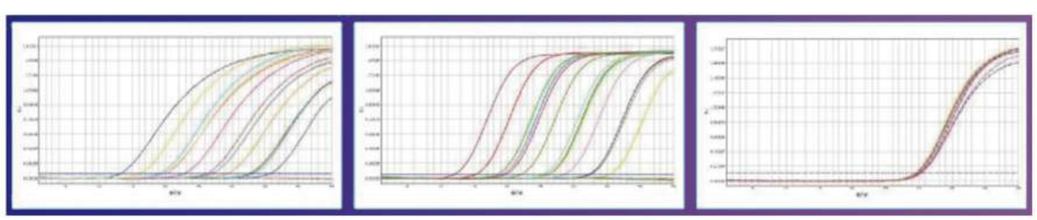
Step 2: Break off the swab head along the kink mark and place it into the sample preservation tube, tighten the cap for safety transportation and convenient detection. Meanwhile, it has the function of inactivating virus and RNA preservation.

■ NOT NEED the RNA extraction and purification - easy to use, labor and time saving

DO NOT NEED the RNA extraction and purification any more, what customer needs to do is to add the sample already in preservation tube into the PCR tube, mixed with the lysis buffer and PCR buffer directly.
VERY EASY TO USE, The test can be started after mixing the enzyme with the reaction solution, no pipette is needed, suitable for POCT scenes

■ Triple PLEX PCR amplification technique and Internal Control inside - monitoring the false negative

Detection the ORFlab gene (FAM) , E gene (CY5) and internal control (HEX/VIC) in one tube at the same time, the recommended platform is YS-qPCR-1,ABI7500 and SLAN.n.



http:// www.egens-bio.com
http://ntys.en.alibaba.com

Product Overview

Fertility&Eugenic Test Kit

Product	Specimen	Format	Catalog
HCG Pregnancy	Urine	Strip/Cassette/Midstream	FE04-01/02/03
HCG Pregnancy	Serum/Urine	Strip/Cassette	FE04-01/02/04
LH ovulation	Urine	Strip/Cassette/Midstream	FE05-01/02/03
fetal fibronectin (fFN)	cervical secretions	Cassette	FE02-01
Follicle-Stimulating Hormone(FSH)	Urine	Strip/Cassette	FE06-01/02
TSH	WB/S/P	Strip/Cassette	FE0701/02
SPERM Concentration	Sperm	Cassette	FE08-01/02
Rv-IgM	WB/S/P	Strip/Cassette	FE09-01/02
CMV-IgM	WB/S/P	Strip/Cassette	FE10-01/02
TOXO IgM	WB/S/P	Strip/Cassette	FE11-01/02
HSV-I-IgM	WB/S/P	Strip/Cassette	FE12-01/02
HSV-II-IgM	WB/S/P	Strip/Cassette	FE12-03/04
Torch-IgM (5 in 1)	WB/S/P	Combo(5 in 1)	FE13-01

Infectious Disease Test

Product	Specimen	Format	Catalog
SARS-CoV-2 Antigen	Oropharyngeal Nasopharyngeal	Cassette	COV01-01
SARS-CoV-2 Antigen(saliva)	Saliva	Cassette	COV02-01
FluA/FluB/SARS-Cov-2 Antigens Multiplex	Oropharyngeal Nasopharyngeal	Cassette	COV03-01
SARS-CoV-2 IGG/IgM Antibody	WB/S/P	Cassette	COV04-01
SARS-CoV-2 Multiplex Antibody	WB/S/P	Cassette	COV05-01
SARS-CoV-2 Neutralizing Antibody	WB/S/P	Cassette	COV06-01
Mycoplasma Pneumoniae(MP) IgM	WB/S/P	Cassette	ID01-01
InfluenzaA /InfluenzaB (FluA+B) Antigens	Oropharyngeal Nasopharyngeal	Cassette	ID02-01
Rotavirus And Adenovirus Antigen combo detection	Feces	Combo(2 in 1)	ID04-01
HAV-IgM	WB/S/P	Strip/Cassette	ID05-01/02
HAV/HEV IgM	WB/S/P	Combo(2 in 1)	ID06-01
HBsAg	WB/S/P	Strip/Cassette	ID07-01/02
HBV Combo(HBsAg,HBsAb,HBeAg,HBeAb,HBcAb)	WB/S/P	Combo(5 in 1)	ID08-01
HCV	WB/S/P	Strip/Cassette	ID09-01/02
HEV-IgM	WB/S/P	Strip/Cassette	ID10-01/02

HIV 1/2 Antibody	WB/S/P	Strip/Cassette	ID11-01/02
HIV 0/1/2 trilines	WB/S/P	Cassette	ID11-03
Syphilis/TP	WB/S/P	Strip/Cassette	ID12-01/02
Malaria PF	WB	Cassette	ID13-01
Malaria PF/Pv	WB	Cassette	ID14-01
Malaria PF/Pan	WB	Cassette	ID15-01
Dengue IgG/IgM	WB/S/P	Cassette	ID16-01
Dengue NSI Antigen	WB/S/P	Cassette	ID17-01
Typhoid IgG/IgM	WB/S/P	Cassette	ID18-01
Chlamydia	Cervical Mucus	Cassette	ID19-01
Gonorrhea	Cervical Mucus	Cassette	ID20-01
H.pylori Antigen	Feces	Strip/Cassette	ID21-01
H.pylori Antibody	WB/S/P	Strip/Cassette	ID22-01

Tumor marker Test

Product	Specimen	Format	Catalog
FOB(Fecal Occult Blood)	Feces	Strip/Cassette	TM01-01/02
CEA(Carcino-Embryonic Antigen)	WB/S/P	Strip/Cassette	TM02-01/02
AFP(Alpha Fetoprotein)	WB/S/P	Strip/Cassette	TM02-03/04
PSA(Prostate Specific Antigen)	WB/S/P	Strip/Cassette	TM02-04/04

Cardiac Marker Test

Product	Specimen	Expiry	Catalog
Troponin(cTnI) Quantitative	Feces	24 Monthes	CM01-01
NT-proBNP Quantitative	WB/S/P	24 Monthes	CM02-01
Myohemoglobin(Myo) Quantitative	WB/S/P	24 Monthes	CM03-01
CK-MB Quantitative	WB/S/P	24 Monthes	CM04-01
H-FABP Quantitative	WB/S/P	24 Monthes	CM05-01
Troponin(cTnI) I	WB/S/P	18 Monthes	CM06-01
cTnI/Myo/CK-MB 3 in 1	WB/S/P	18 Monthes	CM07-01

http:// www.egens-bio.com
http://ntys.en.alibaba.com

Product Overview

Drug Of Abuse Test

Product	Specimen	Format	Catalog
Morphine（MOP、OPI）	Urine	Strip/Cassette	DOA01-01/02
Methyl amphetamine（MET）	Urine	Strip/Cassette	DOA02-01/02
Amphetamine(AMP)	Urine	Strip/Cassette	DOA03-01/02
Cocaine（COC）	Urine	Strip/Cassette	DOA04-01/02
Ketamine（KET）	Urine	Strip/Cassette	DOA05-01/02
Methadone（MTD）	Urine	Strip/Cassette	DOA06-01/02
Marijuana(THC)	Urine	Strip/Cassette	DOA07-01/02
Barbital（BAR）	Urine	Strip/Cassette	DOA08-01/02
MDMA	Urine	Strip/Cassette	DOA09-01/02
Benzodiazepines（BZO）	Urine	Strip/Cassette	DOA10-01/02
Bupivacaine（BUP）	Urine	Strip/Cassette	DOA11-01/02
Phencyclidine (PCP)	Urine	Strip/Cassette	DOA12-01/02
Oxycodone(OXY)	Urine	Strip/Cassette	DOA13-01/02
TCA	Urine	Strip/Cassette	DOA14-01/02
Tramadol(TRA)	Urine	Strip/Cassette	DOA15-01/02
Synthetic Cannabis(K2)	Urine	Strip/Cassette	DOA16-01/02
Carisoprodol/Somadril(SOMA)	Urine	Strip/Cassette	DOA17-01/02
Propoxyphen(PPX)	Urine	Strip/Cassette	DOA18-01/02
Caffeine(CAF)	Urine	Strip/Cassette	DOA19-01/02
Methaqualone(MQL)	Urine	Strip/Cassette	DOA20-01/02
EDDP	Urine	Strip/Cassette	DOA21-01/02
Bupivacaine（BUP）	Urine	Strip/Cassette	DOA22-01/02
Multi-Drug 2-10 Test Panel	Urine	Combo	DOA23
Multi-Drug 2-15 Test Cup	Urine	Cup	DOA24
Morphine（MOP、OPI）	Saliva	Cassette	DOA25-01
Methyl amphetamine（MET）	Saliva	Cassette	DOA26-01
Ketamine（KET）	Saliva	Cassette	DOA27-01
MOR/MET test combo	Saliva	Cassette	DOA28
MOR/MET/KET test combo	Saliva	Cassette	DOA29

CERTIFICATE

EC Certificate No. 1434-IVDD-231/2022
EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre For Testing and Certification certifies that manufactured by:

Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west), No. 1692 Xinghu Avenue, Nantong Economy &Technology Development Zone, 226010 Nantong, PEOPLE'S REPUBLIC OF CHINA.

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test
The list of medical devices covered by this certificate is provided in the annex I

In terms of design documentation, comply with requirements of Annex III (Section II) to Directive 98/79/EC (as amended) implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 24.05.2022 to 27.05.2025
The date of issue of the Certificate: 24.05.2022
The date of the first issue of the Certificate: 24.05.2022

CE 1434

Issued under the Contract No. IND-17/2021
Application No: 332/0321
Certificate bears the qualified signature.
Warsaw, 24/05/2022
Module A1

Director
Medical Device Certification Department

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:cbd@ciotlodz.gov.pl

CERTIFICATE

EC Certificate No. 1434-IVDD-231/2022
EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre For Testing and Certification certifies that manufactured by:

Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west), No. 1692 Xinghu Avenue, Nantong Economy &Technology Development Zone, 226010 Nantong, PEOPLE'S REPUBLIC OF CHINA.

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test Kit
The list of medical devices covered by this certificate is provided in the annex I

In terms of design documentation, comply with requirements of Annex III (Section II) to Directive 98/79/EC (as amended) implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 25.05.2022 to 27.05.2025
The date of issue of the Certificate: 25.05.2022
The date of the first issue of the Certificate: 25.05.2022

CE 1434

Issued under the Contract No. IND-17/2021
Application No: 332/0321
Certificate bears the qualified signature.
Warsaw, 25/05/2022
Module A1

Director
Medical Device Certification Department

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:cbd@ciotlodz.gov.pl

CERTIFICATE

EC Certificate No. 1434-IVDD-228/2022
EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre For Testing and Certification certifies that manufactured by:

Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west), No. 1692 Xinghu Avenue, Nantong Economy &Technology Development Zone, 226010 Nantong, PEOPLE'S REPUBLIC OF CHINA.

In vitro diagnostic medical devices
for self-testing

Multiple Drugs of Abuse Rapid Tests
Type: 6 -panel dip card, Model: D012606
The list of medical devices covered by this certificate is provided in the annex I

In terms of design documentation, comply with requirements of Annex III (Section II) to Directive 98/79/EC (as amended) implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 24.05.2022 to 27.05.2025
The date of issue of the Certificate: 24.05.2022
The date of the first issue of the Certificate: 24.05.2022

CE 1434

Issued under the Contract No. IND-267/2021
Application No: 498/0321
Certificate bears the qualified signature.
Warsaw, 24/05/2022
Module A1

Director
Medical Device Certification Department

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:cbd@ciot.gov.pl

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on in Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 5)
(List A and B and devices for self-testing)

No. V1 063367 0017 Rev. 02

Manufacturer: Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west)
No. 1692 Xinghu Avenue
Nantong Economy & Technology Development Zone
226010 Nantong
PEOPLES REPUBLIC OF CHINA

Facility(ies): Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west), No. 1692 Xinghu Avenue
Nantong Economy & Technology Development Zone, 226010
Nantong, PEOPLE'S REPUBLIC OF CHINA

Nantong Egens Biotechnology Co., Ltd.
Building 9, Building 10, No.1692, Xinghu Avenue, Nantong Economy & Technology Development Zone, 226010 Nantong, Jiangsu Province, PEOPLES REPUBLIC OF CHINA

Product Category(ies): Products for determination of tumor markers (PSA) and products for self testing

Model(s): Prostate Specific Antigen (PSA) Test,
Pregnancy Test for Self Testing,
Ovulation (LH) Test for Self Testing
Follicle Stimulation Hormone (FSH) Test,
Fast Diagnostic Screening Test for Sperm Concentration

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system ascribes to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsudamerica.com/?product=V1 063367 0017 Rev. 02

Report no.: SH2124EXT01

Valid from: 2022-05-12
Valid until: 2025-05-26

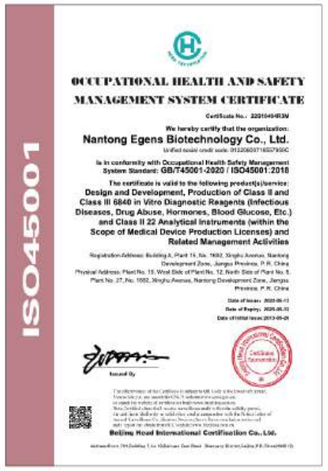
Date, 2022-05-12

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

TÜV®



ISO45001

OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 22O104R0536

We hereby certify that the organization:
Nantong Egens Biotechnology Co., Ltd.
Unified social credit code: 91320600710552795C

is in conformity with Occupational Health Safety Management System Standard: **GB/T45001-2020 / ISO45001:2018**

The certificate is valid to the following product(s)/service:
Design and Development, Production of Class II and Class III 6840 in Vitro Diagnostic Reagents (Infectious Diseases, Drug Abuse, Hormones, Blood Glucose, Etc.) and Class II 22 Analytical Instruments (within the Scope of Medical Device Production Licenses) and Related Management Activities

Registration Address: Building A, Plant 15, No. 1692, Xinghu Avenue, Nantong Development Zone, Jiangsu Province, P.R. China
Physical Address: Plant No. 15, West Side of Plant No. 12, North Side of Plant No. 5, Plant No. 27, No. 1692, Xinghu Avenue, Nantong Development Zone, Jiangsu Province, P.R. China

Date of Issue: 2022-05-12
Date of Expiry: 2025-05-11
Date of Initial Issue: 2013-05-24

Issued By

Beijing Head International Certification Co., Ltd.

ISO14001

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 21E123R0536

We hereby certify that the organization:
Nantong Egens Biotechnology Co., Ltd.
Unified social credit code: 91320600710552795C

is in conformity with Environmental Management System Standard: **GB/T24001-2016 / ISO14001:2015**

The certificate is valid to the following product(s)/service:
Design and Development, Production of Class II and Class III 6840 in Vitro Diagnostic Reagents (Infectious Diseases, Drug Abuse, Hormones, Blood Glucose, Etc.) and Class II 22 Analytical Instruments (within the Scope of Medical Device Production Licenses) and Related Management Activities

Registration Address: Building A, Plant 15, No. 1692, Xinghu Avenue, Nantong Development Zone, Jiangsu Province, P.R. China
Physical Address: Plant No. 15, West Side of Plant No. 12, North Side of Plant No. 5, Plant No. 27, No. 1692, Xinghu Avenue, Nantong Development Zone, Jiangsu Province, P.R. China

Date of Issue: 2021-05-21
Date of Release: 2022-05-12
Date of Expiry: 2024.04.20
Date of Initial Issue:2021-05-20

Issued By

Beijing Head International Certification Co., Ltd.

ISO9001

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 22Q104R1536

We hereby certify that the organization:
Nantong Egens Biotechnology Co., Ltd.
Unified social credit code: 91320600710552795C

is in conformity with Quality Management System Standard: **GB/T19001-2016 / ISO9001:2015**

The certificate is valid to the following product(s)/service:
Design and Development, Production of Class II and Class III 6840 in Vitro Diagnostic Reagents (Infectious Diseases, Drug Abuse, Hormones, Blood Glucose, Etc.) and Class II 22 Analytical Instruments (within the Scope of Medical Device Production Licenses)

Registration Address: Building A, Plant 15, No. 1692, Xinghu Avenue, Nantong Development Zone, Jiangsu Province, P.R. China
Physical Address: Plant No. 15, West Side of Plant No. 12, North Side of Plant No. 5, Plant No. 27, No. 1692, Xinghu Avenue, Nantong Development Zone, Jiangsu Province, P.R. China

Date of Issue: 2021-05-12
Date of Expiry: 2024.04.20
Date of Initial Issue:2015-07-08

Issued By

Beijing Head International Certification Co., Ltd.

Declaration of Conformity

Manufacturer: Nantong Egens Biotechnology Co.,Ltd
Building 15 , Building 12(west) ,
No. 1692 Xinghu Avenue,
Nantong Economy& Technology
Development Zone, 226010 Nantong,
People's Republic of China

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537
Hamburg, Germany

Product Name: COVID-19 IgG/IgM Rapid Test Kit

Model: Strip, Cassette

Classification (IVDD, Annex II): Others

Conformity Assessment Route: Annex III

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives 98/79/EC and Standards EN ISO13485:2016, under our sole responsibility.
All supporting documentations are retained under the premises of the manufacturer.

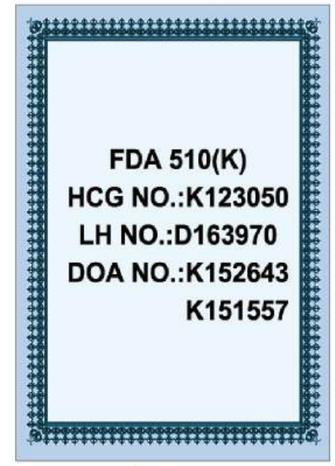
Signature: Su Linping

Name: Su Linping

Position: Management Representative

Date: 13-March-2020

CE



FDA 510(K)
HCG NO.:K123050
LH NO.:D163970
DOA NO.:K152643
K151557

MDSAP

CERTIFICATE
No. QSE 063367 0019 Rev. 02

Certificate Holder: Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west)
No. 1692 Xinghu Avenue
Nantong Economy & Technology Development Zone
226010 Nantong
PEOPLES REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Design and Development, Production and Distribution of Rapid Test Kit for the Detection of Fertility Function Hormones, Pregnancy, Infectious Diseases, Drug of Abuse Test

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to these criteria for the scope of certification listed. Validity of this certificate can be maintained by visiting the website www.tuvsud.com/ps-cert.
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F001709

Effective Date: 2022-07-06

Expiry Date: 2025-01-06

Page 1 of 2
Date of Issue: 2022-07-18

(Renee Walker)
Manager, US Certification Body
Medical and Health Services

TÜV SÜD America, Inc. · 401 Edgewater Place Suite #500 · Wakefield · MA 01880 · USA · www.tuvsud.com

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

伊仕生物
EGENS

NanTong Egens Biotechnology Co.,Ltd

Add:Building 15, Building 12(west) No. 1692 Xinghu Avenue
Nantong Economy & Technology Development Zone
226010 Nantong Jiangsu Province, China.
Tel: +86-513-85920700
+86-513-85356913
E-mail:egens@egens-bio.cn
http://www.egens-bio.com

Subsidiaries

科卫诊断
KEWEI Diagnostic

Beijing Kewei Clinical Diagnostic Reagent Co. Ltd.

Address: No.7,Xi Yi Road, Yanqihe, Yanqi Economic Development Zone,
Huai Rou District, Beijing, China
Zip code: 100043
Phone: +86-010-6886-3176 / 3179 / 3178
Fax: +86-010-6886-3285
Technical service: +86-010-6166-5566 / 4006502862
E-mail:Kewei@keweidiagnostic.com
Http://www.keweidiagnostic.com