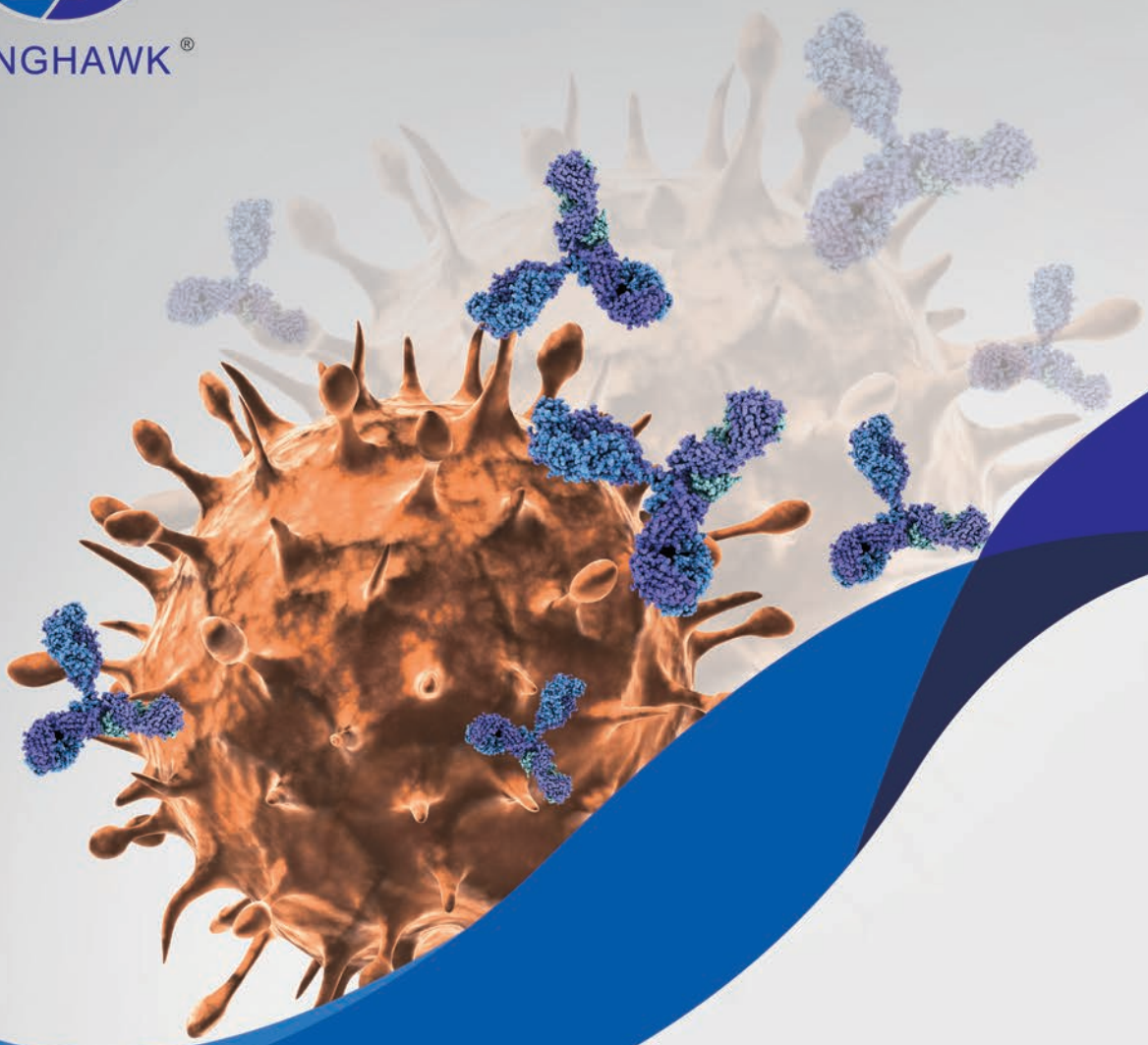
KINGHAWK®



CATALOG

BEIJING KINGHAWK PHARMACEUTICAL CO.,LTD

www.kinghawk828.com

Company profile

Founded in 1993 and located in Beijing Economic and Technological Development Area, Beijing Kinghawk Pharmaceutical Co.,Ltd is a hi-tech enterprise with 156 employees which covers 6000m2 and possesses 2000m2 GMP workshops, and is ISO:13485:2003, ISO:9001:2000 certified by TUV in 2006 and GMP certified by SFDA in 2003, specialized in research, development and production of in-vitro diagnostic reagents in China.

Over 25 years of development, Kinghawk has been transformed into one of the leading IVD companies in China. Now, over 100 kinds of in-vitro diagnosis products of ELISA series, rapid detection series, antiterrorism series, blood grouping series, PCR series are manufactured and marked through out of China. Among them, the ELISA series and rapid test series are ranked the top 10 manufacturer in China, the blood grouping series contain the most completed diagnostic varieties and the antiterrorism series are the sole SFDA approved products to be used in public security area.

With its systematic products and professional services, a good direct sale and service network and effective channels have been established around the country. Kinghawk's sincerely customers range in China CDC, large hospitals, blood stations, and scientific research institutes.



Product catalogue

Enzyme-linked Immunosorbent Assay (ELISA)

Cat.No.	Test Item	Sample Type	Intended Use	Available Size	Approved By
A0111	HIV 1+2 Ab	Serum/Plasma	Blood Screening	96T	SFDA
A1011	HIV 1+2 Ab/Ag	Serum/Plasma	Blood Screening	96T	SFDA
A0211	HCV Ab	Serum/Plasma	Blood Screening	96T	SFDA
A0311	TP Ab	Serum/Plasma	Blood screening	96T	SFDA
A0411	HBsAg	Serum/Plasma	Blood screening	96T	SFDA
A0483	Pre-s HBsAg	Serum/Plasma	Blood Screening	96T	SFDA
A1111	HIV-1 LAg-Avidity	Serum/Plasma	Blood Screening	192T	RUO
A0321	TRUST Test	Serum/Plasma	Blood Screening	120T/320T	SFDA
A0511	Malaria Ab	Serum/Plasma	Tropical Disease	96T	RUO



ELISA kit Features

- High sensitivity and excellent specificity
- 12months shelf life
- Specimen: serum or plasma
- Antigen/antibody sandwich ELISA immunoassay

Blood Typing Reagents

Cat.No.	Product Description	Intend Use	Titer	Size	Approved By
A0111	Anti A and Anti-B Blood Grouping Reagenets (Monoclonal Antibody)	Forward Grouping	1/512	10ml	SFDA
A0221	RhD(IgM) Blood Grouping Reagent (Monoclonal Antibody)	Forward Grouping	1/256	10ml	SFDA
A0331	RhD(IgG) Blood Grouping Reagent (Monoclonal Antibody)	Forward Grouping	1/256	10ml	SFDA



Product Features

- High Titer
- Good stability
- High Specificity
- Easy operation
- Strong Affinity
- Good Repeatability

Sample

- Whole Blood
- 10% or 5% red blood cell suspension

Application

- Slide
- Tube
- Microplate

Rapid Test (Colloidal Gold)

Cat.No.	Test Item	Sample Type	Intended Use	Size	Approved By
A0121	HIV 1/2 Ab	plasma/serum	Blood screening	50T/1T	SFDA
A0221	HIV 1/2 Ab	Urine	HIV Screening	50T/1T	RUO
A0331	TP Ab	plasma/serum	Blood screening	40T/10T	SFDA
A0421	HBsAg	plasma/serum	Blood screening	50T/10T	RUO
A0521	HCV Ab	plasma/serum	Blood screening	50T/10T	RUO
A3001	Malaria P.f / P.v Ag	whole blood	Tropical Disease	50T	RUO
A3012	Malaria P.f / Pan Ag	whole blood	Tropical Disease	50T	RUO
A3013	YFV (Yellow Fever Virus) Ab	plasma/serum	Tropical Disease	50T	RUO
A3014	Zika Ab	plasma/serum	Tropical Disease	50T	RUO
A3015	Dengue Ab	plasma/serum	Tropical Disease	50T	RUO
A3016	Morphine	Urine	Drug Test	50T	RUO
A3017	Methamphetamine	Urine	Drug Test	50T	RUO
A3018	ketamine	Urine	Drug Test	50T	RUO



Product Features

- Easy to use
- Fast to read
- High Specificity
- Excellent Sensitivity
- Reliable

Rapid Test (Colloidal Gold)

Cat.No.	Test Item	Sample Type	Intended Use	Size	Approved By
A1112	Bacillus anthracnose Ag	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	PLA
A1122	Bacillus anthracnose Ab	serum	antiterrorism	10T/1T	SFDA
A1212	Tularemia Ag	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	PLA
A1222	Tularemia Ab	serum	antiterrorism	10T/1T	SFDA
A0912	Yersinia Pestis Ag	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	PLA
A0922	Yersinia Pestis Ab	serum	antiterrorism	10T/1T	SFDA
A1012	Brucella Ag	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	PLA
A1022	Brucella Ab	serum	antiterrorism	10T/1T	SFDA
A1312	Burkholderia mallei Ag	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	PLA
A1322	Burkholderia mallei Ab	serum	antiterrorism	10T/1T	SFDA
A1412	Burkholderia pseudomallei Ag	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	PLA
A1422	Burkholderia pseudomallei Ab	serum	antiterrorism	10T/1T	SFDA
A1512	Botulinum toxin A	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	PLA
A1612	Staphylococcus enterotoxin B	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	PLA
A1712	Ricin	mammal specimens,food, soil,water etc.	antiterrorism	10T/1T	RUO



Product Features

- Easy to use
- Fast to read
- High Specificity
- Excellent Sensitivity
- Reliable

Quality System Certificate



CERTIFICATE

No. Q1N 17 03 61710 005

Holder of Certificate: Beijing Kinghawk Pharmaceutical Co., Ltd.

Facility(ies):

Certification Mark:

Scope of Certificate: Design, Development, Production, Distribution, Installation and Servicing of In-vitro Diagnostic Medical Devices for Enzyme-linked Immunosorbent Assay (ELISA) Kit, Rapid Test Kit, Blood Grouping Kit, Real Time Quantitative PCR Kit.

Applied Standard(s): EN ISO 13485:2012 + AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor 1:2009) DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report-No.: 51000331

Valid from: 2017-11-16

Valid until: 2020-11-15

Date, 2017-11-16

Stefan Pohl

Page 1 of 1



中华人民共和国

药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS

PEOPLE'S REPUBLIC OF CHINA

证书编号：CN20160025

Certificate No.

企业名称：北京金豪制药股份有限公司

Manufacturer：Beijing kinghawk pharmaceutical co.,ltd

地　址：北京市北京经济技术开发区运成街7号

Address：No.7 Yuncheng Street,Beijing Economic-Technological

认证范围：

Scope of Inspection：

经审查，符合中华人民共和国《药品生产质量管理规范》要求，特发此证。

This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至 2021 年 02 月 28 日

This certificate remains valid until 28/02/2021

发证机关：

Issued By

Date for Issuing 29/02/2016 2016 年 02 月 29 日

国家食品药品监督管理总局制

CHINA FOOD AND DRUG ADMINISTRATION



药品销售证明书

FREE SALE CERTIFICATE

编号（No.）：（京）[2016]京食药销第一14（安）-1

中华人民共和国

北京市食品药品监督管理局

BEIJING FOOD AND DRUG ADMINISTRATION

PEOPLE'S REPUBLIC OF CHINA

企业名称：北京金豪制药股份有限公司

Company：Beijing Kinghawk Pharmaceutical CO.,Ltd

住所地址：北京市北京经济技术开发区运成街7号1号楼

Address：Building 1,NO.7 YunCheng St, Beijing Economic-Technological Development Area, Beijing

生产地址：北京市北京经济技术开发区运成街7号1号楼

Address：Building 1,NO.7 YunCheng St, Beijing Economic-Technological Development Area, Beijing

产品名称：抗A和抗B血型定型试剂（单克隆抗体）

Product：Anti-A and Anti-B Blood Grouping Reagent（Monoclonal Antibody）

特此证明上述产品是由中华人民共和国北京药品监督管理局批准生产并经许可在北京地区销售。

It is certified that above-mentioned products have been authorized by China food and Drug Administration to be manufactured and freely sold on the market of China.

该企业符合世界卫生组织（WHO）倡导及中国GMP的要求。

It also certified that the manufacturer conforms to the requirements of the Chinese Good Manufacturing Practice laid down in accordance with recommendation of the World Health Organization.

此证明书仅用于企业在进口国办理药品注册手续，不得用于其他用途。

This certificate can be used by the enterprises for their drug registration transaction in the importing countries,rather than any other purpose.

北京市监局三字

Valid for two years

北京市海淀区中关村学院路70号，100191

No.70 Zaojiayuan Street,XiCheng District,Beijing 100032

（北京人签字）

（Signature）

北京市食品药品监督管理局

Beijing Food and Drug Administration

Real Shot of the Plant





Product SFDA Certificate



中华人民共和国

PEOPLE'S REPUBLIC OF CHINA

医疗器械注册证

REGISTRATION CERTIFICATE FOR MEDICAL DEVICE

注册号：国食药监械（准）字 2007 第 3401035 号

北京金豪制药有限公司：

你单位生产的布鲁氏菌抗原检测试剂（胶体金法），经审查，符合医疗器械产品市场准入规定，准许注册。自批准之日起有效期四年。

特此证明。

国家食品药品监督管理局

State Food and Drug Administration

2007 年 9 月 20 日

附件：医疗器械注册登记表

NO.0009689



中华人民共和国

PEOPLE'S REPUBLIC OF CHINA

医疗器械注册证

REGISTRATION CERTIFICATE FOR MEDICAL DEVICE

注册号：国食药监械（准）字 2007 第 3401034 号

北京金豪制药有限公司：

你单位生产的鼻疽菌抗原检测试剂（胶体金法），经审查，符合医疗器械产品市场准入规定，准许注册。自批准之日起有效期四年。

特此证明。

国家食品药品监督管理局

State Food and Drug Administration

2007 年 9 月 20 日

附件：医疗器械注册登记表

NO.0009694



中华人民共和国

PEOPLE'S REPUBLIC OF CHINA

医疗器械注册证

REGISTRATION CERTIFICATE FOR MEDICAL DEVICE

注册号：国食药监械（准）字 2007 第 3401029 号

北京金豪制药有限公司：

你单位生产的A型肉毒毒素检测试剂（胶体金法），经审查，符合医疗器械产品市场准入规定，准许注册。自批准之日起有效期四年。

特此证明。

国家食品药品监督管理局

State Food and Drug Administration

2007 年 9 月 20 日

附件：医疗器械注册登记表

NO.0009685