编号: 104166503

营业执照

(1-1)

(副 本)

统一社会信用代码 911101161022068352

名　　称	北京科卫临床诊断试剂有限公司
类　　型	有限责任公司(法人独资)
住　　所	北京市怀柔区雁栖经济开发区雁栖河西一路7号
法定代表人	王保君
注册资本	3200万元
成立日期	1990年03月06日
营业期限	2004年02月18日 至 2024年02月17日
经营范围	生产体外诊断试剂[乙型肝炎病毒表面抗原诊断试剂盒（酶联免疫法）、丙型肝炎病毒抗体诊断试剂盒（酶联免疫法）、人类免疫缺陷病毒抗原抗体诊断试剂盒（酶联免疫法）、梅毒螺旋体抗体诊断试剂盒（酶联免疫法）]；生产III、II类：III、II-6840体外诊断试剂；（医疗器械生产许可证有效期至2020年11月01日）；销售医疗器械III：6840临床检验分析仪器及诊断试剂（含诊断试剂）；销售医疗器械II类：6822医用光学器具、仪器及内窥镜设备、6840临床检验分析仪器及诊断试剂（含诊断试剂）、6854手术室、急救室、诊疗室设备及器具；货物进出口、技术进出口、代理进出口；技术开发、咨询；租赁医疗器械。（生产体外诊断试剂[乙型肝炎病毒表面抗原诊断试剂盒（酶联免疫法）、丙型肝炎病毒抗体诊断试剂盒（酶联免疫法）、人类免疫缺陷病毒抗原抗体诊断试剂盒（酶联免疫法）、梅毒螺旋体抗体诊断试剂盒（酶联免疫法）]以及企业依法自主选择经营项目，开展经营活动；依法须经批准的项目，经相关部门批准后依批准的内容开展经营活动；不得从事本市产业政策禁止和限制类项目的经营活动。）

在线扫码获取详细信息

登记机关

北京市工商行政管理局怀柔分局

2018 年 06 月 08 日

提示：每年1月1日至6月30日通过企业信用信息公示系统报送上一年度年度报告并公示。

企业信用信息公示系统网址：qyxy.baic.gov.cn

中华人民共和国国家工商行政管理总局监制

KEWEI

北京科卫临床诊断试剂有限公司

Beijing Kewei Clinical Diagnostic Reagent Inc.

统一社会信用代码：911101161022068352

地址：北京怀柔区雁栖开发区雁栖河西一路 7 号

Address: No.7 Yanqihe xiyi Road. Yanqi Development zone Huairou District Beijing, China

Tel: 86 10 68863176　68863259

Site: hppt://www.keweidignostic.com

Email: kewei@keweidignostic.com.com

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.
No. 7, Yan Qi He Xi Yi Rd.
Huairou District
101407 Beijing
China

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacture and distribution of in-vitro diagnostic reagents used in the detection of cancer, cardiac markers, endocrine disorders and infectious diseases based on immunological method for clinical laboratory use

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-06-11
Certificate Registration No.:	SX 60135417 0001
An audit was performed. Report No.:	16802804 004
This Certificate is valid until:	2021-10-09

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14159-01-02

Date 2019-06-11

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

CE Technical Documentation Review Report

Applicant:	**BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.** No.7,Yan Qi He Xi Yi Rd, Huairou District, 101407, Beijing, China
Report Number:	**16802805.001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	**Troponin I /CK-MB/Myo Test Cassette** **Troponin I Test Cassette**
Type(s)/Model(s):	------
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	July.06.2016
Date of expiry:	July.05.2021
Review result:	During the examination of the provided Technical Documentation (No.: KEWEI DIAGNOSTICS/CE/CARDIAC001, No.: KEWEI DIAGNOSTICS/CE/CARDIAC002, Revision AB/2, Dated 2016-Mar-30) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

TÜV Rheinland (China) Ltd.

Yuhong CHEN
Manager
Medical Services

Rev.01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
Tel: (8610)6566 6660 Fax: (8610)6566 6667
e-mail: info@bj.chn.tuv.com Internet: http://www.chn.tuv.com

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.
Address: No.7,Yan Qi He,Xi Yi Rd.,Huai Rou District,Beijing,China.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- COVID-19 Antigen ELISA Test Kit.

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:

Place Beijing,China

European Representative:

Seal/Stamp:
Lotus NL B.V.

Name of authorized signatory: Wang Baojun
Position held in the company: General Manager

Seal/Stamp:
BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.
Address: No.7,Yan Qi He,Xi Yi Rd.,Huai Rou District,Beijing,China.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- COVID-19 IgM Antibody ELISA Test Kit.

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
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Place Beijing,China.

European Representative:

Name of authorized signatory:
Position held in the company: General Manager

Seal/Stamp:
Lotus NL B.V.

Seal/Stamp:
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European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- COVID-19 IgG Antibody ELISA Test Kit.

Category: Others

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
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Position held in the company: General Manager

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Address: No.7,Yan Qi He,Xi Yi Rd.,Huai Rou District,Beijing,China.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- COVID-19 Antigen Rapid Test Kit.

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
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Signed:

Place Beijing,China.

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Lotus NL B.V.

Name of authorized signatory: Wang Baojun
Position held in the company: General Manager

Seal/Stamp:
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Address: No.7,Yan Qi He,Xi Yi Rd.,Huai Rou District,Beijing,China.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- COVID-19 IgG/IgM Antibody Rapid Test Kit.

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
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Signed:

Place Beijing,China

European Representative:

Seal/Stamp:
Lotus NL B.V.

Name of authorized signatory: Wang Bojun
Position held in the company: General Manager

Seal/Stamp:
BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.

产品 Product

新型冠状病毒 IgM/IgG 抗体检测试剂盒(胶体金法)

COVID-19 IgM/IgG Rapid Test Kit (Colloidal Gold)

KEWEI

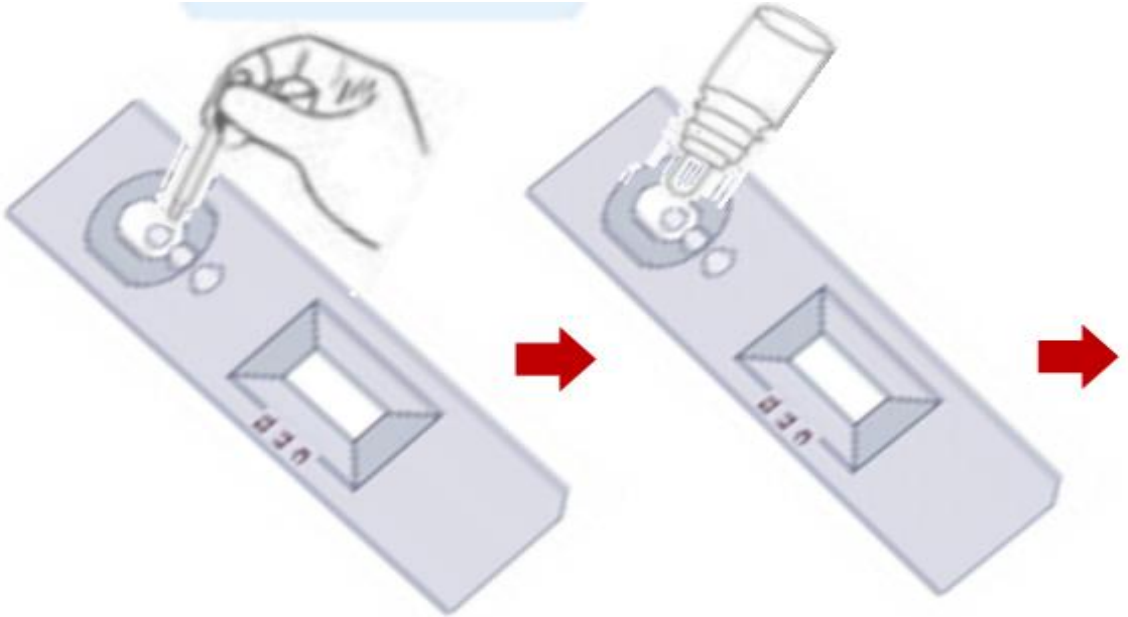
新型冠状病毒 IgM/IgG 抗体检测试剂盒(胶体金法)

COVID-19 IgM/IgG RapidTest Kit(Colloidal Gold)

操作步骤

Operating Procedure

- 检测卡恢复至室温
- The test card is restored to room temperature.
- 在加样孔中加入 10μl 指尖血、全血、血清、血浆，再加两滴稀释液。
- 10μl sample of fingertip blood, whole blood, serum, plasma and two drops diluent were added to that loading well.
- 等待 15 分钟后，判读结果
- After waiting for 15 minutes, read the results.



15 分钟出结果
Results in 15 minutes.

新型冠状病毒 IgM/IgG 抗体检测试剂盒（胶体金法）

COVID-19 IgM/IgG Test Kit (Colloidal Gold)

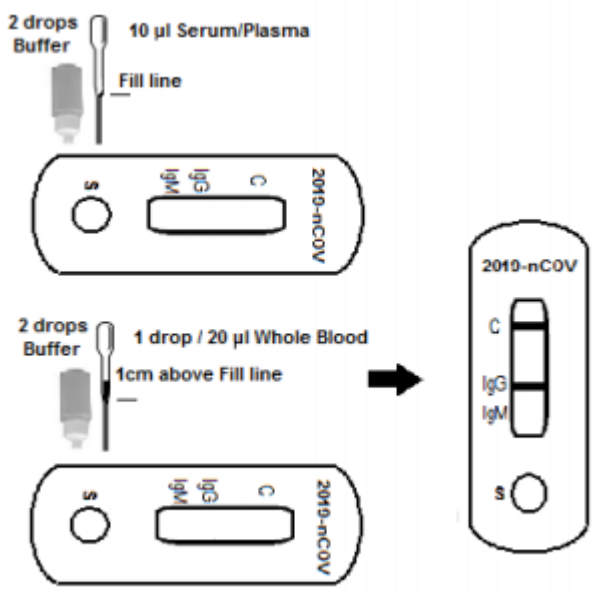
15 分钟实现新冠病毒筛查

Screening for coronavirus in 15 minutes

简单、便携、快速

Simple，Portable and Fast

- 指尖采血
- Fingertip blood collection
- 肉眼判读结果
- Visual interpretation results
- 快速检测
- Rapid detection
- 社区筛查，家庭自诊
- Community Screening family self-diagnosis



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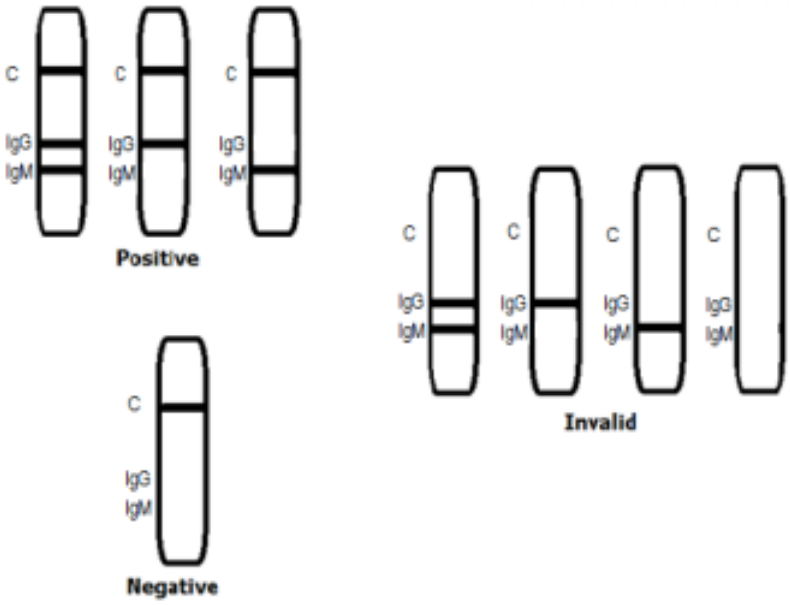
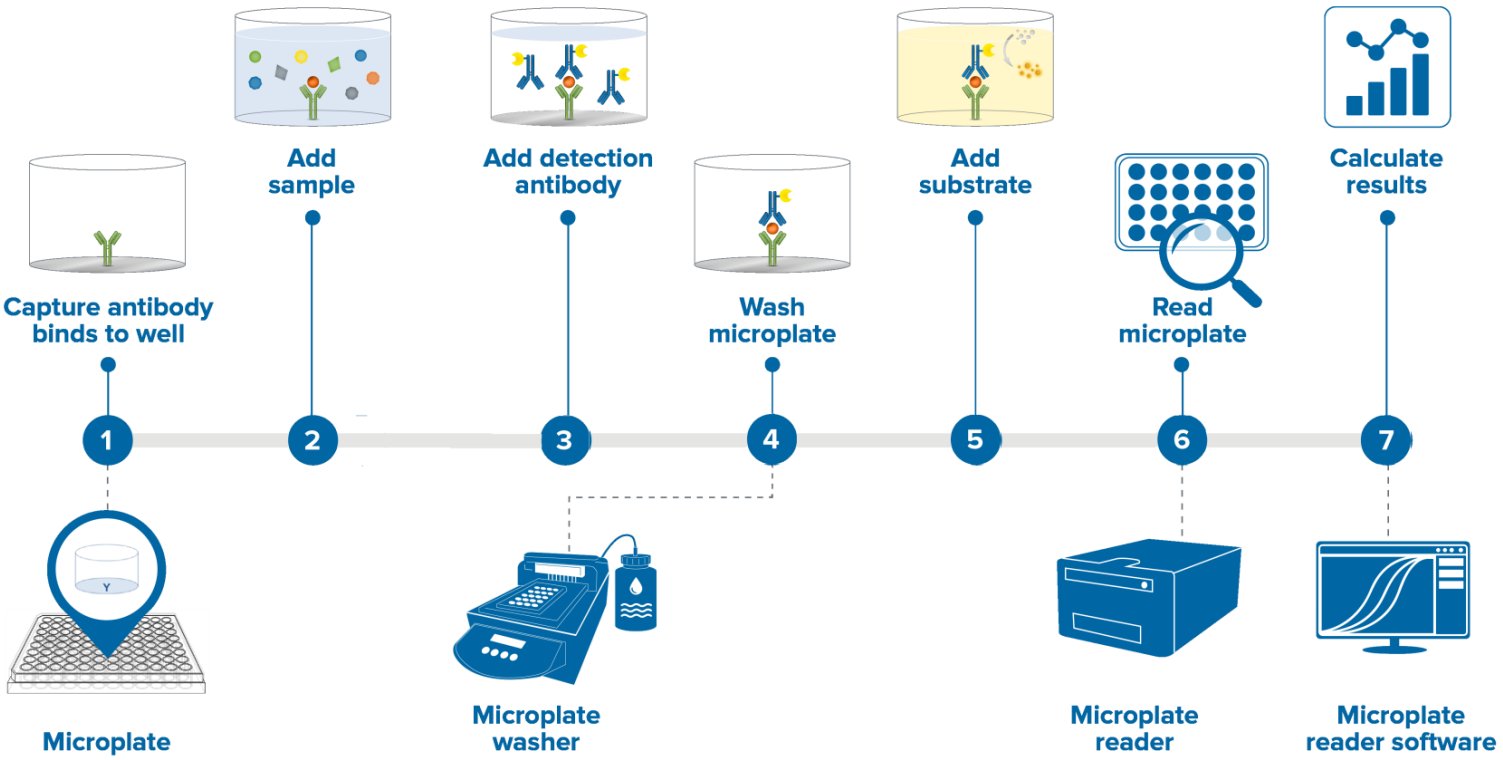


KEWEI

Elisa Kit Operation Steps



COVID-19 产品

COVID-19 Products

1. Antigen Rapid Test Kit

Principle	Sandwich Method
Sample Type	Nasal, throat swab Serum/Plasma
Sample Volume	10 μL
Assay Incubation	15minutes, RT
Total Wash Steps	No
Limit of Detection	200pg/mL
Sensitivity	92.5%
Specificity	100%

2. Antigen Rapid Test Kit

Principle	Captured Method
Sample Type	Whole Blood Serum/Plasma
Sample Volume	10 μL
Assay Incubation	15 minutes, RT
Total Wash Steps	No
Limit of Detection	L3
Sensitivity	95%
Specificity	96%

3. Antigen Elisa Test Kit

Principle	Sandwich Method
Sample Type	Nasal, throat swab Serum/Plasma
Sample Volume	50μL
Assay Incubation	40 minutes, 37° C
Total Wash Steps	1
Limit of Detection	50pg/mL
Sensitivity	93.3%
Specificity	100%

4. IgM Antibody Elisa Test Kit

Principle	Captured Method
Sample Type	Serum
Sample Volume	10 μL
Assay Incubation	60 minutes, 37° C
Total Wash Steps	2
Limit of Detection	L3
Sensitivity	96.6%
Specificity	95%

5. IgG Antibody Elisa Test Kit

Principle	Indirect Method
Sample Type	Serum
Sample Volume	10 μL
Assay Incubation	60 minutes, 37° C
Total Wash Steps	2
Limit of Detection	L3
Sensitivity	98.3%
Specificity	96.5%