版本号 V1.0

Product Recommendation of COVID-19 Neutralizing Antibody

新冠中和抗体检测产品推荐

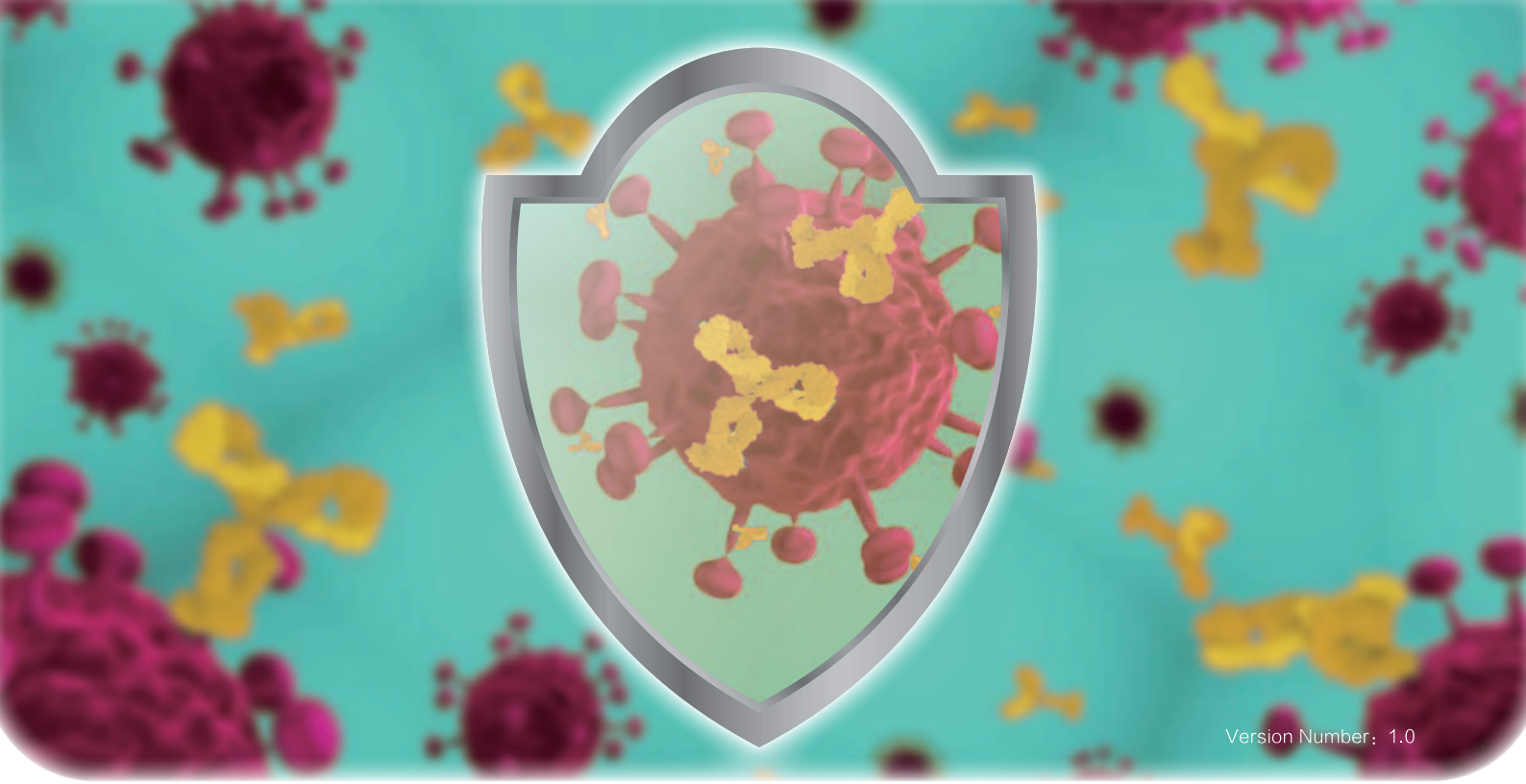
antai
中 检 安 泰

Beijing Zhongjian Antai Diagnostic Technology Co., Ltd.

北京中检安泰诊断科技有限公司

Catalog

目 录



新型冠状病毒（COVID-19）
中和抗体检测试剂盒（胶体金法）
Corona Virus (COVID-19) Neutralizing Antibody Detection Kit (Colloidal Gold)

检测的意义
Significance

免疫系统在经受病毒刺激后会产生相应的抗体，有些抗体可以和病毒颗粒中和表位结合，使病毒失去结合受体的能力，阻止病毒感染细胞，以此把病毒“中和”掉了。这些抗体就称为“中和抗体”。

The immune system will produce corresponding antibodies after being stimulated by the virus. Some antibodies can bind to the neutralizing epitope of the virus particles, making the virus lose the ability to bind to the receptor, preventing the virus from infecting cells, so as to "neutralize" the virus. These antibodies are called neutralizing antibodies.

新冠病毒中和抗体的检测可以反映个人的康复情况以及疫苗的效果，但传统的病毒中和实验需使用活病毒和细胞，且对实验室安全性及操作人员技能要求较高。这种耗时长、要求高的传统中和检测方法显示不适用于传播速度快、感染覆盖范围广的新冠疫情。因此，本试剂盒为检测新冠病毒中和抗体提供了一种无需使用感染性病毒、耗时短、操作简便的辅助诊断方法。

The detection of neutralizing antibody of novel coronavirus can reflect the individual's recovery and the effect of vaccine, but the traditional virus neutralization experiment needs to use live virus and cells, and has high requirements for laboratory safety and operator skills. This time-consuming and demanding traditional neutralization detection method does not apply to COVID-19 with fast transmission speed and wide coverage. Therefore, the kit provides a simple, time-consuming and convenient auxiliary diagnostic method for the detection of of neutralizing antibody against neocoronavirus.

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COVID-19
NAb

COVID-19 NAb

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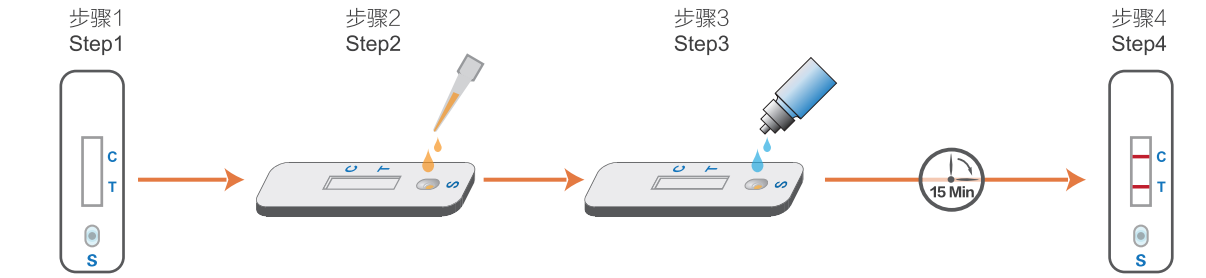
Beijing Zhongjian Antai Diagnostic Technology Co., Ltd.

产品特点 Product features

- 无需检验设备，肉眼判读结果；
  No test equipment, visual interpretation.
- 检测时间短，15-20分钟出结果；
  Test results within 15-20 minutes.
- 样本类型齐全：血清、血浆及全血；
  Complete sample types: serum, plasma and whole blood.
- 操作简便快捷；
  The operation is simple and fast.
- 常温存储，无需冷链
  Room temperature storage without cold chain.

使用方法 Mode of operation

1. 检验操作 Detection operation



检测试剂
平衡至室温
Bring the kit to room temperature

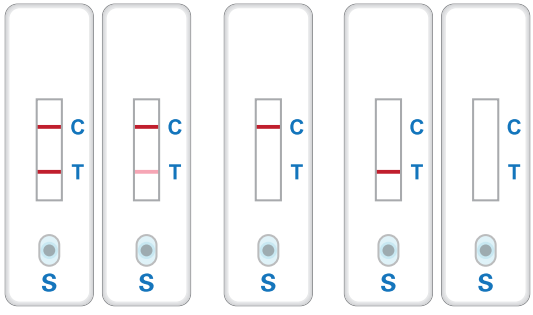
滴加血清或血浆样本 20 μL
或滴加全血样本 40 μL
Add 20 μL serum / plasma or 40 μL whole blood

滴加样本稀释液 100 μL
(2 ~ 3 滴)
Add 100 μL of diluent (2 ~ 3 droplets)

等待 15 - 20
分钟判读
Wait 15 - 20 minutes for interpretation

结果
判读
Result Interpretation

2. 结果判读 Interpretation of Results



阳性结果 Positive　　阴性结果 Negative　　无效结果 Invalid

3. 注意事项 Notice

1. 检测实验必须在 18～30℃之间进行。
   The test must be done at temperature between 18 ~ 30℃.
2. 检测结果只能表明该样本中的中和抗体的水平，不能准确量化中和抗体滴度。
   The test results can only show the level of neutralizing antibody in the sample, and can not accurately quantify the neutralizing antibody titer.
3. 快速测试应密封并保存在干燥的地方，并应在打开包装后立即使用。
   The rapid test should be sealed and kept in dry place and should be used as soon as the packing is opened.
4. 快速检测结果仅供临床参考，不应成为临床诊断和治疗的唯一依据。
   The results of rapid test are only for clinical reference and should not be the only basis for clinical diagnosis and treatment.
5. 废弃样本和检测后的试剂卡应作为潜在的传染源处理。
   Waste samples and test should be treated as potential infectious agents.
6. 质控线出现时间不作为判断检测线结果的依据，应在 15-20 分钟内判读结果。
   The result should be read strictly within a time limit of 15-20 minutes.
7. 该试剂只能用于检测接种疫苗后或感染恢复后的中和抗体水平，不能用于评估抗病毒保护的有效性。
   This reagent can only be used to detect the level of neutralizing antibody after vaccination or recovery from infection, and cannot be used to evaluate the effectiveness of antiviral protection.

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Address: No.29 Qingfeng Road, Daxing Bio-pharmaceutical Industry Base, Zhongguancun Science & Technology Park,Daxing District, Beijing, 102629, P.R.China

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中国医药保健品出口白名单

取得国外标准认证或注册的医疗物资企业清单					
序号	生产企业	统一社会信用代码	国外注册认证情况	省份	产品型号
171	北京中检安泰诊断科技有限公司 Beijing Zhongjian Antai Diagnostic Technology Co., Ltd.	91110115699582197P	CE	北京	Corona Virus (COVID-19) Combined (IgA/IgM/IgG) Rapid Test SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

La notificación se ha realizado correctamente.

Datos de registro	
Código de Expediente:	RPS/1632/2021
Fecha Registro:	07/07/2021 12:24:09
Nº registro General:	RPS/1632/2021
Oficina:	ETEL
Nº registro Oficina:	RPS/1632/2021

CE注册号

⊞ Registro de Responsables de Productos Sanitarios

Usuario: LEI SHI

Desconectar

Registro de Responsables de Productos Sanitarios - RPS/1632/2021

Datos de la notificación

Datos de registro

Nº Registro	RPS/1632/2021	Fecha Registro	07/07/2021

Datos del Responsable

Tipo de Responsable (*)	Rep. Autorizado	Tipo de entidad	Empresa
CIF(*)	B88249594	Nombre (*)	RIOMAVIX,SOCIEDAD LIMITADA
Dirección(*)	CALLE DE ALMANSA 55,1D,MADRID		
Localidad (*)	MADRID		
Provincia(*)	Madrid	CP(*)	28039
Teléfono(*)	658396230	Fax	
e-mail(*)	RIOMAVIX@GMAIL.COM	Web	

Datos del Fabricante

Nombre o Razón Social (*)	Beijing Zhongjian Antai Diagnostic Tech. Co., Ltd.		
Dirección(*)	No.29 Qingfeng Road West, Daxing biological medicine base		
Localidad (*)	Beijing		
País(*)	República Popular China	CP	102629
Teléfono(*)	+86-01065426941	Fax	
e-mail(*)	zjatit@sina.com	Web	

Datos de Productos Comunicados

Estatus(*) Primera Comunicación

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios			
Nombre Comercial	Tipo de Producto	Estado del producto	Acción
CORONA VIRUS (COVID-19) NEUTRALIZING ANTIBODY DETECTION KIT (COLLOIDAL GOLD)	Diagnostico In Vitro	Primera Comunicación	

⊞ Registro de Responsables de Productos Sanitarios

Usuario: LEI SHI

Desconectar

Registro de Responsables de Productos Sanitarios - RPS/1632/2021

Formulario de edición de Productos In Vitro

Listado de Productos Sanitarios In Vitro

Se encontro una fila.

Listado de Productos Sanitarios		
Nombre Comercial	**Tipo de Producto**	**Estado del producto**
CORONA VIRUS (COVID-19) NEUTRALIZING ANTIBODY DETECTION KIT (COLLOIDAL GOLD)	Diagnostico In Vitro	Primera Comunicación

Datos del Producto In Vitro

Tipo de Producto	**In Vitro**
Estado del producto	**Primera Comunicación**
Nombre Comercial (*)	CORONA VIRUS (COVID-19) NEUTRALIZING ANTIBODY DETECTION KIT (COLLOI
Otros Nombres Comerciales	
Modelo(*)	COLLOIDAL GOLD
Clase (*)	IVD-98/79/EC
Nomenclatura (*)	No Asignado
Código nomenclatura (*)	NA **Nomenclatura GMDN** **Nomenclatura ECRI** **Nomenclatura EDMS**
Nombre genérico nomenclatura ESP	
Nombre genérico nomenclatura ING	
Categoría	**Diagnóstico "In vitro"**

Uso

¿Se trata de un producto nuevo? (Según R.D. 1662/2000 art. 3.k) (*) ○ **Si** ◉ **No**

Características relevantes (Indicar como mínimo el analito a detectar y el método analítico)

CE EC Declaration of Conformity CE

Manufacturer:	Beijing Zhongjian Antai Diagnostic Technology Co., Ltd 29 Qingfeng Road West,Daxing biological medicine base,Zhongguancun Science and Technology Park, Daxing, Beijing 102629,P.R.China
Whose Single Authorized EU-Representative:	Riomavix S.L. Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
Product Name:	Corona Virus (COVID-19) Neutralizing Antibody Detection Kit (Colloidal Gold)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016,EN ISO 15223-1:2016,EN ISO 14971:2012, EN 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature: ZHAO ZHENGCHUN

Name:	Mr. Zhao Zhengchun
Title:	Deputy General manager of Operations
Place/Date:	China, July 6,2021

Declaration of Conformity

Manufacturer:	Beijing Zhongjian Antai Diagnostic Technology Co., Ltd 29 Qingfeng Road West,Daxing biological medicine base,Zhongguancun Science and Technology Park, Daxing, Beijing 102629,P.R.China
Whose Single Authorized EU-Representative:	Riomavix S.L. Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
Product Name:	Corona Virus (COVID-19) Neutralizing Antibody Detection Kit (Colloidal Gold)

Classification : **Others of ANNEX II of IVDD**

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General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016,EN ISO 15223-1:2016,EN ISO 14971:2012, EN 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature: ZHAO ZHENGCHUN

Name:	Mr. Zhao Zhengchun
Title:	Deputy General manager of Operations
Place/Date:	China, July 6,2021

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Beijing Zhongjian Antai Diagnostic Technology Co., Ltd

ADDRESS: No.29 Qingfeng Road West, Daxing biological medicine base, Zhongguancun Science and Technology Park, Daxing, Beijing 102629, P.R.China

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices:

Corona Virus (COVID-19) Neutralizing Antibody Detection Kit (Colloidal Gold)

Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notifed of the manufacture's device and has allocated registration. The registration number is RPS/1632/2021

Executive Director

Issue date: 7/JUL/2021
Cert. No.: R20210704

Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

新型冠状病毒（COVID-19）中和抗体检测试剂盒（胶体金法）

【产品名称】

新型冠状病毒（COVID-19）中和抗体检测试剂盒（胶体金法）

【包装规格】

20 人份/盒

【预期用途】

本产品为 CE 认证体系下专业用途类别，用于体外检测接种新型冠状病毒疫苗或从新型冠状病毒中恢复的人体血液样本中的抗体水平。 但它不能用于评估防病毒保护的有效性。

【检测原理】

本试剂盒是采用胶体金免疫层析技术。在硝酸纤维素膜上的对应检测线处（T 线）包被鼠抗人 IgG 单克隆抗体，在质控线（C 线）包被鼠抗 RBD 单克隆抗体，在金标垫固定 COVID-19 重组抗原。检测阳性样本时，样本中的 COVID-19 中和抗体可与胶体金（Au）标记的 COVID-19 Ag 结合形成（Au-COVID-19Ag-[COVID-19-中和抗体]）免疫复合物，通过层析作用，复合物在硝酸纤维素膜内向前流动，当复合物经过检测线时与包被的小鼠抗人 IgG 单克隆抗体结合形成“(Au-COVID-19Ag-[COVID-19-中和抗体])-[小鼠抗人 IgG 单克隆抗体）]”，而凝集显色，剩余的胶体金标记的 COVID-19 重组抗原与质控制线处包被的小鼠抗 RBD 单克隆抗体结合而凝集显色。阴性样本中不含 COVID-19 中和抗体，致使不能形成免疫复合物，则只有质控区（C 线）处显颜色。

【主要成分】

硝酸纤维膜上检测线（T 线）包被小鼠抗人 IgG 单克隆抗体的、质控线（C 线）包被鼠抗 RBD 单克隆抗体，金标垫上固定胶体金标记的 COVID-19 重组抗原。

1. 检测卡(20 份)
2. 样本稀释液 (4mL × 1 瓶)

【储存条件和有效期】

- 4~30℃干燥，避光保存，有效期 12 个月。
- 产品运输时需在 4~30℃干燥避光保存。当湿度 60%以下，开封 1 小时内使用，当湿度 60%以上，应开封即用。
- 生产日期及有效期见标签。

【样本要求】

- 全血应采用静脉血采血。全血样本采集后不做保存，即采即用。血清样本按常规方式由静脉采集。 血浆样品可以用肝素、柠檬酸钠和 EDTA 处理。血清或血浆样本 5 天内测定的样本可放置在 2~8℃保存。样本放置在-20℃至少可以保存 3 个月。
- 样本避免溶血或反复冻融。混浊或有沉淀的样本应离心或过滤澄清后再检测。

【检验方法】

在进行测试之前，必须先完整阅读说明书。检查前请将试剂和样本恢复至室温。实验湿度应小于 60%，实验温度为 18~30℃。 测试程序如下：

1. 从铝箔袋中取出测试卡，放在水平工作台上平置并做好样品标记。
2. 取 20μL 血清、血浆或 40μL 全血样本直接加入到加样孔中。，再滴加样本稀释液 100μL（约 2-3 滴）。
3. 15-20 分钟内判读结果，阴性结果必须在 20 分钟结束时确认。

【检验结果的解释】

1. 阳性：检测线（T 线）和质控线（C 线）位置出现两条红色条带。 表示检测到的新型冠状病毒（COVID-19）中和抗体呈阳性。
2. 阴性：只在质控线（C 线）位置出现一条红色条带。 表示样本中新型冠状病毒（COVID-19）中和抗体浓度未达到检测水平。
3. 无效结果：质控线（C 线）位置没有出现红色条带。对无效的结果应重新试验，重新试验时应严格按照说明书操作，如果重新试验结果依然无效，则与当地供应商联系或联系本公司客服进行技术咨询确定产品是否存在问题。

【检验方法的局限性】

1. 本试剂用于个人全血、血清或血浆的检测。
2. 本试剂检验结果仅供临床参考，不应作为临床诊治的唯一依据。
3. 该试剂只能用于检测疫苗接种或感染恢复后的中和抗体效价，不能用于评价抗病毒保护的有效性。
4. 样本检测结果与样本采集、检测、运输、储存等因素有关。 任何错误都会影响结果的准确性。
5. 干扰物质： 1）当胆红素浓度≤20mg/dL、血红蛋白含量≤500mg/dL、甘油三酯含量≤1500mg/dL 时，不干扰本品的检测结果； 2）当抗核抗体效价≤1:320，风湿因子≤500IU/mL 时，不会干扰本品的检测结果。

【产品性能指标】

1. 阳性参考品符合率：阳性参考品检测符合率应为 8/8。
2. 阴性参考品符合率：阴性参考品检测符合率应为 8/8。
3. 最低检出限：质控品最低检出限不低于 1：8。 (NT50≥10)
4. 重复性：测试 2 个不同水平的内部重复性质控产品，每个测试 10 次，结果应为阳性。

【注意事项】

1. 如果试剂盒和样本的状态没有恢复到 18~30℃，请勿进行操作，以免影响结果的准确性。
2. 应用本试剂盒检测得到的阳性样本，需用其他方法进一步确认。
3. 试剂盒应密封保存于干燥处。 试纸条从包装中取出后应尽快进行试验，避免放置于空气中过长时间，导致受潮。
4. 检测线颜色的深浅程度与样品中抗体的滴度没有一定的必然联系，20 分钟后判读结果无效。
5. 本试剂的测结果仅供临床参考，不应作为临床诊治的唯一依据。
6. 检测后的样本废物及试剂应作为为潜在的传染物质处理。
7. 质控线（C 线）显色时间不能作为判断检测线（T 线）结果的时间依据。 显色结果应在 15-20 分钟内观察和判断。
8. 仅用于体外诊断。

Beijing Zhongjian Antai Diagnostic Technology Co., Ltd.

No.29 Qingfeng Road, Daxing Bio-pharmaceutical Industry Base, Zhongguancun Science & Technology Park, Daxing District, Beijing, 102629, P.R.China

Index of Symbol

	请勿重复使用
	体外诊断器械
	温度限制在 4-30℃
	请参阅使用说明书
	使用期限
	批号
	包装破损切勿使用
	盒内检测总次数
	避免日晒
	保持干燥
	生产日期
	制造商

欧盟 CE 认证

Riomavix S.L.

Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain

E-mail: leis@riomavix.com

Tel.: +34 658 396 230

Version Number : 1.1

Effective Date: June 4, 2021

Corona Virus (COVID-19) Neutralizing Antibody Detection Kit (Colloidal Gold)

【Product name】

Corona Virus (COVID-19) Neutralizing Antibody Detection Kit (Colloidal Gold)

【Packing specification】

20 tests / box

【Intended use】

This product is for professional use and is used for in vitro detection of antibody levels in human blood samples after being vaccinated with the Novel Coronavirus vaccine or recovered from the Novel Coronavirus. But it cannot be used to evaluate the effectiveness of anti-virus protection.

【Test principle】

This kit adopts the principle of colloidal gold immunochromatography technology. The detection area (T line) of the nitrocellulose membrane is coated with mouse anti-human IgG monoclonal antibody, and the quality control area (C line) is coated with Mouse anti-RBD monoclonal antibody, Colloidal gold-labeled COVID-19 recombinant antigen is coated on a gold-labeled pad. When testing the sample, the COVID-19 neutralizing antibody in the sample combines with the COVID-19 Ag labeled with colloidal gold (Au) to form (Au- COVID-19Ag-[COVID-19-Neutralizing antibody]) immune complex, As the chromatographic complex flows forward inside the nitrocellulose membrane, it combines with the coated mouse anti-human IgG monoclonal antibody when passing through the detection area to form "(Au- COVID-19Ag-[COVID-19- Neutralizing antibody])-[mouse anti-human IgG monoclonal antibody)]" form agglutination, and the remaining colloidal gold labeled COVID-19 recombinant antigen combines with the mouse anti-RBD monoclonal antibody coated at the quality control line to agglutinate Color rendering. For example, if the sample does not contain COVID-19 neutralizing antibodies, which prevents the formation of immune complexes in the detection area, only the quality control area will show color.

【Principal component】

The test consists of a membrane strip coated with mouse anti-human IgG on the test line, and the dye pad contains colloidal gold conjugated with COVID-19 recombinant antigen.

1. Test cassette (20 tests)
2. Sample diluent (4mL × 1bottle)

【Storage conditions and expiry date】

- 4~30℃ dry, keep away from light, valid for 12 months.
- The product should be stored in dry condition under 4~30℃ and kept away from light. When humidity is less than 60%, it should be used within 1 hour and when humidity is more than 60%, it should be used immediately.
- Expiration date and lot number are shown in the label.

【Sample requirements】

- The whole blood should be venous blood. Serum samples can be collected by vein in a conventional manner. The plasma samples can be treated with heparin, sodium citrate and EDTA. Above samples can be placed under 2~8℃ for 5 days. Samples under -20℃ can be stored for at least 3 months.
- Samples should avoid hemolysis or repeated freezing-thawing. If the sample is turbid or has precipitation, it should be centrifuged or filtered to clarify before testing.

【Test procedure】

This package insert must be read completely before performing the test. Please restore the reagent and sample to room temperature before inspection. Experimental humidity should be less than 60%, the experiment temperature is 18~30℃. Test procedure is as follows:

1. Remove the test card from the aluminum foil bag, mark the sample and put it on the horizontal work table.
2. Take 20μL serum, plasma samples or 40μL whole blood to be directly added to the add hole or the bottom of the indicator arrow, and then add the sample diluent 100 μL (about 2-3 drops).
3. Result should be read at 15-20 minutes, negative results must be confirmed at the end of 20 minutes.

【Interpetation of assay result】

1. Positive: color development of the detection line and quality control line. It is suggested that the neutralizing antibody of the novel coronavirus (COVID-19) detected is positive.
2. Negative: Only the quality control line develops color in the detection window. It is suggested that the concentration of neutralizing antibody for novel coronavirus (COVID-19) in the sample has not reached the level of detection.
3. Invalid results: The control line has no red stripe. The invalid results should resume experiment again, and the test should be in strict accordance with the instructions operation, if the test result is still invalid, please contact local suppliers or customer service with our company for technical consultation.

【Limitations of the test method】

1. The product is only used for the detection of whole blood, serum or plasma.
2. This product inspection result is only for clinical reference, should not serve as the only basis for clinical diagnosis and treatment.
3. This reagent can only be used to detect the neutralizing antibody titer after vaccination or recovery from infection, and cannot be used to evaluate the effectiveness of antiviral protection.
4. The results of sample testing are related to factors such as sample collection, testing, transportation and storage. Any error will affect the accuracy of the results.
5. Interfering substances: 1) When the bilirubin concentration≤20mg/dL, the hemoglobin content≤500mg/dL, and the triglyceride content≤1500mg/dL, it will not interfere with the test results of this product; 2) when the antinuclear antibody titer≤1:320, rheumatism factor ≤500IU/mL will not interfere with the test results of this product.

【Product performance indicator】

1. Compliance rate of positive quality control products: the positive internal quality control compliance rate should be 8/8.
2. Compliance rate of negative quality control products: the negative internal quality control compliance rate should be 8/8.
3. Minimum detection limit: the minimum detection limit of quality control products should not be lower than 1:8.（NT50≥10）
4. Repeatability: test 2 internal repeatability quality control products, each test for 10 times, results should be

positive.

【Cautions】

1. The operation shouldn't be done if the condition of kit and samples are not restored to 18 ~ 30℃, in case it will affect the accuracy of the results.
2. The positive samples obtained by the rapid test should be confirmed by other methods.
3. The rapid test should be sealed and kept in dry place. The test bar should be tested as soon as possible after being removed from the packaging, so as to avoid placing it in the air for too long, causing the damp.
4. The deepness of the test line color is not necessarily associated with the titer of the antibody in the sample, and the results of the interpretation after 20 minutes are invalid.
5. The results of rapid test are only for clinical reference and should not be the only basis for clinical diagnosis and treatment.
6. Waste samples and test should be treated as potential infectious agents.
7. The appearing time of the Control Line should not be taken as the time basis for judging the results of test line. The color rendering results should be observed and judged within a time limit of 15-20 minutes.
8. The rapid test is only used for in vitro diagnosis.

Beijing Zhongjian Antai Diagnostic Technology Co., Ltd.

No.29 Qingfeng Road, Daxing Bio-pharmaceutical Industry Base, Zhongguancun Science & Technology Park, Daxing District, Beijing, 102629, P.R.China

Index of Symbol

	Do not reuse		For in vitro diagnostic use only
	Store between 4-30℃		Consult instructions for use
	Use by		Lot number
	Do not use if package is damaged		Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturing date		Manufacturer

Authorized representative in the European Community

Riomavix S.L.

Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain

E-mail: leis@riomavix.com

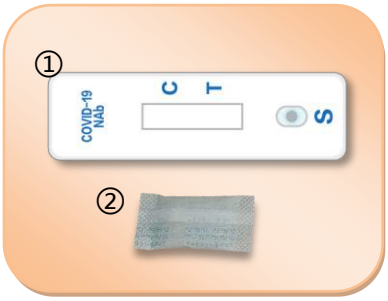
Tel.: +34 658 396 230

Version Number : 1.1

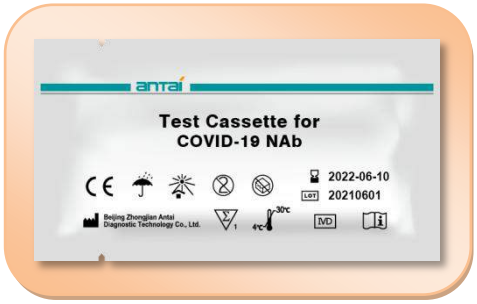
Effective Date: June 4, 2021

新冠中和抗体检测试剂盒

Packaging contents
包装内容物



① Test cassette ×1
测试卡 ×1
② Desiccant ×1
干燥剂 ×1



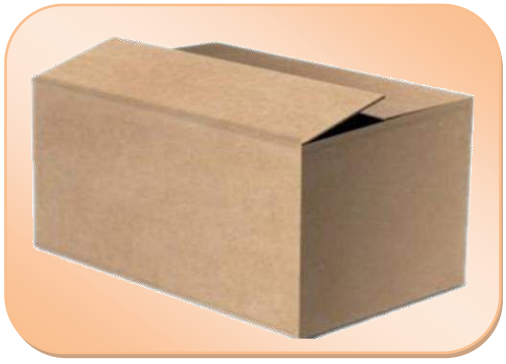
测试卡铝箔袋 ×20
Aluminum foil bag ×20

样本稀释液×1
Sample diluent ×1

使用说明书 ×1
Instruction for Use ×1

150*120*65mm
20 人份
20 Tests

×65



610*410*350mm
G.W. 13kg
1300 人份
1300 Tests

对外贸易经营者备案登记表

备案登记表编号：03175573　　统一社会信用代码：91110115699582197P
进出口企业代码：----------

经营者中文名称	北京中检安泰诊断科技有限公司		
经营者英文名称	Beijing Zhongjian Antai Diagnosis Technology Co.,Ltd.		
组织机构代码	---------	经营者类型（由备案登记机关填写）	有限责任公司
住　所	北京市大兴区中关村科技园区大兴生物医药产业基地庆丰西路29号		
经营场所（中文）	北京市大兴区中关村科技园区大兴生物医药产业基地庆丰西路29号		
经营场所（英文）	No. 29, Qingfeng West Road, Z-Park Daxing Bio-medicine Industry Park,Beijing,China		
联系电话	18601364441	联系传真	010-65426941
邮政编码	102629	电子邮箱	bjzjat@sina.com
工商登记注册日期	2010-1-13	工商登记注册号	----------

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	江军	有效证件号	650102196610244 51X
注册资金	壹仟伍佰万元	（折美元）	

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产		（折美元）	

备注 企业变更法定代表人。旧证号：02129977	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签　章

2021 年 04 月 29 日

海关进出口货物收发货人备案回执

企业名称	北京中检安泰诊断科技有限公司
统一社会信用代码	91110115699582197P
海关编码	111336001Z
检验检疫备案号	1100210104
有效期	长　　期

（注册海关）

亦庄海关

（注册日期）

2018年06月13日

医疗器械生产许可证

许可证编号：京食药监械生产许20100015号

企业名称：北京中检安泰诊断科技有限公司

生产地址：北京市大兴区中关村科技园区大兴生物医药产业基地庆丰西路29号院1号楼E区2层、E2413室

法定代表人：江军

生产范围：2002版分类目录：Ⅱ类：Ⅱ-6840体外诊断试剂；
Ⅲ类：Ⅲ-6840体外诊断试剂***
2017版分类目录：Ⅱ类：Ⅱ-22-04免疫分析设备***

企业负责人：江军

住　　所：北京市大兴区中关村科技园区大兴生物医药产业基地庆丰西路29号

发证部门：北京市药品监督管理局

有效期限：至 2024 年 03 月 12 日

发证日期：2021 年 05 月 28 日

国家药品监督管理局制

印刷流水号NO: 0005518

统一社会信用代码

91110115699582197P

营业执照

（副 本）(2-1)

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息

名　　称　北京中检安泰诊断科技有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　江军

经营范围　销售第三类医疗器械；生物制品、诊断试剂、医疗器械的技术开发、技术转让；经济信息咨询（不含中介服务）；销售实验室设备、仪器仪表、医疗器械（Ⅰ、Ⅱ类）；租赁医疗器械；货物进出口、技术进出口；技术咨询；生产医疗器械Ⅲ类：Ⅲ-6840体外诊断试剂、Ⅱ类：Ⅱ-6840体外诊断试剂、Ⅱ-22-04免疫分析设备（医疗器械生产许可证有效期至2024年03月12日）（该项限在北京市大兴区中关村科技园区大兴生物医药产业基地庆丰西路29号院1号楼E区2层、E2413室经营）。（市场主体依法自主选择经营项目，开展经营活动；销售第三类医疗器械以及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；不得从事国家和本市产业政策禁止和限制类项目的经营活动。）

注册资本　1530.03万元

成立日期　2010年01月13日

营业期限　2010年01月13日 至 2030年01月12日

住　　所　北京市大兴区中关村科技园区大兴生物医药产业基地庆丰西路29号

登记机关　北京市大兴区市场监督管理局　1101150312174

2021 年 06 月 29 日

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

国家市场监督管理总局监制

此为证书 CN18/42005 译本
This is an SGS translation of CN18/42005 Issue 3

下述组织

北京中检安泰诊断科技有限公司

中国北京市大兴区中关村科技园区
大兴生物医药产业基地庆丰西路 29 号

的管理体系已经过审核，并被证明符合下述要求

ISO 13485:2016
EN ISO 13485:2016

所涉及的活动范围覆盖

胶体金免疫层析法检测试剂盒和荧光免疫层析法测定试剂盒的设计、研发与生产；
荧光免疫层析分析仪器的设计、研发与生产

该证书的有效期自 2021-01-18 至 2024-01-17
并须经过符合要求的监督审核保持有效
持续认证需在 2023-11-29 之前执行
版本号 3. 初始注册日期 2018-01-18

签署

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Certificate CN18/42005

The management system of

Beijing Zhongjian Antai Diagnostic Technology Co., Ltd.

No. 29 Qingfeng West Road, Daxing Bio-pharmaceutical Industry Base,
Zhongguancun Science & Technology Park, Daxing District,
Beijing City, 102609, 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 and Manufacture of In Vitro Diagnostic Kits based on Gold immunochromatography Assay and Fluorescence Immunochromatography Assay; Design, Development and Manufacture of Fluorescence Immunochromatography Analyzer

This certificate is valid from 18 January 2021 until 17 January 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 November 2023
Issue 3. Certified since 18 January 2018

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

HC SGS 13485 2016 0118

高新技术企业

证书

企业名称：北京中检安泰诊断科技有限公司

证书编号：GR201911001953

发证时间：2019 年 10 月 15 日

有 效 期：三年

批准机关：

北京市科学技术委员会 市科委

北京市财政局 市财政局

国家税务总局北京市税务局 北京市税务局

北京中检安泰诊断科技有限公司

Beijing Zhongjian Antai Diagnostic Technology Co., Ltd.

北京中检安泰诊断科技有限公司为北京华卫天和健康科技集团旗下控股成员公司。华卫天和集团涉及生物疫苗、医疗器械、诊断试剂、移动医疗、智慧养老、高分子材料等高科技领域。

华卫天和集团依托互联网+医疗器械创新孵化及北京市国际科技创新基地，打造健康产业集群；通过资本纽带建立融资、孵化、研发、生产综合平台。

北京中检安泰诊断科技有限公司立足于体外诊断试剂（IVD）研发、注册、生产与销售。现有胶体金和荧光免疫两大技术平台，胶体金平台以III类产品为主，荧光免疫平台以 II 类定量产品为主。目前公司共拥有12项实用新型专利、1项发明专利、1项外观设计专利、12项软件著作权。公司获得“国家高新技术企业”与“中关村高新技术企业”双高新认定证书，应有证照齐全、资质完备，拥有标准化GMP生产车间。

Beijing Zhongjian Antai Diagnostic Technology Co., Ltd. is a controlling member company of Beijing Hinspire Healthcare Group Co., Ltd. Hinspire Healthcare Group are involved in high-tech fields such as biomedicine, medical instruments, diagnostic reagents, mobile medical treatment, intellectual endowment, high polymer materials and so on.

Hinspire Healthcare Group relies on Internet plus medical innovation incubation and Beijing international science and technology innovation base, create a healthy industry cluster; Establish investment and financing platform through the incubation industry capital link.

Beijing Zhongjian Antai Diagnostic Technology Co., Ltd. is based on the research and development, registration, production and sales of in-vitro diagnostic reagents. At present, there are two technical platforms of colloidal gold and fluorescent immunity, the colloidal gold platform is mainly type III products, while the fluorescent immune platform is mainly type II quantitative products. The company has 12 utility model patents, 1 invention patent, 1 design patent and 12 software copyrights.. As a high-tech enterprise with GMP standard production plant, the company belongs to the national high-tech enterprises and high-tech enterprises in Zhongguancun, had a full set of license.