Test Kit für neuartiges Coronavirus-Antigen (kolloidale Gold-Methode) (Bedienungsanleitung)

【PRODUKTNAME】

Test Kit für neuartiges Coronavirus-Antigen(kolloidale Gold-Methode)

【LIEFERUMFANG UND SPEZIFIKATION】

20 Tests/Karton (1Test/Beutel ×20 Beutel) ,40 Tests/Karton (1Test/Beutel ×40 Beutel)

【VERWENDUNGSZWECK】

Für den qualitativen In-vitro-Nachweis von SARS-CoV-2-Nukleokapsid-Antigen in Mundflüssigkeit direkt von Personen, die innerhalb der ersten fünf Tage nach Auftreten der Symptome von ihrem medizinischen Betreuer auf COVID-19 verdächtigt werden. Dieser Test ist nur für die Verwendung durch klinische Labore oder Mitarbeiter des Gesundheitswesens für Point-of-Care-Tests vorgesehen, nicht für Heimtests.

Das schwere akute respiratorische Syndrom- Coronavirus- 2 (SARS-CoV-2) ist ein umhülltes, nicht segmentiertes Positiv-Sense-RNA-Virus. Es ist die Ursache der Coronavirus-0Krankheit (COVID-19), die für den Menschen ansteckend ist. SARS-CoV-2 hat mehrere Strukturproteine, einschließlich Spike (S), Hülle (E), Membran (M) und Nukleokapsid (N).

Das Antigen ist in oralen Flüssigkeitsproben während der akuten Phase der Infektion nachweisbar. Positive Ergebnisse weisen auf das Vorhandensein viraler Antigene hin, aber die klinische Korrelation mit der Patientengeschichte und anderen diagnostischen Informationen ist notwendig, um den Infektionsstatus zu bestimmen. Positive Ergebnisse schließen eine bakterielle Infektion oder eine Co-Infektion mit anderen Viren nicht aus. Der nachgewiesene Erreger ist möglicherweise nicht die eindeutige Ursache der Erkrankung.

Negative Ergebnisse sollten als Vermutungen behandelt werden, die eine SARS-CoV-2-Infektion nicht ausschließen und nicht als alleinige Grundlage für Entscheidungen zur Behandlung oder zum Patientenmanagement, einschließlich Entscheidungen zur Infektionskontrolle, verwendet werden sollten. Negative Ergebnisse sollten im Zusammenhang mit den jüngsten Expositionen eines Patienten, der Anamnese und dem Vorhandensein von klinischen Anzeichen und Symptomen, die mit COVID-19 übereinstimmen, betrachtet und gegebenenfalls mit einem molekularen Assay für das Patientenmanagement bestätigt werden.

Nur für den in-vitro-diagnostischen Gebrauch. Nur für den professionellen Gebrauch

【TESTPRINZIP】

Das Test Kit für neuartiges Coronavirus-Antigen von JOYSBIO Biotechnology verwendet eine Immunocapture-Methode. Es wurde entwickelt, um das Vorhandensein oder die Abwesenheit von SARS-CoV-2-Nukleokapsidproteinen in Mundflüssigkeitsproben von Patienten mit Anzeichen und Symptomen einer Infektion, bei denen der Verdacht auf COVID-19 besteht, nachzuweisen.

Hauptbestandteile: Der durch kolloidales Gold markierte Anti-Nukleokapsid-Protein-Antikörper und Hühner-IgY, die mit Anti-Nukleokapsid-Protein-Antikörper beschichtete Nitrozellulosemembran und Ziegen-Anti-Hühner-IgY-Antikörper.

Wenn die Proben verarbeitet und in die Testvorrichtung gegeben werden, binden die in der Probe vorhandenen SARS-CoV-2-Antigene an die mit kolloidalem Gold konjugierten Antikörper im Teststreifen. Die Antigen-Konjugat-Komplexe wandern über den Teststreifen in den Reaktionsbereich und werden von einer Linie der an die Membran gebundenen Antikörper eingefangen. Eine Farbbande zeigt sich, wenn sich Antigen-Konjugat an der Test-"T"-Position und an der Kontroll-"C"-Position auf dem Gerät ablagert.

【KOMPONENTE】

bereitgestellte Materialien:

KOMPONENT	20Tests/Kit	40Tests/Kit	Hauptkomponente
Testkarte	20 Tests/Kit (1Test/Beutel ×20 Beutel)	40 Tests/Kit (1Test/Beutel ×40 Beutel)	Der durch kolloidales Gold markierte Anti-Nukleokapsid-Protein-Antikörper und Hühner-IgY, die mit Anti-Nukleokapsid-Protein-Antikörper beschichtete Nitrozellulosemembran und Ziegen-Anti-Hühner-IgY-Antikörper.
Trockenmittel	20 Packungen	40 Packungen	Kieselgel
Puffer	350 μL /Flasche×40 Flasche	350 μL /Flasche×80 Flaschen	Reinigungslösung
Extraktionsröhrchen	20 Einweg-Reaktionsgefäße, jeweils mit 1x Düsenkappe	40 Einweg-Reaktionsgefäße, jeweils mit 1x Düsenkappe	/
Probensammelbeutel	20 sterile Einweg-Probensammelbeutel	40 sterile Einweg-Probensammelbeutel	/
Tropfer	20 Einweg-Tropfer	40 Einweg-Tropfer	/

erforderliche, aber nicht im Kit enthaltene Materialien: N/A

SARS-CoV-2 (+)	1 je – einzeln verpackt für den Einmalgebrauch	Nicht-infektiöses, rekombinantes virales Protein-Antigen mit weniger als 0,1% Proclin 300.
SARS-CoV-2 (–)	1 je – einzeln verpackt für den Einmalgebrauch	Puffer mit weniger als 0,1 % Proclin 300.

【LAGERUNG UND STABILITÄT】

1.Bei 2~30ºC im verschlossenen Beutel bis zum Verfallsdatum aufbewahren, die Gültigkeit beträgt vorläufig 24 Monate. **Nicht einfrieren**.

2. Die Testkassette sollte innerhalb von 1 Stunde nach Entnahme aus dem Aluminiumfolienbeutel verwendet werden.

3. Von Sonnenlicht, Feuchtigkeit und Hitze fernhalten.

【PROBENENTNAHME UND HANDHABUNG】

1. Probenentnahme und -vorbereitung

Die orale Flüssigkeitsprobe sollte mit dem mit dem Kit gelieferten Sammelbeutel entnommen werden. Die korrekten Methoden zur Probenentnahme und -vorbereitung müssen befolgt werden. Mit diesem Assay sollten keine anderen Entnahmegeräte verwendet werden. Proben, die früh während des Auftretens der Symptome entnommen werden, enthalten die höchsten Virustiter; Proben, die nach fünf Tagen nach Auftreten der Symptome entnommen werden, führen mit größerer Wahrscheinlichkeit zu negativen Ergebnissen im Vergleich zu einem RT-PCR-Assay. Eine unzureichende Probenentnahme, eine unsachgemäße Probenbehandlung und/oder ein unsachgemäßer Probentransport können zu einem falsch negativen Ergebnis führen.

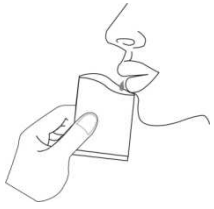
2. Probentransport und -lagerung

Frisch entnommene Proben sollten so schnell wie möglich, jedoch nicht später als eine Stunde nach der Probenentnahme, verarbeitet werden.

3. Entnahme von Mundflüssigkeitsproben

a. Vor der Entnahme der Mundflüssigkeit entspannen Sie Ihre Wangen und massieren Sie die Wangen mit den Fingern für 15-30 Sekunden sanft. Legen Sie die Zunge an den Ober- und Unterkiefer und die Wurzeln, um die Mundflüssigkeit anzureichern.

b. Spucken Sie die Mundflüssigkeit vorsichtig in den Sammelbeutel, die Probe ist nun bereit für die Verarbeitung mit dem Kit.



4.DOs and DON'Ts der Probenentnahme

a.Proben so schnell wie möglich nach dem Auftreten der Symptome sammeln.

b.Die Proben sofort testen.

c.Nur die mit dem Kit gelieferten Sammelbeutel verwenden.

d. Die Probe wird am besten nach dem Aufstehen in den frühen Morgenstunden entnommen.

e. Nicht innerhalb von 1 Stunde vor der Probenentnahme essen und trinken.

f. Die Sammelbeutel nach der Probenentnahme nicht zurück in die Verpackungshülle der Sammelbeutel legen.

5. Vorsichtsmaßnahmen

a. Zur Verwendung in der In-vitro-Diagnostik.

b. Dieser Test ist nur für den Nachweis von SARS-CoV-2-Antigen zugelassen, nicht für andere Viren oder Erreger.

c. Alle Proben als potentiell infektiös behandeln. Beim Umgang mit den Proben, diesem Kit und seinem Inhalt die allgemeinen Vorsichtsmaßnahmen befolgen.

d. Korrekte Probenentnahme, -lagerung und -transport sind für korrekte Ergebnisse unerlässlich.

e. Die Testkarte bis kurz vor dem Gebrauch versiegelt in ihrem Folienbeutel lassen. Nicht verwenden, wenn der Beutel beschädigt oder offen ist.

f. Das Kit nicht nach Ablauf des Verfallsdatums verwenden.

g. Komponenten aus verschiedenen Kit-Chargen nicht mischen.

h. Die benutzte Testkarte nicht wiederverwenden.

i. Unzureichende oder unsachgemäße Probenentnahme, Lagerung und Transport können zu falschen Testergebnissen führen.

j. Die Proben nicht in viralen Transportmedien zur Probenlagerung aufbewahren.

k. Alle Komponenten dieses Kits sollten als biologischer Sondermüll entsprechend den bundes-, landes- und ortsüblichen Vorschriften entsorgt werden.

l. Die zur Herstellung der positiven Kontrollprobe verwendeten Lösungen sind nicht infektiös. Patientenproben, Kontrollen und Testkarten sollten jedoch so behandelt werden, als ob sie Krankheiten übertragen könnten. Die festgelegten Vorsichtsmaßnahmen gegen mikrobielle Gefahren bei der Verwendung und Entsorgung beachten.

m. Bei der Durchführung jedes Tests und bei der Handhabung von Patientenproben geeignete persönliche Schutzausrüstung und Handschuhe tragen. Die Handschuhe zwischen der Handhabung von Proben wechseln, bei denen ein Verdacht auf COVID-19 besteht.

n. UNGÜLTIGE ERGEBNISSE können auftreten, wenn ein unzureichendes Volumen des Extraktionsreagenzes in die Testkarte gegeben wird. Um sicherzustellen, dass ein ausreichendes Volumen abgegeben wird, das Fläschchen senkrecht halten und die Tropfen langsam hinzugeben.

o. Die Sammelbeutel im Kit sind für die Verwendung mit dem Test Kit für neuartiges Coronavirus-Antigen (kolloidales Gold) zugelassen. **Verwenden Sie keine anderen Sammelbeutel.**

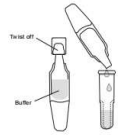
p. Das in diesem Kit verpackte Extraktionsreagenz enthält Kochsalzlösung, Detergenzien und Konservierungsmittel, die Zellen und Viruspartikel inaktivieren. Die in dieser Lösung eluierten Proben sind nicht für die Kultur geeignet.

【TESTVERFAHREN】

1. Das Testkit, die Probe muss vor dem Test bei Raumtemperatur (15~30ºC) sein. Das Kit ist nur für Mundflüssigkeitsproben bestimmt, die direkt entnommen und getestet werden (d. h. Mundflüssigkeit, die NICHT in Transportmedien eingelegt wurde).

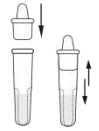
2.Frisch entnommene Proben sollten innerhalb von 1 Stunde verarbeitet werden.

•Schritt 1:
Bitte schrauben Sie die Pufferflasche ab und drücken Sie den gesamten alle 2 flasche puffer in das Extraktionsreagenzglas.



•Schritt 2:
Den Tropfer senkrecht halten und Mundflüssigkeit aus dem Sammelbeutel ziehen und 3 Tropfen Mundflüssigkeit in das Extraktionsröhrchen geben.

•Schritt 3:
Gründlich mischen, indem der Boden des Röhrchens geschwenkt oder geschnippt wird. Das/Die Extraktionsröhrchen in ein Gestell im vorgesehenen Bereich des Arbeitsplatzes stellen.



•Schritt 4:
Den Folienbeutel abreißen, die Testkassette herausnehmen und die Testkassette auf eine saubere und ebene Fläche stellen. Die Testkassette und ein Extraktionsröhrchen für jede zu testende Probe oder Kontrolle beschriften.

•Schritt 5
Den geriffelten Körper des Röhrchens leicht zusammendrücken und **drei (3) Tropfen** der verarbeiteten Probe in die Probenvertiefung geben.

•Schritt 6
Die Testergebnisse zwischen **15 und 20 Minuten** ablesen. Die Ergebnisse nicht nach **20 Minuten** ablesen.

HINWEIS: **Keine Röhrchen oder Spitzen von einem anderen Produkt oder von anderen Herstellern verwenden.**

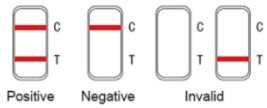
【INTERPRETATION DER TESTERGEBNISSE】

1.POSITIV: Zwei Linien sind vorhanden. Eine farbige Linie sollte sich im Bereich der Kontrolllinie (C) befinden, eine farbige Linie erscheint im Bereich der Testlinie (T). Positive Ergebnisse deuten auf das Vorhandensein von viralen Antigenen hin, aber die klinische Korrelation mit der Patientenanamnese und anderen diagnostischen Informationen ist notwendig, um den Infektionsstatus zu bestimmen. Positive Ergebnisse schließen eine bakterielle Infektion oder eine Co-Infektion mit anderen Viren nicht aus. Der nachgewiesene Erreger ist möglicherweise nicht die eindeutige Ursache der Erkrankung.

2.NEGATIV: Nur eine farbige Kontrolllinie ist vorhanden. Negative Ergebnisse sind präsumptiv. Negative Testergebnisse schließen eine Infektion nicht aus und sollten nicht als alleinige Grundlage für die Behandlung oder andere Entscheidungen zum Patientenmanagement, einschließlich Entscheidungen zur Infektionskontrolle, verwendet werden, insbesondere bei Vorliegen klinischer Anzeichen und Symptome, die mit COVID-19 übereinstimmen, oder bei Personen, die mit dem Virus in Kontakt waren. Es wird empfohlen, dass diese Ergebnisse durch ein molekulares Testverfahren bestätigt werden, falls dies für das Patientenmanagement erforderlich ist.

3.UNGÜLTIG: Die Kontrolllinie erscheint nicht. Unzureichendes Puffervolumen oder falsche Verfahrenstechniken sind die wahrscheinlichsten Gründe für den Ausfall der Kontrolllinie. Das Verfahren überprüfen und den Vorgang mit einer neuen Testkassette wiederholen. Wenn das Problem weiterhin besteht, stellen Sie die Verwendung des Testkits sofort ein und wenden Sie sich an Ihren örtlichen Händler.

4.Ergebnisbestimmungszeit: Das Ergebnis sollte innerhalb von **15~20 Minuten** nach Zugabe der Probe in die Probenvertiefung beurteilt werden; das nach **20 Minuten** angezeigte Ergebnis ist ungültig.



Positiv Negativ Ungültig

(Das Bild dient nur als Referenz)

【EINSCHRÄNKUNG DER TESTMETHODE】

1. Dieses Produkt ist nur für einen qualitativen Test und eine Hilfsdiagnose geeignet.

2. Die Testergebnisse dienen nur als klinische Referenz und sollten nicht als die einzige Grundlage für die klinische Diagnose und Behandlung sein. Die klinische Behandlung von Patienten sollte in Kombination mit ihren Symptomen, körperlichen Anzeichen, Anamnese, anderen Labortests, therapeutischer Reaktion und epidemiologischen Informationen berücksichtigt werden.

3. Die Benutzer sollten die Proben so schnell wie möglich nach der Probenentnahme testen.

4. Positive Testergebnisse schließen Co-Infektionen mit anderen Erregern nicht aus.

5. Die Testergebnisse sollten mit der klinischen Vorgeschichte,

epidemiologischen Daten und anderen Daten, die dem den Patienten beurteilenden Arzt zur Verfügung stehen, korreliert werden.
6. Ein falsch-negatives Testergebnis kann auftreten, wenn die Konzentration des viralen Antigens in einer Probe unter der Nachweisgrenze des Tests liegt oder wenn die Probe unsachgemäß entnommen oder transportiert wurde; daher schließt ein negatives Testergebnis die Möglichkeit einer SARS-CoV-2-Infektion nicht aus.
7. Die Menge des Antigens in einer Probe kann mit zunehmender Krankheitsdauer abnehmen. Proben, die nach dem 5. Krankheitstag entnommen wurden, sind mit größerer Wahrscheinlichkeit negativ im Vergleich zu einem RT-PCR-Assay.
8. Die Nichteinhaltung des Testverfahrens kann die Testleistung beeinträchtigen und/oder das Testergebnis ungültig machen.
9. Die Inhalte dieses Kits sind nur für den qualitativen Nachweis von SARS-CoV-2-Antigenen aus Mundflüssigkeitsproben zu verwenden.
10. Die Leistung des Kits hängt von der Antigenbelastung ab und korreliert möglicherweise nicht mit anderen diagnostischen Methoden, die mit derselben Probe durchgeführt werden.
11. Negative Testergebnisse sind nicht dazu gedacht, andere virale oder bakterielle Infektionen, die nicht SARS-CoV-2 sind, auszuschließen.
12. Positive und negative prädiktive Werte sind stark von den Prävalenzraten abhängig. Positive Testergebnisse stellen eher falsch-positive Ergebnisse in Zeiten geringer/keiner SARS-CoV-2-Aktivität dar, wenn die Krankheitsprävalenz niedrig ist. Falsch-negative Testergebnisse sind wahrscheinlicher ausgefallen, wenn die Prävalenz der durch SARS-CoV-2 verursachten Erkrankung hoch ist.
13. Dieses Kit wurde nur für die Verwendung mit menschlichem Probenmaterial evaluiert.
14. Monoklonale Antikörper können SARS-CoV-2-Viren, die geringfügige Aminosäureveränderungen in der Zielepitopregion erfahren haben, nicht oder mit geringerer Empfindlichkeit nachweisen.
15. Die Leistung dieses Tests wurde nicht für die Verwendung bei Patienten ohne Anzeichen und Symptome einer Infektion evaluiert und die Leistung kann bei asymptomatischen Personen unterschiedlich sein.
16. Es wurde nachgewiesen, dass die Sensitivität des Tests nach den ersten fünf Tagen nach Auftreten der Symptome im Vergleich zu einem RT-PCR SARS-CoV-2 Assay abnimmt.
17. Negative Ergebnisse sollten als präsumptiv behandelt und, falls erforderlich, mit einem molekularen Assay für das klinische Management, einschließlich der Infektionskontrolle, bestätigt werden.
18. Die Empfehlungen zur Probenstabilität basieren auf Stabilitätsdaten von Influenza-Tests und die Leistung kann sich von SARS-CoV-2 unterscheiden. Benutzer sollten Proben so schnell wie möglich nach der Probenentnahme testen, und zwar innerhalb einer Stunde nach der Probenentnahme.
19. Die Validität des Kits wurde für die Identifizierung/Bestätigung von Gewebekulturisolaten nicht nachgewiesen und sollte in dieser Eigenschaft nicht verwendet werden.

【LEISTUNGSCHARAKTERISTIKA】

1. Klinische Leistung

Die Leistung des Kits wurde mit 362 oralen Flüssigkeiten ermittelt, die prospektiv von einzelnen symptomatischen Patienten mit Verdacht auf COVID-19 gesammelt und eingeschrieben wurden. Wie bei allen Antigen-Tests kann die Leistung mit zunehmender Anzahl von Tagen seit Symptombeginn abnehmen.
Orale Flüssigkeit wurde wie in der Gebrauchsanweisung des Kits beschrieben gesammelt und gehandhabt. Alle Proben wurden ausgewählt und dann sequenziell in einer verblindeten Weise getestet. Die Leistung des Kits wurde mit den Ergebnissen eines kommerziellen molekularen Assays verglichen.
Das Kit ergab eine Sensitivität von 95,10% und eine Spezifität von 100%.

Tabelle 1. Klinische Studienergebnisse ab Auftreten der Symptome

Reagenztestergebnisse	PCR Komparator		Zwischensumme
	positiv	negativ	
positiv	97	0	97
negativ	5	260	265
Zwischensumme	102	260	362

Positive Prozentuale Übereinstimmung (PPA)= 97/102(95,10%)
（95%CI: 88,9%~98,4%）
Negative Prozentuale Übereinstimmung (NPA)= 260/260(100%)
（95%CI: 98,6%~100%）
Genauigkeit=(97+260)/362×100%=98,62%
Kappa=2×25220/ 52250=0,97＞0,5

2. Assay-Kreuzreaktivität

Kreuzreaktivität: Es gab keine Kreuzreaktion mit potenziell kreuzreaktiven Substanzen außer dem SARS-Coronavirus.

Tabelle 2: Ergebnisse der Kreuzreaktivität

Potentieller Kreuzreaktant	Konzentration Getestet	Kreuzreaktivität (JA/NEIN)
Influenza A	1,6 x 10^5 $TCID_{50}$/mL	NEIN
Influenza B	1,6 x 10^5 $TCID_{50}$/mL	NEIN
Human coronavirus HKU1	1,6 x10^5 $TCID_{50}$/mL	NEIN
Human coronavirus OC43	1,6 x10^5 $TCID_{50}$/mL	NEIN
Haemophilus influenzae	2,2x 10^5 $TCID_{50}$/mL	NEIN
MERS-coronavirus	2,1 x 10^5 $TCID_{50}$/mL	NEIN
SARS-coronavirus	3,2 x 10^5 PFU/mL	JA
Adenovirus C1	1,5 x 10^5 $TCID_{50}$/mL	NEIN
Adenovirus 71	1,5 x 10^5 $TCID_{50}$/mL	NEIN
Candida albicans	4,2 x 10^5 CFU/mL	NEIN
Respiratorisches Synzytial-Virus	5,1 x 10^5 $TCID_{50}$/mL	NEIN
Enterovirus	5,4 x 10^5 $TCID_{50}$/mL	NEIN
Malaria	2,2 x 10^6 CFU/mL	NEIN
Dengue	1,2 x 10^5 $TCID_{50}$/mL	NEIN
Human coronavirus NL63	1,7x 10^5 $TCID_{50}$/mL	NEIN
Human coronavirus 229E	2,2 x 10^5 $TCID_{50}$/mL	NEIN
Streptococcus pneumoniae	1,1 x 10^6 CFU/mL	NEIN
Pneumocystis jirovecii	1,0 x 10^5 $TCID_{50}$/mL	NEIN
Legionella pneumophila	1,4 x 10^6 CFU/mL	NEIN
Chlamydia pneumoniae	1,1 x 10^6 IFU/mL	NEIN
Human Metapneumovirus (hMPV)	1,1 x 10^5 $TCID_{50}$/mL	NEIN
Parainfluenza virus 1	1,0 x 10^5 $TCID_{50}$/mL	NEIN
Parainfluenza virus 2	1,0 x 10^5 $TCID_{50}$/mL	NEIN
Parainfluenza virus 3	3,5 x 10^5 $TCID_{50}$/mL	NEIN
Parainfluenza virus 4	1,4 x 10^5 $TCID_{50}$/mL	NEIN
Rhinovirus	1,3 x 10^5 PFU/mL	NEIN
Mycoplasma pneumoniae	1,8 x 10^6 CFU/mL	NEIN
Bordetella pertussis	1,5 x 10^6 CFU/mL	NEIN
Mycobacterium tuberculosis	1,0 x 10^6 CFU/mL	NEIN
Gepoolte menschliche Nasenwässche-repräsentativ für die normale mikrobielle Flora der Atemwege	100%	NEIN
Streptococcus pyogenes	1,0 x 10^6 CFU/mL	NEIN

3.Potenziell endogene Störsubstanzen

SARS-CoV-2-Antigenproben wurden mit einer der folgenden Substanzen in bestimmten Konzentrationen versetzt und in mehreren Replikaten getestet. Es wurde keine falsche Positivität oder falsche Negativität mit den folgenden Substanzen gefunden:

Störsubstanzen	Konzentration	Störsubstanzen	Konzentration
Vollblut	5%	Dexamethason	0,7mg/mL
Flunisolid	7,1ng/mL	Muzin	0,54%
CVS Nasentropfen (Phenylephrin)	17%v/v	Orangensaft	100%
Rebetol	4,8 ug/mL	Afrin(Oxymetazolin)	14%v/v
Relenza	290 ng/mL	Mundspülung	2%
Tamiflu	1,1 ug/mL	Koffein	1mg/mL
Tobryamycin	2,45 mg/mL	Mupirocin	12 mg/mL
Tee	33,7 mg/mL	Coca-Cola	/
Milch	11,5%	Zahnpasta	/

4.Nachweisgrenze (ANALYTISCHE SENSITIVITÄT)

Die Nachweisgrenze für den Test Kit für neuartiges Coronavirus-Antigen beträgt 3,2 x $10^2$$TCID_{50}$/mL.
Die Nachweisgrenze für den Test Kit für neuartiges Coronavirus-Antigen wurde mit limitierenden Verdünnungen des aus Zellkulturen stammenden neuartigen Coronavirus ermittelt. Das Material wurde in einer Konzentration von 1,3 x 10^6 $TCID_{50}$/mL geliefert. Eine erste Studie zur Bereichsfindung wurde durchgeführt, bei der die Geräte mit einer 10-fachen Verdünnungsreihe getestet wurden. Es wurde eine Konzentration gewählt, die zwischen der letzten Verdünnung, die 3 positive Ergebnisse liefert, und der ersten, die 3 negative Ergebnisse liefert, liegt. Unter Verwendung dieser Konzentration wurde die Nachweisgrenze mit einer 2-fachen Verdünnungsreihe weiter verfeinert. Die letzte Verdünnung, die 100% Positivität zeigte, wurde dann in weiteren 20 Replikaten getestet, die auf die gleiche Weise getestet wurden.

5.Hook-Effekt:

Im Rahmen der Nachweisgrenze-Studie wurde die höchste Konzentration der Probe (1,3 x 10^6 $TCID_{50}$/mL) getestet. Es wurde kein Hook-Effekt festgestellt.

【WARNUNGEN】

1. Ein negatives Ergebnis kann auftreten, wenn das in der Probe vorhandene SARS-CoV-2-Virus unterhalb der Empfindlichkeit des Kits liegt.
2. Nicht für das Screening von Spenderblut geeignet.
3. In Bereichen, in denen Proben oder Kit-Reagenzien gehandhabt werden, darf nicht geraucht, getrunken oder gegessen werden.
4. Alle Proben und Materialien, die zur Durchführung des Tests verwendet werden, als biologisch gefährlichen Abfall entsorgen.
5. Die Negativ- und Positivkontrollen zum Schutz des Bedieners auf die gleiche Weise wie die Patientenproben behandeln.
6. Den Test nicht in einem Raum mit starker Luftströmung durchführen, d.h. mit einem elektrischen Ventilator oder einer starken Klimaanlage.

【ERKLÄRUNG DER ETIKETTEN】

IVD	In-vitro-diagnostische Anwendung		Siehe Gebrauchsanweisung	REF	Katalog #
LOT	Chargennummer		Verfallsdatum		Herstelldatum
	Nicht wiederverwenden		Zwischen 2 ～ 30℃ lagern		Von Sonnenlicht fernhalten
	Trocken halten		Hersteller	EC REP	Autorisierte Vertretung in der europäischen Gemeinschaft
CE	CE-Kennzeichnung		Biologisches Risiko		

【GRUNDINFORMATIONEN】

JOYSBIO(Tianjin) Biotechnology Co., Ltd.

Adresse: Tianjin International Joint Academy of Biotechnology& Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China

Tel： +86-022-65378415

EC REP Lotus NL B.V.

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

【DATUM DER GENEHMIGUNG UND ÄNDERUNG DER IFU】:

November-2020

正元盛邦（天津）生物科技有限公司

JOYSBIO（Tianjin）Biotechnology Co.,Ltd.

目录

CONTENT

1 公司简介
Company Profile

公司简介 Company Profile

正元盛邦（天津）生物科技有限公司，是以研发、生产、销售诊 断试剂盒为主的高新技术企业，于2010年成立，注册资金6000 万。公司已通过CFDA认证中心及EN ISO13485:2016/ EN ISO13485：2016/AC：2016质量管理体系认证，并被认定为国 家高新技术企业、天津市科技型企业，申请并完成了天津市自主 创新产业化重大项目。 公司自成立以来搭建了新型免疫检测技术平台、多种核酸检测技 术开发平台、第二代实时荧光PCR平台，开发了定量（半定量） 床旁诊断系统，已经成功研发基于多种技术平台的几十种免疫层 析试剂盒、胶体金试纸分析仪，申请专利39项，其中获得专利证书32项和软件著作权2项。在项目注册方面，公司已有20个产品 获CFDA注册证书，同时有7个产品获得CE证书。

JOYSBIO (Tianjin) Biotechnology Co., Ltd. is a Chinese R&D-based biotechnology company that develops, manufactures, and supplies high-quality medical in-vitro diagnostic (IVD) rapid test kits as well as revolutionary customized solution kits to all parts of the world. Founded by a team of professionals with many years of combined technical,marketing/sales, operational and manufacturing expertise in this industry, we offer high quality but cost-effective rapid test kit.Our in vitro diagnostic products screen for a wide range of targets, including infectious diseases, tumors, cardiac abnormalities, drug abuse and fertility. Our focus is to expand our markets internationally by forming strategic alliances and entering into partnerships with distributors worldwide. Joysbio has established a comprehensive Quality Management System that is an applicable international standard (EN ISO 13485), ensuring top quality test results and accuracy. Also, our products are CE and CFDA certified.

呼吸道传染疾病检测经验丰富

Extensive experience in respiratory infectious disease test kits

10年胶体金、8年呼吸道传染病IgM抗体试剂盒研发生产经验，多项呼吸道传染疾病IgM抗体检测产品获得国家第三类医疗器械注册证，同时获得欧盟CE 认证（如肺炎支原体IgM抗体检测产品、肺炎衣原体IgM抗体检测产品等）。

我司早在2016年就已进入TUV名录，通过ISO13485标准中传染病系列的质量体系认证，表明了我司在传染病系列的产品达到了国际医疗器械质量水平，符合ISO13485标准的要求（包含新冠抗体检测试剂盒）。

新型冠状病毒疫情发生后，我公司凭借多年呼吸道传染病IGM抗体检测研发经验，迅速研发出新型冠状病毒抗体检测试剂产品（COVID-19 IgM/IgG Rapid Test Kit (Colloidal Gold)），取得了多项国际医疗器械质量体系认证与注册证书，现在已经出口到全世界，并获得市场的认可。

10 years of colloidal gold, 8 years of experience in R&D and production of IGM antibody kits for respiratory infectious diseases, and Numbers of IGM antibody test kits for respiratory infectious diseases have obtained the national third-class medical device registration certificate and also obtained the EU CE certification.(Such as:Mycoplasma Pneumonia IgM Antibody Test Kit 、Chlamydia pneumonia IgM Antibody Test Kit)

As early as 2016, our company has passed the quality system certification of the infectious disease series in the ISO13485 standard, indicating that our products in the infectious disease series have reached the international medical device quality level and meet the requirements of the ISO13485 standard (including COVID-19 IgG/IgM Rapid Test Kit).

After the outbreak of COVID-19 , our company quickly developed COVID-19 IgM/IgG Rapid Test Kit (Colloidal Gold)) with many years of experience in research and development of IGM antibody test kits of respiratory infectious diseases. which have obtained A number of international medical device quality system certifications and registration certificates ,And exported to all over the world ,in the meantime , It is approved by the market .

近几年，我公司致力于呼吸道传染病检测试剂的研究和研发，其中甲型流感检测试剂、乙型流感检测试剂、合胞病毒检测试剂已研发成功。

In recent years, our company is committed to the research and development of respiratory infectious disease rapid tests, including influenza A test kit, influenza B test kit, syncytial virus rapid test kit has been developed successfully.

2 企业资质

Enterprise Qualifications

正元盛邦企业资质
JOYSBIO Enterprise Qualifications

统一社会信用代码
91120116553445456F

营业执照

名　　称　正元盛邦（天津）生物科技有限公司
类　　型　有限责任公司
法定代表人　霍五奎
经营范围　许可项目：第二类医疗器械生产；第三类医疗器械生产；第三类医疗器械经营；医护人员防护用品生产（Ⅱ类医疗器械）；消毒剂生产（不含危险化学品）；卫生用品和一次性使用医疗用品生产；货物进出口；进出口代理；技术进出口；化妆品生产；医用口罩生产。（依法须经批准的项目，经相关部门批准后方可开展经营活动，具体经营项目以相关部门批准文件或许可证件为准）。一般项目：第二类医疗器械零售；第二类医疗器械批发；医护人员防护用品批发；医用口罩批发；消毒剂销售；日用化学产品制造；化妆品批发；化妆品零售；日用百货批发；日用品零售；技术服务、技术开发、技术咨询、技术交流、技术转让、技术推广；医用口罩零售；眼镜制造；医护人员防护用品零售；日用口罩（非医用）销售；日用口罩（非医用）生产；第一类医疗器械生产；第一类医疗器械批发；第一类医疗器械零售；医护人员防护用品生产（Ⅰ类医疗器械）（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）。

注册资本　陆仟万元人民币
成立日期　二〇一〇年五月十三日
营业期限　2010年05月13日至2030年05月12日
住　　所　天津开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层

登记机关　2020年 03月 03日

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

营业执照　Business license

高新技术企业
证书

企业名称：正元盛邦（天津）生物科技有限公司　证书编号：GR201812000609
发证时间：2018年11月23日　有效期：三年
批准机关：

国家高新技术企业证书
national high-tech enterprise certification

天津市科技型企业
认定证书

企业名称：正元盛邦（天津）生物科技有限公司
认定编号：1805ZK01128748　有效期：三年
天津市科学技术委员会
2018年 5月28日

医疗器械生产许可证
Medical device manufacturing license

医疗器械生产许可证

许可证编号：津食药监械生产许20190028
企业名称：正元盛邦（天津）生物科技有限公司　生产地址：天津开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层
法定代表人：霍五奎
企业负责人：何俊
生产范围：Ⅲ类：6840-1-体外诊断试剂；Ⅱ类：6840-1-体外诊断试剂，6840-3-免疫分析系统
住　所：天津开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层
发证部门：天津市药品监督管理局
有效期限：至　2024 年 06 月 01 日　发证日期：2019 年 07 月 [illegible]
国家药品监督管理局制

医疗器械生产许可证
Medical device manufacturing license

第二类医疗器械经营备案凭证
The second type medical device operation record certificate

第二类医疗器械经营备案凭证

备案编号： 津滨食药监械经营备20194018号

企业名称	正元盛邦（天津）生物科技有限公司
法定代表人	霍五奎
企业负责人	何玺
经营方式	批发兼零售
住所	天津开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层
经营场所	天津开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层
仓库地址：	天津开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层
经营范围	2002年分类目录：6820，6840（含诊断试剂），6857，6864 2017年分类目录：07，11，6840体外诊断试剂（不需冷链运输、贮存）

备案部门（公章）： 天津市滨海新区市场监督管理局

备案日期： 2019年7月30日

天津市医疗器械备案专用章(1)

对外贸易经营者备案登记表
Registration Form for Foreign Trade Operators

对外贸易经营者备案登记表

备案登记表编号： 02578078　　统一社会信用代码： 91120116553445456F
进出口企业代码：

经营者中文名称	正元盛邦（天津）生物科技有限公司		
经营者英文名称	JOYSBIO(Tianjin)Biotechnology 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	天津开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层		
经营场所（中文）	天津开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层		
经营场所（英文）	Tianjin International Jiont Academy of Biomedicine 9th floor,No.220,Dongting Road,TEDA,Tianjin,China		
联系电话	022-65378415	联系传真	022-65378415
邮政编码	300457	电子邮箱	452756179@qq.com
工商登记注册日期	2010-5-13	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	霍五奎	有效证件号	142632196508285013
注册资金	陆仟万元		（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	

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
2018 年 07 月 30 日

中华人民共和国海关报关单位注册登记证书
Registration Certificate of Customs Declaration Unit of the People's Republic of China

QG07

中 华 人 民 共 和 国 海 关
报 关 单 位 注 册 登 记 证 书

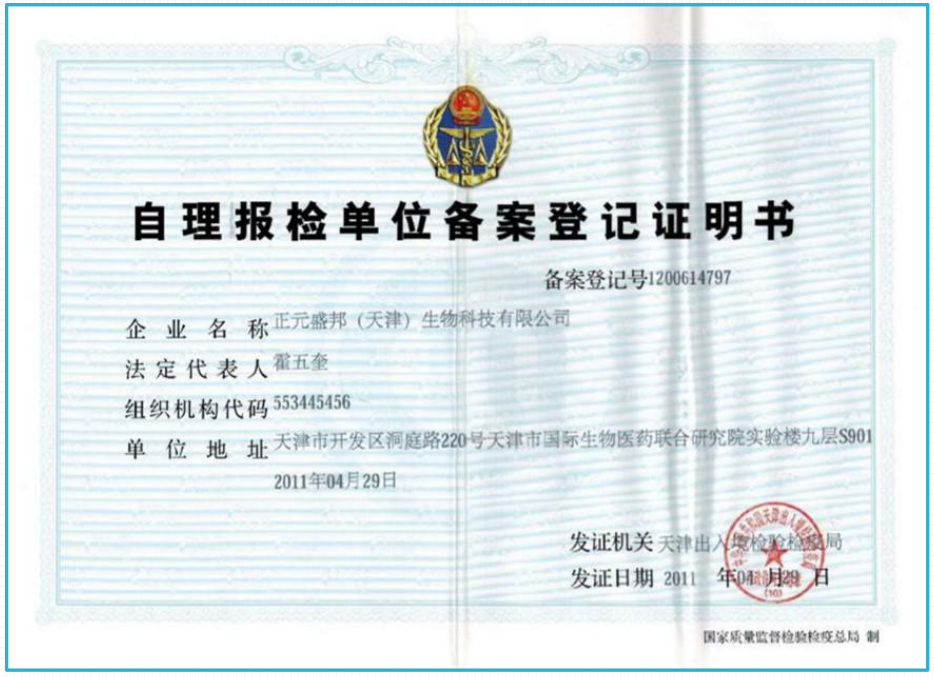
海关注册编码: 1207260977
组织机构代码: 553445456
企 业 名 称: 正元盛邦（天津）生物科技有限公司
企 业 住 所: 天津开发区洞庭路 220 号天津市国际生物医药联合研究院实验楼九层
企业经营类别: 进出口货物收发货人
注册登记日期: 2018 年 8 月 29 日
法定代表人: 霍五奎
有 效 期: 长期
注册海关: 滨开发区
核发日期: 2018 年 8 月 29 日

重 要 提 示

报关单位应当在每年6月30日前向海关提交《报关单位注册信息年度报告》，不再另行通知。

中华人民共和国海关总署监制

自理报检单位备案登记证明书
Registration Form for Foreign Trade Operators



自理报检单位备案登记证明书

备案登记号1200614797

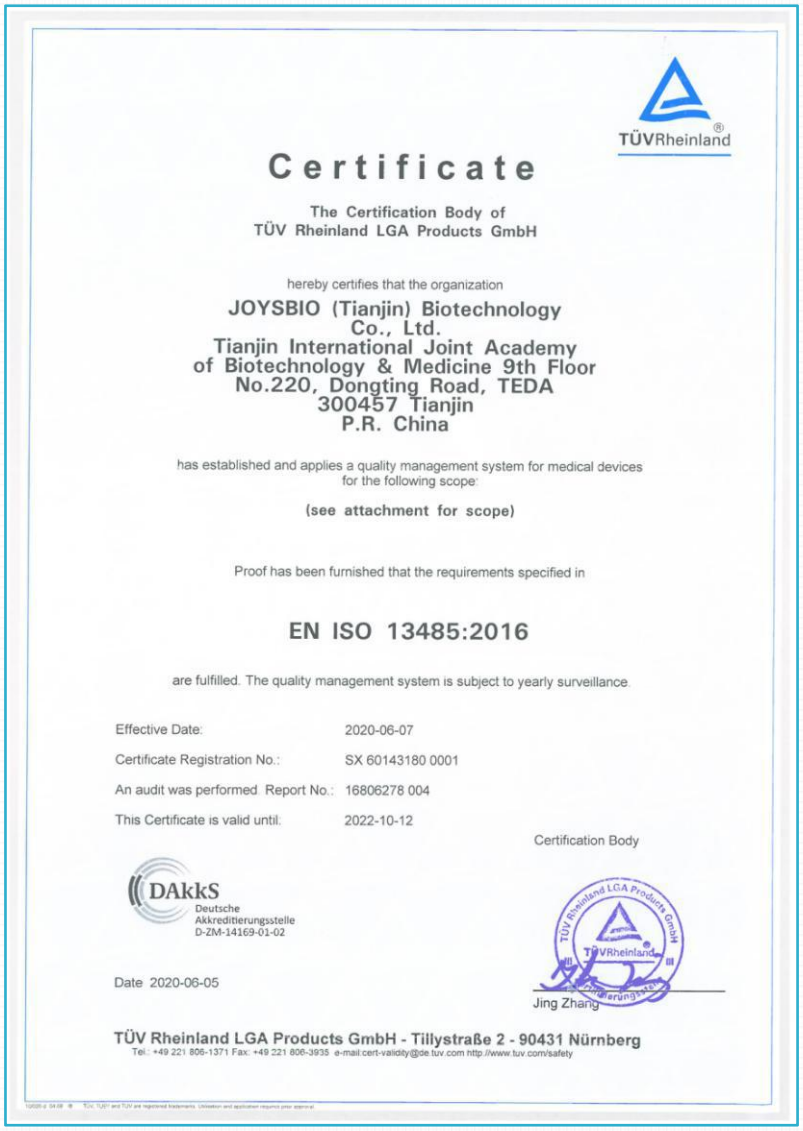
企 业 名 称 正元盛邦（天津）生物科技有限公司
法 定 代 表 人 霍五奎
组织机构代码 553445456
单 位 地 址 天津市开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层S901

2011年04月29日

发证机关 天津出入境检验检疫局
发证日期 2011 年04月29 日

国家质量监督检验检疫总局 制

TUV名录 ISO13485质量管理体系认证
ISO13485 Quality System Certification



TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

JOYSBIO (Tianjin) Biotechnology
Co., Ltd.
Tianjin International Joint Academy
of Biotechnology & Medicine 9th Floor
No.220, Dongting Road, TEDA
300457 Tianjin
P.R. China

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

(see attachment for scope)

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:	2020-06-07
Certificate Registration No.:	SX 60143180 0001
An audit was performed. Report No.:	16806278 004
This Certificate is valid until:	2022-10-12

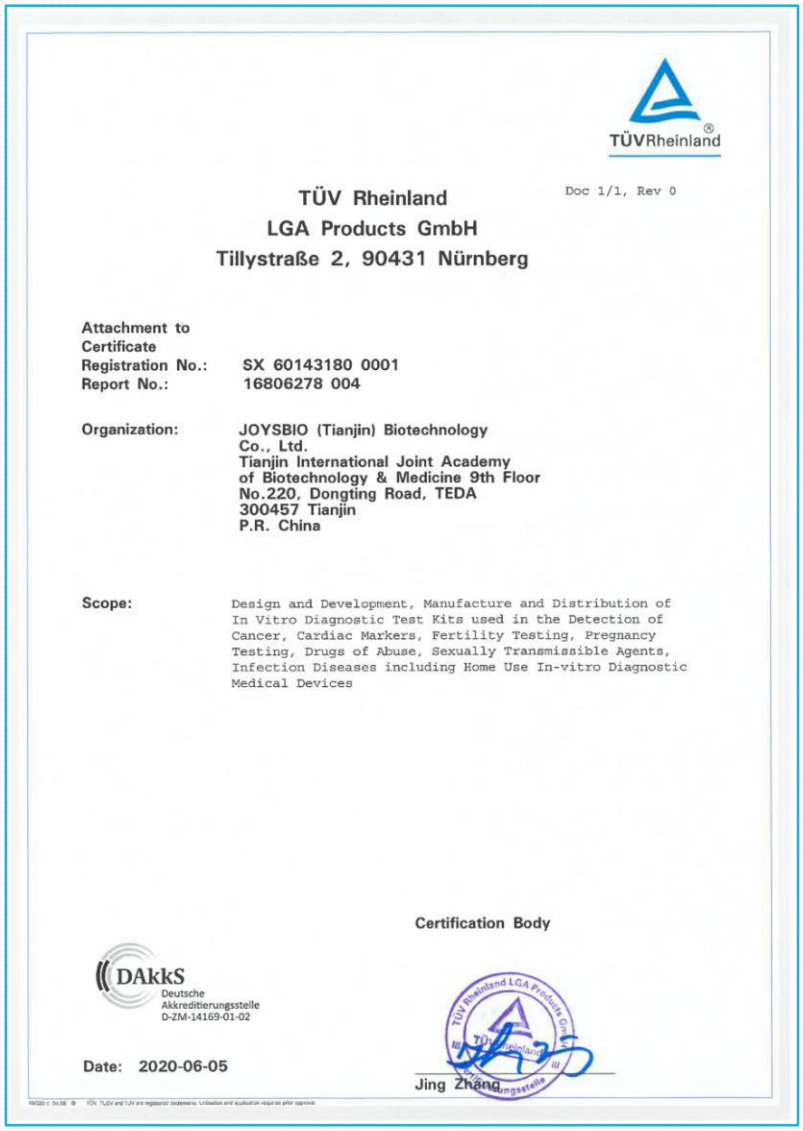
Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2020-06-05

Jing Zhang

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

Doc 1/1, Rev 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60143180 0001
Report No.: 16806278 004

Organization: JOYSBIO (Tianjin) Biotechnology
Co., Ltd.
Tianjin International Joint Academy
of Biotechnology & Medicine 9th Floor
No.220, Dongting Road, TEDA
300457 Tianjin
P.R. China

Scope: Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test Kits used in the Detection of Cancer, Cardiac Markers, Fertility Testing, Pregnancy Testing, Drugs of Abuse, Sexually Transmissible Agents, Infection Diseases including Home Use In-vitro Diagnostic Medical Devices

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date: 2020-06-05

Jing Zhang

公司7项产品获得欧盟准入资格
Seven products passed CE Certification

TÜVRheinland

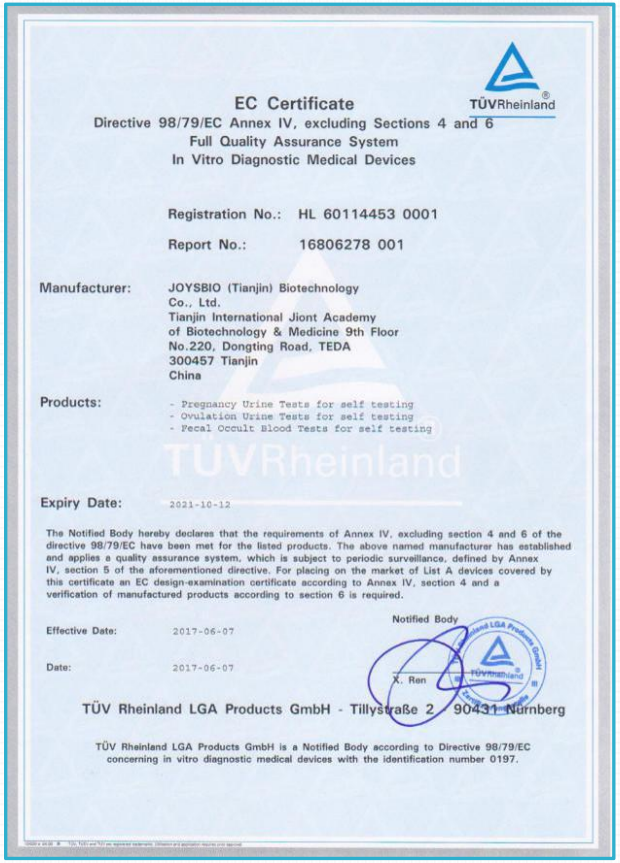
CE Technical Documentation Review Report

Applicant:	**JOYSBIO Biotechnology Co., LTD** Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220, Dongting Road, TEDA, 300457, Tianjin, China
Report Number:	**16806167.001**
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):	**Myoglobin/Creatinekinase-MB/Cardiac Troponin I Test Kit (Colloidal Gold)**
Type(s)/Model(s):	------
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	July.04.2016
Date of expiry:	July.03.2021
Review result:	During the examination of the provided Technical Documentation (No.: CE-JSWD-004, Revision 1.6, Dated 2016-Jul-15) 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



TÜVRheinland

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60114453 0001

Report No.: 16806278 001

Manufacturer: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin International Jiont Academy of Biotechnology & Medicine 9th Floor No.220, Dongting Road, TEDA
300457 Tianjin
China

Products:
- Pregnancy Urine Tests for self testing
- Ovulation Urine Tests for self testing
- Fecal Occult Blood Tests for self testing

Expiry Date: 2021-10-12

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

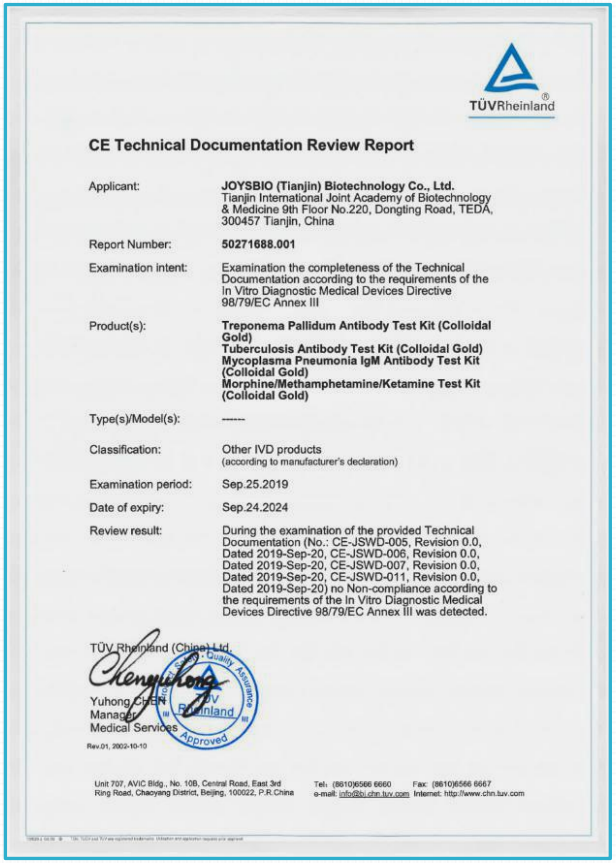
Effective Date: 2017-06-07

Date: 2017-06-07

Notified Body
X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.



TÜVRheinland

CE Technical Documentation Review Report

Applicant:	**JOYSBIO (Tianjin) Biotechnology Co., Ltd.** Tianjin International Joint Academy of Biotechnology & Medicine 9th Floor No.220, Dongting Road, TEDA, 300457 Tianjin, China
Report Number:	**50271688.001**
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):	**Treponema Pallidum Antibody Test Kit (Colloidal Gold)** **Tuberculosis Antibody Test Kit (Colloidal Gold)** **Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold)** **Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)**
Type(s)/Model(s):	------
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Sep.25.2019
Date of expiry:	Sep.24.2024
Review result:	During the examination of the provided Technical Documentation (No.: CE-JSWD-005, Revision 0.0, Dated 2019-Sep-20, CE-JSWD-006, Revision 0.0, Dated 2019-Sep-20, CE-JSWD-007, Revision 0.0, Dated 2019-Sep-20, CE-JSWD-011, Revision 0.0, Dated 2019-Sep-20) 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

3 生产能力
Production Capacity

日产能50万人份

Daily capacity is about 500,000 tests per day

拥有三大GMP洁净生产车间
It has 3 GMP grade of clean production workshops

两条全自动加工生产线
2 automatic processing lines

生产工人50人，日均产能50万人份
50 production workers, daily capacity is about 500,000 tests per day

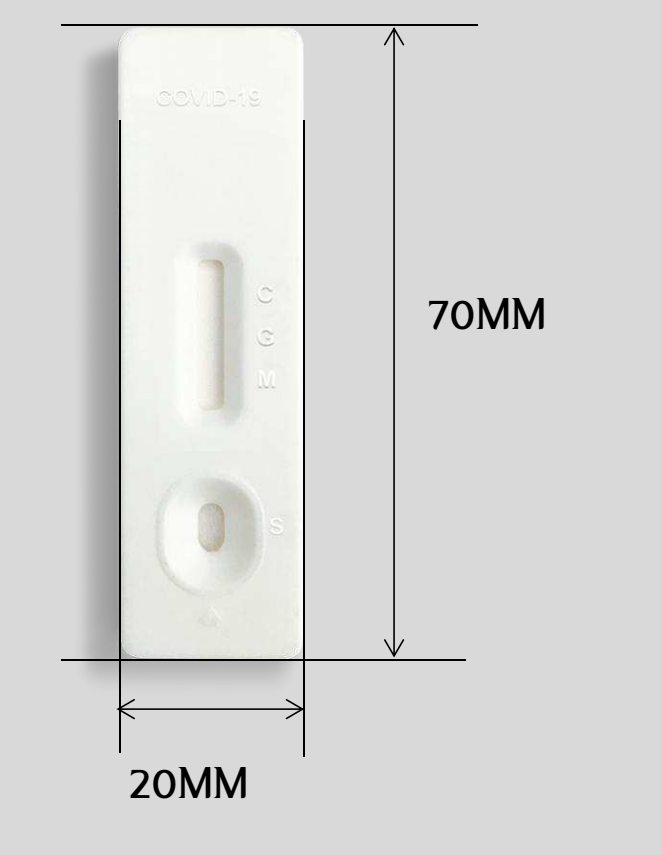
生产车间
Production Workshop

4 新冠检测产品

COVID-19 Test Kit

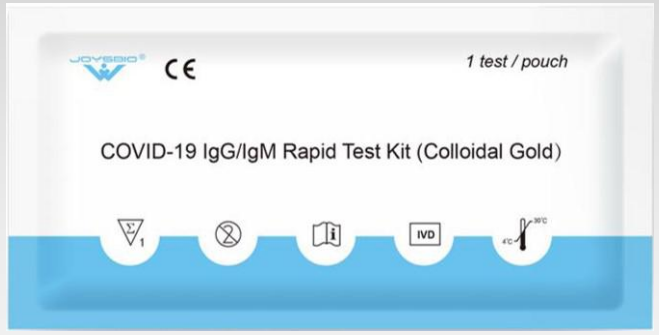
新型冠状病毒（COVID-19 ）IgG/IgM 抗体 检测试剂盒（胶体金法）

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



单人份检测试剂卡外观
Appearance of single rapid test kit

高（Height）：70MM　宽（Width）：20MM



单人份检测试剂铝箔袋包装正面
Single test Aluminum foil bag packaging(Front side)

单人份检测试剂铝箔袋包装背面
Single test Aluminum foil bag packaging(Back side)

单人份检测试剂铝箔袋包装
Aluminum foil bag Package of single test

长(Length):120MM　宽(Width)：60MM

新冠检测试剂20人份包装盒尺寸规格

Product package size (BOX)

Product package size：
Length:190mm
Width:60mm
Height:120mm
Weight:168g

Include： Test kit (20 pcs/box)

包装尺寸：
长：190mm
宽：60mm
高：120mm
重：168g

净含量：20人份检测试剂/盒

新冠检测试剂1000人份包装箱尺寸规格

Product package size (CARTON)

Product package size：
Length:639mm
Width:395mm
Height:325mm
Weight:9700g

Include：50 box ,1000 PCS (product &carton)

包装尺寸：
长：639mm
宽：395mm
高：325mm
重：9700g

净含量：50盒，1000人份/箱

单人份检测试剂包装组件（需定制）

Ingredients for single serving test kit（Need to customize）

检测卡	稀释液	滴管	酒精消毒片	采血针
Test Kit	Sample Diluent	Dropper	Alcohol Wipes	Lancet

可检测的样本
Detectable Samples

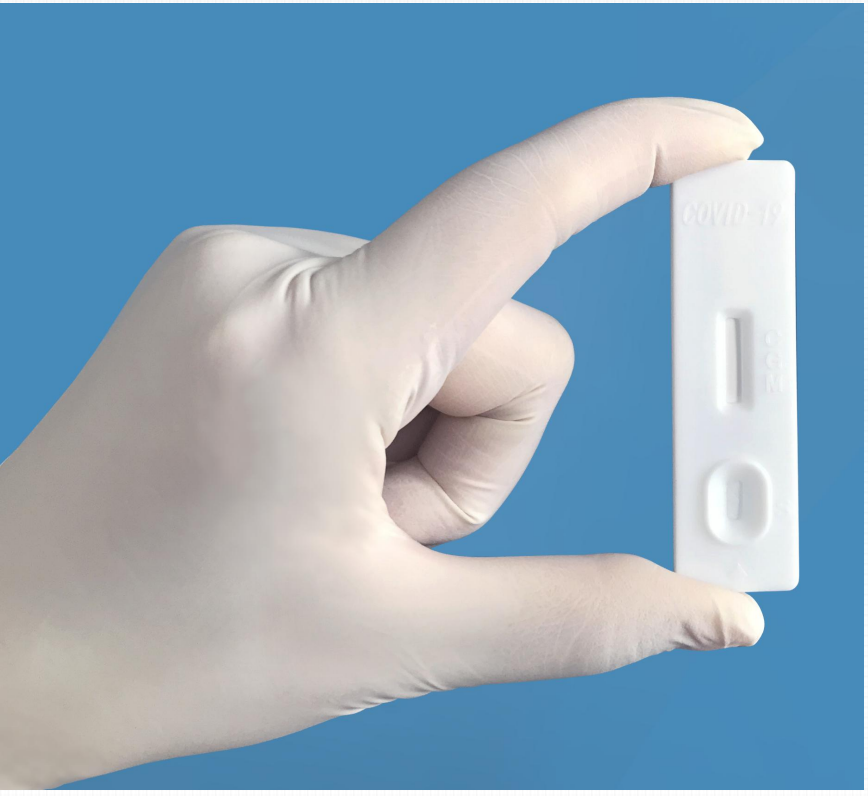
全血样本
Whole blood

血清样本
serum

血浆样本
plasma

我公司胶体金新冠检测产品与核酸检测方法对比，其优势在于

JOYSBIO COVID-19 IgG/IgM Rapid Test Kit Advantages



取样简单，无需处理	Simple sample collection ， no processing required
弱阳性结果清晰明了	Weak positive result is clear
操作简单	Simple operation
常温运输	Normal temperature transport
4~30 摄氏度储存	Storage at 4℃ -30 ℃
价格低	Competitive price
15分钟出检测结果	Test result will come out in 15 minutes
检测结果直观可见	The test results are clear and intuitive
根据说明书即可操作	Operate according to the instruction

我公司双抗体新冠检测产品优势

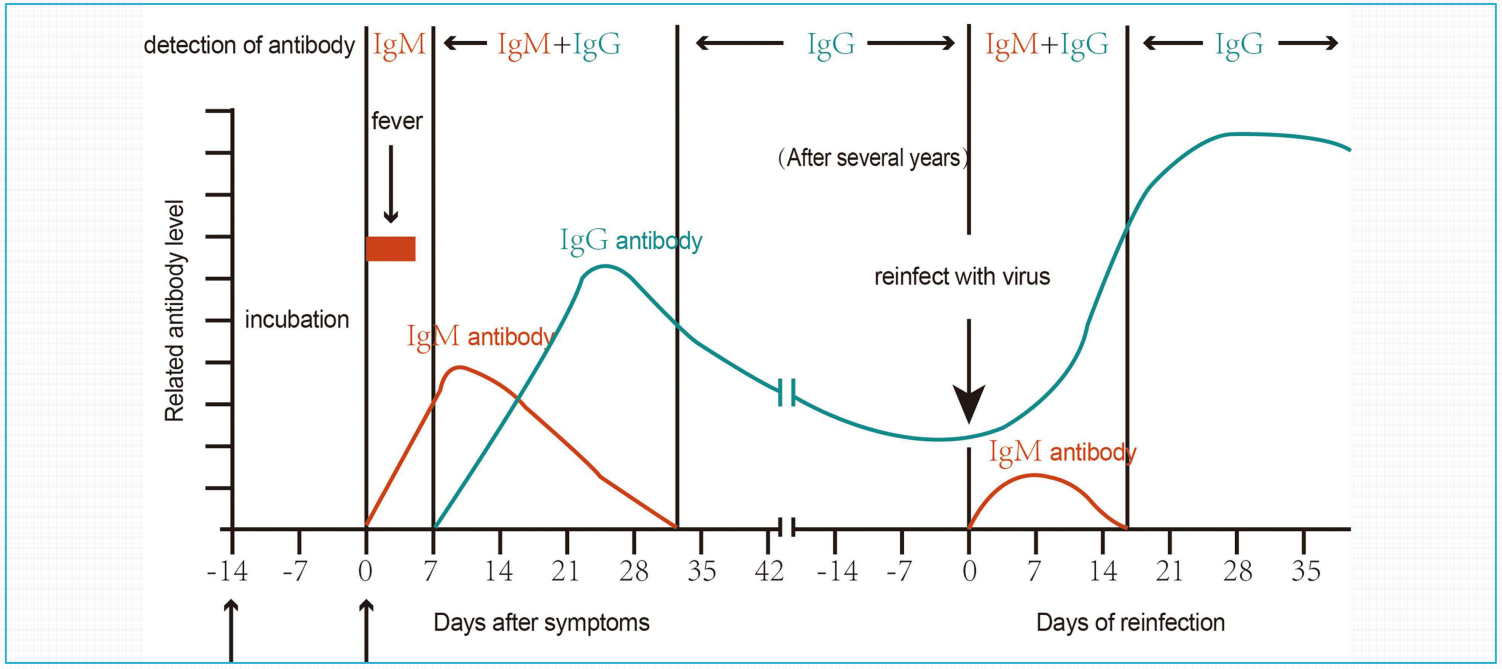
JOYSBIO COVID-19 IgG/IgM Rapid Test Kit Advantages

为什么用抗体检测?

因为人体感染病毒后,人体免疫系统会自动产生免疫球蛋白, 人感染后七天内会产生免疫球蛋白M,检测方法是IgM检测法,七天后会产生免疫球蛋白G,也就是IgG检测法,我们就是IgM和Ig G双联检测,一个试剂盒同时测两种抗体,更加方便快捷，同时更有助于推算感染时间，精确筛查感染期间接触人群。在感染初期，体内抗体比较少的时候，俗称弱阳，这是很多产品容易漏检的时候，我公司检测试剂能够检测出来，这也是我公司产品的过硬之处，综合准确率95%以上!

Why should we choose"antibody test kit" ?

After infection, the body's immune system will produce immunoglobulin automatically , within seven days after infection can produce immunoglobulin M, What we called this detection method is IgM test, After seven days or a second infection to produce immunoglobulin G, what we called this is IgG test .We are double detection of IgM and IgG,one kit can detect two antibodies simultaneously , its more convenient. At the same time, it is more helpful to calculate the time of infection and accurately screen the people exposed during the infection. In the early stage of infection, antibodies are less , commonly call as "weak Positive" At this stage which is easy to miss diagnosis , however we can detect out, that is our test kit 's Selling point and advantage, what's more， comprehensive accuracy can up to more than 95% .

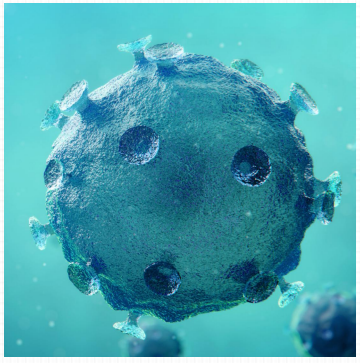


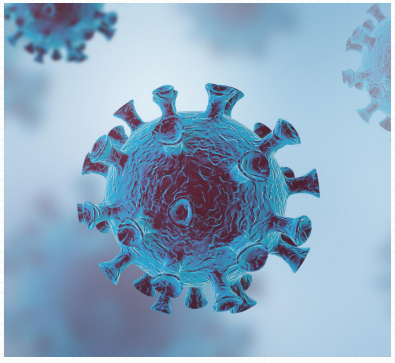
针对病毒变异的特性，我们采取的解决方案

For the characteristics of virus variation, we take the solution ， as follows:

冠状病毒有不断变异的特性，而市面上大部分抗体检测产品均有单一性限制，无法及时更新技术及原料，容易导致病毒变异后漏检的现象出现。针对这一现象，我公司生产的抗体检测试剂盒针对变异及非变异进行了独家技术的双向融合，保证了产品的稳定性，同时针对感染病毒的变异非变异均可及时检测出来，避免了漏检现象出现！

Due to coronaviruses have the property of constantly mutating, Most antibody test kits on the market have a single limitation ,which is easy to lead to “missing detection ” due to virus mutation .However, the antibody test kit produced by our company has the exclusive technology of “bidirectional fusion” for mutation and non-mutation.This can gurantee the absolute stability of the test kit, at the same time for the virus infection of the variation and non-variation can be timely detected, to avoid “missing detectio.





技术参数（数据表）

JOYSBIO COVID-19 Test Kit Data Sheet

1.整体临床研究结果

试剂测试结果		PCR对比测试结果		合计
		阳性	阴性	
阳性	IgG+/IgM+	148	0	148
	IgG-/IgM+	4	4	8
	IgG+/IgM-	18	5	23
阴性	IgG-/IgM-	12	209	221
合计		182	218	400

灵敏度 (PPA)= (IgM 阳性和 IgG 阳性)/(PCR 阳性)
灵敏度 (PPA)= 170/182 (93.41%) （95%CI:88.8%~96.5%）
特异性 (NPA) = (IgM 阴性和 IgG 阴性)/(PCR 阴性)
特异性 (NPA)= 209/218 (95.87%)（95%CI:92.3%~98.1%）

2.IgM 检测结果

IgM检测结果	PCR对比测试结果		合计
	阳性	阴性	
阳性	152	4	156
阴性	30	214	244
合计	182	218	400

灵敏度 (PPA)= IgM 阳性 /PCR 阳性
灵敏度 (PPA)= 152/182 (83.52%) （95%CI:77.3%~88.6%）
特异性 (NPA) = IgM 阴性 /PCR 阴性
特异性 (NPA)= 214/218 (98.17%) （95%CI:95.4%~99.5%）

3.IgG 检测结果

IgG检测结果	PCR对比测试结果		合计
	阳性	阴性	
阳性	166	5	171
阴性	16	213	229
合计	182	218	400

灵敏度 (PPA)= IgG 阳性/PCR 阳性
灵敏度 (PPA)= 166/182 (91.21%) （95%CI:86.1%~94.9%）
特异性 (NPA) = IgG 阴性 /PCR 阴性
特异性 (NPA)= 213/218 (97.71%) （95%CI:94.7%~99.3%）

技术参数（数据表）

JOYSBIO COVID-19 Test Kit Data Sheet

1.Overall Clinical Study Results

Reagent test results		PCR Comparator		Subtotal
		positive	negative	
positive	IgG+/IgM+	148	0	148
	IgG-/IgM+	4	4	8
	IgG+/IgM-	18	5	23
negative	IgG-/IgM-	12	209	221
Subtotal		182	218	400

Positive Percent Agreement (PPA)= (IgM positive or IgG positive)/(PCR positive)
Positive Percent Agreement (PPA)= 170/182 (93.41%)
Negative Percent Agreement: (NPA) = (IgM negative and IgG negative)/(PCR negative)
Negative Percent Agreement (NPA)= 209/218 (95.87%)

2.IgM Results

Reagent test results of IgM	PCR Comparator		Subtotal
	positive	negative	
positive	152	4	156
negative	30	214	244
Subtotal	182	218	400

Positive Percent Agreement (PPA)= IgM positive /PCR positive
Positive Percent Agreement (PPA)= 152/182 (83.52%)
Negative Percent Agreement: (NPA) = IgM negative /PCR negative
Negative Percent Agreement (NPA)= 214/218 (98.17%)

3.IgG Results

Reagent test results of IgG	PCR Comparator		Subtotal
	positive	negative	
positive	166	5	171
negative	16	213	229
Subtotal	182	218	400

Positive Percent Agreement (PPA)= IgG positive /PCR positive
Positive Percent Agreement (PPA)= 166/182 (91.21%)
Negative Percent Agreement: (NPA) = IgG negative /PCR negative
Negative Percent Agreement (NPA)= 213/218 (97.71%)

正元盛邦新冠抗体检测试剂盒 预期用途

JOYSBIO COVID-19 IgG/IgM Rapid Test Kit **Intended Use**

供体外定性检测人全血、血浆和血清样本中的新型冠状病毒（COVID-19）IgG/IgM 抗体用。本检测法 仅供临床实验室或医护人员即时检测使用，不作家居检测使用。 若结果呈阳性，则需进一步确诊；若结果呈阴性，则不能排除感染的可能性。本试剂盒的检测结果仅 供临床参考。建议结合临床表现及其他化验对患者状况进行综合分析。

For in vitro qualitative determination of the content of COVID-19 IgG/IgM antibody in human serum, plasma and whole blood. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing. A positive test result requires further confirmation, and a negative test result cannot rule out the possibility of infection. The test results of this kit are only for clinical reference. It is recommended to conduct a comprehensive analysis of the patient's condition in combination with clinical manifestations and other laboratory tests.

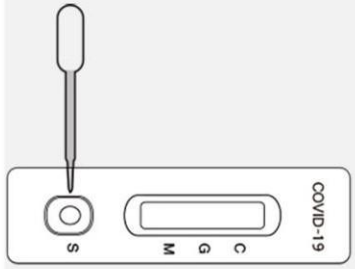
Rapid
Sensitive
Accurate
Convenient

使用方法图解

JOYSBIO COVID-19 IgG/IgM Rapid Test Kit **Test Method**

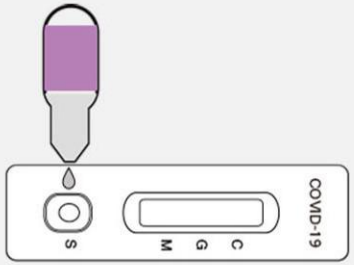
全血样本检测法方图

Whole Blood Test Method



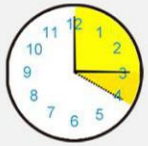
1 Add 20μl Whole Blood into sample well

在加样窗加入20μL全血样本



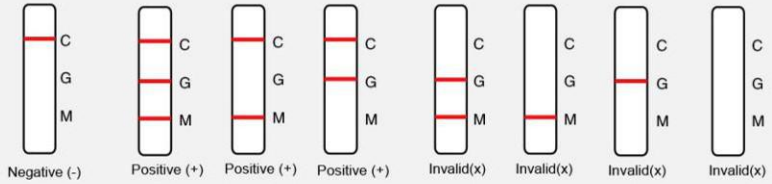
2 Add diluent into sample well

在加样窗加入样品稀释液



With in 15~20 minutes

等待15-20分钟

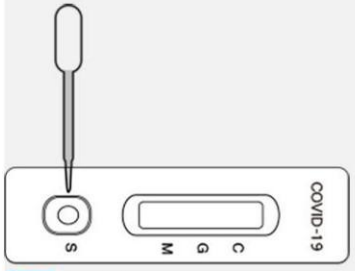


3 The results were observed at room temperature for 15-20 minutes.

在室温下，15至20分钟内读取检测结果

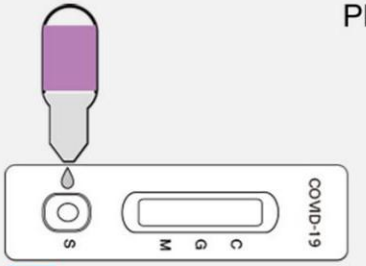
血清或血浆样本检测法方图

Plasma or Serum Test Method



1 Add 10μl Plasma or serum into sample well

在加样窗加入10 μL全血样本

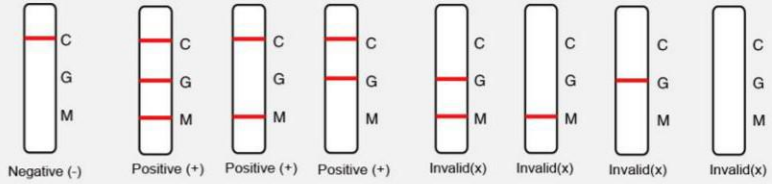


2 Add diluent into sample well

在加样窗加入样品稀释液

With in 15~20 minutes

等待15-20分钟



3 The results were observed at room temperature for 15-20 minutes.

在室温下，15至20分钟内读取检测结果

正元盛邦医疗器械进出口备案凭证
JOYSBIO Medical device export record certificate

天津市医疗器械出口备案凭证

备案号：津滨20200074

生产企业名称	正元盛邦（天津）生物科技有限公司		
生产地址	天津市开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层		
是否具有生产许可证或者备案	是	生产许可/备案编号	津食药监械生产许20100326
是否具有第三方认证	是	第三方认证机构	TUV莱茵检测认证服务（中国）有限公司
联系方式	13821759311		
出口产品名称	COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)		
是否境内注册/备案	否	注册号/备案号	
出口企业名称	自营出口		
出口企业地址	自营出口		
销往国家（地区）	盟成员国：法国、德国、意大利、荷兰、比利时、卢森堡、丹麦、爱尔兰、希腊、葡萄牙、西班牙、奥地利、瑞典、芬兰、马耳他、塞浦路斯、波兰、匈牙利、捷克、斯洛伐克、斯洛文尼亚、爱沙尼亚、拉脱维亚、立陶宛、罗马尼亚，保加利亚、克罗地亚。EEA、瑞士、和土耳其，挪威，柬埔寨，越南，韩国，日本，菲律宾，黎巴嫩，泰国，新加坡，巴基斯坦，伊朗，澳洲，马来西亚，印度尼西亚，沙特，尼泊尔、老挝、缅甸，文莱、不丹、孟加拉国、印度、斯里兰卡、哈萨克斯坦、吉尔吉斯斯坦、塔吉克斯坦、乌兹别克斯坦、阿富汗、伊拉克、叙利亚、约旦、以色列、巴勒斯坦、巴林、卡塔尔、科威特、阿拉伯联合酋长国（阿联酋）、格鲁吉亚、亚美尼亚、白俄罗斯、俄罗斯、乌克兰、奥地利、、摩纳哥、英国、埃及、利比亚、苏丹、突尼斯、阿尔及利亚、摩洛哥、埃塞俄比亚、厄立特里亚、索马里、吉布提、肯尼亚、坦桑尼亚、乌干达、卢旺达、布隆迪、塞舌尔乍得、中非、喀麦隆、赤道几内亚、加蓬、刚果共和国（刚果（布））、刚果民主共和国（刚果（金）毛里塔尼亚、、塞内加尔、冈比亚、马里、几内亚、几内亚比绍、佛得角、塞拉利昂、利比里亚、科特迪瓦、加纳、多哥、贝宁、尼日尔、尼日利亚赞比亚、安哥拉、津巴布韦、马拉维、莫桑比克、博茨瓦纳、纳米比亚、南非、斯威士兰、莱索托、马达加斯加、科摩罗、毛里求斯、澳大利亚、新西兰、巴布亚新几内亚、帕劳、瑙鲁、基里巴斯、图瓦卢、萨摩亚、斐济群岛、汤加、库克群岛（新）、关岛（美）、纽埃（新）、加拿大、美国、墨西哥、格陵兰哥伦比亚、委内瑞拉、圭亚那、法属圭亚那、苏里南厄瓜多尔、秘鲁、玻		

	利维亚巴西、智利、阿根廷、乌拉圭、巴拉圭、伯利兹、萨尔瓦多、尼加拉瓜、哥斯达黎加、巴拿马		
是否境外委托境内生产	否	是否获准境外上市	是
境外委托企业名称			
境外委托企业地址			
出口合同编号	无	出口合同期限	2022-03-31
产品规格	卡型、条型		
包装规格	20人份/盒（1人份/袋×20袋）、40人份/盒（1人份/袋×40袋）、50条（1人份/袋×50袋）100条（1人份/袋×100袋）		
出口数量	5000000		
本企业承诺保证所生产出口的医疗器械符合进口国（地区）的要求，所提交的全部备案资料真实有效，并承担一切法律责任。 法定代表人（签字）：　　（企业盖章）			
备案部门（公章）： 备案日期：2020年03月27日			

我公司新冠检测试剂产品在中国医药保健品进出口商会网站可查询

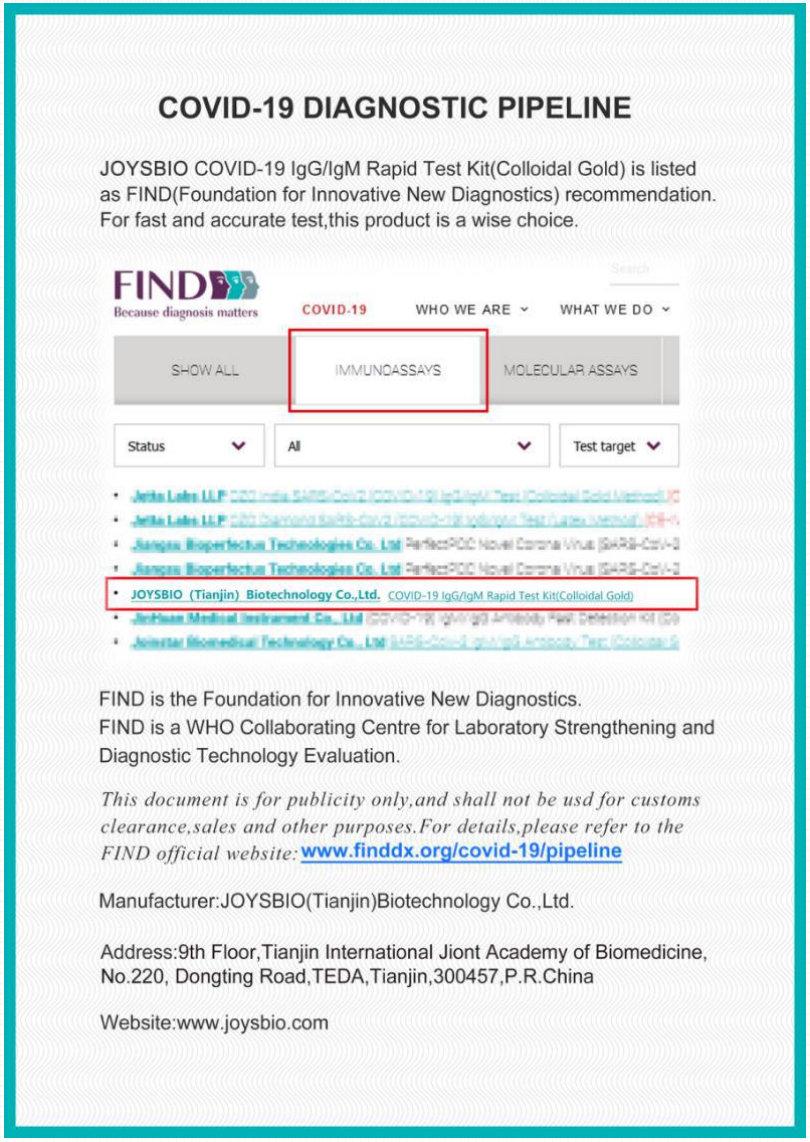
Our COVID-19 rapid test kits can be found on the website of China Chamber of Commerce for the import and export of medical and health products

我公司新冠检测产品被列入国外标准认证或注册的医疗物资生产企业名单，**可以正常报关出口**

Our company's COVID-19 IgG/IgM Rapid Test Kit is listed in "Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries"

COVID-19抗体检测产品进入FIND组织推荐名单

JOYSBIO COVID-19 IgG/IgM rapid test kit (colloidal gold) product developed by our company has entered the publicity list recommended by FIND



COVID-19 DIAGNOSTIC PIPELINE

JOYSBIO COVID-19 IgG/IgM Rapid Test Kit(Colloidal Gold) is listed as FIND(Foundation for Innovative New Diagnostics) recommendation. For fast and accurate test,this product is a wise choice.

FIND
Because diagnosis matters

COVID-19 | WHO WE ARE | WHAT WE DO

SHOW ALL | IMMUNOASSAYS | MOLECULAR ASSAYS

Status | All | Test target

- JOYSBIO (Tianjin) Biotechnology Co.,Ltd. COVID-19 IgG/IgM Rapid Test Kit(Colloidal Gold)

FIND is the Foundation for Innovative New Diagnostics.
FIND is a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation.

This document is for publicity only,and shall not be usd for customs clearance,sales and other purposes.For details,please refer to the FIND official website: www.finddx.org/covid-19/pipeline

Manufacturer:JOYSBIO(Tianjin)Biotechnology Co.,Ltd.

Address:9th Floor,Tianjin International Jiont Academy of Biomedicine, No.220, Dongting Road,TEDA,Tianjin,300457,P.R.China

Website:www.joysbio.com

The JOYSBIO COVID-19 IgG/IgM rapid test kit (colloidal gold) product developed by our company has entered the publicity list recommended by FIND (Innovative New Diagnostic Foundation).

COVID-19抗体检测试剂获得欧盟准入资格

CE Certification of COVID-19 IgG/IgM Rapid Test Kit

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 12 mei 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 29 april 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam JOYSBIO (Tianjin) Biotechnology Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-50908)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Farmatec
Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
R.A.C. Ori

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20201797

Bijlagen
-

Uw aanvraag
29 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Pagina 1 van 2

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, JOYSBIO (Tianjin) Biotechnology Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde
Dhr. M.J. van de Velde

Pagina 2 van 2

COVID-19抗体检测产品FDA-EUA注册回执
Acknowledgment Letter of FDA-EUA

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

7/1/2020

Iven Wang
Aurora Biomed Inc.
1001 E Pender Street
Vancouver, BC V6A 1W2
CANADA

Dear Iven Wang:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA201925
Received: 6/30/2020
Applicant: Joysbio (Tianjin) Biotechnology Co., Ltd.
Device: COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

我公司新冠检测试剂获得巴西 ANVISA 注册批复
Brazil ANVISA Registration Approval

ANVISA
Agência Nacional de Vigilância Sanitária

Quarta Diretoria
Coordenação de Autorização de Funcionamento de Empresas
S.I.A. Trecho 5, Área Especial 57, Brasília/DF, CEP 71.205.050
Telefone: 0800 642 9782 - www.anvisa.gov.br

Ofício nº 138/2020/SEI/COAFE/DIRE4/ANVISA

Assunto: **Priorização Covid-19**

Referência: Caso responda este Ofício, indicar expressamente o Processo nº 25351.910630/2020-97.

Prezados,

1. Informamos que o pedido de ampliação de atividades na AFE, expediente nº 1641426/20-8, da empresa APIS VIDA INDUSTRIA E COMÉRCIO DE PRODUTOS FARMACEUTICOS LTDA - 02.943.733/0001-95 - foi deferido e a empresa já está autorizada a funcionar (AFE nº 8.02036-4) para as atividades de fabricar, importar, armazenar e expedir produtos para saúde no endereço RUA ALCIDIO PAGANELLI 412, JARDIM CANADA, BEBEDOURO/SP - CEP 14707016.

2. Tendo em vista o recebimento deste ofício e as medidas referentes a emergência de saúde pública internacional relacionada ao SARS-CoV-2, não é necessário aguardar a publicação no DOU da alteração da AFE para o início da realização das atividades. Apesar do exposto, informamos que a publicação em DOU ocorrerá normalmente de acordo com a fila de análise de expedientes disponibilizada no portal da agência.

Atenciosamente,

Coordenação de Autorização de Funcionamento de Empresas - Coafe

Documento assinado eletronicamente por **Raquel Santana Costa, Técnico em Regulação e Vigilância Sanitária**, em 30/05/2020, às 20:54, conforme horário oficial de Brasília, com fundamento no art. 6º, § 1º, do Decreto nº 8.539, de 8 de outubro de 2015 http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Decreto/D8539.htm.

A autenticidade deste documento pode ser conferida no site https://sei.anvisa.gov.br/autenticidade, informando o código verificador **1034634** e o código CRC **D2BC2F7F**.

国家食品药品监督管理局天津医疗器械质量监督检验中心检验报告

National Medical Products Administration Tianjin Medical Devices Quality Supervision and Testing Center Test Report

检 验 报 告

报告编号：2020-GJ-0375

委 托 方　正元盛邦（天津）生物科技有限公司

样品名称　新型冠状病毒（COVID-19）IgG/IgM 抗体检测试剂盒（胶体金法）

型　　号　/

检验类别　注册检验（）

注册补充检验（）

其他检验（√）　委托检验

国家食品药品监督管理局天津医疗器械质量监督检验中心

TEST REPORT

Report No.: 2020-GJ-0375

Entrusting Party: JOYSBIO (Tianjin) Biotechnology Co., Ltd.

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

Model No.: /

Kind of Testing: Registered Test( )

Registered Supplementary Test( )

Other Test (√) Entrusted Test

Tianjin Medical Devices Quality Supervision and Testing Center,

China Food and Drug Administration

(seal): Special seal for detection of Tianjin Medical Devices Quality Supervision and Testing Center,

China Food and Drug Administration

国家食品药品监督管理局天津医疗器械质量监督检验中心检验报告

National Medical Products Administration Tianjin Medical Devices Quality Supervision and Testing Center Test Report

国家食品药品监督管理局天津医疗器械质量监督检验中心

检 验 报 告 首 页

报告编号：2020-GJ-0375　　共 4 页　第 1 页

样品名称	新型冠状病毒（COVID-19）IgG/IgM 抗体检测试剂盒（胶体金法） 送样（）　现场（）　抽样（√）	样品编号	1#～30#
商　标	/	型号规格	20 人份/盒
委 托 方	正元盛邦（天津）生物科技有限公司	检验类别	委托检验
委托方地址	天津开发区洞庭路 220 号天津市国际生物医药联合研究院实验楼九层	产品编/批号	见备注
生产单位	正元盛邦（天津）生物科技有限公司	抽样单编号	122068400003024
受检单位	正元盛邦（天津）生物科技有限公司	生产日期	见备注
抽样单位	天津市药品监督管理局	样品数量	叁拾盒（陆佰人份）
抽样地点	库房	抽样基数	柒佰叁拾捌人份
抽样日期	2020 年 4 月 30 日	检验地点	正元盛邦（天津）生物科技有限公司质控室
收样日期	2020 年 4 月 30 日	检验日期	2020 年 4 月 30 日～2020 年 5 月 15 日
检验项目	全项目		
检验依据	正元盛邦（天津）生物科技有限公司《新型冠状病毒（COVID-19）IgG/IgM 抗体检测试剂盒（胶体金法）技术要求》		
检验结论	被检样品符合正元盛邦（天津）生物科技有限公司《新型冠状病毒（COVID-19）IgG/IgM 抗体检测试剂盒（胶体金法）技术要求》的规定。 （检验报告专用章或检验单位公章） 签发日期：2020 年 5 月 20 日		
备注	（1）报告中的“——”表示此项不适用，报告中的“/”表示此项空白。 （2）样品编号　生产批号　生产日期 1#～10#　2020031906　2020 年 3 月 18 日 11#～20#　2020032107　2020 年 3 月 20 日 21#～30#　2020032408　2020 年 3 月 23 日 6#～10#样品于 2020 年 4 月 30 日，置 37℃培养箱放置 14 天后用于稳定性检测。 （3）本报告仅提供使用企业参考品的实测数据。		

批 准：　　审 核：　　检 验：

职 务：

Tianjin Medical Devices Quality Supervision and Testing Center, China Food and Drug Administration

First Page of Test Report

Report No.: 2020-GJ-0375　　Page 1 of 4

Sample Name:	COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) Sample presentation()　On-site()　Sampling(√)	Sample No.:	1# ~ 30#
Trademark:	/	Model Specification:	20 T/box
Entrusting Party:	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Test Category:	Entrusted Test
Address of Entrusting Party:	Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China	Product Serial / Batch No.:	See remarks.
Manufacture:	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Sampling Sheet No.:	122068400003024
Subject Company:	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Date of Production:	See remarks.
Sampling Institution:	Tianjin Medical Products Administration	Sample Quantity:	Thirty boxes(six hundred T)
Sampling Site:	Warehouse	Sampling Basic No.:	Seven hundred and thirty-eight T
Sampling Date:	April 30, 2020	Testing Site:	Quality Control Room of JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Date Received:	April 30, 2020	Test Date:	April 30, 2020 ~ May 15, 2020
Testing Item:	All the items		
Testing Basis:	*Technical Requirements for the COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)* of JOYSBIO (Tianjin) Biotechnology Co., Ltd.		
Testing Conclusion:	The tested samples conform to the specifications of the *Technical Requirements for the COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)* of JOYSBIO (Tianjin) Biotechnology Co., Ltd. Date of Issue: May 20, 2020		
Remarks:	(1) The “——” in this Test Report indicates that this item is not applicable. The “/” in this Test Report indicates that this item is blank. (2) Sample No. / Production Batch No. / Date of Production 1# ~ 10 # / 2020031906 / March 18, 2020 11# ~ 20# / 2020032107 / March 20, 2020 21# ~ 30# / 2020032408 / March 23, 2020 Samples 6#~10# were placed in 37°C incubator on April 30, 2020 for stability test after 14 days. (3) This Report only provides test data of the enterprise’s reference products.		

Approved by:　　Checked by:　　Tested by:

Position:

国家食品药品监督管理局天津医疗器械质量监督检验中心检验报告

National Medical Products Administration Tianjin Medical Devices Quality Supervision and Testing Center Test Report

国家食品药品监督管理局天津医疗器械质量监督检验中心

检 验 报 告 内 容

报告编号：2020-GJ-0375　　共 4 页　第 2 页

序号	检验项目	条款	要求	样品编号	检验结果	单项结论	备注
1	外观	2.1.1	试剂盒外观应完整，无破损；试剂盒中的铝箔袋应密封，无漏气；干燥剂包装完整，无洒漏；稀释液成分应澄清、透明、无絮状、粒状等杂质。检测试剂应平整、无瑕疵，材料附着牢固，内容齐全。	1#、11#、21#	符合要求	符合	/
2	膜条宽度	2.1.2	膜条宽度不小于3mm。	1#、11#、21#	3.00～3.02	符合	/
3	移行速度	2.1.3	移行速度不小于10mm/min。	1#、11#、21#	40.70～50.00	符合	/
4	阴性参考品符合率	2.2	用企业参考品（内控盘）中的20份IgG阴性参考品检测，阴性符合率均为20/20。 用企业参考品（内控盘）中的20份IgM阴性参考品检测，阴性符合率均为20/20。	1#、11#、21#	1# 11# 21# IgG 20/20 20/20 20/20 IgM 20/20 20/20 20/20	符合	/
5	阳性参考品符合率	2.3	用企业参考品（内控盘）中的10份IgG阳性参考品（P1～P10）检测，阳性符合率均为10/10。 用企业参考品（内控盘）中的10份IgM阳性参考品（P11～P20）检测，阳性符合率均为10/10。	2#、12#、22#	2# 12# 22# IgG 10/10 10/10 10/10 IgM 10/10 10/10 10/10	符合	/
6	最低检出限	2.4	用企业参考品（内控盘）中的3份IgG 最低检出量参考品检测，L1-IgG、L2-IgG应为阳性、L3-IgG应为阴性。 用企业参考品（内控盘）中的3份IgM 最低检出量参考品检测，L1-IgM、L2-IgM应为阳性、L3-IgM应为阴性。	3#、13#、23#	L1-IgG：均为阳性 L2-IgG：均为阳性 L3-IgG：均为阴性 L1-IgM：均为阳性 L2-IgM：均为阳性 L3-IgM：均为阴性	符合	/
7	精密性	2.5	用企业参考品（内控盘）中的IgG（J1-IgG阳性、J2-IgG阴性）、IgM（J1-IgM阳性、J2-IgM阴性）精密性参考品平行测试10份检测试剂，反应结果一致，显色度均一。	4#、5#、14#、15#、24#、25#	J1-IgG：均为阳性，显色度均一 J2-IgG：均为阴性 J1-IgM：均为阳性，显色度均一 J2-IgM：：均为阴性	符合	/

Tianjin Medical Devices Quality Supervision and Testing Center, China Food and Drug Administration

Contents of Test Report

Report No.: 2020-GJ-0375　　Page 2 of 4

Serial No.	Tested Item	Article	Requirements	Sample No.	Testing Conclusion	Single Conclusion	Remarks
1	Appearance	2.1.1	The appearance of the kit shall be intact; The aluminum foil bag in the kit shall be sealed without air leakage; The desiccant shall be packed completely without leakage. Diluent components shall be clear and transparent without flocculent, granular and other impurities; The detection reagent shall be flat without flaw, and the material of it shall be firmly attached with complete contents.	1#; 11#; 21#	Conform to Requirements	Conform	/
2	Membrane Strip Width	2.1.2	The membrane strip shall not be less than 3mm.	1#; 11#; 21#	3.00~3.02	Conform	/
3	Migration Velocity	2.1.3	The migration velocity shall not be less than 10mm/ min.	1#; 11#; 21#	40.70~50.00	Conform	/
4	Coincidence Rate of Negative Reference	2.2	The negative coincidence rate was 20/20 when tested with 20 IgG negative reference products from enterprise's reference products(internal control plate). The negative coincidence rate was 20/20 when tested with 20 IgM negative reference products from enterprise's reference products(internal control plate).	1#; 11#; 21#	1#; 11#; 21# IgG: 20/20 20/20 20/20 IgM: 20/20 20/20 20/20	Conform	/
5	Coincidence Rate of Positive Reference	2.3	The positive coincidence rate was 10/10 when tested with 10 IgG positive reference products (P1 - P10) from the enterprise's reference products(internal control plate); The positive coincidence rate was 10/10 when tested with 10 IgM positive reference products (P11 - P20) from the enterprise's reference products(internal control plate);	2#; 12#; 22#	2#; 12#; 22# IgG: 10/10 10/10 10/10 IgM: 10/10 10/10 10/10	Conform	/
6	Min. Detection Limit	2.4	The L1-IgG and L2-IgG shall be positive and the L3-IgG shall be negative when tested with 3 IgG reference products of min. detection limit from the enterprise's reference products(internal control plate). The L1-IgM and L2-IgM shall be positive and the L3-IgM shall be negative when tested with 3 IgM reference products of min. detection limit from the enterprise's reference products(internal control plate).	3#; 13#; 23#	L1-IgG: All positive L2- IgG- All positive L3- IgG - All negative L1- IgM: All positive L2- IgM: All positive L3- IgM: All negative	Conform	/
7	Precision	2.5	Ten detection reagents were tested in parallel with IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) precision reference products from enterprise's reference products, and the reaction results were consistent and the color rendering was uniform.	4#; 5#; 14#; 15#; 24#; 25#;	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.	Conform	/
8	Inter-batch Variation Coefficient	2.6	IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) in enterprise reference products were used to detect 10 detection reagents in each batch of the three batches of products, and the reaction results of 30 detection reagents were consistent, with uniform color rendering.	4#; 5#; 14#; 15#; 24#; 25#;	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.	Conform	/

国家食品药品监督管理局天津医疗器械质量监督检验中心检验报告

National Medical Products Administration Tianjin Medical Devices Quality Supervision and Testing Center Test Report

国家食品药品监督管理局天津医疗器械质量监督检验中心

检 验 报 告 内 容

报告编号：2020-GJ-0375　　共 4 页　第 3 页

序号	检验项目	条款	要求	样品编号	检验结果	单项结论	备注
8	批间差	2.6	用 3 个批号的产品，每个批次 10 份检测试剂，分别用企业参考品（内控盘）中的 IgG（J1-IgG 阳性、J2-IgG 阴性）、IgM（J1-IgM 阳性、J2-IgM 阴性）检测，30 份检测试剂反应结果一致，显色度均一。	4#、5#、14#、15#、24#、25#	J1-IgG：均为阳性，显色度均一 J2-IgG：均为阴性 J1-IgM：均为阳性，显色度均一 J2-IgM：：均为阴性	符合	/
9	稳定性（使用 37℃培养箱放置 14 天后的产品进行试验）	2.7	外观：试剂盒外观应完整，无破损；试剂盒中的铝箔袋应密封，无漏气；干燥剂包装完整，无洒漏；稀释液成分应澄清、透明、无絮状、粒状等杂质。检测试剂应平整、无瑕疵，材料附着牢固，内容齐全。	6#	符合要求	符合	/
			膜条宽度：膜条宽度不小于 3mm。	6#	3.00 3.01 3.02		
			移行速度：移行速度不小于 10mm/min。	6#	41.98 41.28 45.28		
			阴性参考品符合率：用企业参考品（内控盘）中的 20 份 IgG 阴性参考品检测，阴性符合率均为 20/20。 用企业参考品（内控盘）中的 20 份 IgM 阴性参考品检测，阴性符合率均为 20/20。	6#	IgG 20/20 IgM 20/20		
			阳性参考品符合率：用企业参考品（内控盘）中的 10 份 IgG 阳性参考品（P1～P10）检测，阳性符合率均为 10/10。 用企业参考品（内控盘）中的 10 份 IgM 阳性参考品（P11～P20）检测，阳性符合率均为 10/10。	7#	IgG 10/10 IgM 10/10		
			最低检出限：用企业参考品（内控盘）中的 3 份 IgG 最低检出量参考品检测，L1-IgG、 L2-IgG 应为阳性、L3-IgG 应为阴性。 用企业参考品（内控盘）中的 3 份 IgM 最低检出量参考品检测，L1-IgM、L2-IgM 应为阳性、L3-IgM 应为阴性。	8#	L1-IgG：均为阳性 L2-IgG：均为阳性 L3-IgG：均为阴性 L1-IgM：均为阳性 L2-IgM：均为阳性 L3-IgM：均为阴性		
			精密性：用企业参考品（内控盘）中的 IgG（J1-IgG 阳性、J2-IgG 阴性）、IgM（J1-IgM 阳性、J2-IgM 阴性）精密性参考品平行测试 10 份检测试剂，反应结果一致，显色度均一。	9#、10#	J1-IgG：均为阳性，显色度均一 J2-IgG：均为阴性 J1-IgM：均为阳性，显色度均一 J2-IgM：：均为阴性		

Tianjin Medical Devices Quality Supervision and Testing Center, China Food and Drug Administration

9	Stability (use the product placed in a 37℃ incubator for 14 days.)	2.7	Appearance: The appearance of the kit shall be intact; The aluminum foil bag in the kit shall be sealed without air leakage; The desiccant shall be packed completely without leakage. Diluent components should be clear and transparent without flocculent, granular and other impurities; The detection reagent shall be flat without flaw, and the material of it shall be firmly attached with complete contents.	6#	Conform to Requirements	Conform	/
			The membrane strip shall not be less than 3mm.	6#	3.00 3.01 3.02		
			Migration velocity: The migration velocity shall not be less than 10mm/ min.	6#	41.98 41.28 45.28		
			Coincidence Rate of Negative Reference: The negative coincidence rate was 20/20 when tested with 20 IgG negative reference products from enterprise's reference products(internal control plate). The negative coincidence rate was 20/20 when tested with 20 IgM negative reference products from enterprise's reference products(internal control plate).	6#	IgG: 20/20 IgM: 20/20		
			Coincidence Rate of Negative Reference: The positive coincidence rate was 10/10 when tested with 10 IgG positive reference products (P1 - P10) from the enterprise's reference products(internal control plate); The positive coincidence rate was 10/10 when tested with 10 IgM positive reference products (P11 - P20) from the enterprise's reference products(internal control plate);	7#	IgG: 10/10 IgM: 10/10		
			Min. Detection Limit: The L1-IgG and L2-IgG shall be positive and the L3-IgG shall be negative when tested with 3 IgG reference products of min. detection limit from the enterprise's reference products(internal control plate). The L1-IgM and L2-IgM shall be positive and the L3-IgM shall be negative when tested with 3 IgM reference products of min. detection limit from the enterprise's reference products(internal control plate).	8#	L1-IgG: All positive L2- IgG- All positive L3- IgG - All negative L1- IgM: All positive L2- IgM: All positive L3- IgM: All negative		
			Precision: Ten detection reagents were tested in parallel with IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) precision reference products from enterprise's reference products, and the reaction results were consistent and the color rendering was uniform.	9#; 10#	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.		

国家食品药品监督管理局天津医疗器械质量监督检验中心检验报告

National Medical Products Administration Tianjin Medical Devices Quality Supervision and Testing Center Test Report

国家食品药品监督管理局天津医疗器械质量监督检验中心

检 验 报 告 照 片 页

报告编号：2020-GJ-0375　　共 4 页　第 4 页

照片和说明

样品描述
/
型号规格或其它说明
/

Tianjin Medical Devices Quality Supervision and Testing Center, China Food and Drug Administration

Photo Page of Test Report

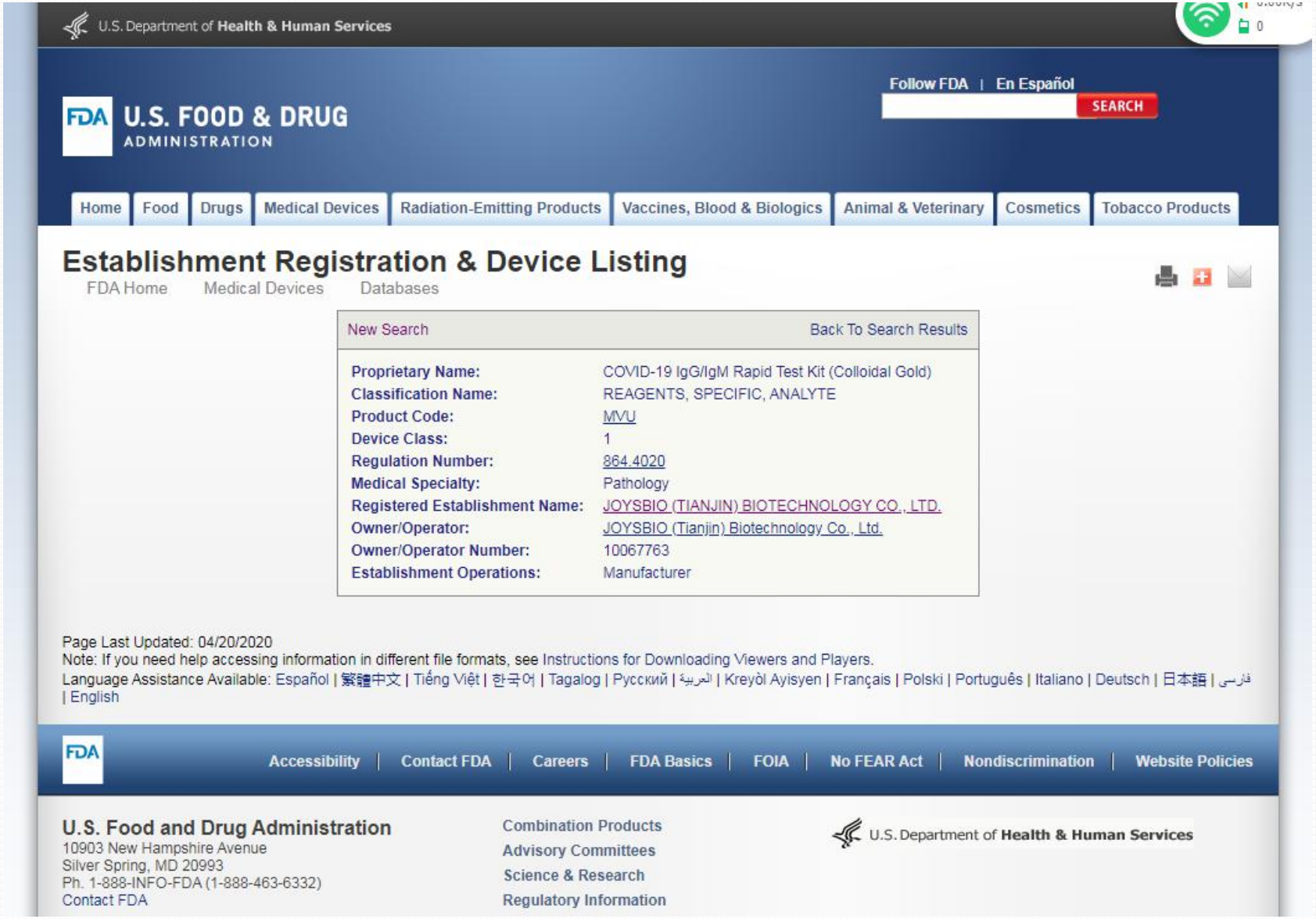
Report No.: 2020-GJ-0375　　Page 4 of 4

Photos and Descriptions

Sample Description
/
Model Specification or other Description
/

我公司生产的新型冠状病毒检测试剂在美国FDA官网可查询

Information of Covid-19 rapid test manufactured by our company can be found on FDA official website



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search | Back To Search Results

Proprietary Name:	COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)
Classification Name:	REAGENTS, SPECIFIC, ANALYTE
Product Code:	MVU
Device Class:	1
Regulation Number:	864.4020
Medical Specialty:	Pathology
Registered Establishment Name:	JOYSBIO (TIANJIN) BIOTECHNOLOGY CO., LTD.
Owner/Operator:	JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Owner/Operator Number:	10067763
Establishment Operations:	Manufacturer

Page Last Updated: 04/20/2020
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Combination Products
Advisory Committees
Science & Research
Regulatory Information

U.S. Department of Health & Human Services

临床研究报告
Clinical Research Report

临床研究报告

1.产品名称和批号

产品名字：新型冠状病毒（**COVID-19**）**IgG / IgM**抗体检测（胶体金法）

批　　号：卡型：**2020022101**

条型：**2020022101**

2.制造商

名　　称：正元盛邦（天津）生物科技有限公司

地　　址：天津开发区洞庭路**220**号

天津国际生物医药联合研究院 **9**楼

邮　　编：**300457**

Clinical Research Report

1.Name and Lot No. of the kit

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

Lot No.: Cassette： 2020022101

Strip： 2020022101

2. Manufacturer

Name: JOYSBIO(Tianjin) Biotechnology Co., Ltd.

Address: Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China

临床研究报告
Clinical Research Report

临床报告总结

由正元盛邦（天津）生物科技有限公司（以下简称“ 正元盛邦”）委托武汉市汉阳区中央健康检查中心、黑龙江省医院、天津市疾病预防控制中心对诊断试剂盒进行了临床试验。 正元盛邦（天津）生物科技有限公司根据体外诊断试剂临床研究技术指导原则（CFDA MD（2014）16）研发生产了新型冠状病毒（COVID-19）IgG/IgM抗体检测试剂盒（胶体金法）。

需评估的试剂盒使用免疫色谱法和捕获法原理定性检测人血清（或血浆或全血）中的COVID-19 IgG/IgM抗体，可用于临床辅助诊断。该试剂盒由正元盛邦(天津）生物科技有限公司生产。

批号2020022101，规格：50人份/盒，类型：条型
批号2020022101，规格：20人份/盒，类型：卡型
保质期：24个月

条型：

在这项临床研究中，总共测试了300个样本，其中包括160个已确认的新型冠状病毒和140个阴性样本。结果：在160份阳性样本中，有3例与检测试剂盒结果的比较不一致，而140例阴性病例的结果与检测试剂盒结果的比较，所有结果均一致。通过统计分析，评估试剂盒的灵敏度为98.12%，特异性为100%，假阳性率为0%，假阴性率为1.88%，总合格率为99%。

卡型：

在这项临床研究中，总共测试了300个样本，其中包括160个已确认的新型冠状病毒和140个阴性样本。结果：在160份阳性样本中，有3例与检测试剂盒结果的比较不一致，而140例阴性病例的结果与检测试剂盒结果的比较，所有结果均一致。通过统计分析，评估试剂盒的灵敏度为98.12%，特异性为100%，假阳性率为0%，假阴性率为1.88%，总合格率为99%。临床研究结果表明，该试剂盒可靠，准确，方便，实用性强。临床应用价值。

介绍

1.分析物的来源，生物学和理化性质

因新型冠状病毒肺炎病例发现在2019年新型冠状病毒，称为“ COVID-19”于2019年年底在武汉发现，并于2020年1月12日被世界卫生组织命名。冠状病毒是一大类病毒，已知会引起感冒和更严重的疾病，例如：包括中东呼吸综合征（MERS）和严重急性呼吸综合征（SARS）等。新型冠状病毒是一种在人类之前从未发现过的新型冠状病毒。中国报告了数以万计的实验室确诊病例，并且这一数字每天都在增加。起初大多数报告来自湖北和周边省份，而许多案件也来自其他省市的报告。后来其他国家也报告了多数病例，包括亚洲和欧洲国家，澳大利亚，美国（华盛顿州，伊利诺伊州，加利福尼亚州，亚利桑那州和马萨诸塞州）和加拿大。人与人之间的传播COVID-19已在中国得到确认，并在其他国家/地区发现，包括美国。到目前为止，这种新型冠状病毒的传播快速，风险很大。该病的主要表现是发烧，咳嗽，呼吸困难和胸部影像学表现。双肺浸润，潜伏期在暴露后14天内。大约20%的诊断为严重病例状况，呼吸衰竭，败血性休克或其他器官衰竭需要重症监护。大多数死亡是由于潜在的并发症。全基因组测序和系统分析表明，COVID-19是一种新型的β冠状病毒，与严重的急性呼吸道疾病属于不同的进化分支综合征（SARS）和中东呼吸综合征（MERS）相关的新型β冠状病毒。COVID-19与蝙蝠冠状病毒非常相似，并且蝙蝠可能是主要来源，但是它尚不清楚它是直接从蝙蝠传播给人类还是通过其他机制传播，例如一些中间宿主。

2.预期适应症的临床使用目的和诊断方法

目前，主要有核酸检测（RT-PCR）和胶体金免疫色谱法（GICA）。与核酸检测相比，快速诊断试剂盒用于COVID-19的样品适用于血清，血浆和全血样品。方便，快捷灵敏度高，适合大规模筛选。可以在15分钟内获得结果。同时，使用单一样品可以避免样品之间的交叉污染。此外，它可以降低医护人员的暴露风险并促进早期诊断和排除可疑病例。

3.产品的测试原理和检测方法

本试剂应用免疫层析胶体金技术检测样本中的新型冠状病毒（COVID-19）IgG/IgM抗体。检测试剂含有：

a. 胶体金标记的重组新冠状病毒抗原和质控抗体金标物；
b. 固定有两条检测线（G线和M线）和一条质控线C线的纤维素膜。检测线 G线包被有鼠抗人IgG抗

Summary of Research

Entrusted by JOYSBIO(Tianjin) Biotechnology Co., Ltd. (hereinafter referred to as “JOYSBIO”), Hanyang District Central Health Examination Centre, Wuhan, Heilongjiang Hospital, Tianjin Center for Disease Control and Prevention admission hospital implemented clinical test on Diagnostic kit for COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)researched and produced by JOYSBIO(Tianjin) Biotechnology Co., Ltd. according to Guiding Principle for Clinical Research Technology of In Vitro Diagnostics Reagent (CFDA MD(2014) 16).

The kit to be evaluated uses immunochromatography and the principle of Capture ELISA to qualitatively detect COVID-19 IgG/IgM Antibodies in human serum (or plasma or whole blood) for clinical auxiliary diagnosis. The test kit is produced by JOYSBIO(Tianjin) Biotechnology Co., Ltd.

Lot No. 2020022101, Specification: 50 Test Kit /box, Type: Strip
Lot No. 2020022101, Specification: 20 Test Kit /box, Type: Cassette
Shelf life: 24 months

Strip Type

In this clinical study, a total of 300 samples were tested, including 160 confirmed samples of novel coronavirus and 140 negative samples. Result: among the 160 positive samples, 3 case was inconsistent according to the comparison of test kit results, while the results of 140 negative cases were all in conformance according to the comparison of test kit results. Through statistical analysis, the sensitivity of the assessed kits is 98.12%, the specificity is 100%, the false positive rate is 0%, the false negative rate is 1.88%, and the total conformity rate is 99%.

Cassette Type

In this clinical study, a total of 300 samples were tested, including 160 confirmed samples of novel coronavirus and 140 negative samples. Result: among the 160 positive samples, 3 case was inconsistent according to the comparison of test kit results, while the results of 140 negative cases were all in conformance according to the comparison of test kit results. Through statistical analysis, the sensitivity of the assessed kits is 98.12%, the specificity is 100%, the false positive rate is 0%, the false negative rate is 1.88%, and the total conformity rate is 99%.The results of clinical study show that this kit is reliable, accurate, convenient, and has high clinical application value.

Introduction

1. Source, biological and physicochemical properties of analyte The 2019 novel coronavirus, known as the " COVID-19", was found due to viral pneumonia cases in Wuhan in 2019 and was named by the world health organization on January 12, 2020.Coronaviruses are a large family of viruses known to cause colds and more serious illnesses such as Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS). The novel coronavirus is a new strain of coronavirus that has never been found in humans before.China has reported tens of thousands of laboratory-confirmed cases, and the number is rising daily. Most reports have come from Hubei and surrounding provinces, while many cases have also been reported from other provinces and municipalities. Sporadic cases are also being reported in other countries, including Asian and European countries, Australia, the United States (Washington, Illinois, California, Arizona and Massachusetts) and Canada. Human-to-human transmission of COVID-19 has been confirmed in China and has been found in other countries, including the United States. So far the dissemination risk of this novel coronavirus is not clear. The main manifestations of the disease are fever, cough, dyspnea, and chest imaging findings of double lung infiltration, and the incubation period is within 14 days after exposure. Although many of the cases reported so far are not severe, about 20% of those diagnosed are in critical condition, with respiratory failure, septic shock or other organ failure requiring intensive care. Most of the deaths were due to underlying complications. Whole-genome sequencing and phylogenetic analysis showed that the COVID-19 is a novel β coronavirus, which belongs to a different evolutionary branch from the severe acute respiratory syndrome (SARS) and MiddleEast respiratory syndrome (MERS) related novel β coronavirus. The COVID-19 is very similar to the bat coronavirus, and bats are likely to be the main source, but it is unclear whether it is transmitted directly from bats to humans or through other mechanisms, such as with some intermediate hosts.

2. Expected clinical using purpose and the diagnosis methods applied to such adaptation disease .At present, there are mainly nucleic acid detection (RT-PCR) and colloidal gold immunochromatography (GICA). Compared with nucleic acid detection, the rapid diagnostic kit for COVID-19 is suitable for samples of serum, plasma and whole blood. It is convenient, rapid and highly sensitive, and suitable for large-scale screening. Results can be obtained within 15 minutes. At the same time, cross contamination between samples can be avoided by using single reagent

临床研究报告
Clinical Research Report

体，用于检测新型冠状病毒（COVID-19）IgG抗体；检测线M线包被有鼠抗人IgM抗体，用于检测新型冠状病毒（COVID-19）IgM抗体；质控线（C线）包被有羊抗鸡IgY抗体，在胶体金垫上含有胶体金标记的鸡IgY抗体。

c. 检测时，若样本中含有新型冠状病毒IgG抗体，样本中的新型冠状病毒（COVID-19）IgG抗体先与胶体金垫上的新型冠状病毒（COVID-19）重组抗原反应，形成抗体-金标抗原复合物，在NC膜上层析至检测线G线时，会与鼠抗人IgG抗体形成抗体-抗体-金标抗原复合物，并在G线位置显示出色带；若样本中含有新型冠状病毒IgM抗体，样本中的新型冠状病毒（COVID-19）IgM抗体与胶体金垫上的新型冠状病毒（COVID-19）重组抗原反应，形成抗体-金标抗原复合物，在NC膜上层析至检测线M线时，会与鼠抗人IgM抗体形成抗体-抗体-金标抗原复合物，并在M线位置显示出色带；若样本中无新型冠状病毒（COVID-19）IgG/IgM抗体，则不能形成复合物，检测线G线和M线位置上不出现色带。胶体金标记的鸡IgY抗体与质控线C线包被的羊抗鸡IgY抗体结合呈现紫红色条带。C线在检测样本时均应出现色带，否则试验无效。

测试方法：
在测试之前，请仔细阅读产品使用说明书。
条型（图1）
1. 将试剂盒（不打开铝箔袋）恢复到室温。
2. 从包装盒中取出铝箔袋并打开，然后取出检测条，将其平放在桌子上。
3. 抽取10μl血清/血浆样本或20μl全血样本，用定量滴管将其添加到暴露的带状紫色胶体金中（箭头指向）。然后将2滴稀释剂垂直添加到试纸条下端的样品垫上。
4. 实验结果在15～20分钟内解释并记录下来，但在20分钟内无效。（当测试一个强阳性样品时，在1-3分钟内会出现阳性结果。）

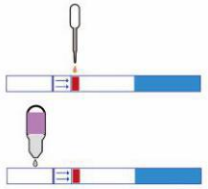


图1

卡型（图2）
1. 将试剂盒（不打开铝箔袋）恢复到室温。
2. 从包装盒中取出铝箔袋并打开，取出检测卡，然后将其平放在桌子上。
3. 抽取10μl血清/血浆样品或20μl全血样品，用定量滴管将其添加到加样孔中。然后2滴稀释液垂直加入加样孔中。
4. 实验结果在15～20分钟内解释并记录下来，但在20分钟以上无效。（当测试一个强阳性样品时，在1-3分钟内会出现阳性结果。）

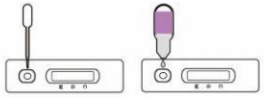
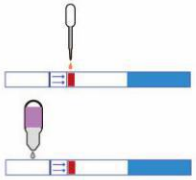


图2

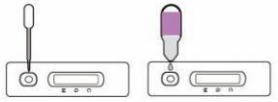
1. 测试目的
用于新型冠状病毒（COVID-19）IgM/IgG抗体检测试剂盒（胶体金法）临床诊断，通过验证一定数量的确诊新型冠状病毒样本，从而判断其安全性和有效性，已使产品的质量要求已得到满足。
2. 测试管理
开发了新型冠状病毒(COVID-19)IgM/IgG抗体检测试剂盒（胶体金法）的诊断试剂盒，该产品由正元盛邦（天津）生物科技有限公司生产，临床评估由武汉市汉阳区中央健康检查中心、黑龙江省医院、天津市疾病预防控制中心住院医院进行。在执行测试之前，正元盛邦（天津）生物科技有限公司与武汉市汉阳区中央健康检查中心、黑龙江医院、天津市疾病预防控制中心住院医院的代表应共同讨论。双方应根据《临床研究技术指导原则和IVD试剂规则》等有关规定，签署临床试验方案并设计临床试验方案，以明确双方的试验目的，内容和职责。在开始临床研究之前，研究参与者必须熟悉并掌握产品的操作，技术性能等，以便尽最大努力控制实验误差以及统一的记录方法和判断标准；研究人员应根据记录表内容，详细、真实地填写每一项，以确保记录表内容完整、真实、可靠；所有观察到的结果都应记录。为确保临床试验中的每个结论均源于原始记录；应该有临床试验和数据处理阶段的相应数据管理措施。在临床研究期间，方案之外的任何其他情况均应由当事人解决。

3. Testing principle and detection method of the product
Test principle: This reagent uses immunochromatographic colloidal gold technique to detect 2019-ncov (COVID-19) IgG/IgM antibodies in samples.The detection card contains: 1) Recombinant COVID Antigen labeled colloidal gold Cellulose Membrane fixed with three lines (G line and M line) and one quality control line (C line) .The M line was coated with mouse anti-human IgM antibody for detection of 2019-ncov (COVID-19) IGM antibody .The G line was coated with mouse anti-human IgG antibody for detection of 2019-ncov (COVID-19) IgM antibody. The C line was coated with sheep anti-chicken antibody. When specimen is added to sample well, capillary effect causes the fluid to flow to the NC membrane, COVID IgM (if present) will bind with mouse anti-human IgM and the M line will be visible., COVID IgG (if present) will bind with mouse anti-human IgG and the G line will be visible. No matter whether the specimen is positive or negative, the C line should be visible, otherwise the test is invalid.

Test method:
Completely read the manual of the products before test.
Strip Type (figure 1)
1. Restore the test strip (without opening the foil bag) to room temperature.
2. Remove the foil pouch from the box and open it, take out the strip, and lay it flat on a table.
3. Draw 10μl of serum/plasma sample or 20μl of whole blood sample with a quantitative dropper and add to the exposed purplish colloidal gold of the strip (arrow pointing). Then add 2 drops of diluent vertically to the sample pad at the lower end of the strip.
4. The experimental results were interpreted and recorded in 15～20 minutes, but were not valid in 20 minutes. (when a strongly positive sample is tested, a positive result can appear in 1-3 minutes.)



Cassette Type (figure 2)
1. Restore the test strip (without opening the foil bag) to roomtemperature.
2. Remove the foil pouch from the box and open it, take out the cassette, and lay it flat on a table.
3. Draw 10μl of serum/plasma sample or 20μl of whole blood sample with a quantitative dropper and add to hole A. Then add 2 drops of diluent vertically to hole B.
4. The experimental results were interpreted and recorded in 15～20 minutes, but were not valid in 20 minutes. (when a strongly positive sample is tested, a positive result can appear in 1-3 minutes.)



1. Test purpose
The purpose of the Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) clinical trial is to verify the accuracy of this product in clinical test by verifying a certain number of confirmed samples of novel coronavirus, so as to judge whether the safety and effectiveness requirements of the marketed products have been met.
2. Test Management
The Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) is developed and produced by JOYSBIO (Tianjin) Biotechnology Co.,Ltd., and the clinical evaluation was conducted by Hanyang District Central Health Examination Centre, Wuhan, Heilongjiang Hospital, Tianjin Center for Disease Control and Prevention admission hospital. Before implementation of the test, JOYSBIO(Tianjin) Biotechnology Co., Ltd. and representatives of Hanyang District Central Health Examination Centre, Wuhan, Heilongjiang Hospital, Tianjin Center for Disease Control and Prevention admission hospital should discuss together. According to relevant regulations of "Clinical Research Technical Guidelines and Rules of IVD Reagents" etc., both parties should sign clinical test protocol and design clinical test scheme to clarify test purpose, content and responsibilities of both parties. Before the start of clinical research, participants in the research must be familiar with and master the operation of the product, technical performance, etc., so as to do their utmost to take control of the experimental error as well as unify record method and judgment standard; Researcher should fill in every item in detail and faithfully according to record chart to make sure content of record chart is complete, true and reliable; all observed results should be verified to ensure every conclusion in clinical trial is derived from the original records; there should be corresponding data management

临床研究报告
Clinical Research Report

3. 测试内容
3.1. 测试样本的选择
1）年龄和性别不受限制
2）可以根据需要提供足够的试样
3）新型冠状病毒确诊样本
4）考虑可疑的流感，呼吸道合胞病毒，肠病毒，腺病毒和其他病毒感染
3.2. 测试试剂信息
测试试剂名称为新型冠状病毒（COVID-19）IgM/IgG抗体检测试剂盒（胶体金法）由正元盛邦（天津）生物科技有限公司生产。有两种规格，包括条型和卡型。检测试剂，每种选用一批。
条型：规格为50测试盒/盒；批号为2020022101，有效期为24个月，保存条件为4-30℃，干燥避光。
卡型：规格为20测试套件/盒；批号为2020022101，有效期为24个月，保存条件为4-30℃，干燥避光。
3.3. 样品收集和序列号
以常规方式从静脉或指尖内收集血清（或血浆）、全血样本。待测样本血清（血浆）5天之内可以在4℃下保存，样本可以在-20℃下保存至少6个月，尽量避免样品反复冻融。全血则为新鲜血液。为样本编号（001-100），以避免样品混乱。
3.4. 测试程序
3.4.1. 阅读说明书
研究人员首先应仔细阅读诊断试剂盒的说明书，以了解样本添加，结果确定时间和结果解释的基本内容。
3.4.2. 具体操作
研究人员用测试试剂测试具有编号的样本，并记录测试结果，真实地填写临床试验登记表中的相应内容。样本收集后应尽快使用。测试样本可在4℃内存放五天，样本可以在-20℃下保存至少六个月。样本应尽可能避免重复冻融。
4，临床测试结果的安排与分析
4.1 条型诊断试剂盒结果的分析
对于试验的条型诊断试剂盒，规格为50人份/盒，批号为2020022101，测试的样本数为300。结果如下：

测试条型诊断试剂盒		临床诊断	
		+	−
	+	160	0
	−	3	140

结果表明，在160份阳性样本中，有3例与检测试剂盒检测结果不一致，而140例阴性样本的结果全部一致。根据测试结果的比较，通过统计分析，这种试剂盒灵敏度为98.12%，特异性为100%，假阳性率为0%，假阴性率为1.88%，总合格率为99%。
4.2 卡型诊断试剂盒结果的分析
对于试验的卡型诊断试剂盒，规格为20人份/盒，批号为2020022101，测试的样本数为300。结果如下：

测试卡型诊断试剂盒		临床诊断	
		+	−
	+	160	0
	−	3	140

measures in clinical trial and data processing phases. During the clinical research any other situation outside the scheme shall be settled by the parties through negotiation.**3. Test Content**
3.1. Selection of test subjects
1) Age and gender are not limited
2) Can provide enough test specimens as required
3) Confirmed samples of novel coronavirus
4) Consider cases of suspected influenza, respiratory syncytial virus, enterovirus, adenovirus and other viral infections
3.2. Information of the test reagent
The test reagent is Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) produced by JOYSBIO (Tianjin) Biotechnology Co., Ltd.. There are two types, including strip-type and cassette-type, and one batch of each type is used. Strip type: specification is 50 Test Kit/box; batch number is 2020022101, valid for 24 months, the preservation condition is 4-30 ° C, dry and light-avoiding. Cassette type: specification is 20 Test Kit/box; batch number is 2020022101, valid for 24 months, the preservation condition is 4-30 ° C, dry and light-avoiding.
3.3. Sample collection and serial number
Serum samples were collected intravenously in the conventional way. The samples to be tested within five days can be stored at 4℃, and the samples can be stored at -20℃ for at least six months.Avoid repeated freezing-thawing of samples as far as possible. Number the samples (001-100) to avoid sample disorder.
3.4. Test procedures
3.4.1. Read instruction book
Sample provider first should read the instructions for the diagnostic kit carefully, to learn about sample adding, time for result determination and the basis of result interpretation.
3.4.2. Specific operations
The researchers tested the numbered samples with the test reagent and recorded the test results faithfully after the corresponding number in the clinical trial registration form. Samples should be used as soon as possible after collection. Samples to be tested within five days can be stored at 4℃. The specimens can be stored at -20℃ for at least six months. Avoid repeated freezing-thawing of samples as far as possible.
4.Arrangement and analysis of clinical test results
4.1.Arrangement and analysis of strip-type diagnostic kit results
For the strip-type diagnostic kits assessed, the specification is 50 Test Kit/box, batch number is 2020022101,and the number of samples tested is 300. The results are as follows:
by JOYSBIO(Tianjin) Biotechnology Co., Ltd.. There are two types, including strip-type and cassette-type, and one batch of each type is used. Strip type: specification is 50 Test Kit/box; batch number is 2020022101, valid for 24 months, the preservation condition is 4-30 ° C, dry and light-avoiding.
Cassette type: specification is 20 Test Kit/box; batch number is 2020022101, valid for 24 months, the preservation condition is 4-30 ° C, dry and light-avoiding.
3.3. Sample collection and serial number
Serum samples were collected intravenously in the conventional way. The samples to be tested within five days can be stored at 4℃, and the samples can be stored at -20℃ for at least six months.Avoid repeated freezing-thawing of samples as far as possible. Number the samples (001-100) to avoid sample disorder.
3.4. Test procedures
3.4.1. Read instruction book
Sample provider first should read the instructions for the diagnostic kit carefully, to learn about sample adding, time for result determination and the basis of result interpretation.
3.4.2. Specific operations
The researchers tested the numbered samples with the test reagent and recorded the test results faithfully after the corresponding number in the clinical trial registration form. Samples should be used as soon as possible after collection. Samples to be tested within five days can be stored at 4℃. The specimens can be stored at -20℃ for at least six months. Avoid repeated freezing-thawing of samples as far as possible.
4.Arrangement and analysis of clinical test results

临床研究报告
Clinical Research Report

结果表明，在160份阳性样本中，有3例与检测试剂盒检测结果不一致，而140例阴性样本的结果全部一致。根据测试结果的比较，通过统计分析，这种试剂盒灵敏度为98.12%，特异性为100%，假阳性率为0%，假阴性率为1.88%，总合格率为99%。

5.讨论与结论

在测试过程中，研究人员已仔细阅读使用说明并独立完成评估试剂盒的操作，以避免因操作不当而导致的结果错误。真实地填写了测试记录，从而确保了数据的真实性和可靠性。通过对测试数据的分析，我们可以看到，正元盛邦（天津）生物科技有限公司生产的新型冠状病毒（COVID-19）IgM/IgG抗体检测试剂盒（胶体金法）诊断试剂盒的两种类型（条型，卡型）与确诊样本的结果高度一致。较高的符合率表明正元盛邦（天津）生物科技有限公司生产的新型冠状病毒（COVID-19）IgM/IgG抗体检测试剂盒（胶体金法）可靠、准确、安全、方便、稳定，具有很高的临床应用价值。

4.1.Arrangement and analysis of strip-type diagnostic kit results

For the strip-type diagnostic kits assessed, the specification is 50 Test Kit/box, batch number is 2020022101,and the number of samples tested is 300. The results are as follows:

Assessed reagent-Strip-type diagnostic kits		Clinical diagnosis	
		+	-
	+	160	0
	-	3	140

The results indicate that among the 160 positive samples, 3 case was inconsistent according to the comparison of test kit results, while the results of 140 negative cases were all in conformance according to the comparison of test kit results. Through statistical analysis, the sensitivity of this kit is 98.12%, the specificity is 100%, the false positive rate is 0%, the false negative rate is 1.88%, and the total conformity rate is 99%.

4.2.Arrangement and analysis of strip-type diagnostic kit results For the cassette-type diagnostic kits assessed, the specification is 20 Test Kit/box, batch number is 2020022101, and the number of samples tested is 300. The results are as follows:

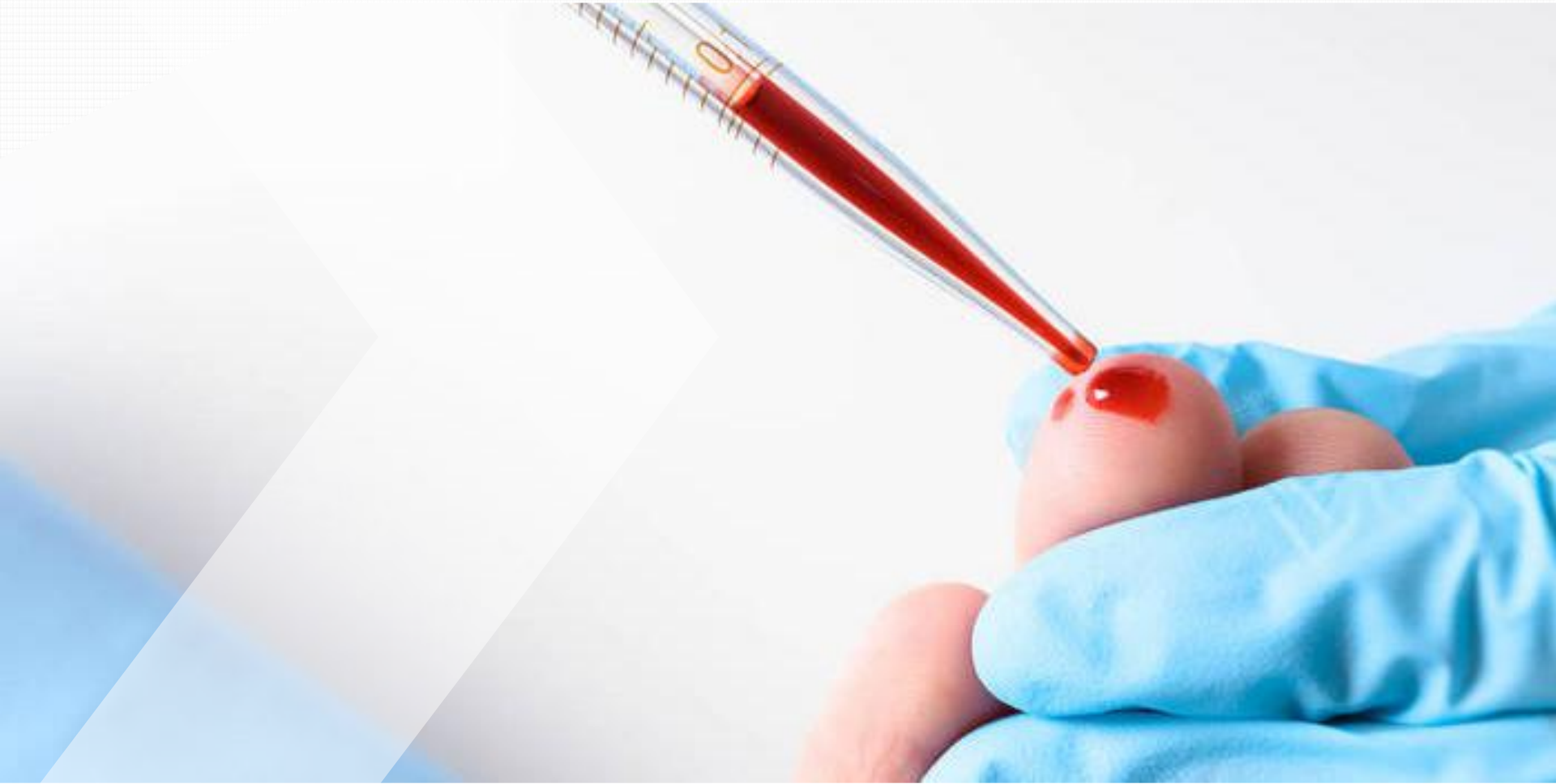
Assessed reagent-Cassette -type diagnostic kits		Clinical diagnosis	
		+	-
	+	160	0
	-	3	140

The results indicate that among the 160 positive samples, 3 case was inconsistent according to the comparison of test kit results, while the results of 140 negative cases were all in conformance according to the comparison of test kit results. Through statistical analysis, the sensitivity of this kit is 98.12%, the specificity is 100%, the false positive rate is 0%, the false negative rate is 1.88%, and the total conformity rate is 99%.

5. Discussion and Conclusion

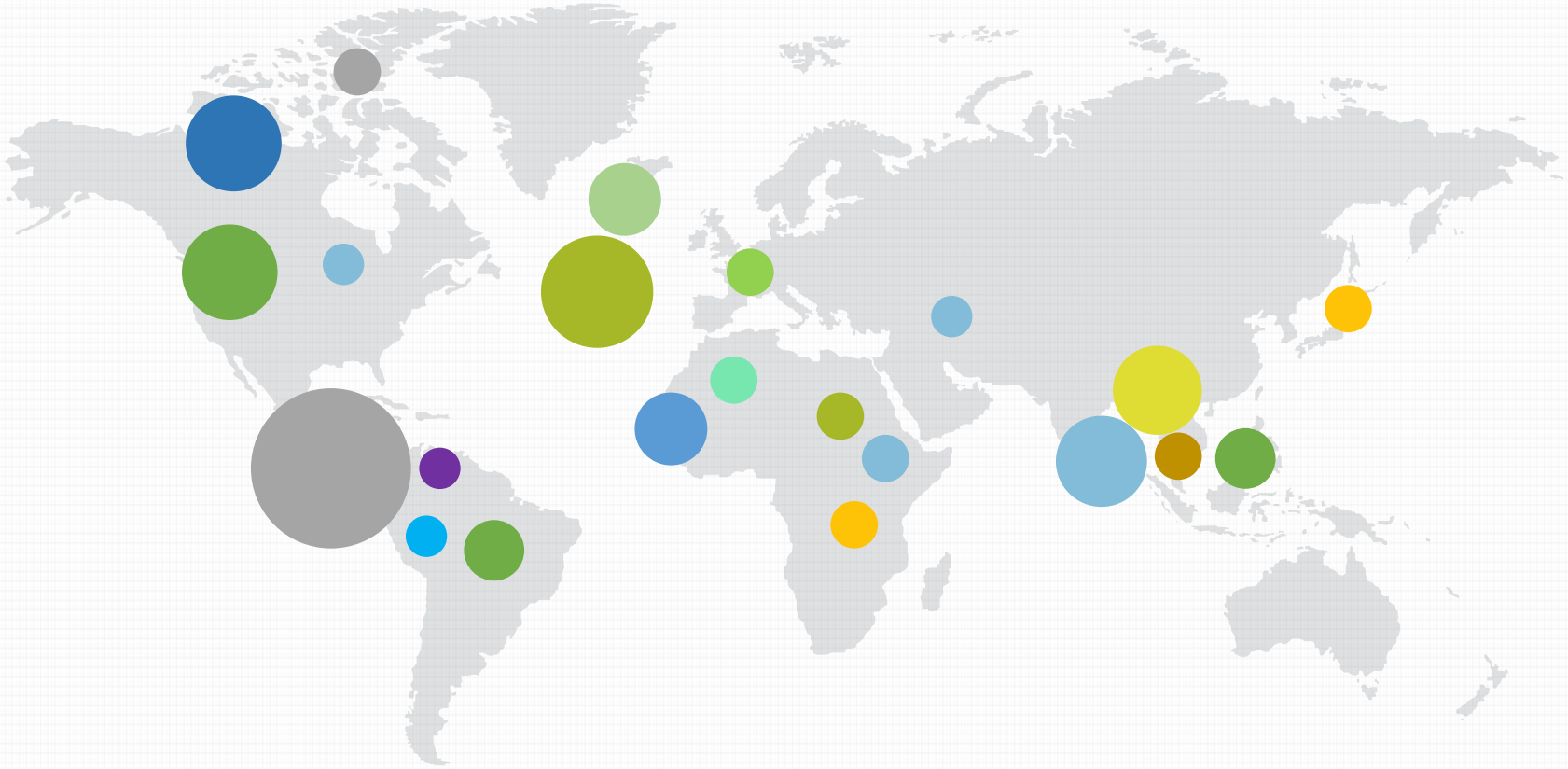
In the process of test, the researchers carefully read the instructions and independently completed the operation of the assessed reagent kits to avoid the result error caused by improper operation. They filled in the test record faithfully, thus ensuring the reliability of the data. Through the analysis of the test data, we can see that the two types (strip type, cassette type) of the Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) produced by JOYSBIO(Tianjin) Biotechnology Co., Ltd.are highly consistent with the results of confirmed samples. A high coincidence rate indicates that the Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) produced by JOYSBIO(Tianjin) Biotechnology Co., Ltd. is reliable, accurate, safe, convenient, stable and has high clinical application value.

5 附录
Annex



截至目前已出口21个国家及地区
So far, it has been exported to 21 countries

销售产品(Product)：COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)



公司其他产品目录
Other products list of JOYSBIO

类别	产品名称	检测样本	定性/定量	质量认证
心肌类	肌红蛋白/肌酸激酶同工酶/心肌肌钙蛋白检测试剂盒（胶体金免疫层析法）	全血/血清/血浆	定性/定量	CFDA/CE
	心肌肌钙蛋白I(cTnI)检测试剂盒（胶体金免疫层析法）	全血/血清/血浆	定性/定量	CFDA/CE
	肌酸激酶同工酶（CK-MB）检测试剂盒（胶体金免疫层析法）	全血/血清/血浆	定性/定量	CFDA/CE
	肌红蛋白（Myo）检测试剂盒（胶体金免疫层析法）	全血/血清/血浆	定性/定量	CFDA/CE
肿瘤类	大便隐血（FOB)检测试剂盒（胶体金免疫层析法）	粪便	定性	CFDA/CE
激素类	人绒毛膜促性腺激素（HCG)检测试剂盒（胶体金免疫层析法）	尿液	定性	CFDA/CE
	促黄体生成素（LH)检测试剂盒（胶体金免疫层析法）	尿液	定性	CFDA/CE
传染病类	梅毒螺旋体抗体检测试剂盒（胶体金法）	血清/血浆	定性	CFDA/CE
	乙型肝炎病毒表面抗原(HBsAg)检测试剂盒（胶体金法）	血清/血浆	定性	CFDA
	乙型肝炎病毒表面抗体(HBsAb)检测试剂盒（胶体金法）	血清/血浆	定性	CFDA
	丙型肝炎病毒（HCV）抗体检测试剂盒（胶体金法）	血清/血浆	定性	CFDA
	结核分枝杆菌抗体检测试剂盒（胶体金法）	血清	定性	CFDA/CE
	肺炎支原体IgM抗体检测试剂盒（胶体金法）	血清/血浆	定性	CFDA/CE
	肺炎衣原体IgM抗体检测试剂盒（胶体金法）	血清/血浆	定性	CFDA
	人类免疫缺陷病毒(HIV1+2)抗体检测试剂盒（胶体金法）	血清/血浆	定性	CFDA
毒品检测类	甲基安非他明检测试剂盒（胶体金法） MET	尿液	定性	CFDA
	吗啡检测试剂盒（胶体金法） MOP	尿液	定性	CFDA
	氯胺酮检测试剂盒（胶体金法） KET	尿液	定性	CFDA
	吗啡/甲基安非他明/氯胺酮联合检测试剂盒（胶体金法）	尿液	定性	CFDA/CE
即将上市产品	人类免疫缺陷病毒抗体（HIV1/2）口腔粘膜渗出液检测试剂盒（胶体金法）		定性	
	幽门螺杆菌抗体检测试剂盒（胶体金法）		定性	
	幽门螺杆菌抗原检测试剂盒（胶体金法）		定性	
	降钙素原（PCT）定量检测试剂盒（胶体金法）		定性/定量	
	C反应蛋白（CRP）定量检测试剂盒（胶体金法）		定性/定量	
	D-二聚体（D-Dimer）定量检测试剂盒（胶体金法）		定性/定量	
	N末端B型脑钠肽前体（NT-proBNP）定量检测试剂盒（胶体金免疫层析法）		定性/定量	
	B型脑钠肽（BNP）定量检测试剂盒（胶体金免疫层析法）		定性/定量	
	心肌脂肪酸结合蛋白（H-FABP）定量检测试剂盒（胶体金免疫层析法）		定性/定量	
	乙肝五项（HBV）检测试剂盒（胶体金法）		定性	
	甲型/乙型流感病毒抗原检测试剂盒（胶体金法）		定性	

公司其他产品目录
Other products list of JOYSBIO

Classificaion	Product description	Sample	Qualitative/Quantitative	Certification
Cardiovascular	Myoglobin/Creatine Kinase MB/Cardiac Troponin I Test Kit (Colloidal Gold)	Whole blood/serum/plasma	Qualitative/Quantitative	CFDA/CE
	Cardiac Troponin I Test Kit (Colloidal Gold)	Whole blood/serum/plasma	Qualitative/Quantitative	CFDA/CE
	Creatine Kinase MB Test Kit (Colloidal Gold)	Whole blood/serum/plasma	Qualitative/Quantitative	CFDA/CE
	Myoglobin Test Kit (Colloidal Gold)	Whole blood/serum/plasma	Qualitative/Quantitative	CFDA/CE
Tumor markers	Fecal Occult Blood Test Kit (Colloidal Gold)	Stool	Qualitative	CFDA/CE
Fertility	Human Chorionic Gonadotrophin Test Kit (Colloidal Gold)	Urine	Qualitative	CFDA/CE
	Luteinizing Hormone Test Kit (Colloidal Gold)	Urine	Qualitative	CFDA/CE
Infectious diseases	Treponema Pallidum Antibody Test Kit (Colloidal Gold)	Serum/plasma	Qualitative	CFDA/CE
	Hepatitis B Virus Surface Antigen Test Kit (Colloidal Gold)	Serum/plasma	Qualitative	CFDA
	Hepatitis B Virus Surface Antibody Test Kit (Colloidal Gold)	Serum/plasma	Qualitative	CFDA
	Hepatitis C Virus Antibody Test Kit (Colloidal Gold)	serum/plasma	Qualitative	CFDA
	Tuberculosis Antibody Test Kit (Colloidal Gold)	serum	Qualitative	CFDA/CE
	Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold)	serum/plasma	Qualitative	CFDA/CE
	Chlamydia pneumonia IgM Antibody Test Kit (Colloidal Gold)	serum/plasma	Qualitative	CFDA
	HIV 1/2 Antibody Test Kit (Colloidal Gold)	serum/plasma	Qualitative	CFDA
Drugs of Abuse	Methamphetamine Test Kit (Colloidal Gold)	Urine	Qualitative	CFDA
	Morphine Test Kit (Colloidal Gold)	Urine	Qualitative	CFDA
	Ketamine Test Kit (Colloidal Gold)	Urine	Qualitative	CFDA
	Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)	Urine	Qualitative	CFDA/CE
Upcoming product	HIV1/2 Antibody in human Oral mucosal exudate test kit (Colloidal Gold)		Qualitative	
	Helicobacter pylori（HP）Antibody test kit (Colloidal Gold)		Qualitative	
	Helicobacter pylori（HP）Antigen test kit (Colloidal Gold)		Qualitative	
	Procalcitonin（PCT）quantitative test kit (Colloidal Gold)		Qualitative/Quantitative	
	C-reactive protein(CRP)quantitative test kit (Colloidal Gold)		Qualitative/Quantitative	
	D-Dimer quantitative test kit (Colloidal Gold)		Qualitative/Quantitative	
	N-terminal pro b-type natriuretic peptide(NT-ProBNP)quantitative test kit (Colloidal Gold)		Qualitative/Quantitative	
	Brain natriuretic peptide（BNP）quantitative test kit(colloidal gold)		Qualitative/Quantitative	
	Heart-type fatty acid binding protein（H-FABP）quantitative test kit (Colloidal Gold)		Qualitative/Quantitative	
	Hepatitis B （HBV）test kit (Colloidal Gold)		Qualitative	
	Influenza A & B Antigen test kit (Colloidal Gold)		Qualitative	

正元盛邦（天津）生物科技有限公司
JOYSBIO（Tianjin）Biotechnology Co.,Ltd.

地址：天津开发区洞庭路220号，天津国际生物医药联合研究院实验楼九层
Tianjin International Joint Academy of Biotechnology& Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China

Tel：+8622 65378415/65378699
Email：info@joysbio.com
Web：www.joysbio.com

JOYSBIO®

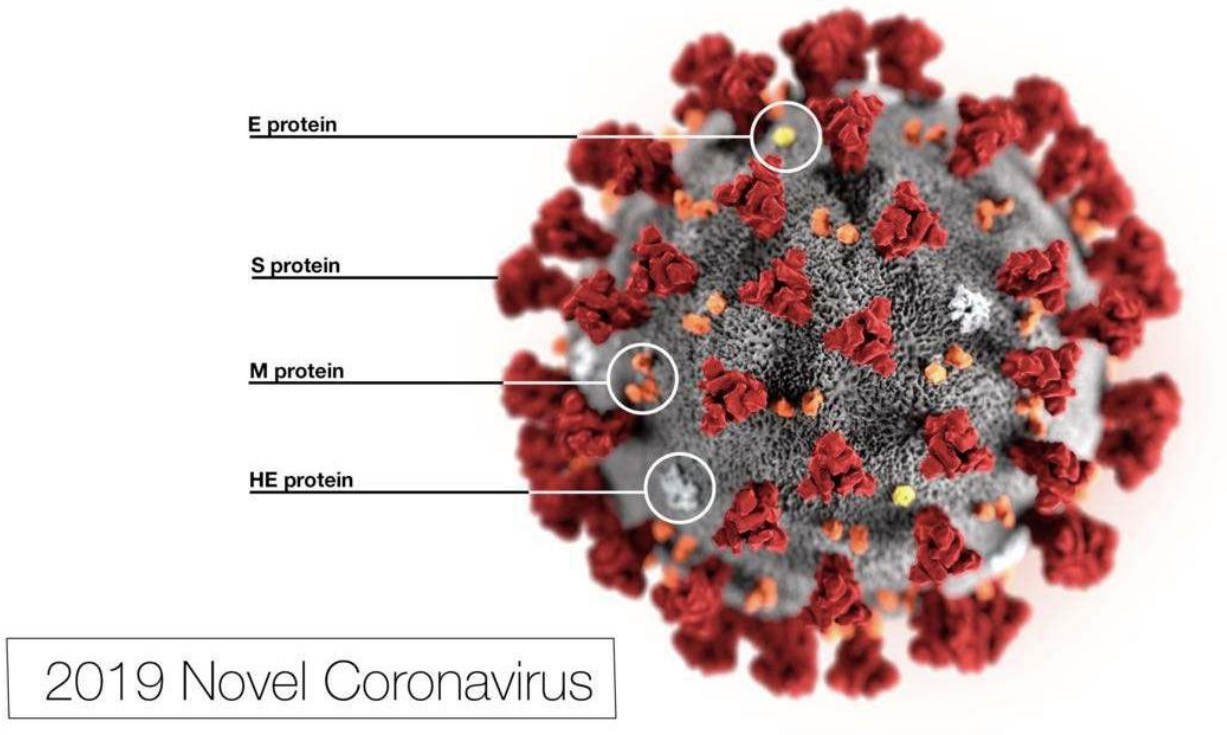
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

SARS-CoV-2 Antigen

PREFACE

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, or 2019-nCoV) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease 2019 (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N).

The antigen is generally detectable in upper respiratory samples during the acute phase of infection.



SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

INTRODUCTION

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

INTENDED USE

For in vitro qualitative detect of SARS-CoV-2 nucleocapsid antigen in nasal(NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of the symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

PRODUCT PHOTOS

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

PACKAGE SIZE (BOX)

Product package size:

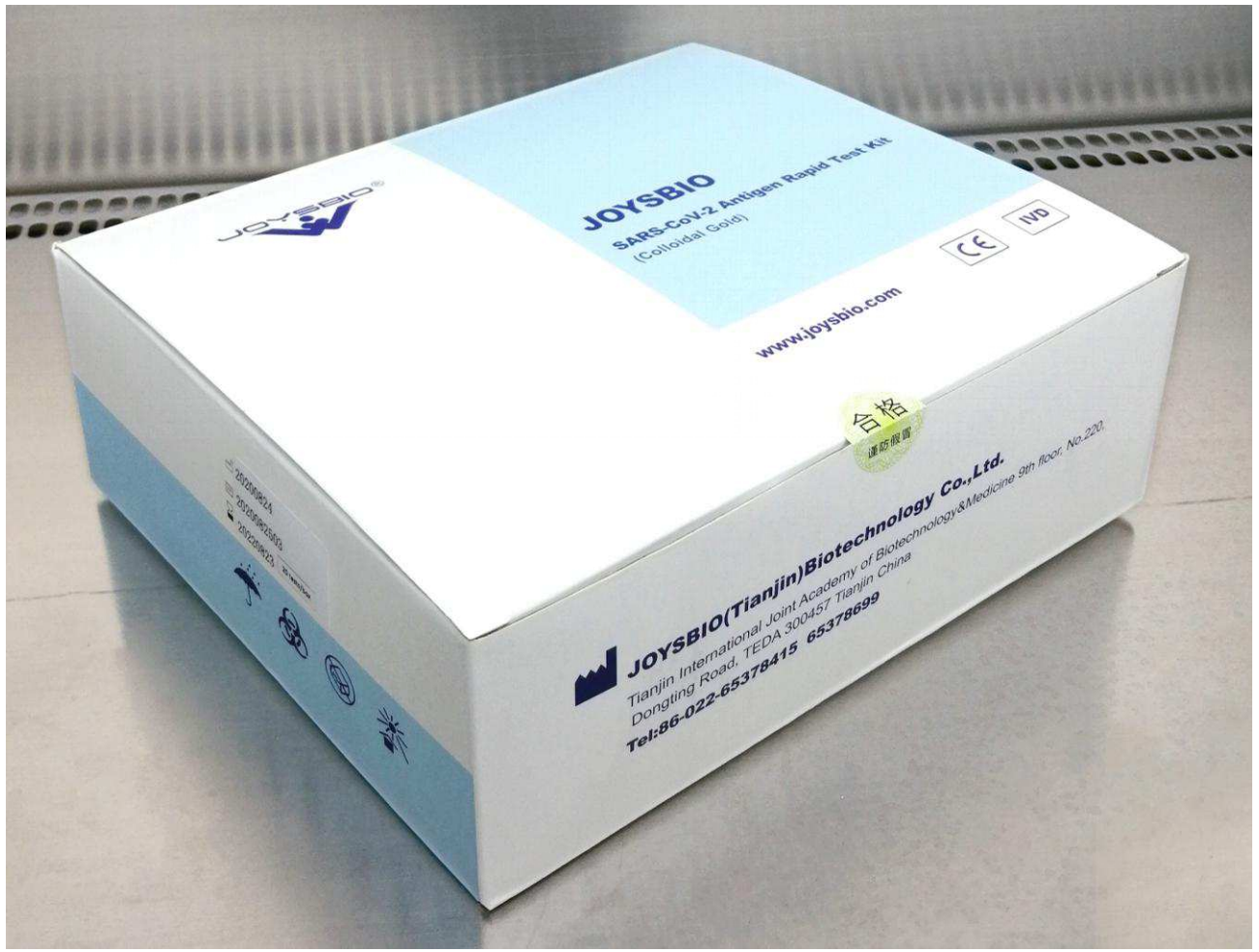
Length:195mm

Width:165mm

Height:68mm

Weight:308g

Include:20 Test Kit，20 pcs/box



SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

PACKAGE SIZE (CARTON)

Product package size:

Length:410mm
Width:510mm
Height:610mm
Weight:17.4kg

Include:50 box，1000 PCS（product& carton）

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

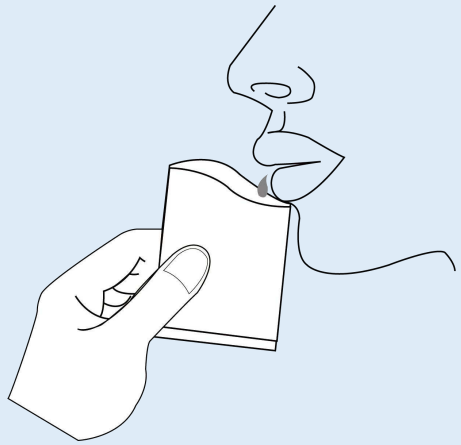
TEST PRINCIPLE

The Kit use immunocapture method, it is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from patients with signs and symptoms of infection who are suspected of COVID-19.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

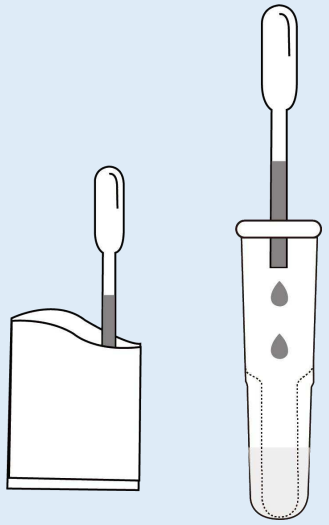
TEST METHOD

1



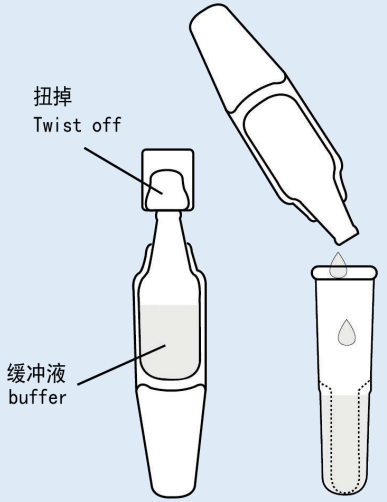
1. Before collecting oral fluid relax your cheeks and gently massage cheeks with fingers for 15-30 seconds, Gently spit oral fluid into the collection bag.

2



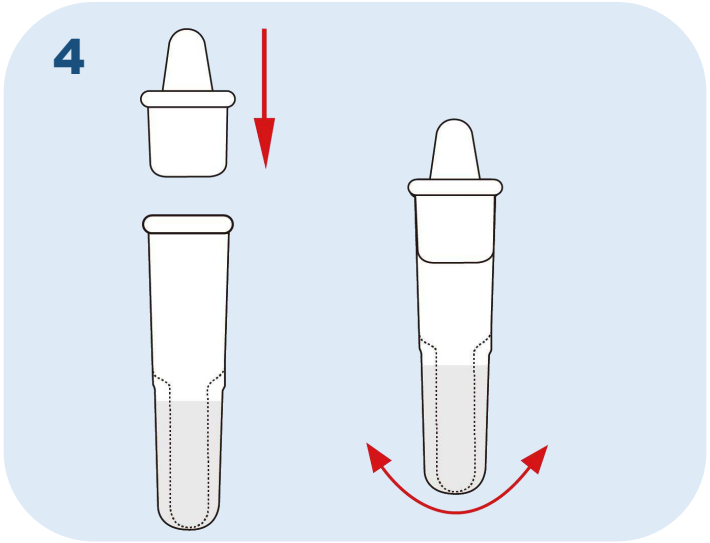
2. Hold the dropper vertically and **draw oral fluid from** collection bag and transfer 3 drops of oral fluid into the buffer bottle.

3

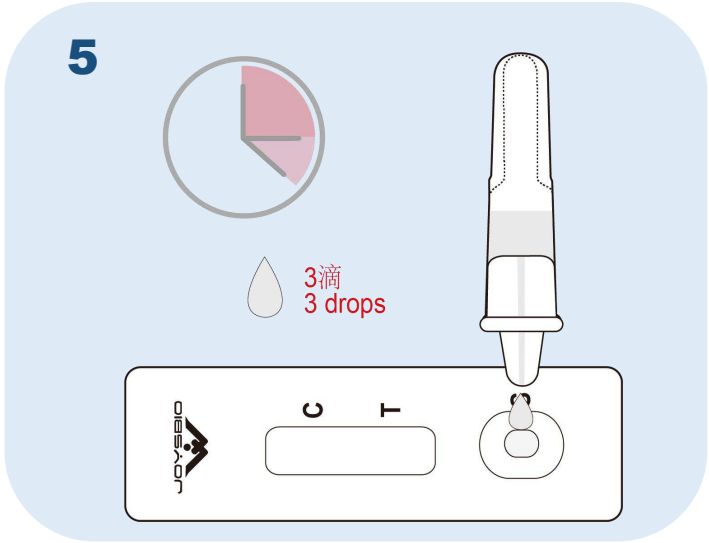


3. Twist off the top of the buffer bottle, slowly dispense all of the buffer into the extraction Tube.

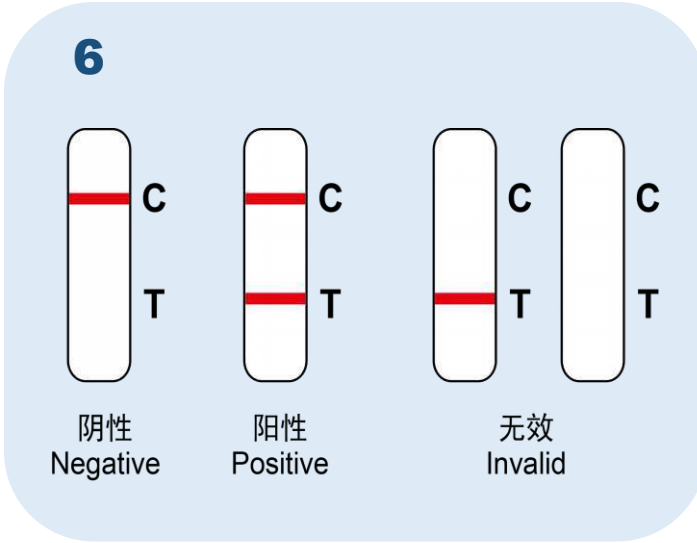
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)



4. Tighten the cap of the buffer bottle. Gently shake the buffer bottle for **10 seconds.**



5. Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface. Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well. Read the test results between 15 and 20 minutes.



6.POSITIVE: Two lines appear. One colored line should be in the control line region (C), a colored line appears in test line (T) region. NEGATIVE: Only one colored control line appear. INVALID: Control line fails to appear.

Consistency analysis of test results

There were 772 nasal swab specimens were collected to evaluate the clinical performance of the SARS-CoV-2 Antigen Rapid Test Kit Specimen Stability Study. The nasal swabs prospectively collected and enrolled from individual symptomatic patients (within 5 days of onset) who were suspected of COVID-19 and no duplicate samples were selected. Nasal swabs were collected following the dual nares method and handled as described in the package insert of the collection device.

A total of 154 samples were tested positive by SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold). There were 2 samples in which the SARS-CoV-2 Antigen Rapid Test Kit ware positive and the Real-time fluorescent RT-PCR kit for detecting 2019-nCoV produced by BGI BIOTECHNOLOGY (WUHAN) ware negative, and 6 samples in which the SARS-CoV-2 Antigen Rapid Test Kit ware negative and the Real-time fluorescent RT-PCR kit for detecting 2019-nCoV produced by BGI BIOTECHNOLOGY (WUHAN) was positive.

There were 610 samples with negative test results in experimental reagent and 612 samples with negative test results in reference reagent. Hence, the sensitivity and specificity were 96.25% and 99.67% respectively.

The Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 produced by BGI BGI Genomics Co. Ltd was used as a comparator test. This is an FDA approved for EUA use product.

Overall Clinical Study Results

Reagent test results	PCR Comparator		Subtotal
	positive	negative	
positive	154	2	156
negative	6	610	616
Subtotal	160	612	772

Positive Percent Agreement (PPA)= 96.25% (95%CI:92.0%~98.6%)

Negative Percent Agreement (NPA)= 99.67% (95%CI:98.8%~100%)

Accuracy=98.96%

Kappa=0.97＞0.5

Conclusion:

This clinical trial has performed a full analysis of the experimental reagents through methodological comparisons, and the results all meet the criteria for clinical evaluation. All the results showed that SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)meet the needs of clinical test.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

SIGNIFICANCE

RESEARCH BACKGROUND

During the epidemic Situation, many countries have the following problems:

Existing detection methods cannot achieve large-scale rapid screening.

lack of technical expertise and inadequate laboratory capacity, Erroneous Operation can easily lead to missed inspections.

Can't afford high testing costs.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Globally, as of 3:59pm CEST, 17 August 2020, there have been 21,549,706 confirmed cases of COVID-19, including 767,158 deaths, reported to WHO.

SIGNIFICANCE

According to the WHO, during the outbreak of SARS-CoV-2, in areas with confirmed SARS-CoV-2 community-wide transmission; confirmed outbreaks in closed or semi-closed communities; in high-risk groups; among contacts of confirmed cases; SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) as a tool to monitor disease incidence is a particularly effective detection method.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

ADVANTAGE

1.Easy to collect samples， simple operation，without professional equipment.

2.The test results are available in 15 minutes, and the test results are clearly visible.

3.Convenient transportation and low price, higher accuracy.

4.Suitable for large-scale rapid screening.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

REGISTERED

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

REGISTERED

EU CE Certification

Emergency Use Authorization

WHO-Emergency Use Listing

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

CE CERTIFICATE

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 18 augustus 2020
Betreft: aanmelding In-vitro diagnostica

Farmatec
Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161
http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M.P. Meijer - Michiels
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20204011

Bijlagen
-

Uw aanvraag
13 augustus 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Geachte heer Wei,

Op 13 augustus 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam JOYSBIO (Tianjin) Biotechnology Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

SARS-CoV-2 IgG/Neutralizing antibody Rapid Test Kit(Colloidal Gold) ,SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold),Immunochromatography analyzer
(geen merknaam) (NL-CA002-2020-53008)

Tuberculosis Antibody Test Kit (Colloidal Gold) ,Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold),Treponema Pallidum Antibody Test Kit (Colloidal Gold),Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-53009)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, JOYSBIO (Tianjin) Biotechnology Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

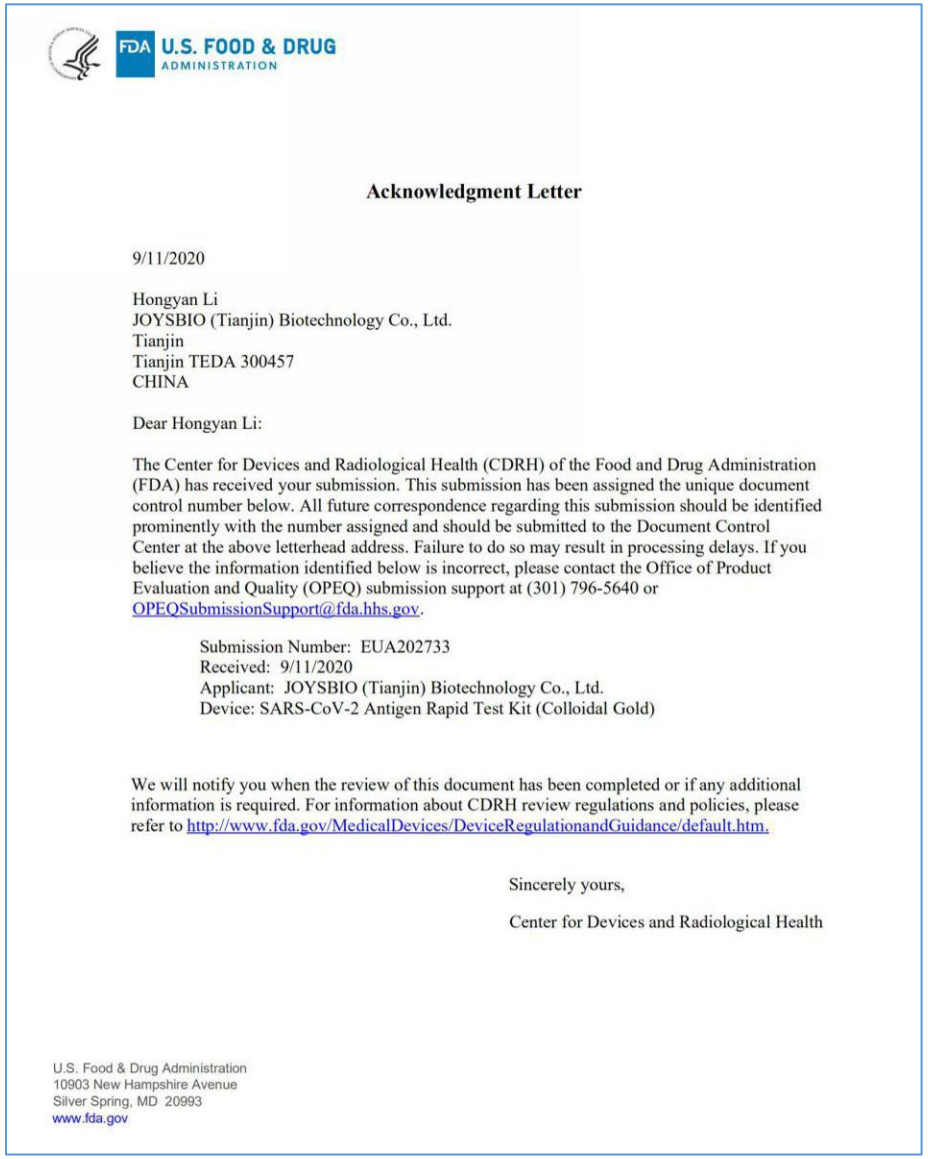
De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

FDA-EUA Acknowledgment letter



U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

9/11/2020

Hongyan Li
JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin
Tianjin TEDA 300457
CHINA

Dear Hongyan Li:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA202733
Received: 9/11/2020
Applicant: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Device: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

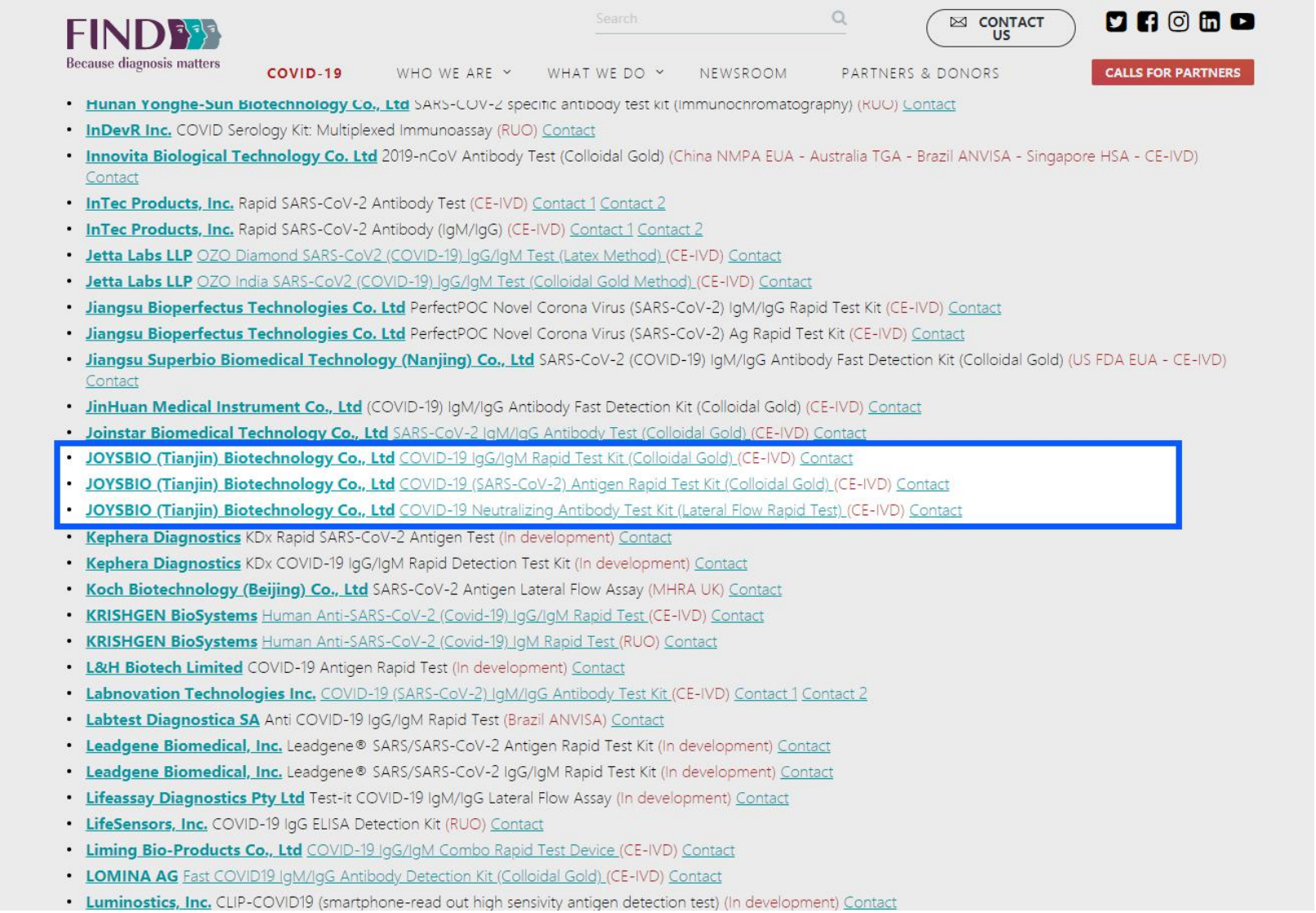
Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Has entered the FIND recommended list



FIND
Because diagnosis matters

Search

CONTACT US

COVID-19 | WHO WE ARE | WHAT WE DO | NEWSROOM | PARTNERS & DONORS | CALLS FOR PARTNERS

- **Hunan Yonghe-Sun Biotechnology Co., Ltd** SARS-CoV-2 specific antibody test kit (immunochromatography) (RUO) Contact
- **InDevR Inc.** COVID Serology Kit: Multiplexed Immunoassay (RUO) Contact
- **Innovita Biological Technology Co. Ltd** 2019-nCoV Antibody Test (Colloidal Gold) (China NMPA EUA - Australia TGA - Brazil ANVISA - Singapore HSA - CE-IVD) Contact
- **InTec Products, Inc.** Rapid SARS-CoV-2 Antibody Test (CE-IVD) Contact 1 Contact 2
- **InTec Products, Inc.** Rapid SARS-CoV-2 Antibody (IgM/IgG) (CE-IVD) Contact 1 Contact 2
- **Jetta Labs LLP** OZO Diamond SARS-CoV2 (COVID-19) IgG/IgM Test (Latex Method) (CE-IVD) Contact
- **Jetta Labs LLP** OZO India SARS-CoV2 (COVID-19) IgG/IgM Test (Colloidal Gold Method) (CE-IVD) Contact
- **Jiangsu Bioperfectus Technologies Co. Ltd** PerfectPOC Novel Corona Virus (SARS-CoV-2) IgM/IgG Rapid Test Kit (CE-IVD) Contact
- **Jiangsu Bioperfectus Technologies Co. Ltd** PerfectPOC Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit (CE-IVD) Contact
- **Jiangsu Superbio Biomedical Technology (Nanjing) Co., Ltd** SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) (US FDA EUA - CE-IVD) Contact
- **JinHuan Medical Instrument Co., Ltd** (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) (CE-IVD) Contact
- **Joinstar Biomedical Technology Co., Ltd** SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) (CE-IVD) Contact
- **JOYSBIO (Tianjin) Biotechnology Co., Ltd** COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) (CE-IVD) Contact
- **JOYSBIO (Tianjin) Biotechnology Co., Ltd** COVID-19 (SARS-CoV-2) Antigen Rapid Test Kit (Colloidal Gold) (CE-IVD) Contact
- **JOYSBIO (Tianjin) Biotechnology Co., Ltd** COVID-19 Neutralizing Antibody Test Kit (Lateral Flow Rapid Test) (CE-IVD) Contact
- **Kephera Diagnostics** KDx Rapid SARS-CoV-2 Antigen Test (In development) Contact
- **Kephera Diagnostics** KDx COVID-19 IgG/IgM Rapid Detection Test Kit (In development) Contact
- **Koch Biotechnology (Beijing) Co., Ltd** SARS-CoV-2 Antigen Lateral Flow Assay (MHRA UK) Contact
- **KRISHGEN BioSystems** Human Anti-SARS-CoV-2 (Covid-19) IgG/IgM Rapid Test (CE-IVD) Contact
- **KRISHGEN BioSystems** Human Anti-SARS-CoV-2 (Covid-19) IgM Rapid Test (RUO) Contact
- **L&H Biotech Limited** COVID-19 Antigen Rapid Test (In development) Contact
- **Labnovation Technologies Inc.** COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test Kit (CE-IVD) Contact 1 Contact 2
- **Labtest Diagnostica SA** Anti COVID-19 IgG/IgM Rapid Test (Brazil ANVISA) Contact
- **Leadgene Biomedical, Inc.** Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test Kit (In development) Contact
- **Leadgene Biomedical, Inc.** Leadgene® SARS/SARS-CoV-2 IgG/IgM Rapid Test Kit (In development) Contact
- **Lifeassay Diagnostics Pty Ltd** Test-it COVID-19 IgM/IgG Lateral Flow Assay (In development) Contact
- **LifeSensors, Inc.** COVID-19 IgG ELISA Detection Kit (RUO) Contact
- **Liming Bio-Products Co., Ltd** COVID-19 IgG/IgM Combo Rapid Test Device (CE-IVD) Contact
- **LOMINA AG** Fast COVID19 IgM/IgG Antibody Detection Kit (Colloidal Gold) (CE-IVD) Contact
- **Luminostics, Inc.** CLIP-COVID19 (smartphone-read out high sensivity antigen detection test) (In development) Contact

Search Website

https://www.finddx.org/covid-19/pipeline/

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

The Emergency Use Listing

World Health Organization

SARS-CoV-2 Rapid Antigen Tests: progress of the active applications in the emergency use listing assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	QMS Desk Assessment
ESPLINE SARS-CoV-2	231906	Fujirebio, Inc	R	🗁
BIOEASY Diagnostic kit for SARS-CoV-2 Ag (Fluorescence Immunochromatographic Assay)	YRLF04401025, YRLF04401050 and YRLF04401100	Shenzhen Bioeasy Biotechnology Co., Ltd	awaiting submission	awaiting submission
LumiraDx SARS-CoV-2 Ag Test	L0160001nnxxx	LumiraDx UK Ltd	awaiting submission	awaiting submission
SARS-CoV-2 Rapid Antigen Test	9327592190	Roche Diagnostics GmbH	🗁	🗁
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	G10313	JOYSBIO (Tianjin) Biotechnology CO., LTD	🗁	🗁

Progress of the active applications in the emergency use listing assessment pipeline.

JOYSBIO (Tianjin) Biotechnology Co., Ltd.

COMPANY PROFILE

JOYSBIO (Tianjin) Biotechnology Co., Ltd. is a Chinese R&D-based biotechnology company that develops, manufactures, and supplies high-quality medical in-vitro diagnostic (IVD) rapid test kits as well as revolutionary customized solution kits to all parts of the world. Founded by a team of professionals with many years of combined technical,marketing/sales, operational and manufacturing expertise in this industry, we offer high quality but cost-effective rapid test kit.

JOYSBIO (Tianjin) Biotechnology Co., Ltd.