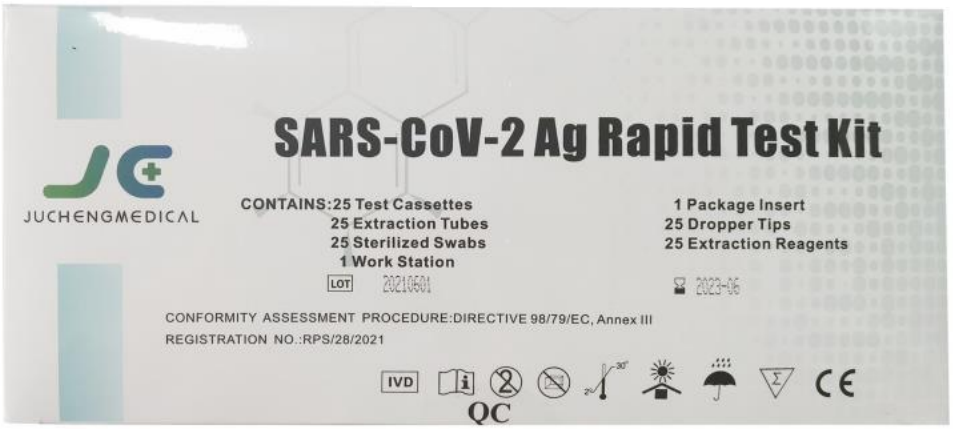
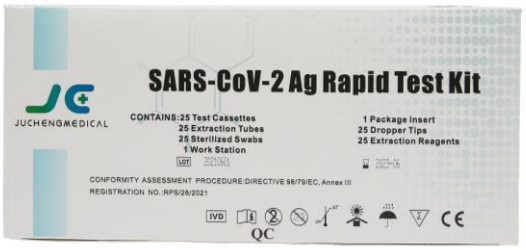
JUCHENGMEDICAL

# SARS-CoV-2 Ag

# Rapid Tesk kit












JUCHENGMEDICAL

CE EN

# SARS-CoV-2 Ag Rapid Test Kit

**Kat: 6973315390026**

[PRODUKTNAME]

SARS-CoV-2 Ag Rapid Test Kit

[VERPACKEN]

1 Stück/Beutel, 5 Stück/Karton, 25 Stück/Karton

[VERWENDUNGSZWECK]

Dieses Produkt ist für qualitative Bestimmung von neuartigem Coronavirus (COVID-19) in Nasenabstrichproben bestimmt. Es hilft bei der Diagnose einer Infektion mit dem neuartigen Coronavirus. Dieses Produkt kann für Selbsttests verwendet werden.

[ZUSAMMENFASSUNG]

Das neuartige Coronavirus (SARS-CoV-2) gehört zur β-Gattung. COVID-19 ist eine akute Infektionskrankheit der Atemwege. Die Menschen sind generell anfällig für diese Infektion. Derzeit sind die mit dem neuartigen Coronavirus infizierten Patienten die Hauptinfektionsquelle; asymptomatische Infizierte können ebenfalls eine Infektionsquelle sein. Nach den derzeitigen epidemiologischen Untersuchungen beträgt die Inkubationszeit 1 bis 14 Tage, in der Regel 3 bis 7 Tage. Zu den Hauptsymptomen gehören Fieber, Müdigkeit und trockener Husten. In einigen Fällen treten auch Nasenverstopfung, laufende Nase, Halsschmerzen, Myalgie und Durchfall auf.

[PRINZIP]

Das SARS-CoV-2 Ag Rapid Test Kit basiert auf einen immunchromatographischer Membrantest, der hochempfindliche monoklonale Antikörper zum Nachweis des Nukleokapsidproteins von SARS-CoV-2 in Nasenabstrichproben verwendet. Der Teststreifen besteht aus folgenden Teilen: Probenpad, Reagenzpad, Reaktionsmembran und Absorptionspad. Der Reagenzpad enthält den kolloidale Gold, der mit den monoklonalen Antikörpern gegen das Nukleokapsidprotein von SARS-CoV-2 konjugiert ist; die Reaktionsmembran enthält die sekundären Antikörper für das Nukleokapsidprotein von SARS-CoV-2. Der gesamte Streifen ist in einer Kunststoffkassette fixiert. Wenn die Probe ins Probenloch zugegeben wird, werden die trocken Konjugate im Reagenzpad gelöst und zusammen mit der Probe wandern. Wenn die Probe SARS-CoV-2-Antigen enthält, bilden der Anti-SARS-2-Konjugat und Virus einen Komplex. Dieser Komplex werden von den spezifischen monoklonalen Anti-SARS-2-Antikörpern auf der Testlinie (T) erfasst. Das Fehlen der farblichen T-Linie deutet auf ein negatives Ergebnis hin. Zur Verfahrenskontrolle erscheint im Bereich der Kontrolllinie (C) stets eine rote Linie, die darauf hinweist, dass das zugegebene Probenvolumen geeignet ist und die Membran richtig arbeitet.

[Bestandteile]

1. Einweg-Testkassette
2. Einweg-Probenextraktionsröhrchen
3. Tupfer zur Probenentnahme (Nasentupfer)

[LAGERUNG UND STABILITÄT]

1. Bewahren Sie das Kit in dem hermetisch verschlossenen Beutel bei einer Temperatur von 2-30℃ oder 38-86℉ und vermeiden Sie direkte Sonnenstrahlung. Das Kit ist bis zu dem auf Etikett angegebenen Verfallsdatum (2 Jahre) haltbar.
2. Nach dem Öffnen des versiegelten Beutels ist der Test innerhalb einer Stunde durchzuführen. Längere Exposition bei heißer und feuchter Umgebung kann das Produkt beschädigen.
3. Die Chargennummer und das Verfallsdatum werden auf jedem versiegelten Beutel aufgedruckt.

[TESTVORGANG]

Die Testkassette und die Proben müssen vor dem Test auf Raumtemperatur (15-30℃ oder 59-86℉) gebracht werden.

**NASENABSTRICHPROBE:**


1. Verwenden Sie den im Kit enthaltenen Nasentupfer, um den vorderen Teil der Nasenhöhle abzustreichen.
2. Öffnen Sie den Deckel des Einweg-Probenextraktionsröhrchens, schneiden Sie die Spitze des in das Reagenzglas eingeführten Wattestäbchens ab und verschließen Sie das Extraktionsröhrchen.
3. Schütteln Sie das Einweg-Probenextraktionsröhrchen, um die Probe am Tupfer aufzulösen.
4. Nehmen Sie die Testkassette aus dem Verpackungsbeutel und legen Sie sie auf einen Tisch.
5. Schneiden Sie den überstehenden Teil vom Sammelröhrchen ab.
6. Geben Sie 3 Tropfen der Probe senkrecht ins Probenloch und warten Sie 15 Minuten, bis die T-Linie erscheint.

[INTERPRETATION DER ERGEBNISSE (INNERHALB VON 15 MINUTEN)]

**Positiv (+)**: Sowohl die T- als auch die C-Linie erscheinen innerhalb von 3-15 Minuten.

**Negativ (-)**: Die C-Linie erscheint, während 15 Minuten nach der Probengabe keine T-Linie erscheint.

**Ungültig:** Wenn die C-Linie nicht erscheint, ist das Testergebnis ungültig und Sie sollen die Probe mit einem anderen Testkassette prüfen.


[ANMERKUNGEN]

1. Das SARS-CoV-2 Ag Rapid Test Kit ist nur für Nasenabstrichproben geeignet. Blut, Serum, Plasma, Urin und andere Proben können zu abnormalen Ergebnissen führen, wenn sie ins Probenloch zugegeben werden. Wenn eine Probe positiv getestet wird, wenden Sie sich bitte an Ihre lokale Gesundheitsbehörde, um weitere klinische Diagnose zu erhalten und das Ergebnis zu melden.
2. Bitte achten Sie darauf, dass 3 Tropfen der Probe ins Probenloch zugegeben werden. Zu viel oder zu wenig Probe kann zu ungenauen Ergebnissen führen.
3. Wenn sowohl die T- als auch die C-Linie erschienen sind, ist das Testergebnis als positiv zu beurteilen. In der Regel erscheinen sie 3-15 Minuten nach der Probengabe. Wenn die C-Linie erscheint allein, während keine T-Linie erscheint, ist das Testergebnis als negativ zu beurteilen. Für eine negative Beurteilung warten Sie bitte 15 Minuten nach der Probengabe.
4. Die Testkassette ist ein Einwegprodukt und enthält nach dem Gebrauch biologische Gefahrstoffe. Bitte entsorgen Sie die Testkassette, die Proben und alle bei Probennahme verwendeten Materialien nach dem Test ordnungsgemäß.
5. Das Produkt muss vor dem auf dem Produktetikett angegebenen Verfallsdatum t verwendet werden.

   Wenn ein Teil der Testmembran, die die Reagenzien enthält, aus dem Testfenster herausragt oder mehr als 2 mm Filterpapier oder Latex-Pad im Testfenster offensteht, sollen Sie das Testkit nicht verwenden, weil es zu ungültigem Testergebnis führt. Verwenden Sie stattdessen ein neues Testkit.

**LEISTUNGSMERKMALE:**

**1. Klinische Leistung**

Eine klinische Bewertung wird durchgeführt, um die Sensitivität und Spezifität von SARS-CoV-2 Ag Rapid Test Kit für SARS-CoV-2 zu bestätigen. Die Ergebnisse von SARS-CoV-2 Ag Rapid Test Kit werden mit denen von RT-PCR verglichen. Die Ergebnisse sind wie folgt zusammengefasst:

| NASENABSTRICHPROBE | | RT-PCR | | Summe |
|---|---|---|---|---|
| | | Positiv | Negativ | |
| Testreagenz | Positiv | 116 | 0 | 116 |
| | Negativ | 5 | 105 | 110 |
| Summe | | 121 | 105 | 226 |

Nasenabstrichproben: Das SARS-CoV-2 Ag Rapid Test Kit zeigte eine Sensitivität von 95,9 % und eine Spezifität von 100 % bei Nasenabstrichproben.

Klinische Sensitivität (%) = [ 116/ (116+ 5) ] x100% = 95,9%

Klinische Spezifität (%) = [105/ (0+ 105) ] x100% = 100%

Gesamte Übereinstimmungsrate (%) = [ (116 +105) / (116+ 5+ 0+105) ] x100% = 97,8%

2. Nachweisgrenze (LoD)

Das in vitro exprimierte SARS-COV-2-Nukleokapsidprotein und die nationale Standardreferenzprobe von SARS-CoV-2 werden zur Bestimmung von Nachweisgrenze (LoD) verwendet. Der LoD von SARS-CoV-2 Ag Rapid Test Kit beträgt 0,5 pg/mL SARS-COV-2 Nukleokapsidprotein. Der LoD-Wert von SARS-CoV-2 Ag Rapid Test Kits beträgt 1 x $10^4$TCID50/mL SARS-COV-2.

| | Nasenabstrichprobe |
|---|---|
| 10 pg/ml | 30/30 (100%) |
| 5 pg/ml | 30/30 (100%) |
| 1 pg/ml | 30/30 (100%) |
| 0,5 pg/ml | 29/30 (96,7%) |
| 0,1 pg/ml | 7/30 (23,3%) |
| 0,05 pg/ml | 0/30 (0%) |
| 0 pg/ml | 0/30 (0%) |

| | Nasenabstrichprobe |
|---|---|
| $1x10^5$ TCID50/mL | 30/30 (100%) |
| $1x10^4$TCID50/m | 30/30 (100%) |
| $1x10^4$ TCID50/mL | 28/30 (93.3%) |
| $1x10^3$ TCID50/mL | 6/30 (20%) |
| $1x10^0$ TCID50/mL | 0/30 (0%) |
| 0 TCID50/mL | 0/30 (0%) |

**3. Kreuzreaktivität:**

Die Kreuzreaktivität mit den folgenden Organismen und Viren wird untersucht. Folgenden Substanzen führe nicht zu falsch positiven oder falsch negativen Reaktionen, wenn sie mit dem SARS-CoV-2 Ag Rapid Test Kit für SARS-CoV-2 getestet werden.

| Organismus | Konzentration ($TCID_{50}$/mL) | Organismus | Konzentration ($TCID_{50}$/mL) |
|---|---|---|---|
| HKU1 | $1,5x10^6$ | EnterovirusD | $4x10^5$ |
| Oc43 | $1,5x10^6$ | Epstein-Barr-Virus | $2,5 x10^5$ |
| NI63 | $1,5x10^6$ | Masern-Virus | $3x10^5$ |
| 229E | $1,5x10^6$ | Humanes Zytomegalievirus | $3x10^5$ |
| MERS | $1,5x10^6$ | Rotavirus | $5x10^5$ |
| Grippe A H1N1 | $3x10^5$ | Norovirus | $5x10^5$ |
| Saisonale Grippe H1N1 | $2x10^5$ | Mumps-Virus | $5x10^5$ |
| Grippe A H3N2 | $3x10^5$ | Varizella-Zoster-Virus | $5x10^5$ |
| Grippe A H5N1 | $3x10^5$ | Menschliches Metapneumovirus (hMPV) | $4x10^5$ |
| Grippe A H7N9 | $3x10^5$ | Paragrippe-Virus 1 | $4x10^5$ |
| Grippe B | $5x10^5$ | Paragrippe-Virus 2 | $2,5 x10^5$ |
| Syncytialvirus | $4x10^5$ | Paragrippe-Virus 3 | $3x10^5$ |
| Rhinovirus A | $2,5x10^5$ | Paragrippe-Virus 4 | $3x10^5$ |
| Rhinovirus B | $2,5 x10^5$ | Respiratorisches Synzytialvirus | $3,5x10^5$ |
| Rhinovirus C | $2,5 x10^5$ | Hämophilus influenzae | $5x10^5$ |
| Adenovirus Typ 1 | $5x10^5$ | Mycoplasma pneumoniae | $6x10^4$Zellen/ml |
| Adenovirus Typ 2 | $5x10^5$ | Chlamydia pneumoniae | $4,5x10^4$Zellen/ml |
| Adenovirus Typ 3 | $5x10^5$ | Legionella pneumophila | $6x10^4$ Zellen/ml |
| Adenovirus Typ 4 | $3,5 x10^5$ | Staphylococcus aureus | $6x10^4$Zellen/ml |
| Adenovirus 5 | $5x10^5$ | Streptokokkus pneumoniae | $5x10^4$Zellen/ml |
| Adenovirus Typ 7 | $3,5x10^5$ | Streptokokkus pyogenes | $5x10^4$Zellen/ml |
| Adenovirus 55 | $4x10^5$ | Candida albicans | $5x10^4$ Zellen/ml |
| Enterovirus A | $4x10^5$ | Gepooltes Waschwasser von menschlichen Probenahmestellen - repräsentativ für die normale Mikroflora im Atemweg | $4,5x10^4$ Zellen/ml |
| Enterovirus B | $4x10^5$ | Bordetella pertussis | $4,5x10^4$ Zellen/ml |
| Enterovirus C | $4x10^5$ | | |

**4. Interferenztest mit endogenen/exogenen Substanzen**

Die folgenden Substanzen, die natürlich in Atemproben vorkommen oder künstlich in die Atemwege eingebracht werden können, werden wie unten aufgeführt getestet. Das SARS-CoV-2 Ag Rapid Test Kit liefert kein falsch positives oder falsch negatives Ergebnis.

| Substanz | Substanz | Substanz |
|---|---|---|
| Gereinigtes Muzin | Alpha-Interferon | Tobramycin |
| Bilirubin | Zanamivir | Histamin-Hydrochlorid |
| Blutlipide | Ribavirin | Benfurin |
| Hämoglobin | Oseltamivir | Oxymetazolin |
| Rheumafaktor | Paramivir | Natriumchlorid |
| Antinukleäre Antikörper | Lopinavir | Beclomethason |
| Antimitochondrialer Antikörper | Ritonavir | Dexamethason |
| HAMA | Abidol | Flunisolon |
| Gesamtes IgG | Levofloxacin | Triamcinolon |
| Gesamtes IgM | Azithromycin | Budesonid |
| Hämatokrit | Ceftriaxon | Momisson |
| Meropenem | Fluticason | |

**5. Hakeneffekt**

Der Hakeneffekt bezieht sich auf das falsch negative Phänomen, das durch das falsche Verhältnis von Antigen zu Antikörper verursacht wird. Der Antikörperüberschuss wird als Proband-Effekt bezeichnet.

Für das SARS-CoV-2 Ag Rapid Test Kit gilt:selbst wenn die Konzentration an SARS-COV-2-Nukleokapsidprotein oder des Spikerprotein 200μg/ml erreicht, zeigt das SARS-CoV-2 Ag Rapid Test Kit keinen Hakenefffekt.

[INDEX DER SYMBOLE]

| | | | | | |
|---|---|---|---|---|---|
| | Gebrauchsanweisung beachten | Σ | Tests pro Kit | EC REP | Bevollmächtigter Vertreter |
| IVD | Nur für In-vitro-Diagnostik bestimmt | | Verwendbar bis | | Nicht wiederverwendbar |
| 2°C 30°C | Bei 2-30°C lagern | LOT | Chargennummer | REF | Katalognummer |

Hangzhou Jucheng Medical Products Co., Ltd
3rd floor, Building 1, No.8 Mingyuan Road, Gaohong Town,
Lin'an District, Hangzhou City, Zhejiang Province, China

EC REP
CMC Medical Devices & Drugs S.L
C/Horacio Lengo N°18
CP 29006, Málaga-Spain

JUCHENGMEDICAL

CE EN

# SARS-CoV-2 Ag Rapid Test Kit

**Cat: 6973315390026**

## [PRODUCT NAME]

SARS-CoV-2 Ag Rapid Test Kit

## [PACKING]

1 piece/bag, 5 pieces/box, 25 pieces/box.

## [INTENDED USE]

This product is intended for the qualitative detection of novel coronavirus, or COVID-19, in Nasal swab samples. It aids in the diagnosis of infection with novel coronavirus. This product can be used for self-test.

## [SUMMARY]

The novel coronaviruses (SARS-CoV-2) belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible to infection. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, particularly 3 to 7 days. The main symptoms include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are also found in some cases.

## [PRINCIPLE]

The SARS-CoV-2 Ag Rapid Test Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in Nasal swab samples. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If the SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). The absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C), indicating that proper volume of sample has been added, and membrane wicking has occurred.

## [COMPOSITION]

1. Disposable test device
2. Disposable sample extraction tube
3. Specimen collection swab (nasal swab)

## [STORAGE AND STABILITY]

1. Store as packaged in the hermetically-sealed bag at the temperature (2-30°C or 38-86°F) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once the sealed bag is opened, the test should be used within one hour. Prolonged exposure to hot and humid environments will cause product deterioration.
3. The lot number and the expiration date are printed on each sealed bag.

## [TEST PROCEDURE]

Allow the test device and specimens to equilibrate to room temperature (15-30°C or 59-86°F) prior to testing.

**NASAL SWAB SAMPLE:**


1. Use the nasal swab provided in the kit to wipe the anterior part of the nasal cavity.
2. Open the cap of the disposable sample extraction tube, cut off the tip of the cotton swab inserted into the test tube and close the extraction tube.
3. Shake the disposable sample extraction tube to dissolve the sample on the swab.
4. Take the test cassette from the packaging bag and place it on a table.
5. Cut off the protrusion of the collection tube.
6. Add 3 drops of the sample into the sample hole vertically and wait 15 minutes for the appearance of the T line.

## [INTERPRETATION OF RESULTS (AFTER 15 MINUTES)]

**Positive (+)**: Both of T and C lines appear in 3-15 minutes.
**Negative (-)**: C line appears while no T line appears in 15 minutes after the sample is added.
**Invalid**: If the C line does not appear, indicating that the test result is invalid, and you should retest specimen with another test device.


## [NOTES]

1. SARS-CoV-2 Ag Rapid Test Kit is only applicable to Nasal swabs samples. Blood, serum, plasma, urine, and other samples may cause abnormal results if placed in device sample hole. If any sample is tested positive, please see your local healthcare authority for further clinical diagnosis and reporting of results.
2. Please make sure that 3 drops of the sample are added to the sample hole. Too much or too little sample may cause deviations in results.
3. For positive judgment, it can be confirmed as soon as both T and C lines have appeared, typically 3-15 minutes after the sample has been added. For negative judgment, please wait for 15 minutes after the sample has been added. The C line will appear alone while no T line will be present.
4. The test device is a disposable product and will contain biohazards after use. Please properly dispose of the test devices, specimens, and all collection materials after use.
5. The product must be used prior to the expiration date on product labeling.
   If part of the test membrane containing the reagents is out of the test window, or more than 2 mm of filter paper or latex pad is exposed in the test window, do not use it because the test results will be invalid. Use a new test kit instead.

**PERFORMANCE CHARACTERISTICS:**

**1. Clinical Performance**

A clinical evaluation was carried out to confirm that the sensitivity and specificity of the SARS-CoV-2 Ag Rapid Test Kit for SARS-CoV-2, and the results of SARS-CoV-2 Ag Rapid Test Kit were compared with those of RT-PCR. The results are as follows summarized:

| Nasal Swab Sample | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Test reagent | Positive | 116 | 0 | 116 |
| | Negative | 5 | 105 | 110 |
| Total | | 121 | 105 | 226 |

Nasal swab samples: The SARS-CoV-2 Ag Rapid Test Kit showed 95.9% sensitivity and 100% specificity in nasal swab samples.
Clinical sensitivity (%) = [ 116/ (116+ 5) ] x100% = 95.9%
Clinical specificity (%) = [105/ (0+ 105) ] x100% = 100%
Total agreement rate (%) = [ (116 +105) / (116+ 5+ 0+105) ] x100% = 97.8%

3. Limit of Detection (LoD)

SARS-COV-2 nucleocapsid protein expressed in vitro and National Standard Reference sample of SARS-CoV-2 were used for Limit of Detection (LoD) tests. The LoD of the SARS-CoV-2 Ag Rapid Test Kit is 0.5 pg/mL SARS-COV-2 nucleocapsid protein. The LoD of the SARS-CoV-2 Ag Rapid Test Kit is 1 x$10^4$TCID50/mL SARS-COV-2.

| | Nasal Swab Sample |
|---|---|
| 10 pg/mL | 30/30 (100%) |
| 5 pg/mL | 30/30 (100%) |
| 1 pg/mL | 30/30 (100%) |
| 0.5 pg/mL | 29/30 (96.7%) |
| 0.1 pg/mL | 7/30 (23.3%) |
| 0.05 pg/mL | 0/30 (0%) |
| 0 pg/mL | 0/30 (0%) |

| | Nasal Swab Sample |
|---|---|
| 1x$10^4$TCID50/mL | 30/30 (100%) |
| 1x$10^3$TCID50/m | 30/30 (100%) |
| 1x$10^2$TCID50/mL | 28/30 (93.3%) |
| 1x$10^1$TCID50/mL | 6/30 (20%) |
| 1x$10^0$TCID50/mL | 0/30 (0%) |
| 0 TCID50/mL | 0/30 (0%) |

3. Cross-reactivity:

The cross-reactivity with the following organisms and viruses was examined. The following substances will not produce false positive or false negative reactions when tested with the SARS-CoV-2 Ag Rapid Test Kit for the SARS-CoV-2.

| Organism | Concentration (TCID50/mL) | Organism | Concentration (TCID50/mL) |
|---|---|---|---|
| HKU1 | 1.5x$10^6$ | EnterovirusD | 4x$10^5$ |
| Oc43 | 1.5x$10^6$ | Epstein-Barr virus | 2.5 x$10^5$ |
| NI63 | 1.5x$10^6$ | Measles virus | 3x$10^5$ |
| 229E | 1.5x$10^6$ | Human cytomeg alovirus | 3x$10^5$ |
| MERS | 1.5x$10^6$ | Rotavirus | 5x$10^5$ |
| Influenza A H1N1 | 3x$10^5$ | Norovirus | 5x$10^5$ |
| Seasonal Influenza H1N1 | 2x$10^5$ | Mumps virus | 5x$10^5$ |
| Influenza A H3N2 | 3x$10^5$ | Varicella-zoster virus | 5x$10^5$ |
| Influenza A H5N1 | 3x$10^5$ | Human Metapneumovirus (hMPV) | 4x$10^5$ |
| Influenza A H7N9 | 3x$10^5$ | Parainfluenza virus 1 | 4x$10^5$ |
| Influenza B | 5x$10^5$ | Parainfluenza virus 2 | 2.5 x$10^5$ |
| Syncytial virus | 4x$10^5$ | Parainfluenza virus 3 | 3x$10^5$ |
| Rhinovirus A | 2.5x$10^5$ | Parainfluenza virus 4 | 3x$10^5$ |
| Rhinovirus B | 2.5 x$10^5$ | Respiratory syncytial virus | 3.5x$10^5$ |
| Rhinovirus C | 2.5 x$10^5$ | Haemophilus influenzae | 5x$10^5$ |
| Adenovirus type 1 | 5x$10^5$ | Mycoplasma pneumoniae | 6x$10^4$cells/mL |
| Adenovirus type 2 | 5x$10^5$ | Chlamydia pneumoniae | 4.5x$10^4$cells/mL |
| Adenovirus type 3 | 5x$10^5$ | Legionella pneumophila | 6x$10^4$ cells/mL |
| Adenovirus type 4 | 3.5 x$10^5$ | Staphylococcus aureus | 6x$10^4$cells/mL |
| Adenovirus 5 | 5x$10^5$ | Streptococcus pneumoniae | 5x$10^4$cells/mL |
| Adenovirus type 7 | 3.5x$10^5$ | Streptococcus pyogenes | 5x$10^4$cells/mL |
| Adenovirus 55 | 4x$10^5$ | Candida albicans | 5x$10^4$ cells/mL |
| Enterovirus A | 4x$10^5$ | Pooled human sampling site wash - representative of normal I respiratory microbial flora | 4.5x$10^4$ cells/mL |
| Enterovirus B | 4x$10^5$ | Bordetella pertussis | 4.5x$10^4$ cells/mL |
| Enterovirus C | 4x$10^5$ | | |

**4. Endogenous/exogenous material interference test**

The following substances, which occur naturally in breath samples or which can be artificially introduced into the airways, were evaluated as listed below. The SARS-CoV-2 Ag Rapid Test Kit does not report false positive or false negative.

| Substance | Substance | Substance |
|---|---|---|
| Purified Mucin | alpha-interferon | Tobramycin |
| Bilirubin | Zanamivir | Histamine hydrochloride |
| Blood lipids | Ribavirin | Benfurin |
| Hemoglobin | Oseltamivir | Oxymetazoline |
| Rheumatoid factor | Paramivir | Sodium chloride |
| Antinuclear antibody | Lopinavir | Beclomethasone |
| Antimitochondrial antibody | Ritonavir | Dexamethasone |
| HAMA | Abidol | Flunisolone |
| Total IgG | Levofloxacin | Triamcinolone |
| Total IgM | Azithromycin | Budesonide |
| Hematocrit | Ceftriaxone | Momisson |
| Meropenem | Fluticasone | |

**5. Hook effect**

The hook effect refers to the false-negative phenomenon caused by the incorrect ratio of antigen to antibody. Antibody excess is called proband effect.
For SARS-CoV-2 Ag Rapid Test Kit, even if the concentration of SARS-COV-2 nucleocapsid protein reaches 200 μ g/mL, the SARS-CoV-2 Ag Rapid Test Kit still has no hook effect.

## [INDEX OF SYMBOLS]

| | | | | | |
|---|---|---|---|---|---|
| | Consult instructions for use | Σ | Tests per kit | EC REP | Authorized Representative |
| IVD | For in vitro diagnostic use only | | Use by | | Do not reuse |
| | Store between 2-30°C | LOT | Lot Number | REF | Catalogue number |

Hangzhou Jucheng Medical Products Co., Ltd
3rd floor, Building 1,No.8 Mingyuan Road, Gaohong Town,
Lin'an District, Hangzhou City, Zhejiang Province, China

EC REP
CMC Medical Devices & Drugs S.L
C/Horacio Lengo N°18
CP 29006, Málaga-Spain

# EC REP CERTIFICATE

## CMC MEDICAL DEVICES & DRUGS SL
## NO. CMC/CE/2020/07012021.20

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

**Hangzhou Jucheng Medical Products Co., Ltd**
**3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/28/2021**

CE

Issued on: 07/01/2021

Valid until: 06/01/2022

Authorized Signatory
CMC Medical Devices & Drugs SL

# EC REP CERTIFICATE

**ANNEX I Medical Device Products**

**SARS-CoV-2 Ag Rapid Test Kit**

**COVID-19 Neutralizing Antibody Detection Kit**

**SARS-CoV-2 / Influenza Virus A/B Antigens Multiple Detection Kit**

CE

N/REF: PS/CLV/MR/0509/2021-CLV

**Carmen Ruiz-Villar Fernández-Bravo**
**LA JEFE DEL DEPARTAMENTO DE PRODUCTOS SANITARIOS**

**AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS)**

CERTIFICA: Que en base a las declaraciones y/o certificados aportados:

La empresa CMC MEDICAL DEVICES & DRUGS S.L., con sede en Calle HORACIO LENGO, nº 18, 29006 - MÁLAGA ESPAÑA, es Representante Autorizado en la Unión Europea del fabricante Hangzhou Jucheng Medical Products Co., Ltd, con sede en 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA, de los productos relacionados en el **Anexo I**.

Los productos relacionados en el **Anexo I**, disponen de marcado CE de acuerdo a lo previsto en el Real Decreto 1662/2000 de 29 de septiembre, transposición a la legislación nacional de la Directiva 98/79/CE del Parlamento Europeo y del Consejo de 27 de octubre de 1998 sobre productos sanitarios para diagnóstico *in vitro*, lo que permite su comercialización en España y en el resto de países de la Unión Europea, no existiendo trabas para su exportación.

Este certificado se expide en base a la documentación presentada por la empresa en el momento de su emisión y no supone una autorización sanitaria de comercialización de los productos por parte de esta Agencia.

**THE SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES (AEMPS)**

CERTIFIES: On the basis of the declarations and/or certificates provided:

The company CMC MEDICAL DEVICES & DRUGS S.L., based in Calle HORACIO LENGO, nº 18, 29006 - MÁLAGA SPAIN, is the Authorised Representative in the European Union of the manufacturer Hangzhou Jucheng Medical Products Co., Ltd, based in 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, PEOPLES REPUBLIC OF CHINA, of the products listed in **Annex I**.

The products listed in **Annex I**, have been affixed with the CE mark under the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, on *in vitro* diagnostic medical devices and the Royal Decree 1662/2000 of 29 September, transposition to the Spanish legislation, and therefore they can be marketed in Spain and in the rest of the European Union countries, without export restrictions.

This certificate is issued on the basis of the documentation provided by the company at the time of its issuance and it should not be taken as an AEMPS marketing authorization of the products.

N/REF: PS/CLV/MR/0509/2021-CLV

Y para que conste y surta los efectos oportunos ante las Autoridades Sanitarias de **India**, lo firmo en Madrid.

Signed and issued as evidence thereof to be effective with the Health Authorities of **India**, in Madrid.

agencia española de medicamentos y productos sanitarios
Departamento de Productos Sanitarios

Fdo. Carmen Ruiz-Villar Fernández-Bravo

D. Antonio González Fernández, Jefe de Sección de la Subdirección General de Relaciones Internacionales y Publicaciones del Ministerio de Sanidad, reconoce como auténtica la firma de este documento mediante el certificado electrónico del sello AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) emitido por la FNMT-RCM (Fábrica Nacional de Moneda y Timbre - Real Casa de la Moneda), certificado conforme al Reglamento 910/2014, anexo III, de la Unión Europea.

Madrid,

12 MAY. 2021

# APOSTILLE

(Convention de La Haye du 5 octobre 1961)

| | |
|---|---|
| **1. País:** Country/Pays: | **España** |
| **El presente documento público** This public document/Le présent acte public | |
| **2. ha sido firmado por** has been signed by a été signé par | GONZÁLEZ FERNÁNDEZ, ANTONIO |
| **3. quien actúa en calidad de** acting in the capacity of agissant en qualité de | JEFE DE SECCIÓN |
| **4. y está revestido del sello / timbre** bears the seal / stamp of est revêtu du sceau / timbre de | MINISTERIO DE SANIDAD |
| **Certificado** Certified/Attesté | |
| **5. en** at/à | MALAGA |
| **6. el día** the/le | 19/05/2021 |
| **7. por** by/par | MAQUEDA PEREZ , JORGE MANUEL FUNCIONARIO RESPONSABLE |
| **8. bajo el número** Nº/sous nº | GTJ29/2021/001508 |
| **9. Sello / timbre:** Seal / stamp: Sceau / timbre: | MINISTERIO DE JUSTICIA * MALAGA * GERENCIA TERRITORIAL |
| **10. Firma:** Signature: Signature: | MAQUEDA PEREZ , JORGE MANUEL |

**Esta Apostilla certifica únicamente la autenticidad de la firma, la calidad en que el signatario del documento haya actuado y, en su caso,la identidad del sello o timbre del que el documento público esté revestido.**

**Esta Apostilla no certifica el contenido del documento para el cual se expidió.**

**Esta Apostilla se puede verificar en la dirección siguiente: "https://sede.mjusticia.gob.es/eregister"**

**Código de verificación de la Apostilla (*):** AD:yeNS-cBZN-egMx-fNrU

**Este documento está firmado electrónicamente de acuerdo con lo dispuesto en los artículos 42 y 43 de Ley 40/2015, de 1 de octubre, de Régimen Jurídico del Sector Público.**

---

**This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.**

**This Apostille does not certify the content of the document for which it was issued.**

**To verify the issuance of this Apostille, see "https://sede.mjusticia.gob.es/eregister"**

**Verification code of the Apostille (*):** AD:yeNS-cBZN-egMx-fNrU

**This document has been electronically signed in accordance with the provisions of Articles 42 and 43 of Law 40/2015 of October 1st, of Legal Regime of the Public Sector.**

---

**Cette Apostille atteste uniquement la véracité de la signature, la qualité en laquelle le signataire de l'acte a agi et, le cas échéant, l'identité du sceau ou timbre dont cet acte public est revêtu.**

**Cette Apostille ne certifie pas le contenu de l'acte pour lequel elle a été émise.**

**Cette Apostille peut être vérifiée à l'adresse suivante : "https://sede.mjusticia.gob.es/eregister"**

**Code de vérification de l'Apostille (*):** AD:yeNS-cBZN-egMx-fNrU

**Ce document a été signé électroniquement d'accord avec le disposé dans les articles 42 et 43 de Loi 40/2015 du 1 octobre, de Régime Juridique du Secteur Public.**

**(*) Juego de caracteres del código de verificación / Verification Code Characters Set / Ensemble de caractères du code de vérification:**

ABCDEFGHJKLMNPQRSTUVWXYZ abcdefghijkmnopqrstuvwxyz 23456789 - :

N/REF: PS/CLV/MR/0509/2021-CLV

# ANEXO I DEL CERTIFICADO Nº 0509/2021-CLV
# ANNEX I TO THE CERTIFICATE Nº 0509/2021-CLV

PRODUCTOS SANITARIOS PARA DIAGNÓSTICO *IN VITRO* REFERENCIADOS EN EL CERTIFICADO
*IN VITRO* DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

| **Producto / Product**<br>Referencia y modelo / Reference and model | **Empresa(s) / Company(s)**<br>Domicilio social / Registered office |
|---|---|
| **1 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 1 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |
| **2 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 25 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |
| **3 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 5 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |

N/REF: PS/CLV/MR/0507/2021-CLV

**Carmen Ruiz-Villar Fernández-Bravo**
**LA JEFE DEL DEPARTAMENTO DE PRODUCTOS SANITARIOS**

**AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS)**

**THE SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES (AEMPS)**

CERTIFICA: Que en base a las declaraciones y/o certificados aportados:

CERTIFIES: On the basis of the declarations and/or certificates provided:

La empresa CMC MEDICAL DEVICES & DRUGS S.L., con sede en Calle HORACIO LENGO, nº 18, 29006 - MÁLAGA ESPAÑA, es Representante Autorizado en la Unión Europea del fabricante Hangzhou Jucheng Medical Products Co., Ltd, con sede en 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA, de los productos relacionados en el **Anexo I**.

The company CMC MEDICAL DEVICES & DRUGS S.L., based in Calle HORACIO LENGO, nº 18, 29006 - MÁLAGA SPAIN, is the Authorised Representative in the European Union of the manufacturer Hangzhou Jucheng Medical Products Co., Ltd, based in 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, PEOPLES REPUBLIC OF CHINA, of the products listed in **Annex I**.

Los productos relacionados en el **Anexo I**, disponen de marcado CE de acuerdo a lo previsto en el Real Decreto 1662/2000 de 29 de septiembre, transposición a la legislación nacional de la Directiva 98/79/CE del Parlamento Europeo y del Consejo de 27 de octubre de 1998 sobre productos sanitarios para diagnóstico *in vitro*, lo que permite su comercialización en España y en el resto de países de la Unión Europea, no existiendo trabas para su exportación.

The products listed in **Annex I**, have been affixed with the CE mark under the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, on *in vitro* diagnostic medical devices and the Royal Decree 1662/2000 of 29 September, transposition to the Spanish legislation, and therefore they can be marketed in Spain and in the rest of the European Union countries, without export restrictions.

Este certificado se expide en base a la documentación presentada por la empresa en el momento de su emisión y no supone una autorización sanitaria de comercialización de los productos por parte de esta Agencia.

This certificate is issued on the basis of the documentation provided by the company at the time of its issuance and it should not be taken as an AEMPS marketing authorization of the products.

N/REF: PS/CLV/MR/0507/2021-CLV

Y para que conste y surta los efectos oportunos ante las Autoridades Sanitarias de **Turquía**, lo firmo en Madrid.

Signed and issued as evidence thereof to be effective with the Health Authorities of **Turkey**, in Madrid.

agencia española de medicamentos y productos sanitarios
Departamento de Productos Sanitarios

Fdo. Carmen Ruiz-Villar Fernández-Bravo

D. Antonio González Fernández, Jefe de Sección de la Subdirección General de Relaciones Internacionales y Publicaciones del Ministerio de Sanidad, reconoce como auténtica la firma de este documento mediante el certificado electrónico del sello AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) emitido por la FNMT-RCM (Fábrica Nacional de Moneda y Timbre - Real Casa de la Moneda), certificado conforme al Reglamento 910/2014, anexo III, de la Unión Europea.

Madrid,

12 MAY. 2021

SUBDIRECCIÓN GENERAL DE RELACIONES INTERNACIONALES

# APOSTILLE

(Convention de La Haye du 5 octobre 1961)

| | |
|---|---|
| **1. País:** Country/Pays: | **España** |
| **El presente documento público** This public document/Le présent acte public | |
| **2. ha sido firmado por** has been signed by a été signé par | GONZÁLEZ FERNÁNDEZ, ANTONIO |
| **3. quien actúa en calidad de** acting in the capacity of agissant en qualité de | JEFE DE SECCIÓN |
| **4. y está revestido del sello / timbre** bears the seal / stamp of est revêtu du sceau / timbre de | MINISTERIO DE SANIDAD |
| **Certificado** Certified/Attesté | |
| **5. en** at/à | MALAGA |
| **6. el día** the/le | 19/05/2021 |
| **7. por** by/par | MAQUEDA PEREZ , JORGE MANUEL FUNCIONARIO RESPONSABLE |
| **8. bajo el número** Nº/sous nº | GTJ29/2021/001510 |
| **9. Sello / timbre:** Seal / stamp: Sceau / timbre: | MINISTERIO DE JUSTICIA * GERENCIA TERRITORIAL * MALAGA |
| **10. Firma:** Signature: Signature: | MAQUEDA PEREZ , JORGE MANUEL |

**Esta Apostilla certifica únicamente la autenticidad de la firma, la calidad en que el signatario del documento haya actuado y, en su caso,la identidad del sello o timbre del que el documento público esté revestido.**

**Esta Apostilla no certifica el contenido del documento para el cual se expidió.**

**Esta Apostilla se puede verificar en la dirección siguiente: "https://sede.mjusticia.gob.es/eregister"**

**Código de verificación de la Apostilla (*):** AD:zaXp-BttP-aKcN-Zr4N

**Este documento está firmado electrónicamente de acuerdo con lo dispuesto en los artículos 42 y 43 de Ley 40/2015, de 1 de octubre, de Régimen Jurídico del Sector Público.**

---

**This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.**

**This Apostille does not certify the content of the document for which it was issued.**

**To verify the issuance of this Apostille, see "https://sede.mjusticia.gob.es/eregister"**

**Verification code of the Apostille (*):** AD:zaXp-BttP-aKcN-Zr4N

**This document has been electronically signed in accordance with the provisions of Articles 42 and 43 of Law 40/2015 of October 1st, of Legal Regime of the Public Sector.**

---

**Cette Apostille atteste uniquement la véracité de la signature, la qualité en laquelle le signataire de l'acte a agi et, le cas échéant, l'identité du sceau ou timbre dont cet acte public est revêtu.**

**Cette Apostille ne certifie pas le contenu de l'acte pour lequel elle a été émise.**

**Cette Apostille peut être vérifiée à l'adresse suivante : "https://sede.mjusticia.gob.es/eregister"**

**Code de vérification de l'Apostille (*):** AD:zaXp-BttP-aKcN-Zr4N

**Ce document a été signé électroniquement d'accord avec le disposé dans les articles 42 et 43 de Loi 40/2015 du 1 octobre, de Régime Juridique du Secteur Public.**

**(*) Juego de caracteres del código de verificación / Verification Code Characters Set / Ensemble de caractères du code de vérification:**

ABCDEFGHJKLMNPQRSTUVWXYZ abcdefghijkmnopqrstuvwxyz 23456789 - :

N/REF: PS/CLV/MR/0507/2021-CLV

# ANEXO I DEL CERTIFICADO Nº 0507/2021-CLV
# ANNEX I TO THE CERTIFICATE Nº 0507/2021-CLV

PRODUCTOS SANITARIOS PARA DIAGNÓSTICO *IN VITRO* REFERENCIADOS EN EL CERTIFICADO
*IN VITRO* DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

| **Producto / Product**<br>Referencia y modelo / Reference and model | **Empresa(s) / Company(s)**<br>Domicilio social / Registered office |
|---|---|
| **1 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 1 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |
| **2 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 25 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |
| **3 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 5 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |

N/REF: PS/CLV/MGCO/0431/2021-CLV

**Carmen Ruiz-Villar Fernández-Bravo**
**LA JEFE DEL DEPARTAMENTO DE PRODUCTOS SANITARIOS**

**AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS)**

CERTIFICA: Que en base a las declaraciones y/o certificados aportados:

La empresa CMC MEDICAL DEVICES & DRUGS S.L., con sede en Calle HORACIO LENGO, nº 18, 29006 - MÁLAGA ESPAÑA, es Representante Autorizado en la Unión Europea del fabricante Hangzhou Jucheng Medical Products Co., Ltd, con sede en 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA, de los productos relacionados en el **Anexo I**.

Los productos relacionados en el **Anexo I**, disponen de marcado CE de acuerdo a lo previsto en el Real Decreto 1662/2000 de 29 de septiembre, transposición a la legislación nacional de la Directiva 98/79/CE del Parlamento Europeo y del Consejo de 27 de octubre de 1998 sobre productos sanitarios para diagnóstico *in vitro*, lo que permite su comercialización en España y en el resto de países de la Unión Europea, no existiendo trabas para su exportación.

Este certificado se expide en base a la documentación presentada por la empresa en el momento de su emisión y no supone una autorización sanitaria de comercialización de los productos por parte de esta Agencia.

**THE SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES (AEMPS)**

CERTIFIES: On the basis of the declarations and/or certificates provided:

The company CMC MEDICAL DEVICES & DRUGS S.L., based in Calle HORACIO LENGO, nº 18, 29006 - MÁLAGA SPAIN, is the Authorised Representative in the European Union of the manufacturer Hangzhou Jucheng Medical Products Co., Ltd, based in 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, PEOPLES REPUBLIC OF CHINA, of the products listed in **Annex I**.

The products listed in **Annex I**, have been affixed with the CE mark under the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, on *in vitro* diagnostic medical devices and the Royal Decree 1662/2000 of 29 September, transposition to the Spanish legislation, and therefore they can be marketed in Spain and in the rest of the European Union countries, without export restrictions.

This certificate is issued on the basis of the documentation provided by the company at the time of its issuance and it should not be taken as an AEMPS marketing authorization of the products.

N/REF: PS/CLV/MGCO/0431/2021-CLV

Y para que conste y surta los efectos oportunos ante las Autoridades Sanitarias de **Arabia Saudí**, lo firmo en Madrid.

Signed and issued as evidence thereof to be effective with the Health Authorities of **Saudi Arabia**, in Madrid.

agencia española de medicamentos y productos sanitarios
Departamento de Productos Sanitarios

Fdo. Carmen Ruiz-Villar Fernández-Bravo

D. Antonio González Fernández, Jefe de Sección de la Subdirección General de Relaciones Internacionales y Publicaciones del Ministerio de Sanidad, reconoce como auténtica la firma de este documento mediante el certificado electrónico del sello AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) emitido por la FNMT-RCM (Fábrica Nacional de Moneda y Timbre - Real Casa de la Moneda), certificado conforme al Reglamento 910/2014, anexo III, de la Unión Europea.

Madrid, 05 MAY. 2021

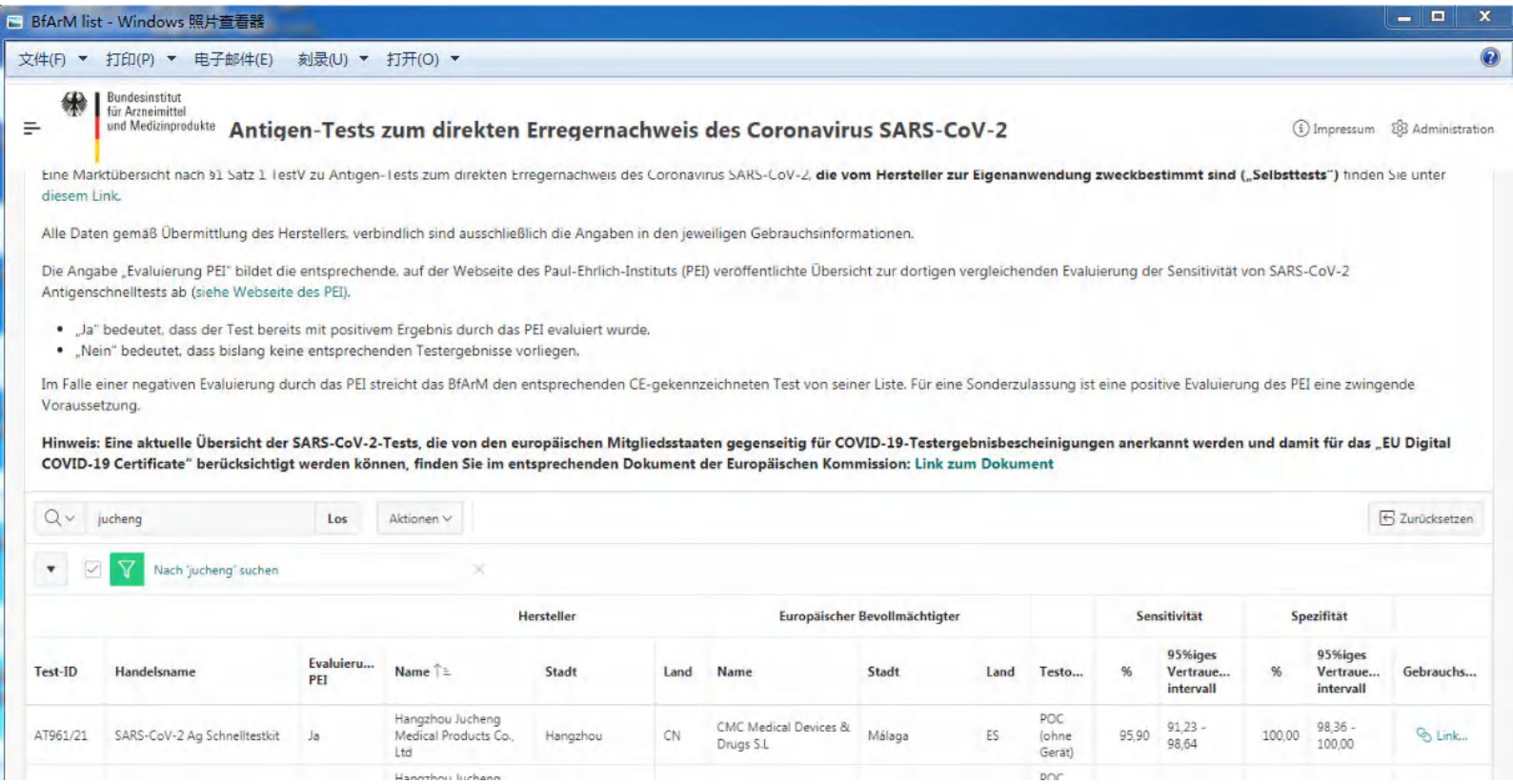
SUBDIRECCIÓN GENERAL DE RELACIONES INTERNACIONALES Y PUBLICACIONES

N/REF: PS/CLV/MGCO/0431/2021-CLV

# ANEXO I DEL CERTIFICADO Nº 0431/2021-CLV
# ANNEX I TO THE CERTIFICATE Nº 0431/2021-CLV

PRODUCTOS SANITARIOS PARA DIAGNÓSTICO *IN VITRO* REFERENCIADOS EN EL CERTIFICADO
*IN VITRO* DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

| **Producto / Product**<br>Referencia y modelo / Reference and model | **Empresa(s) / Company(s)**<br>Domicilio social / Registered office |
|---|---|
| **1 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 1 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |
| **2 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 25 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |
| **3 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 5 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |


BfArM list - Windows 照片查看器
文件(F) 打印(P) 电子邮件(E) 刻录(U) 打开(O)
Bundesinstitut für Arzneimittel und Medizinprodukte
Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2
Impressum
Administration
Eine Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests") finden Sie unter diesem Link.
Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.
Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).
„Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
„Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.
Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.
Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument
jucheng
Los
Aktionen
Zurücksetzen
Nach 'jucheng' suchen
Hersteller
Europäischer Bevollmächtigter
Sensitivität
Spezifität
Test-ID
Handelsname
Evaluieru... PEI
Name
Stadt
Land
Name
Stadt
Land
Testo...
%
95%iges Vertraue... intervall
%
95%iges Vertraue... intervall
Gebrauchs...
AT961/21
SARS-CoV-2 Ag Schnelltestkit
Ja
Hangzhou Jucheng Medical Products Co., Ltd
Hangzhou
CN
CMC Medical Devices & Drugs S.L
Málaga
ES
POC (ohne Gerät)
95,90
91,23 - 98,64
100,00
98,36 - 100,00
Link...


الامارات العربية المتحدة
UNITED ARAB EMIRATES
Ministry of Foreign Affairs and International Cooperation
وزارة الخارجية والتعاون الدولي
Date: 08/06/2021 16:03
التاريخ :
No : 21031001358
رقم :
Fee : EUR 447.65
الرسوم : اليورو
تصادق على صحة ختم و توقيع
وزارة شؤون الخارجية و التعاون الإسيائية
دون تحمل اي مسؤولية تجاه المحتويات
11950275
المتحدة - مدريد
Embassy of The United Arab Emirates - Madrid - Consular Section

DEPARTAMENTO DE
PRODUCTOS SANITARIOS

N/REF: PS/CLV/MR/0508/2021-CLV

**Carmen Ruiz-Villar Fernández-Bravo**
**LA JEFE DEL DEPARTAMENTO DE PRODUCTOS SANITARIOS**

**AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS)**

**THE SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES (AEMPS)**

CERTIFICA: Que en base a las declaraciones y/o certificados aportados:

CERTIFIES: On the basis of the declarations and/or certificates provided:

La empresa CMC MEDICAL DEVICES & DRUGS S.L., con sede en Calle HORACIO LENGO, nº 18, 29006 - MÁLAGA ESPAÑA, es Representante Autorizado en la Unión Europea del fabricante Hangzhou Jucheng Medical Products Co., Ltd, con sede en 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA, de los productos relacionados en el **Anexo I**.

The company CMC MEDICAL DEVICES & DRUGS S.L., based in Calle HORACIO LENGO, nº 18, 29006 - MÁLAGA SPAIN, is the Authorised Representative in the European Union of the manufacturer Hangzhou Jucheng Medical Products Co., Ltd, based in 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, PEOPLES REPUBLIC OF CHINA, of the products listed in **Annex I**.

Los productos relacionados en el **Anexo I**, disponen de marcado CE de acuerdo a lo previsto en el Real Decreto 1662/2000 de 29 de septiembre, transposición a la legislación nacional de la Directiva 98/79/CE del Parlamento Europeo y del Consejo de 27 de octubre de 1998 sobre productos sanitarios para diagnóstico *in vitro*, lo que permite su comercialización en España y en el resto de países de la Unión Europea, no existiendo trabas para su exportación.

The products listed in **Annex I**, have been affixed with the CE mark under the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, on *in vitro* diagnostic medical devices and the Royal Decree 1662/2000 of 29 September, transposition to the Spanish legislation, and therefore they can be marketed in Spain and in the rest of the European Union countries, without export restrictions.

Este certificado se expide en base a la documentación presentada por la empresa en el momento de su emisión y no supone una autorización sanitaria de comercialización de los productos por parte de esta Agencia.

This certificate is issued on the basis of the documentation provided by the company at the time of its issuance and it should not be taken as an AEMPS marketing authorization of the products.



CORREO ELECTRÓNICO
soportecertps@aemps.es



C/ CAMPEZO, 1 - EDIFICIO 828022 MADRID
Tel.: 91 822 54 99
Fax: 91 822 52 89

11950275

N/REF: PS/CLV/MR/0508/2021-CLV

Y para que conste y surta los efectos oportunos ante las Autoridades Sanitarias de **Emiratos Árabes Unidos**, lo firmo en Madrid.

Signed and issued as evidence thereof to be effective with the Health Authorities of **United Arab Emirates**, in Madrid.

agencia española de medicamentos y productos sanitarios
Departamento de Productos Sanitarios

Fdo. Carmen Ruiz-Villar Fernández-Bravo

MINISTERIO DE ASUNTOS EXTERIORES Y DE COOPERACION
LEGALIZACIONES
Visto Bueno para legalizar la firma que antecede por ser, al parecer, auténtica, sin prejuzgar la veracidad del contenido del documento ni ulterior destino que pueda dársele.
Madrid, 21 MAY 2021
P. EL SUBSECRETARIO
M.ª Teresa Surroca Casas
Jefa de Servicio

D. Antonio González Fernández, Jefe de Sección de la Subdirección General de Relaciones Internacionales y Publicaciones del Ministerio de Sanidad, reconoce como auténtica la firma de este documento mediante el certificado electrónico del sello AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) emitido por la FNMT-RCM (Fábrica Nacional de Moneda y Timbre - Real Casa de la Moneda), certificado conforme al Reglamento 910/2014, anexo III, de la Unión Europea.

Madrid, 12 MAY. 2021

SUBDIRECCIÓN GENERAL DE RELACIONES INTERNACIONALES Y PUBLICACIONES

N/REF: PS/CLV/MR/0508/2021-CLV

# ANEXO I DEL CERTIFICADO Nº 0508/2021-CLV
# ANNEX I TO THE CERTIFICATE Nº 0508/2021-CLV

PRODUCTOS SANITARIOS PARA DIAGNÓSTICO *IN VITRO* REFERENCIADOS EN EL CERTIFICADO
*IN VITRO* DIAGNOSTIC MEDICAL DEVICES LISTED IN THE CERTIFICATE

| **Producto / Product**<br>Referencia y modelo / Reference and model | **Empresa(s) / Company(s)**<br>Domicilio social / Registered office |
|---|---|
| **1 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 1 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |
| **2 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 25 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |
| **3 - SARS-CoV-2 Ag Rapid Test Kit**<br>( Ref: G-C-0104 ) ( Mod: 5 tests/box ) | **Hangzhou Jucheng Medical Products Co., Ltd**<br>3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province, REPÚBLICA POPULAR CHINA / PEOPLES REPUBLIC OF CHINA<br>**Representante autorizado / Authorised representative**<br>CMC Medical Devices & Drugs S.L<br>HORACIO LENGO 18, 29006 - ESPAÑA / SPAIN |

# SARS-CoV-2 Ag Rapid Test Kit

# Limit of Detection Study Report

**Study Summary**

This study tested the limit of detection (LOD) of the SARS-CoV-2 Ag Rapid Test Kit on testing SARS-COV-2 nucleocapsid protein.

**1.Purpose**

This study was to find out the LOD of the SARS-CoV-2 Ag Rapid Test Kit using SARS-COV-2 nucleocapsid protein expressed in vitro and National Standard Reference sample of SARS-CoV-2.

The eligibility standard of the product is: When the SARS-CoV-2 Ag rapid detection kit is used to detect a pre-diluted low-concentration positive sample, and the positive rate is still ≥90%, it can be determined as the LoD value

**2.Reference**

The study was performed according to the technical specification of the SARS-CoV-2 Ag Rapid Test Kit.

**4.Method**

Spike a Sputum/oropharyngeal saliva samples into saline water, respectively. Prepare the supernatant for subsequent use. Spiked a group of serially diluted SARS-COV-2 nucleocapsid protein (500 pg/mL, 100 pg/mL, 50 pg/mL, 10 pg/mL, 0.5 pg/mL , 0 pg/mL) in supernatant described above, respectively. Each supernatant is tested 30 times.

And then，spike a Sputum/oropharyngeal saliva samples into saline water, respectively. Prepare the supernatant for subsequent use. Spiked a group of serially diluted National Standard Reference sample of SARS-CoV-2 ($10^6$TCID$_{50}$/mL, $1\times10^5$TCID$_{50}$/mL, $1\times10^4$TCID$_{50}$/mL, $1\times10^3$TCID$_{50}$/mL, $1\times10^2$TCID$_{50}$/mL, 0TCID$_{50}$/mL) in supernatant described above, respectively. Each supernatant are tested 30 times.

**6.Result**

| | (Sputum/oropharyngeal saliva) Sample |
|---|---|
| 500 pg/mL | 30/30 (100%) |
| 100 pg/mL | 30/30 (100%) |
| 50 pg/mL | 30/30 (100%) |
| 10 pg/mL | 28/30 (93.3%) |
| 0.5 pg/mL | 6/30 (20%) |
| 0 pg/mL | 0/30 (0%) |

| | (Sputum/oropharyngeal saliva) Sample |
|---|---|
| $1\times10^{6}TCID_{50}$/mL | 30/30 (100%) |
| $1\times10^{5}TCID_{50}$/mL | 30/30 (100%) |
| $1\times10^{4}TCID_{50}$/mL | 30/30 (100%) |
| $1\times10^{3}TCID_{50}$/mL | 29/30 (96.7%) |
| $1\times10^{2}TCID_{50}$/mL | 6/30 (20%) |
| 0 $TCID_{50}$/mL | 0/30 (0%) |

Test results presented above shows that the LOD of the SARS-CoV-2 Ag Rapid Test Kit is 10 pg/mL SARS-COV-2 nucleocapsid protein. The LOD of the SARS-CoV-2 Ag Rapid Test Kit is $1\times10^{3}TCID_{50}$/mL SARS-COV-2.

**7. Conclusion**

The SARS-CoV-2 Ag rapid detection kit is superior to the requirements in the product specifications, supporting its feasibility in clinical applications.

Hangzhou Jucheng Medical Products Co., Ltd
Cheng Yinkai

For and on behalf of
HANGZHOU JU CHENG MEDICAL PRODUCTS CO.,LTD
Authorized Signature(s)