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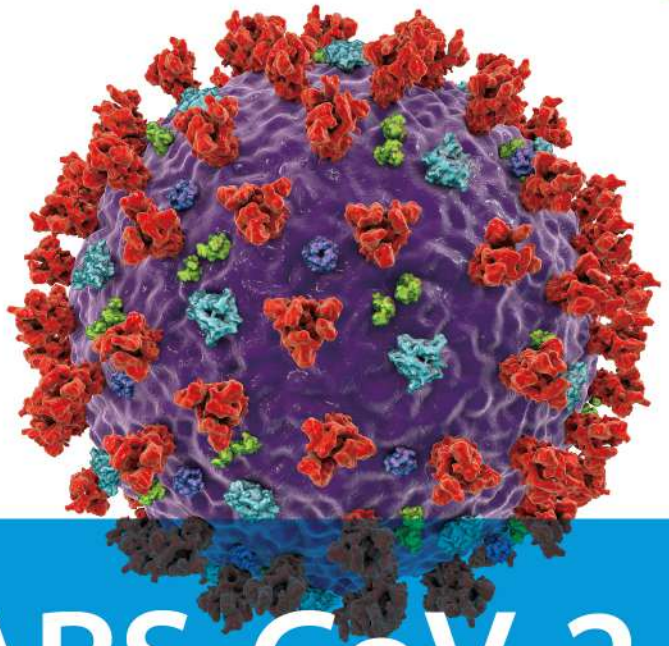



# SARS-CoV-2
## Antigen Rapid Test

A rapid, highly reliable and affordable kit, providing an aid in early diagnosis of individuals who are suspected of COVID-19 by their healthcare provider.

The King of Rapid Test with 25 Years Experience.


ACON®

*ACON* Biotech (Hangzhou) Co., Ltd.

Flowflex™

# SARS-CoV-2 Antigen Rapid Test
## Package Insert

| REF L031-11815 | English |
|---|---|

*A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens.*
*For professional in vitro diagnostic use only.*

## INTENDED USE

The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results, from patients with symptom beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
The SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

## SUMMARY

The novel coronaviruses belong to the β genus.[1] COVID-19 is an acute respiratory infectious disease. People are generally susceptible. 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, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

## PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab specimens.
When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibody bound on the membrane. Test results are interpreted visually at 15 minutes based on the presence or absence of visually colored lines.
To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

## REAGENTS

The test cassette contains anti-SARS-CoV-2 antibodies coated particles on the membrane. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the swab.

## PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations. The used test should be considered potentially infectious and be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample passes the test line region.
- The test line for a low viral load sample may become visible within 30 minutes.

## STORAGE AND STABILITY

- The kit can be stored at temperatures between 2 - 30 °C.
- The test is stable until the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use after the expiration date.

## MATERIALS

**Materials Provided**

- Test Cassettes
- Positive Control Swab
- Disposable Swabs*
- Extraction Buffer Tubes
- Negative Control Swab
- Package Insert

* *The Disposable Swabs are produced by another manufacturer.*

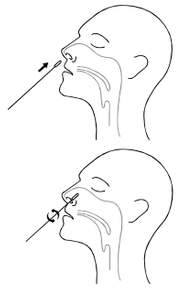
**Materials Required But Not Provided**

- Personal Protective Equipment
- Timer

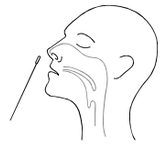
## SPECIMEN COLLECTION AND PREPARATION

- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal swab specimens.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- To collect a nasal swab sample:

1. Carefully insert a Disposable Swab, **provided with your kit**, into one nostril. Using gentle rotation, push the swab up to 2.5 cm (1 inch) from the edge of the nostril.
2. Rotate the swab 5 times against the mucosa inside the nostril to ensure sufficient specimen collection.



3. Using the same swab, repeat this process in the other nostril to ensure that an adequate amount of sample is collected from both nasal cavities.

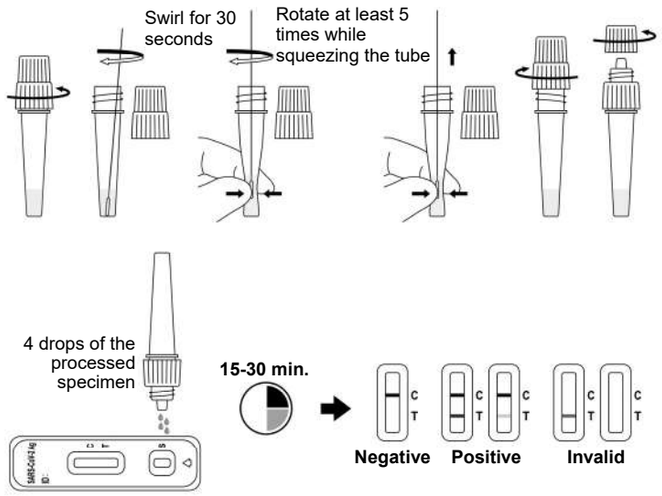


4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer tubes.

## DIRECTIONS FOR USE

**Allow the test and extraction buffer to reach room temperature (15-30 °C) prior to testing.**

1. Use an extraction buffer tube for each specimen to be tested and label each tube appropriately.
2. Unscrew the dropper cap from the extraction buffer tube without squeezing.
3. Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times while squeezing the sides of the tube. Take care to avoid splashing contents out of the tube.
4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
5. Screw the dropper cap firmly onto the extraction buffer tube containing the sample. Mix thoroughly by swirling or flicking the bottom of the tube.
6. Remove the test cassette from the foil pouch and use it as soon as possible.
7. Place the test cassette on a flat and clean surface.
8. Add the processed specimen to the sample well of the test cassette.
   a. Unscrew the small cap from the dropper tip.
   b. Invert the extraction buffer tube with the dropper tip pointing downwards and hold it vertically.
   c. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.
9. Wait for the colored line(s) to appear. The result should be read at 15-30 minutes. **Do not read the result after 30 minutes.**



## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:** Only one colored control line appears in the control region (C). No apparent colored line appears in the test line region (T). This means that no SARS-CoV-2 antigen was detected.

**POSITIVE:*** Two distinct colored lines appear. One line in the control line region (C) and the other line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected.

***NOTE:** The intensity of the color in the test line (T) may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Positive and Negative control swabs are supplied with each kit. These control swabs should be used to ensure that the test cassette and that the test procedure is performed correctly. Follow the "**DIRECTIONS FOR USE**" section to perform the control test.

## LIMITATIONS

1. The SARS-CoV-2 Antigen Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in nasal swab specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
2. Specimens should be tested as quickly as possible after specimen collection and at most within the hour following collection.
3. Use of viral transport media may result in decreased test sensitivity.
4. A false-negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.
5. Test results should be correlated with other clinical data available to the physician.
6. A positive test result does not rule out co-infections with other pathogens.
7. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not intended to rule out other viral or bacterial infections.
9. A negative result, from a patient with symptom onset beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.
   (If the differentiation of specific SARS viruses and strains is needed, additional testing is required.)

## PERFORMANCE CHARACTERISTICS

### Clinical Sensitivity, Specificity and Accuracy

The performance of SARS-CoV-2 Antigen Rapid Test was established with 304 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

**Clinical Performance for SARS-CoV-2 Antigen Rapid Test**

| Method | | RT-PCR | | Total Results |
|---|---|---|---|---|
| SARS-CoV-2 Antigen Rapid Test | Results | Negative | Positive | |
| | Negative | 269 | 1 | 270 |
| | Positive | 1 | 33 | 34 |
| Total Results | | 270 | 34 | 304 |

Relative Sensitivity: 97.1% (83.8%-99.9%)* Relative Specificity: 99.6% (97.7%-99.9%)*

Accuracy: 99.3% (97.5%-99.9%)* *95% Confidence Intervals

### Limit of Detection (LoD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The viral sample was spiked with negative human nasal sample pool into a seral of concentrations. Each level was tested for 30 replicates. The results show that the LOD is $1.6*10^2$ $TCID_{50}$/mL.

| Sample SARS-CoV-2 Concentration | % Positive (Tests) |
|---|---|
| $1.28*10^3$ $TCID_{50}$/mL | 100% (30/30) |
| $6.4*10^2$ $TCID_{50}$/mL | 100% (30/30) |
| $3.2*10^2$ $TCID_{50}$/mL | 100% (30/30) |
| $1.6*10^2$ $TCID_{50}$/mL | 96.7% (29/30) |
| $8*10$ $TCID_{50}$/mL | 0% (0/30) |

### Cross-Reactivity and Interference

No cross reactivity was observed with specimens from patients infected with coronavirus-229E, coronavirus-NL63, coronavirus-OC43, coronavirus-HKU1[1, 2], parainfluenza virus type (Type 1, Type 2, Type 3 and Type 4), Influenza A/B, Human rhinovirus, Human Bocavirus, Human respiratory syncytial virus, Human metapneumovirus, Human adenovirus, Enterovirus , Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Candida albicans, MERS-coronavirus, Pneumocystis jirovecii.

The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

The interfering substances (Whole Blood, Dafenlin Oxymetazoline Hydrochloride Spray, Mometasone Furoate Nasal Spray, Fluticasone Propionate, Physiological Seawater Nasal Cleaner) with a certain concentration have no interference on the test of SARS-CoV-2 Antigen Rapid Test.

## PRECISION

### Intra-Assay

Within-run precision was determined using 10 replicates of specimens: negative control and SARS-CoV-2 antigen positive controls. The specimens were correctly identified >99% of the time.

### Inter-Assay

Between-run precision was determined using 10 independent assays on the same specimen: negative specimen and SARS-CoV-2 antigen positive specimen. Three different lots of the SARS-CoV-2 Antigen Rapid Test were tested using these specimens. The specimens were correctly identified >99% of the time.

## BIBLIOGRAPHY


1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164


### Index of Symbols

| | | | | | |
|---|---|---|---|---|---|
| | Manufacturer | Σ | Contains sufficient for <*n*> tests | | Temperature limit |
| IVD | *In vitro* diagnostic medical device | | Use-by date | | Do not reuse |
| | Consult instructions for use | LOT | Batch code | REF | Catalogue number |
| EC REP | Authorized representative in the European Community | | | | Date of manufacture |

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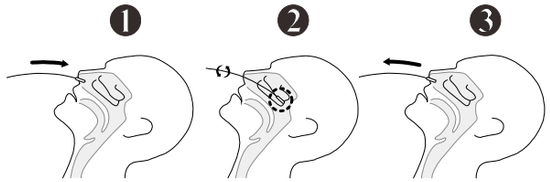
CE

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



Number: 1151256801
Effective date: 2020-12-01




**English**

## Specimen Collection Guide - Nasopharyngeal Swabs

**How to collect a nasopharyngeal swab sample:**

1. Tilt patient's head back 70 degrees. Gently and slowly insert a nasopharyngeal swab, provided with your kit, through the nostril parallel to the palate until resistance is encountered.
2. Gently rub and roll the swab, leaving it in place for several seconds to absorb secretions. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
3. Slowly remove swab while rotating it. The specimen is now ready for preparation using the extraction buffer tubes.

**Français**

## Guide de prélèvement des échantillons - Écouvillons nasopharyngés

**Comment recueillir un échantillon d'écouvillon nasopharyngé:**

1. Inclinez la tête du patient vers l'arrière de 70 degrés. Insérez doucement et lentement un écouvillon nasopharyngé, fourni avec votre kit, à travers la narine parallèle au palais jusqu' à ce qu'une résistance soit rencontrée.
2. Frottez et roulez doucement l'écouvillon, en le laissant en place pendant plusieurs secondes pour absorber les sécrétions. Si un septum dévié ou un blocage rend difficile l'obtention de l'échantillon à partir d'une narine, utiliser le même écouvillon pour obtenir l'échantillon à partir de l'autre narine.
3. Retirez lentement l'écouvillon tout en le faisant tourner. L'échantillon est maintenant prêt à être préparé à l'aide des tubes tampons d'extraction.

**Deutsch**

## Anleitung zur Probenentnahme - Nasopharyngeale Abstriche

**So entnehmen Sie eine nasopharyngeale Abstrichprobe:**

1. Neigen Sie den Kopf des Patienten um 70 Grad zurück. Führen Sie einen Nasopharyngealtupfer, den Sie mit Ihrem Kit erhalten haben, sanft und langsam durch das Nasenloch parallel zum Gaumen ein, bis Sie auf Widerstand stoßen.
2. Reiben und rollen Sie den Tupfer sanft und warten Sie ihn einige Sekunden, damit er Sekrete aufnehmen kann. Wenn eine Nasenscheidewandverbiegung oder eine Verstopfung Schwierigkeiten bei der Entnahme der Probe aus einem Nasenloch verursacht, verwenden Sie denselben Tupfer zur Entnahme der Probe aus dem anderen Nasenloch.
3. Entfernen Sie den Tupfer langsam und drehen Sie ihn dabei. Die Probe ist nun bereit für die Vorbereitung mit den Extraktionspufferröhrchen.

**Italiano**

## Guida alla raccolta dei campioni - Tamponi nasofaringei

**Come prelevare un campione nasofaringeo con un tampone:**

1. Inclinare indietro la testa del paziente di 70 gradi. Inserire con cautela e lentamente un tampone nasofaringeo incluso nel kit nella narice, parallelamente al palato, fino a quando viene incontrata una resistenza.
2. Strofinare e ruotare gentilmente il tampone, lasciandolo in posizione alcuni secondi per assorbire le secrezioni. Se una deviazione o una ostruzione del setto rendono difficile la raccolta del campione da una narice, usare lo stesso tampone per prelevarlo dall'altra narice.
3. Rimuovere lentamente il tampone mentre lo si fa ruotare. Il campione è ora pronto per la preparazione usando le provette di estrazione.

**Español**

## Guía de recolección de muestras - Bastoncillos nasofaríngeos

**Para obtener una muestra de hisopado nasofaríngeo:**

1. Incline la cabeza del paciente hacia atrás 70 grados. Delicada y lentamente introduzca un bastoncillo nasofaríngeo (provisto en el kit) a través de la fosa nasal de forma paralela al paladar hasta sentir resistencia.
2. Gire el bastoncillo suavemente y frote, dejándolo en su lugar durante varios segundos para absorber las secreciones. Si hay una desviación u obstrucción del tabique que producen dificultades para obtener la muestra de una fosa nasal, utilice el mismo bastoncillo para obtener la muestra de la otra fosa nasal.
3. Retire lentamente el bastoncillo mientras lo gira. Con esto, la muestra estará lista para prepararse utilizando los tubos de extracción con disolución amortiguadora.

**Português**

## Guia de colheita de amostras - Zaragatoas nasofaríngeas

**Como colher uma amostra com uma zaragatoa nasofaríngea:**

1. Incline a cabeça do paciente para trás num ângulo de 70 graus. Delicada e lentamente, insira uma zaragata nasofaríngea, fornecida com o seu kit, na narina de forma paralela ao palato até encontrar resistência.
2. Esfregue suavemente e role a zaragatoa, deixando-a no respetivo local durante alguns segundos para absorver as secreções. Se um desvio de septo ou bloqueio criar dificuldade na obtenção da amostra de uma narina, utilize a mesma zaragatoa para obter a amostra da outra narina.
3. Remova lentamente a zaragatoa enquanto a gira. A amostra agora está pronta para a preparação utilizando os tubos de tampão de extração.

**Ελληνικά**

## Οδηγός συλλογής δειγμάτων - Ρινοφαρυγγικοί στυλεοί

**Για να συλλέξετε ένα δείγμα ρινοφαρυγγικού επιχρίσματος:**

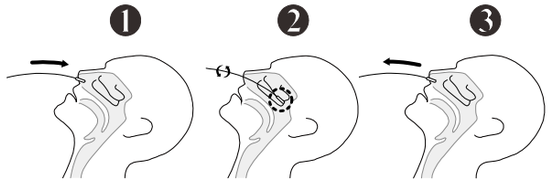
1. Ο ασθενής πρέπει να γείρει πίσω το κεφάλι του σε γωνία 70 μοιρών. Εισάγετε αργά και μαλακά τον ρινοφαρυγγικό στυλεό που παρέχεται με το κιτ σας μέσα στο ρουθούνι παράλληλα με τον ουρανίσκο, έως ότου βρείτε αντίσταση.
2. Τρίψτε ελαφρά και στρίψτε τον στυλεό, κρατώντας τον στο σημείο για αρκετά δευτερόλεπτα ώστε να απορροφήσει τις εκκρίσεις. Σε περίπτωση που υπάρχει στραβό διάφραγμα ή εμπόδιο που δυσκολεύει τη λήψη δείγματος από το ένα ρουθούνι, χρησιμοποιήστε τον ίδιο στυλεό για να λάβετε δείγμα από το άλλο ρουθούνι.
3. Αφαιρέστε τον στυλεό αργά ενώ τον περιστρέφετε. Το δείγμα είναι τώρα έτοιμο για προετοιμασία με τη χρήση των σωληναρίων ρυθμιστικού διαλύματος.

**Svenska**

## Guide för provtagning - Nasofaryngeala provpinnar

**Så här samlar du in ett nasofaryngealt prov:**

1. Luta patientens huvud bakåt 70 grader. För försiktigt och långsamt in av de medföljande nasofaryngeala provpinnarna i näsborren parallellt med gommen tills motstånd uppstår.
2. Gnugga och rulla försiktigt provpinnen och låt den vara på plats i flera sekunder för att absorbera sekret. Om ett avvikande septum eller en blockering skapar svårigheter att få provet från en näsborre kan du använda samma pinne för att ta provet från den andra näsborren.
3. Ta långsamt bort pinnen medan du vrider den. Provet är nu klart för beredning med hjälp av rören med extraktionsbuffert.




**Türkçe**

## Örnek Toplama Rehberi
## - Nazofarengeal Çubuklar

**Nazofaringeal sürüntü örneği nasıl toplanır:**

1. Hastanın başını arkaya doğru 70 derece eğin. Kitinizle birlikte sağlanan nazofaringeal çubuğu, dirençle karşılaşılıncaya kadar, damağa paralel olarak burun deliğinden nazik bir şekilde ve yavaşça sokun.
2. Çubuğu nazikçe sürün ve çevirin, salgıları emmesi için birkaç saniye yerinde bırakın. Septum deviasyonu veya tıkanma, bir burun deliğinden numuneyi elde etmede zorluk yaratırsa, numuneyi diğer burun deliğinden almak için aynı çubuğu kullanın.
3. Çubuğu döndürerek yavaşça çıkarın. Numune artık ekstraksiyon tamponu tüpleri kullanılarak hazırlanmaya hazırdır.

**Dansk**

## Prøveindsamlings-vejledning
## - Nasopharyngeale podningspinde

**Sådan indsamles en nasopharyngeal podningsprøve:**

1. Vip patientens hoved 70 grader tilbage. Indsæt forsigtigt og langsomt en nasopharyngeal podningspind, der leveres med dit sæt, gennem næseboret parallelt med ganen, indtil der mødes modstand.
2. Gnid og rul forsigtigt podepinden, og lad den sidde i flere sekunder for at absorbere sekreter. Hvis en septumdeviation eller blokering skaber problemer med at få prøven fra det ene næsebor, skal du bruge den samme podepind til at tage prøven fra det andet næsebor.
3. Fjern langsomt podepinden, mens du roterer den. Prøven er nu klar til klar til klargøring ved hjælp af ekstraktionsbuffer-rørene.

**Suomeksi**

## Näytteenkeruuopas
## - Nenänielupumpulipuikot

**Nenänielupumpulipuikkonäytteen ottaminen:**

1. Kallista potilaan päätä taakse 70 astetta. Vie paketissa toimitettu nenänielupumpulipuikko varovasti ja hitaasti sieraimeen kitalaen suuntaisesti, kunnes kohtaat vastusta.
2. Hankaa ja kierrä pumpulipuikkoa varovasti, jätä se paikoilleen useammaksi sekunniksi, jotta siihen imeytyy eritteitä. Jos nenän väliseinän (septumin) muoto tai tukkeutuminen estää näytteenoton yhdestä sieraimesta, käytä samaa pumpulipuikkoa ottamaan näyte toisesta sieraimesta.
3. Vedä pumpulipuikko hitaasti pois pyörittäen sitä. Näyte on valmis preparoitavaksi käyttäen uuttopuskuripulloja.

**Nederlands**

## Verzamelingsgids voor specimen
## - Nasofaryngeale uitstrijkjes

**Een monster afnemen via de neuskeelholte:**

1. Kantelt u het hoofd van de patiënt ongeveer 70 graden naar achteren. Schuift u voorzichtig een wattenstaafje, dat meegeleverd wordt bij uw kit, in een van de neusgaten, totdat u weerstand van het neusgehemelte voelt.
2. Draai en wrijf het wattenstaafje een paar seconden op zijn plaats om afscheiding af te nemen. Als een afwijkend neustussenstuk of verstopping het afnemen van monster uit een neusgat bemoeilijkt, gebruik dan hetzelfde wattenstaafje om het monster in het andere neusgat af te nemen.
3. Haal het wattenstaafje langzaam en met een draaiende beweging uit de neus. Het monster kan nu in het reageerbuisje worden gestopt en worden onderzocht.

**Polski**

## Przewodnik po pobieraniu próbek
## - Wymazy z nosogardzieli

**Sposób pobierania próbek z nosogardzieli:**

1. Odchylić głowę pacjenta w tył o 70 stropni. Delikatnie i powoli wsunąć wymaz do nosogardzieli, dostarczony z zestawem, przez nozdrze równolegle do podniebienia, aż do napotkania oporu.
2. Delikatnie pocierać i okręcać wymaz, a następnie pozostawić go na kilka sekund na miejscu, aby wchłonął wydzielinę. Jeśli skrzywiona przegroda lub zator powoduje trudności w uzyskaniu próbki z jednego nozdrza, należy użyć tego samego wymazu do uzyskania próbki z drugiego nozdrza.
3. Powoli wyjąć wymaz, obracając go. Próbka jest teraz gotowa do przygotowania przy użyciu probówek z buforem ekstrakcyjnym.

**Hrvatski**

## Vodič za prikupljanje uzoraka
## - Vatirani štapići za nazofarinks

**Kako prikupiti uzorak brisa iz nazofarinksa:**

1. Nagnite glavu pacijenta unazad, za 70 stupnjeva. Nježno i lagano uvlačite priloženi vatirani štapić za nazofarinks u nosnicu, paralelno s nepcem, sve dok ne osjetite otpor.
2. Lagano protrljajte i zakrenite vatirani štapić i ostavite ga na mjestu nekoliko sekundi kako bi upio sekret. Ako iskrivljeni septum ili zapušenost stvara poteškoće za dobivanje uzorka iz jedne nosnice, uporabite isti vatirani štapić kako biste uzeli uzorak iz druge nosnice.
3. Lagano izvucite vatirani štapić istodobno ga rotirajući. Uzorak je sad spreman za pripremu pomoću epruveta s puferom za ekstrakciju.

**العربية**

## دليل جمع العينات
## -المسحات البلعومية الأنفية

**كيفية جمع عينة مسحة البلعوم الأنفي: !**

1. قم بإمالة رأس المريض للخلف 70 درجة. ادخل المسحة البلعومية الأنفية برفق وببطء، المقدمة إليك في مجموعة أدواتك، من خلال فتحة الأنف بشكل موازي للحنك حتى تجد مقاومة.
2. حرك المسحة ولفها برفق، ثم اتركها في مكانها لعدة ثوانٍ لامتصاص الإفرازات. إذا تسبب الحاجز المنحرف أو الانسداد في صعوبة الحصول على العينة من إحدى فتحات الأنف، فاستخدم نفس المسحة للحصول على العينة من فتحة الأنف الأخرى.
3. قم بإزالة المسحة ببطء بينما تقوم بلفها. الآن أصبحت العينة جاهزة للتحضير باستخدام أنابيب الاستخراج العازلة.

**Slovenščina**

## Smernice za odvzem vzorcev
## - Nazofaringealni brisi

**Para obtener una muestra de hisopado nasofaríngeo:**

1. Nagnite glavo bolnika za 70 stopinj. Nežno in počasi vstavite nazofaringealni bris, ki je priložen kompletu, skozi nosnico vzporedno z nebom, dokler ne naletite na odpor.
2. Bris nežno podrgnite in zavrtite, tako da ostane nekaj sekund na mestu, da absorbira sekrecijo. Če odstopajoči septum ali blokada povzroča težave pri pridobivanju vzorca iz ene nosnice, uporabite isti bris, da vzamete vzorec iz druge nosnice.
3. Počasi odstranite bris, medtem ko ga vrtite. Vzorec je zdaj pripravljen za pripravo z uporabo ekstrakcijskih puferskih cevi.

Number: 1151279901
Effective Date: 2021-02-20

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

# Certificate

## No. Q5 042074 0031 Rev. 01

**Holder of Certificate:** **Acon Biotech (Hangzhou) Co., Ltd.**
No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District, 310030 Hangzhou,
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**


**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Test Kits and Related Instruments, Lancet and Lancing Device**

**Applied Standard(s):** EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

**Report No.:** SH1910622

**Valid from:** 2019-07-15
**Valid until:** 2022-07-14

**Date,** 2019-07-09

Stefan Preiß
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®



A4 / 07.17

# Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R. China, 310030

**We declare under our sole responsibility that the in vitro diagnostic device:**

Flowflex SARS-CoV-2 Antigen Rapid Test
REF No.:L031-11815
EAN code: 6921756492175 for Nasal swab
6921756492274 for Nasopharyngeal swab

**classified as Others according to the Annex II of the directive 98/79/EC, meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it**

**This declaration is according to Annex III (excluding Section 6) of the Directive.**

Authorized Representative:
MedNet GmbH
Borkstrasse 10
48163 Muenster, Germany

This Declaration of Conformity is valid until 25 May, 2022.

Signed this 28 day of 9, 2020
in Hangzhou, China

Junny You
International Regulatory Affairs Senior Director
ACON Biotech (Hangzhou) Co., Ltd.

ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030
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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
**Health Security and Vaccination**

# EU health preparedness:

# A common list of COVID-19 rapid antigen tests, including those of which their test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

*This document was agreed by the HSC on 17 February 2021*

*A first update to Annex II was agreed by the HSC on 19 March 2021*

*A first update to Annex I was agreed by the HSC on 10 May 2021*

# I. Introduction

Robust testing strategies are an essential aspect of preparedness and response to the COVID-19 pandemic, allowing for early detection of potentially infectious individuals and providing visibility on infection rates and transmission within communities. Moreover, they are a prerequisite to adequate contact tracing to limit the spread through prompt isolation. Also in the context of the circulation of SARS-CoV-2 variants of concern, surge testing in addition to existing testing deployment has proven to be key for controlling and suppressing further spread of the virus.

While the reverse transcription real-time polymerase chain reaction (RT-PCR) assay, which is a nucleic acid amplification test (NAAT) remains the 'gold standard' for COVID-19 diagnosis, new tests are rapidly entering the market, allowing faster and cheaper ways to detect ongoing infection. Rapid antigen tests, which detect the presence of viral proteins (antigens), are increasingly being used by Member States as a way of further strengthening countries' overall testing capacity, particularly in case of limited NAAT capacities or where prolonged testing turnaround times results in no clinical utility.

The Health Security Committee agreed on 17 September 2020 on Recommendations for a common EU testing approach for COVID-19[1], setting out various actions for consideration by countries when updating or adapting their testing strategies. The Recommendations included Member States' first experiences with rapid antigen tests and their deliberations concerning the settings and situations in which these tests should be used. Since then, the Committee has been discussing the use and application of rapid antigen tests in great depth, and has brought together a wealth of (technical) information on the types of tests used in European countries and the conditions applied.

On 21 January 2021, Member States unanimously agreed on a Council Recommendation setting a common framework for the use of rapid antigen tests and the mutual recognition of COVID-19 test results across the EU[2]. The Council Recommendation called on Member States to agree on three concrete deliverables:

1. **A common list of COVID-19 rapid antigen tests** that are considered appropriate for use in the context of the situations described in the Council Recommendation, that are in line with countries' testing strategies and that:
    a. carry CE marking;
    b. meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and
    c. have been validated by at least one Member State as being appropriate for their use in the context of COVID-19, providing details on the methodology and results of such studies, such as the sample type used for validation, the setting

[1] https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/common_testingapproach_covid-19_en.pdf
[2] https://data.consilium.europa.eu/doc/document/ST-5451-2021-INIT/en/pdf

in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

2. A selection of rapid antigen tests of which Member States will **mutually recognise the test results for public health measures**.
3. **A common standardised set of data to be included in COVID-19 test result certificates**, further facilitating the mutual recognition of COVID-19 test results.

Based on the information collected by the Health Security Committee, and taking into consideration the current epidemiological situation and the testing strategies and approaches that have been put in place across the EU, this document sets out the three deliverables as agreed by Member States. Its content is prepared based on the criteria set out in the Council Recommendation and considers the relevant recommendations published by the Commission[3] and technical guidance issued the European Centre for Disease Prevention and Control (ECDC)[4] and the World Health Organization (WHO)[5].

## II. Common list of rapid antigen tests

Point 11 of the Council Recommendation of 21 January 2021, calls on Member States to, without prejudice to Directive 98/79/EC, agree on and maintain a common and updated list of COVID-19 rapid antigen tests that are considered appropriate for use in the context of the situations described under point 6 and are in line with countries' testing strategies. Moreover, the antigen tests included in the list should:

(a) Carry CE marking;

(b) Meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and

(c) Have been validated by at least one Member State as being appropriate for their use in the context of COVID-19, providing details on the methodology and results of such studies, such as the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

This list should be shared with ECDC and the Commission to prevent duplication of work and to feed into ongoing initiatives, particularly the "COVID-19 In Vitro Diagnostic Devices and Test Methods Database[6], hosted by the Joint Research Centre (JRC). Annex I to this document sets out a common list of rapid antigen tests that meet the criteria as specified above. This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database. An update to Annex I was agreed by the Health Security Committee on 10 May 2021.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595 and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H1743&from=EN
[4] https://www.ecdc.europa.eu/en/publications-data/options-use-rapid-antigen-tests-covid-19-eueea-and-uk
[5] https://www.who.int/publications/i/item/9789240017740
[6] https://covid-19-diagnostics.jrc.ec.europa.eu/devices

The common list of rapid antigen tests is regularly being reviewed by Member States in the context of Health Security Committee meetings, and, if necessary, be updated in line with new results from independent validation studies becoming available and new tests entering the markets. These updates are also taking into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of NAAT, in particular RT-PCR assays, will also be kept under review.

## III. Rapid antigen tests of which the test results are mutually recognised

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will **mutually recognise the test results for public health measures**, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, those rapid antigen tests for which Member States agree that their results will be mutually recognised for public health measures, are highlighted in yellow in Annex I[7]. An update to Annex I, including the selection of tests of which their results are mutually recognised, was agreed by the Health Security Committee on 10 May 2021.

Whenever Member States will review the common list of rapid antigen tests and consider whether any tests should be added or deleted, they will also take into account – also based on new results from independent national validation studies - whether any rapid antigen tests should be removed from or added to the selection of rapid antigen tests of which their results are being mutually recognised. This information will be provided to the JRC, who will update its database accordingly.

## IV. Common standardised set of data for COVID-19 test certificates

In order to facilitate in practice the mutual recognition of results of rapid antigen tests as well as NAAT, including RT-PCR assays, point 18 of Council Recommendation 2020/1475 defines that Member States should agree on a common standardised set of data to be included in the form for test result certificates.

Based on information that was submitted by members of the Health Security Committee in response to a survey on mutual recognition on COVID-19 test results and further discussions that took place in the context of the Health Security Committee, Member States agree on the common standardised set of data for COVID-19 test result certificates as presented in Annex II. An update to this Annex was agreed by the Health Security Committee on 19 March 2021, addressing input received from the eHealth Network and in particular the Semantic Subgroup

[7] This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database.

and based on discussions that took place in the context of the EU Digital Green Certificate. Member States agree that COVID-19 test results should be made available in the national language(s) of the country where the test was taken, as well as English.

The Health Security Committee will discuss, whenever relevant, possible updates to the agreed common standardised set of data for COVID-19 test certificates, and publish, if necessary, an updated agreed document.

## V. Continuous discussions and further work on the common rapid antigen tests list and common dataset for COVID-19 test result certificates

As described in the sections above, the content of this document, as agreed by the Health Security Committee on 17 February 2021, will continue to be discussed by Member States and updated whenever deemed relevant. Whenever updates are required, these will be published as an update to this current document and/or as an update to the JRC COVID-19 In Vitro Diagnostic Devices and Test Methods Database, depending on scope of the update.

Based on the increasing political and commercial interest in the HSC agreed common rapid antigen test list, including those of which their results are mutually recognised by EU Member States, on 21 April 2021, the Commission and JRC presented to the HSC a new procedure for updating the lists. This includes setting up a HSC Technical Working Group on rapid antigen tests, who will play a key role in reviewing the information submitted by EU countries (as well as manufactures) on the use and performance of rapid antigen tests that are available on the market. Once established, the HSC Technical Working Group will, in particular, address the following points:

**Common RAT list**

- **Sampling methods to be used**

The current HSC agreed common list of rapid antigen tests includes tests for which their clinical performance was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens. Other rapid antigen tests exist that have been validated in EU Member States based on alternative samples, such as saliva, sputum and/or faeces. Further discussions are required to reach consensus on whether these tests should also be included in the HSC agreed common RAT list.

- **Harmonised methodology for national validation studies on the clinical performance of rapid antigen tests**

This will be addressed by future guidelines to be developed by the JRC and the ECDC, also taking into consideration the implementation guide published by WHO on 21 December 2020 on SARS-CoV-2 antigen-detecting rapid diagnostic tests[8] as well as the guidance that is being developed by the MDCG-IVD Working Group.

[8] https://www.who.int/publications/i/item/9789240017740

Moreover, Member States will continue sharing details via the HSC on the implementation of national validation studies, particularly concerning the validation methodologies and protocols applied.

- **Quality of data produced through independent validation studies**

It is key that the sensitivity levels of the rapid antigen tests, as reported by independent national validation studies, reflect clinical performance as measures in practice, rather than the sensitivity reported by the manufacturer. In this context, the JRC is planning to verify the science behind the validation data that has been made available from the Member States through the Health Security Committee, and to verify the findings (eventually in laboratory settings). For the validation of rapid antigen tests, the JRC plans to use the "gold standard" method of NAAT, in particular RT-PCR, by benchmarking the antigen test samples against qPCR and digital PCR.

Moreover, Member States will continue sharing details via the HSC on the results produced by national validation studies, particularly concerning the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

- **Occurrence of SARS-CoV-2 variants of concern**

Future updates to the common rapid antigen tests list should also take into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of RT-PCR tests should also be kept under review. In particular, in the current context of circulation of variants of concern, the use of rapid antigen tests does not allow samples to be used for subsequent detection of new variants (by NAAT and/or sequencing).

**Mutual recognition of COVID-19 test results**

- **Criteria to be used for the mutual recognition of rapid antigen test results**

At the moment, the extent to which rapid antigen tests are being used in practice by Member States differs greatly. In this context, Member States have agreed that, for now, the criterion that at least 3 Member States should be using a specific type of rapid antigen test in practice for it to be mutually recognised, applies. Member States will further discuss and explore whether other criteria should be used in the future. It is key that such discussions are held in the context of quality assurance measures.

- **Context in which mutual recognition should be applied**

Member States should further discuss the situation in which there is a need for mutual recognition of rapid antigen test results (as well as other COVID-19 test results). In addition to the context of travel, it is relevant to further discuss between countries when the list of rapid antigen tests of which their results will be mutually recognised should be applied.

## ANNEX I: Common list of rapid antigen tests[9]

As agreed by Member States on 17 February 2021 and updated on 10 May 2021

*The entries highlighted in yellow are the RATs of which Member States have agreed to mutually recognise their test results for public health measures*

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| AAZ-LMB | COVID-VIRO® Rapid antigen test COVID-19 | Yes | 96.1% sensitivity<br>100% specificity | **BE**:<br>96.6% sensitivity, 100% specificity, NP swab<br><br>**FR:**<br>>95%% sensitivity, 100% specificity<br><br>**SI**:<br>96.6% sensitivity, 100% specificity, NP swab | | BE, FR, SI | CH | FR<br>CH | | Yes<br>(1833) | Yes |
| Abbott Rapid Diagnostics | Panbio™ COVID-19 Ag Rapid Test | Yes | 91.4% sensitivity<br>99.8% specificity<br>Nasal/NP swab | **BE**:<br>93.3% sensitivity, 99.4% specificity, NP Swab<br>98.1% sensitivity, 99.8% specificity, Nasal swab<br><br>**DE**:<br>91.4% sensitivity 99.8% specificity, NP swab<br>98.1% sensitivity, 99,8 specificity, Nasal swab | FIND Evaluation - Studies in DE and CH, NP swab, 10 Dec 2020 | AT, BE, BG, CY, CZ, DE[2], DK, EE, EL, ES, FR[1], HR, IT, LT, LV, MT, NL[5], PL, PT, RO, SE, SK | CH, ME, MK, NO, UK, UA | DE[2], ES, NL[5]<br>CH, NO | CY, ES, HR, HU, IE, LU, PT, SE | Yes<br>(1232) | Yes |
| Acon Biotech (Hangzhou) Co., Ltd | Flowflex SARS-CoV-2 Antigen Rapid Test | Yes | 97.1% sensitivity<br>99.6% specificity<br>Nasal swab | **BE:**<br>96.9% sensitivity, 99.5% specificity, NP swab<br><br>**DE:**<br>97.1% sensitivity, 99.5% specificity, NP/Nasal swab | Ongoing | AT, BE, LT, LV, SI | | DE[2] | | Yes<br>(1468) | Yes |
| AESKU.DIAGNOSTICS GmbH & Co, KG | AESKU.RAPID SARS-CoV-2 | Yes | | **DE**:<br>96% sensitivity, 98% specificity<br><br>**SI**:<br>96% sensitivity, 98% specificity, Nasal swab | | AT, DE[2], SI | | DE[2] | | No | No |

[9] This is the list of RATs as referred to by the Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate), COM/2021/130 final, of 17 March 2021, which is currently being negotiated in the European Parliament and the Council. Member States shall issue and accept Digital Green Certificates based on this list (and subsequent updates).

[10] In case rapid antigen tests are not included in the JRC Database, manufacturers are invited to submit this information here: https://covid-19-diagnostics.jrc.ec.europa.eu/contact/feedback_ant.

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Affimedix | TestNOW® - COVID-19 Antigen | Yes | | **DE**:<br>93.7% sensitivity, 99.2% specificity | | DE[2] | | DE[2] | | No | No |
| AMEDA Labordiagnostik GmbH | AMP Rapid Test SARS-CoV-2 Ag | Yes | 97.3% sensitivity<br>100% specificity<br>NP swab<br><br>97.3% sensitivity<br>98.8% specificity<br>Nasal swab | **BE**:<br>97.3% sensitivity, 100% specificity, NP swab<br>**DE**: 97.3% sensitivity, 100% specificity<br>**SI**:<br>97.3% sensitivity, 100% specificity, NP swab | | AT, BE, BG, DE[2] HR, PT, SI | CH, UA | DE[2]<br>CH | HR | Yes<br>(1304) | Yes |
| AmonMed Xiamen Biotechnology Co., Ltd. | COVID-19 Antigen Rapid Test Kit (Collodial Gold) | Yes | 95.05% sensitivity<br>Nasal swab | **DE**:<br>98.02% sensitivity , 99.6% specificity | | DE[2] | | DE[2] | | Yes<br>(1763) | Yes |
| Anbio (Xiamen) Biotechnology Co., Ltd. | Rapid COVID-19 Antigen-Test (colloidal Gold) | Yes | 99.2% sensitivity<br>100% specificity | **DE**:<br>99.27% sensitivity, 100% specificity | | AT, DE[2] | | DE[2] | | Yes<br>(1822) | No |
| Anhui DeepBlue Medical Technology Co. Ltd | COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) | Yes | | **BE**: 95% sensitivity, 99% specificity, NP/OP swab<br>**DE**: 97.1% sensitivity, 99.8% specificity | | BE, DE[2] | UK | DE[2] | | Yes<br>(1589 or 1736) | Yes |
| ArcDia International Ltd | mariPOC SARS-CoV-2 | Yes | 92.3% sensitivity<br>100% specificity | **FI:** Meets the minimum performance requirements – see the report for details. | | FI | | FI | | No | Yes |
| Asan Pharmaceutical CO., LTD | Asan Easy Test COVID-19 Ag | Yes | 94.7% sensitivity<br>97.7% specificity | **DE**:<br>94.67% sensitivity, 97.71% specificity | | DE[2] | | DE[2] | | Yes<br>(1654) | Yes |
| Atlas-Link (Beijing) Technology Co. Ltd | NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) | Yes | | **DE**:<br>97.6% sensitivity, 99.2% specificity | | AT, DE[2] | CH | DE[2]<br>CH | | Yes<br>(2010) | Yes |
| AXIOM Gesellschaft für Diagnostica und Biochemica mbH | COVID-19 Antigen Rapid Test | Yes | | **DE**:<br>98.1% sensitivity, 100% specificity | | DE[2] | | DE[2] | | No | No |
| Azure Biotech, Inc. | Dia Sure COVID-19 Antigen Rapid Test Device | Yes | | **DE**:<br>94.3% sensitivity, 99.1% specificity | | DE[2] | | DE[2] | | No | No |
| Beijing Hotgen Biotech Co., Ltd. | Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) | Yes | 97.1% sensitivity<br>99.76% specificity | **BE**:<br>98.6% sensitivity, 100% specificity, NP Swab<br>97.3% sensitivity, 99.2% specificity. OP swab<br>**DE**:<br>95.37% sensitivity, 99.13% specificity<br>**SI**:<br>96.6% sensitivity, 99.8% specificity, NP swab | Validation study to start | AT, BE, DE[2], RO, SI | | DE[2] | | Yes<br>(1870) | No |

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Beijing Lepu Medical Technology | SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography) | Yes | 92% sensitivity<br>unknown specificity<br>Nasal swab | **BE**:<br>92% sensitivity, 99.3% specificity, Nasal<br>**DE**:<br>92.0% sensitivity, 99.26% specificity<br>**SI**:<br>92% sensitivity, 99.2% specificity, NP swab | | AT, BE, DE[2], SI, RO | UA | DE[2] | | Yes<br>(1331) | Yes |
| Beijing Wantai Biological Pharmacy Enterprise Co Ltd | WANTAI SARS-CoV-2 Ag Rapid Test (FIA) | Yes | 96.6% sensitivity,<br>unknown specificity<br>Nasal swab | **DE**:<br>96.6% sensitivity, 96.9% specificity | | DE[2] | | DE[2] | | Yes<br>(1484) | Yes |
| BIOSYNEX SWISS SA | BIOSYNEX COVID-19 Ag BSS | Yes | | **BE**:<br>96% sensitivity, 100% specificity, NP swab<br>**DE**:<br>96% sensitivity, 100% specificity | | AT, BE, DE[2], DK,FR, NL[5], PT | CH | DE, NL[5], CH | | Yes<br>(1223) | Yes |
| BTNX Inc. | Rapid Response COVID-19 Antigen Rapid Test Device | Yes | 94.55% sensitivity<br>100% specificity | **DE**:<br>94.55% sensitivity, 100% specificity | | AT, DE[2] | | DE[2] | | Yes<br>(1236) | No |
| CerTest Biotect S.L. | CerTest SARS-CoV-2 CARD TEST | Yes | 92.9% sensitivity<br>99.6% specificity<br>NP swab | **BE**:<br>92.9% sensitivity, 99.6% specificity, NP swab<br>**SI**:<br>92.9% sensitivity, 98.4% specificity, NP/OP swab | | ES, PT, SI | | ES | | Yes<br>(1173) | Yes |
| Core Technology Co., ltd | Canea Covid-19 Antigen Rapid Test | Yes | | **DE**:<br>97.5% sensitivity, 100% specificity | | DE[2] | | DE[2] | | No | No |
| Core Technology Co., ltd | Coretests COVID-19 Ag Test | Yes | 98.1% sensitivity | **DE**:<br>98.1% sensitivity, 99.6% specificity | | AT, DE[2], RO | | DE[2] | | Yes<br>(1786) | No |
| Dialab | DIAQUICK COVID -19 Ag Cassette | Yes | | **BE**:<br>Z20401CE: 93.2% sensitivity, 100% specificity, NP swab<br>Z20601CE: 96.4% sensitivity, 99.2% specificity, NP swab<br>**DE**:<br>97.3% sensitivity, 100% specificity | | AT, BE, DE[2] | | DE[2] | | Yes<br>(1375) | Yes |
| DDS DIAGNOSTIC | Test Rapid Covid-19 Antigen (tampon nazofaringian) | Yes | 98.77% sensitivity<br>99.03% specificity | **RO:**<br>Meets the minimum performance requirements. | | RO | | RO<br>China | RO | Yes<br>(1225) | No |

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| GenBody Inc | GenBody COVID-19 Ag Test | Yes | 90% sensitivity<br>98% specificity<br>NP/OP swab | **DE**:<br>90% sensitivity 98% specificity | Withdrawn | DE[2] | UA | DE[2] | | Yes<br>(1244) | Yes |
| GenSure Biotech Inc | Gensure COVID-19 Antigen Rapid Test Kit (REF: P2004) (DIA-COVID - 19 Ag Rapid Test) | Yes | | **DE**:<br>96.86% sensitivity, 100% specificity | | DE[2] | | DE[2] | | Yes<br>(1253) | Yes |
| Green Cross Medical Science Corp. | GENEDIA W COVID-19 Ag | Yes | | **BE**:<br>90.2% sensitivity, 100% specificity, NP swab<br>**DE**:<br>90.1% sensitivity, 100% specificity | | AT, BE, DE[2] | | DE[2] | | Yes<br>(1144) | Yes |
| Guangdong Hecin Scientific, Inc. | 2019-nCoV Antigen Test Kit (colloidal gold method) | Yes | 96.23% sensitivity<br>98.51% specificity<br>Nasal swab | **DE**:<br>96.6% sensitivity, 99.07% specificity | | AT, DE[2] | | DE[2] | | Yes<br>(1747) | No |
| Guangdong Wesail Biotech Co. Ltd | COVID-19 AG Test Kit | Yes | 90% sensitivity<br>98% specificity<br>NP/Nasal swab | **DE**:<br>90% sensitivity, 99.2% specificity<br>**SI**:<br>90% sensitivity, 98% specificity, NP/Nasal swab | | DE[2], SI | | DE[2] | | Yes<br>(1360) | No |
| Guangzhou Wondfo Biotech Co., Ltd | Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) | Yes | | **BE**:<br>96.2% sensitivity, 99.7% specificity, NP/OP swab<br>**DE**:<br>96.18 % sensitivity, 99.72% specificity | | AT, BE, BG, DE[2], FR | CH | DE[2] | | Yes<br>(1437) | Yes |
| Hangzhou AllTest Biotech Co., Ltd | ALL TEST Covid 19 Antigen- Rapidtest (Swab) | Yes | | **AT:**<br>96,4% sensitivity, 99,0% specificity, specimen type: NP; if N sens reduced to: 92,9% | | AT | | AT | AT | Yes<br>(1256) | Yes |
| Hangzhou Clongene Biotech Co., Ltd. | COVID-19 Antigen Rapid Test Kit | Yes | 98.5% sensitivity<br>unknown specificity<br>Nasal swab | **BE**:<br>91.4% sensitivity, 100% specificity, NP/OP swab<br>**DE**:<br>91.4% sensitivity, 99.4% specificity<br>**SI**:<br>91.4% sensitivity, 100% specificity, NP/OP swab | | AT,BE, DE[2], FR, SI | CH | DE[2]<br>CH | HR | Yes<br>(1363) | No |

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Hangzhou Clongene Biotech Co., Ltd. | COVID-19/Influenza A+B Antigen Combo Rapid Test | Yes | 91% sensitivity<br>100% specificity<br>NP swab | **DE**:<br>97.7% sensitivity, 99.8% specificity | | DE[2] | | DE[2] | | Yes<br>(1365) | Yes |
| Hangzhou Laihe Biotech Co. | LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) | Yes | | **DE**:<br>96.29% sensitivity, 100% specificity | | AT | CH | DE[2] | | Yes<br>(1215) | No |
| Hangzhou Lysun Biotechnology Co., Ltd. | COVID-19 antigen Rapid Test Device (Colloidal Gold) | Yes | | **DE**:<br>96.29% sensitivity, 100% specificity | | DE[2] | CH | DE[2] | | No | No |
| Hangzhou Testsea Biotechnology Co., Ltd. | Testsealabs Covid-19 Antigen Rapid Test Cassette | Yes | 92.1% sensitivity<br>98.1% specificity<br>Nasal swab | **DE**:<br>97.6% sensitivity 98.4% specificity | | DE[2] | | DE[2] | | Yes<br>(1392) | No |
| Hangzhou Immuno BiotechCo., Ltd | SARS-CoV2 Antigen Rapid Test | Yes | | **DE**:<br>95.6% sensitivity, 100% specificity | | AT, DE[2] | | DE[2] | | No | No |
| Hangzhou Immuno BiotechCo., Ltd | Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasiv) | Yes | 94% sensitivity<br>100% specificity<br>Nasal swab, NP | **DE**:<br>94.39% sensitivity 97.67% specificity | | DE[2] | | DE[2] | | Yes<br>(1844) | No |
| Healgen Scientific Limited | Coronavirus Ag Rapid Test Cassette (Swab) | Yes | | **DE**:<br>97.25% sensitivity, 100% specificity<br>**SI**:<br>96.7% sensitivity, 99.2% specificity, NP/Nasal swab | | AT, DE[2], NL[5], SE, SI | CH | DE[2], NL[5] | SE[3] | Yes<br>(1767) | No |
| Humasis Co. Ltd | HUMASIS COVID-19 Ag test | Yes | | **BE**:<br>95.5% sensitivity, 100% specificity, NP swab<br>**DE**:<br>95.5% sensitivity, 100% specificity<br>**SI**:<br>95.5% sensitivity, 100% specificity, NP swab | | AT, BE, BG, DE[2], FR, HR, SE, SI | | DE[2] | HR, SE | Yes<br>(1263) | Yes |
| Joinstar Biomedical Technology | COVID-19 Antigen Rapid Test (Colloidal Gold) | Yes | 96.1% sensitivity<br>98.1% specificity<br>Nasal swab | **DE**:<br>96.1% sensitivity, 98.1% specificity<br>**SI**:<br>96.1% sensitivity, 98.1% specificity, NP swab | | AT, DE[2], PT, SI | | DE[2] | | Yes<br>(1333) | Yes |
| JOYSBIO (Tianjin) Biotechnology Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography) | Yes | 98.13% sensitivity | **SI:**<br>Meets the minimum performance requirements – see the report for details. | FIND evaluation studies in CH 11 Feb 2021 | CZ, SI | | SI<br>CH | | Yes<br>(1764) | Yes |

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Labnovation Technologies Inc. | SARS-CoV-2 Antigen Rapid Test Kit | Yes | | **DE**:<br>96.3% sensitivity, 97.3% specificity<br>**SI**:<br>96.3% sensitivity, 97.3% specificity, NP/OP swab | | DE[2], SI | | DE[2] | | Yes<br>(1266) | Yes |
| Lumigenex (Suzhou) Co., Ltd | PocRoc SARS-Cov-2 Antigen Schnellnachweiskit (Gold kolloidal) | Yes | | **DE**:<br>93.33% sensitivity , 99.16% specificity | | DE[2] | | DE[2] | | No | No |
| LumiQuick Diagnostics Inc. | QuickProfile™ COVID-19 ANTIGEN Test | Yes | | **BE**:<br>94% sensitivity, 99% specificity, NP swab<br>**DE**:<br>93.7% sensitivity, 98.8% specificity<br>**SI**:<br>93.7% sensitivity, 98.8% specificity, NP swab | | BE, DE[2] ,FR, SI, | | DE[2] | | Yes<br>(1267) | Yes |
| LumiraDX UK LTd | LumiraDx SARS-CoV-2 Ag Test | Yes | 97.6% sensitivity<br>96.7% specificity<br>Nasal swab | **DE**:<br>93.8% sensitivity, 98.8% specificity<br>**SI**:<br>97.6% sensitivity, 97.7% specificity,<br>NP/Nasal swab | | DE[2], ES, SI | CH | DE[2], ES<br>CH | | Yes<br>(1268) | No |
| MEDsan GmbH | MEDsan® SARS-CoV-2 Antigen Rapid Test | Yes | 92.5% sensitivity<br>99.8% specificity<br>NP/OP swab | **BE**:<br>92.5% sensitivity, 99.8% specificity,<br>Nasal/OP swab<br>**DE**:<br>92.5% sensitivity, 99.8% specificity | | AT, BE, DE[2] | CH | DE[2]<br>CH | | Yes<br>(1180) | No |
| MöLab | COVID-19 Rapid Antigen Test | Yes | | **DE**:<br>97.25% sensitivity , 99.99% specificity | | DE[2] | | DE[2] | | Yes<br>(1190) | No |
| MP Biomedicals Germany | Rapid SARS-CoV-2 Antigen Test Card | Yes | 96.39% sensitivity<br>99.03% specificity<br>Nasal swab | **BE**:<br>96.4% sensitivity, 99% specificity, NP/OP swab<br>**DE:**<br>96.39 % sensitivity, 99.03% specificity | | AT, BE, DE[2] | CH | DE[2]<br>CH | | Yes<br>(1481) | Yes |
| nal von minden GmbH | NADAL COVID -19 Ag +Influenza A/B Test | Yes | | **DE**:<br>97.6% sensitivity, 99.9% specificity | | DE[2] | | DE[2] | | No | No |

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| nal von minden GmbH | NADAL COVID -19 Ag Test | Yes | 97.6% sensitivity<br>99.9% specificity<br>Nasal swab | **BE**: 97.6% sensitivity, 99.9% specificity, NP/OP swab<br>**DE**:97.6% sensitivity, 99.9% specificity<br>**SI**: 97.6% sensitivity, 99.9% specificity, NP/OP swab | FIND Evaluation studies 26 April 21 | AT, BE, DE[2], PT, SI | | DE[2], FR<br>China | HR | Yes<br>(1162) | No |
| NanoEntek | FREND Covid-19 Ag | Yes | 94.12% sensitivity<br>100% specificity<br>NP swab | **DE**:<br>94.12% sensitivity , 100% specificity | | DE[2] | | DE[2] | | Yes<br>(1420) | Yes |
| Oncosem Onkolojik Sistemler San. ve Tic. A.S. | CAT | Yes | 93.75% sensitivity<br>98.04% specificity<br>Nasal swab | **DE**:<br>96.36% sensitivity, 98.04% specificity | | DE[2] | | DE[2] | | Yes<br>(1199) | No |
| PCL Inc | PCL COVID19 Ag Rapid FIA | Yes | | **DE**:<br>94,92 % sensitivity, 99,99 % specificity<br>**SI**:<br>95.5% sensitivity, 98.6% specificity, NP/OP swab, sputum | | FR, DE, RO, SI | | DE[2] | | Yes<br>(308) | No |
| PerGrande Biotech Development Co., Ltd. | SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic assay) | Yes | | **DE**:<br>94.28% sensitivity, 99.11% specificity | | AT, DE[2] | | DE[2] | | No | No |
| Precision Biosensor Inc (Axon Lab SG) | Exdia COVI-19 Ag Test | Yes | 93.9% sensitivity<br>98% specificity<br>NP swab | **DE**:<br>93.88% sensitivity , 98% specificity<br>**SI**:93.9% sensitivity, 98% specificity, NP swab | | SI, DE[2] | CH | DE[2]<br>CH | | Yes<br>(1271) | Yes |
| Qingdao Hightop Biotech Co Ltd | SARS-CoV-2 Antigen Rapid Test | Yes | 95% sensitivity<br>unknown specificity<br>Nasal swab | **DE**:<br>95% sensitivity 99.75% specificity | | AT, DE[2] | | DE[2] | | Yes<br>(1341) | No |
| Quidel Corporation | Sofia 2 SARS Antigen FIA | Yes | 96.7% sensitivity<br>100% specificity<br>NP/Nasal swab | **BE**:<br>96.7% sensitivity, 100% specificity, NP/nasal swab<br>**DE**:<br>96.7% sensitivity , 100% specificity<br>**SI**:<br>96.7% sensitivity, 100% specificity, NP/Nasal swab | | AT, BE, DE[2], FI, NL[5], PT, SI | CH | DE[2], NL[5]<br>CH | SI | Yes<br>(1097) | Yes |

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Rapigen Inc. | BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test | Yes | 90.2% sensitivity<br>100% specificity<br>NP swab | **SI**:<br>90.2% sensitivity, 100% specificity, NP swab | | AT, RO, SK, FR, SI | | HU | PT | Yes<br>(1606) | Yes |
| Roche (SD BIOSENSOR) | SARS-CoV-2 Antigen Rapid Test | Yes | 96.52% sensitivity<br>99.2% specificity<br>NP | **DE**:<br>96.52% sensitivity, 99.68% specificity | | AT, DE[2], NL, RO | CH, NO | DE[2] | | Yes<br>(1604) | Yes |
| Safecare Biotech Hangzhou Co | COVID-19 Antigen Rapid Test Kit (Swab) | Yes | 97.04% sensitivity<br>unknown specificity<br>Nasal swab | **DE**:<br>97.27 % sensitivity , 99.42% specificity | | AT, DE[2], FR | CH | DE[2] | | Yes<br>(1489) | No |
| Safecare Biotech Hangzhou Co | Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19) | Yes | Sensitivity: 97.04% | **DE**:<br>97.04% sensitivity , 99.44% specificity | | DE[2] | | DE[2] | | Yes<br>(1490) | No |
| SD BIOSENSOR, Inc.; Roche | STANDARD F COVID-19 Ag FIA | Yes | 94,09% sensitivity<br>98.52% specificity | **BE**:<br>96.5% sensitivity, 99.7% specificity, NP swab<br>**DE**:<br>94% sensitivity 97% specificity | FIND Evaluation - Studies in DE and Brazil, 10 Dec 2020 | AT, BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK | CH | DE[2], IT, NL[5], DK<br>CH, UK, BR | LU, PT | Yes<br>(344) | Yes |
| SD BIOSENSOR, Inc.; Roche | STANDARD Q COVID-19 Ag Test | Yes | 96.52% sensitivity<br>99.68% specificity<br>NP swab | **BE**:<br>96.5% sensitivity, 99.7% specificity, NP swab<br>**DE**:<br>96.52% sensitivity, 99.68% specificity<br>**SI**:<br>96.5% sensitivity, 99.7% specificity, NP swab | FIND Evaluation - Studies in DE, CH and Brazil, 10 Dec 2020 | AT, BE, BG, CY, DE[2], DK, EE, ES, FI, FR, HR, IT, LU, LV, MT, NL[5], RO, SE, SK, SI | ME, NO, CH | DE[2], ES, IT, NL[5], DK<br>CH, UA, UK, BR | HR, IE, LU, SI, SE | Yes<br>(345) | Yes |
| SGA MÜHENDİSLİK DANIŞMANLIK EĞİTİM İÇ VE DIŞ TİC. A.Ş. | V-Chek SARS-CoV2- Rapid Ag Tets (Coloidal Gold) | Yes | 96.6% sensitivity,<br>Nasal swab | **DE**:<br>96.6% sensitivity, 99% specificity | | DE[2] | | DE[2] | | Yes<br>(1319) | No |
| Shenzen Ultra-Diagnostics Biotec Co. | SARS-COV-2 Antigen test Kit (colloidal gold) | Yes | | **BE**:<br>92% sensitivity, 100% specificity, NP swab<br>100% sensitivity, 100% specificity, OP swab<br>96% sensitivity, 100% specificity, Saliva<br>**SI**:<br>95.9% sensitivity, 99.9% specificity,<br>NP/OP/Nasal swab, saliva | | AT, BE, ES, SI | | BE, SI | | No | No |
| Shenzhen Lvshiyuan Biotechnology Co., Ltd. | Green Spring SARS-CoV-2-Antigen-Schnelltests-Set | Yes | | **DE**:<br>98% sensitivity , 100% specificity | | DE[2] | | DE[2] | | No | Yes |

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Shenzhen Watmind Medical Co., Ltd | SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold) | Yes | 95.15% Sensitivity<br>Nasal swab, Salvia | **DE**:<br>95.15% sensitivity , 99.12% specificity | | AT, DE[2], FR | | DE[2] | | Yes<br>(1769) | No |
| Shenzhen Zhenrui Biotech Co., Ltd | Zhenrui ®COVID-19 Antigen Test Cassette | Yes | 96% sensitivity<br>Nasal swab, Salvia | **DE**:<br>96% sensitivity 97% specificity | | DE[2] | | DE[2] | | Yes<br>(1574) | No |
| Siemens Healthineers | CLINITEST Rapid COVID-19 Antigen Test | Yes | 96.72% sensitivity<br>96.72% specificity<br>Nasal swab | **BE**:<br>98.32% sensitivity, 99.6% specificity, NP swab<br>97.25% sensitivity, 100% specificity, Nasal swab<br>**SI**:<br>96.7% sensitivity, 99.2% specificity, NP/Nasal swab | | AT, BE, DE[2], FR, HR, NL[5], PT, SE, SI | CH | DE[2], ES, NL[5] | HR, PT, SE[3] | Yes<br>(1218) | Yes |
| Sugentech, Inc. | SGTi-flex COVID-19 Ag | Yes | | **DE**:<br>95.1% sensitivity, 99% specificity | | AT, DE[2] | | DE[2] | | Yes<br>(1114) | No |
| TODA Pharma | TODA CORONADIAG Ag® | Yes | 98.6% sensitivity<br>unknown specificity<br>Nasal swab | **BE**:<br>96.6% sensitivity, 100% specificity, NP/OP swab<br>**DE**:<br>96.6% sensitivity, 100 specificity<br>**SI**:<br>96.6% sensitivity, 100% specificity, NP/OP swab | | BE, DE[2], SI | | DE[2] | | Yes<br>(1466) | No |
| Tody Laboratories Int. | Coronavirus (SARS-CoV 2) Antigen - Oral Fluid | Yes | 90.1% sensitivity<br>99.3% specificity | **RO**:<br>Meets the minimum performance requirements. | | RO | | ES<br>UA, China | RO | No | Yes |
| Vitrosens Biyoteknoloji Ltd. Şti. | RapidFor SARS-CoV-2 Ag Test Kit | Yes | 97.3% sensitivity<br>unknown specificity<br>Nasal swab, saliva | **DE**:<br>97.3% sensitivity, 99% specificity<br>**SI**:<br>97.3% sensitivity, 99% specificity, NP/OP/Nasal swab | | DE[2], SI | | DE[2] | | Yes<br>(1443) | Yes |
| VivaChek Biotech (Hangzhou) Co., Ltd. | VivaDiagTM Pro SARS-CoV-2 Ag Rapid Test | Yes | | **AT**:<br>97,06% sensitivity, 100% specificity, all specimen types, i.e. N&OP&NP swab | | AT | | AT | AT | Yes<br>(1246) | Yes |
| Wuhan EasyDiagnosis Biomedicine Co., Ltd. | Antigen-Testkit für COVID-19 (SARS-Cov-2) | Yes | | **DE**:<br>96.15% sensitivity , 99.26% specificity | | DE[2] | | DE[2] | | No | Yes |

| Manufacturer | RAT commercial name | CE marking | Clinical performance *Data by manufacturer* | Clinical performance *Data used in MS* | FIND evaluation studies | EU Member States using in practice | Other countries using in practice | Countries that have completed practical validation studies | MS currently validating | In JRC database (Device ID #)[10] | In FIND database |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Xiamen Boson Biotech Co | Rapid SARS-CoV-2 Antigen Test card | Yes | Not specified | **BE**:<br>93.8% sensitivity, 100% specificity, NP swab<br>**DE**:<br>96.49% sensitivity, 99.03% specificity | | AT, BE, BG, DE[2], FR, RO | CH | DE[2]<br>CH | | Yes<br>(1278) | Yes |
| Xiamen Wiz Biotech Co., Ltd. | SARS-CoV-2 Antigen Rapid Test | Yes | | **DE**:<br>96.3% sensitivity, 100% specificity | | AT, DE[2] | | DE[2] | | No | Yes |
| Xiamen Wiz Biotech Co., Ltd. | SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) | Yes | | **DE**:<br>95.91% sensitivity , 100% specificity | | AT, DE[2] | | DE[2] | | No | No |
| Zhejiang Anji Saianfu Biotech Co.., Ltd. | AndLucky COVID-19 Antigen Rapid Test | Yes | 95.8% sensitivity, Nasal swab, Saliva | **DE**:<br>97.5% sensitivity, 99.1% specificity | | AT, DE[2] | | DE[2] | | Yes<br>(1296) | No |
| Zhejiang Anji Saianfu Biotech Co.., Ltd. | reOpenTest COVID-19 Antigen Rapid Test | Yes | 95.8% sensitivity, Nasal swab, Saliva, Plasma | **DE**:<br>95.8% sensitivity, 99% specificity | | DE[2] | | DE[2] | | Yes<br>(1295) | No |
| Zhejiang Orient Gene Biotech Co., Ltd | Coronavirus Ag Rapid Test Cassette (Swab) | Yes | 96.72% sensitivity<br>unknown specificity<br>Nasal swab | **BE**:<br>98.32% sensitivity, 99.6% specificity, NP swab<br>97.25% sensitivity, 100% specificity, Nasal swab<br>**DE**:<br>96.72% sensitivity, 99.22% specificity | | AT, BE, BG, DE[2], PT | CH, UK | DE[2] | SE[3] | Yes<br>(1343) | No |

*Notes:*

[1] FR: Reference to validation study (not specifying which specific RAT is being recommended or was tested in practice): https://www.has-sante.fr/upload/docs/application/pdf/2020-10/synthese_tests_antigeniques_vd.pdf

[2] DE: Rapid antigen tests that have completed practical validation studies in Germany: See: https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?__blob=publicationFile&v=43

[3] SE: Smaller evaluations ongoing in some of the regions.

[4] BE: In the clinical performance study performed in three different clinical laboratories during the ascendant phase of the epidemiological curve, we found an overall sensitivity and specificity of 57.6 and 99.5%, respectively with an accuracy of 82.6%.

[5] NL: Collected validation data from accredited laboratories in the Netherlands. The report includes evaluations of various RAT that labs performed at their own initiative. https://lci.rivm.nl/antigeensneltesten

**ANNEX II:** Common standardised set of data to be included in COVID-19 test result certificates, as agreed by Member States on 17 February 2021 and updated on 19 March 2021

| Section | Data element | Description | Preferred Code System |
|---|---|---|---|
| **Person identification** | Person name | The legal name of the tested person.<br>Surname(s) and forename(s), in that order. | |
| | Person identifier<br>*(optional)* | An identifier of the tested person, according to the policies applicable in each country.<br>Examples: citizen ID and/or document number (ID-card/passport). | |
| | Person date of birth<br>*(optional)* | Tested person's date of birth.<br>Mandatory if no Person identifier is provided. | Complete date, without time, following the ISO 8601. |
| **Test information** | Disease or agent targeted | Specification that it concerns the detection of SARS-CoV-2 infection. | ICD-10, SNOMED CT |
| | Type of test | Description of the type of test that was conducted, e.g. NAAT or rapid antigen test. | LOINC, NPU |
| | Test name<br>*(optional for NAAT)* | Commercial or brand name of the test. | |
| | Test Manufacturer<br>*(optional for NAAT)* | Legal manufacturer of the test. | |
| | Sample origin<br>*(optional)* | The type of sample that was taken (e.g. nasopharyngeal swab, oropharyngeal swab, nasal swab, saliva). | SNOMED CT |
| | Date and time of the test sample collection | Date and time when the sample was collected. | Complete date, with time and time zone, following ISO 8601 |
| | Date and time of the test result production<br>*(optional)* | Date and time when the test result was produced. | Complete date, with time and time zone, following ISO 8601 |
| | Result of the test | For example, negative, positive, inconclusive or void. | SNOMED CT |
| | Testing centre or facility<br>*(mandatory for NAAT)* | Name/code of testing centre, facility or a health authority responsible for the testing event.<br>*Optional*: address of the testing facility. | |
| | Health Professional identification<br>*(optional)* | Name or health professional code responsible for conducting (and validating) the test.<br>Surname(s) and forename(s), in that order. | |
| | Country where the test was taken | The country in which the individual was tested. | ISO 3166 Country Codes |
| **Test certificate metadata** | Test result certificate issuer | Entity that issued the COVID-19 test result certificate (allowing to check the certificate). | |
| | Certificate identifier | Reference of the COVID-19 test result certificate (unique identifier). | |

**Risk Management Report**

CoV g-03-06

# SARS-CoV-2 Antigen Rapid Test

| Revision | Description | By | Date |
|---|---|---|---|
| A | Initial release | Diana Zheng | 2020.09.01 |
| | | | |
| | | | |
| | | | |
| | | | |

**Risk Management Report**

## Table of Contents

# Risk Management Report

## 1. Introduction

The SARS-CoV-2 Antigen Rapid Test is a qualitative detection based on lateral immunoassay for SARS-CoV-2 antigen.

## 2. Overview

This document provides a safety risk management for SARS-CoV-2 Antigen Rapid Test.

## 3. Intended Use/Purpose

1） Medical purpose:

Qualitative detection of SARS-CoV-2 antigen.

For professional in vitro diagnostic use only.

2）Part of the body, type of tissue applied to or interacted with, or sample type：

This product is intended to test nasal swab specimens.

3）Operator profile：

Read the package insert carefully before the test. No special training is required.

4）Application：

Add 4~5 drops (approximately 100~125 ul) samples onto the Specimen well of the test cassette, and then start the timer. Wait for the colored line(s) to appear. Read results at 15~20minutes. Allow the test, the specimen should reach room temperature (15-30℃) prior to testing.

## 4. Scope

This risk management report addresses the safety risks that may affect the patient or the operator as associated with the operation of the SARS-CoV-2 Antigen Rapid Test.

## 5. Software Safety Classification

There is no software related with this product.

## 6. Definitions:

### i. Severity Safety Classification:

| Severity Ranking | Severity Ranking (Descriptive) | S/W Safety Classification | Description |
|---|---|---|---|
| 1 | Negligible | Class A | Inconvenience or temporary discomfort; no injury to user / operator. |

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| | | | |
|---|---|---|---|
| 2 | Minor | Class B | Results in temporary injury or impairment to user / operator. Not requiring professional medical intervention. |
| 3 | Serious | Class C | Results in injury or impairment requiring professional medical intervention. |
| 4 | Critical | | Results in permanent impairment or life-threatening injury. |
| 5 | Catastrophic | | Results in patient death. |

### ii. Probability of Occurrence

| Severity Ranking | Likelihood | Description | Probability Range |
|---|---|---|---|
| 1 | Improbable | Almost impossible to occur | $< 10^{-6}$ |
| 2 | Remote | Unlikely to occur | $< 10^{-5}$ and $\geq 10^{-6}$ |
| 3 | Occasional | Unlikely but possible to occur sometime | $< 10^{-4}$ and $\geq 10^{-5}$ |
| 4 | Probable | Likely to occur | $< 10^{-3}$ and $\geq 10^{-4}$ |
| 5 | Frequent | Likely to occur several times | $> 10^{-3}$ |

### iii. Risk Assessment Table:

Risk Assessment

| Probability | Negligible | Minor | Serious | Critical | Catastrophic |
|---|---|---|---|---|---|
| Frequent | | | | | |
| Probable | | | | | |
| Occasional | | | | | |
| Remote | | | | | |
| Improbable | | | | | |

Severity

**Risk Management Report**

### iv. Risk Assessment Levels:

| Level | Risk Acceptability | Description |
|---|---|---|
| Grey | Unacceptable Risk | Risk in this region is not tolerated Resolution Required – Redesign, Do not release |
| Clear | Acceptable risk | Risk is considered to be negligible compared to the risk of other hazards. |

# Risk Management Report

## 7. Failure Mode and Effects Analysis Table:

For Risk analysis it is recommended to consider each of these potential sources of error, as applicable to the device, and also consider any other potential system failures that may be specific to the device.

| Potential source of Error | | | | Adverse effect | Risk Assessment before mitigation | | | Risk Control Measure/ Mitigation | Risk Assessment after mitigation | | | Supporting Documents (Risk control Measure/Risk Mitigation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Risk Definition | | | | Risk Definition | | | |
| Risk Factor | Possible Error | Cause | Hazard | | Severity | Probability of Occurrence | Risk Evaluation | | Severity | Probability of Occurrence | Risk Evaluation | |
| | Use of incorrect specimen type | Use of specimen other than nasal swab | Wrong test result | Misdiagnosis | Serious | Occasional | Unacceptable | Product labeling instruct user to use appropriate specimen type | Serious | Improbable | Acceptable | Package Insert |
| | Incorrect application of the specimen or buffer to the device | Insufficient specimen /buffer or too much specimen/buffer | Wrong test result | Misdiagnosis | Serious | Occasional | Unacceptable | 1.Product labeling instruct user to get enough specimen;<br>2.A control line is set to ensure enough specimen<br>3. Sample volume flex study was performed in validation study report | Serious | Improbable | Acceptable | Package Insert Validation Study Report, sample and buffer volume flex study |
| | | Incorrect placement specimen | Wrong test result | Misdiagnosis | Serious | Occasional | Unacceptable | Product labeling instruct user how to apply specimen | Serious | Improbable | Acceptable | Package Insert |

*Risk Management Report*

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Operator error/ Human factors** | Incorrect handling of reagents | Device pouch was opened for long time before test | Wrong test result | Misdiagnosis | Serious | Occasional | Unacceptable | Product labeling instruct user to use the test as soon as possible after the sealed pouch is opened | Serious | Improbable | Acceptable | Package Insert Validation Study Report, Open pouch study |
| | | Control swab pouch was opened for long time before test | Wrong test result | Misdiagnosis | Serious | Occasional | Unacceptable | Product labeling instruct user to use the test as soon as possible after the sealed pouch is opened | Serious | Improbable | Acceptable | Package Insert Validation Study Report, Open pouch study |
| | Incorrect placement of device | The device doesn't lay on a flat surface after specimen applying | Wrong test result | Misdiagnosis t | Serious | Probable | Unacceptable | Product labeling instruct user to lay the device on a flat surface before specimen applying | Serious | Improbable | Acceptable | Package Insert |
| | Incorrect timing of procedures | Read result before the time required | Wrong test result | Misdiagnosis | Serious | Occasional | Unacceptable | 1. Time flex study was performed<br>2. Product labeling instruct user to read the result at appropriate time interval | Serious | Improbable | Acceptable | Package Insert Validation Study Report, time flex study |
| | | Read result after the time required | Wrong test result | Misdiagnosis | Serious | Occasional | Unacceptable | 1. Time flex study was performed<br>2. Product labeling instruct user to read the result at appropriate time interval | Serious | Improbable | Acceptable | Package Insert Validation Study Report, time flex study |
| | Incorrect reading of test results | Confuse the control line and the test line | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to read the appropriate result. | Serious | Improbable | Acceptable | Package Insert |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Product labeling add the graphic result display. | | | | |
| | Incorrect reading due to color blindness | Lose sight of the low positive line | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to read the appropriate result. Product labeling add the graphic result display. | Serious | Improbable | Acceptable | Package Insert |
| | Use of polluted device or control swab | Reuse of device | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user not to reuse | Serious | Improbable | Acceptable | Package Insert |
| | | Reuse of control swab | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user not to reuse | Serious | Improbable | Acceptable | Package Insert |
| **Specimen Integrity and Handling** | Error in specimen handling | The swab is not swirled in the fluid | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to swirl the swab in the fluid | Serious | Improbable | Acceptable | Package Insert |
| | | The sample temperature doesn't reach to room temperature prior to testing | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to bring specimens to room temperature prior to testing | Serious | Improbable | Acceptable | Package Insert |
| | Use of inappropriate swab | swab interference | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to use the appointed swab | Serious | Improbable | Acceptable | package Insert |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Incorrect specimen transport and/or storage. | The specimen is not stored in appropriate temperature and time | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to store the specimen in appropriate temperature and time | Serious | Improbable | Acceptable | Package Insert Sample stability study |
| | Presence of interfering substances | The test is interfered by other antigens in specimen | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product design to eliminate the interference from other disease. | Serious | Improbable | Acceptable | Validation Study Report, cross reaction study |
| **Reagent integrity** | Use of Improperly Stored Test reagent | The test is damaged by high temperature | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to store the test in the appropriate temperature | Serious | Improbable | Acceptable | Package Insert Stability study |
| | | The test is damaged by high humidity | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product designed to packaged with a desiccant | Serious | Improbable | Acceptable | Package Insert |
| | Use of Outdated/ Expired reagents | The product is Outdated | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to run the test before the expiration date. | Serious | Improbable | Acceptable | Package Insert |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Environmental Factors** | Impact of key environmental factors (heat, humidity, barometric pressure changes, altitude (if applicable), sunlight, surface angle, device movement, etc.) on reagents, specimens, and test results. | The environmental temperature is too low or too high | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Product labeling instruct user to run the test in appropriate environmental temperature | Serious | Improbable | Acceptable | Validation Study Report, temperature flex study |
| Product package factors | Impact of pouch on testing results such as material and integrity, or impact of product appearance shape on pouch integrity | The product was damaged when transporting | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Shipping study was performed to validate the packaging | Serious | Improbable | Acceptable | Shipping study report |
| | | The desiccant is missing or disabled in the pouch | Wrong test result | Misdiagnosis | Serious | Probable | Unacceptable | Double check the desiccant in the manufacture.<br>Raw material inspection. | Serious | Improbable | Acceptable | C-0828 Packaging SOP |

Risk Management Report

## 8. Signature Page

**The Risk Management Plan has been effectively implemented for this device. The Risk Control Measures' effectiveness and verification methods have been reviewed and all hazards and risks have been reduced to acceptable levels.**

**Product Identification:** SARS-CoV-2 Antigen Rapid Test

**Team Leader:** Jianxi Kong

**Risk Analysis Team Membership** **Date:** 2020.09.09

**Attendees:**

| Printed Name | Signature | Department | Affiliation |
|---|---|---|---|
| Jordan Chen | Jordan Chen | MF | Acon bio |
| Sihong Zhang | Sihong Zhang | RC | Acon bio |
| Bryan Jiang | Bryan Jiang | Quality | Acon bio |
| Lily Tan | Lily Tan | Int'l RA | Acon bio |
| Daniel Tao | Daniel Tao | IP | Acon bio |
| Nancy | Nancy | MFT | Acon bio |
| | | | |
| | | | |
| | | | |
| | | | |

**Design Review Committee Disposition**

| Department | Recommend Approval | Printed Name | Signature | Date |
|---|---|---|---|---|
| R & D | [Y] Yes [ ] No [ ] Cond | Tao Shang | Tao Shang | 2020.09.09 |
| Manufacturing | [X] Yes [ ] No [ ] Cond | Winston Chen | Winston Chen | 2020.9.9 |
| QC | [X] Yes [ ] No [ ] Cond | Andy Xu | Andy Xu | 2020.9.9 |
| Regulatory | [X] Yes [ ] No [ ] Cond | Alyssa Lu | Alyssa Lu | 2020.9.11 |
| Marketing | [X] Yes [ ] No [ ] Cond | William Chang | William Chang | 2020.9.9 |

**Risk Analysis Report Final Disposition (The final disposition is ruled by majority vote of the Design Review Committee. This portion is filled out by the Regulatory representative.)**

☐ Approved

☐ Approved, but requires follow-up (see comments)

☐ Not approved, requires additional work (see comments)

Comments: _____

# SAFETY DATA SHEET

## SECTION 1: INDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

### 1.1 Product identifier

**Product name:** SARS-CoV-2 Antigen Rapid Test

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

**Relevant identified uses:**

The SARS-CoV-2 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal swab specimens. The SARS-CoV-2 Antigen Rapid Test is for professional in vitro diagnostics use only.

**Uses advised against:**

None.

### 1.3 Details of the supplier of the safety data sheet

**Manufacturer:**

Name: ACON Biotech (Hangzhou) Co., Ltd.

Address: No.210 Zhenzhong Road,
West Lake District, Hangzhou,
P.R. China, 310030

Phone: +86 571 87 96 35 69

E-mail: info@aconlabs.com

**Authorized Representative in the EU:**

Name: MedNet GmbH

Address: Borkstrasse 10
48163 Muenster, Germany

Phone: +49 251 32266-0

### 1.4 Emergency telephone number: +49 030/19240

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1 Classification of substance or mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

### 2.2 Label elements

The product does not need to be labelled according to Regulation (EC) No. 1272/2008.

### 2.3 Other Hazards

The product does not contain any substance that meet the criteria for PBT/vPvB according to Annex XIII of Regulation (EC) No. 1907/2006.

## SECTION 3: COMPOSITION /INFORMATION ON INGREDIENTS

### 3.1 Substance

Not Applicable.

### 3.2 Mixtures

#### 3.2.1 Hazardous ingredients in Test Cassette

As per the Regulation (EC) No 1907/2006, the cassette and control swab is defined as an "Article" for which an SDS is not legally required. Thus, no substance need to be listed in this Section.

#### 3.2.2 Hazardous ingredients in Buffer:

Extraction Buffer solution is accompanied with the SARS-CoV-2 Antigen Rapid Test in the kit box. Then concentration of the hazardous ingredients in the buffer is shown in below table:

| Components | CAS number | Concentration | Classification according to Regulation (EC) No. 1278/2008 (CLP) | Specific Concentration. Limits, M-factors |
|---|---|---|---|---|
| Sodium azide | 26628-22-8 | 0.02% | Acute Tox. 2 * (H300)<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410) | N/A |

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

**If INHALATION:** Move to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

**If SKIN Contact:** Take off immediately all contaminated clothing. Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.

**If EYE Contact:** Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.

**If INGESTION:** Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep airways free. Pulmonary failure possible after aspiration of vomit. Call a physician or Poison Control Center immediately.

### 4.2 Most important symptoms and effects, both acute and delayed

**Symptoms/effects after skin contact:** May cause skin irritation, corrosion and dermatitis. Drying-out effect resulting in rough and chapped skin.

**Symptoms/effects after eye contact:** May cause eye damage and corneal clouding.

**Symptoms/effects after ingestion:** May cause vomit.

### 4.3 Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Use water spray, dry chemical or carbon dioxide.

### 5.2 Special hazards arising from the substance or mixture

No data available.

### 5.3 Advice for firefighters

Wear protective eyewear, gloves and clothing. Ensure self-safety.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

Not applicable.

### 6.2 Environmental precautions

Dispose the tests as medical rubbish.

### 6.3 Methods and material for containment and cleaning up

Dispose the tests as medical rubbish.

### 6.4 Reference to other sections

None.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Wear suitable laboratory coat and gloves. Avoid contacting with skin, eyes and mucous membranes. Take care not to splash, spill or splatter the buffer. Do not eat, drink or smoke in laboratory areas. Do not pipette the buffer by mouth. Wash hands and remove contaminated clothing after use.

### 7.2 Conditions for safe storage, including any incompatibilities

Store in the sealed package either at room temperature or refrigerated (2-30℃) and keep out of direct sunlight to ensure the product quality.

### 7.3 Specific end use(s)

No specific uses.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### 8.1.1 Occupational Exposure Limit Values:

| **Substance:** | **Sodium azide** | | | | |
|---|---|---|---|---|---|
| **CAS No.** | **26628-22-8** | | | | |
| **Country** | **Limit Value-Eight hours** | | **Limit Value-Short term** | | **Legal basis** |
| | **ppm** | **mg/m$^3$** | **ppm** | **mg/m$^3$** | |
| Belgium | | 0.1 | | 0.3 | Data from GESTIS |

| | | | | | |
|---|---|---|---|---|---|
| Denmark | | 0.1 | | 0.2 | Database |
| European Union | | **0.1** | | **0.3 (1)** | |
| Finland | | 0.1 | | 0.3 (1) | |
| France | | **0.1** | | **0.3** | |
| Germany (AGS) | | 0.2 | | 0.4 (1) | |
| Germany (DFG) | | 0.2 inhalable aerosol | | 0.4 inhalable aerosol | |
| Hungary | | 0.1 | | 0.3 | |
| Ireland | | 0.1 | | 0.3 (1) | |
| Italy | | 0.1 | | 0.3 | |
| Latvia | | 0.1 | | 0.3 (1) | |
| Poland | | 0.1 | | 0.3 | |
| Spain | | 0.1 | | 0.3 | |
| Sweden | | | | 0.29 (1) | |
| Switzerland | | 0.2 inhalable aerosol | | 0.4 inhalable aerosol | |
| The Netherlands | | 0.1 | | 0.3 | |
| Turkey | | 0.1 | | 0.3 (1) | |
| United Kingdom | | 0.1 | | 0.3 | |

| | **Remarks** |
|---|---|
| European Union | Bold-type: Indicative Occupational Exposure Limit Values and Limit Values for Occupational Exposure Binding Occupational Exposure Limit Value - BOELV ~ (1) 15 minutes average value |
| Finland | (1) 15 minutes average value |
| France | Bold type: Restrictive statutory limit values |
| Germany (AGS) | (1) 15 minutes average value |
| Germany (DFG) | STV 15 minutes average value |
| Ireland | (1) 15 minutes reference period |
| Italy | skin |
| Latvia | (1) 15 minutes average value |
| Spain | Skin |
| Sweden | (1) Ceiling Limit value |
| Turkey | (1) 15 minutes average value |

**8.1.2 Biological Limit Values:**

No data available.

**8.1.3 Monitoring Methods:**

No data available.

### 8.2 Exposure controls

#### 8.2.1 Appropriate engineering controls:

Use with adequate ventilation.

#### 8.2.2 Personal protective equipment:

Use with adequate ventilation.

**Eye/face protection:** Not applicable.

**Skin protection:**

**Hand protection:** Not applicable.

**Body protection:** Not applicable.

**Respiratory protection:** Not applicable.

**Thermal hazards:** Not applicable.

#### 8.2.3 Environmental exposure controls:

Do not allow to enter into surface water or drains.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

The below data applies to the buffer solution:

| | |
|---|---|
| **Appearance** | colorless Liquid |
| **Odor** | odorless |
| **Odor threshold** | No data available |
| **pH** | 8.0~9.0 |
| **Melting point/freezing point** | No data available |
| **Initial boiling point and boiling range** | No data available |
| **Flash point** | No data available |
| **Evaporation rate** | No data available |
| **Flammability (solid, gas)** | No data available |
| **Upper/lower flammability or explosive limits** | No data available |
| **Vapor pressure** | No data available |
| **Vapor density** | No data available |
| **Relative density** | No data available |
| **Solubility (ies)** | No data available |
| **Partition coefficient: n-octanol/water** | No data available |
| **Auto-ignition temperature** | No data available |
| **Decomposition temperature** | No data available |
| **Viscosity** | No data available |
| **Explosive properties** | No data available |
| **Oxidising properties** | No data available |

### 9.2 Other information

No data available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

| Sodium azide (CAS No. 26628-22-8) | |
|---|---|
| Reaction | No data available. |

### 10.2 Chemical stability

No known instability under normal conditions of use or storage.

### 10.3 Possibility of hazardous reactions

No data available.

### 10.4 Conditions to avoid

Keep away from open flames, hot surfaces and sources of ignition. Avoid dust formation.

### 10.5 Incompatible material

Acids, Oxidizing agents, Peroxides, Acid chlorides, Metals.

### 10.6 Hazardous decomposition products

Nitrogen oxides (NOx), Sodium oxides, Carbon monoxide (CO), Carbon dioxide (CO2).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

**Acute toxicity**

| Sodium azide (CAS No. 26628-22-8) | |
|---|---|
| $LD_{50}$ Oral (Mouse) | 27 mg/kg |
| $LC_{50}$ Inhalation (Rats) | 0.054 and 0.52 mg/L |
| $LD_{50}$ Dermal (Rabbits) | 500-1000mg/kg |

**Skin corrosion/irritation** No data available.

**Serious eye damage/irritation** No data available.

**Respiratory or skin sensitization** No data available.

**Germ cell mutagenicity** No data available.

**Carcinogenicity** No component in this product is confirmed carcinogenicity by ACGIH, IARC, NTP or OSHA.

**Reproductive toxicity** Sodium azide has a drastically toxic effect on the in vitro growth of mouse embryos at concentrations of $10^{-4}$ mol/L in the petri dish or greater.

**STOT-single exposure** No data available.

**STOT-repeated exposure** No data available.

**Aspiration hazard** No data available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

| Sodium azide (CAS No. 26628-22-8) | |
|---|---|
| $LC_{50}$ (Fish 1) | 0.7 mg/L (96h, Lepomis macrochirus) |
| $LC_{50}$ (Fish 2) | 5.46 mg/L (96h, flow-through (Pimephales promelas) |
| $LC_{50}$ (Fish 3) | 0.8 mg/L (96h, Oncorhynchus mykiss) |

### 12.2 Persistence and degradability

| Sodium azide (CAS No. 26628-22-8) | |
|---|---|
| Persistence and degradability | Soluble in water Persistence is unlikely based on information available. |

### 12.3 Bioaccumulative potential

| Sodium azide (CAS No. 26628-22-8) | |
|---|---|
| Bioaccumulative potential | No data available. |

### 12.4 Mobility in soil

| Sodium azide (CAS No. 26628-22-8) | |
|---|---|
| Mobility in soil | Will likely be mobile in the environment due to its water solubility. |

### 12.5 Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be PBT or vPvB.

### 12.6 Other adverse effects

No data available

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

**Product**

Dispose as medical rubbish after being used

**Contaminated packaging**

Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product.

## SECTION 14: TRANSPORT INFORMATION

### 14.1 UN number

This product is not regulated for transport.

### 14.2 UN proper shipping name

This product is not regulated for transport.

### 14.3 Transport hazard class (es)

This product is not regulated for transport.

**14.4 Packing group**

This product is not regulated for transport.

**14.5 Environmental hazards**

No data available.

**14.6 Special precautions for user**

No data available.

**14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code**

No data available.

## SECTION 15: REGULATORY INFORMATION

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Not data available.

**15.2 Chemical safety assessment**

No data available.

## SECTION 16: OTHER INFORMATION

**16.1 Indication of Changes:**

Version 1 Revision 0: First version, document in accordance with requirements for safety data sheets introduced by Regulation (EC) No 1907/2006 (REACH).

Version 2 Revision 0: Correct the PH value from “8.0” to “8.0~9.0” in section 9.1.

Version 3 Revision 0: Update the Relevant identified uses in section 1.2 to add the specimen type of “nasopharyngeal swab”.

**16.2 Abbreviations and acronyms:**

Acute Tox. 2: Acute Toxicity, Category 2

Aquatic Acute 1: Hazard to the aquatic environment – Acute, category 1

Aquatic Chronic 1: Hazard to the aquatic environment – Chronic, category 1

PBT: Persistent, Bioaccumulative and Toxic;

vPvB: Very Persistent and Very Bioaccumulative

**16.3 Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No 1272/2008 (CLP):**

The product is not classified as a hazard mixture as per Regulation (EC) No 1272/2008 (CLP).

**16.4 Relevant H-statements (number and full text):**

H300 Fatal if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

**16.5 Further information**

This information is based upon the present state of our knowledge.

This SDS has been compiled and is solely intended for this product.

# Clinical Study Report
# for
# *Flowflex* SARS-CoV-2 Antigen Rapid Test

## I. Intend for Use

The Flowflex SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. The Flowflex SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

## II. Objective

A multi-site clinical study was conducted in China and USA to evaluate the performance of the Flowflex SARS-CoV-2 Antigen Rapid Test when compared to RT-PCR method.

## III. Clinical Study Site and Study Period

Clinical Study Sites in USA:

| Sample collection sites in USA | Testing sites in USA |
|---|---|
| Site 1:<br>Boca Raton<br>6877 SW 18th Street<br>Boca Raton, FL 33433 | Site 1:<br>Dr. Fowl<br>7200 Parkway drive,<br>Suite 117, La Mesa, CA91942 |
| Site 2:<br>COVID CLINIC<br>Westminster (WM)<br>2109 Westminster Mall<br>Westminster, CA 92683 | Site 2:<br>COVID CLINIC<br>Westminster (WM)<br>2109 Westminster Mall<br>Westminster, CA 92683 |
| Site 3:<br>COVID CLINIC<br>La Mesa (LM)<br>5601 Grossmont Center Drive<br>La Mesa, CA 91942 | Site 3:<br>COVID CLINIC<br>La Mesa (LM)<br>5601 Grossmont Center Drive<br>La Mesa, CA 91942 |
| Site 4:<br>COVID CLINIC<br>Down Town San Diego (DTSD)<br>1350 Third Avenue<br>San Diego - San Diego County | Site 4:<br>COVID CLINIC<br>Down Town San Diego (DTSD)<br>1350 Third Avenue<br>San Diego - San Diego County |

Clinical Study Sites in China:

| Sample collection sites in China | Testing sites in China |
|---|---|
| Site 1:<br>Shenzhen CDC<br>No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China | Site 1:<br>Shenzhen CDC<br>No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China |
| Site 2:<br>Adicon<br>No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China | Site 2:<br>Adicon<br>No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China |

Study Period

Study Initiation Date: September, 2020

Study Completion Date: December, 2020

## IV. Study acceptance criteria

Total Sensitivity: ≥85%

Total Specificity: ≥98%

## V. Study Procedure:

The clinical performance of the Flowflex SARS-CoV-2 Antigen Rapid Test was evaluated at four (4) investigational sites in U.S and two (2) investigational sites in China using a total of 605 nasal swab specimens collected from the patients at multiple sites in U.S and China.

### 5.1 Clinical Study in USA

**Material:**

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Comparison method:

TaqPath COVID-19 Combo Kit, FDA authorized RT-PCR test for emergency use, manufactured by Thermo Fisher Scientific, Inc.
CDC 2019-nCoV RT-PCR, ABI 7500DX, FDA authorized RT-PCR test for emergency use

- Nasal swab samples from infected patients and non-infected patients

**Procedure:**

A total of 153 nasal swab specimens were collected from the patients at multiple sites in U.S. The patients presenting the COVID-19 like symptoms within 14 days of symptom onset at the collection sites are enrolled.

The nasal swabs were randomized and blinded tested by operators following product package insert.

A companion nasopharyngeal (NP) swab was also collected from the same patient and confirmed as positive or negative and validated with Ct counts by the FDA EUA RT-PCR as a comparator method.

**Test results:**

| Candidate method | | RT-PCR method | | |
|---|---|---|---|---|
| | | Negative | Positive | Total |
| Flow*flex* Test Results | Negative | 52 | 3* | 55 |
| | Positive | 1 | 97 | 98 |
| | Total | 53 | 100 | 153 |

***3 samples with PCR CT value 32.9-33**
Relative Sensitivity: 97.0% (95% CI: 91.2%-99.4%)
Relative Specificity: 98.1% (95% CI: 89.1%-99.9%)
Accuracy: 97.4% (95% CI: 93.2%-99.2%)

## 5.2 Clinical Study in China

**Material:**

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), FDA authorized RT-PCR test for emergency use, manufactured by Sansure BioTech Inc.
- Nasal swab samples from infected patients and non-infected patients

**Procedure:**
A total of 452 nasal swab specimens were collected from the patients at multiple sites in China. The patients presenting the COVID-19 like symptoms within 14 days of symptom onset at the collection sites are enrolled.

The nasal swabs were randomized and blinded tested by operators following product package insert.

A companion nasopharyngeal (NP) swab was also collected from the same patient and confirmed as positive or negative and validated with Ct counts by the FDA EUA RT-PCR as a comparator method.

Also the RT-PCR test results were confirmed by the clinical diagnostic result. RT-PCR positive specimens were all from diagnosis of COVID-19 patients

and RT-PCR negative specimens were all from non COVID-19 patients.

**Test results:**

| Candidate method | | RT-PCR method | | |
|---|---|---|---|---|
| | | Negative | Positive | Total |
| Flow*flex* Test Results | Negative | 381 | 2* | 383 |
| | Positive | 1 | 68 | 69 |
| | Total | 382 | 70 | 452 |

***2 samples with PCR CT value 34-35**

Relative Sensitivity: 97.1% (95% CI: 89.6%-99.8%)

Relative Specificity: 99.7% (95% CI: 98.4%-99.9%)

Accuracy: 99.3% (95% CI: 98.0%-99.9%)

**5.3 Summary of combined clinical studies at all sites:**

| Candidate method | | RT-PCR method | | |
|---|---|---|---|---|
| | | Negative | Positive | Total |
| Flow*flex* Test Results | Negative | 433 | 5 | 438 |
| | Positive | 2 | 165 | 167 |
| | Total | 435 | 170 | 605 |

Relative Sensitivity: 97.1% (95% CI: 93.1%-98.9%)

Relative Specificity: 99.5% (95% CI: 98.2%-99.9%)

Accuracy: 98.8% (95% CI: 97.6%-99.5%)

**5.4 Positive results to be reported by different Ct value range**

| Ct value | RT-PCR Positive (+) | Proportion | Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+) | PPA |
|---|---|---|---|---|
| ≤27 | 86 | 50.6% | 86 | 100% |
| 27-30 | 38 | 22.4% | 38 | 100% |
| >30-33 | 29 | 17.1% | 27 | 93.1% |
| >33 | 9 | 5.3% | 6 | 66.7% |

Note: There are eight samples only have the PCR result of positive and no Ct value available.

Comparing with RT-PCR, the positive percent agreement (PPA) of the Flowflex SARS-CoV-2 Antigen Rapid Test is 100% for samples with Ct value ≤30, 93.1% for samples with Ct value from >30 to 33. For samples with Ct value >33, the PPA is 66.7%.

**5.5 Positive results to be reported by days since symptom onset**

| Days Since Symptom Onset | RT-PCR Positive (+) | Proportion | Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+) | PPA |
|---|---|---|---|---|
| 0-3 | 81 | 46.3% | 80 | 98.8% |
| 4-7 | 62 | 37.0% | 60 | 96.8% |
| >7 | 19 | 11.7% | 17 | 89.5% |

Note: There are four patients is asymptomatic individuals. And there are four patients lack "Days Since Symptom Onset" information.

Nasal swab specimens obtained early (≤7 days) after symptom onset may contain higher viral concentration.

**5.6 Patient Demographics**

| Age Group | Total | RT-PCR Positive (+) | Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+) | PPA |
|---|---|---|---|---|
| Children (Age < 18) | 13 | 12 | 11 | 91.7% |
| Adult (Age 18 to 60) | 565 | 132 | 128 | 97.0% |
| Elderly (Age ≥ 60) | 23 | 22 | 22 | 100% |

Note: There are four patients lack age information.

**VI. Conclusions:**

Using a total of 605 specimens tested at multiple sites in U.S and China, the Flowflex SARS-CoV-2 Antigen Rapid Test has sensitivity of 97.1%, specificity of 99.5%, and accuracy of 98.8% when comparing with FDA EUA RT-PCR.

*Clinical study data was collected from USA and China. Data analysis was performed by Azure Institute.

12/20/2020

Azure Institute
10125 Mesa Rim Road,
San Diego, CA 92130, USA

# Clinical Study Report
# for
# *Flowflex* SARS-CoV-2 Antigen Rapid Test

## I. Intend for Use

The Flowflex SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab and nasopharyngeal specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. The Flowflex SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

## II. Objective

A multi-site clinical study was conducted in China and USA to evaluate the performance of the Flowflex SARS-CoV-2 Antigen Rapid Test when compared to RT-PCR method.

## III. Clinical Study Site and Study Period

Clinical Study Sites in USA:

| Sample collection sites in USA | Testing sites in USA |
|---|---|
| Site 1:<br>Boca Raton<br>6877 SW 18th Street<br>Boca Raton, FL 33433 | Site 1:<br>Dr. Fowl<br>7200 Parkway drive,<br>Suite 117, La Mesa, CA91942 |
| Site 2:<br>COVID CLINIC<br>Westminster (WM)<br>2109 Westminster Mall<br>Westminster, CA 92683 | Site 2:<br>COVID CLINIC<br>Westminster (WM)<br>2109 Westminster Mall<br>Westminster, CA 92683 |
| Site 3:<br>COVID CLINIC<br>La Mesa (LM)<br>5601 Grossmont Center Drive<br>La Mesa, CA 91942 | Site 3:<br>COVID CLINIC<br>La Mesa (LM)<br>5601 Grossmont Center Drive<br>La Mesa, CA 91942 |
| Site 4:<br>COVID CLINIC<br>Down Town San Diego (DTSD)<br>1350 Third Avenue<br>San Diego - San Diego County | Site 4:<br>COVID CLINIC<br>Down Town San Diego (DTSD)<br>1350 Third Avenue<br>San Diego - San Diego County |
| Site 5:<br>Dr. Comunale's Office (DC) 502 | Site 5:<br>Dr. Comunale's Office (DC) 502 |

| | |
|---|---|
| Euclid Ave #205 National City, CA 91950 | Euclid Ave #205 National City, CA 91950 |
| Site 6:<br>Dr. Jonathan Leibowitz office<br>1343 55th street<br>Brooklyn, NY 11219 | Site 6:<br>Dr. Jonathan Leibowitz office<br>1343 55th street<br>Brooklyn, NY 11219 |
| Site 7:<br>Dr. Aline Benjamin office<br>624 Kings Highway<br>Brooklyn, NY 11223 | Site 7:<br>Dr. Aline Benjamin office<br>624 Kings Highway<br>Brooklyn, NY 11223 |

Clinical Study Sites in China:

| Sample collection sites in China | Testing sites in China |
|---|---|
| Site 1:<br>Shenzhen CDC<br>No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China | Site 1:<br>Shenzhen CDC<br>No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China |
| Site 2:<br>Adicon<br>No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China | Site 2:<br>Adicon<br>No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China |

Study Period

Study Initiation Date: September, 2020

Study Completion Date: May, 2021

## IV. Study acceptance criteria

Total Sensitivity: ≥85%

Total Specificity: ≥98%

## V. Study Procedure:

### 5.1 Procedure 1 for nasal swab specimens:

#### 5.1.1 Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001

- Comparison method:

TaqPath COVID-19 Combo Kit, FDA authorized RT-PCR test for emergency use, manufactured by Thermo Fisher Scientific, Inc.
CDC 2019-nCoV RT-PCR, ABI 7500DX, FDA authorized RT-PCR test for emergency use
RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), FDA authorized RT-PCR test for emergency use, manufactured by Sansure BioTech Inc.

- Nasal swab samples from infected patients and non-infected patients

**5.1.2 Procedure:**

A total of 882 nasal swab specimens were collected from the patients at multiple sites in USA and China. The patients presenting the COVID-19 like symptoms within 14 days of symptom onset at the collection sites are enrolled.

The nasal swabs were randomized and blinded tested by operators following product package insert.

A companion nasopharyngeal (NP) swab was also collected from the same patient and confirmed as positive or negative and validated with Ct counts by the FDA EUA RT-PCR as a comparator method.

**5.1.3 Test results:**

| Candidate method | | RT-PCR method | | |
|---|---|---|---|---|
| | | Negative | Positive | Total |
| Flow*flex* Test Results | Negative | 587 | 8 | 595 |
| | Positive | 3 | 284 | 287 |
| | Total | 590 | 292 | 882 |

Relative Sensitivity: 97.3% (95% CI: 94.6%-98.7%)
Relative Specificity: 99.5% (95% CI: 98.4%-99.9%)
Accuracy: 98.8% (95% CI: 97.8%-99.3%)

**5.1.4 Positive results to be reported by different Ct value range**

| Ct value | RT-PCR Positive (+) | Proportion | Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+) | PPA |
|---|---|---|---|---|
| ≤27 | 163 | 55.8% | 163 | 100% |
| 27-30 | 55 | 18.8% | 55 | 100% |
| >30-33 | 47 | 16.1% | 45 | 95.7% |
| >33 | 19 | 6.5% | 13 | 68.4% |

Note: There are eight samples only have the PCR result of positive and no Ct value available.

Comparing with RT-PCR, the positive percent agreement (PPA) of the Flowflex SARS-CoV-2 Antigen Rapid Test is 100% for samples with Ct value ≤30, 95.7% for samples with Ct value from >30 to 33. For samples with Ct value >33, the PPA is 68.4%.

### 5.1.5 Positive results to be reported by days since symptom onset

| Days Since Symptom Onset | RT-PCR Positive (+) | Proportion | Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+) | PPA |
|---|---|---|---|---|
| **0-3** | 152 | 52.1% | 150 | 98.7% |
| **4-7** | 87 | 29.8% | 85 | 97.7% |
| **>7** | 23 | 7.9% | 20 | 87.0% |
| **Asymptomatic individuals** | 11 | 3.8% | 10 | 90.9% |

Note: There are 19 patients lack "Days Since Symptom Onset" information.

Nasal swab specimens obtained early (≤7 days) after symptom onset may contain higher viral concentration. The SARS-CoV-2 Antigen Rapid Test can also test specimens from asymptomatic individuals.

## 5.2 Procedure 2 for nasopharyngeal swab specimens:

### 5.2.1 Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Comparison method:

  Hologic Panther SARS-CoV-2 (T000896), FDA authorized RT-PCR test for emergency use.

  RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), FDA authorized RT-PCR test for emergency use, manufactured by Sansure BioTech Inc.

- Nasopharyngeal swab specimens from infected patients and non-infected patients

### 5.2.2 Procedure:

A total of 299 nasopharyngeal swab specimens were collected from the patients at multiple sites in UAS and China. The patients presenting the

COVID-19 like symptoms within 14 days of symptom onset at the collection sites are enrolled.

The nasopharyngeal swabs were randomized and blinded tested with SARS-CoV-2 Antigen Rapid Test by operators following product package insert. And all the specimens were also confirmed with an EUA RT- PCR as a comparator method.

### 5.2.3 Test results:

| Candidate method | | RT-PCR method | | |
|---|---|---|---|---|
| | | Negative | Positive | Total |
| Flow*flex* Test Results | Negative | 175 | 3 | 178 |
| | Positive | 1 | 120 | 121 |
| | Total | 176 | 123 | 299 |

Relative Sensitivity: 97.6% (95% CI: 92.8% to 99.5%)
Relative Specificity: 99.4% (95% CI: 96.5% to 99.9%)
Accuracy: 98.7% (95% CI: 96.5% to 99.6%)

### 5.2.4 Positive results to be reported by different Ct value range

| Ct value | RT-PCR Positive (+) | Proportion | Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+) | PPA |
|---|---|---|---|---|
| ≤27 | 58 | 47.2% | 58 | 100% |
| >27-30 | 32 | 26.0% | 32 | 100% |
| >30-33 | 21 | 17.1% | 20 | 95.2% |
| >33 | 5 | 4.1% | 3 | 60% |

Note: There are 7 samples only have the PCR result of positive and no Ct value available.

Comparing with RT-PCR, the positive percent agreement (PPA) of the Flowflex SARS-CoV-2 Antigen Rapid Test is 100% for samples with Ct value ≤30, 95.2% for samples with Ct value from >30 to 33. For samples with Ct value >33, the PPA is 60%.

### 5.2.5 Positive results to be reported by days since symptom onset

| Days Since Symptom Onset | RT-PCR Positive (+) | Proportion | Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+) | PPA |
|---|---|---|---|---|
| 0-3 | 41 | 33.3% | 41 | 100% |
| 4-7 | 60 | 48.8% | 59 | 98.3% |

| | | | | |
|---|---|---|---|---|
| >7 | 12 | 9.6% | 10 | 83.3% |

Note: There are 10 patients lack "Days Since Symptom Onset" information. Specimens obtained early (≤7 days) after symptom onset may contain higher viral concentration.

**5.3 Summary of combined clinical studies at all sites and with two sample types (nasal and nasopharyngeal swab specimens):**

| Candidate method | | RT-PCR method | | |
|---|---|---|---|---|
| | | Negative | Positive | Total |
| Flow*flex* Test Results | Negative | 762 | 11 | 773 |
| | Positive | 4 | 404 | 408 |
| | Total | 766 | 415 | 1181 |

Relative Sensitivity: 97.4% (95% CI: 95.3% to 98.6%)
Relative Specificity: 99.5% (95% CI: 98.6% to 99.9%)
Accuracy: 98.7% (95% CI: 97.9% to 99.3%)

## VI. Conclusions:

Combine nasal swab specimens and nasopharyngeal swab specimens, a total of 1181 specimens tested at multiple sites in U.S and China, the Flowflex SARS-CoV-2 Antigen Rapid Test has sensitivity of 97.4%, specificity of 99.5%, and accuracy of 98.7% when comparing with FDA EUA RT-PCR.