# ZandCell COVID-19 Rapid Antigen Test

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**ZandCell Rapid Tests for the detection of Covid-19 infections during each phase of the disease: Reliable, fast, and cost-effective**

The golden standard by WHO for the diagnosis of Covid-19 infection is based upon a so-called PCR (polymerase chain reaction) method, multiplying the RNA of the virus obtained from mucous tissue in the nose or throat with a swab.
Although this method is direct, precise, and without interference from similar or totally different viruses, the processing is very time consuming, costly and requires skilled personnel and advanced laboratory equipment.

The more recently introduced antibody tests from fingerstick blood samples are rapid, within 10 min. But are less specific and or less sensitive, but most importantly this test can only detect the response to the virus several days after getting symptoms of the disease. On the other hand, response to antibody, IgG will last for several months at least. The antibody test is therefore a good instrument to monitor the development of the disease at a later stage.

In the Figure below the timeline of the disease and the corresponding response

## Test Value

### SARS-CoV-2 Ag

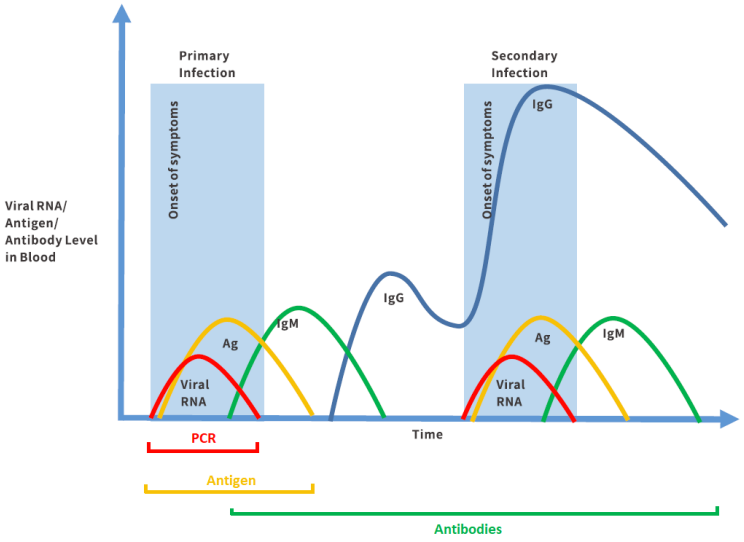
- A part of virus & earliest biomarker
- Direct proof of SARS-CoV-2 infection

### SARS-CoV-2 IgM

- The first antibody appeared in blood
- Detectable in 3-5 days after onset

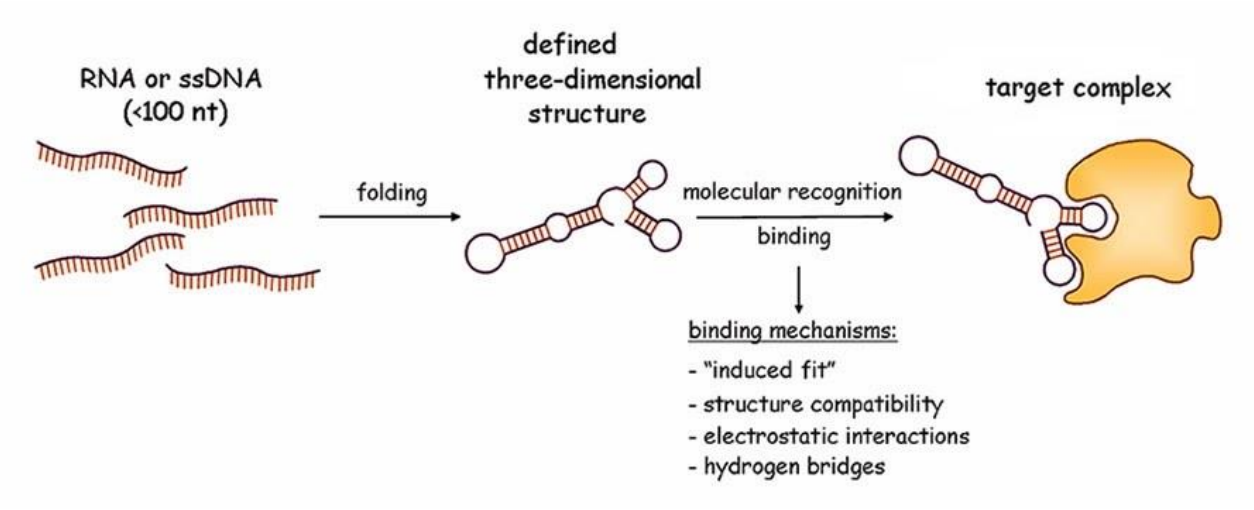
### SARS-CoV-2 IgG

- Most abundant part of total antibodies
- Enable to be detected most easily



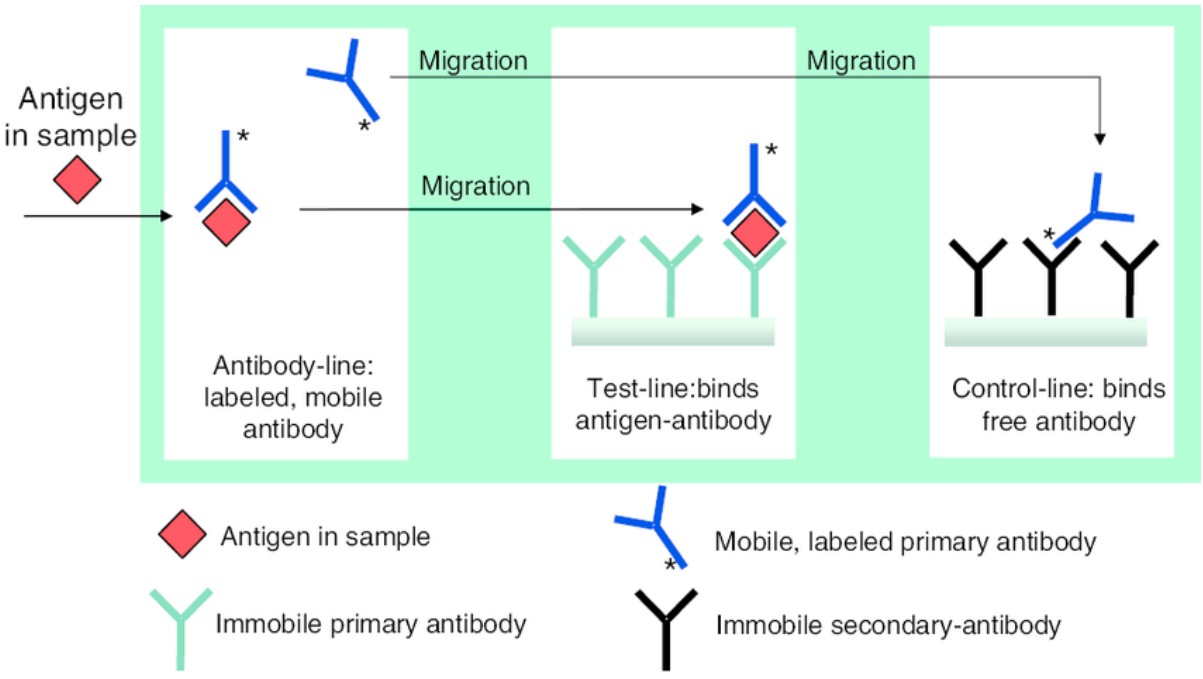
**ZandCell Covid-19 Rapid Antigen Test**

To combine the accuracy and sensitivity of the PCR method, with the speed of the antibody test, ZandCell has developed the antigen test.
The antigen test is based upon the binding with one of the "arms" of the virus into a " lock". The formed complex can be made visible with coloring techniques.




Quality Parameters ZandCell Covid-19 rapid Antigen Test:

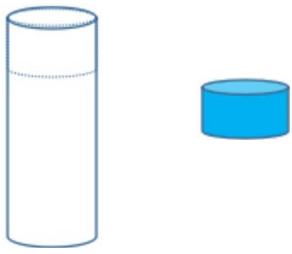
Detection limit: 4,3 viral particles per ml of saliva
Accuracy: 99.1%  Sensitivity: 98,1%  Specificity: 100%



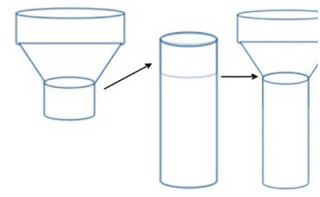

6 Tests
CE IVD
COVID-19 (SARS-CoV-2) Antigen Test Kit
(Hypersensitive Colloidal Gold)
For in vitro diagnostic use only
Store at 2°C to 30°C (36-86°F)
COVID-19
RAPID ANTIGEN TEST

# Saliva & Swabs test comparison for COVID-19

| | Saliva from Deep Throat | Nasal/throat swabs |
|---|---|---|
| **Test convenience** | Non-invasive<br>More convenience<br>Perform by self-test | Invasive<br>No convenience<br>Perform by medical personnel |
| **Accuracy** | More accuracy<br>Higher sensitivity | Less accuracy<br>Lower sensitivity |
| **Specimen homogeneity** | Better homogeneity<br>Closer to sputum with respiratory secretions | Less homogeneity<br>Depends on professional sampling with great changes |
| **SARS-CoV-2 in different specimens** | Detection positive rate:<br>1. Brochoalveolar lavage fluid (93%) > sputum, or deep throat saliva (72%) > nasal swabs (63%) > throat swabs (32%)<br>2. Deep throat saliva samples are non-invasive specimen with more viral load than swabs and more acceptable to patients and health-care workers. | |
| **References** | 1. Yokota I, Shane PY, Okada K, Unoki Y, Yang Y, Inao T, et al. Mass Screening of Asymptomatic Persons for SARS-CoV-2 Using Saliva. SSRN Electron J [Internet]. 2020 Aug 31 [cited 2020 Oct 19]; Available from: https://papers.ssrn.com/abstract=3668435<br>2. Wyllie AL, Fournier J, Casanovas-Massana A, Campbell M, Tokuyama M, Vijayakumar P, et al. Saliva is more sensitive for SARS-CoV-2 detection in COVID-19 patients than nasopharyngeal swabs. Camila Odio 8 [Internet]. 2020 Apr 22 [cited 2020 Oct 19];3:12. Available from: https://doi.org/10.1101/2020.04.16.20067835<br>3. Wyllie AL, Fournier J, Casanovas-Massana A, Campbell M, Tokuyama M, Vijayakumar P, et al. Saliva or nasopharyngeal swab specimens for detection of SARS-CoV-2 [Internet]. Vol. 383, New England Journal of Medicine. Massachussetts Medical Society; 2020 [cited 2020 Oct 19]. p. 1283–6. Available from: http://www.nejm.org/doi/10.1056/NEJMc2016359<br>4. To KKW, Tsang OTY, Leung WS, Tam AR, Wu TC, Lung DC, et al. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. Lancet Infect Dis. 2020 May 1;20(5):565–74.<br>5. Azzi L, Carcano G, Gianfagna F, Grossi P, Gasperina DD, Genoni A, et al. Saliva is a reliable tool to detect SARS-CoV-2. J Infect [Internet]. 2020 Jul 1 [cited 2020 Oct 19];81(1):e45–50. Available from: https://doi.org/10.1016/j.jinf.2020.04.005<br>6. Wang W, Xu Y, Gao R, Lu R, Han K, Wu G, et al. Detection of SARS-CoV-2 in Different Types of Clinical Specimens [Internet]. Vol. 323, JAMA - Journal of the American Medical Association. American Medical Association; 2020 [cited 2020 Oct 19]. p. 1843–4. Available from: https://jamanetwork.com/ | |



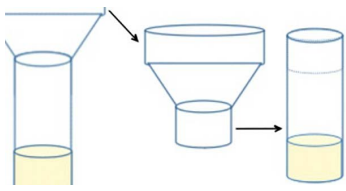
1. Open the cover of the sample tube



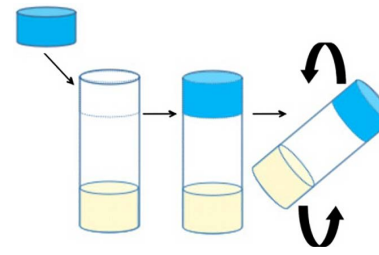
2. Screw on the salivary funnel


3. Make a <Kruuua> sound in the throat to clear saliva from the throat

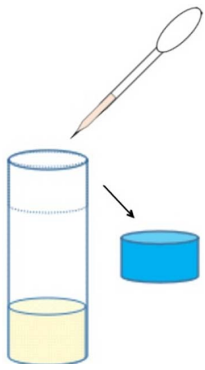

4. Collect saliva to 2 ml



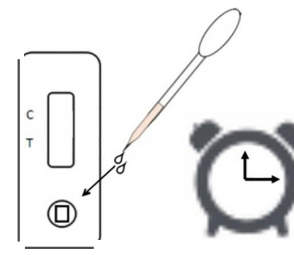
5. Remove the salivary funnel



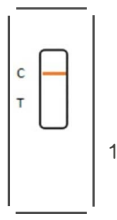
6. Cover and mix well upside down



7. Open the lid and suck a tube of liquid with a dropper

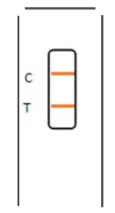



8. Add 2–3 drops into the sample hole and wait for 10–15 minutes for the result




9.

Figure 1: If only C line is shown, it is negative. There is no SARS-CoV-2 in saliva




10.

Figure 2: If both C and T lines are shown, it is positive. Saliva contains SARS-CoV-2

11. If there is no C line, no matter whether T line is shown, the reaction is invalid and needs to be retested

# Instructions for use

## ZandCell COVID-19 Antigen Test
## (hypersensitive colloidal gold)

**[Product Name]**
ZandCell COVID-19 Antigen Test (hypersensitive colloidal gold)
**[Model]**
One test per bag for one person, 6 tests/kit

**[Intended Use]**
This product is used for qualitative detection of coronavirus-19 antigen in saliva, sputum or nasopharyngeal swab samples.

**[Summary]**
Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is the N protein (nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses.

**[Principle]**
The kit works with the principle of antigen-antibody reaction and immunochromatography. The device includes monoclonal antibody 1 against sars-cov-2 surface protein labeled by hypersensitive colloidal gold; monoclonal antibody 2 against sars-cov-2 surface protein is coated at T line of reaction zone; Goat anti chicken antibody is coated at position of quality control line (C).
In the process of the test, when the level of coronavirus-19 in the sample reaches or exceeds the detection threshold, the antigen of coronavirus-19 in the sample binds with the monoclonal antibody 1 precoated on the gold pad. The conjugates migrated upward through capillary effect, and then bound to the coated mcab-2 at the T-line. If there is no coronavirus-19 in the sample, there will be no purple red band on the T line. No matter whether there is coronavirus-19 in the sample, purple red band will appear at the position of quality control line (C). The purplish red band of quality control line (C) can be used as the standard to judge whether the sample is sufficient and whether the chromatographic process is normal or not. It can also be used as the internal control standard of reagents.

**[Components]**
The products of different specifications contain one or six test cassettes, one instruction manual and 1ml sample diluent. Each kit contains a test cassette and a bag of desiccant, a set of saliva collector (including a saliva funnel and a collection tube containing 1 ml diluent), and a dropper.
The test cassette consists of gold label pad, sample pad, nitrocellulose membrane, absorbent paper, PVC board and plastic card.

**[Storage and Stability]**
It should be stored at 2℃~ 30℃, be kept dry and away from sunlight.
The shelf life is 18 months.
For per test, it should be used within 30 minutes after unsealing.
Production date and expiration date are shown in the package label.

**[Sample Requirements]**
The test cassette is suitable for detecting coronavirus-19 antigen in saliva, blood, sputum, feces, sewage, food, seafood, aerosol and other samples.
Samples should be used as soon as possible after collection and should not be stored for a long time at room temperature. If the sample can not be detected in time, the sample can be stored for 48 hours at 2 ℃ - 8 ℃. Long term storage should be frozen at - 20 ℃, avoid repeated freezing and thawing.

**[Test Method]**
Please read the instructions carefully before testing.
1. Open the aluminum foil bag of the test cassette, take out the test cassette, and mark the inspected person or sample number on the cassette. Use within 30 minutes, especially at room temperature above 30 ° C or high humidity, as soon as possible.
2. Put the kit on a clean platform, open the cover of the diluent tube, screw on the saliva funnel, and collect the saliva to 2ml; screw off the saliva funnel, cover it, turn upside down and mix well, then screw off the cover, suck a tube of liquid with a dropper, drop 2-3 drops into the sample hole, and start to count for 10-15 minutes.
3. Wait for the purple stripe to appear. The test results should be read within 10-15 minutes, after more than 15 minutes, the reading results are invalid.

**[The Explanation of the Testing Results]**
Positive (+): As Fig.1 showed, there should be purple-red bands in C and T areas ;
Negative (-): As Fig.2 showed, there should be purple-red band only in C areas.

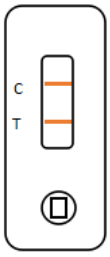


Figure 1 positive (+)

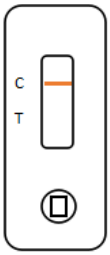


Figure 2 negative (-)

Invalid results: no matter whether there is purple red band at T line position, if there is no purple red band at quality control line (C), it indicates that the operation procedure is incorrect or the test kit has been invalid. In this case, you must read the instruction manual carefully, and then test again with a new test kit. If the problem persists, stop using this batch number and contact your local supplier immediately.

**[Limitation of Procedure]**
1. This reagent is a qualitative and preliminary screening

method, which can not determine the content of coronavirus-19 in saliva. This reagent provides only one preliminary analysis result, and a second analysis method must be used to determine the result.
2. The possible causes of negative results of this product include:
1) There is no virus in the sample, or the virus content in the sample is very low, which is lower than the critical detection concentration of reagent, and the low concentration sample cannot be detected.
2) The virus may have been inactivated in the sample. Although the nucleic acid fragment may still exist, the virus antigen may have been destroyed and inactivated.
3) Incorrect operation or other factors that may affect the detection, such as improper transportation and storage, leading to reagent failure.
3. When the epidemic degree of the disease decreases, the positive predictive value decreases, so the interpretation of positive results of low-risk population should be cautious.

**[Product Performance Index]**
1. Physical Property
1.1 Appearance
The test cassette should be clean and integral, no burrs, no damage, no pollution; the label should be clear and not damaged. The sample dilution should be clear without impurities and flocs.
1.2 Liquid migration speed
The liquid migration speed should be no less than 10mm/min.
1.3 Strip width
The membrane strip width of the testing strip should be≥2.5mm.
1.4 Sample dilution volume
The sample dilution volume should be no less than the indicated value.
2. Detection Limit
For the detection of the manufacturer's sensitivity reference materials, the results should meet its requirements.
3. Negative reference material compliance rate
For the detection of the manufacturer's negative reference materials, the negative detection rate should be 100%.
4. Positive reference material compliance rate
For the detection of the manufacturer's positive reference materials, the positive detection rate should be 98,1%.
5. Precision
For the detection of the manufacturer's precision reference materials, the results should all be positive and the color rendering should be uniform.
6. Analysis Specificity
6.1 Cross-reactivity: The test device has no cross reactivity with endemic human coronavirus OC43 antibody ⩽ $10^3$ cfu/ml, influenza A virus antibody⩽$5X10^4$ TCID50/0.1 ml, influenza B virus antibody⩽$2X10^5$ TCID50/0.1ml, respiratory syncytial virus antibody ⩽ 1 TCID50/0.1 ml, adenovirus antibody ⩽ 4.85 × $10^8$IFU/mL, EB virus antibody, measles virus antibody ⩽ 48.2Units/ml, cytomegalovirus antibody, rotavirus antibody, norovirus antibody⩽1.36g/$cm^3$, mumps virus antibody, varicella-zoster virus antibody, and mycoplasma pneumoniae antibody⩽ 5mg/(kg • d).
6.2 The test results do not be interfered with the substance at the following concentration: bilirubin concentration≤250μmol/L; triglycerides concentration ≤15mmol/L; hemoglobin concentration ≤10g/dL.
The test results do not be influenced by the following substance: α-interferon, zanamivir, ribavirin, oseltamivir, and paramivir, Lopinavir, ritonavir, abidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride (containing Preservatives), beclomethasone, dexamethasone, flunisolide, triamcinolone, budesonide, mometasone and fluticasone.

**[Precautions]**
1. Do not use expired products.
2. Do not freeze. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should be 15℃~30℃ and the humidity should be below 70%.
3. The package bag contains desiccant, and it should not be taking orally.
4. When testing, please wear protective clothing, gloves and eye shields.
5. Do not use the test cassette with broken single packaging, unclear marks, and past the expiration date.
6. Dispose of used specimens, test kit and other waste in accordance with relevant local laws and regulations.

**[References]**
1. Regulations on registration of IVD Reagents, October 1, 2014.
2. Guidelines for the Preparation of IVD Reagent Specifications, September 11, 2014
3. Guidelines for Technical Review of Pathogen specific M immunoglobulin Qualitative Detection Reagent Registration, May 17,2013.

**[Explanation of Symbols]**

| | | | |
|---|---|---|---|
| IVD | IN VITRO DIAGNOSTIC MEDICAL DEVICE | | CONSULT INSTRUCTIONS FOR USE |
| | EXPIRY DATE | | DO NOT REUSE |
| | DATE OF MANUFACTURER | | MANUFACTURER |
| 2℃-30℃ | TEMPERATURE LIMIT | LOT | BATCH CODE |
| EC REP | EC REPRESENTATIVE | CE | CE Symbol |

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EC REP ZandCell AB

CE

# *Declaration of Conformity*

*Regarding In Vitro Diagnostic Directive (98/79/EC)*

Manufacturer: ZandCell AB
Address: Locketorp Liden 2, 54191 Skövde, Sweden

European Representative:
Name: ZandCell AB
Address: Locketorp Liden 2, 54191 Skövde, Sweden

Product Name: ZandCell COVID-19 Rapid Antigen Test
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding point 6)
EDMA Code: 15 70 90 90 00

We, ZandCell AB, herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

## DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011

michael zand

Michael Zand – CEO ZandCell AB

Date: 11 September, 2020
ZandCell AB
Locketorp Liden 2
541 91 Skövde
Sweden

# Registreringsbekräftelse / Confirmation of registration

| | |
|---|---|
| Företagsnamn / Company name: | ZandCell AB |
| Organisationsnummer / Company registration number: | 5567021935 |
| Utdelningsadress / Address: | Locketorp Liden 2<br>54191 Skövde<br>Sverige |

**Registrering enligt förordning (EU) 2017/745 (MDR) om medicintekniska produkter, förordning (EU) 2017/746 (IVDR) om medicintekniska produkter för in vitro-diagnostik, Läkemedelsverkets föreskrifter (LVFS 2003:11) om medicintekniska produkter, Läkemedelsverkets föreskrifter (LVFS 2001:5) om aktiva medicintekniska produkter för implantation och/eller Läkemedelsverkets föreskrifter (LVFS 2001:7) om medicintekniska produkter för in vitro-diagnostik**

*ZandCell AB* intygar i och med att de registrerar sin verksamhet hos Läkemedelsverket att de fullgör sina skyldigheter i enlighet med tillämpliga krav i gällande förordning(ar)/föreskrift(er).

**Registreringen avser roll:** Tillverkare av CE-märkta produkter

**Registration according to Regulation (EU) 2017/745 (MDR) on medical devices, Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices, the Swedish Medical Products Agency's Regulations (LVFS 2003:11) on medical devices, the Swedish Medical Products Agency's Regulations (LVFS 2001:5) on active implantable medical devices and/or the Swedish Medical Products Agency's Regulations (LVFS 2001:7) on in vitro diagnostic medical devices**

*ZandCell AB* declares by registering their business at the Swedish Medical Products Agency that they fulfil their obligations in accordance with applicable requirements in existing Regulation(s).

**The registration relates to actor role:** Manufacturer of CE marked devices

# CE-märkta produkter / CE marked devices

| Produkttyp / Device type | Riskklass / Risk class | Antal produkter (antal unika UDI-DI) / Number of devices (number of unique UDI-DI) |
|---|---|---|
| In vitro diagnostic devices (d. Lgs. 332/2000) | IVDD generell | 2 |

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0) 18 17 46 00 Fax: +46 (0) 18 50 31 15
Webbplats: www.lakemedelsverket.se E-post: registrator@lakemedelsverket.se

# Clinical Study Report

## Performance of the ZandCell Rapid Antigen Test Covid-19 in comparison with PCR in a population of 102 subjects with confirmed, or suspected infection with SARS-CoV2 and healthy subjects

TEST Product: ZandCell rapid antigen test

Batch number LOT: 20200905 EXP 2022.02.17

Author: Dr. Michael Zand CEO

Signature:

Oct 13, 2020, final version

## Summary

The present study was undertaken to evaluate the performance of the ZandCell rapid antigen test for Covid-19 in comparison with PCR.

In this study 102 subjects were investigated after giving written informed consent.

30 subjects were healthy subjects without any symptoms, whereas 72 subjects had suspected disease as based on symptoms. In both study populations a sample for PCR and antigen was obtained from nasopharyngeal swab and saliva respectively, and samples were immediately processed.

Results were tabulated and sensitivity, specificity and positive and negative conformity, overall conformity were calculated, statistical methods included fourfold table.

Sensitivity was 98,1 %, specificity 100 %, pos conformity 98,1 %, neg conformity 100 %,

**The results of the present study confirmed that the ZandCell rapid antigen test is a highly reliable and convenient non-invasive method, to diagnose the absence and the presence of Covid-19 in a population of healthy subjects and patients with suspected diagnosis of SARS-CoV 2.**

## Objective

The objective of the present study is to investigate the performance of the ZandCell Rapid Antigen Test in a population of healthy subjects and patients with symptoms congruent with infection with SARS-CoV2 in comparison with PCR

Materials

ZandCell rapid antigen COVID -19 Test

Lot No : 20200905

PCR Roche standard method

Population

30 healthy subjects

70 suspected patients for infection with SARS-CoV2 based on clinical signs and symptoms

## Method

After giving written informed consent a nasopharyngeal swab was taken for PCR and processed according to standard methods. Simultaneously a saliva sample was obtained after a 30 min fasting. 2 ml saliva was obtained and spilled into a prepared tube containing one ml of buffer. 2 drops were after gentle mixing put on the cassette of the diagnostic device using a pipette and the result was read after 15 min.

## Results

The individual results are tabulated in appendix 1.

| | PCR | Antigen | conformity |
|---|---|---|---|
| Positive samples | 52 | 51* | 98.1 % |
| Negative samples | 50 | 50 | 100 % |
| Total | 102 | 101 | |

- 1 sample processing error

Based on those figures the sensitivity is 98,1 % and the specificity is 100 %.

Pos conformity is 98,1 %, the neg conformity 100 %, overall conformity 99.1 %

## Discussion and Conclusion

The results of the were obtained in a real-life situation from healthy subjects and patients with signs and symptoms of SARS-CoV2 infection. It is obvious that not all symptoms are specific for the mentioned virus but can also be a result from a common cold or influenza. Therefore, many test results in this group were negative with both methods.

The easiness of the saliva sampling technique was evident and no assistance of a medical qualified person would normally be needed. Saliva contains a high number of viral particles and is therefore considered superior to the nasal pharyngeal swab technology.

The PCR method using the nasopharyngeal technique to obtain sufficient viral material is usually painful and associated with discomfort.

The results of the antigen test were mimicking the PCR results almost completely. In early onset of the disease it is expected that RNA of the virus and antigen of the virus is present at the same time of the infection. This would mean that if the antigen test has a similar level of quantification, a similar result might be expected. The ultra-sensitive nanogold technology is obviously superior to the classical technology as competitors reach only a sensitivity in the order of 70-85 %. A drawback of both PCR and antigen method is that late and past infection as with the Antibody testing can't be detected. A combination of technologies might therefore be advisable to monitor the stage of the disease accurately.

**In conclusion, the ZandCell rapid antigen is a highly precise and accurate, non-invasive device for the detection of SARS-CoV2 in human saliva samples. It mimics the results closely of the golden standard PCR technique. The device can easily be operated and used by non-medically trained personnel and does not need a laboratory setting.**

## Literature

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Appendix I Individual data

| Subject number | PCR | Antigen |
|---|---|---|
| 1 | + | + |
| 2 | + | + |
| 3 | + | + |
| 4 | - | - |
| 5 | + | + |
| 6 | + | + |
| 7 | + | + |
| 8 | + | + |
| 9 | + | + |
| 10 | + | • Sample processing error |
| 11 | + | + |
| 12 | + | + |
| 13 | + | + |
| 14 | + | + |
| 15 | + | + |
| 16 | - | - |
| 17 | - | - |
| 18 | + | + |
| 19 | + | + |
| 20 | + | + |
| 21 | - | - |
| 22 | + | + |
| 23 | + | + |
| 24 | + | + |
| 25 | - | - |
| 26 | - | - |
| 27 | + | + |
| 28 | + | + |
| 29 | - | - |
| 30 | - | - |
| 31 | + | + |
| 32 | + | + |
| 33 | + | + |
| 34 | - | - |
| 35 | - | - |
| 36 | + | + |
| 37 | + | + |
| 38 | + | + |
| 39 | - | - |
| 40 | - | - |
| 41 | + | + |
| 42 | + | + |
| 43 | + | + |
| 44 | + | + |
| 45 | + | + |

| | | |
|---|---|---|
| 46 | + | + |
| 47 | + | + |
| 48 | + | + |
| 49 | - | - |
| 50 | - | - |
| 51 | - | - |
| 52 | + | + |
| 53 | + | + |
| 54 | + | + |
| 55 | - | - |
| 56 | + | + |
| 57 | + | + |
| 58 | + | + |
| 59 | + | + |
| 60 | + | + |
| 61 | + | + |
| 62 | - | - |
| 63 | - | - |
| 64 | + | + |
| 65 | + | + |
| 66 | + | + |
| 67 | + | + |
| 68 | + | + |
| 69 | + | + |
| 70 | + | + |
| 71 | - | - |
| 72 | - | - |
| 73 | - | - |
| 74 | - | - |
| 75 | - | - |
| 76 | - | - |
| 77 | - | - |
| 78 | - | - |
| 79 | - | - |
| 80 | - | - |
| 81 | - | - |
| 82 | - | - |
| 83 | - | - |
| 84 | - | - |
| 85 | - | - |
| 86 | - | - |
| 87 | - | - |
| 88 | - | - |
| 89 | - | - |
| 90 | - | - |
| 91 | - | - |
| 92 | - | - |
| 93 | - | - |
| 94 | - | - |
| 95 | - | - |

| | | |
|---|---|---|
| 96 | - | - |
| 97 | - | - |
| 98 | - | - |
| 99 | - | - |
| 100 | - | - |
| 101 | - | - |
| 102 | - | - |
| TOTAL 102 | ´TOTAL POSITIVE 52<br>TOTAL NEGATIVE 50 | TOTAL POSITIVE 51<br>TOTAL NEGATIVE 50 |

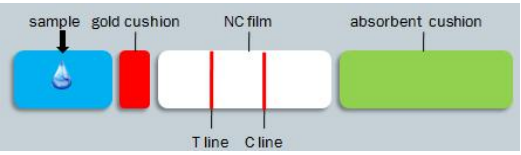
Numbers 1-72 patients with signs and symptoms

Numbers 73-102 healthy subjects

# Test Procedure and Result Analysis

ZandCell COVID-19 Rapid Antigen Test
Results Protocol and Interpretation

2-10 minutes User Protocol



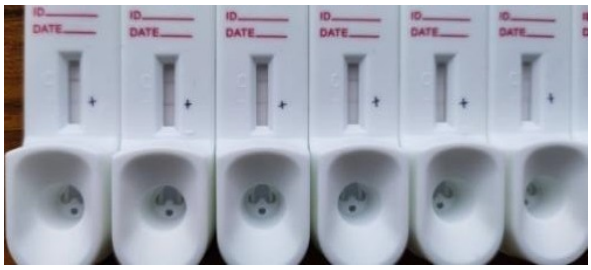

Simple Results Analysis

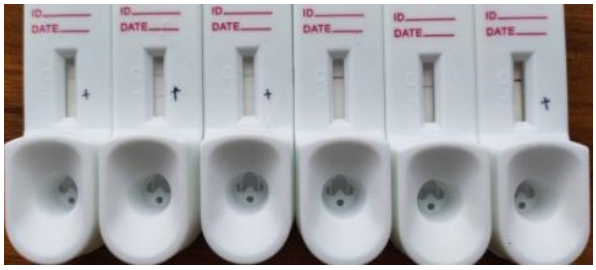
positive

negative

## Quality Standards

- 500 clinical samples for validation tests (saliva).
- Consistent quality with validations from different institutions.





## Performance

| | |
|---|---|
| Antigen Rapid Test | COVID-19 Antigen |
| Positive Coincident Rate | 91.70% |
| Negative Coincident Rate | 99.60% |
| Total Coincident Rate | 96.80% |

# Comparative Test Report

# ZandCell COVID-19 Rapid Antigen Test

# (Immunochromatographic)

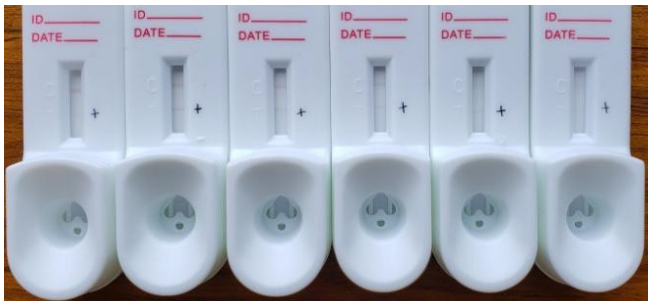
## 1. Method

In this trial, 500 clinical samples were selected. There were 181 positive samples and 319 negative samples.

The COVID-19 Antigen rapid test and the COVID-19 PCR test were detected simultaneously, and the positive coincidence rate, negative coincidence rate, and total coincidence rate were calculated.

## 2. Result

(1) 181 positive samples confirmed by Nucleic Acid Test have been tested by rapid COVID-19 Antigen rapid test, 166 samples were positive and 15 samples were negative (show a partial result).





(2) 319 negative samples confirmed by Nucleic Acid Test were tested by rapid COVID-19 Antigen rapid test, 318 samples were negative, 1 sample were positive (data not shown).

## 3. Analysis

(1) Results statistics table

| PCR Test | COVID-19 Antigen Rapid Test | | Total |
|---|---|---|---|
| | Positive | Negative | |
| Positive | 166 | 15 | 181 |
| Negative | 1 | 318 | 319 |
| Total | 167 | 333 | 500 |

(2) Analysis of coincidence rate of rapid COVID-19 Antigen rapid test and PCR test in saliva samples:

Positive coincidence rate = 166 / (166+15)x 100% = 91.7%

Negative coincidence rate = 318/(318+1)x 100% =99.6%

Total coincidence rate = (166+318)/500x 100% = 96.8%

## 4. Conclusion

Rapid COVID-19 Antigen rapid test and PCR test positive coincidence rate of 91.7%, negative coincidence rate of 99.6%, total coincidence rate of 96.8%.