ZandCell COVID-19 RapidAnti gen Test

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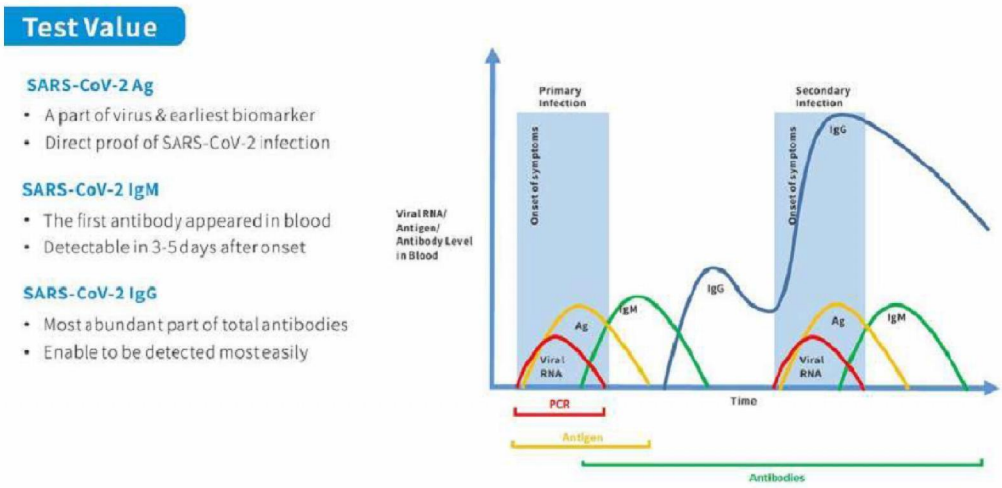
ZandCell Rapid Tests for the detection of Covid-19 infections during each phase of the disease: Reliable, fast, and cost-effective

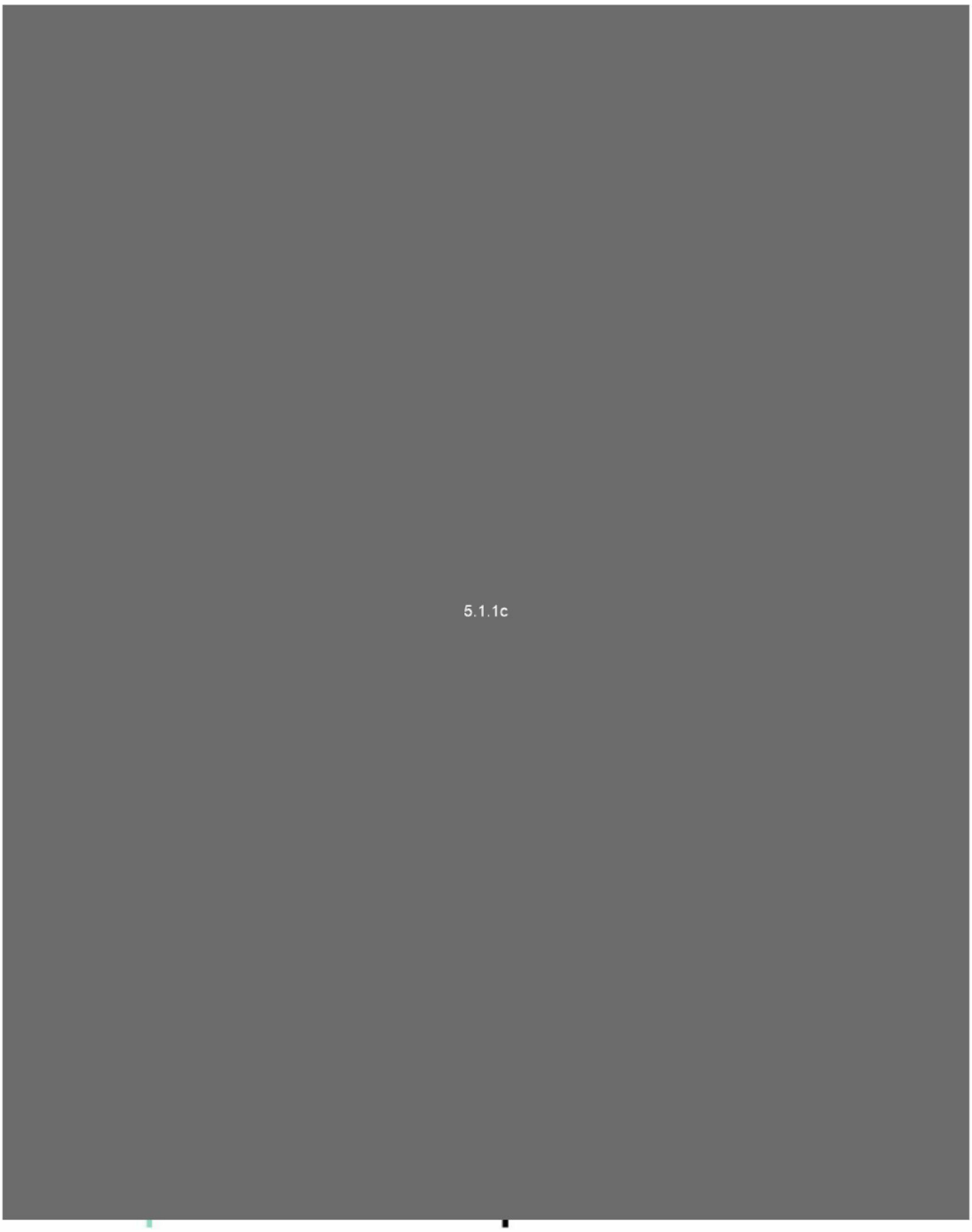
The golden standard by WHO for the diagnosis of Covid-19 infection is based upon a so-called PCR (polymerase chain reaction) method, multiplying the RNA of the virus obtained from mucous tissue in the nose or throat with a swab.
Although this method is direct, precise, and without interference from similar 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



ZandCell Covid-19 Rapid Antigen Test



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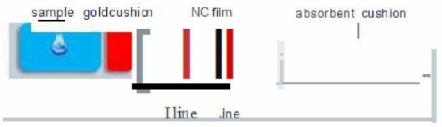
U E L L

Test Procedure and Result Analysis

ZandCell COVID-19 Rapid Antigen Test
Results Protocoland Interpretation

2-10 minutes User Protocol



Simple Results Analysis

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

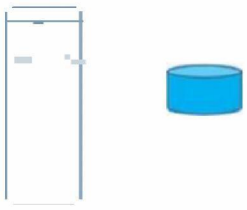
PCR Test	COVID-19 Antigen Rapid Test		Total
	Positive	Negative	
Positive	166	15	181
Negative	1	318	319
Total	167	333	500

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

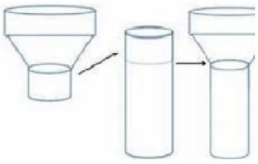
Positive coincidence rate= 166 / (166+15)x 100% = 91.7%Negative coincidence rate= 318/ (318+1)x 100% =99. 6%Total coincidence rate = (166+318)/500x 100% = 96. 8%

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%.



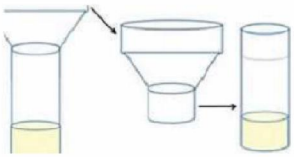
1. Open the cover of the sample tube



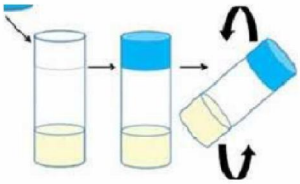
2. Screw on the salivary funnel

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

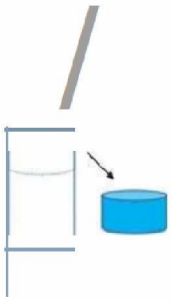
4. Collect saliva to 2 ml



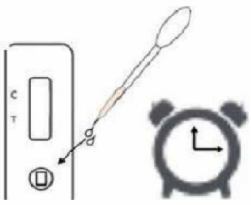
5. Remove the salivary funnel



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 2-10 minutes for the result

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

2020-09-14 Referensnummer: 5.1.1c

Registreringsbekraftelse/ Confirmation of registration

Foretagsnamn / Company name:	ZandCellAB
Organisationsnummer / Company registration number:	5567021935
Utdelningsadress/ Address:	Locketorp Liden 2 54191 Skovde Sverige

Registrering enligt forordning (EU) 2017/745 (MDR) om medicintekniska produkter, forordning (EU) 2017/746 (IVDR) om medicintekniska produkter for in vitro-diagnostik, Lakemedelsverkets foreskrifter (LVFS 2003:11) om medicintekniska produkter, Lakemedelsverkets foreskrifter (LVFS 2001:5) om aktiva medicintekniska produkter for implantation och/eller Lakemedelsverkets foreskrifter (LVFS 2001:7) om medicintekniska produkter for in vitro-diagnostik

ZandCell AB intygar i och med att de registrerar sin verksamhet hos Lakemedelsverket att de fullgor sina skyldigheter i enlighet med tillampliga krav i gallande forordning(ar)lforeskrift(er).

Registreringen avser roll: Tillverkare av CE-markta 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

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

2020-09-14 Referensnummer: 1599829169176

CE-markta produkter / CE marked devices

Prodokttyp / Device type	Riskklass / Risk class	Antal produkter (antal unika UDI-DI) / Number of devices (number of unique UDI-DI)
5.1.1c		

Verification

Transaction 09222115557434959905

Document

ZandCell COVID-19 Rapid Antigen Test - Package Public
Main document
11 pages
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5.1.2e
Finalised on 2020-09-18 11:16:18 CEST (+0200)

Signing parties

5.1.2e 5.1.2e

Signed 2020-09-18 11:16:18 CEST (+0200)

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