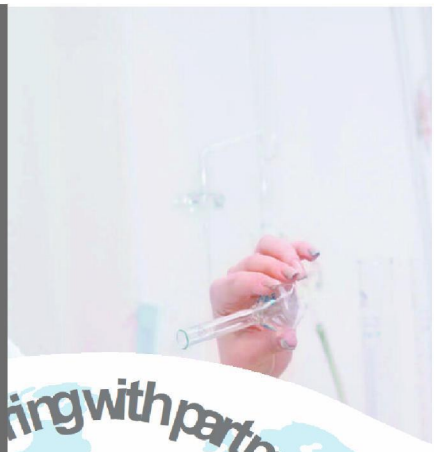
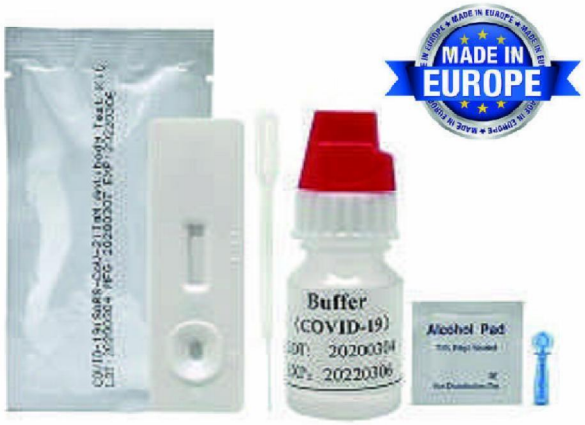
5.1.2e





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EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011,
EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

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Official representative and sales agency - Netherlands

Email: info@whatsmyn.com

Africa's main agent and distributor is STG1 UG on behalf of ZandCell LLC

www.stg1-ug.com info@stg1-ug.com

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ZandCell COVID-19 Rapid Test

TEST REPORT

Clinical Study Report of ZandCell COVID-19 Rapid Test

1. Purpose of the test

Through test on certain quantity of representative clinical specimens, and scientific and rational statistical analysis on the test result, evaluate the consistency of the result of COVID-19 Rapid Test produced by ZandCell LLC and compare with RT-PCR product, and evaluate its clinical application capacity.

2. Overall design of the test

The test of parallel contrast is adopted, and RT-PCR similar product which has been launched is taken as comparison device. The COVID-19 Rapid Test produced by ZandCell and the comparison device will parallel test on the same specimens, and the result will be recorded respectively.

3. Study method

Perform the clinical study by ZandCell COVID-19 Rapid Test, and compare with RT-PCR similar product. In this case, the **Roche LightCycler Model 1536** was used.

3.1 Specimens size and its confirmation basis

To investigate the function of product, a side-by-side comparison was conducted using The ZandCell COVID-19 Rapid Test and a commercially available RT-PCR. Testing was performed on 98 clinical specimens collected from subjects present for COVID-19 testing. Blood specimen was allowed to reach room temperature (15-30°C) prior to testing.

3.2 Selection of specimen

The samples were selected from medical institution. To protect the privacy of the specimen suppliers, the providers' name does not appear in the test record.

3.3 The selection of comparison device and confirmation method

RT-PCR product is selected as the comparison method, and the collection time information will be a supplementary explanation.

4. Clinical test result

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No.	Date of COVID-19 Rapid Test	COVID-19 Rapid Test Result Date	COVID-19 Rapid Test Result	PCR Collection Date	PCR Test Result Date	PCR Result
1	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
2	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
3	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
4	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
5	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
6	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
7	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Neg
8	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
9	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
10	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
11	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
12	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
13	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
14	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
15	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Neg
16	03.31.20	03.31.20	Pos	03.31.20	4.01.20	Pos
17	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
18	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Neg
19	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
20	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
21	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
22	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
23	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos

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24	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
25	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
26	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
27	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
28	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Neg
29	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
30	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
31	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
32	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
33	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
34	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
35	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
36	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
37	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
38	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
39	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
40	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
41	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
42	03.31.20	03.31.20	Neg	03.31.20	04.01.20	Pos
43	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
44	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
45	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Neg
46	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
47	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
48	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
49	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
50	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos

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51	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
52	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Neg
53	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
54	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
55	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
56	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
57	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
58	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
59	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
60	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
61	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
62	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
63	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
64	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
65	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
66	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
67	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
68	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
69	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
70	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
71	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
72	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
73	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
74	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
75	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
76	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
77	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Neg

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78	04.01.20	04.01.20	Neg	04.01.20	4.01.20	Neg
79	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
80	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
81	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
82	03.31.20	03.31.20	Neg	03.31.20	04.01.20	Neg
83	04.01.20	04.01.20	Neg	04.01.20	4.01.20	Neg
84	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
85	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
86	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
87	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
88	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
89	04.01.20	04.01.20	Neg	04.01.20	4.01.20	Neg
90	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
91	04.01.20	04.01.20	Neg	04.01.20	4.01.20	Neg
92	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos
93	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
94	03.31.20	03.31.20	Pos	03.31.20	04.01.20	Pos
95	03.30.20	03.30.20	Neg	03.30.20	04.01.20	Neg
96	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
97	04.01.20	04.01.20	Pos	04.01.20	4.01.20	Pos
98	03.30.20	03.30.20	Pos	03.30.20	04.01.20	Pos

-

4.1 Statistic analysis method of test result

This test will adept statistical analysis on pair enumeration data, and will record analysis in the form of fourfold table, see below:

Table 1 fourfold table for evaluating diagnostic tests

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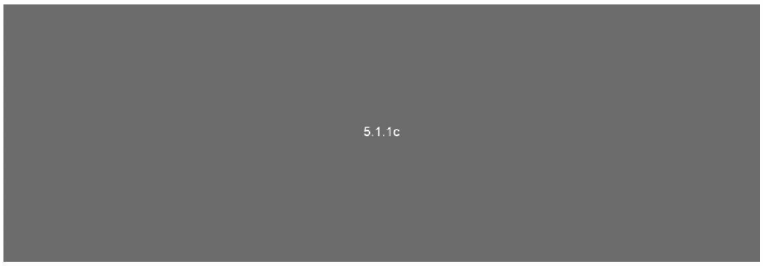
Method		PCR		Total results
ZandCell COVID-19 Rapid Test	Results	Positive	Negative	
	Positive	a	b	r1
	Negative	c	d	r2
Total results		C1	C2	N



4.2 Discussion and conclusion

Table 2 fourfold table for ZandCell COVID-19 Rapid Test result

Method		PCR		Total results
ZandCell COVID-19 Rapid Test	Results	Positive	Negative	
	Positive	72	6	78
	Negative	0	20	20
Total results		72	26	98

% Agreement	≥96%	>99.9%	>98%

Positive Agreement=100%
Negative Agreement=76.9%
Total Agreement= 93.9%
Kappa=0.83

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This clinical study has been conducted on altogether 98 specimens. The tests were parallel comparison studied with comparison device, the total conformity rate of the test result of the test and of PCR product for comparison is >96%.

This new rapid SARS-CoV-2 IgG-IgM combined antibody test kit has several advantages. Compared to RT-PCR, it saves time and it does not require equipment, it is simple to perform and only requires minimal training. It can be performed at the bedside, in any clinic or laboratory, or even outdoor screening clinics. Our initial test results using fingertip blood (Table 2) suggests that the SARS-CoV-2 IgG-IgM combined antibody test kits can be developed as agents for rapid field detection. Another potential application of this test is screening asymptomatic SARS-CoV-2 carriers, it was reported that asymptomatic carriers could spread SARS-CoV-2 virus. This finding made the current COVID-19 outbreak control more difficult, because there is no method available to screen asymptomatic carriers. This rapid IgM-IgG combined antibody test kit makes large scale screening of asymptomatic carriers possible. At least some if not all of the carriers are likely to have anti-SARS-CoV- 2 antibodies, as demonstrated by asymptomatic Zika virus carriers. Because this test can detect IgM and IgG simultaneously, it could be used for both early diagnosis (IgM) and for monitoring during treatment. SARS-CoV-2 infection starts at the lungs, not in the upper respiratory tract. therefore, sampling during the early infection stage using throat swab or sputum may not detect the virus. This is one possible explanation for high false negatives in nucleic acid PCR test. However, this sampling effect should not have any effect on IgM and IgG detection with this rapid test.

Conclusion

We developed a rapid SARS-CoV-2 IgG-IgM combined antibody test using lateral flow immune assay techniques. It takes less than 10 minutes to generate results and determine whether there is recent SARS-CoV-2 infection. It is easy to use, and no additional equipment is required. Results from this study demonstrated that this test is sensitive and specific. This rapid test has great potential benefit for the fast screening of SARS-CoV-2 infections, and it has already generated tremendous interest and increased clinical uses after being tested in the hospital setting.

Sign: 5.1.2e

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Greater El Monte Community Hospital – California. USA
Phone: +1 (949) 5.1.2e

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EC Declaration of Conformity

Manufacturer:
Name: ZandCell LLC
Address: 125 S King Street, Suite 2A, Jackson WY 83001, USA

European Representative:
Name: ZandCell AB
Address: Meteorvägen 15, 30235 Halmstad, Sweden

Product Name: ZandCell COVID-19 Rapid Test (Whole Blood/Serum/Plasma)

Model: Cassette
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex 111 (excluding point 6)
EDMA Code: 15 70 90 90 00

We, ZandCell LLC, 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 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

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ZandCell LLC
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USA
+1-702-425-9049

I, The undersigned, JONAS KENNE, Ass. Notary Public of the City of Skövde, Sweden, certify that

h oing document
F 2020-05-15

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Conformity Assessment Route: IVDD 98/79/EC Annex 111 (excluding point 6)
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Michael Zand – CEO ZandCell LLC.

ZandCell LLC
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I, The undersigned, JONAS KENNE, Ass. Notary Public of the City of Skövde, Sweden, certify that

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F…

2020-05-15

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(Convention de La Haye du 5 octobre 1961)

1. Country: SWEDEN
2. This public document has been signed by
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3. acting in the capacity of
NOTARY PUBLIC

Certified

4. at Skövde, Sweden 2020-05-15
6. by 5.1.2e
7 5.1.2e

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FDA U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

4/5/2020

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Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway
Suite 510(K)
Laguna Niguel, CA 92677
UNITED STATES

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

Submission Number: EUA200169
Received: 4/4/2020
Applicant: ZandCell, LLC
Device: ZandCell COVID-19 Rapid Test

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

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
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An overview of available tests for detection of coronavirus

Introduction

Since the outbreak of the Coronavirus end of 2019, it has been of utmost importance to detect as early as possible the virus in the human body. For this reason, a direct test has been developed on the basis of PCR technology, detecting specific genetic material of the virus. For this reason, this test was considered the golden standard until recently. Later also so-called antibody (immunoglobulin (Ig) tests became available, as the body's innate immune system reacts to a virus by producing antibodies very rapidly within hours, the so-called IgM antibodies. A later reaction is an IgG which remains elevated up to several years. In this presentation the various methods and supplies of the antibody tests will be discussed.

PCR Test

Since PCR detects genetic in the foundation of the virus, which is specific for a certain virus this test measures the presence of coronaviruses directly and is proof of the presence of the virus. A sample is usually taken by a swop from the nose mucosa or from saliva. Although the test is very reliable in case of a positive result, a problem associated with this method is the relatively low sensitivity. If not, sufficient virus is present in the swab sample, PCR is not able to detect this. This will lead to al false-negative result. During a mature infection, the number of the virus may increase and therefore, the PCR test may become positive during a longer period of infection. As soon as the virus leaves the body PCR test will be negative.

This means that it is not possible to detect with PCR if a patient would have had an infection

IgM/IgG Antibody test

After infection the early response in the body is the production of IgM antibodies. One late response IgG. To detect those antibodies a test using chromatography with references has been developed both IgG and IgM.
This test uses a drop of blood and is highly sensitive provided that the kits have adaptively been developed and validated. Early detection of infection will result in a test. IgG test, whereas data IgG will be positive only if response means early infection IgG+ IgM response means mature infection.

IgG response only means immunization. The patient has had an infection previously. This means that the so-called antibody test has several theoretical advantages:
High sensitivity (early detection)
High accuracy (no false pos) (false neg)
Knowledge about history of infection.
Compared with PCR, the high sensitivity and immunization status are key elements in favor of the AB test. The relatively low cost and simplicity add on this. (see Table 1. Comparison PCR/AB)
In the practice of all these advantages may be severely jeopardized by lack of adequacy of the test used.

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Shelf Life Statement

We, at ZandCell LLC, an organiza on legally cons uted under the laws of the United States of America, as the manufacturer of the product to be registered, declare that it has an es mated shelf life considered to be the following:

Product Descrip on	**Shelf Life**
ZandCell COVID-19 Rapid Test	24 months

The ZandCell COVID-19 Rapid Test shelf life is determined base don tes ng demonstra ng the product meets its specifica on and intended use a er accelerated shelf life, supplemented by real- me shelf life.

According to the features of the medical device the useful life of the device depends on several factors including but not limited to the package integrity as well as an appropriate and suitable use according to the instruc ons for use provided with the product.

Declared by:

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1,2 5.1.2e 5.1.2e

March 1, 2020

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ZandCell COVID-19 Rapid Test Components

The reagent components included in the cassette kit information and the number of each component included in the cassette kit:

Cassette kit Components	Capture Reagents Components	Number of bottle/vials and Volume per container
Test cassette with test strip Negative control Positive control	Goat Anti-mouse IgG Anti-human IgM + Anti-human IgG	1
Sample Buffer (bottle)		1
Transfer Pipettes		1
Lancet (for fingerstick only)		1
Package inserts		1

Materials required by not provided:

Specimen collec[illegible]n containers
Capillary tubes
Centrifuge (for plasma only)
Timer
Pipe[illegible]e

Declared by:

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5.1.2e 5.1.2e

March 1, 2020

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MOVEMENT CERTIFICATE

1. Exporter (Name, full address, country) ZandCell AB Locketorp Liden 2 54191 Skövde Sweden	2020-06-05
3. Consignee (Name, full address, country) (Optional)	**2.** Certificate used in preferential trade between The European Community and USA (Insert appropriate countries, groups of countries or territories)
	4. Country, group of countries or territory in which the products are considered as originating: European Community **5.** Country, group of countries or territory of destination: USA
6. Transport details (Optional)	7. Remarks

8. Item number; Marks and numbers; Number and kind of packages (1); Description of goods	9. Gross weight (kg) or other measure (litres, m³, etc.)	10. Invoices (Optional)
ZandCell COVID-19 Rapid Test - box containing 10, 20 25, 50 or 100 tests		

Stamp 5.1.2e	**11. DECLARATION BY THE EXPORTER** I, the undersigned, declare that the goods described above meet the conditions required for the issue of this certificate. Stockholm, June 5, 2020 5.1.2e (Signature)