Cellex

Catalog Number：5513C

In Vitro Diagnostic

INTENDED USE

The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow immunoassay for qualitative detection of antibodies to 2019 novel coronavirus (SARS-CoV-2) in serum、plasma or whole blood specimens. It is intended to be used as an aid in the diagnosis of SARS-CoV-2 viral infections. Any reactive specimen with the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test must be confirmed with alternative testing method(s).

For prescription use only. For in vitro diagnostic use only. For emergency use, authorization use only.

SUMMARY AND EXPLANATION OF THE TEST

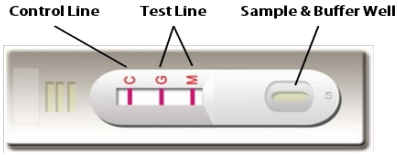
Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). SARS-CoV-2 is a new strain that has not been previously identified in humans. Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Detailed investigations found that SARS-CoV was transmitted from civet cats to humans and MERS-CoV from dromedary camels to humans. Several known coronaviruses are circulating in animals that have not infected humans yet.

2019 Novel Coronavirus (SARS-CoV-2) is a virus (more specifically, a coronavirus) identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Patients reported with SARS-CoV-2 viral infections had mild to severe respiratory illness with symptoms of: fever, cough, shortness of breath. There is an urgent need for rapid tests to manage the ongoing pandemic.

The qSARS-CoV-2 IgG/IgM Rapid Test is intended for rapid and qualitative detection of antibodies indicative of SARS-CoV-2 infection and used as an aid for diagnosis of SARS-CoV-2 infection.

TEST PRINCIPLE

The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow chromatographic immunoassay which can detect antibodies against the SARS-CoV-2 virus. The test cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 recombinant antigens conjugated with colloidal gold (SARS-CoV-2 conjugates) and rabbit IgG-gold conjugates; 2) a nitrocellulose membrane strip containing an IgG line (G Line) coated with anti-human IgG, an IgM line (M Line) coated with anti-human IgM, and the C line (C Line) coated with



goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the cassette. The anti-SARS-CoV-2 virus IgG, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the anti-human IgG line, forming a burgundy colored G line, indicating a SARS-CoV-2 virus IgG positive test result suggesting a secondary infection or previous infection.

IgM anti-SARS-CoV-2 virus, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the anti-human IgM line, forming a burgundy colored M line, indicating a SARS-CoV-2 virus IgM positive test result suggesting a fresh primary infection.

If both G line and M line are visible, the test result suggests late primary or early secondary SARS-CoV-2 infection. Absence of both test bands (G and M) suggests a negative result.

The test contains an internal control (C line) which should exhibit a burgundy colored band of goat anti-rabbit IgG/rabbit IgG-gold conjugate immunocomplex regardless of the color development on any of the test bands (G and M). Otherwise, the test result is invalid and the specimen must be retested again.

REAGENTS AND MATERIALS

Reagents and Materials Provided

There are three kit sizes. Their kit component configurations are provided below:

	Kit Size (#of Test)	1	25	50	100
Components	Test Cassette (#)	1	25	50	100
	Sample Diluent (# of Bottle)	1	1	1	1
	Transfer pipette (#)	1	25	50	100
	IFU Leaflet	1	1	1	1

Composition and Concentration

Conjugate pad Monoclonal Anti-SARS-CoV-2 antigen conjugated on the membrane

G line Anti human IgG

M line Anti human IgM

C line Goat anti rabbit IgG

Sample Buffer 0.01M PBS; PH 7.4

Material Required But Not Provided

1) Transfer Pipette Set; 2) Timer; 3) Specimen Collection Containers

WARNINGS AND PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay. Once opened, the cassettes should be used within 2 hours.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15℃-30℃) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.
9. Handle the Negative and Positive Control in the same manner as patient specimens.
10. The testing results should be read between 15 and 20 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results.
11. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

STORAGE AND STABILITY

1. Store the sample diluent at 4-30℃. The buffer is stable up to 30 months.
2. Store Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test at 4-30℃; shelf life is up to 30 months.
3. If stored at 2℃-8℃, ensure that the test device is brought to 15℃-30℃ before opening.
4. Do not freeze the kit or store the kit over 30℃.

SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
2. Allow the blood to clot, and then separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.
5. Test specimens as soon as possible after collecting. If specimens are not tested immediately store at 2°C-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

For frozen samples, avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Whole Blood

Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2℃-8℃) if not tested immediately. The specimens must be tested within 24 hours of collection.

TEST PROCEDURE

Step 1: For fresh sample, begin with Step 2. For frozen samples, bring the specimens and test components to room temperature, mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

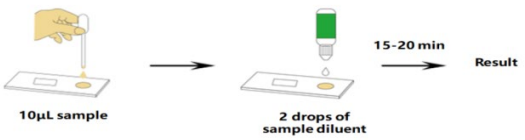
Step 3: Label the device with specimen ID number.

Step 4: Using a transfer pipette, transfer serum, plasma or whole blood not to exceed the specimen line. The volume of the specimen is around 10μL. For better precision, transfer specimen by a pipette capable of delivering 10μL of volume.

Holding the transfer pipette vertically, dispense the entire specimen into the center of the sample well (S well) making sure that there are no air bubbles.

Then add 2 drops (about 70-100 μL) of Sample Diluent immediately into the sample well (S well).

Step 5: Set up a timer.



Step 6: Read the result in 15-20 minutes.

Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. If the C line does not develop, review the whole procedure and repeat test with a new device.

2. External Control: Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:

A. New operator uses the kit, prior to performing testing of specimens.

B. A new lot of test kits is used.

C. A new shipment of kits is used.

D. The temperature used during storage of the kit falls outside of 2-30℃.

E. The temperature of the test area falls outside of 15 -30℃.

F. To verify a higher than expected frequency of positive or negative results.

G. To investigate the cause of repeated invalid results.

H. A new test environment is used (e.g., natural light vs. artificial light).

When performed properly, in addition to the presence of C band, no line should be visible for the negative control and the G or M or both lines are visible for the positive control. Additional controls may be qualified and tested by the user.

INTERPRETATION OF ASSAY RESULT

2. NEGATIVE RESULT: If only the C band is present, the absence of any burgundy color in the both test bands (G and M) indicates that no anti-SARS-CoV-2 virus antibodies are detected. The result is negative or non-reactive.

3. POSITIVE RESULT:

3.1 In addition to the presence of C band, if only G band is developed, the test result indicates for the presence of IgG anti- SARS-CoV-2 virus; the result is IgG positive or reactive, suggesting late stage primary, early secondary or previous infection.

3.2 In addition to the presence of C band, if only M band is developed, the test indicates for the presence of IgM anti-SARS-CoV-2 virus. The result is IgM positive or reactive, suggesting fresh primary SARS-CoV-2 virus infection.

3.3 In addition to the presence of C band, both G and M bands are developed, the test indicates for the presence of IgG and IgM anti-SARS-CoV-2 virus. The result is IgG and IgM positive or reactive, suggesting current primary or early secondary SARS-CoV-2 virus infection.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

4. INVALID: If the C line is not developed, the assay is invalid regardless of color development of the T band as indicated below. Repeat the assay with a new device

PERFORMANCE CHARACTERISTICS

1. Clinical Performance

1.1 Testing of clinical specimens

Ninety-eight (98) positive serum or plasma samples collected from individuals who were tested positive with an RT-PCR method for SARS-CoV-2 infection and were quarantined in a makeshift hospital were used in this study.

These patients, at the time of sample collected, exhibited mild or no clinical symptoms. These samples, along with 180 negative serum or plasma samples collected prior to September 2019, were coded and tested together with the qSARS-CoV-2 IgG/IgM Rapid Test. Of the 98 positive samples, ninety-one (91) were tested positive with IgG or IgM or both bands. Of the 180 negative samples, one hundred seventy four (174) were tested negative.

Another 30 samples were collected from hospitalized individuals who were clinically confirmed positive and exhibited severe symptoms. These samples, along with 70 negative serum or plasma samples collected prior to September 2019, were coded and tested together with the qSARS-CoV-2 IgG/IgM Rapid Test. Of the 30 positive samples, twenty-nine (29) were tested positive with IgG or IgM or both bands. Of the 70 negative samples, sixty-five (65) were tested negative.

Taken together, the qSARS-CoV-2 IgG/IgM Rapid Test had a sensitivity and specificity of 93.75% (95% CI: 88.06-97.26%) and 96.40% (95% CI: 92.26-97.78%), respectively.

qSARS-CoV-2 IgG/IgM Rapid Test						
N/A		IgG+ IgM+	IgG- IgM+	IgG+ IgM-	IgG- IgM-	Sub
Clinical Status	Pos.	65	46	9	8	128
	Neg.	0	5	4	241	250
Subtotal		65	51	13	249	378

1.2 Testing of Specimens that were RT-PCR negative but clinical positive

Fifty (50) specimens collected from suspected patients who were RT-PCR negative but had history of being exposed and showed clinical symptoms consistent with an infection were tested with the qSARS-CoV-2 IgG/IgM Rapid Test. Of these samples, twelve (12) or 24% were positive with the test.

1.3 Whole blood specimens spiked with positive samples

Fifty negative whole blood samples were spiked with positive serum at 1:100. Another 50 whole blood specimens were spiked with negative serum at same dilution. These 100 specimens were coded and tested with the qSARS-CoV-2 IgG/IgM Rapid Test. All spiked samples were correctly identified by the test except for one of the negative samples, which was tested positive with the test.

2. Limit of Detection

Four positive samples were serially diluted, coded and tested in 20 replicates. The most diluted replicates at which 19 or 20 replicates were tested positive for these four samples were 1:60,000, 1:11,000, 1:2000, and 1:500, respectively.

3. Assay Cross Reactivity

A low titer sample was diluted 1:100 to a serum or plasma sample containing antibodies reactive to one of following pathogens were tested along with unspiked samples in duplicate. No false positivity or false negativity was found:

Human coronavirus(collected before Oct 2019)
HBV
HCV
HIV-1
HIV-2
Adenovirus
Human Metapneumovirus (hMPV)
Parainfluenza virus 1-4
Influenza A
Influenza B
Enterovirus 71
Respiratory syncytial virus
Rhinovirus
Chlamydia pneumoniae
Streptococcus pneumoniae
Mycobacterium tuberculosis
Mycoplasma pneumoniae
EB Virus

4. Potentially Interference Substances

A low titer positive serum sample or negative serum sample was spiked with one of the following substances to specified concentrations and tested in duplicate. No false positivity or false negativity was found:

Hemoglobin	10 mg/mL
Bilirubin Conjugated	0.4 mg/mL
Bilirubin Unconjugated	0.4 mg/mL
Triglycerides	15 mg/mL
Cholesterol	4 mg/mL
Human Anti-mouse Antibody	800 ng/mL
Rheumatoid Factor	2000 IU/mL

Human Serum Albumin	60 mg/mL
Histamine hydrochloride	4 mg/L
α-IFN	200 mg/L
Zanamivir	1 mg/L
Oseltamivir carboxylate	1 mg/L
Abidol	40 mg/L
Levofloxacin	200 mg/L
Ceftriaxone	400 mg/L
Meropenem	200 mg/L
Tobramycin	10 mg/L
Ribavirin	40 mg/L
Human IgG	8 mg/mL
Human IgM	0.4 mg/mL

5. Hook Effects

Positive samples with titers up to 1:60,000 were found to be reactive when tested with the qSARS-CoV-2 IgG/IgM Rapid Test.

LIMITATIONS OF THE PROCEDURE

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum or plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is limited to the qualitative detection of antibodies specific for SARS-CoV-2 virus. The intensity of the test line does not necessarily have linear correlation with virus titer in the specimen.
3. A negative or non-reactive result for an individual subject indicates absence of detectable antibodies for SARS-CoV-2 virus. However, a negative or non-reactive result does not preclude the possibility of SARS-CoV-2 virus infection.
4. A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limits of the assay, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.
5. If symptoms persist, while the result from the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

OTHER INFORMATION

1. This test is being reviewed by the FDA
2. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
5. Not for the screening of donated blood.

ORDERING INFORMATION

Contact Cellex's distributors or

Contact Cellex via email: sales@cellex.us

TECHNICAL INFORMATION

Via email: tech@cellex.us

Index of CE Symbols

	Consult instructions for use		For in vitro diagnostic use only		Use by
	Catalog #		Lot Number		Tests per kit
	Store between 2-30°C		Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

Cellex, Inc.

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Tel: 0512-66897003

MedPath GmbH

Mies-van-der-Rohe-strasse 8, 80807 Munich, Germany

Clinical Evaluation Report of

Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test

1. Purpose

The purpose of this report is to provide information regarding the clinical performance of the "Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test", compared to the already well-established PCR system, present on world market.

2. Introduction

2.1 Description of qSARS-CoV-2 IgG/IgM Cassette Rapid Test

Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a product for in-vitro analysis of whole blood, serum and plasma, designed to deliver qualitative results for a panel of tests. The resulting complex overflows a nitrocellulose membrane where the specific antigens against IgG or IgM antibodies are immobilized on the test zone and forms the pink to purple line at the "G" or "M" position of the window. The unreacted colloidal gold-labeled antigens react with the antibodies on the control zone and forms the pink to purple line at the "C" position of the window. The intensity and speed at which the color develops depends on the concentration of 2019-nCoV IgG/IgM antibodies in the specimen. The user can get the qualitative result by observing the G/M-line.

Result Interpretation

- In addition to the presence of C band, if only G line is developed, the test result indicates the presence of IgG anti- SARS-CoV-2 virus; the result is IgG positive or reactive, suggesting late stage primary, early secondary or previous infection.
- In addition to the presence of C band, if only M band is developed, the test indicates for the presence of IgM anti-SARS-CoV-2 virus. The result is IgM positive or reactive, suggesting a primary SARS-CoV-2 virus infection.
- In addition to the presence of C line, both G and M lines are developed, the test indicates for the presence of IgG and IgM anti-SARS-CoV-2 virus. The result is IgG and IgM positive or reactive, suggesting current primary or early secondary SARS-CoV-2 virus infection.
- If only the C band is present, the absence of any burgundy color in the both test bands (G and M) indicates that no anti-SARS-CoV-2 virus antibodies are detected. The result is negative or non-reactive. However, a negative or non-reactive result does not preclude the possibility of SARS-CoV-2 virus infection.A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limits of the assay, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.

Product	Lot #	Manufacturer
qSARS-CoV-2 IgG/IgM Cassette Rapid Test	20200131	Cellex Inc.

2.2 Intended Use

The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow immunoassay for the qualitative detection of 2019-nCoV IgM/IgG antibodies in serum, plasma or whole blood specimens. It is intended to be used as a screening test and aid in the diagnosis of SARS-CoV-2 viral infections. Any reactive specimen with the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test must be confirmed with alternative testing method(s).

3. Clinical Methods

3.1 Performance evaluation of an IVD medical device

Comparative method of Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is done according to the established and standardized guideline NCCLS Evaluation Protocol.

3.2 Clinical Evaluation

Ninety-eight (98) positive serum or plasma samples collected from individuals who were tested positive with an RT-PCR method for SARS-CoV-2 infection and were quarantined in a makeshift hospital were used in this study. These patients, at the time of sample collected, exhibited mild or no clinical symptoms. These samples, along with 180 negative serum or plasma samples collected prior to September 2019, were coded and tested together with the qSARS-CoV-2 IgG/IgM Rapid Test.

Another 30 samples were collected from hospitalized individuals who were clinically confirmed positive and exhibited severe symptoms. These samples, along with 70 negative serum or plasma samples collected prior to September 2019, were coded and tested together with the qSARS-CoV-2 IgG/IgM Rapid Test.

A total of 378 samples were collected for this clinical evaluation test, of which 128 confirmed positive samples and 250 negative samples

Using the NCCLS Evaluation Protocol as a guideline, the following table provides the suggested distribution of sample concentrations:

Sample will be used throughout the study period. The positive and negative coincidence rate will be analysis as following.

	Test Method	Total

		+	-	
Reference Method	**+**	a	b	a+b
	-	c	d	c+d
Total		**a+c**	**b+d**	**a+b+c+d**

Positive coincidence rate =a/(a+b)*100%
Negative coincidence rate =d/(c+d)*100%
Total coincidence rate =(a+d)/(a+b+c+d)*100%

3.3 Clinical Performance

The conclusion is as below. A very good coincidence rate was found between the two methods. Of the 128 positive samples, one hundred twenty (120) were tested positive with IgG or IgM or both lines. Of the 250 negative samples, two hundred forty one (241) were tested negative.

Taken together, the qSARS-CoV-2 IgG/IgM Rapid Test had a sensitivity and specificity of 93.75% (95% CI: 88.06-97.26%) and 96.40% (95% CI: 92.26-97.78%), respectively.

		qSARS-CoV-2 IgG/IgM Rapid Test				
		IgG+ IgM+	IgG- IgM+	IgG+ IgM-	IgG- IgM-	Sub
PCR & Clinical Status	Pos.	65	46	9	8	128
	Neg.	0	5	4	241	250
Subtotal		65	51	13	249	378

Positive coincidence rate =93.75%
Negative coincidence rate =96.40%
Total coincidence rate =95.50%

4. Conclusion

Method comparison shows good agreement between Cellex and comparative method. Positive coincidence rate is 93.75%, Negative coincidence rate is 96.40%, and Total coincidence rate is 95.50%.

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

APPENDIX A: TEST DATA OF CLINICAL EVALUATION

No.	qSARS-CoV-2 IgG/IgM Cassette Rapid Test		PCR & Clinical Status	No.	qSARS-CoV-2 IgG/IgM Cassette Rapid Test		PCR & Clinical Status
	IgG	IgM			IgG	IgM	
1	+	+	+	2	+	+	+
3	+	+	+	4	-	-	-
5	-	-	-	6	-	-	-
7	+	-	+	8	-	-	-
9	-	-	-	10	-	-	-
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	-	-	-
103	-	-	-	104	-	-	-
105	+	+	+	106	+	+	+
107	-	-	-	108	-	-	-
109	+	+	+	110	+	+	+
111	-	-	-	112	-	-	-
113	+	-	+	114	+	+	+
115	-	-	-	116	-	-	-
117	-	-	-	118	-	-	-
119	-	-	-	120	-	-	-
121	+	+	+	122	-	-	+
123	-	+	-	124	-	-	-
125	-	+	+	126	+	+	+
127	-	-	-	128	-	-	-
129	-	-	-	130	-	-	-
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133	-	-	-	134	-	-	-
135	-	-	-	136	-	-	-
137	-	+	+	138	+	+	+
139	-	-	-	140	-	-	-
141	+	+	+	142	-	+	+
143	-	-	-	144	+	-	-
145	-	-	-	146	-	-	-
147	+	+	+	148	-	+	+
149	-	-	-	150	-	-	-
151	-	-	-	152	-	-	-
153	-	-	+	154	+	+	+
155	-	-	-	156	-	-	-
157	-	-	-	158	-	-	-

159	+	+	+	160	-	+	+
161	-	-	-	162	-	-	-
163	+	+	+	164	-	+	+
165	-	+	-	166	-	-	-
167	-	-	-	168	-	-	-
169	-	-	-	170	-	-	-
171	-	-	-	172	-	-	-
173	-	-	-	174	-	-	-
175	-	+	+	176	+	+	+
177	-	-	-	178	-	-	-
179	+	+	+	180	-	+	+
181	-	-	-	182	-	-	-
183	-	-	-	184	-	-	-
185	-	+	+	186	+	-	+
187	-	-	-	188	-	-	-
189	-	+	+	190	+	+	+
191	+	+	+	192	-	+	+
193	-	-	-	194	-	-	-
195	-	-	-	196	-	-	-
197	-	-	-	198	-	-	-
199	-	-	-	200	-	-	-
201	+	+	+	202	-	-	+
203	-	-	-	204	-	+	-
205	-	+	+	206	+	+	+
207	-	-	-	208	-	-	-
209	-	-	-	210	-	-	-
211	-	-	-	212	-	-	-
213	-	-	-	214	-	-	-
215	-	-	-	216	-	-	-
217	-	+	+	218	+	+	+
219	-	-	-	220	-	-	-
221	+	+	+	222	-	+	+
223	-	+	+	224	+	+	+
225	-	-	-	226	-	-	-
227	-	-	-	228	-	-	-
229	-	-	-	230	-	-	-
231	-	-	-	232	-	-	-
233	-	-	-	234	-	-	-
235	-	-	-	236	-	-	-
237	-	+	+	238	-	+	+
239	+	+	+	240	+	+	+
241	-	-	-	242	-	-	-
243	+	+	+	244	-	+	+

245	-	-	-	246	-	-	-
247	-	-	-	248	+	-	-
249	-	-	-	250	-	-	-
251	-	-	-	252	-	-	-
253	-	-	-	254	-	-	-
255	-	-	+	256	+	+	+
257	-	-	-	258	-	-	-
259	-	-	-	260	-	-	-
261	-	-	-	262	-	-	-
263	-	-	-	264	-	-	-
265	-	-	-	266	-	-	-
267	+	+	+	268	-	-	+
269	-	-	-	270	-	-	-
271	-	+	+	272	-	-	+
273	-	+	-	274	-	-	-
275	-	-	-	276	-	-	-
277	-	-	-	278	-	-	-
279	-	-	-	280	-	-	-
281	-	+	+	282	+	+	+
283	-	+	+	284	+	+	+
285	-	-	-	286	-	-	-
287	+	+	+	288	-	+	+
289	-	-	-	290	-	-	-
291	-	-	-	292	-	-	-
293	+	+	+	294	-	+	+
295	-	-	-	296	-	-	-
297	-	+	+	298	+	+	+
299	-	-	-	300	-	-	-
301	-	-	-	302	-	-	-
303	-	-	-	304	-	-	-
305	-	-	-	306	-	-	-
307	-	-	-	308	-	-	-
309	-	+	+	310	-	+	+
311	-	-	-	312	-	-	-
313	-	+	+	314	-	+	+
315	-	-	-	316	-	-	-
317	-	-	-	318	-	-	-
319	+	+	+	320	+	+	+
321	-	-	-	322	-	-	-
323	-	-	-	324	-	-	-
325	-	+	+	326	+	+	+
327	-	-	-	328	-	-	-
329	-	-	-	330	-	-	-

331	+	+	+	332	+	-	+
333	-	-	-	334	-	-	-
335	-	+	+	336	+	-	+
337	-	-	-	338	-	-	-
339	-	-	-	340	-	-	-
341	-	-	-	342	-	-	-
343	-	-	-	344	-	-	-
345	-	-	-	346	-	-	-
347	+	+	+	348	-	+	+
349	-	-	-	350	-	-	-
351	+	+	+	352	-	+	+
353	-	-	-	354	-	-	-
355	-	-	-	356	-	-	-
357	-	+	+	358	+	+	+
359	-	-	-	360	-	-	-
361	-	+	+	362	+	-	+
363	-	+	+	364	+	+	+
365	-	-	-	366	-	-	-
367	+	+	+	368	-	+	+
369	-	-	-	370	-	-	-
371	-	+	+	372	-	+	+
373	+	+	+	374	+	+	+
375	-	-	-	376	-	-	-
377	-	-	-	378	-	-	-

MedPath

EC-Registration Certificate

Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices (IVDD), Article 10

No. R A000 03/C Rev. 01

Manufacturer: Cellex, Inc.

76 TW Alexander Drive, Research Triangle Park,
NC 27709-0002, USA

Product Category(ies): See Appendix A

CE

This is to certify that, in accordance of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the aforementioned manufacturer as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's medical device(s) shown in Appendix A. The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity confirming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Directive.

Date, 2020-03-25

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

MedPath

Appendix A

Products	Classification	EDMA Code	DIMDI Form No.
Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	others	15-04-80-90-00	00153907

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

CE

Declaration of Conformity

CE

Manufacturer:

Cellex, Inc.

Address：

Headquarter:

76 TW Alexander Drive, Research Triangle Park, NC 27709-0002, USA

TEL: 1-919-314-5536 FAX: 1-919-314-5536

Manufacture Location:

1F, North Black, 16 Building, 8 Jinfeng Road, Suzhou New District, Jiangsu, P.R. China, 215011

TEL: +86-512-66897003 FAX: +86-512-66897002

European Representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Tel: +49-89-189174476 FAX: +49-89-54858884

Email: info@medpath.pro

Product Name:

Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test

（Lateral Flow Chromatographic Immunoassay）

Classification: Others (IVDD, Annex II)

Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare under sole responsibility 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 DIAGNOSTICS MEDICAL DEVICES

Standard Applied:

EN ISO 13485: 2016 EN 13612:2002EN 13695: 2002EN 980:2016

EN ISO 14971: 2012 EN 13640: 2002 EN 17511: 2003EN 375:2001

Start of CE-MARK: Mar 02, 2020

Place: Headquarter: Research Triangle Park, NC, USA

Manufacture Location: Suzhou, Jiangsu, P.R. China

Date of Issue: Mar 02, 2020

Signature: 

Position: General Manager

Product Name	Cat. No
Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	5513

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 18 02 03200 001

Holder of Certificate: **Cellex, Inc.**
76 TW Alexander Dr
Research Triangle Park
Durham NC 27709-0002
USA

Facility(ies):
Cellex, Inc.
76 TW Alexander Dr, Research Triangle Park,
Durham NC 27709-0002, USA

CELLEX BIOTECH (Suzhou) Co., Ltd.
1F, North Black, 16 Building, 8 Jinfeng Road,
Suzhou New District, 215011 Suzhou,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Test Kit based on Lateral Flow Chromatographic Immunoassay and In Vitro Diagnostic Test Kit and Analyzer based on Immunofluorescence Assay, Homogeneous Biochemiluminescence Assay(HBA)**

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.: SH17125501

Valid from: 2018-06-26
Valid until: 2021-06-25

Date, 2018-06-26

Stefan Preiß

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

Page 1 of 1

TÜV®

DAkkS CRT2 / A4 07.17 ZM

U.S. FOOD & DRUG ADMINISTRATION

April 1, 2020

James X. Li, Ph.D.
Chief Executive Officer,
76 TW Alexander Drive
Research Triangle Park, NC 27709 US

Device:	qSARS-CoV-2 IgG/IgM Rapid Test
Company:	Cellex Inc.
Indication:	Qualitative detection of IgM and IgG antibodies against SARS-CoV-2 in serum, plasma (EDTA or citrate), or venipuncture whole blood from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate and high complexity tests.

Dear Dr. Li:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[3] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[4]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to the Cellex Inc..
[2] For ease of reference, this letter will use the term "your product" to refer to the qSARS-CoV-2 IgG/IgM Rapid Test used for the indication identified above.
[3] On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). This document uses the updated names.
[4] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. February 4, 2020.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the scope Section of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[5]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a qualitative test for the detection of IgM and IgG antibodies against SARS-CoV-2 in serum and plasma (EDTA or citrate) blood specimens and venipuncture whole blood specimens collected from individuals suspected of COVID-19 by their healthcare provider. Results are for the detection of SARS-CoV-2 antibodies, IgM and IgG that are generated as part of the human immune response to the virus. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection.

To use your product, the device cassette, specimen, and buffer solution are allowed to equilibrate to room temperature. Specimen (10 μL) is transferred to the center of the sample well. After the sample well is free of liquid, two drops of Sample Diluent are then added to the sample well. Wait for fifteen to twenty minutes and read the test results. Results are not to be read after twenty minutes. An IgM Positive Result occurs when a colored band appears at both the M Test Line (M) and Control Line (C) and indicates that IgM against SARS-CoV-2 is present. An IgG Positive Result occurs when a colored band appears at both the G Test Line (G) and Control Line (C) and indicates that IgG against SARS-CoV-2 is present. A positive result for IgM and IgG occurs when colored bands occur at both M and G as well as at C. A Negative Result occurs

[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

when a colored band appears at C only and indicates that IgM and IgG antibodies against SARS-CoV-2 were not detected. An Invalid Result occurs when no colored band occurs at C and the test should be repeated.

Your product requires the following internal control, that are processed along with the patient sample on the device cassette. The internal control listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Internal Control – The C line should appear for every test and checks that flow of reagents is satisfactory.

Your product also includes external positive and negative controls, or other authorized controls, to be run as outlined in the Instructions for Use:

- Positive Control – Spiked, chemically inactivated, human serum containing IgM and IgG antibodies against SARS-CoV-2 close to the cutoff of the test. The M, G, and C lines should all appear. The positive control is used to monitor for failures of antibody detection reagents and reaction conditions.
- Negative Control – Previously characterized, chemically inactivated, negative human serum.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The above described product, when labeled consistently with the labeling authorized by FDA, entitled "Cellex qSARS-CoV-2 IgG/IgM Rapid Test" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), which may be revised in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of Health Technology 7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

Your product is authorized to be accompanied by the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: qSARS-CoV-2 IgG/IgM Rapid Test
- Fact Sheet for Patients: qSARS-CoV-2 IgG/IgM Rapid Test

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your authorized product, when used for the qualitative detection of IgM and IgG against SARS-CoV-2 and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific

evidence available to FDA, that it is reasonable to believe that your product may be effective for the indication above, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), your product is authorized for the indication above.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Cellex Inc. (You) and Authorized Distributor(s)[6]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

[6] "Authorized Distributor(s)" are identified by you, Cellex Inc., in your EUA submission as an entity allowed to distribute your device.

B. You and authorized distributor(s) will make your product available with the authorized labeling to authorized laboratories. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

C. You and authorized distributor(s) will provide to authorized laboratories the Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. You may request changes to the authorized Fact Sheets. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

D. You and authorized distributor(s) will make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

E. You and authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product, authorized labeling and authorized Fact Sheets.

F. Through a process of inventory control, you and authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

G. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

I. You and authorized distributor(s) will make available the control material or other authorized control materials for purchase at the same time as your product.

Cellex Inc. (You)

J. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

K. You will provide its authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

L. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and

Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

M. You may request the addition of other ancillary methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You may request substitution for or changes to the authorized materials used in the detection process of human antibodies against SARS-CoV-2. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You will evaluate the performance and assess traceability[7] of your product with any FDA-recommended reference material(s) or established panel(s) of characterized clinical specimens. After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

S. You will complete the agreed upon capillary fingerstick whole blood study. After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, you will update your product labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH

T. You will complete the agreed upon real-time stability study for your product. After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, you will update your product labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

U. You will evaluate different transfer pipettes capable of consistently delivering 10 µL to mitigate possible operator error. After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, you will update your product

[7] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

labeling to reflect the additional testing and the recommendation for inclusion of acceptable pipettes for use with your device. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

Authorized Laboratories

V. Authorized laboratories using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

W. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

X. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

Y. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

Z. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and You (tech@cellex.us) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

AA. All laboratory personnel using your product must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

Cellex Inc. (You), Authorized Distributors and Authorized Laboratories

BB. You, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

CC. All advertising and promotional descriptive printed matter relating to the use of your product shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

DD. All advertising and promotional descriptive printed matter relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

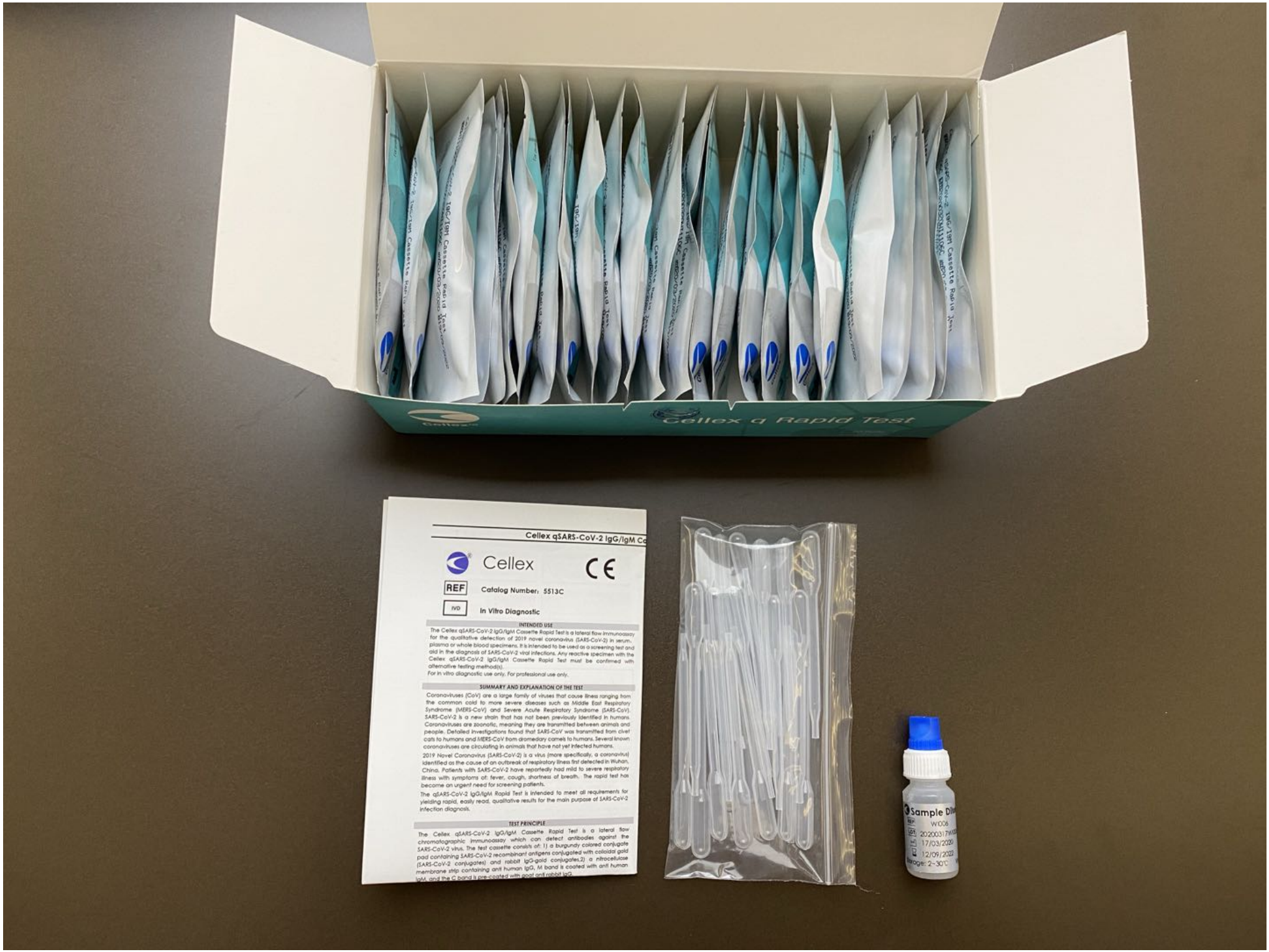
This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures


Cellex™
Cellex q Rapid Test
We Are In The Business of Saving Lives
www.cellex.us
Cellex q Rapid Test
Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test
SARS-CoV-2 IgG/IgM
C
IgG
IgM
S
SARS-CoV-2 IgG/IgM
C
IgG
IgM
S


Cellex q Rapid Test
Cellex qSARS-CoV-2 IgG/IgM Co
Cellex
REF
Catalog Number: 5513C
IVD
In Vitro Diagnostic
INTENDED USE
The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow immunoassay for the qualitative detection of 2019 novel coronavirus (SARS-CoV-2) in serum, plasma or whole blood specimens. It is intended to be used as a screening test and aid in the diagnosis of SARS-CoV-2 viral infections. Any reactive specimen with the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test must be confirmed with alternative testing method(s).
For in vitro diagnostic use only. For professional use only.
SUMMARY AND EXPLANATION OF THE TEST
Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). SARS-CoV-2 is a new strain that has not been previously identified in humans. Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Detailed investigations found that SARS-CoV was transmitted from civet cats to humans and MERS-CoV from dromedary camels to humans. Several known coronaviruses are circulating in animals that have not yet infected humans.
2019 Novel Coronavirus (SARS-CoV-2) is a virus (more specifically, a coronavirus) identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Patients with SARS-CoV-2 have reportedly had mild to severe respiratory illness with symptoms of: fever, cough, shortness of breath. The rapid test has become an urgent need for screening patients.
The qSARS-CoV-2 IgG/IgM Rapid Test is intended to meet all requirements for yielding rapid, easily read, qualitative results for the main purpose of SARS-CoV-2 infection diagnosis.
TEST PRINCIPLE
The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow chromatographic immunoassay which can detect antibodies against the SARS-CoV-2 virus. The test cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 recombinant antigens conjugated with colloidal gold (SARS-CoV-2 conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing anti human IgG, M band is coated with anti human IgM, and the C band is pre-coated with goal anti rabbit IgG
Sample Di
W006
17/03/2020
12/09/2022
Storage: 2~30℃


Cellex™
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SARS-CoV-2 IgG/IgM
C
IgG
IgM
S
SARS-CoV-2 IgG/IgM
C
IgG
IgM
S
REF
W1006
LOT
17/03/2020
12/09/2022
Storage: 2~30°C

Cellex qSARS-CoV-2 IgG/IgM Rapid TEST

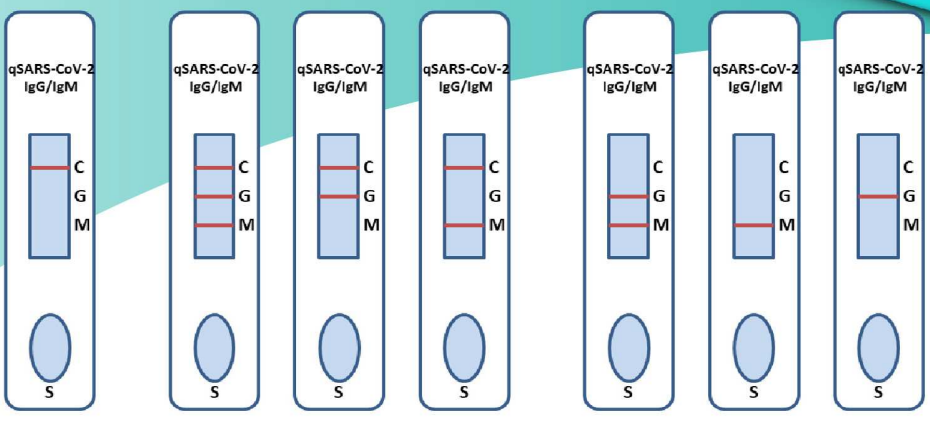
Lateral flow chromatographic immunoassay | Point-of-care | Easiest handling

The 15-minute Ideal Diagnostic Test For COVID-19

- Sample: Serum\Plasma\Whole Blood
- Accurate and reliable results
- Easy to operate
- Robust performance
- Affordable for different health systems

- To provide efficient and accurate diagnosis for patients with suspected 2019-nCoV infection;
- To provide guidance for treatment and patients management;
- To provide epidemiologic information for surveillance of circulating 2019-nCoV viruses

INTERPRETATION OF RESULT



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