

FDA Approval Pending



**COVID-19 IgG/IgM
RAPID TEST**

Presentation Outline

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- About CHIL COVID-19 IgG/IgM Rapid Test
- How We Present the Product
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LIST OF KEY CONCEPTS

Presentation Outline

- How To Use COVID-19 IgG/IgM Test
- How to Interpret COVID-19 IgG/IgM Test
- Storage and Stability & Warning and Precautions
- Performance Evaluation Results
- Republic of Turkey Ministry of Health Approval
- CE Certification
- ISO 9001- ISO 13485 Certification
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LIST OF KEY CONCEPTS

About Adams Medical

We provide Personal Protective Equipment to medical caregivers, government sectors, and the private companies.

Great stories written in the hard times.

With the outbreak of the coronavirus in different parts of the world, we at Adams Group believe that it is our responsibility to support hospitals and people who need safety equipment in facing this global challenge.

As we go about our cross-industry journey with establishing Adams Medical to help battle COVID-19 by providing Personal Protective Equipment for the PPE shortage we use and share Adams Group sources and experience from USA, Germany and Turkey.

About Sars-Cov-2

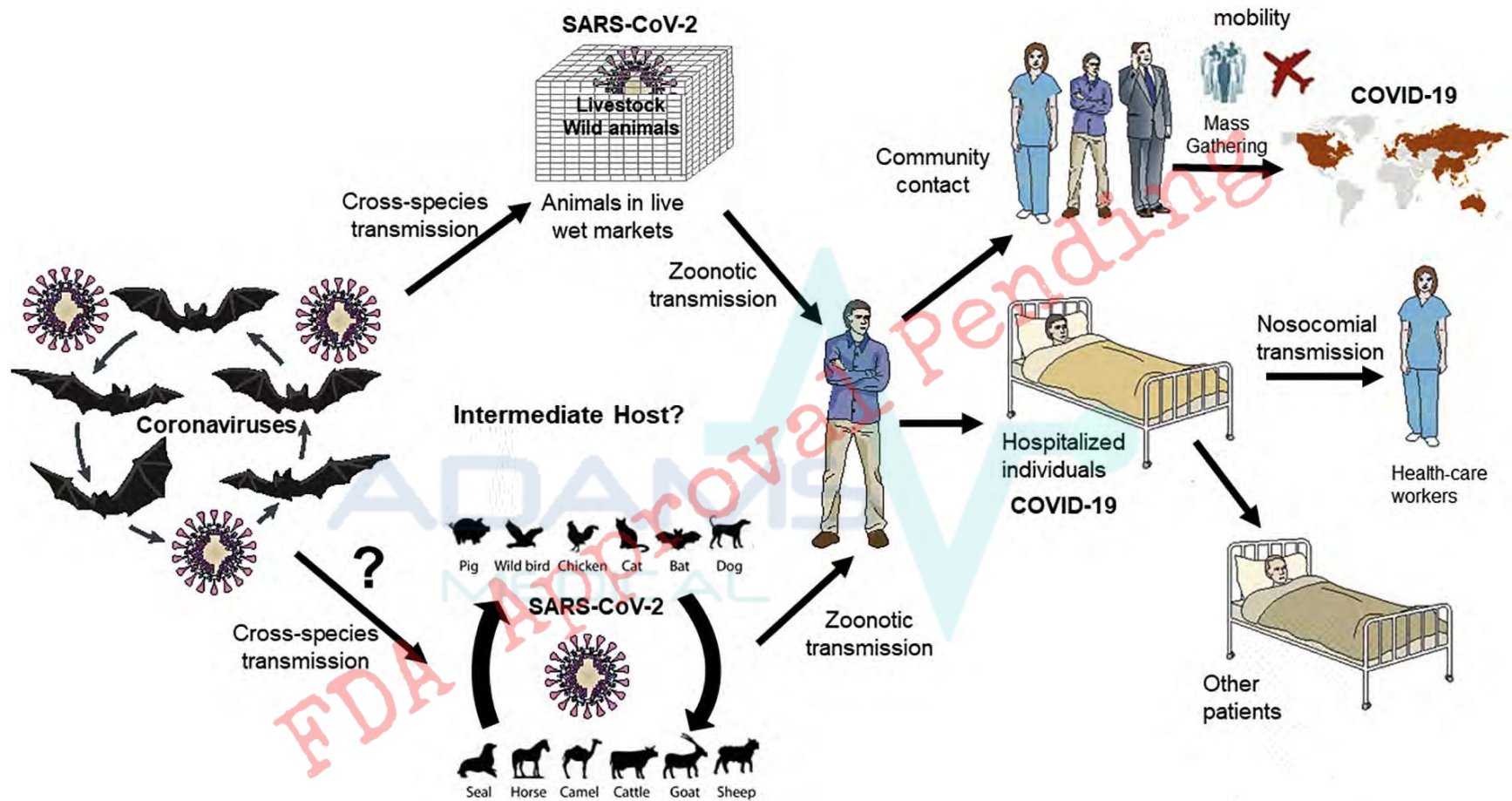


WHAT IS CORONAVIRUS?

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was first reported from China in December 2019.

- The entire world is anxiously watching as COVID-19, that become a global pandemic (WHO 2020)
- The probable transmission pathways of SARS-CoV-2 are airborne transmission and contact-based inoculation of infectious material in droplets through the eyes, nose, or mouth
- Patients infected by SARSCoV-2 manifested a range of symptoms including fever, tiredness, and dry cough

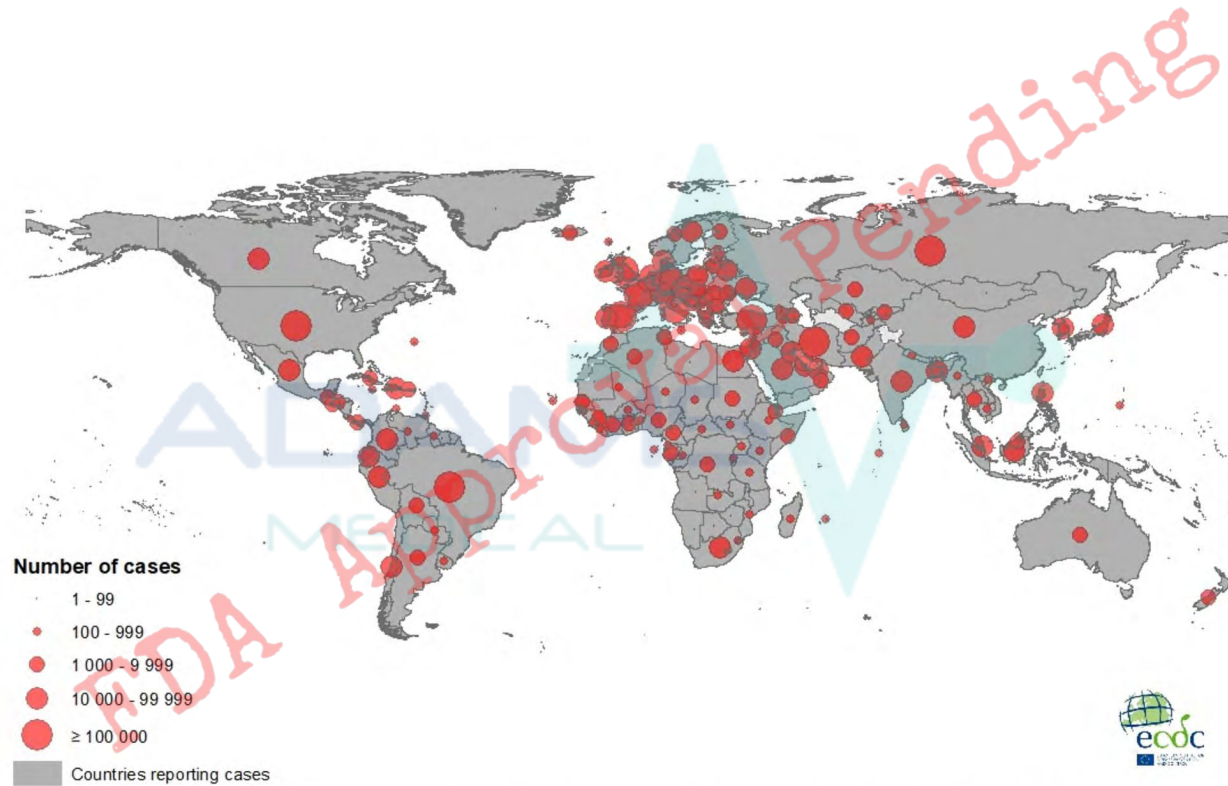
(El Zowalatyet al., 2020)



The emergence of SARS-CoV-2 and the outbreak of COVID-19

(El Zowlaty et al., 2020)

Epidemiology of SARS-CoV-2

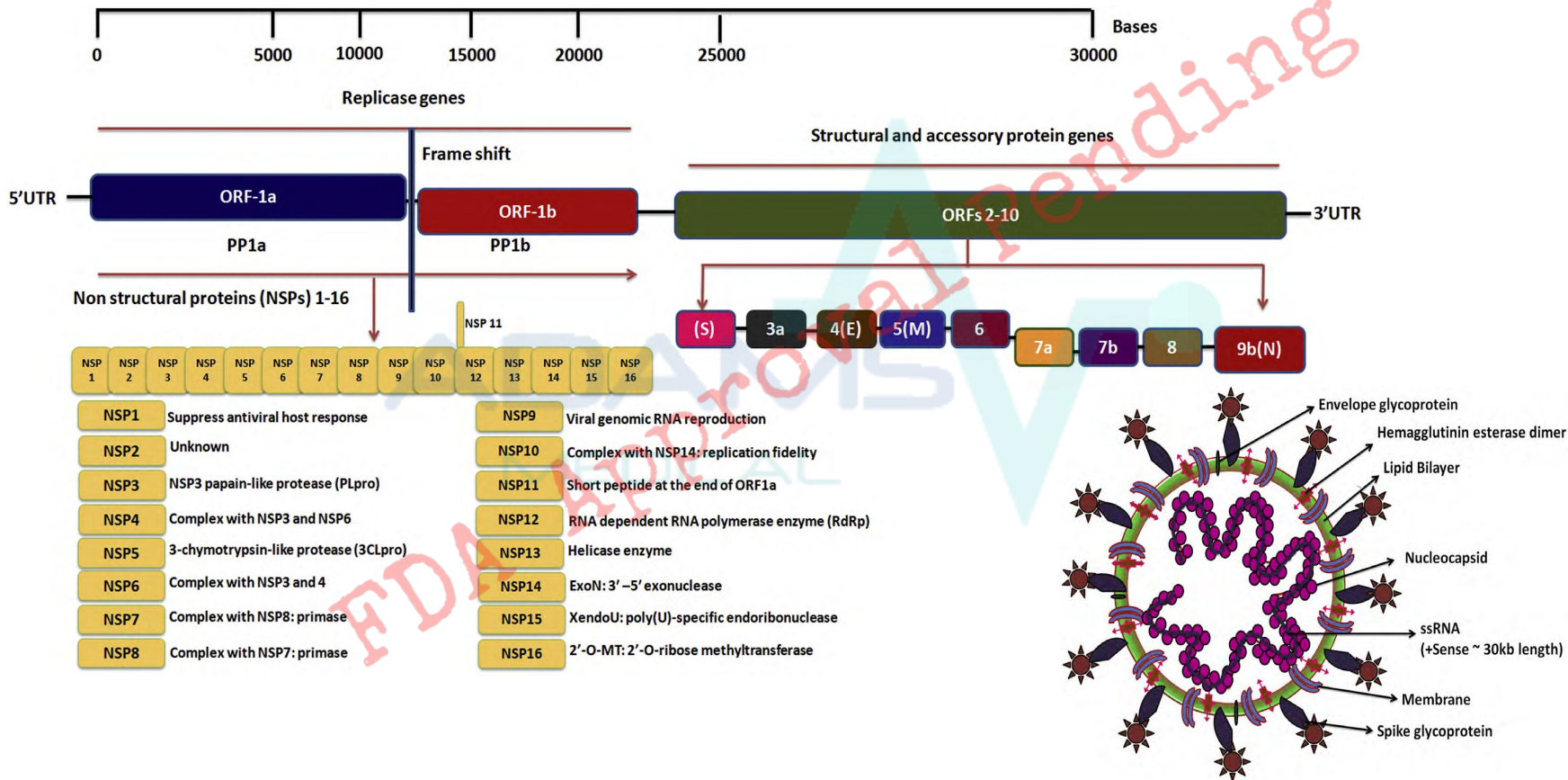


Date of production: 15/05/2020

The boundaries and names shown on this map do not imply official endorsement or acceptance by the European Union.

Structure of SARS-CoV-2

Genomic structure of SARS-COV-2



Assay Techniques For COVID-19 Diagnosis

Currently, two types of techniques are used in diagnosis of COVID-19:

I. Nucleic acid-based tests (detection of SARS-COV-2 RNA)

- RT-qPCR
- Loop-mediated isothermal amplification (LAMP) test
- CRISPR-based methodologies

II. Serological-based tests (detection of SARS-COV-2-specific antibodies)

- Lateral flow test
- ELISA test
- Specific chemosensors

I. Nucleic Acid-based Tests RT-qPCR

RT-qPCR is a highly sensitive test that has been widely used in diagnosis of COVID-19.

However, RT -qPCR has some disadvantages

- Requiring expensive laboratory instrumentation
- Highly skilled laboratory personnel
- False negative test with no sufficient viral RNA
- Take hours to generate results.
- Cannot be applied to broad identification of past infection (The real issue emerges when dealing with a global pandemic with potentially millions of people to test).
- Cannot be used to monitor the progress of the disease stages

II. Serological Test

- Serological testing is defined as an analysis of blood (whole blood, serum, or plasma) and other biological fluids for the presence of antibodies (generally immunoglobulin IgM/IgG)
- The serological determination of SARS-CoV-2 relies on the detection of IgM and IgG antibodies- specific for SARS-COV-2 antigens
- Among the SARS-COV-2 structural proteins, the receptor-binding domain(RBD) and the nucleocapsid (N) are the main immunogen protein

There are two types of serological tests that are being validated for the detection of antibodies-specific for SARS-COV-2 antigens

I. ELISA tests, that are carried out on a blood sample, which must be performed under the usual conditions of safety and quality in medical biology. It requires laboratory instrumentation and skilled laboratory personnel

II. Rapid tests, that allow rapid detection (10-20 minutes) of antibodies by a simple drop of blood deposited on a small device. The rapid tests are easy to use and can be performed by a healthcare professional.

Serological Rapid Test

The main objective of serological rapid test in diagnosis of COVID-19:

Finding people who have had infectious contact with the virus (symptomatic or not) and who have developed antibodies.

Therefore, rapid tests have two importance:

– **Collective public health:** Knowing the immunization rate of a population allows authorities to make the right social, economic, and political decisions

– **Individual:** Would allow vulnerable people to continue to protect themselves if they are negative. Rapid tests are recommended to be used during deconfinement to complete the Covid-19 diagnostic offer on the territory and limit its spread

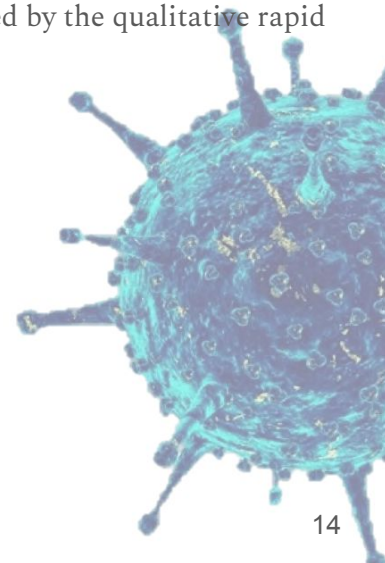
Serological rapid tests offer some advantages over RT-qPCR:

- + Rapid tests are easy to use, no specific device is needed
- + Rapid tests give fast qualitative results
- + Rapid tests can be used in large-scale, whole-population, testing to assess the overall immune response to the virus and identify asymptomatic carriers of the virus
- + They can detect past infection because virus-specific antibodies can persist in the blood for several months after onset of symptoms (unlike RT-qPCR)
- + Immunoglobulins are more stable than viral RNA. So, serological specimens are less sensitive to spoilage during collection, transport, and storage compared to RT-qPCR specimens

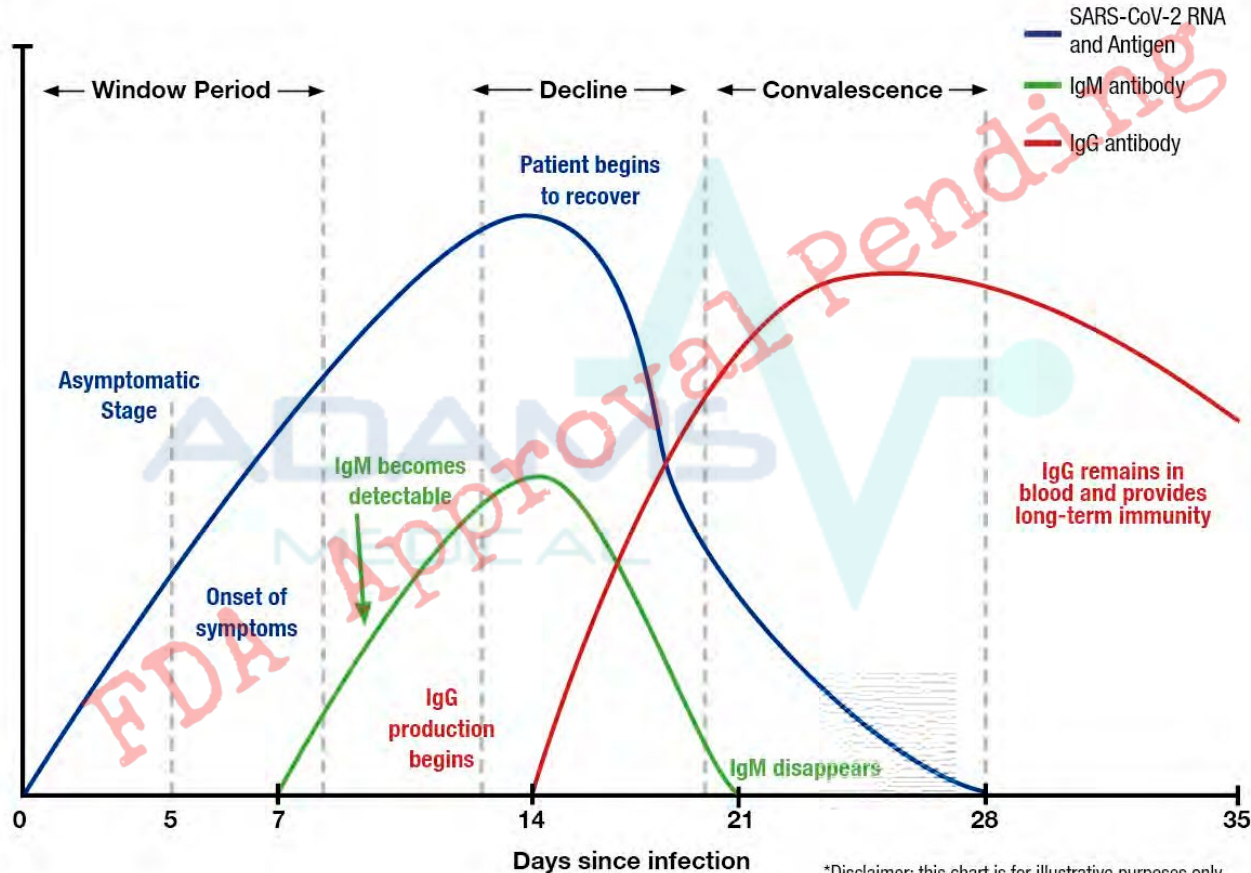
BENEFITS OF SEROLOGICAL RAPID TEST

Limitations of Serological Rapid Test

- Should not be used as the sole criteria for the diagnosis of SARS-CoV-2. they can be a valuable diagnostic tool when combined with RT-qPCR
- The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy
- Neither the quantitative value nor the rate of increase in SARS-CoV-2 antibody concentration can be determined by the qualitative rapid test
- They do not make it possible to document if the person is contagious, or not



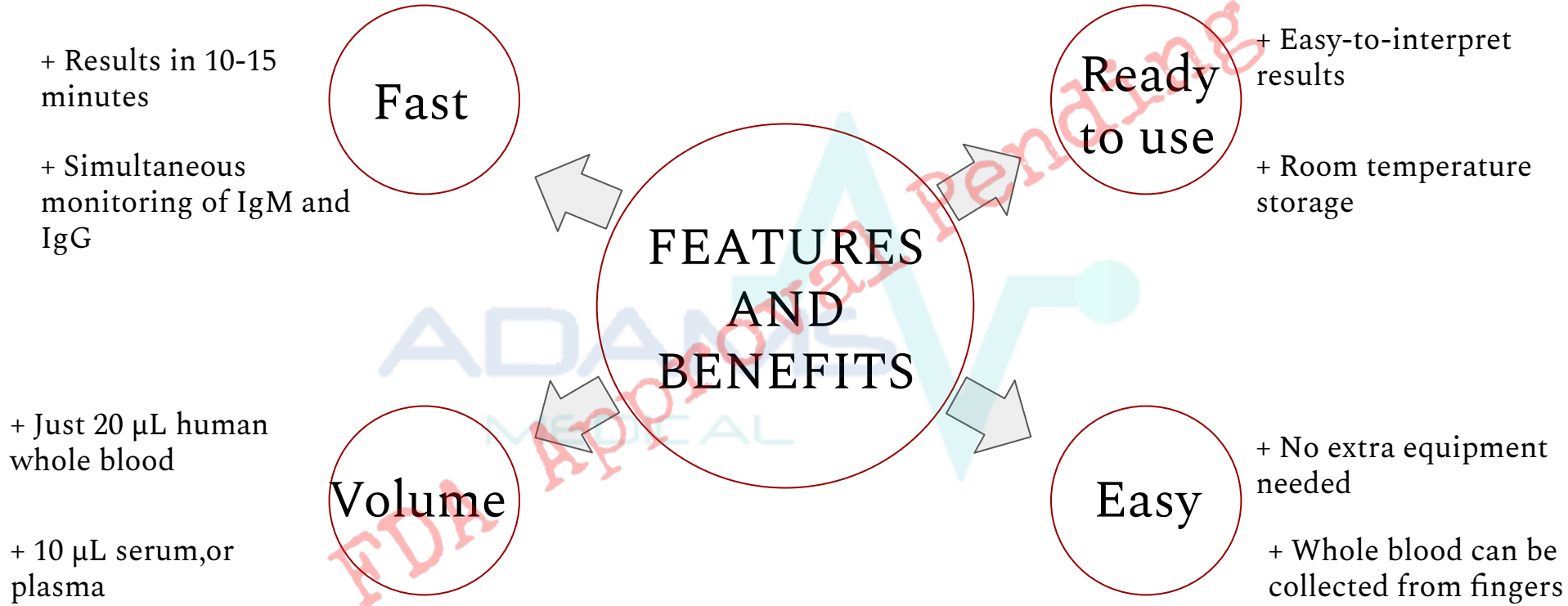
Profiles of viral load and antibody (IgM and IgG) response during infection by SARS-CoV-2



ABOUT CHIL COVID-19 IgG/IgM RAPID TEST



CHIL COVID-19 IgG/IgM Rapid Test is a lateral flow immunoassay test designed for the simultaneous in vitro detection of IgM and IgG antibodies to SARS-CoV-2 virus in human whole blood, serum, or plasma.



HOW WE PRESENT OUR PRODUCT

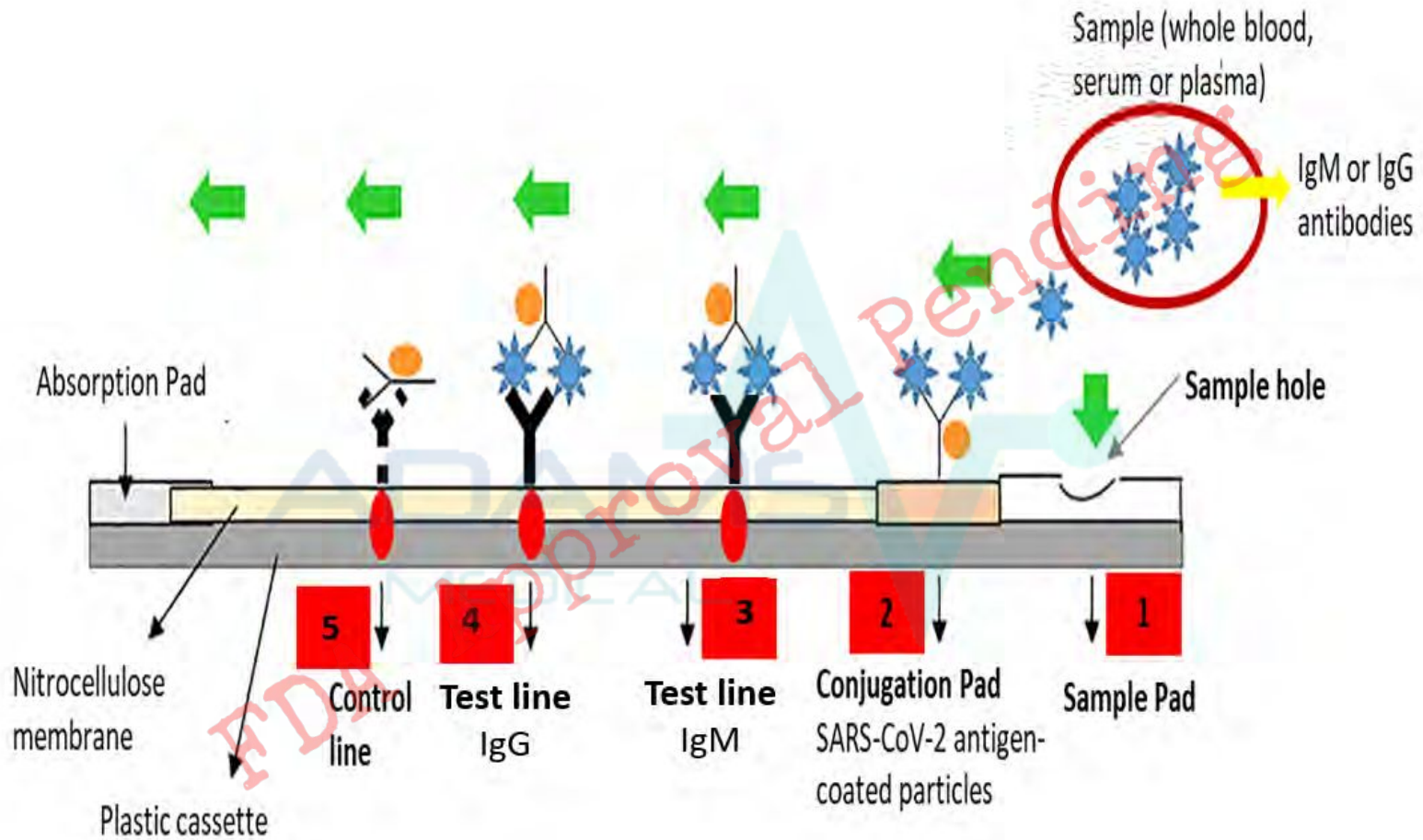
1. 50 CASSETTE TESTS
2. BUFFER
3. 50 SMALL PIPETTE DROPPERS
4. INSTRUCTIONS FOR US



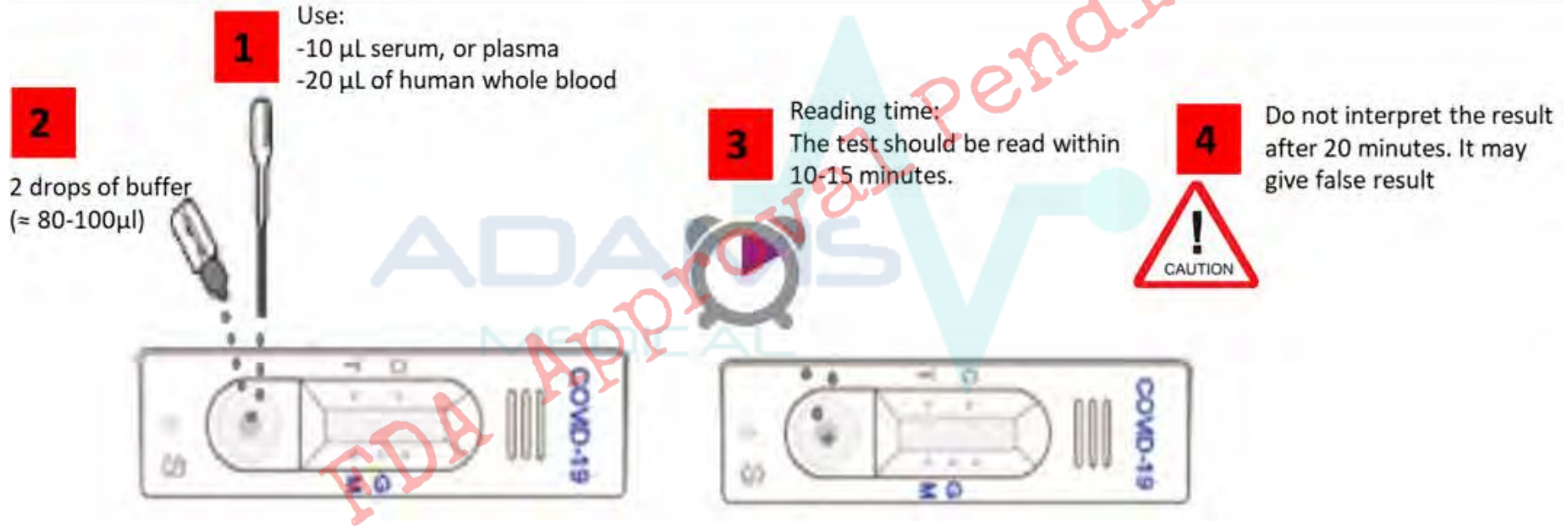
*Specific packaging is done on request for different quantity and content per box.

- The clinical specimen (whole blood, serum, or plasma) is added to the sample hole. Then, the dilution buffer is added. The combined sample flows down to the sample pad
- The specimen reacts with SARS-CoV-2 antigen-coated particles in the conjugation pad. The mixture then migrates upward on the membrane chromatographically by capillary action.
- Reaction starts in the test region. First is the M line, which contains an immobilised anti-human IgM. Any IgM antibodies will bind here. Thus, human IgM antibody/COVID-19 antigen/gold nanoparticle complexes will produce a visible coloured line. The same process is performed for IgG antibodies.
- If the specimen does not contain antibodies to SARS-CoV-2, no coloured line will appear in either of the test line regions, indicating a negative result.
- To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

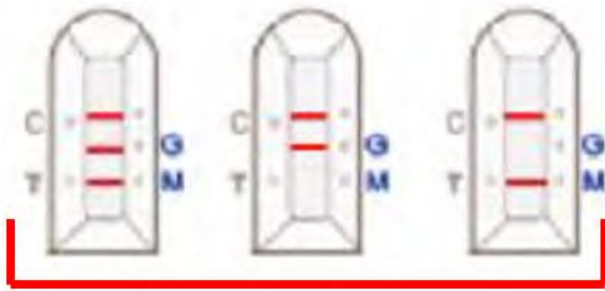
PRINCIPLE OF THE CHIL COVID-19 IgG/IgM TEST



HOW TO USE COVID-19 IgG/IgM TEST



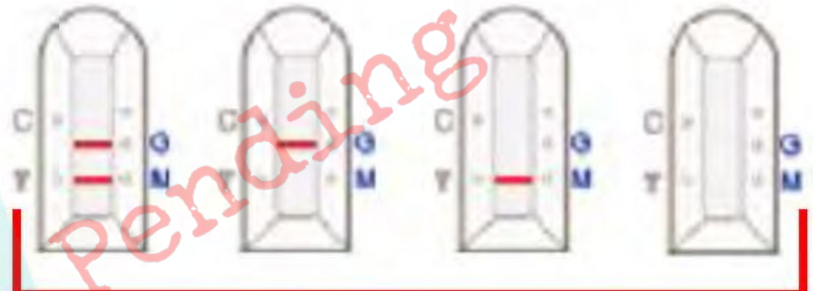
HOW TO INTERPRET COVID-19 IgG/IgM TEST RESULTS



Positive



Negative



Invalid

TEST RESULTS	INTERPRETATION	MOLECULAR TEST NEEDED?
IgM neg – IgG neg, no symptoms	Pt not suspected of having COVID-19.	NO
IgM neg – IgG neg, with symptoms	Pt could have been recently infected and is in the lag period for the test. Retest later or proceed immediately to the molecular test.	YES
IgM pos – IgG pos	Active case – Pt is infective and must be isolated.	CONFIRMATION RECOMMENDED
IgM pos – IgG neg	Active case – Pt is infective and must be isolated. Pt has been recently infected.	CONFIRMATION RECOMMENDED
IgM neg – IgG pos	Pt may have had an infection previously, but recovered. Further molecular testing for the virus is needed to determine if the Pt is still infective to others.	YES

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test cassette is stable through the expiration date printed on the sealed pouch.
- The test cassette must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- For single use only.
- Apply the specimen dropping right exactly into specimen well carefully to be sure that all specimen is transferred into strip inside the cassette.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect the results.

PERFORMANCE EVALUATION RESULTS

PURPOSE

- The purpose of the retrospective study is to testing CHIL Covid-19 IgG/IgM Rapid Test on 87 specimens from patients infected SARS-COV-2 (COVID19) and 393 specimens from the SARS-COV-2 (Covid-19) negative cases collected.

PRODUCT INFORMATION:

- REF:CCOV-200

- LOT:CCOV-200.19.02a

CCOV-200.19.02b

CCOV-200.19.02c

SPECIMEN INFORMATION

- 87 Covid-19 Positive Confirmed Specimen

- 393 Covid-19 Negative Confirmed Specimen

PERFORMANCE EVALUATION RESULTS

SENSITIVITY AND SPECIFICITY

- The COVID-19 IgG/IgM Rapid Test Cassette was compared with a leading commercial PCR. The study included 468 specimens for IgG and 480 specimens for IgM.

IgG Results		Confirmed Clinical		Total Results
COVID-19 IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	75	2	77
	Negative	0	391	391
Total Results		75	393	468

Sensitivity: 100% (95%CI: 96.1%~100.0%)*

Specificity: 99.5% (95%CI: 98.1%~99.9%)*

Accuracy: 99.6 % (95%CI: 98.4%~99.9%)* *CI

IgM Results		Confirmed Clinical		Total Results
COVID-19 IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	79	3	82
	Negative	8	390	398
Total Results		87	393	480

Sensitivity: 91.0% (95%CI: 83.8%~96.6%)*

Specificity: 99.2% (95%CI: 97.7%~99.8%)*

Accuracy: 98.0 % (95%CI: 96.0%~98.9%)* *CI

PERFORMANCE EVALUATION RESULTS

TEST RESULTS

1. POSITIVE SPECIMENS



NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result	Background of Clinical Diagnosis
1	Conf.cp1	18.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Community acquired pneumonia, non severe viral pneumonia
2	Conf.cp2	18.02.2020	Plasma	Neg	Pos	Neg	Definitive Diagnosis	Viral Pneumonia
3	Conf.cp3	17.02.2020	Serum	Neg	Neg	Neg	Clinical Diagnosis	Covid-19
4	Conf.cp4	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
5	Conf.cp5	16.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Acute bronchitis
6	Conf.cp6	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Pulmonary infection
7	Conf.cp7	18.02.2020	Serum	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
8	Conf.cp8	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
9	Conf.cp9	18.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
10	Conf.cp10	18.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
11	Conf.cp11	18.02.2020	Plasma	Pos	Neg	Neg	Definitive Diagnosis	Covid-19/Community acquired pneumonia, severe viral pneumonia/Acute respiratory failure/Acute exacerbation of chronic bronchitis
12	Conf.cp12	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result	Background of Clinical Diagnosis
13	Conf.cp13	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
14	Conf.cp14	18.02.2020	Serum	Pos	Pos	-	Definitive Diagnosis	Fever
15	Conf.cp15	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
16	Conf.cp16	17.02.2020	Plasma	Neg	Neg	Neg	Clinical Diagnosis	Community acquired pneumonia, severe viral pneumonia
17	Conf.cp17	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
18	Conf.cp18	16.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
19	Conf.cp19	16.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
20	Conf.cp20	17.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19/Community acquired pneumonia, severe viral pneumonia/Acute respiratory failure
21	Conf.cp21	18.02.2020	Serum/Wb	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
22	Conf.cp22	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
23	Conf.cp23	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
24	Conf.cp24	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
25	Conf.cp25	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
26	Conf.cp26	16.02.2020	Plasma	Neg	Neg	Neg	Definitive Diagnosis	Covid-19
27	Conf.cp27	17.02.2020	Serum	Neg	Pos	Neg	Definitive Diagnosis	Covid-19

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result	Background of Clinical Diagnosis
28	Conf.cp28	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
29	Conf.cp29	18.02.2020	Plasma	Neg	Pos	Pos	Definitive Diagnosis	Covid-19/Community acquired pneumonia, severe viral pneumonia
30	Conf.cp30	18.02.2020	Plasma/Wb	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
31	Conf.cp31	17.02.2020	Plasma	Neg	Pos	Neg	Definitive Diagnosis	Covid-19/Community acquired pneumonia, non severe viral pneumonia
32	Conf.cp32	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
33	Conf.cp33	16.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19/Community acquired pneumonia, severe viral pneumonia/Chronic bronchitis with emphysema
34	Conf.cp34	16.02.2020	Plasma(Wb	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
35	Conf.cp35	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
36	Conf.cp36	18.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
37	Conf.cp37	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
38	Conf.cp38	18.02.2020	Plasma	Neg	Pos	-	Definitive Diagnosis	Fever
39	Conf.cp39	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
40	Conf.cp40	18.02.2020	Plasma	Pos	Pos	-	Definitive Diagnosis	Fever
41	Conf.cp41	18.02.2020	Serum	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
42	Conf.cp42	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result	Background of Clinical Diagnosis
43	Conf.cp43	18.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
44	Conf.cp44	17.02.2020	Plasma	Neg	Neg	Pos	Definitive Diagnosis	Fever
45	Conf.cp45	16.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19/ History of nasopharyngeal cancer
46	Conf.cp46	16.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
47	Conf.cp47	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
48	Conf.cp48	18.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
49	Conf.cp49	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Viral pneumonia
50	Conf.cp50	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
51	Conf.cp51	18.02.2020	Serum/Wb	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
52	Conf.cp52	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Viral pneumonia
53	Conf.cp53	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
54	Conf.cp54	18.02.2020	Serum	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
55	Conf.cp55	16.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
56	Conf.cp56	17.02.2020	Serum	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
57	Conf.cp57	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19/Community acquired pneumonia, severe viral pneumonia/Chronic bronchitis with emphysema

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result	Background of Clinical Diagnosis
58	Conf.cp58	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
59	Conf.cp59	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19/ Emphysema
60	Conf.cp60	16.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
61	Conf.cp61	16.02.2020	Serum	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
62	Conf.cp62	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19/ Pulmonary infections, viral pneumonia
63	Conf.cp63	16.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19
64	Conf.cp64	18.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
65	Conf.cp65	17.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
66	Conf.cp66	17.02.2020	Plasma	Neg	Neg	Neg	Clinical Diagnosis	Viral pneumonia
67	Conf.cp67	18.02.2020	Plasma	Neg	Neg	-	Clinical Diagnosis	Covid-19
68	Conf.cp68	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19/ Community acquired pneumonia, non severe viral pneumonia
69	Conf.cp69	17.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Pulmonary infections, viral pneumonia
70	Conf.cp70	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
71	Conf.cp71	18.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
72	Conf.cp72	18.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result	Background of Clinical Diagnosis
73	Conf.cp73	17.02.2020	Plasma	Neg	Neg	Pos	Definitive Diagnosis	Fever
74	Conf.cp74	18.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19/Community acquired pneumonia, severe viral pneumonia
75	Conf.cp75	17.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19/Emphysema
76	Conf.cp76	18.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
77	Conf.cp77	16.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
78	Conf.cp78	16.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
79	Conf.cp79	17.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
80	Conf.cp80	17.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
81	Conf.cp81	18.02.2020	Plasma	Pos	Pos	Neg	Definitive Diagnosis	Covid-19/Community acquired pneumonia, non severe viral pneumonia
82	Conf.cp82	17.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
83	Conf.cp83	18.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
84	Conf.cp84	17.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
85	Conf.cp85	16.02.2020	Plasma	Pos	Pos	Pos	Definitive Diagnosis	Covid-19
86	Conf.cp86	18.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19
87	Conf.cp87	17.02.2020	Plasma	Pos	Pos	Neg	Clinical Diagnosis	Covid-19

PERFORMANCE EVALUATION RESULTS

TEST RESULTS

1. NEGATIVE SPECIMENS

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
1	Conf.cn1	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
2	Conf.cn2	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
3	Conf.cn3	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
4	Conf.cn4	18.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
5	Conf.cn5	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
6	Conf.cn6	18.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
7	Conf.cn7	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
8	Conf.cn8	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
9	Conf.cn9	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
10	Conf.cn10	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
11	Conf.cn11	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
12	Conf.cn12	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
13	Conf.cn13	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid- 19 RT IgG Result	CHIL Covid- 19 RT IgM Result	PCR Result	Diagnostic Result
14	Conf.cn14	18.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
15	Conf.cn15	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
16	Conf.cn16	19.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
17	Conf.cn17	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
18	Conf.cn18	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
19	Conf.cn19	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
20	Conf.cn20	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
21	Conf.cn21	18.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
22	Conf.cn22	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
23	Conf.cn23	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
24	Conf.cn24	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
25	Conf.cn25	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
26	Conf.cn26	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
27	Conf.cn27	18.02.2020	Serum	Neg	Neg	Neg	Covid-19 Negative
28	Conf.cn28	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
29	Conf.cn29	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
30	Conf.cn30	19.02.2020	Plasma/Wb	Neg	Neg	Neg	Covid-19 Negative
31	Conf.cn31	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
32	Conf.cn32	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
33	Conf.cn33	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
34	Conf.cn34	16.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
35	Conf.cn35	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
36	Conf.cn36	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
37	Conf.cn37	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
38	Conf.cn38	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
39	Conf.cn39	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
40	Conf.cn40	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
41	Conf.cn41	19.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
42	Conf.cn42	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
43	Conf.cn43	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
44	Conf.cn44	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
45	Conf.cn45	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
46	Conf.cn46	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
47	Conf.cn47	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
48	Conf.cn48	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
49	Conf.cn49	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
50	Conf.cn50	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
51	Conf.cn51	18.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
52	Conf.cn52	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
53	Conf.cn53	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
54	Conf.cn54	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
55	Conf.cn55	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
56	Conf.cn56	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
57	Conf.cn57	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
58	Conf.cn58	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
59	Conf.cn59	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
60	Conf.cn60	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
61	Conf.cn61	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
62	Conf.cn62	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
63	Conf.cn63	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
64	Conf.cn64	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
65	Conf.cn65	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
66	Conf.cn66	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
67	Conf.cn67	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
68	Conf.cn68	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
69	Conf.cn69	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
70	Conf.cn70	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
71	Conf.cn71	17.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
72	Conf.cn72	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
73	Conf.cn73	16.02.2020	Serum	Neg	Neg	Neg	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
74	Conf.cn74	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
75	Conf.cn75	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
76	Conf.cn76	17.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
77	Conf.cn77	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
78	Conf.cn78	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
79	Conf.cn79	18.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
80	Conf.cn80	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
81	Conf.cn81	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
82	Conf.cn82	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
83	Conf.cn83	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
84	Conf.cn84	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
85	Conf.cn85	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
86	Conf.cn86	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
87	Conf.cn87	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
88	Conf.cn88	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
89	Conf.cn89	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
90	Conf.cn90	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
91	Conf.cn91	17.02.2020	Plasma	Pos	Pos	/	Covid-19 Negative
92	Conf.cn92	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
93	Conf.cn93	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
94	Conf.cn94	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
95	Conf.cn95	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
96	Conf.cn96	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
97	Conf.cn97	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
98	Conf.cn98	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
99	Conf.cn99	16.02.2020	Serum/Wb	Neg	Neg	Neg	Covid-19 Negative
100	Conf.cn100	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
101	Conf.cn101	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
102	Conf.cn102	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
103	Conf.cn103	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
104	Conf.cn104	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
105	Conf.cn105	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
106	Conf.cn106	18.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
107	Conf.cn107	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
108	Conf.cn108	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
109	Conf.cn109	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
110	Conf.cn110	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
111	Conf.cn111	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
112	Conf.cn112	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
113	Conf.cn113	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
114	Conf.cn114	19.02.2020	Serum	Neg	Neg	Neg	Covid-19 Negative
115	Conf.cn115	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
116	Conf.cn116	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
117	Conf.cn117	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
118	Conf.cn118	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
119	Conf.cn119	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
120	Conf.cn120	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
121	Conf.cn121	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
122	Conf.cn122	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
123	Conf.cn123	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
124	Conf.cn124	17.02.2020	Plasma	Neg	Pos	/	Covid-19 Negative
125	Conf.cn125	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
126	Conf.cn126	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
127	Conf.cn127	20.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
128	Conf.cn128	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
129	Conf.cn129	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
130	Conf.cn130	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
131	Conf.cn131	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
132	Conf.cn132	18.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
133	Conf.cn133	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
134	Conf.cn134	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
135	Conf.cn135	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
136	Conf.cn136	19.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
137	Conf.cn137	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
138	Conf.cn138	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
139	Conf.cn139	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
140	Conf.cn140	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
141	Conf.cn141	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
142	Conf.cn142	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
143	Conf.cn143	20.02.2020	Plasma/Wb	Neg	Neg	Neg	Covid-19 Negative
144	Conf.cn144	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
145	Conf.cn145	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
146	Conf.cn146	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
147	Conf.cn147	17.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
148	Conf.cn148	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
149	Conf.cn149	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
150	Conf.cn150	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
151	Conf.cn151	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
152	Conf.cn152	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
153	Conf.cn153	16.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
154	Conf.cn154	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
155	Conf.cn155	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
156	Conf.cn156	15.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
157	Conf.cn157	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
158	Conf.cn158	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
159	Conf.cn159	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
160	Conf.cn160	18.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
161	Conf.cn161	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
162	Conf.cn162	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
163	Conf.cn163	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
164	Conf.cn164	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
165	Conf.cn165	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
166	Conf.cn166	17.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
167	Conf.cn167	20.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
168	Conf.cn168	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
169	Conf.cn169	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
170	Conf.cn170	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
171	Conf.cn171	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
172	Conf.cn172	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
173	Conf.cn173	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
174	Conf.cn174	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
175	Conf.cn175	19.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
176	Conf.cn176	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
177	Conf.cn177	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
178	Conf.cn178	16.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
179	Conf.cn179	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
180	Conf.cn180	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
181	Conf.cn181	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
182	Conf.cn182	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
183	Conf.cn183	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
184	Conf.cn184	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
185	Conf.cn185	17.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
186	Conf.cn186	17.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
187	Conf.cn187	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
188	Conf.cn188	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
189	Conf.cn189	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
190	Conf.cn190	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
191	Conf.cn191	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
192	Conf.cn192	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
193	Conf.cn193	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
194	Conf.cn194	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
195	Conf.cn195	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
196	Conf.cn196	21.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
197	Conf.cn197	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
198	Conf.cn198	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
199	Conf.cn199	18.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
200	Conf.cn200	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
201	Conf.cn201	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
202	Conf.cn202	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
203	Conf.cn203	17.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
204	Conf.cn204	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
205	Conf.cn205	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
206	Conf.cn206	18.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
207	Conf.cn207	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
208	Conf.cn208	18.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
209	Conf.cn209	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
210	Conf.cn210	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
211	Conf.cn211	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
212	Conf.cn212	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
213	Conf.cn213	16.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
214	Conf.cn214	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
215	Conf.cn215	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
216	Conf.cn216	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
217	Conf.cn217	20.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
218	Conf.cn218	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
219	Conf.cn219	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
220	Conf.cn220	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
221	Conf.cn221	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
222	Conf.cn222	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
223	Conf.cn223	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
224	Conf.cn224	19.02.2020	Plasma	Neg	Pos	/	Covid-19 Negative
225	Conf.cn225	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
226	Conf.cn226	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
227	Conf.cn227	16.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
228	Conf.cn228	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
229	Conf.cn229	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
230	Conf.cn230	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
231	Conf.cn231	21.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
232	Conf.cn232	21.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
233	Conf.cn233	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
234	Conf.cn234	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
235	Conf.cn235	22.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
236	Conf.cn236	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
237	Conf.cn237	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
238	Conf.cn238	22.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
239	Conf.cn239	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
240	Conf.cn240	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
241	Conf.cn241	18.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
242	Conf.cn242	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
243	Conf.cn243	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
244	Conf.cn244	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
245	Conf.cn245	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
246	Conf.cn246	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
247	Conf.cn247	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
248	Conf.cn248	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
249	Conf.cn249	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
250	Conf.cn250	19.02.2020	Plasma	Pos	Neg	/	Covid-19 Negative
251	Conf.cn251	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
252	Conf.cn252	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
253	Conf.cn253	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
254	Conf.cn254	18.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
255	Conf.cn255	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
256	Conf.cn256	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
257	Conf.cn257	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
258	Conf.cn258	20.02.2020	Plasma/Wb	Neg	Neg	Neg	Covid-19 Negative
259	Conf.cn259	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
260	Conf.cn260	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
261	Conf.cn261	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
262	Conf.cn262	19.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
263	Conf.cn263	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
264	Conf.cn264	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
265	Conf.cn265	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
266	Conf.cn266	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
267	Conf.cn267	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
268	Conf.cn268	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
269	Conf.cn269	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
270	Conf.cn270	19.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
271	Conf.cn271	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
272	Conf.cn272	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
273	Conf.cn273	19.02.2020	Serum	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
274	Conf.cn274	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
275	Conf.cn275	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
276	Conf.cn276	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
277	Conf.cn277	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
278	Conf.cn278	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
279	Conf.cn279	16.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
280	Conf.cn280	16.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
281	Conf.cn281	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
282	Conf.cn282	17.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
283	Conf.cn283	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
284	Conf.cn284	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
285	Conf.cn285	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
286	Conf.cn286	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
287	Conf.cn287	17.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
288	Conf.cn288	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
289	Conf.cn289	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
290	Conf.cn290	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
291	Conf.cn291	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
292	Conf.cn292	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
293	Conf.cn293	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid- 19 RT IgG Result	CHIL Covid- 19 RT IgM Result	PCR Result	Diagnostic Result
294	Conf.cn294	18.02.2020	Plasma/Wb	Neg	Neg	Neg	Covid-19 Negative
295	Conf.cn295	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
296	Conf.cn296	16.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
297	Conf.cn297	16.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
298	Conf.cn298	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
299	Conf.cn299	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
300	Conf.cn300	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
301	Conf.cn301	22.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
302	Conf.cn302	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
303	Conf.cn303	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
304	Conf.cn304	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
305	Conf.cn305	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
306	Conf.cn306	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
307	Conf.cn307	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
308	Conf.cn308	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
309	Conf.cn309	17.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
310	Conf.cn310	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
311	Conf.cn311	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
312	Conf.cn312	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
313	Conf.cn313	19.02.2020	Plasma	Neg	Neg	/	Co+ A295:H314vid-19 NegativeCovid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
314	Conf.cn314	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
315	Conf.cn315	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
316	Conf.cn316	17.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
317	Conf.cn317	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
318	Conf.cn318	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
319	Conf.cn319	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
320	Conf.cn320	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
321	Conf.cn321	17.02.2020	Serum	Neg	Neg	Neg	Covid-19 Negative
322	Conf.cn322	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
323	Conf.cn323	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
324	Conf.cn324	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
325	Conf.cn325	20.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
326	Conf.cn326	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
327	Conf.cn327	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
328	Conf.cn328	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
329	Conf.cn329	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
330	Conf.cn330	22.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
331	Conf.cn331	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
332	Conf.cn332	17.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
333	Conf.cn333	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
334	Conf.cn334	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
335	Conf.cn335	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
336	Conf.cn336	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
337	Conf.cn337	17.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
338	Conf.cn338	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
339	Conf.cn339	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
340	Conf.cn340	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
341	Conf.cn341	16.02.2020	Plasma/Wb	Neg	Neg	Neg	Covid-19 Negative
342	Conf.cn342	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
343	Conf.cn343	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
344	Conf.cn344	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
345	Conf.cn345	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
346	Conf.cn346	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
347	Conf.cn347	17.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
348	Conf.cn348	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
349	Conf.cn349	18.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
350	Conf.cn350	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
351	Conf.cn351	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
352	Conf.cn352	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
353	Conf.cn353	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
354	Conf.cn354	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
355	Conf.cn355	19.02.2020	Plasma/Wb	Neg	Neg	/	Covid-19 Negative
356	Conf.cn356	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
357	Conf.cn357	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
358	Conf.cn358	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
359	Conf.cn359	16.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative
360	Conf.cn360	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
361	Conf.cn361	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
362	Conf.cn362	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
363	Conf.cn363	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
364	Conf.cn364	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
365	Conf.cn365	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
366	Conf.cn366	20.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
367	Conf.cn367	20.02.2020	Serum	Neg	Neg	/	Covid-19 Negative
368	Conf.cn368	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
369	Conf.cn369	17.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
370	Conf.cn370	21.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
371	Conf.cn371	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
372	Conf.cn372	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
373	Conf.cn373	18.02.2020	Serum/Wb	Neg	Neg	/	Covid-19 Negative

NO	ID NO	Specimen Collecting Date	Specimen Type	CHIL Covid-19 RT IgG Result	CHIL Covid-19 RT IgM Result	PCR Result	Diagnostic Result
374	Conf.cn374	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
375	Conf.cn375	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
376	Conf.cn376	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
377	Conf.cn377	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
378	Conf.cn378	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
379	Conf.cn379	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
380	Conf.cn380	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
381	Conf.cn381	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
382	Conf.cn382	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
383	Conf.cn383	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
384	Conf.cn384	16.02.2020	Plasma	Neg	Neg	Neg	Covid-19 Negative
385	Conf.cn385	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
386	Conf.cn386	18.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
387	Conf.cn387	17.02.2020	Plasma/Wb	Neg	Neg	Neg	Covid-19 Negative
388	Conf.cn388	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
389	Conf.cn389	21.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
390	Conf.cn390	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
391	Conf.cn391	17.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
392	Conf.cn392	19.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative
393	Conf.cn393	16.02.2020	Plasma	Neg	Neg	/	Covid-19 Negative

PERFORMANCE EVALUATION RESULTS

CROSS-REACTIVITY

The COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/Plasma) has been tested for;

- anti-influenza A virus,
- anti-influenza B virus,
- anti-RSV,
- anti-Adenovirus,
- HBsAg,
- anti-Syphilis,
- anti-H.Pylori,
- anti-HIV,
- anti-HCV

THE RESULTS
SHOWED NO
CROSS-REACTIVI
TY

PERFORMANCE EVALUATION RESULTS

INTERFERENCE

The following potentially interfering substances were added to SARS-CoV-2 negative specimens;

- Acetaminophen: 20 mg/dL
- Acetylsalicylic Acid: 20 mg/dL
- Ascorbic Acid: 2g/dL
- Bilirubin: 1g/dL
- Creatine: 200 mg/dL
- Caffeine: 20 mg/dL

NONE OF THE
SUBSTANCES AT
THE
CONCENTRATION
TESTED
INTERFERED IN
THE ASSAY

PERFORMANCE EVALUATION RESULTS

REAL-TIME STABILITY

Three consecutive lots of Covid-19 IgG/IgM Rapid Test are stored at 2°C and 30°C for 26 months to be tested in the 3rd, 6th, 12th, 18th, 24th, and 26th months, respectively, according to the technical requirements of the company's products; physical properties, Positive Reference Product Compliance Rate, Negative Reference Product Compliance Rate, Minimum Detection Limit, and Precision.

The study result has not been completed because it has not yet ended. However, the test results meet the technical requirements of the product, so the product is tentatively valid for 12 months.

PERFORMANCE EVALUATION RESULTS

TRANSPORT STABILITY

The transportation condition may influence the stability of the products.

The Covid-19 IgG/IgM Rapid Test can be transported at temperature 2°C to 30°C, considering the severe winter and the hot summer, choosing two extreme temperature (-20°C and 50°C) to verify the influence on the products lasting for 30 days. And then placing the above products at the temperature 2°C to 30°C to the end of the expiry date to study the expired products.

The Covid-19 IgG/IgM Rapid Test have been stored at extreme temperature -20°C and 50°C for 30 days, its test results meet all the requirements. Even though the study on expired products has begun, but the first detection time has not arrived. In response to this, the Covid-19 IgG/IgM Rapid Test can be transported at normal temperature in short period, but certain precautions must be taken to avoid high temperature and freeze thawing in extreme summer and winter.

PERFORMANCE EVALUATION RESULTS

ACCELERATED STABILITY

Three consecutive lots of Covid-19 IgG/IgM Rapid Test are stored at 37 °C for 22 days. At first, 8, 15, 25, 30 days, according to the technical requirements of the manufacturer CHIL; physical properties, positive reference rate, negative reference rate, Minimum Detection Limit and Precision are tested respectively.

The physical properties, compliance rate of positive reference, compliance rate of negative reference, Minimum Detection Limit and Precision of the three lots of Covid-19 IgG/IgM Rapid Test are all met the technical requirements of the products. The test results of high temperature damage test at 37 °C for 22 days met the technical requirements of the product. Therefore, the validity of the product is tentatively determined to be 12 months.

PERFORMANCE EVALUATION RESULTS

IN USE STABILITY

The external factors affecting the quality of reagents mainly are temperature and humidity. The external environmental conditions are selected as follows: temperature 20 °C to 30°C, humidity 20% to 70% and three consecutive lots of Covid-19 IgG/IgM Rapid Test are placed for 1.5 hours. According to the technical requirements of the company's product, physical properties, Positive Reference Product Compliance Rate, Negative Reference Product Compliance Rate, Minimum Detection Limit, and Precision are tested separately. The product must be used in 1hour at room temperature 20 to 30°C and humidity below 60% after opening the inner package;and must be used immediately at humidity above 60%.

No change in performance results is observed when the product placing for 1.5 hours at the temperature 20°C to 30°C and humidity below 60%. In response to this, the life of the product after unsealing set as this product must be used in 1hour at room temperature 20 to 30°C and humidity below 60% after opening the inner package;and must be used immediately at humidity above 60%.

Number: 80962070-605.02

Subject: Result of the Chil Evaluation Report

The kits, supplied by the manufacturers to the domestic market in order to diagnose the COVID-19 infection in accordance with the medical device definitions specified in the "in Vitro Diagnostic Medical Devices Regulations" published on the Official Gazette dated 09.01.2007 numbered 26398, are considered as in vitro diagnostic medical devices and must meet the requirements of the mentioned regulations.

Because the kits used for diagnosing COVID-19 have been developed hastily and have not been tested with a sufficient number of clinic samples and similar technical inadequacies their error margins may be larger than the defined confidence interval; therefore UTS Product Tracking System registrations and import of those kits have been subjected to the prior permission of TİTCK (Turkish Medicines and Medical Devices Agency) ("Le Communiqué on Import of Medical Diagnosis Kits" published on the Official Gazette dated 14.02.2020 dated 31807). Within the described context Public Health General Directorate have been authorized to determine the efficiency of the COVID-19 Diagnosis Kits, by the official letter dated 03.04.2020 numbered 4853586-511-E.85079 of TİTCK. While the registrations of COVID-19 Diagnosis Kits are being made to in the UTS by TİTCK we are required to perform compliance testing of the kits to determine whether or not they meet the basic confidence and performance requirements of the regulations and to send the results of the tests to TİTCK for enabling the said agency to register those results in UTS.

Accordingly the COVID-19 antibody kit developed by the company Chil Tibbi Malzeme San. Tic. Şirketi were tested on clinical samples from 200 patients suspected of having COVID-19. The results of the tests have been compared with those of the Kit named Bio-speedy COVID-19 Rt-qPCR Kit the use of which has been approved by Ministry of Health and concluded that the aforesaid COVID-19 Antibody Kit of Chil Brand is technically appropriate for use.

Kindly submitted for necessary action.

Associate Prof. Dr. Fatih KARA
General Director
(Signed by electronic signature)

Annex: Application of the Company Chil for COVID-19 Test Evaluation

You may access this document signed by electronic signature by entering the code e0cb227f-927d-4da3-bb6c-202a37b1f555 at the internet address <http://e-belge.saglik.gov.tr>.

This document has been translated by me from its Turkish into English.
İşbu belge tarafımdan Türkçe suretinden İngilizceye tercüme edilmiştir.

Onay:

İşbu belgenin dairem yeminli tercümanı SEDA TÜRKAN İLHAN tarafından Türkçe suretinden İngilizceye tercüme edildiğini onaylarım. İki bin yirmi yılı, mayıs ayının yedinci günü. 07.05.2020.



**REPUBLIC OF
TURKEY
MINISTRY OF
HEALTH
APPROVAL**

CHIL COVID-19 IgG/IgM Rapid
Test Cassette (Whole
blood/Serum/Plasma) has been
tested with comparison to Rt-qPCR
by REPUBLIC OF TURKEY
MINISTRY OF HEALTH Public
Health General Directorate, and
approved for the quality

EC DECLARATION OF CONFORMITY

General In vitro Diagnostic Medical Devices in
accordance with Directive 98/79/EC

Manufacturer : Chil Tibbi Mal. San. Tic. Ltd. Şti.
Address : 10028 Sok. No:11 AOSB 35620 Çiğli/Izmir-Turkey
Product name : COVID-19 IgG/IgM Rapid Test
Brand : CHIL®
Classification : Professional usage IVD
Route : Annex III

We, here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In-Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Applied Standards & regulations : List is available in QAS

Start of CE Marking

Date/Revision No : 17.02.2020/0

Signature: Name : Senay ÇİL

Position : MANAGEMENT RESPONSIBLE

CE

CHIL

CHİL TIBBİ MAL. SAN. VE TİC. LTD. ŞTİ.
10028 Sok. No:11 AOSB 35620 Çiğli-IZMİR
Çiğli V.D. 2020544495 Tic Sic.No:159143
Mersis No:026905444500019

CHİL TIBBİ MAL. SAN. TİC. LTD. ŞTİ.
10028 Sok. No:11 AOSB 35620 Çiğli-Izmir/Turkey
Tel: +90 232 2610321 Fax: +90 232 2610388
info@chil.com.tr www.chil.com.tr

CE CERTIFICATION

CHIL COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/Plasma) meets the provisions of the council directive 98/79/EC for In-Vitro Diagnostic Medical Devices. All supporting documentation is retained under the manufacturing premises of CHIL.

ISO 9001- ISO 13485 CERTIFICATION



No. J - 2645/2/2018

This is to certify that:

CHIL TIBBİ MAL. SAN. TİC. LTD. ŞTİ.
10028 Sokak No:11 A.O.S.B 35620 Çiğli
İzmir, Turkey

is in conformance with

EN ISO 9001:2015

In the following scope of activities:

development, manufacturing final release and distribution of
List A, List B, self-control and self-declared in-vitro
diagnostic medical devices

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.
This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 17.08.2018 to 16.08.2021



Michał Pachowski, Ph.D.
President of PCBC

CHIL's Quality Assurance
System is established
since it was founded, and
certified by European
Notified Bodies. CHIL
continually improve its
effectiveness in
accordance with national
and international
regulations.



CERTIFICATE

No. M - 49/2/2018

This is to certify that:

CHIL TIBBİ MAL. SAN. TİC. LTD. ŞTİ.
10028 Sokak No:11 A.O.S.B 35620 Çiğli
İzmir, Turkey

is in conformance with

EN ISO 13485:2016

In the following scope of activities:

development, manufacturing final release and distribution of
List A, List B, self-control and self-declared in-vitro
diagnostic medical devices

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.
This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 17.08.2018 to 16.08.2021



Michał Pachowski, Ph.D.
President of PCBC

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REFERENCES

- Carter, L. J., Garner, L. V., Smoot, J. W., Li, Y., Zhou, Q., Saveson, C. J., ... & Jervey, S. R. (2020). Assay Techniques and Test Development for COVID-19 Diagnosis
- Chen, W. H., Hotez, P. J., & Bottazzi, M. E. (2020). Potential for developing a SARS-CoV receptor-binding domain (RBD) recombinant protein as a h
- Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
- El Zowalaty, M. E., & Järhult, J. D. (2020). From SARS to COVID-19: A previously unknown SARS-CoV-2 virus of pandemic potential infecting humans–Call for a One Health approach. One Health, 100124
- Pooladanda, V., Thatikonda, S., & Godugu, C. (2020). The current understanding and potential therapeutic options to combat COVID-19. Life Sciences, 117765
- Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502
- To, K. K. W., Tsang, O. T. Y., Leung, W. S., Tam, A. R., Wu, T. C., Lung, D. C., ... & Lau, D. P. L. (2020). Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. The Lancet Infectious Diseases
- Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164
- World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020
- Zeng, W., Liu, G., Ma, H., Zhao, D., Yang, Y., Liu, M., ... & Ding, C. (2020). Biochemical characterization of SARS-CoV-2 nucleocapsid protein. Biochemical and Biophysical Research Communications