REALTIME LABORATORIES INC.
Cutting edge. Breaking barriers.

December 10, 2020

Chinese Embassy Guidelines

Results of PCR and IgM for Travelers to China

RealTime Laboratories, Inc. meets all the requirements set forth by the Chinese Embassy in Washington, DC and its test results are approved for travel to China.

RealTime Laboratories is a fully credentialed and certified laboratory in the U.S. (See Page 1). The CMS certificate ensures all users that the lab is compliant with all regulations.

As directed by the Chinese Embassy in Washington, D.C., RealTime Laboratories has been compliant in its testing and reporting for the PCR (RT-PCR) NA/NAAT/RNA report (See Page 2).

As further directed by the Chinese Embassy in Washington, D.C., RealTime Laboratories has been compliant in testing and reporting the Rapid IgM Antibody Report. The report has the Specimen Type Serum and Venous Blood (See Page 3).

We have attached those forms to this letter in a pdf to assure our patients and travelers that such results are present on our reports.

D.G. Hooper, M.D., Ph.D.
RealTime Laboratories, Inc.
Medical Department

P 972.492.0419
F 972.243.7759

4100 Fairway Court, Suite 600
Carrollton, TX 75010

CAP #7210193 CLIA #: 45D1051736

www.RealTimeLab.com

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

REAL TIME LABORATORIES, INC
4100 FAIRWAY COURT, SUITE 600
CARROLLTON, TX 75010

CLIA ID NUMBER

45D1051736

EFFECTIVE DATE

10/19/2019

LABORATORY DIRECTOR

GEOFFREY A LAND Ph.D.

EXPIRATION DATE

10/18/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

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REALTIME LABORATORIES INC.
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Carrollton, TX 75010
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COVID-19 REVERSE TRANSCRIPTASE PCR (RT-PCR) NAA/NAAT/RNA REPORT 12/07/2020

PATIENT INFORMATION	ORDER INFORMATION	SAMPLE INFORMATION	LAB INFORMATION
Patient: [redacted]	**Accession No:** [redacted]	**Date of Receipt:** 12/07/2020	**Phone:** 1-972-492-0419
Patient Date of Birth: [redacted]	**Date of Report:** 12/07/2020	**Time of Receipt:** 12:38 CDT	**Fax:** 1-972-243-7759
Patient Sex: M	**Ordering Physician:** NA	**Date of Collection:** 12/7/2020	**Email:** info@realtimelab.com
Patient MRN: NA	**Practice:** RealTime Laboratories, Inc.	**Time of Collection:** 09:15 CDT	**CLIA #:** 45D1051736
Patient Passport No: [redacted]		**Specimen Type:** Nasal Swab	**CAP #:** 7210193
Patient Email: NA		**Collector Initials:** TR	**Tax ID #:** 0669342

COVID-19 PANEL RESULT

SARS-CoV-2 Not Detected (Test type: RealTime PCR)

TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific Inc.) is for use only under Emergency Use Authorization (EUA). Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. The test has been validated in accordance with the FDA's Guidance Document (Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency) issued on February 29th, 2020. FDA independent review of this validation is pending. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/or diagnosis of COVID-19 infecttion under section 564(b) (1) of the Act, 21 U.S.C. 360bbb-3 (b) (1), unless the authorization is terminated or revoked sooner.

Report Comments:

Passport No. [redacted]

Director or Designee Signature _____

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COVID-19 Rapid IgM Antibody (Serology) Report 12/07/2020

PATIENT INFORMATION	ORDER INFORMATION	SAMPLE INFORMATION	LAB INFORMATION
Patient: [redacted]	**Accession No:** [redacted]	**Date of Receipt:** 12/07/2020	**Phone:** 1-972-492-0419
Patient Date of Birth: [redacted]	**Date of Report:** 12/07/2020	**Time of Receipt:** 10:55 CDT	**Fax:** 1-972-243-7759
Patient Sex: M	**Ordering Physician:** NA	**Date of Collection:** 12/07/2020	**Email:** info@realtimelab.com
Patient MRN: NA	**Practice:** RealTime Laboratories, Inc.	**Time of Collection:** 09:15 CDT	**CLIA #:** 45D1051736
Patient Passport No: [redacted]		**Specimen Type:** Serum	**CAP #:** 7210193
Patient Email: NA		**Collector Initials:** TR	**Tax ID #:** 0669342

COVID-19 RAPID IgM RESULT

COVID-19 IgM Antibody Negative (Solid phase immunochromatographic assay (Rapid Test) for IgM)

COVID-19 IgG/IgM Rapid Test Cassette (Healgen Scientific LLC) has been authorized by FDA under an EUA for use by authorized laboratories.This test has not been FDA cleared or approved. 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.This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics 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.

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.

RTL maintains liability limited to cost of analysis. Interpretation of the data contained in this report is the responsibility of the client. This report relates only to the samples reported above and may not be reproduced, except in full, without written approval by RTL. The above test report relates only to the items tested. RTL bears no responsibility for sample collection activities or analytical method limitations.

Procedure Type: IgG and IgM Antibody Detection by Solid Phase Immunochromatographic Assay.

Report Comments:

Passport No. [redacted]; Venous Blood

Director or Designee Signature _____