SYNTRON
Bioresearch, Inc.

2774 LOKER AVENUE WEST, CARLSBAD, CALIFORNIA 92010

TEL: 760-930-2200 • FAX: 760-930-2212

May 5, 2020

COVID EUA status attestation

This letter is to update Syntron's policy on COVID-19 EUA strategy. As noted below, Tianjin New Bay Bioresearch previously notified FDA that they have validated a serology test and are distributing it for clinical use as outlined in Section IV.D of FDA's March 16th Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency as follows:

Product Code: 83QKO
Device Name: Quikpac II COVID-19 IgG/IgM
Intended Use Code: 081.006: Enforcement
Device Listing: D3484471

Sponsor/Developer: TIANJIN NEW BAY BIORESEARCH CO., LTD.
Establishment Registration Number: 3004561580
Address: 1 JIENSHE ROAD, BA LI TAI Industrial Are, Jin Nan District, Tianjin CHINA 300350
Contact Person: Tony Shan
Phone: 86 22-28751515
email: 2483879178@qq.com<mailto:2483879178@qq.com>

US Agent: Arjang Amini
US Agent/Distributor: SoCal Devices
Address: 999 Fifth Avenue, Suite 230
Address2: San Rafael, California, 94901
Phone: 858 218 6348
email: arjang@socaldevices.com<mailto:arjang@socaldevices.com>

This product is contract Manufactured at the following GMP facility:
Contract Manufacturer: SYNTRON BIORESEARCH, INC.
Establishment Registration Number: 2025760
Address: 2774 LOKER AVENUE, WEST
Contact Person: Charles Yu (General Manager)
Phone: 760 930 2200
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The FDA's policy for serology testing during the public health emergency was updated on May 4th, 2020. As indicated in the updated Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, FDA expects manufacturers of serology tests who have already notified FDA as outlined in the March 16th policy to submit an EUA within 10 business days from May 4th, 2020.

Based on our prior notification, FDA expects an EUA request by May 18, 2020. To facilitate preparation and submission of an EUA, FDA has incorporated a template for commercial manufacturers of serological tests in Appendix A of the guidance. Tianjin New Bay Bioresearch will submit their EUA by May 18, 2020, via e-mail to cdrh-eua-templates@fda.hhs.gov.

Sincerely,

SYNTRON BIORESEARCH, INC. INCORPORATED NOV 7 1986 CALIFORNIA

Arjang Amini
Compliance and QAManager

May 5/2020
Date