

Acknowledgment Letter

6/2/2020

John Chiang Molecular Vision Laboratory 1920 NE Stucki Avenue, Suite 150 Hillsboro, OR 97006 UNITED STATES

Dear John Chiang:

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

Submission Number: EUA201561

Received: 6/2/2020

Applicant: Molecular Vision Laboratory

Device: Molecular Vision Lab (MVL) SARS-CoV-2 assay

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

Sincerely yours,

Center for Devices and Radiological Health