



## Acknowledgment Letter

9/21/2020

William Nelson  
Tetracore, Inc.  
9901 Belward Campus Drive  
Rockville, MD 20850  
UNITED STATES

Dear William Nelson:

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 contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or [OPEQSubmissionSupport@fda.hhs.gov](mailto:OPEQSubmissionSupport@fda.hhs.gov).

Submission Number: EUA202777

Received: 9/19/2020

Applicant: Tetracore, Inc.

Device: Tetracore, Inc. EZ-SARS-CoV-2 Real-Time RT-PCR

We will notify you when the review of this document has been completed or if any additional information is required. 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