



Acknowledgment Letter

5/4/2020

William Lee
EpiGentek Group, Inc.
110 Bi County Blvd., Ste. 122
Farmingdale, NY 11735
UNITED STATES

Dear William Lee:

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: PEUA200958
Received: 5/4/2020
Applicant: EpiGentek Group, Inc.
Device: SeroFlash SARS-CoV2 IgM/IgG Antibody Detection Kit

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