

Emergency Use Authorization

- A. THIS PRODUCT HAS NOT BEEN FDA CLEARED OR
- B. APPROVED; BUT HAS BEEN AUTHORIZED BY FDA UNDER AN EUA FOR USE BY AUTHORIZED LABORATORIES;
- C. THIS PRODUCT HAS BEEN AUTHORIZED ONLY FOR THE DETECTION OF PROTEINS FROM SARS-COV-2, NOT FOR ANY OTHER VIRUSES OR PATHOGENS; AND,
- D. THIS PRODUCT 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.