



WARNING LETTER

Date: March 6, 2020

TO: david@... – David, Midwest Biotech, Inc.
272 West Lincoln
Sarnia, ON, Canada, N7T 1H2

RE: Unapproved Product (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) has received information that you have marketed and/or sold in the United States a product that you have marketed and/or sold in the United States that is not approved by the FDA. The product is a diagnostic kit for COVID-19. The product is marketed and/or sold in the United States in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 352. The information received indicates that the product is not approved by the FDA and is therefore in violation of the FDCA. The FDA has the authority to take action against you if you do not take the necessary steps to bring your product into compliance with the FDCA. You are advised that the FDA is currently reviewing information regarding your product and may take further action if necessary. You are advised that the FDA is currently reviewing information regarding your product and may take further action if necessary.

