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CUSTOMER TECHNICAL BULLETIN
ePlex® RP IVD Panel
January 28, 2020
Subject: 2019 Novel Coronavirus (2019-nCoV)

PURPOSE:
The 2019 Novel Coronavirus (2019-nCoV) which was first detected in Wuhan, China, has been identified as the cause of an outbreak of respiratory illness. Since the discovery of this novel coronavirus, it has now spread outside of Wuhan, China into other nations, including the United States. As a manufacturer of the ePlex® System and Respiratory Pathogen Panel (ePlex RP Panel) which detects coronavirus, we are aware of your need to understand whether the ePlex RP Panel is capable of detecting the 2019-nCoV strain. The purpose of this notification is to provide an update on initial bioinformatic analyses conducted on the coronavirus assays of the ePlex RP Panel.

THE ePLEX RESPIRATORY PATHOGEN PANEL:
The ePlex RP Panel coronavirus assays test for human coronaviruses 229E, HKU1, NL63, and OC43, which reports out as "Coronavirus" when detected. During the FDA clinical study, the only coronavirus that was tested for cross-reactivity was the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), strain EMC/2012[a], at a concentration of 1×10^5 copies/mL, with no cross-reactivity observed. At the time of the FDA clinical study, the 2019-nCoV was not available to test and therefore was not able to be included in this data.

***IN SILICO* ANALYSIS OF 2019-nCoV:**
According to the World Health Organization interim guidance titled "Laboratory testing for 2019 novel coronavirus"[1], the 2019-nCoV is a novel betacoronavirus, which is similar in nature to MERS-CoV and Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV). Among the subtypes detected by the ePlex RP Panel, human coronaviruses NL63 (HCoV-NL63) and 229E (HCoV-229E) belong to the alphacoronavirus genus while human coronaviruses HKU1 (HCoV-HKU1) and OC43 (HCoV-OC43) belong to the betacoronavirus genus. *In silico* analysis of the complete genome of 2019-nCoV (Genbank accession MN908947) concluded that none of the ePlex RP Panel coronavirus assays are expected to cross-react with the 2019-nCoV strain and, therefore, would result in a "Not Detected" result for Coronavirus on the ePlex RP Panel report.

Given the ability to mutate, which could cause future diversity in the target RNA for the 2019-nCoV, GenMark can only comment on the sequences currently available to date. At this time, due to *in silico* analysis being the only form of analysis performed, GenMark cannot make any claims to wet testing of the 2019-nCoV. If a sample is suspected to have 2019-nCoV, laboratories should follow their own local guidelines and standard operating

1. World Health Organization. (2020, January 17) Interim Guidance: Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases. WHO/2019-nCoV/laboratory/2020.3

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procedures for testing any suspected respiratory pathogens that are not present on the ePlex RP Panel.

If you encounter a sample that is positive for 2019-nCoV, please contact GenMark Technical Support at 1-800-eSensor (373-6767), Option 2 or technicalsupport@genmarkdx.com for immediate data review.

If you have any questions regarding this bulletin or further inquiries on the 2019-nCoV, please contact GenMark Dx Scientific and Medical Affairs at scientificaffairs@genmarkdx.com.

Sincerely,

Natalie Whitfield, PhD, D(ABMM)
Director of Scientific and Medical Affairs