From: Dr. William G. Kearns, CEO, Chief Scientific Officer and Director

I am writing to share with you that AdvaGenix has completed and submitted to the Centers for Medicare and Medicaid Services (CMS) an in-house specimen stability study, in response to preliminary findings issued by CMS's CLIA office on August 12, 2020.

The results of AdvaGenix's specimen stability study replicate the results of the manufacturer's own specimen stability study. Our study confirms that specimens are stable and are not adversely affected by the high temperatures that are common in Montgomery County during the summer.

An additional review of local temperature data in Montgomery County from June 1 - August 16 revealed that daily high temperatures did not exceed the upper stability limit on any given day.

Our preanalytical temperature stability study demonstrates that no saliva sample was compromised by excessive heat.

AdvaGenix has completed the assignments communicated to us in the preliminary inspection report. We submitted our temperature stability study to CLIA and the State on August 22nd. We look forward to prompt review by CMS and the State so that we can resume the important work of testing during this public health crisis.

8.22.20

Commander Lane Vause, CMS/CCSQ:

AdvaGenix initiated an investigation in response to the preliminary findings discussed with AdvaGenix on August 12, 2020.

Regarding pre-analytic specimen stability and interferences, the following studies were performed:

Temperature and Storage

AdvaGenix determined that previously tested positive and negative saliva specimens in both the Oracollect OR-100 and Spectrum SDNA1000 devices were stable at 40°C (104 ^{0}F) under simulated hot outdoor and hot-temperature shipping conditions.

Review of temperature data from June 1- August 16 shows that in Montgomery County, Maryland, and Orlando, Florida, the locations where the specimens were collected, temperature did not exceed the upper stability limit on any day. Furthermore, specimens originating from Florida were held at the clinic at room temperature until shipping in the evening. Based on AdvaGenix's own study and based on review of local temperatures, we have determined that zero patient specimens were adversely affected by temperature.

A review of specimen receipt and analysis logs revealed that the maximum amount of time specimens were held at room temperature at AdvaGenix before analysis was 6 days. AdvaGenix studied spiked specimens of both high and low copy number over 6 days and has determined that they are stable at room temperature for the amount of time the patient specimens were stored at AdvaGenix at room temperature (18.5 (65 ^{0}F)-27.7°C) (82 ^{0}F) before analysis. Based on this study, AdvaGenix has determined that storage of saliva specimens at room temperature for up to 6 days has no adverse effect on the specimens.

Interfering Substances

AdvaGenix observed that common oral contaminants such as drinking coffee, soda, eating food, smoking or using Chapstick did not affect the expected result and there is low risk of specimen

invalidity resulting therefrom. However, we require that patients must not eat, drink, smoke, or chew gum 30 minutes prior to specimen collection.

Refer to attachments:

- VAL002A COVID-19 by qPCR Validation Plan and VAL002B COVID-19 by qPCR Validation Report for study plans, acceptability criteria and results

- Temperature Data for temperatures recorded for the time period reviewed Jun 1-August 16 for Montgomery County, MD and Orlando, FL.

Respectfully,

DocuSigned by:
William G. Kearns
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8/22/2020

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