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THE POLICE OFFICERS
OF THE CITY
OF LOS ANGELES

November 22, 2021

General Manager Wendy G. Macy
City of Los Angeles Personnel Department
700 E. Temple Street
Los Angeles, CA 90012

RE: FDA Compliance Issues w/Pension Commissioner Salimpour's No-Bid Bluestone Covid Testing Contract No: C-139018

Dear Ms. Macy,

Setting aside the serious concerns we have voiced about the secret process and lobbying of City officials by Los Angeles Pension Commissioner Salimpour that secured a no-bid $3 million COVID testing contract, the League has identified significant violations of the US Food and Drug Administration (FDA) Emergency Use Authorization requirements granted to Clinical Reference Laboratory, Inc. to process the COVID tests being distributed by Bluestone.[1]

Since Commissioner Salimpour's Bluestone does not manufacture a COVID test nor does it own a testing laboratory, Bluestone must procure test kits from another vendor and contract out actual testing of the other vendor's test kits. Bluestone was able to procure the GENOTEK OMNIgene ORAL OM-505 and OME-505 saliva collection devices. Bluestone also contracted out the testing of the saliva samples from these test kits to Clinical Reference Laboratory, Inc..

To protect against the many fly-by-night, newly formed, and/or unqualified entities from promoting themselves as being qualified to test for COVID, the FDA issues very detailed conditions within an Emergency Use Authorization (EUA) that testing companies must adhere to. An EUA was issued for Bluestone's contracted testing entity to process the GENOTEK OMNIgene ORAL OM-505 test kits, we are unable to locate the EUA for the OME-505 test kit.

The FDA's EUA issued to Clinical Reference Laboratory is not being followed and Bluestone's complicity in disregarding the EUA requirements is putting the health of officers and all city workers in jeopardy. Clearly, the City did not conduct ample due diligence to determine if Bluestone was capable performing this work, the City was either asleep at the switch or was bamboozled by Bluestone into believing that they were capable of deploying a COVID testing program that followed the FDA's requirements.

[1] FDA EMERGENCY USE AUTHORIZATION (EUA) SUMMARY, CRL Rapid Response (Clinical Reference laboratory, Inc.)

For instance, under INTENDED USE, on page 1, paragraph 2 of the EUA it states:

> "Saliva specimens are self-collected at home or in a healthcare setting by individuals using the CRL COVID-19 Self Collection Testing Kit collection device ***when determined to be appropriate by a healthcare provider***."

We are unaware of any healthcare provider determining that taking this test is appropriate.

Further on page 1, paragraph 3 of the EUA it states;

> "Positive results are indicative of the presence of SARS-CoV-2 RNA; ***clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.***"

There is no clinical correlation with patient history and/or other diagnostic information provided to anyone to determine patient infection status.

Page 1, paragraph 4 of the EUA for Clinical Reference Laboratory states:

> "Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. ***Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results from SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated***."

Bluestone and the City are not combining clinical observations, patient history, and epidemiological information to ensure a negative result. In fact, Bluestone personnel are not at any testing locations to observe anyone. Police officers and other city employees are handing out test kits to other employees. There is no clinical observation, no patient history taken, and certainly no epidemiological information being conducted by Bluestone.

Also, any negative test will not be confirmed by testing of an alternative specimen type if clinically indicated.

At the top of page 2 of the EUA under 2) Special Conditions for Use Statements it states:

> "For prescription use only"
> "For invitro diagnostic use only"
> "For Emergency Use Authorization Only"
> "Authorized for use only with the CRL COVID-19 Self Collection Testing Kit which includes the GENOTEK OMNIgene ORAL OM-505 collection device"

Not a single prescription has been written for these test kits by a medical professional. We have been unable to locate an EUA issued to Clinical Reference Laboratory to test the Bluestone provided GENOTEK OMNIgene ORAL ***OME***-505 collection device that are being handed out throughout the City.

Further on page 2 under DEVICE DESCRPTION AND TEST PRINCIPLE paragraph 2 states;

> "The test uses proprietary CoPrimers and probes that were developed and validated under the Emergency Use Authorization (EUA) for the Logix Smart Coronavirus Disease 2019 (COVID-19) test and are designed to detect RNA from SARS-CoV-2 in saliva specimens from individuals suspected of COVID-19 by their healthcare provider."

The test that Bluestone is deploying is designed to detect RNA from COVID in saliva specimens from individuals (city workers) SUSPECTED of COVID-19 by their healthcare provider. It is ludicrous to think that city workers with zero indications of being sick or having been exposed to someone who was sick are being mandated to use this particular test.

On page 2 under MEDICAL OVERSIGHT AND PROCESS TO BE USED it states:

> "Once CRL[2] receives the order from the medical director, authorized person or physician, the individual is cleared to be tested. Individuals are not permitted to request a CRL Rapid Response test or CRL VODIR-19 Self Collection Testing Kit without a request from an authorized physician or healthcare provider."

Bluestone's testing process that the City is utilizing makes a mockery out of this provision of the EUA. There is no medical order that is clearing officers and other city workers to be tested. Individuals are specifically barred from requesting these test kits, yet that is what Bluestone's process prescribes. Officers simply walk up and ask another officer for a test kit. No medical evaluation, these test takers are not suspected of having COVID-19, no determination by any healthcare provider that taking this test is appropriate, and no medical history or epidemiological information is collected. It's simply grab a test and go.

We cannot fathom how Bluestone was able to secure this contract and how the City relied upon Pension Commissioner Salimpour's unproven COVID testing system that appears to violate numerous provisions of the US Food and Drug Administration's Emergency Use Authorization granted to Bluestone's testing sub-contractor, Clinical Reference Laboratory.

We are forwarding a complaint to the FDA and we urge you to comply with the numerous requests you have received to release all relevant emails, text messages, phone logs and other materials about Bluestone and how they were awarded this contract.

Sincerely,

Craig Lally, President
Los Angeles Police Protective League

C: Matt Szabo
Los Angeles City Council

[2] Clinical Reference Laboratory, Inc.

EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
CRL Rapid Response
(Clinical Reference Laboratory, Inc.)

For in vitro diagnostic use
Rx only
For use under Emergency Use Authorization (EUA) Only

The CRL Rapid Response test will be performed at Clinical Reference Laboratory, Inc., located at 8433 Quivira Rd., Lenexa, KS 66215 which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high-complexity tests, per the Standard Operating Procedures that were reviewed by the FDA under this EUA.

INTENDED USE

The CRL Rapid Response test is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in saliva specimens from individuals suspected of COVID-19 by a healthcare provider. Saliva specimens are self-collected at home or in a healthcare setting by individuals using the CRL COVID-19 Self Collection Testing Kit collection device when determined to be appropriate by a healthcare provider.

Testing is limited to Clinical Reference Laboratory, Inc., located at 8433 Quivira Rd., Lenexa, KS 66215 which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high-complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

The CRL Rapid Response is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR assay and *in vitro* diagnostic procedures. The CRL Rapid Response is only for use under the Food and Drug Administration's Emergency Use Authorization.

2) <u>Special Conditions for Use Statements</u>

For prescription use only
For *in vitro* diagnostic use only
For Emergency Use Authorization Only
Authorized for use only with the CRL COVID-19 Self Collection Testing Kit which includes the Genotek OMNIgene ORAL OM-505 collection device

DEVICE DESCRIPTION AND TEST PRINCIPLE

The CRL COVID-19 Self Collection Testing Kit, which includes the DNA Genotek OMNIgene ORAL OM-505 collection device, collects and stabilizes viral RNA from saliva specimens. The CRL COVID-19 Self Collection Testing Kit consists of an empty collection tube for saliva, sealed funnel lid containing stabilizing liquid, cap to seal the collection tube for transport, and instructions. Upon contacting saliva cells, the stabilizing liquid lyses cellular and nuclear membranes to release and stabilize nucleic acids. The sponsor will perform the shipping and sample stability study with appropriate material (clinical samples) as a post-market study.

The CRL Rapid Response test is a single-step real-time reverse transcription PCR test based on the Logix Smart Coronavirus Disease 2019 (COVID-19) test (EUA200049). The test uses proprietary CoPrimers and probes that were developed and validated under the Emergency Use Authorization (EUA) for the Logix Smart Coronavirus Disease 2019 (COVID-19) test and are designed to detect RNA from SARS-CoV-2 in saliva specimens from individuals suspected of COVID-19 by their healthcare provider. This test is authorized to test saliva specimens including unsupervised saliva specimens collected in the home environment or supervised collection of saliva specimens by a healthcare provider in a healthcare setting (e.g., assisted living setting, doctor's office, drive through collection).

The CoPrimers and probes in the CRL Rapid Response test are designed to detect nucleic acid sequences in the *RdRp* gene. The test also includes an internal positive control (IPC) that acts as an extraction control to confirm the performance of the extraction.

SPECIAL INSTRUMENTS USED WITH THE TEST

Automated RNA extractions will be performed using the Zymo *Quick* RNA/DNA Viral MagBead kit (Catalog No. R2141). The instrument used for automated extractions is the Tecan Fluent 780/480 DreamPrep.

The CRL Rapid Response test is to be used with the BioRad CFX-96 TOUCH Thermal Cycler instrument using the CFX Manager 3.1 software.

MEDICAL OVERSIGHT AND PROCESS TO BE USED

Once CRL receives the order from the medical director, authorized person or physician, the individual is cleared to be tested. Individuals are not permitted to request a CRL Rapid Response test or CRL COVID-19 Self Collection Testing Kit without a request from an authorized physician or healthcare provider. Patients cannot order the at-home collection kit; the physician orders the kit and the kit is shipped to patient's home. CRL does not provide follow-up care with a healthcare provider for tested individuals.

The consent form is completed online, and available to the laboratory immediately upon completion. The saliva specimen is collected in accordance with the collection instructions included in the collection kit.

The individual using the CRL COVID-19 Self Collection Testing Kit to collect a saliva specimen follows the written instruction provided in the kit. Once the saliva is collected, the device is placed into a sealed bag for shipping. The bag is further inserted into a box, which is then inserted in the FedEx envelope. The kit includes a pre-paid return FedEx label, addressed to the laboratory. All shipping occurs at ambient temperature, with drop box and pickup options available. All shipments are FedEx Express for overnight delivery and tracked via standard FedEx processes. The kit materials and shipping processes are compliant with PHMSA requirements.

Test results are communicated back to individuals that used the CRL COVID-19 Self Collection Testing Kit via text or voice message, which directs the individual to a dual factor authenticated web portal that displays the result. Results are also returned to the ordering physician, who is responsible for following up with the tested individual. Fact sheets will be made available to the individual for whom testing was performed.

CONTROL MATERIALS TO BE USED WITH THE CRL RAPID RESPONSE TEST

CRL Rapid Response test utilizes the Co-Diagnostics Logix Smart Coronavirus Disease 2019 (COVID-19) Kit that includes the following controls:

- An endogenous internal positive control (IPC), which also acts as an extraction control, targets the human RNase P gene. The IPC is used to verify both the performance of the master mix in each well and also the performance of the extraction, as the RNase P gene is co-extracted from the patient sample, verifying a successful extraction. The IPC is contained in every well as part of the master mix, and the process does not need to be altered in any way. Saliva samples that are extracted and fail to have RNase P amplification are considered to be invalid and recollection is required.

- A positive template control is needed to check the performance of the master mix, and more specifically, the performance of the SARS-CoV-2 CoPrimers. The positive control is a proprietary blend of SARS-CoV-2 synthetic templates and is used with each PCR run by plating a single well with 5µL of master mix and 5 µL of the positive control.

- A "no template control" is provided as part of the Logix Smart COVID- 19 test kit (clear cap tube) to check for contamination in the master mix. The "no template control" is nuclease-free water and is run in parallel with every sample batch starting with extraction of the samples and including RT-PCR reaction.

INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

Fluorescent intensity from the FAM (SARS-CoV-2 RdRp) and ROX (RNase P) channels is measured following each of the 50 thermocycles. All samples except for the non-template control (NTC) should have amplification of the internal control (RNase P, ROX fluorophore). Only samples positive for the presence of SARS-CoV-2 viral RNA will have amplification of the FAM fluorophore.

1) CRL Rapid Response Controls - Positive, Negative and Internal

After the run completes, the results can be interpreted by evaluating the Ct or Cq values. The process for evaluating results are as follows:

1**.** Check for amplification of the positive control (PC) for SARS-CoV-2 and RNase P in the appropriate channel. There should be amplification in every channel for the PC before cycle 45**.**
2. Check for amplification of the no template control (NTC) for SARS-CoV-2 and RNase P in the appropriate channel. There should be NO amplification in any of the channels before cycle 45.
3**.** Check for amplification of the internal positive control (IPC) for RNase P in the appropriate channel. Every sample should show a positive result for RNase P (IPC) before cycle 45.
4. Check for amplification of the positive extraction control (BEI heat inactivated virus, catalog no. NR-52286 spiked in saliva) for SARS-CoV-2 and RNase P in the appropriate channel. There should be amplification in every channel before cycle 45.

2) ***Examination and Interpretation of Patient Specimen Results:***

Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted. A new plate with the same layout should be rerun and the controls should be re-evaluated. If it fails again, the kit should be quarantined in an appropriate location and a new kit should be opened and tested. The decision should be taken after internal investigation for potential deviations.

After the positive, negative, and internal positive controls have been interpreted and are determined to be valid and within the acceptable ranges, then the results for the clinical specimen can be evaluated. If the results for the controls are not valid, the results cannot be interpreted.

Check for amplification for SARS-CoV-2 in the appropriate channel. Samples are considered positive with amplification before cycle 45. See table below detailing interpretation of results.

Table 1. Interpretation of Patient Results

	Sample Result		Logix Smart™ COVID-19 Positive Control	No Template Control (NTC) (Master Mix + Water)	Interpretation of Results
	COVID-19 (SARS-CoV-2)	Internal Positive Control (RNaseP) CF610 channel			
Instrument Reading	+	+	+	-	COVID-19 +
	-	+	+	-	COVID-19 -
	Any Result (+/-)	-	+	-	Retest the sample
		+	-	-	Retest the plate
		+	+	+	Retest the plate
Anything before 45 cycles is considered a positive reading (+). Anything after 45 cycles is considered a negative reading (-). When possible, always check that the medical history and/or symptoms match the result before treatment.					

Performance Evaluation

Limit of Detection (LoD) – Analytical Sensitivity:

LOD of the CRL Rapid Response for Saliva Samples

To determine the limit of detection, a series of samples were created by spiking heat-inactivated SARS-CoV-2 virus (BEI Resources Catalog No. NR-52286, Lot 70033548) into confirmed SARS-CoV-2 negative saliva. The negative saliva was collected in the DNA Genotek OMNIgene ORAL OM-505 device from asymptomatic volunteers.

These samples were tested using the established CRL Rapid Response protocol. Four low concentrations of spiked virus were extracted using an automated extraction method and subsequently tested. All four concentrations were tested with at least 20 replicates. The concentrations ranged from 1000 copies/mL to 125 copies/mL. A concentration that achieves amplification in ≥95% of replicates is considered a valid LOD. The LOD of the CRL Rapid Response for saliva was determined to be 250 copies/mL or 0.25 viral copy/µl, with 95.8% of replicates amplified. For all replicates at each concentration, an average Ct value was calculated for the control gene amplification (RNaseP) as well as the COVID-19 target gene. See table below for results.

Table 2. CLR Rapid Response LoD in Saliva

Target Level*	Valid tested replicates n	SARS-CoV-2 Target			Internal Control		
		n detected	Mean Ct	Detection Rate	n detected	Mean Ct	Detection Rate
1	24	24	36.91	100.00%	24	23.95	100.00%
0.5	24	24	37.79	100.00%	24	22.36	100.00%
0.25	24	23	37.78	95.8%	24	21.97	100.00%
.125	23	6	38.86	26.1%	23	24.97	100.00%

*Concentration in cp/µL in Sample dilution tested

Inclusivity (Analytical Sensitivity):

The CRL Rapid Response test is a modification that uses the exact same primers and probes as a previously authorized assay, Co-Diagnostics Logix Smart COVID-19 RT-PCR assay (EUA200049). The inclusivity of the Co-Diagnostics EUA was evaluated by wet testing and *in silico* analysis. Based on the data at that time, there was no prediction of false-negative results. Co-Diagnostics has provided a right of reference to utilize the inclusivity study data. No additional *in silico* analysis is needed at this time.

Cross-Reactivity (Analytical Specificity):

The CRL Rapid Response test is a modification that uses the exact same primers and probes as a previously authorized assay, Co-Diagnostics Logix Smart COVID-19 RT-PCR assay (EUA200049). The cross-reactivity of the Co-Diagnostics EUA was evaluated by wet testing and *in silico* analysis. The data supports that there is a low likelihood of false positive results. CRL has been granted Right to Reference from Co-Diagnostics to utilize the cross-reactivity study data. No additional *in silico* analysis is needed at this time.

Clinical Evaluation:

Saliva (Nasopharyngeal Swabs and Saliva Clinical Study)

A study was performed to evaluate the use of saliva as a specimen type for detection of SARS-CoV-2 in patients who were suspected of COVID-19 by their healthcare provider. Thirty-two COVID-19 positive individuals were enrolled in the study, positivity for SARS-CoV-2 was established by nasopharyngeal (NP) swab tested with an FDA EUA authorized molecular diagnostic assay. Saliva was collected from enrolled patients 1-3 days after the NP swab was collected.

In this study, participants self-collected the saliva sample using the DNA Genotek OMNIgene ORAL OM-505 device with no guidance, while under observation by the healthcare professional. Saliva was tested using the CRL Rapid Response test at Clinical Reference Laboratory, Inc. Saliva was transported at ambient temperature and tested within 48 hours of collection. Results are presented in the table below.

Table 3. Qualitative Results of Saliva Tested with the CRL Rapid Response and Results of the Comparator NP Swabs Tested at Reference Labs

Patient ID	CRL Saliva	NPS result	Source of NPS result
CRL-Spec 1	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 2	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 3	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 4	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 5	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 6	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 7	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 8	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 9	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 10	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 24	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 25	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 26	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 27	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 28	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 29	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 30	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CRL-Spec 31	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-101	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-102	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-103	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-104	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-108	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-109	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-110	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-116	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-117	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-118	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-119	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-120	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-123	Positive/Detected	Positive/Detected	High Complexity CLIA Lab
CV-CRL-130	Positive/Detected	Positive/Detected	High Complexity CLIA Lab

In addition to the positive samples summarized above, 27 negative samples were collected with 100% negative percent agreement between the comparator EUA-RT-PCR assay(s) used to test NP swab and the saliva samples tested with the CRL Rapid Response.

Performance of the CRL Rapid Response relative to the reference NP swab is summarized in the table below.

Table 4. Summary of Qualitative Results Comparing Saliva Tested with the CRL Rapid Response and the NP Swab Tested with FDA EUA RT-PCR Assay

		FDA EUA (Nasopharyngeal Swab)		
		Positive	**Negative**	**Total**
CRL Rapid Response (Saliva)	**Positive**	32	0	32
	Negative	0	27	27
	Total	32	27	59
Positive Agreement		PPA = 100% (32/32); 89.11 - 100.00%[1]		
Negative Agreement		NPA = 100% (27/27); 87.23 - 100.00%[1]		

[1]Two-sided 95% score confidence intervals

The sponsor also submitted data from 18 paired anterior nares (nasal) swabs and saliva. These paired samples were obtained from patients enrolled into the study based on NP swabs that were positive when tested at reference lab using an EUA authorized assay. Paired nasal and saliva samples were collected 1-3 days after the positive NP swab was collected. The agreement between nasal swabs and saliva was poor resulting in 11 false positive results. However, there was 100% qualitative agreement between the positive and negative results of the CRL Rapid Response on saliva and the comparator EUA RT-PCR assay(s) on NP swab. Available data establishes NP swabs as a reliable specimen type for the detection of SARS-CoV-2 and it was determined to be the preferred comparator specimen for establishing performance of the CRL Rapid Response Test.

Evaluation of the Ct Cycle Differences Between Nasopharyngeal and Saliva Samples
The sponsor obtained a subset of Ct values from nasopharyngeal swabs tested with comparator EUA RT-PCR assay(s). In this subset Ct values for saliva ranged from 29.14 - 40.11 and for NP swabs tested with comparator EUA RT-PCR assay(s) from 22.88 – 38.70. In this subset, Ct values for saliva samples were higher than those for nasopharyngeal swab samples, with the ΔCt between saliva and NP specimens ranging from -0.52 to -6.26. For a different subset of patients, a second NP swab was collected with the saliva sample for testing with the CRL Rapid Response Test. While results of NP swabs tested with the sponsor assay cannot be used to evaluate assay performance, they can provide an indication of differences in Ct values observed between saliva and NP swabs. In this subset, there was no clear trending of the Ct difference between saliva and NP swabs.

Differences observed between the two subsets is likely due to differences of temporal pairing of NP and saliva samples.

LIMITATIONS:
• Testing of saliva specimens is limited to patients with symptoms of COVID-19.
• Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

WARNINGS:
• This test has not been FDA cleared or approved;
• This test has been authorized by FDA under an EUA for use by Clinical Reference Laboratory, Inc., located at 8433 Quivira Rd., Lenexa, KS 66215;

• This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and
• This test 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.