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# State of California—Health and Human Services Agency California Department of Public Health



GAVIN NEWSOM  
Governor

To Whom It May Concern

In a table included in the EUA package insert, it indicates that if the cycle threshold (CT) value for two identified nucleic acid targets are >42 for a patient specimen, the result interpretation is "SARS-CoV-2 not detected." However, if the CT value for one or both of the nucleic acid targets is <42, the result interpretation is "SARS-CoV-2 detected."

“According to laboratory personnel,

1. **Immediate Corrective Action** The best clinical interpretation for low viral load (high Ct values) was determined with the original laboratory directors Dr. Shantelle Lucas and Dr. Haleh Farzanmehr and subsequently has been also reviewed by Dr. Rosendorff when he joined on January 27, 2021.
  - From November 2, 2020 to November 11, 2020: if a patient specimen received CT values for the two identified nucleic acid targets of <42, the test result was reported as "positive."
  - From November 11, 2020, if a patient specimen received CT values for the two identified nucleic acid targets of <37, the test result was reported as "positive."
  - From December 12, 2020 the VBL started reporting CT values between 37 - 42 using the INC code. From December 12, 2020 to December 16, 2020 the INC code was reported to patients as 'inconclusive'. Beginning on December 16, 2020 the INC code was reported to patients as 'presumptive positive'.

**Response:** At the time of the validation study and review of the report there was not a comparable assay on the market to make a comparison of the higher sensitivity of the assay. Because of this, the laboratory directors were uncomfortable with calling samples in this range as detected. The changes made in December only changed the way the result was worded to the patient. For formal reporting to the state and local health jurisdictions, these results continued to be termed "inconclusive". As transmission rose, and as the state received feedback from patients and partners, we recognized that the term inconclusive was not instructive and did not provide sufficient direction to patients. In order to alleviate confusion, and in the interest of public health given the spike in cases at the time, we provided clearer direction to the patient to isolate and be retested.

2. **Patient Impact:** A presumptive positive result indicates that the sample had a low presence of the virus. The recommended follow-up was for the patient to self-quarantine and be retested. This is a conservative clinical approach that is unlikely to result in patient harm. Ct values are not part of the patient report, however they are provided by the laboratory director, to authorized CDPH staff, upon request and are used at the provider's discretion when making individualized treatment decisions.



3. **Preventative Measure:** Any change in clinical interpretation will be reviewed with Laboratory Director Dr. Rosendorff, the California Department of Public Health leadership and other program stakeholders to ensure that patients are given information in accordance with, and healthcare recommendations based on current scientific and clinical understanding.
4. **Monitoring Mechanism:** Scientific understanding of and clinical recommendations for cases with load viral load (high Ct values) will continue to change as new information is reported. The best clinical recommendations will be evaluated in accordance with CDPH recommendations, and state and federal guidelines.

Sincerely,

*Paul B. Kimsey PhD*

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