Response to 5-17-2021 public comment on item 21-0511 Member of public's questions with responses in blue

What does the sensitivity % represent?

The proportion of test specimens known to contain COVID-19 virus particles that produce a positive test result. Each lab sets its own cycle threshold to achieve the desired sensitivity for its test. Cycle thresholds may vary from lab to lab.

Does this mean that the tests will be using a higher cycle threshold?

No. The testing that will be provided by this Avellino contract will be the exact same as has always been performed by Avellino.

We know that the higher the cycle threshold, the higher the positivity rate and potential for false positives.

Again, there has been no change to Avellino's setting of its cycle threshold or sensitivity.

The CDC has recently changed the guidelines for testing vaccinated individuals by limiting the cycle thresholds to under 28 (link and picture below).

This information was taken out of context. CDC has <u>not</u> set a maximum value for the Ct used to determine positive results from PCR testing. Rather, CDC's guideline refers to the *subsequent* submittal of specimens (*already* identified as being positive for COVID-19) for genomic sequencing. Specifically, the guidance applies to specimens from people who became infected despite being fully vaccinated. Sequencing determines which variants they were infected with. This information helps public health experts continue to monitor the effectiveness of vaccines.

The maximum cycle count of 28 that was set by CDC indicates which positive specimens can reasonably be sequenced. [Lower Ct values mean more viral material is present in the specimens, so they are easier to sequence.] CDC's limit of 28 has no bearing on whether a patient's PCR test was previously interpreted as positive or negative. Each lab sets its own value for maximum cycles that will be counted as positive.

If you all want to renew the the contract with Avellino please include some of the verbiage that Florida used in it's public health directive requiring labs to report cycle thresholds along with their results (pictured below)

<u>If</u> subject-matter experts recommend that labs in California report Ct values, that decision should be made at the state, not local, level, and be applied to <u>all</u> labs. It would make little sense for El Dorado County to place that requirement on a single lab when results from more than a hundred *other* labs would not be reporting them to us. Public Health can obtain these values if needed by directly asking the labs.

It would also be great to specify that all tests be run with the same protocols whether the subject is vaccinated or not.

[This also seems to refer to the out-of-context quote from CDC.] They (PCR tests) <u>are</u> run on the same protocols regardless of whether the subject is vaccinated. This has always been true. A person's vaccination status does not influence how PCR tests are run (and it's very likely that the lab performing the test even knows a person's vaccination status).

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These are simple steps to insure transparency and public confidence that our case numbers are accurately reported.

Our case numbers are already are being accurately reported.

Nancy Williams Public Health Officer

Final comments in response to verbal public comment spoken during the meeting:

1. There is no "manipulation" of cycle thresholds taking place to get desired results. As I noted above and explained in the detailed document posted with this board item on 1/26/2021 about cycle thresholds, each lab sets its test's threshold value to achieve the desired testing sensitivity. Ct values above the threshold are considered negative and those below are considered positive. These PCR tests are intended to be qualitative, producing a positive/negative result only. There is not intended to be a numeric interpretation of them.

Reference:

https://eldorado.legistar.com/LegislationDetail.aspx?ID=4926918&GUID=50CB3430-CD5B-414B-A7E9-4A8CC3A2A195 (Attachments 23–25)

2. Swabs that have been sterilized with ethylene oxide are not hazardous. The claim that they are has circulated widely on the internet and was fact-checked by Reuters, excerpted below.

"VERDICT: While it is true that ethylene oxide is carcinogenic, it is not accurate to say it poses a danger in medical swabs after sterilisation. The sterilisation process is tightly controlled to ensure any residue left over is negligible, making medical equipment safe to use."

 $\begin{tabular}{ll} Source: $\underline{$https://www.reuters.com/article/factcheck-eo-swabs/fact-check-nasal-swabs-sterilised-with-ethylene-oxide-are-safe-to-use-the-sterilisation-process-is-tightly-regulated-by-international-standards-idUSL1N2LU1H0 \\ \end{tabular}$