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Fwd: Who PCR

Kim Dawson <kim.dawson@edcgov.us>

Thu, Jan 21, 2021 at 2:11 PM

To: EDC COB <edc.cob@edcgov.us>

Can you please send this to all the BOS emails. It was sent directly to a couple of Supervisors but I want to stay consistent. Also, include with the public comment for the COVID item. Thanks, Kim

----- Forwarded message -----

From: keeley link <keeley.link@gmail.com>

Date: Thu, Jan 21, 2021 at 2:03 PM

Subject: Fwd: Who PCR

To: Sue Novaser <bosfive@edcgov.us>, Nancy Williams <nancy.williams@edcgov.us>, Michael Ungeheuer <michael.ungeheuer@edcgov.us>, Lynnan Svensson <lynnan.svensson@edcgov.us>, Lori Parlin <bosfour@edcgov.us>, Kim Dawson <kim.dawson@edcgov.us>, John Hidahl <bosone@edcgov.us>, John D'Agostini <john.dagostini@edso.org>, Greg Stanton <greg.stanton@edcgov.us>, George Turnboo 2 <bostwo@edcgov.us>, Don Semon <don.semon@edcgov.us>, Don Ashton <don.ashton@edcgov.us>, David Livingston <david.livingston@edcgov.us>, Brian Veerkamp <bosthree@edcgov.us>

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<https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05?fbclid=IwAR2FnuSkln9qtxve9EEEEK9ht5WVw-QzWyeRUJJ203q0II4YBJecbJRyIra>

Nancy Williams and Supervisors,

Below is an excerpt of the WHO new guidance for PCR testing and confirmation of Covid Cases (see link to WHO Guidance above).

Myself and many others have expressed concern over false positives for months now. We have been dismissed and ignored. Now the WHO is acknowledging the need for new guidance as the previous methods caused many false positives. There isn't any representation of the percentage of cases that may have resulted from the current practices. This has been a very frustrating situation for the public as we have been quarantined, had businesses shut down, schools closed and many other negative restrictions imposed on our lives. All we have asked for is transparency on the CT (cycle threshold) of the PCR tests being done. This information has been and continues to be held from the public, this is unacceptable and we expect immediate action to provide this transparency. Please let me know how the county plans address this issue.

Description of the problem: WHO requests users to follow the instructions for use (IFU) when interpreting results for specimens tested using PCR methodology.

Users of IVDs must read and follow the IFU carefully to determine if manual adjustment of the PCR positivity threshold is recommended by the manufacturer.

WHO guidance [Diagnostic testing for SARS-CoV-2](#) states that careful interpretation of weak positive results is needed (1). The cycle threshold (Ct) needed to detect virus is inversely proportional to the patient's viral load. Where test results do not correspond with the clinical

presentation, a new specimen should be taken and retested using the same or different NAT technology.

WHO reminds IVD users that disease prevalence alters the predictive value of test results; as disease prevalence decreases, the risk of false positive increases (2). This means that the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as prevalence decreases, irrespective of the claimed specificity.

Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information.

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Thank you,
Keeley Link
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