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Comments on

The PHLN Document titled:

Public Health Laboratory Network Statement on Nucleic Acid Test False Positive Results for SARS-CoV-2

Dated: Tuesday, 9th June 2020

Pathology Technology Australia has reviewed this PHLN document and offers the following comments and observations.

1) This PHLN paper only addresses the topic of false positives relating to infection. It doesn't distinguish between biological positive and disease negative which is an accurate and relevant result. In all likelihood these would be classified as true positives when a confirmatory test is available.
2) As pointed out in the document, false positives are extremely rare (at 0.003% of all tests) and ignores the higher incidence of false negative results with COVID-19 testing. Pathology Technology Australia would be happy to collaborate with the PHLN on a paper which addresses the potential of false negatives. As we all recognise, bit of extra work on some false positives pales into insignificance next to the potential damage of false negatives being released back into the population, when we are dealing with such a highly contagious pathogen. We recommend all results, positive or negative need to be reviewed in light of the clinical observations and index of suspicion.
3) There is very little distinction in the paper of the different considerations for commercially available tests compared to in-house or lab determined tests. It is important to clearly distinguish between these as the claims made about the performance of commercial kits form part of their registration and instructions for use. It should be stressed that there is often a lot more validation work required by manufacturers and often a lot more samples tested compared to in-house IVDs. Once again Pathology Technology Australia would be happy to collaborate in clarifying this distinction.
4) It may be an artifact of the phraseology, but there is a reference to asymptomatic testing. It should be noted that this could be seen as an 'off-label' use of the test and appropriate validation would have to be completed by the laboratory. Most commercial assays are approved for symptomatic patients and/or that meet epidemiological criteria. A key point here is that highly sensitive tests are critical for the public health response to COVID-19 pandemic. Highly sensitive tests are important for the intended use of COVID-19 IVDs (to diagnose suspected infection). However, when highly sensitive tests are used off-label for other uses (eg. screening asymptomatic people) the significance of a false positive result should be investigated.
5) The paper indicates one cause of false positive results as the suitability and set up of the testing platform. Use of commercial kits with their respective platforms leave little room for such latitude and no room for misinterpretation of results.

P PO BOX 298 PARRAMATTA NSW 2124 E INFO@PATHOLOGYTECHNOLOGY.ORG.AU
T +61 (0)497 777 688 W WWW.PATHOLOGYTECHNOLOGY.ORG.AU

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However, we note that good laboratory practice includes a trained laboratory scientist reviewing a validating all results.

6) Interpreting Ct values on most qualitative commercial kits would be regarded as an 'off-label' use and laboratories would need to validate accordingly and be audited on this.
7) Many commercial tests have certain functionality and control measures built in, to minimise errors leading to false positive results; such as counter measures for amplicon contamination.
8) Many commercial kits have internal controls to demonstrate the PCR reaction has proceeded as expected; minimizing the occurrence of false results.
9) Pathology Technology Australia participates in a number of committees and advisory boards and is happy to be consulted should future documents relate to our member's products.

Dean Whiting
CEO, Pathology Technology Australia
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