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We declare no competing interests.

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For FIND's SARS-CoV-2 molecular diagnostics evaluation see https://www. finddx.org/covid-19/sarscov2eval-molecular/

Buyer beware: inflated claims of sensitivity for rapid COVID-19 tests

Widespread COVID-19 testing is paramount for the receipt of timely medical care and for curtailing transmission. The USA continues to face formidable challenges in making testing accessible for all because efforts to scale up COVID-19 testing have fallen short.¹ RT-PCR testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is considered to be the gold standard for identifying cases, is limited by processing time, exacerbating delays that are generated by surging demand. To expand testing capacity and accelerate diagnosis, the US Food and Drug Administration has issued an emergency use authorisation (EUA) for several diagnostic products, including six rapid antigen tests.² Although EUA for the rapid antigen tests provides essential countermeasures during this public health crisis, we outline the causes for concern regarding claims by manufacturers about performance metrics that might engender misinterpretation.

The sensitivity and specificity of these tests have been presented by manufacturers in a way that inflates these performance characteristics. For example, the manufacturers of the BinaxNOW test (Abbott; Chicago, IL, USA) claimed a sensitivity of 97.1% (95% CI 85.1-99.9)3 and the manufacturers of BD Veritor tests (Becton Dickinson; Franklin Lakes, NJ, USA) have claimed a sensitivity of 83.9% (66.3-94.5). However, the reported accuracy of these rapid antigen tests is actually the percent positive agreement (PPA) and not sensitivity. The PPA is measured relative to an RT-PCR test, which is imperfect itself.⁴ Due to variation in the diagnostic sensitivity of different RT-PCR tests, which are evaluated by the Foundation for Innovative New Diagnostics (FIND), understanding the accuracy of a rapid antigen test requires knowledge of the exact RT-PCR test that is selected as the comparator. However, manufacturers of most rapid antigen tests have not specified the test comparator. Compounding this uncertainty, the minimum sample size that is required to apply for EUA is 30 positive cases. Such small sample sizes have led to large CIs for the PPA. For example, the BD Veritor EUA study had 31 positive cases (PPA 83.9%, 95% CI 66.3-94.5). Combining the effect of small sample size with the reported sensitivity that is typical of RT-PCR (92.1%, 95% CI 86.6-95.9; over the first 7 days after symptom onset)⁴ would correspond to diagnostic sensitivities of 89.4%

(81.7-94.7) for BinaxNOW and 77.3%(63.5-87.8) for BD Veritor.

Furthermore, the real-world use of these antigen tests has extended beyond the EUA for postsymptom diagnosis to encompass routine screening. Screening is fundamental to the control of COVID-19, particularly because silent infections (ie, asymptomatic and presymptomatic infections) are major drivers of transmission.⁵ However, the performance of rapid antigen tests has not been evaluated for detection of asymptomatic infections or during the incubation phase. The dangers of disregarding or misunderstanding the imperfections in test sensitivity are evidenced by the outbreak that unfolded in the White House, which relied exclusively on rapid antigen screening as a sufficient measure to prevent transmission.

Policy optimisation and implementation requires an accurate understanding of testing sensitivity. Numerous universities rely on antigen testing to screen students in congregate living facilities and identify infectious individuals for isolation. Many schools are examining testing as a pathway for safe instruction in person, despite high incidence in the community. University and school decisions about testing frequency and closing or isolation criteria often rely on risk tolerance for missing infections, the probabilities of which depend on test sensitivity. Adjusting from the reported test performance to real-world diagnostic sensitivity shows that such decision makers could be substantially underestimating the number of missed infections. For example, organisations relying on BinaxNOW miss three times as many infections as they have been led to believe. If rapid testing is going to become a viable, trusted screening strategy for control of COVID-19, then performance characteristics should be well understood and screening strategies should be designed with test imperfections clearly in mind.

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Reduced mortality in New Zealand during the COVID-19 pandemic

New Zealand has had low case rates, hospital admissions, and deaths from COVID-19.¹ Stringent public health interventions (eg, compulsory selfisolation following travel, early border closure, nationwide lockdown, and isolation of cases and close contacts) were instituted in week 12 of 2020 (ie, March 16–19, 2020). Combined with its geographical isolation, these interventions meant that New Zealand eliminated COVID-19 in week 24 (ie, June 8, 2020),¹ although there have been subsequent cases due to border incursions.

To investigate the temporal association between these public health measures and all-cause mortality, we compared weekly death rates from 2015 to 2020 (appendix p 1) using data from Stats NZ Tatauranga Aotearoa. Reported weekly all-cause mortality in 2020 was similar to mortality in 2015–19 until week 17 (ie, the fifth week of public health measures) when mortality fell below historical rates, a trend which is still evident at week 42. There were a total of 25 deaths from COVID-19 from the start of the pandemic in New Zealand to week 42.

Interpretation of these time trends is limited by an absence of data on specific causes of death, due to coding delays and coronial inquiries. However, several important observations can be made. First, according to data collated in The Economist, New Zealand's reduction in mortality contrasts with the international experience of excess mortality during the COVID-19 pandemic. Second, the reduction in deaths is substantive. Across weeks 13-42 (ie, during and after lockdown), the mean weekly death rate was 11% lower than in 2015-19 (123.4 deaths per million population vs 138.5 deaths per million population, p<0.0001). The same pattern exists when compared with historical mortality rates from the longer period of 2011-19 (appendix p 2). Third, the reduction in allcause mortality became apparent in week 17, after 5 weeks of lockdown, and remained below historical levels despite public health restrictions easing, during a period that is usually marked by an increase in all-cause mortality due to seasonal influenza and pneumonia. This continued reduction might be primarily due to the absence of an influenza epidemic in New Zealand in 2020 (appendix p 3), presumably because of public health measures that were introduced to stop the spread of COVID-19.²

However, alternative factors, such as fewer deaths from road traffic accidents, occupational causes, air pollution, and postsurgical complications, might also have had a role in the reduction of all-cause mortality,³ although these effects would often manifest during, rather than after, a strict lockdown. Finally, potential late adverse effects on mortality, resulting from reduced access to health care, have not become apparent.

As the costs and benefits of strict public health measures are debated, New Zealand's low all-cause mortality during this period is a striking observation. Further research, including monitoring of all-cause and diseasespecific mortality in different countries, is needed to better understand the direct effects of COVID-19 and the measures that can be taken to reduce its burden.

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Legalisation of undocumented immigrants in the USA

In November, 2020, Joseph R Biden Junior was elected to become president of the USA. During his presidential campaign, Biden placed great emphasis on immigration and vowed to reverse many of the existing policies that were enacted under the leadership of President Donald Trump.

One of the major hallmarks of Biden's plan is to modernise the immigration system by ending family separation at the border, providing additional protections for refugees, and reinstating the Deferred Action for Childhood Arrivals programme.¹ For more on **Stats NZ Tatauranga Aotearoa** see https://www.stats.govt.nz/ experimental/covid-19-dataportal

For more on the **data collated in The Economist** see https://www.economist.com/ graphic-detail/2020/07/15/ tracking-covid-19-excessdeaths-across-countries



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See Online for appendix