Letters

RESEARCH LETTER

False-Positive Results in Rapid Antigen Tests for SARS-CoV-2

Concerns have been raised whether rapid antigen tests for SARS-CoV-2 can result in false-positive test results[1,2] and undermine pandemic management for COVID-19. This study investigated the incidence of false-positive results in a large sample of rapid antigen tests used to serially screen asymptomatic workers throughout Canada.

Methods | Rapid antigen tests for SARS-CoV-2 were implemented as an extra layer of protection to control transmission in workplaces throughout Canada by the Creative Destruction Lab Rapid Screening Consortium (CDL RSC). Asymptomatic employees were screened twice weekly. Workplace participation was voluntary. From January 11 to October 13, 2021, tests were conducted by employees, with some workplaces providing at-home screening and others on-site screening programs. Over this period, Canada experienced 2 significant Delta variant–driven waves from March to June and August to October. Screening results were recorded, including a deidentified record identifier, the place of employment, the test, and (optionally) the lot number. If a test result was positive, the patient was immediately referred for a confirmatory polymerase chain reaction (PCR) test to be completed within 24 hours. Initial data validation was completed at the point of collection. All data collected before June 26 and presumptive positive screen results and PCR test results reported before September 15 were externally verified through an audit process by participant organizations. False-positive results were matched to lot number and test manufacturer. A false-positive result was defined as a positive screen on a rapid antigen test and a subsequent negative confirmatory PCR.

The data from the CDL RSC were collected to inform the operational requirements of deploying rapid antigen screens in workplaces. All participants provided written consent to participate in the screening program and to share their deidentified data with the CDL RSC, including for publication, and with public health authorities. This study was approved by the University of Toronto Research Ethics Board.

Results | There were 903 408 rapid antigen tests conducted over 537 workplaces, with 1322 positive results (0.15%), of which 1103 had PCR information. Approximately two-thirds of screens were trackable with a lot number. The number of false-positive results was 462 (0.05% of screens and 42% of positive test results with PCR information). Of these, 278 false-positive results (60%) occurred in 2 workplaces 675 km apart run by different companies between September 25 and October 8, 2021. All of the false-positive test results from these 2 workplaces were drawn from a single batch of Abbott's Panbio COVID-19 Ag Rapid Test Device.

Discussion | The overall rate of false-positive results among the total rapid antigen test screens for SARS-CoV-2 was very low, consistent with other, smaller studies.[3] The cluster of false-positive results from 1 batch was likely the result of manufacturing issues rather than implementation. These results inform the discussion of whether rapid antigen tests will result in too many false-positives that could overwhelm PCR testing capacity in other settings.[1,2] Also, the results demonstrate the importance of having a comprehensive data system to quickly identify potential issues. With the ability to identify batch issues within 24 hours, workers could return to work, problematic test batches could be discarded, and the public health authorities and manufacturer could be informed. Aside from issues with the batch, false-positives are possible due to the timing of the test (ie, too early or too late in the infectious stage) or quality issues in how the self-test was completed.

Limitations of the study include the convenience sample of workplaces and that reporting of PCR confirmatory results and identification of lot number was not compulsory. In addition, these results reflect the epidemiology experienced in Canada and may not generalize to other countries experiencing different COVID-19 incidence.

Joshua S. Gans, PhD
Avi Goldfarb, PhD
Ajay K. Agrawal, PhD
Sonia Sennik, MBA
Janice Stein, PhD
Laura Rosella, PhD

Author Affiliations: University of Toronto, Toronto, Ontario, Canada (Gans, Goldfarb, Agrawal, Stein, Rosella); Creative Destruction Lab, Toronto, Ontario, Canada (Sennik).

Accepted for Publication: December 20, 2021.

Published Online: January 7, 2022. doi:10.1001/jama.2021.24355

Corresponding Author: Joshua S. Gans, PhD, Rotman School of Management, University of Toronto, 105 St George St, Toronto, ON M5S3E6, Canada (joshua.gans@utoronto.ca).

Author Contributions: Drs Goldfarb and Rosella had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Goldfarb, Agrawal, Sennik, Stein, Rosella.
Acquisition, analysis, or interpretation of data: Gans, Goldfarb, Agrawal, Sennik, Rosella.
Drafting of the manuscript: Gans, Goldfarb.
Critical revision of the manuscript for important intellectual content: Goldfarb, Agrawal, Sennik, Stein, Rosella.
Statistical analysis: Goldfarb, Rosella.
Obtained funding: Agrawal, Sennik, Stein.
Administrative, technical, or material support: Gans, Goldfarb, Agrawal, Sennik.
Supervision: Agrawal, Sennik.

Conflict of Interest Disclosures: All authors are members of the Steering Committee of the Creative Destruction Lab Rapid Screening Consortium (CDL RSC; a nonprofit organization in Canada). Dr Agrawal reported serving on the boards of Genpact and Sanctuary.

Funding/Support: The CDL RSC was founded with financial support from 12 corporations: Air Canada, CPP Investments, Genpact, Loblaw Companies Limited, Magna, MDA, Maple Leafs Sports & Entertainment Partnership,

Nutrien, Rogers, Scotiabank, Shoppers Drug Mart, and Suncor and received funding from the Safe Restart Agreement from the Government of Canada (Health Canada).

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: We thank Kyle Robinson, PhD, Devon Elke, HBSc, and Evgenia Gatov, MPH (all paid employees of CDL RSC, Toronto, Ontario, Canada), for assistance in collating the data.

1. Kretschmer A, Kossow A, Grüne B, Schildgen O, Mathes T, Schildgen V. False positive rapid antigen tests for SARS-CoV-2 in the real-world and their economic burden. *J Infect*. Published online August 17, 2021. doi:10.1016/j.jinf.2021.08.020

2. Ogawa T, Fukumori T, Nishihara Y, et al. Another false-positive problem for a SARS-CoV-2 antigen test in Japan. *J Clin Virol*. 2020;131:104612. doi:10.1016/j.jcv.2020.104612

3. Kanji JN, Proctor DT, Stokes W, et al. Multicenter postimplementation assessment of the positive predictive value of SARS-CoV-2 antigen-based point-of-care tests used for screening of asymptomatic continuing care staff. *J Clin Microbiol*. 2021;59(11):e0141121. doi:10.1128/JCM.01411-21