Saskatchewan Health Authority

University of Saskatchewan

COVID-19 Evidence Support Team
EVIDENCE SEARCH REPORT

Review Question:	Omicron Variant: In real world settings, what is the validity of RATs in identifying COVID-19 (sensitivity, specificity), and how well do they predict disease (positive and negative predictive values)?
Context:	Supplementary search to EOC211201, including primary studies and preprints
Review Code:	EOC211201-02 ESR **Complete Date:** January 5, 2022
Cite As:	Miller, Lukas. Howell-Spooner, Brianna. Omicron Variant: In real world settings, what is the validity of RATs in identifying COVID-19 (sensitivity, specificity), and how well do they predict disease (positive and negative predictive values)? 2022 Jan 05. Document no.: EOC211201-02 ESR. In: COVID-19 Rapid Evidence Reviews [Internet]. SK: SK COVID Evidence Support Team, c2022. 12 p. (CEST rapid review report).

Librarian Notes & Comments

Hello,

Hi Andreea,

This follow-up search on omicron rapid testing produced a total of 14 articles (5 published/peer reviewed, 9 preprints). I also came across some recent updates from Ontario's Ministry of Health, the FDA, ECDC, and the UK Health Security Agency.

I also gathered as many statements/press releases from rapid antigen test manufacturers as I could find. Hope this helps!

/Lukas

Sincerely,
Lukas

Disclaimer

Search Results: Guidelines, Summaries & Other Grey Literature

Ontario Ministry of Health

- COVID-19 Integrated Testing & Case, Contact and Outbreak Management Interim Guidance: Omicron Surge. 30 December 2021. https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/contact_mngmt/management_cases_contacts_omicron.pdf

UK Health Security Agency

- SARS-CoV-2 variants of concern and variants under investigation in England: Technical briefing 33. England: GOV.UK; 2021 December 23 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043807/technical-briefing-33.pdf
- Underlying data (tables) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1044468/variants-of-concern-technical-briefing-data-england-Omicron-Update-31-December_vFINAL.ods

U.S. Food & Drug Administration.

- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests - Omicron Variant: Impact on Antigen Diagnostic Tests (As of 12/28/2021) United States: U.S. Food & Drug Administration; 2021 [updated 28 December 2021. Available from: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests#omicronvariantimpact

European Center for Disease Control (ECDC)

- Methods for the detection and characterisation of SARS-CoV-2 variants – first update. 20 December 2021. https://www.ecdc.europa.eu/sites/default/files/documents/Methods-for-the-detection-and-characterisation-of-SARS-CoV-2-variants-first-update.pdf

Search Results: News, Blogs, & Social Media

Manufacturer Statements / Press Releases

Abbott (BinaxNOW)

- An Update on Omicron and Test Effectiveness. 28 December 2021. https://www.abbott.com/corpnewsroom/diagnostics-testing/an-update-on-omicron-and-test-effectiveness.html

Quidel Corporation (QuickVue, Sofia, Solana, Lyra, Triage)

- Quidel's Antigent Tests Detect the Omicron Variant. 28 December 2021. https://ir.quidel.com/news/news-release-details/2021/Quidels-Antigen-Tests-Detect-the-Omicron-Variant/default.aspx

Becton Dickinson and Company [BD] (Veritor)

- BD Statement on Testing for the COVID-19 Omicron Variant of Concern. 30 November 2021. https://news.bd.com/2021-11-30-BD-Statement-on-Testing-for-the-COVID-19-Omicron-Variant-of-Concern

BTNX Inc. (Rapid Response)

- Impact of the Omicron variant of SARS-CoV-2 on BTNX's Rapid Response COVID-19 Antigen Rapid Test Device. 23 December 2021. https://www.btnx.com/files/BTNX%20Statement%20on%20the%20Omicron%20Variant.pdf

SD Biosensor

- Confirmation of validity of COVID-19 mutation 'Omicron' test. 2021 December 3. https://www.sdbiosensor.com/board/news_view?post_no=13417&no=1&total=2&search_key=&search_text=omicron&category=0

Ellume Limited

- [Video] Ellume founder Dr Parsons on COVID testing, Omicron. 3 December 2021. https://www.ellumehealth.com/2021/12/03/ellume-founder-dr-parsons-on-covid-testing-omicron/

LumiraDx (LumiraDx)

- LumiraDx Monitoring of New and Emerging Variants of Concern and Detection of the Omicron Variant. 29 November 2021. https://www.lumiradx.com/us-en/news-events/lumiradx-monitoring-of-new-and-emerging-variants-of-concern-and-detection-of-the-omicron-variant

Searched FDA-approved tests: Found no statements from: Orasure Technologies (Inteliswab), Empowered Diagnostics LLC (Covclear), Lumos Diagnostics (COVIDx), Artron Laboratories Inc. (Artron), CareStart (CareStart).

Search Results: Journal Articles (includes preprints)

Sorted by newest-oldest.

1. Apurvasinh P, Rameshchandra P, Armi MC, et al. A simple and quick PCR based method for detection of Omicron variant of SARS-CoV-2. 2021.

ABSTRACT: SARS-CoV-2 pandemic has changed the global landscape since last two years. Against many challenges posed by the COVID-19 pandemic to the humanity, the pace of solutions created by mankind is exemplary; diagnostics, vaccines, alternate therapies, to name a few. With a rapidly changing virus strain, its early identification in the community can be a quick solution to trace the individuals and thus control its spread. This paper describes PCR based quick method for differentiation of Omicron variant of SARS-CoV-2 from other variants. Timely identification of this new variant will enable better management of pandemic control in the population. Graphical Abstract O_FIG O_LINKSMALLFIG WIDTH=200 HEIGHT=104 SRC="FIGDIR/small/21268053v1_ufig1.gif" ALT="Figure 1"> View larger version (24K): org.highwire.dtl.DTLVardef@1ab30fborg.highwire.dtl.DTLVardef@1cb7ccorg.highwire.dtl.DTLVardef@166f2c3org.highwire.dtl.DTLVardef@1cbe81b_HPS_FORMAT_FIGEXP M_FIG C_FIG
URL: https://medrxiv.org/cgi/content/short/2021.12.20.21268053

2. Deerain J, Druce J, Tran T, et al. Assessment of the analytical sensitivity of ten lateral flow devices against the SARS-CoV-2 omicron variant. J Clin Microbiol. 2021:jcm0247921. DOI: 10.1128/jcm.02479-21

ABSTRACT: Timely and accurate diagnostic testing is a critical component of the public health response to COVID-19. Antigen tests are used widely in many countries to provide rapid, economical and accessible point-of-care testing (1). The vast majority of antigen tests detect nucleocapsid (N) protein, a structural protein that displays less variation than the spike (S) protein across different SARS-CoV-2 lineages. Although antigen tests are less sensitive than RT-PCR tests, their ability to quickly detect individuals with high viral loads provides clinical and public health utility in many countries, including Australia, where antigen tests have recently been approved for self-testing (2). As new variants arise, including the recent emergence of the SARS-CoV-2 omicron variant, it is essential to rapidly assess the performance of diagnostic assays. Here, in order to assess and compare the ability of antigen tests to detect delta and omicron variants, we performed a rapid assessment of ten commercially available antigen tests.

URL: https://www.ncbi.nlm.nih.gov/pubmed/34936477

DOI: 10.1128/jcm.02479-21

3. Erster OBDAAHLVKAMBARSOLsMMFSMEZN. Specific detection of sars-cov-2 b.1.1.529 (omicron) variant by four rt-qpcr differential assays (preprint). 2021.

ABSTRACT: In this report, we describe four RT-qPCR assays that enable rapid identification of the newly emerging SARS-COV-2 Omicron (B.1.1.529) variant of concern. The assays target Omicron characteristic mutations in the nsp6 (Orf1a), spike and nucleocapsid genes. We demonstrate that the assays are straightforward to assemble and perform, are amendable for multiplexing, and may be used as a reliable first-line tool to identify B.1.1.529 suspected samples. Importantly, this is a preliminary development report. Further validation and optimization of the assays described herein will be published hereafter.

URL: https://doi.org/10.1101/2021.12.07.21267293

DOI: 10.1101/2021.12.07.21267293

4. James R, James F, Manish C, et al. Detection of the omicron variant virus with the Abbott BinaxNow SARS-CoV-2 Rapid Antigen Assay. 2021.

ABSTRACT: The US Centers for Disease Control and Prevention recommends rapid testing for SARS-CoV-2 infection as a key element of epidemic control. The Abbott BinaxNow is in widespread use in the United States for self-testing and as part of public health screening campaigns, but has not been evaluated for use with the omicron variant of SARS-CoV-2. We recruited individuals testing positive for COVID-19 PCR at an academic medical center. Anterior nasal swabs were stored in viral transport media and evaluated by viral load quantification and whole genome sequencing. We created serial dilutions from 2.5x103-2.5x105 viral copies/specimen for two delta and omicron specimens, respectively, and tested each with the BinaxNow assay per manufacturer instructions. Results were interpreted by three readers, blinded to the specimen variant and concentration. All omicron and delta specimens with concentrations of 100,000 copies/swab or greater were positive by the BinaxNow Assay, a concentration similar to previously reported limits of detection for this assay. Assay sensitivity diminished below that. This study demonstrates that Omicron variant SARS-CoV-2 infections are detected by the BinaxNow rapid antigen assay. Additional laboratory and clinical validation assessments are needed to better determine their limits of detection and performance in real-world settings.

URL: https://medrxiv.org/cgi/content/short/2021.12.22.21268219

5. Kruger LJ, Tanuri A, Lindner AK, et al. Accuracy and ease-of-use of seven point-of-care SARS-CoV-2 antigen-detecting tests: A multi-centre clinical evaluation. EBioMedicine. 2021;75:103774. DOI: 10.1016/j.ebiom.2021.103774

ABSTRACT: BACKGROUND: Antigen-detecting rapid diagnostic tests (Ag-RDTs) for SARS-CoV-2 are important diagnostic tools. We assessed clinical performance and ease-of-use of seven Ag-RDTs in a prospective, manufacturer-independent, multi-centre cross-sectional diagnostic accuracy study to inform global decision makers. METHODS: Unvaccinated participants suspected of a first SARS-CoV-2 infection were recruited at six sites (Germany, Brazil). Ag-RDTs were evaluated sequentially, with collection of paired swabs for routine reverse transcription polymerase chain reaction (RT-PCR) testing and Ag-RDT testing. Performance was compared to RT-PCR overall and in sub-group analyses (viral load, symptoms, symptoms duration). To understandusability a System Usability Scale (SUS) questionnaire and ease-of-use (EoU) assessment were performed. FINDINGS: 7471 participants were included in the analysis. Sensitivities across Ag-RDTs ranged from 70.4%-90.1%, specificities were above 97.2% for all Ag-RDTs but one (93.1%).Ag-RDTs, Mologic, Bionote, Standard Q, showed diagnostic accuracy in line with WHO targets (> 80% sensitivity, > 97% specificity). All tests showed high sensitivity in the first three days after symptom onset (>/=87.1%) and in individuals with viral loads>/= 6 log10SARS-CoV2 RNA copies/mL (>/= 88.7%). Usability varied, with Rapigen, Bionote and Standard Q reaching very good scores; 90, 88 and 84/100, respectively. INTERPRETATION: Variability in test performance is partially explained by variable viral loads in population evaluated over the course of the pandemic. All Ag-RDTs reach high sensitivity early in the disease and in individuals with high viral loads, supporting their role in identifying transmission relevant infections. For easy-to-use tests, performance shown will likely be maintained in routine implementation. FUNDING: Ministry of Science, Research and Arts, State of Baden-Wuerttemberg, Germany, internal funds from Heidelberg University Hospital, University Hospital Charite - Universitatsmedizin Berlin, UK Department of International Development, WHO, Unitaid.
URL: https://www.ncbi.nlm.nih.gov/pubmed/34959134
DOI: 10.1016/j.ebiom.2021.103774

6. Lippi G, Adeli K, Plebani M. Commercial immunoassays for detection of anti-SARS-CoV-2 spike and RBD antibodies: urgent call for validation against new and highly mutated variants. Clin Chem Lab Med. 2021;16:16-. DOI: 10.1515/cclm-2021-1287

ABSTRACT: Measuring the level of protection conferred by anti-SARS-CoV-2 (trimeric) spike or RBD (receptor binding domain) antibodies (especially total and IgG) is a suitable and reliable approach for predicting biological protection against the risk of infection and severe coronavirus disease 2019 (COVID-19) illness. Nonetheless, SARS-CoV-2 has undergone a broad process of recombination since the identification of the prototype lineage in 2019, introducing a huge number of mutations in its genome and generating a vast array of variants of interest (VoI) and concern (VoC). Many of such variants developed several mutations in spike protein and RBD, with the new Omicron (B.1.1.529) clade displaying over 30 changes, 15 of which concentrated in the RBD. Besides their impact on virus biology, as well as on the risk of detection failure with some molecular techniques (i.e., S gene dropout), recent evidence suggests that these mutations may also jeopardize the reliability of currently available commercial immunoassays for detecting anti-SARS-CoV-2 antibodies. The antigen (either spike or RBD) and epitopes of the prototype SARS-CoV-2 coated in some immunoassays may no longer reflect the sequence of circulating variants. On the other hand, anti-SARS-CoV-2 antibodies elicited by highly mutated SARS-CoV-2 variants may no longer be efficiently recognized by the currently available commercial immunoassays. Therefore, beside the compelling need to regularly re-evaluate and revalidate all commercially available immunoassays against live virus neutralization assays based on emerging VoCs or VoIs, diagnostic companies may also consider to redevelop their methods, replacing former SARS-CoV-2 antigens and epitopes with those of the new variants.

URL: https://www.ncbi.nlm.nih.gov/pubmed/34911171
DOI: 10.1515/cclm-2021-1287

7. Marais G, Hsiao N-y, Iranzadeh A, et al. Saliva swabs are the preferred sample for Omicron detection. medRxiv. 2021:2021.12.22.21268246. DOI: 10.1101/2021.12.22.21268246
ABSTRACT: The Omicron variant is characterised by more than 50 distinct mutations, the majority of which are located in the spike protein. The implications of these mutations for disease transmission, tissue tropism and diagnostic testing are still to be determined. We evaluated the relative performance of saliva and mid-turbinate swabs as RT-PCR samples for the Delta and Omicron variants. The positive percent agreement (PPA) of saliva swabs and mid-turbinate swabs to a composite standard was 71% (95% CI: 53-84%) and 100% (95% CI: 89-100%), respectively, for the Delta variant. However, for the Omicron variant saliva and mid-turbinate swabs had a 100% (95% CI: 90-100%) and 86% (95% CI: 71-94%) PPA, respectively. This finding supports ex-vivo data of altered tissue tropism from other labs for the Omicron variant. Reassessment of the diagnostic testing standard-of-care may be required as the Omicron variant become the dominant variant worldwide.Competing Interest StatementThe authors have declared no competing interest.Funding StatementThis research was funded in whole, or in part, by Wellcome [203135/Z16/Z]. For the purpose of Open Access, the author has applied a CC BY public copyright licence to any Author Accepted Manuscript version arising from this submission. This study was funded in whole, or in part, by National Health Laboratory Service in South Africa.Author DeclarationsI confirm all relevant ethical guidelines have been followed, and any necessary IRB and/or ethics committee approvals have been obtained.YesThe details of the IRB/oversight body that provided approval or exemption for the research described are given below:This research has been approved by the University of Cape Town Human Research Ethics Committee (Ref: 420/2020).I confirm that all necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived, and that any patient/participant/sample identifiers included were not known to anyone (e.g., hospital staff, patients or participants themselves) outside the research group so cannot be used to identify individuals.YesI understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).YesI have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.YesAll data produced in the present study are available upon reasonable request to the authors.
URL: http://medrxiv.org/content/early/2021/12/24/2021.12.22.21268246.abstract
DOI: 10.1101/2021.12.22.21268246

8. Meriem B, Kenneth A, Catia A, et al. Analytical sensitivity of seven SARS-CoV-2 antigen-detecting rapid tests for Omicron variant. 2021.
ABSTRACT: The emergence of novel SARS-CoV-2 variants of concern (VOCs) requires investigation of a potential impact on diagnostic performance, such as Antigen-detecting rapid diagnostic tests (Ag-RDT). Although anecdotal reports have been circulating that Omicron is in principle detectable by Ag-RDTs, no published data are a yet available for the newly emerged Omicron variant. Here, we have performed an analytical sensitivity testing with cultured virus in seven Ag-RDTs for their sensitivity to Omicron compared to data earlier obtained on VOCs Alpha, Beta, Gamma and Delta and a pre-VOC isolate of SARS-CoV-2. Overall, we have found a tendency towards lower sensitivity for Omicron compared to pre-VOC SARS-CoV-2 and the other VOCs across tests. Importantly, while analytical testing with cultured

virus may be a proxy for clinical sensitivity, is not a replacement for clinical evaluations which are urgently needed for Ag-RDT performance in Omicron-infected individuals.
URL: https://medrxiv.org/cgi/content/short/2021.12.18.21268018

9. Nicholas Jacob B, James I, Marvin C, et al. Utilization of a SARS-CoV-2 Variant Assay for the Rapid Differentiation of Omicron and Delta. 2021.
ABSTRACT: The emergence of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant (B.1.1.529), creates a diagnostic vacuum, since differentiation of Omicron from Delta relies on relatively slow next generation sequencing (NGS) technology delaying epidemiologic understanding and therapeutic intervention. The RUO SARS-CoV-2 Variant Set 1 Test (RSCov2V1) RT-PCR for detection of spike gene N501Y, E484K and del69-70 was designed to differentiate Alpha from Beta and Gamma variants. While Delta lacks these three variants, Omicron has the N501Y and del69-70 mutation. We submitted 88 samples for RSCov2V1 identifying 9 samples with the N501Y and del69-70 mutations while all other samples (79) were negative for all three variants. 9/9 samples with the del69-70 and N501Y were identified by NGS to be Omicron while 47/47 other samples assessed by NGS were confirmed to be Delta family variants. We demonstrate here that an immediately available RT-PCR assay for detection of spike gene N501Y and del69-70 can be utilized to rapidly differentiate Omicron from Delta variants in the proper epidemiologic context
URL: https://medrxiv.org/cgi/content/short/2021.12.22.21268195

10. Paul E, Barbara B, Oliver E, et al. Rapid increase in Omicron infections in England during December 2021: REACT-1 study. 2021.
ABSTRACT: BackgroundThe highest-ever recorded numbers of daily severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections in England has been observed during December 2021 and have coincided with a rapid rise in the highly transmissible Omicron variant despite high levels of vaccination in the population. Although additional COVID-19 measures have been introduced in England and internationally to contain the epidemic, there remains uncertainty about the spread and severity of Omicron infections among the general population. MethodsThe REal-time Assessment of Community Transmission-1 (REACT-1) study has been monitoring the prevalence of SARS-CoV-2 infection in England since May 2020. REACT-1 obtains self-administered throat and nose swabs from a random sample of the population of England at ages 5 years and over. Swabs are tested for SARS-CoV-2 infection by reverse transcription polymerase chain reaction (RT-PCR) and samples testing positive are sent for viral genome sequencing. To date 16 rounds have been completed, each including [~]100,000 or more participants with data collected over a period of 2 to 3 weeks per month. Socio-demographic, lifestyle and clinical information (including previous history of COVID-19 and symptoms prior to swabbing) is collected by online or telephone questionnaire. Here we report results from round 14 (9-27 September 2021), round 15 (19 October - 05 November 2021) and round 16 (23 November - 14 December 2021) for a total of 297,728 participants with a valid RT-PCR test result, of whom 259,225 (87.1%) consented for linkage to their NHS records including detailed information on vaccination (vaccination status, date). We used these data to estimate community prevalence and trends by age and region, to evaluate vaccine effectiveness against infection in children ages 12 to 17 years, and effect of a third (booster) dose in adults, and to monitor the emergence of the Omicron variant in England. ResultsWe observed a high overall prevalence of 1.41% (1.33%, 1.51%) in the community during round 16. We found strong evidence of an increase in prevalence during round 16 with an estimated reproduction number R of 1.13 (1.06, 1.09) for the whole of round 16 and 1.27 (1.14, 1.40) when restricting to observations from 1 December onwards. The reproduction number in those aged 18-54 years was estimated at 1.23 (1.14, 1.33) for the whole of round 16 and 1.41 (1.23, 1.61) from 1 December. Our data also provide strong evidence of a steep increase in prevalence in London with an estimated R of 1.62 (1.34, 1.93) from 1

December onwards and a daily prevalence reaching 6.07% (4.06%, 9.00%) on 14 December 2021. As of 1 to 11 December 2021, of the 275 lineages determined, 11 (4.0%) corresponded to the Omicron variant. The first Omicron infection was detected in London on 3 December, and subsequent infections mostly appeared in the South of England. The 11 Omicron cases were all aged 18 to 54 years, double-vaccinated (reflecting the large numbers of people who have received two doses of vaccine in this age group) but not boosted, 9 were men, 5 lived in London and 7 were symptomatic (5 with classic COVID-19 symptoms: loss or change of sense of smell or taste, fever, persistent cough), 2 were asymptomatic, and symptoms were unknown for 2 cases. The proportion of Omicron (vs Delta or Delta sub-lineages) was found to increase rapidly with a daily increase of 66.0% (32.7%, 127.3%) in the odds of Omicron (vs. Delta) infection, conditional on swab positivity. Highest prevalence of swab positivity by age was observed in (unvaccinated) children aged 5 to 11 years (4.74% [4.15%, 5.40%]) similar to the prevalence observed at these ages in round 15. In contrast, prevalence in children aged 12 to 17 years more than halved from 5.35% (4.78%, 5.99%) in round 15 to 2.31% (1.91%, 2.80%) in round 16. As of 14 December 2021, 76.6% children at ages 12 to 17 years had received at least one vaccine dose; we estimated that vaccine effectiveness against infection was 57.9% (44.1%, 68.3%) in this age group. In addition, the prevalenc of swab positivity in adults aged 65 years and over fell by over 40% from 0.84% (0.72%, 0.99%) in round 15 to 0.48% (0.39%,0.59%) in round 16 and for those aged 75 years and over it fell by two-thirds from 0.63% (0.48%,0.82%) to 0.21% (0.13%,0.32%). At these ages a high proportion of participants (>90%) had received a third vaccine dose; we estimated that adults having received a third vaccine dose had a three- to four-fold lower risk of testing positive compared to those who had received two doses. ConclusionA large fall in swab positivity from round 15 to round 16 among 12 to 17 year olds, most of whom have been vaccinated, contrasts with the continuing high prevalence among 5 to 11 year olds who have largely not been vaccinated. Likewise there were large falls in swab positivity among people aged 65 years and over, the vast majority of whom have had a third (booster) vaccine dose; these results reinforce the importance of the vaccine and booster campaign. However, the rapidly increasing prevalence of SARS-CoV-2 infections in England during December 2021, coincident with the rapid rise of Omicron infections, may lead to renewed pressure on health services. Additional measures beyond vaccination may be needed to control the current wave of infections and prevent health services (in England and other countries) from being overwhelmed. SummaryThe unprecedented rise in SARS-CoV-2 infections is concurrent with rapid spread of the Omicron variant in England and globally. We analysed prevalence of SARS-CoV-2 and its dynamics in England from end of November to mid-December 2021 among almost 100,000 participants from the REACT-1 study. Prevalence was high during December 2021 with rapid growth nationally and in London, and of the proportion of infections due to Omicron. We observed a large fall in swab positivity among mostly vaccinated older children (12-17 years) compared with unvaccinated younger children (5-11 years), and in adults who received a third vs. two doses of vaccine. Our results reiterate the importance of vaccination and booster campaigns; however, additional measures may be needed to control the rapid growth of the Omicron variant.
URL: https://medrxiv.org/cgi/content/short/2021.12.22.21268252

11. Ramazzotti DMDAFAMPRGA. Early detection and improved genomic surveillance of SARS-CoV-2 variants from deep sequencing data (preprint). 2021.
ABSTRACT: In the definition of fruitful strategies to contrast the worldwide diffusion of SARS-CoV-2, maximum efforts must be devoted to the early detection of dangerous variants. An effective help to this end is granted by the analysis of deep sequencing data of viral samples, which are typically discarded after the creation of consensus sequences. Indeed, only with deep sequencing data it is possible to identify intra-host low-frequency mutations, which are a direct footprint of mutational processes that may eventually lead to the origination of functionally advantageous variants. Accordingly, a timely and statistically robust identification of such mutations might inform political decision-making with

significant anticipation with respect to standard analyses based on consensus sequences. To support our claim, we here present the largest study to date of SARS-CoV-2 deep sequencing data, which involves 220,788 high quality samples, collected over 20 months from 137 distinct studies. Importantly, we show that a relevant number of spike and nucleocapsid mutations of interest associated to the most circulating variants, including Beta, Delta and Omicron, might have been intercepted several months in advance, possibly leading to different public-health decisions. In addition, we show that a refined genomic surveillance system involving high- and low-frequency mutations might allow one to pinpoint possibly dangerous emerging mutation patterns, providing a data-driven automated support to epidemiologists and virologists.
URL: https://doi.org/10.1101/2021.12.14.21267810
DOI: 10.1101/2021.12.14.21267810

12. Thomas E, Delabat S, Carattini YL, et al. SARS-CoV-2 and Variant Diagnostic Testing Approaches in the United States. Viruses. 2021;13(12):2492-. DOI: 10.3390/v13122492
ABSTRACT: Purpose of Review Given the rapid development of diagnostic approaches to test for and diagnose infection with SARS-CoV-2 and its associated variants including Omicron (B.1.1.529), many options are available to diagnose infection. Multiple established diagnostic companies are now providing testing platforms whereas initially, testing was being performed with simple PCR-based tests using standard laboratory reagents. Recent Findings Additional testing platforms continue to be developed, including those to detect specific variants, but challenges with testing, including obtaining testing reagents and other related supplies, are frequently encountered. With time, the testing supply chain has improved, and more established companies are providing materials to support these testing efforts. In the United States (U.S.), the need for rapid assay development and subsequent approval through the attainment of emergency use authorization (EUA) has superseded the traditional arduous diagnostic testing approval workflow mandated by the FDA. Through these efforts, the U.S. has been able to continue to significantly increase its testing capabilities to address this pandemic; however, challenges still remain due to the diversity of the performance characteristics of tests being utilized and newly discovered viral variants. Summary This review provides an overview of the current diagnostic testing landscape, with pertinent information related to SARS-CoV-2 virology, variants and antibody responses that are available to diagnose infection in the U.S.
URL: https://www.ncbi.nlm.nih.gov/pubmed/34960762
DOI: 10.3390/v13122492

13. Tran NK, May L. Evolution of COVID-19 Testing and the Role of Rapid Antigen Testing in Molecular-Focused World. Arch Pathol Lab Med. 2021. DOI: 10.5858/arpa.2021-0610-ED
URL: https://www.ncbi.nlm.nih.gov/pubmed/34964814
DOI: 10.5858/arpa.2021-0610-ED

14. Varsha AP, Pragya Y, Kavita l, et al. Detection of the omicron variant in international travellers and their family contacts in India. 2021.
ABSTRACT: HighlightsWith the emergence of the Variant of Concern, omicron (B.1.1.529), India has enhanced genomic surveillance in international travellers. The omicron variant was detected in 59 cases from different States; 40 from Maharashtra, 17 from Rajasthan and one each from Gujrat and Tamil Nadu. The positive cases and their contacts were asymptomatic and genomic surveillance could identify two clusters, one from Maharashtra and another from Rajasthan.
URL: https://medrxiv.org/cgi/content/short/2021.12.27.21268429

Appendix 1: Evidence Search Details

Filters, Limits & Exclusions:	English only 2021 – Current …
Sources Searched:	• CanCOVID • CDC • Center for Infectious Disease Research and Policy (CIDRAP) • Cochrane Library • COVID-19 Immunity Task Force • COVID-END • Embase • European Centre for Disease Prevention and Control (ECDC) • Google • Google Scholar • Medline • medRxiv, bioRxiv • Public Health England | UK Health Security Agency • Public Health Ontario • PubMed / LitCovid • Science Table (Ontario) • Strategy for Patient-Oriented Research • WHO
Librarian(s):	Lukas Miller, Clinical Librarian, Saskatchewan Health Authority Brianna Howell-Spooner, Clinical Librarian, Saskatchewan Health Authority

Appendix 2: Search Strategies

Database: Ovid MEDLINE(R) ALL <1946 to January 04, 2022>
Search Strategy:
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1 COVID-19/ or exp COVID-19 Testing/ or COVID-19 Vaccines/ or SARS-CoV-2/ (131662)
2 (coronavirus/ or betacoronavirus/ or coronavirus infections/) and (disease outbreaks/ or epidemics/ or pandemics/) (40102)
3 (nCoV* or 2019nCoV or 19nCoV or COVID19* or COVID or SARS-COV-2 or SARSCOV-2 or SARS-COV2 or SARSCOV2 or SARS coronavirus 2 or Severe Acute Respiratory Syndrome Coronavirus 2 or Severe Acute Respiratory Syndrome Corona Virus 2).ti,ab,kf,nm,ot,ox,rx,px. (206515)
4 ((new or novel or "19" or "2019" or Wuhan or Hubei or China or Chinese) adj3 (coronavirus* or corona virus* or betacoronavirus* or CoV or HCoV)).ti,ab,kf,ot. (60606)
5 (longCOVID* or postCOVID* or postcoronavirus* or postSARS*).ti,ab,kf,ot. (24)
6 ((coronavirus* or corona virus* or betacoronavirus*) adj3 (pandemic* or epidemic* or outbreak* or crisis)).ti,ab,kf,ot. (10931)
7 ((Wuhan or Hubei) adj5 pneumonia).ti,ab,kf,ot. (380)
8 or/1-7 (216740)
9 exp Antigens, Viral/ (105308)
10 antigen*.tw,kf. (662081)
11 9 or 10 (711118)

12 (rapid* adj5 (test or testing or tests or tested or diagnos* or detect* or identification or screen* or assay? or immunoassay?)).tw,kf. or (rapid* and (test or testing or tests or tested or diagnos* or detect* or identification or screen* or assay? or immunoassay?)).ti,ot,kf. (127458)
13 11 and 12 (11624)
14 (rapid antigen* test* or ag-rdt or antigen* rapid diagnostic test* or rapid antigen* detect* or antigen* rapid test* or RADT or RDT or RAD test* or lateral flow or LFT).tw,kf. (8348)
15 COVID-19 Testing/ and exp Antigens, Viral/ and rapid*.ti,kf. (70)
16 13 or 14 or 15 (18068)
17 exp *"Sensitivity and Specificity"/ (6124)
18 (sensitivity or sensitive or specificity or specific or accuracy or accurate* or inaccurat* or inaccurac* or predict* value or false positive? or false negative? or ROC curve? or receiver operating characteristics or "signal-to-noise ratio" or "limit of detection" or "limits of detection" or detection limit? or gold standard or validity or reliability or efficacy or effective* or ineffect* or failure? or failed).tw,kf. (8136547)
19 17 or 18 (8137986)
20 8 and 16 and 19 (1048)
21 limit 20 to (english language and yr="2021 -Current") (827)
22 (omicron or "B.1.1.529" or "B11529").ti,ab,kf,nm,ot,ox,rx,px. (527)
23 16 and 22 (2)
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Database: Embase <1974 to 2022 January 04>
Search Strategy:
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1 sars-related coronavirus/ (485)
2 (coronavirinae/ or betacoronavirus/ or coronavirus infection/) and (epidemic/ or pandemic/) (10679)
3 (nCoV* or 2019nCoV or 19nCoV or COVID19* or COVID or SARS-COV-2 or SARSCOV-2 or SARS-COV2 or SARSCOV2 or SARS coronavirus 2 or Severe Acute Respiratory Syndrome Coronavirus 2 or Severe Acute Respiratory Syndrome Corona Virus 2).ti,ab,kw,hw,ot. (209987)
4 ((new or novel or "19" or "2019" or Wuhan or Hubei or China or Chinese) adj3 (coronavirus* or corona virus* or betacoronavirus* or CoV or HCoV)).ti,ab,kw,hw,ot. (185639)
5 (longCOVID* or postCOVID* or postcoronavirus* or postSARS*).ti,ab,kw,hw,ot. (59)
6 ((coronavirus* or corona virus* or betacoronavirus*) adj3 (pandemic* or epidemic* or outbreak* or crisis)).ti,ab,kw,ot. (12475)
7 ((Wuhan or Hubei) adj5 pneumonia).ti,ab,kw,ot. (428)
8 or/1-7 (228287)
9 exp *virus antigen/ (46099)
10 (antigen* and (virus* or viral*)).tw,kf. (138053)
11 9 or 10 (162889)
12 (rapid* adj5 (test or testing or tests or tested or diagnos* or detect* or identification or screen* or assay? or immunoassay?)).tw,kf. or (rapid* and (test or testing or tests or tested or diagnos* or detect* or identification or screen* or assay? or immunoassay?)).ti,ot,kf. (156610)
13 11 and 12 (4384)
14 (rapid antigen* test* or ag-rdt or antigen* rapid diagnostic test* or rapid antigen* detect* or antigen* rapid test* or RADT or RDT or RAD test* or lateral flow or LFT).tw,kf. (12528)
15 exp covid-19 testing/ and exp virus antigen/ and rapid.tw,kf. (29)
16 13 or 14 or 15 (16049)

17 exp *"sensitivity and specificity"/ (2432)
18 (sensitivity or sensitive or specificity or specific or accuracy or accurate* or inaccurat* or inaccurac* or predict* value or false positive? or false negative? or ROC curve? or receiver operating characteristics or "signal-to-noise ratio" or "limit of detection" or "limits of detection" or detection limit? or gold standard or validity or reliability or efficacy or effective* or ineffect* or failure? or failed).tw,kf. (10447187)
19 17 or 18 (10447254)
20 8 and 16 and 19 (865)
21 (omicron or "B.1.1.529" or "B11529").ti,ab,kf,ot,ox,px. (187)
22 20 and 21 (1)
23 16 and 21 (1)

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Other Terms Used
rapid testing
rapid detection
rapid diagnosis
test validity
antigenic
immunoassay
assays
sensitivity
specificity
accuracy
predictive value
false positive
false negative
detection limit
failure rate
accuracy
reliability
validity