SARS-CoV-2 testing in the face of omicron wave and other future variants

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Assays for SARS-CoV-2 detection

Suspected case

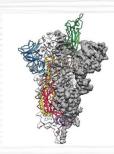
Virologic assays



Genetic material

Molecular test (e.g., RT-PCR)

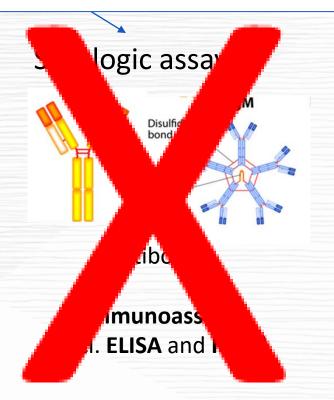
Gold standard



Proteins = Antigens

Immunoassays (incl. ELISA and RDTs)

do **NOT** confirm active infection







Currently recommended assays and Omicron

- Molecular tests (RT-PCR)
 - No impact on the recommended RT-PCR protocols
 - Charité (Berlin) for SARS-CoV-2 universal surveillance
 - CDC Influenza SARS-CoV-2 multiplex for integrated sentinel surveillance
 - WHO Emergency Use Listing (EUL) assays
 - Some multitarget assays targeting the S gene show an S gene target failure (SGTF) which might be use as a proxy for some of the Omicron sublineages
- Ag-RDT
 - Preliminary data show similar performance for the detection of viral cultures of Omicron vs Delta/other lineages
 - Prospective clinical studies ongoing in particular for the tests that are listed in the WHO EUL





How to specifically detect Omicron (and other variants)?

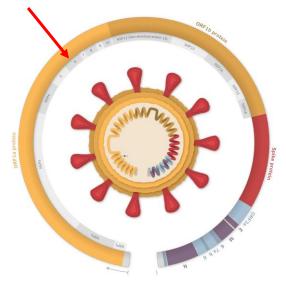
- Identification of SARS-CoV-2 lineage/variants require full genome sequencing
 - Capacity available at UWI T&T (PAHO Sequencing Reference Laboratory), CARPHA, SGU (Grenada)...
- Alternative approaches
 - Sequencing targeted regions of the genome (e.g., Spike [S] gene) using Sanger sequencing
 - Screening for specific mutations found in variants by RT-PCR
- Advantages of screening RT-PCRs
 - Shorter turnaround
 - Easy to implement in labs with RT-PCR experience
 - Many commercial and non-commercial protocols available
- Disadvantages of screening RT-PCRs
 - Not confirmatory
 - Variants are characterized by a number of mutations found throughout the viral genome
 - Mutations found in VOCs might arise in other lineages that may or may not be of concern
 - Can only detect known mutations



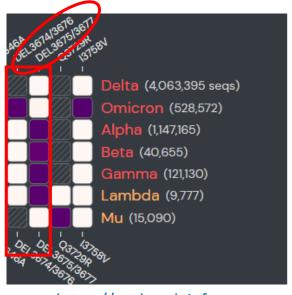


Screening RT-PCR for ORF1a/NSP6 deletion

- Naveca et al., COVID-19 in Amazonas, Brazil, was driven by the persistence of endemic lineages and P.1 emergence, Nat Med 27, 1230–1238 (2021), https://doi.org/10.1038/s41591-021-01378-7
- Used to track Gamma in the Brazilian Amazonas context



https://www.nytimes.com/interactive/ e/2021/health/coronavirus-varianttracker.html



https://outbreak.info

Protocol detects two deletions:

Deletion: NSP6 S106/G107/F108 ⇔ ORF1a S3675/G3676/F3677
Present in Alpha, Beta, Gamma, Lambda, and Omicron BA.2 and BA.3

Deletion: NSP6 L105/S106/G107 ⇔ ORF1a L3674/S3675/G3676

Present in Omicron B.1.1.529 and BA.1

Deletions NOT present in Delta, Mu, and non-VOC/VOI

Reagents and implementation support available from PAHO





Testing strategies in the context of Omicron circulation

- Main challenge in terms of testing is the significant increase in cases/testing requests
- Shift of the burden to the first level of care
- Need to expand testing capacities at the first level of care
 - Implementation of Ag-RDTs
 - In general, there is **no need** to confirm Ag-RDT results using RT-PCR

 High-quality Ag-RDTs are available through the PAHO Strategic Fund mechanism at globally negotiated prices



SD Biosensor STANDARD Q COVID-19 Ag Test (\$3.30 per test incl. shipping)



Abbott Panbio COVID-19 Ag Rapid Test Device nasopharyngeal and nasal versions (\$2.25 per test incl. shipping)





Testing strategies in the context of Omicron circulation



Epidemiological Alert Rational use of COVID-19 diagnostic tests

10 January 2022

In the context of the rapid increase in COVID-19 cases following a sudden increase in the use of COVID-19 diagnostic tests in several countries within and outside of the Americas Region, the Pan American Health Organization / World Health Organization (PAHO/WHO) recommends Member States to take appropriate measures for the rational use of diagnostic tests and thus ensure their provision for both surveillance and medical care.

Rational use of COVID-19 diagnostic tests in the context of Omicron transmission

Since epidemiological week (EW) 40 of 2021, there has been an increasing trend in COVID-19 cases in several countries in Europe and more recently in the Region of the Americas. In some countries, the increase in cases reported at the end of the year exceeded the historical peaks reported throughout the pandemic (Figure 1). Indeed, during the last week of 2021, a total 9.7 million cases of COVID-19 were reported globally, representing an increase of 72% compared to the previous week and the highest number of weekly reported since the beginning of the pandemic.

https://www.paho.org/en/documents/epidemiological-alertrational-use-covid-19-diagnostic-tests-10-january-2022





When capacity is limited, who should be tested for SARS-CoV-2?

Prioritization





Strongly recommend to test*.

Population Groups



- Symptomatic health or care worker with no known COVID-19 contact
- Individual meeting case definition for COVID-19, requiring admission to health care facility



Recommend to test*.

If testing is not available, register as a suspected case and isolate.

- Symptomatic health or care worker identified as a contact
- Individual meeting case definition for COVID-19 with mild disease without underlying health conditions.



Test* a subset of the cases.

Consider all other symptomatic individuals as probable cases and isolate.

- Increased number of suspected cases in a specific group (potential cluster)
- Symptomatic individuals in closed settings, including schools, hospitals and long-term living facilities



Testing* is lowest priority / not required.

- Asymptomatic contacts of confirmed or probable cases
- Recovering patients
- Other asymptomatic individuals

Patients who need to be hospitalized for other reasons, to detect COVID-19 according (PAHO alerts on rational use and organization of services, 10 and 21 January 2022)

Recommendations for national SARS-CoV-2 testing strategies and diagnostic capacities

25 June 2021

https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng





*Testing can be done using nucleic acid amplification test (NAAT) or Ag-RDTs. NAAT is the reference standard but Ag-RDTs are a crucial tool used to increase access to testing. Ag-RDTs may be used to test for SARS-CoV-2 without the need to confirm the result using NAAT.

Conclusions

- The emergence of mutations and variants is part of the viral evolution process
- Higher transmission rates will contribute to continuous virus evolution
- No silver bullet for COVID-19 control
 - Need testing, surveillance, public health and social measures, vaccination...
- Need to expand testing capacity
 - To this end, Ag-RDTs are key tools
- Need testing strategies that are aligned with testing capacity
 - Clear prioritization criteria



Thank you!! PAHO Laboratory Response Team



