Member States Briefing

ACT-A Diagnostics Pillar

31 March 2022

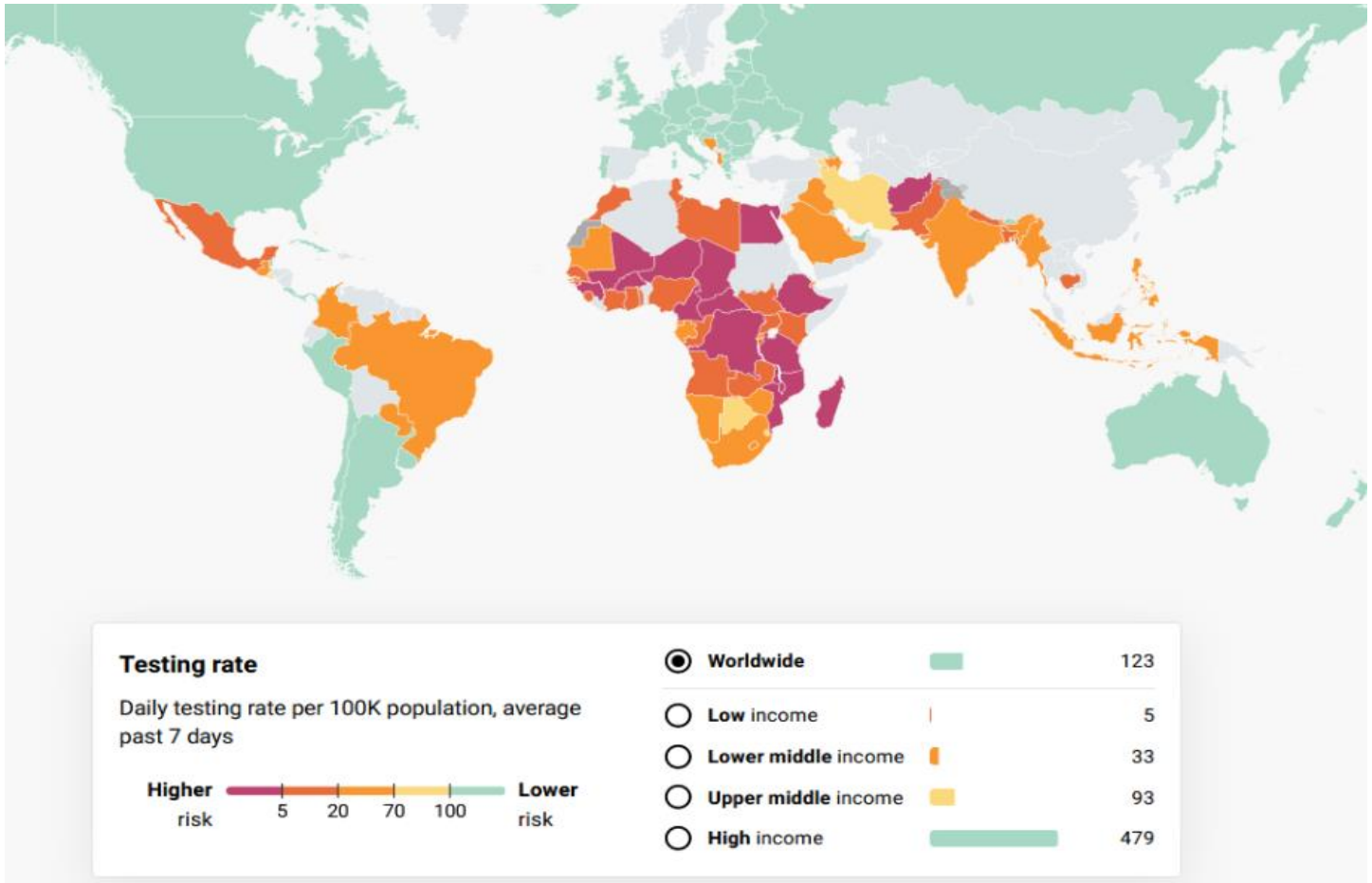
FIND
Diagnosis for all

World Health Organization

THE GLOBAL FUND

21.7% of global tests have been used in LICs & LMICs, despite comprising 50.8% of the global population

Average daily tests per 100K population



Testing rates and targets

ACT-A minimum testing target
100 test per 100K population per day

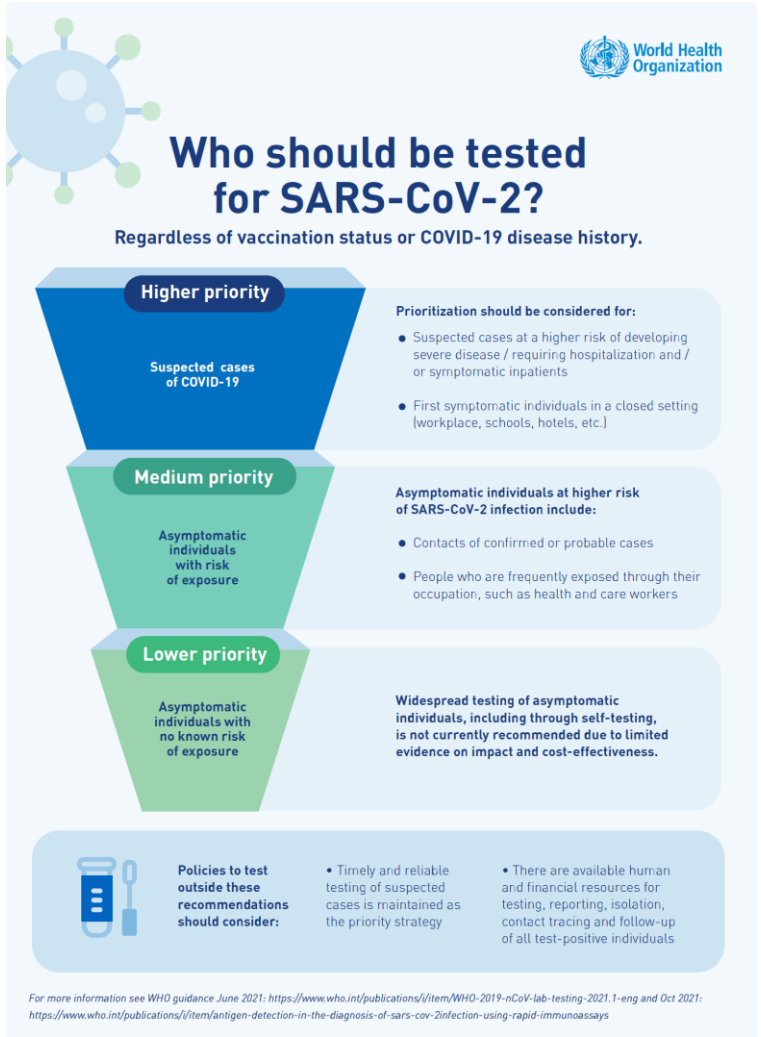
While testing rates have substantially decreased in all parts of the world since Jan 2022,

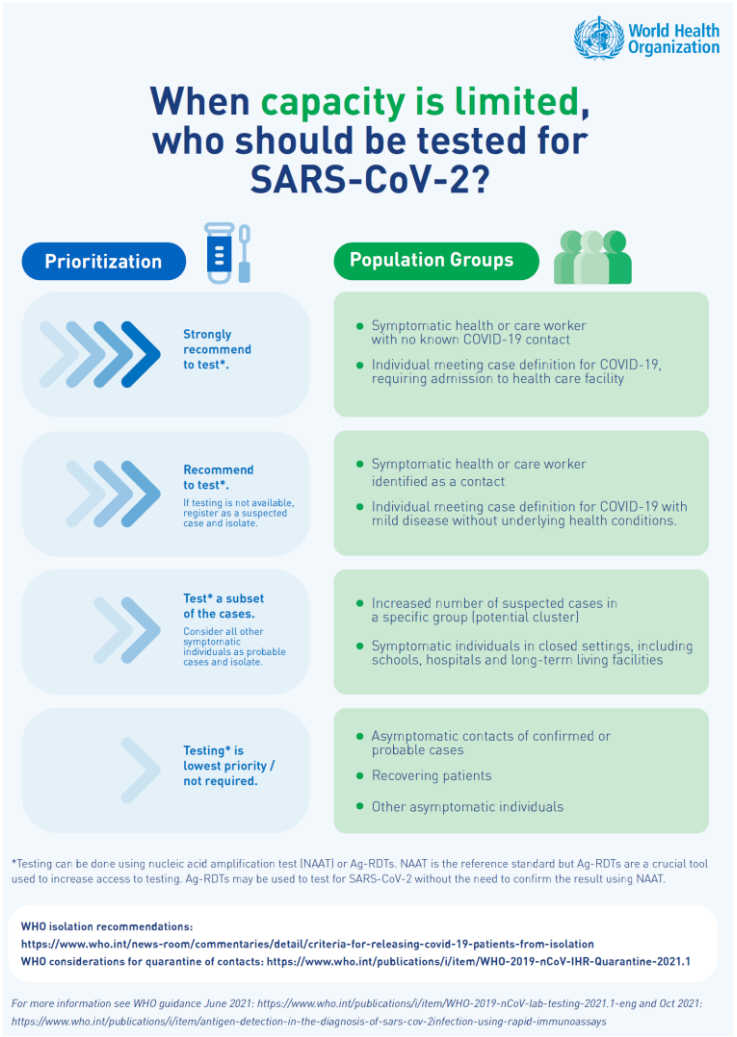
Tests per 100K people per day

- *High-income countries: 479*
- *Upper-middle income countries: 93*
- *Lower-middle income countries: 33*
- *Low-income countries: 5*

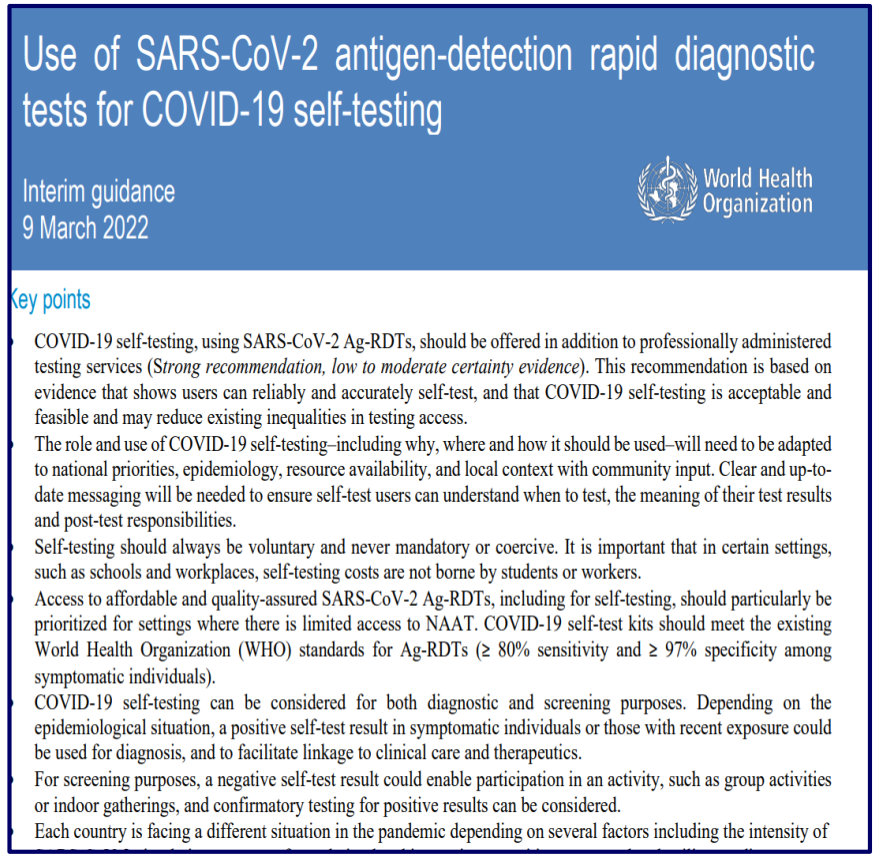
Data as of 23 March 2022 Source: FIND test tracker https://www.finddx.org/covid-19/test-tracker/

Strategic and prioritized testing policies are key





WHO released additional guidance on use of Ag-RDTs for COVID-19 self-testing



Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing

Interim guidance
9 March 2022

World Health Organization

Key points

- COVID-19 self-testing, using SARS-CoV-2 Ag-RDTs, should be offered in addition to professionally administered testing services (*Strong recommendation, low to moderate certainty evidence*). This recommendation is based on evidence that shows users can reliably and accurately self-test, and that COVID-19 self-testing is acceptable and feasible and may reduce existing inequalities in testing access.
- The role and use of COVID-19 self-testing–including why, where and how it should be used–will need to be adapted to national priorities, epidemiology, resource availability, and local context with community input. Clear and up-to-date messaging will be needed to ensure self-test users can understand when to test, the meaning of their test results and post-test responsibilities.
- Self-testing should always be voluntary and never mandatory or coercive. It is important that in certain settings, such as schools and workplaces, self-testing costs are not borne by students or workers.
- Access to affordable and quality-assured SARS-CoV-2 Ag-RDTs, including for self-testing, should particularly be prioritized for settings where there is limited access to NAAT. COVID-19 self-test kits should meet the existing World Health Organization (WHO) standards for Ag-RDTs (≥ 80% sensitivity and ≥ 97% specificity among symptomatic individuals).
- COVID-19 self-testing can be considered for both diagnostic and screening purposes. Depending on the epidemiological situation, a positive self-test result in symptomatic individuals or those with recent exposure could be used for diagnosis, and to facilitate linkage to clinical care and therapeutics.
- For screening purposes, a negative self-test result could enable participation in an activity, such as group activities or indoor gatherings, and confirmatory testing for positive results can be considered.
- Each country is facing a different situation in the pandemic depending on several factors including the intensity of

*Antigen-detection in the diagnosis of SARS-CoV-2 infection

Issued by WHO on **9 March 2022.**

Based on evidence that shows users can reliably and accurately self-test, and that **COVID-19 self-testing is acceptable and feasible and may reduce existing inequalities** in testing access.

This guidance should be **read in conjunction with the latest guidance on the use of Ag-RDTs***

Relevant to policy makers, program managers, implementers, health workers and pharmacists **responsible for planning and implementing SARS-CoV-2 testing**, prevention, care and treatment services, particularly in LMICs

WHO Global Survey: Many countries have already incorporated self-tests into overall COVID-19 testing policies

>100 countries already implementing, piloting or have policies being planned for COVID-19 self testing

- 32 countries w/ policy in development & pilots
- Many countries (LMIC/HIC) had at least 1 place where self tests could be accessed freely (more so in HIC)
- Reach of self tests greater in HIC than LMIC

High willingness to self-test reported

- Respondents across all regions, with experience implementing self-testing, indicate high willingness to use

Numerous self test products available

- Many not quality-assured nor regulated
- Critical to enable WHO EUL products

Source: Divala, Sakala, Chirombo, WHO Survey, Web Annex D

World Health Organization

Key points: WHO guidance on use of Ag-RDTs for self testing

- The role & use of COVID-19 self-testing (why, where and how to be used) will need to be **adapted to national priorities, epidemiology, resources, and local context with community input**.
- Access to affordable and quality assured SARS-CoV-2 Ag-RDTs, including for self-testing, should be prioritized. **Self-test kits should meet the existing WHO standards** for Ag-RDTs (≥ 80% sensitivity and ≥ 97% specificity among symptomatic)
- Self-testing should **always be voluntary.** It is important that in certain settings, such as schools and workplaces, self-testing **costs are not borne by students or workers.**
- **Clear messaging is needed** so users understand when and how to test, the meaning of test results and what to do after a positive or negative result.
- COVID-19 self-testing can be considered for both diagnostic and screening purposes.
    1. Depending on the epidemiological situation**, a positive self-test result in symptomatic individuals or those with recent exposure could be used for diagnosis**, and to facilitate linkage to clinical care and therapeutics.
    2. For screening purposes**, a negative self-test result could enable participation in an activity**, and confirmatory testing for positive results can be considered.

Clinical CARE Pathway

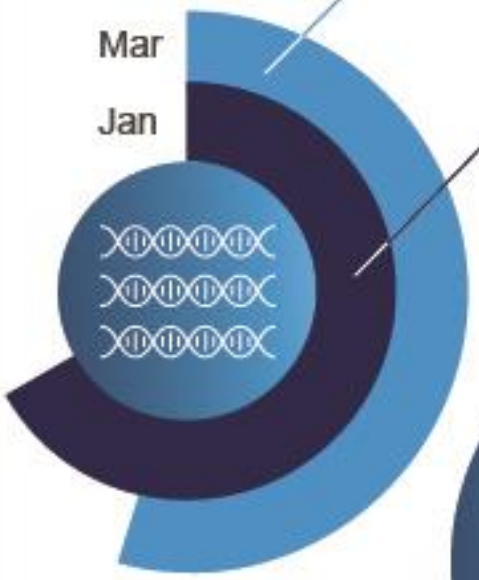
Depending on the epidemiological situation**, self-testing using Ag-RDT can be used for diagnosis** to facilitate linkage to clinical care and therapeutics.

Improving access to reliable and affordable tests

- Self-testing provides a way for people to test and make personal risk-based decisions that may affect their health and the health of their families and communities. It is an additional option that can expand access to testing services.
- Although there is increasing availability of antigen-detecting rapid tests, prices remain out of reach of most, particularly people in lower-income countries.
- WHO encourages manufacturers to submit applications for antigen tests intended for self-testing for emergency use listing (EUL). The quality and efficacy of these tests will be assessed in order to enable increased access in lower income countries.
  - Invitation to submit an expression of interest for EUL
  - Instructions and requirements for EUL submission
  - WHO offers an abridged EUL assessment pathway for products that already have WHO EUL approval for professional POC use or that have already been approved/authorized by US FDA, Health Canada (HC) or Australian Therapeutic Goods Administration (TGA).

Gains in data sharing and sequencing capability

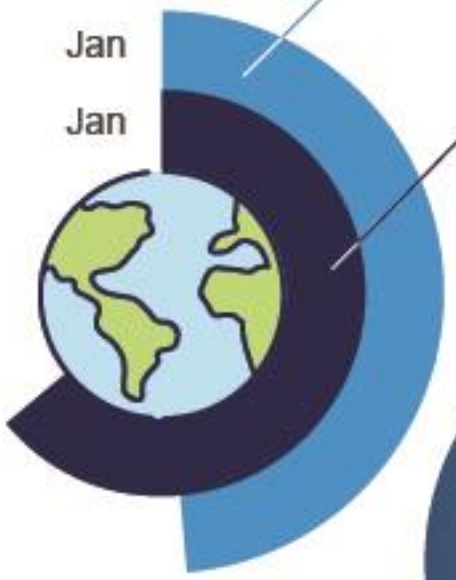
In March 2021, **105 of 194 WHO Member States** had sequencing capacity for SARS-CoV-2



In January 2022, this increased to **132 WHO Member States**

This represents an **increase of 26%** of Member States with sequencing capability

In January 2021 **94 of 194 WHO Member States** were publicly sharing SARS-CoV-2 virus sequence data



In January 2022 this increased to **134 WHO Member States**

This represents an **increase of 43%** of Member States publicly sharing sequence data

World Health Organization

What is the global genomic surveillance strategy for pathogens with pandemic and epidemic potential?

A 10-year unifying framework to strengthen country, regional and global genomic surveillance.

IT AIMS TO:

- Link and embed pathogen monitoring within broader surveillance systems
- Identify opportunities to strengthen and establish capacities and systems
- Bring partners and stakeholders together to work on a common vision

The COVID-19 pandemic showed how critical it is to use genomics to protect public health. Genomics is just as relevant to help prevent and control other public health challenges, like influenza, Ebola virus disease and antimicrobial resistance. This is why the Strategy is pathogen agnostic.

The Strategy aims to mobilize genomic surveillance efforts against any pandemic or epidemic threat by strengthening and linking laboratories around the world.

There are four important considerations for genomic surveillance

01 Amount of testing to detect infections

02 Representativeness of sampling

03 Time from sample collection to sequence

04 Amount of sequencing

Current recommendations – WHO/ECDC 2021

Guidance for surveillance of SARS-CoV-2 variants

Interim guidance
9 August 2021

World Health Organization

# of positive cases	Sequenced samples to detect variant at 1%
≤1,000	141
1,001 - 2,500	196
2,501 - 5,000	243
5,001 - 10,000	270
≥10,000	285

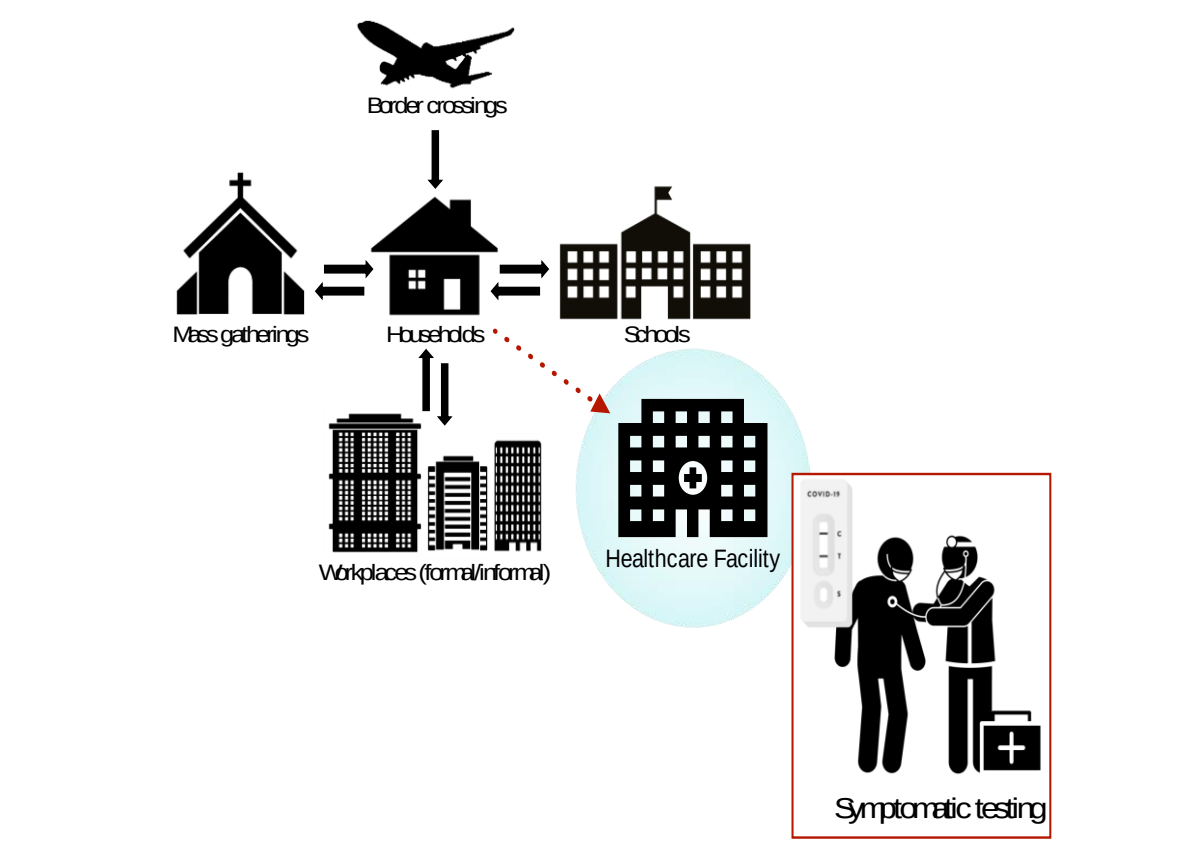
Critical Considerations

- Variant agnostic; **assumes random representative sampling**
- Large amount of testing required for random representative testing and to detect ≥10,000 cases per week

LMIC testing average
27 tests/100K people/day

- Random representative testing is mostly infeasible

An LMIC focused, agent-based modelling framework was used to evaluate current guidance



- Use the model to **evaluate current sequencing guidance**
- Given importance of 'random representative sampling': **are we doing enough testing to generate this sample?**

Evaluation of current recommendations given current rates of testing

Guidance for surveillance of SARS-CoV-2 variants

Interim guidance
9 August 2021

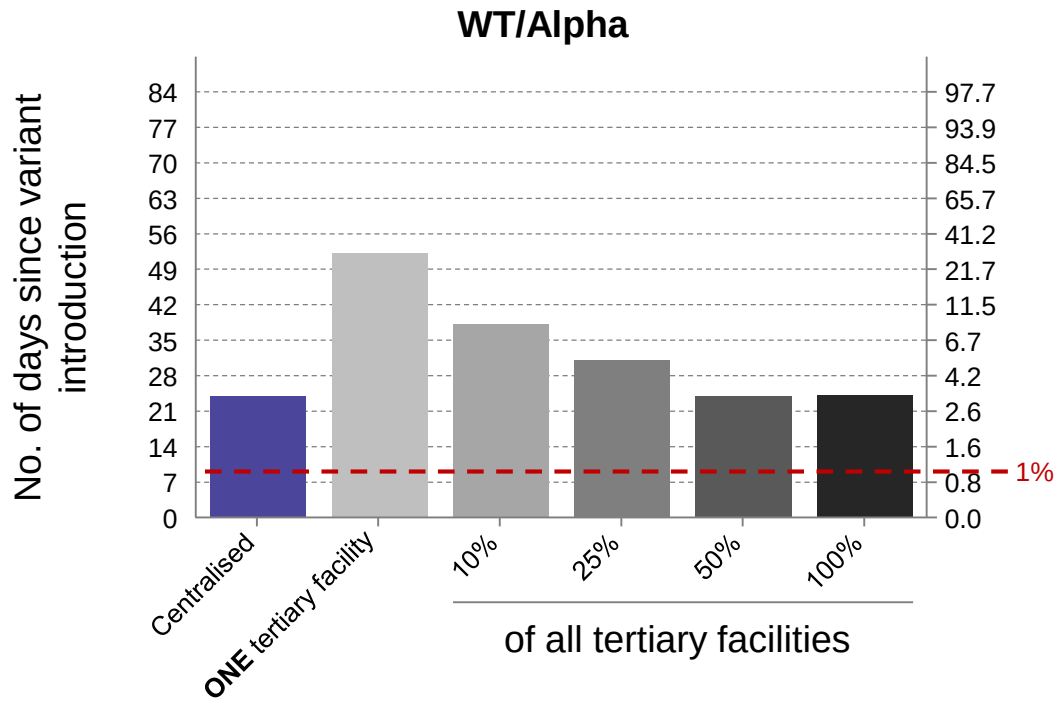
World Health Organization

Goal of guidance: to detect variants at 1% prevalence

In the context of: 27 tests / 100,000 people / day

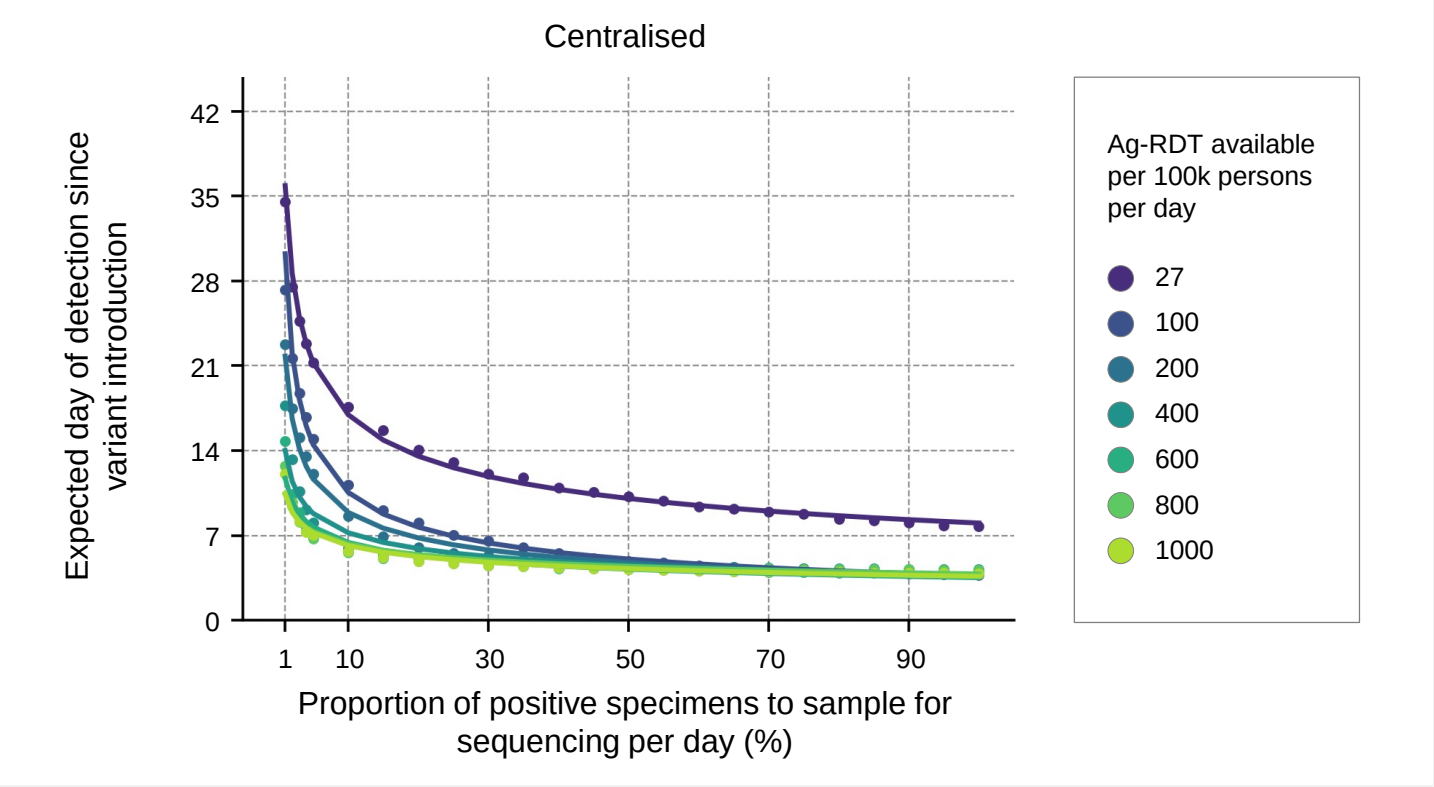
Even with optimal in-country conditions (**sampling across all healthcare facilities, rapid turnaround times**), at current testing rate, the earliest you can detect a new variant would be 3-4 weeks after it's introduction, circulating at ≥3% prevalence

Time to first collection of new variant sample



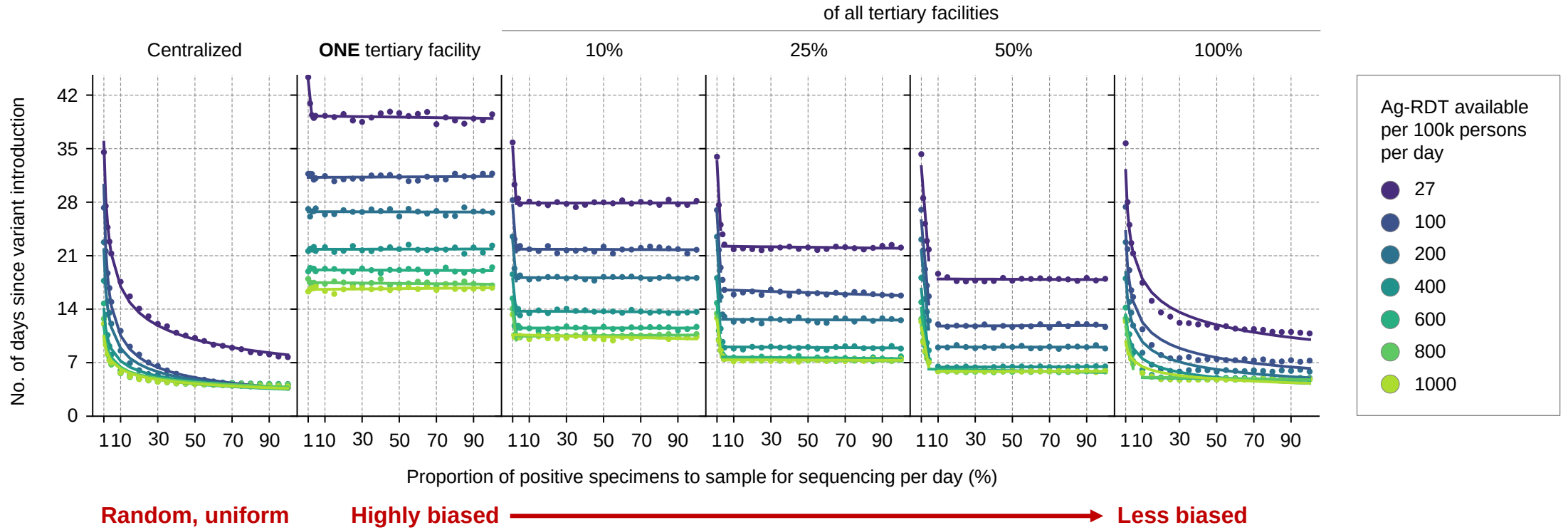
Impact of daily testing rate on new variant detection

Time to new variant detection



Testing **less than 100 tests / 100,000 people / day** severely compromises new variant detection and ability to reliably measure prevalence

Impact of geographic coverage on new variant detection



Testing **more** and testing **broadly in communities**
are the **most effective strategies to identify new variants early**

Conclusions from modelling work

01

Increasing access to healthcare-provided diagnostic testing is essential for genomic surveillance

- **Testing target = 100 tests / 100,000 people / day**

02

Assuming the testing target can be reached with good geographic coverage and low turnaround times

- **Sequencing target = 10% of positive samples (average = ~20 samples / 1,000,000 people /week)**

Source: Modelling data obtained from Diagnostics Consortium

We need to ensure strategic and intelligent testing

- Testing remains one of the critical components of an effective COVID-19 response strategy
- Recent reductions in testing rates is concerning as data may become progressively less representative, less timely and less robust, which can inhibit collective efforts to track the virus, how it is spreading and how it is evolving, all of which are critical to effectively ending the acute phase of the pandemic
- It is important to tailor testing and surveillance efforts to be right-sized to inform public health objectives, considering representativeness and quality, not only quantity.
- Member states are encouraged to support access to testing that is affordable and can be used by individuals to take decisions about their own health and the health of their families and communities, as well as by the community for evidence-based, operational decision making on public health actions through surveillance.