Summary of WHO's COVID Ag RDT guidance

14 September 2020

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Ag RDTs can help countries expand access where PCR testing is limited

NAAT testing

- Can **diagnose acute infection** through presence of SARS-COV-2 virus and are a critical tool for COVID public health measures
- Were able to be developed and **deployed rapidly**
- Good **clinical performance,** with high sensitivity and specificity
- But, **requires laboratory infrastructure** and highly trained staff
- **Turn around time may be long**, often >48h, which could reduce benefits of a high performing test
- May be **challenging to rapidly scale** in many LMICs

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Antigen RDTs

- Also used to **diagnose acute infection**
- Typically perform less well than NAAT, however new tests reaching market **perform at levels of the WHO TPPs**
- Can be deployed into **decentralized settings,** including clinics and communities by HCWs
- Provide **rapid results** in under 30 minutes

WHO has released new interim guidance on the use of COVID Ag RDTs

"**Ag-RDTs that meet the minimum performance requirements** of ≥80% sensitivity and ≥97% specificity compared to a NAAT .. can be used to **diagnose SARS-CoV-2** infection in a range of settings **where NAAT is unavailable or where prolonged turnaround times preclude clinical utility.**

..Ag-RDTs should be conducted by trained operators in strict accordance with the manufacturer's instructions and within **the first 5-7 days following the onset of symptoms.** "

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Source: World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020

The interim guidance describes five scenarios

1. **Respond to suspected outbreaks** in remote settings, institutions and semi closed communities where multiple positive AgRDTs are highly suggestive of a COVID outbreak

2. **Support outbreak investigations,** where Ag RDTs can help screen at-risk individuals and rapidly isolate positive cases

3. **Monitor trends in disease incidence in communities**, particularly for essential workers and HCWs during outbreaks

4. Where there is widespread community transmission, RDTs may be **used for early detection and isolation, including for contact tracing**

5. **Testing of asymptomatic contacts of cases** may be considered even if the Ag-RDT is not specifically authorized for this use

Source: World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020

The interim guidance also highlights three practical considerations for Ag RDT roll-out

1

Consider **initially deploying Ag RDTs in settings where NAAT is currently available** to confirm performance & allow staff to gain confidence

2

Where NAAT confirmation is not feasible, **triangulation with clinical symptoms or settings is needed** to confirm result validity

3

Use of Ag-RDTs **is not recommended in low prevalence settings** until specificity of tests is >99% because of high rate of false positives

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Source: World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020

10 factors are important when selecting which Ag RDTs to use

1	**Quality of available data** used to validate the test
2	**Reported performance** of the test
3	**Manufacturing quality and regulatory** status of the test
4	**Manufacturing capacity** and further evidence of quality, including other products manufacturers have on the market and surveillance capacity
5	**Distribution and technical support** provided by suppliers
6	Shipping and **storage conditions** and shelf life
7	**Specimen collection** requirements
8	Contents of test **kit**
9	The **cost** of the test
10	Availability, completeness and **clarity of instructions for use.**

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Source: World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020

The guidance also highlights 6 scenarios in which Ag RDT should not be used, based on expected initial test performance

Scenario	Explanation
In individuals without symptoms unless the person is a contact of a confirmed case	Pre-test probability is low.
Where there are zero or only sporadic cases	Ag-RDTs are not recommended for routine surveillance purposes or case management in this setting. Positive test results would likely be false positives. Molecular testing is preferred.
Appropriate biosafety and infection prevention and control measures (IPC) are lacking	To safeguard health workers, testing requires that operators wear gloves, gown, mask and face shield or goggles
Management of the patient does not change based on the result of the test	If test-positive and test-negative patients will be treated the same way because of unknown or low PPV and/or NPV, then there is no benefit to testing.
For airport or border screening at points of entry	Prevalence of COVID-19 will be highly variable among travellers, and it is therefore not possible to determine PPV and NPV of test results.
In screening prior to blood donation	A positive RDT result would not necessarily correlate with presence of viremia.

Source: World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020

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