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## Guidelines

# TESTING STRATEGY INCORPORATING COVID-19 ANTIGEN DETECTION RAPID DIAGNOSTIC TESTS (Ag-RDT)

### 1. General

Diagnostic testing is a key element of disease control strategies across the world. RT-PCR test which directly detects the virus presence in human body is considered “Gold Standard Test” in diagnosis of corona virus. After the onset of the pandemic, **testing strategies across the world have been predominantly based on RT-PCR**, however, after availability of Ag-RDT for diagnosis, **many countries across the world have incorporated antigen testing in their respective testing strategies for disease mapping purposes**. [Pakistan’s current testing strategy is based on RT-PCR test only](#) and has worked well (played a pivotal role in disease control worked well so far). However, since Ag-RDT has proven itself effective for disease mapping, therefore, Pakistan has considered to incorporate Ag-RDT in its testing strategy for disease surveillance and screening.

### 2. Antigen Detection Rapid Test (Ag-RDT)

“Rapid antigen tests are commonly used in the diagnosis of respiratory pathogens, including influenza viruses and respiratory viruses. Ag-RDT is being widely used across the world to diagnose SARS-CoV-2”. Ag-RDT has certain advantages, such as relatively lower cost and return results in approximately 15 minutes etc. Comparison of PCR with Ag-RDT is as under:-

Feature	RT-PCR Tests	Ag - RDT
Target	Viral RNA	Viral Antigens (Nucleocapsid protein)
Specimen Type (s)	Nasopharyngeal and Oral Swab	Nasopharyngeal Swab
Sensitivity	High	Moderate More False Negatives
Specificity	High	High
Test Complexity	Complex	Easy to use
Lab Settings	Highly sophisticated lab settings req	May be performed outside conventional lab setting
Time	6-8 Hours	Approximately 15-20 Min
Cost Effectiveness	Expensive	Lower cost

### 3. Guidelines for Usage

- WHO



- To respond to **suspected outbreaks in remote settings**, institutions and semi-closed communities.
- Ag-RDT could be used to **screen High Risk Individuals**, isolate positive cases and PCR for prioritized negative individuals.
- Monitor trends in **disease incidence in communities** and essential workers, healthcare workers during outbreaks or in regions of widespread community transmission.
- A negative Ag-RDT should not remove a contact from quarantine requirements.

b. **CDC USA**

- FDA granted Emergency Use Authorization (EUA) to use Ag-RDT to meet testing demand.
- Antigen tests performs best if a person is tested in the early stages of infection.
- May be used for screening in **high-risk congregate settings**.
- Ag-RDT performance characteristics to give **false negative** results needs to be accounted for in true assessment.

c. **European CDC**

- Rapid antigen tests can contribute to overall COVID-19 testing capacity, offering advantages in terms of shorter turnaround times and reduced costs, especially in situations in which RT-PCR testing capacity is limited.
- Test sensitivity for rapid antigen tests is generally lower than for RT-PCR.
- Rapid antigen tests perform best in cases with high viral load, in pre-symptomatic and early symptomatic cases up to five days from symptom onset.
- ECDC agrees with the minimum performance requirements set by WHO at  $\geq 80\%$  sensitivity and  $\geq 97\%$  specificity.
- ECDC recommends that EU Member States perform independent and setting-specific validations of rapid antigen tests before their implementation.
- The use of rapid antigen tests is appropriate in high prevalence settings when a positive result is likely to indicate true infection, as well as in low prevalence settings to rapidly identify highly infectious cases.
- Rapid antigen tests can help reduce further transmission through early detection of highly infectious cases, enabling a rapid start of contact tracing

## 4. Testing Strategies Around the World

Large size Ag-RDT is being used around the world to supplement PCR based testing and to accurately map the disease. It is being used mainly in high risk sectors. An overview of Ag-RDT in various sectors is mentioned below:-



Country	General	High Risk Groups / Communities	Suspects / Symptomatic	Contacts	Surveillance Testing / Disease Mapping	Procurement Plan
	<ul style="list-style-type: none"><li>Screening</li><li>At Airports</li><li>Educational Institutions</li></ul>	Yes	No	No	For inbound passengers only	5 Mn Tests tendered
	<ul style="list-style-type: none"><li>To meet high testing demand</li><li>In comb with PCR for groups where regular testing required</li></ul>	Yes	Yes	Yes	Yes	20 Million Test from Abbot
	<ul style="list-style-type: none"><li>Will become part of "Free-for-all-testing" Policy</li><li>Initially for mob Screening Centers and Airports</li></ul>	No	Yes	Yes	Yes	Planning Phase (indigenous kits)
	<ul style="list-style-type: none"><li>Plans to supplement PCR due to shortage</li></ul>	Yes	Yes	Yes	Yes	9 Million / Month
	<ul style="list-style-type: none"><li>To meet testing requirements</li></ul>	Yes	No	Yes	Yes	Purchased 150 Mn Kits from Abbot in last week of Aug

## 5. Conclusions from Global Trends

- Given massive spread of COVID-19, PCR testing capacity across the globe is stressed, therefore, many countries (including USA, UK, Germany, France, Italy, Canada and regional countries etc.) are incorporating Ag-RDT in disease mapping strategy.
- WHO and CDC have recommended use of Ag-RDT** for high risk groups, communities, areas of large transmission, surveys and large-sized screening.
- Ag-RDT is being used in combination with PCR test. Due to its false negativity aspects, RT PCR is compulsory for every symptomatic Ag-RDT negative case.

## 6. Rationale for Ag-RDT in Pakistan

Based on global experience of employing Ag-RDT in disease mapping, Pakistan (after a thorough consultative process) has decided to adopt Rapid Antigen Testing for enhanced disease mapping and to compliment PCR based Testing **but under strict control/monitoring**. This will expand the number and reach of testing especially in certain defined settings.

## 7. Testing Strategy incorporating Ag - RDT

### Parameters of the Strategy

- Antigen testing is recommended for response to suspected outbreaks of COVID-19 in remote settings, institutions and semi-closed communities where RT-PCR test is not immediately available. It is important to note that positive Ag-RDT results from multiple suspects is highly suggestive of a COVID-19 outbreak and would allow for early implementation of interventions. The use of RDT is also recommended for testing of healthcare and other frontline workers, schools, sentinel sites or to monitor trends in disease incidence in communities.
- The RT-PCR will continue to be administered as per procedure in vogue i.e. for diagnosis of diseases in symptomatic persons and their contacts. The rapid antigen tests are NOT meant to replace the currently used method.



- c) A proportion of the total Ag-RDT (around 20% of antigen tests) shall be re-confirmed via additional testing through RT-PCR test. For this purpose, requisite samples will be collected from different sectors for analysis at public labs.
- d) Data flow and management of antigen testing will be ensured with separate data fields for both types of testing [Ag-RDT and RT-PCR]. Results will be documented and entered in IDIMS (similar to PCR tests) under a separate field. Statistics for both types of testing will be presented by NEOC as part of daily epidemiologic reporting at the NCOC.
- e) Existing RRTs/Sample Collection Teams to be trained, equipped and employed to carry out RDT testing in addition to staff at THQs/DHQs and teaching/tertiary care hospitals.
- f) Ag-RDT may be used for clinical purposes only if the result is positive.
- g) Phased induction of RAT as under:-

### **Phase-1**

Only a defined list of approved labs in the public sector as adjudged by the Provincial/Regional authorities, already conducting PCR testing will be allowed to conduct antigen testing. The RDT-Ag testing by private labs will be at the discretion of provincial/regional authorities; however, only those labs would be officially allowed which are already performing COVID-19 PCR, and submitting data to the national/provincial hubs.

### **Subsequent Phases**

Ag-RDT test to be reviewed after phase-1; may consider additional private labs conducting PCR test and over-the-counter at selected pharmacies in due course of time.

- a. Provinces will procure Ag-RDT kits by themselves from approved (WHO/DRAP) manufacturers.
- b. **Timeline**  
All federating units to commence RAT testing as per these instructions as soon as the Ag-RDT kits/devices are available.

## **8. Manifestation of Strategy Phase-1**

### **c. Roll Out**

Ag-RDT will be allowed in all federating units for testing in public sector labs; private labs as specified above. Provincial Health Departments may however use Ag-RDT based at their own preference, such as rolling out the Ag-RDT at the healthcare facilities/establishments only.

### **Conduct Methodology of Ag - RDT Testing and Record Keeping / Reporting**

Ag-RDT will be employed as given below:-



	Testing Sectors	Types of Tests to be employed
<b>Existing Testing Sectors</b>	Contact Tracing	RT PCR only – No Ag-RDT testing except remote settings
	Symptomatic Testing	<b>RT PCR only</b> – No Ag-RDT testing. However, areas with no or limited access to PCR or delays in shipment of samples and reporting is expected antigen testing may be done. Provincial Health Departments may however use Ag-RDT based on their own preference, such as testing of individuals with ILI/SARI or those with symptoms compatible with case definition of COVID-19.
	Surgeries/ procedures	Invasive Mandatory PCR based test for Elective surgeries/invasive procedures  For Emergency surgeries, Ag-RDT may be used.
	High Risk Sectors Testing <ul style="list-style-type: none"> <li>• HCWs</li> <li>• Markets/Malls</li> <li>• Hotels/Restaurants</li> <li>• <b>Prisons (new addition)</b></li> <li>• <b>Public Gatherings (new addition)</b></li> </ul>	Provinces can decide about the preference area and methodology <b>For Antigen Tests</b> <ul style="list-style-type: none"> <li>• In each sector PCR tests must be at least 20% of total tests conducted</li> </ul>
	Rural Areas Testing	
	Educational Institutes Testing	
<b>Additional Testing Sectors</b>	High Risk Residential Areas (Colonies / slums etc identified through SARI/ILI reporting or sample testing or based on local authorities' assessment / decision)	As given above
	Hotspot areas (under SLDs) with a predefined perimeter especially areas with high prevalence.	As given above

### Conduct of Tests

Existing RRTs/Sample Collection Teams will be trained, equipped and employed to carry out on site RAT testing. Necessary logistics including instruments, PPEs and other support elements such as vehicles, chairs / table etc to be worked out and provided to the RRTs designated to carryout Ag-RDT testing. RRT will carry out following actions:-



1. Data / Particulars filling (Ag-RDT) on a given form or in an app (as may be applicable).
2. Submit entire record with DHO office.
3. In case of Positive result:-
  - a. Advise isolation.
  - b. Prepare Line list.
  - c. Inform management of the institutions.
  - d. Inform DHO Office.

**a. Demo / Training of RRTs**

NIH to prepare a model RRT for conduct of (Ag-RDT) testing, and develop a movie clip explaining following aspects and share with provinces:-

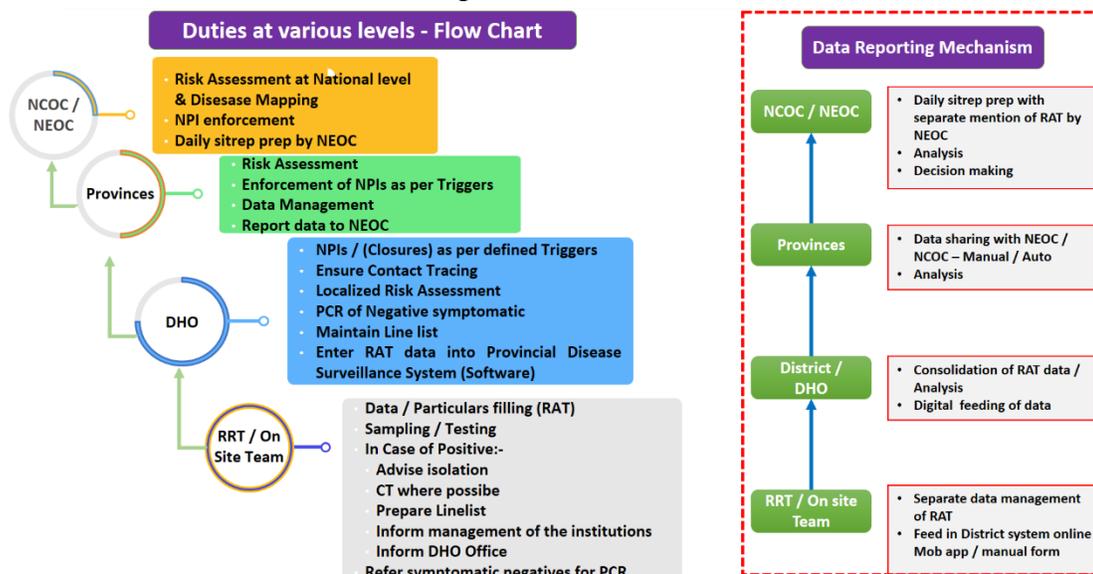
1. Composition of Team.
2. Logistic support required such as PPEs, Instruments etc.
3. Conduct of on-site testing.

*Note: Separate instruction for online training will be issued by NIH*

**b. Ag-RDT Data Recording & Reporting**

1. Separate record including number of tests conducted in each sector, positive cases, negative cases and malfunctioning of the kit to be maintained at District, Province and National level.
2. Data will be separately recorded in provincial Disease Reporting Systems / IDIMS. The data will also be reported to NEOC as per existing procedures through existing means.
3. Private labs will follow same protocols for data reporting as being followed for PCR tests.

a) Functions at various levels are given below





### 1. **Phase-II**

After successful completion of phase-I, authorized/additional private sector labs and selected pharmacies will be allowed to start using RDT testing after approval by the respective Provincial Health Departments. The following considerations shall be applicable for rolling out Ag-RDT in private sector as under:-

- b) Only those labs which are already integrated into national data base will be allowed to use Ag-RDT.
- c) Labs will be bound to enter data of Ag-RDT as per practice in vogue for PCR tests.
- d) Price control will be ensured by MoNHSRC and provinces.
- e) MoNHSRC will issue explicit instructions for use of Ag -RDT by private sector.

### 2. **Key Enablers**

- f) Timely completion of registration process by DRAP.
- g) MoNHSRC to ensure tax exemption on import of Ag-RDT Kits, if deemed appropriate.
- h) Expediting procurement process by provinces and NDMA.
- i) Training of HR by NIH team.
- j) Completion of data integration process by C4I, NITB and NEOC.

### 3. **Procurement**

Provinces may procure antigen testing kits for themselves as per their resources while NDMA / MoNHSRC will also ensure centralized procurement and distribution to all provinces/area/regions. The selection of a Ag-RDT device should be done based on the criteria mentioned below:-

- k) Ag-RDT Kit should meet the minimum performance requirements of  $\geq 80\%$  sensitivity and  $\geq 97\%$  specificity compared to a PCR-based reference assay.
- l) Regulatory considerations with WHO Emergency Use Listing/ EU regulatory status or CE marked/US FDA approval or Emergency Use Authorization kits for undertaking SARS-CoV-2 Ag-RDT.