# SARS-CoV-2 Antigen Rapid Diagnostic Test –

# Testing Site Readiness Checklist

This tool has been designed to assess the readiness of testing sites to implement antigen testing for SARS-CoV-2, the virus that causes novel coronavirus disease 2019 (COVID-19). This tool is based on WHO’s [*Assessment tool for laboratories implementing SARS-CoV-2 testing: interim guidance*](https://www.who.int/publications/i/item/assessment-tool-for-laboratories-implementing-covid-19-virus-testing)(October 2020).

Overall, this tool enables rapid identification of a testing site’s strengths and weaknesses in order to determine its readiness for SARS-CoV-2 Antigen Rapid Diagnostic Test (RDT) testing.

### Testing Site Identification

|  |  |  |
| --- | --- | --- |
| Name of assessor(s) |  | |
| Title & organization of assessor |  | |
| Name of testing site being assessed |  | |
| Type of testing site | ◻︎Primary Health Care Centre  ◻︎District Hospital  ◻︎Regional Hospital  ◻︎Tertiary Hospital  ◻︎Laboratory  ◻︎Other:\_\_\_\_\_\_\_\_\_\_\_\_ | ◻︎Public  ◻︎Private  ◻︎Academic  ◻︎Nongovernmental Organization  ◻︎Other:\_\_\_\_\_\_\_\_\_\_\_\_ |
| Type of services offered | ◻︎Medical  ◻︎Surgical  ◻︎Paediatrics  ◻︎Other (specify)\_\_\_\_\_\_\_\_\_ | ◻︎Intensive Care Unit  ◻︎Obstetrics / Gynae  ◻︎Emergency / Trauma |
| Location of testing site being assessed (City/Town, District and Country) |  | |
| Contact details for person at testing site | | |
| Name |  | |
| Position |  | |
| Email |  | |
| Phone |  | |
| Date of the current assessment visit |  | |
| Number of health care workers at the testing site who have successfully completed SARS-CoV-2 Antigen RDT training (obtained certificate) |  | |
| Number of health care workers at the testing site who have received on-the-job training for SARS-CoV-2 Antigen RDT testing |  | |

### Infrastructure

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the space allocated for SARS-CoV-2 Antigen RDT testing adequate to perform the work without compromising the quality and safety of patients and personnel? |  |  |  |  |
| Are the allocated workstations clean and well maintained? |  |  |  |  |
| Is the intended sample collection area separate from the patient examination room(s)? |  |  |  |  |

## Staff & Training

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Are personnel trained in sample collection for SARS-CoV-2 Antigen RDT testing? |  |  |  |  |
| Are personnel trained in safety for sample collection and SARS-CoV-2 Antigen RDT testing? |  |  |  |  |
| Are personnel trained in running SARS-CoV-2 Antigen RDTs? |  |  |  |  |
| Have personnel that are performing SARS-CoV-2 Antigen RDT testing been certified as competent through a proficiency (competency) assessment? |  |  |  |  |

## Safety

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Has a risk assessment[[1]](#footnote-1) related to the procedures for SARS-CoV-2 virus testing at the testing site been performed and documented? |  |  |  |  |
| Are written biosafety procedures related to the handling and management of samples tested for SARS-CoV-2 available? |  |  |  |  |
| Is appropriate personal protective equipment (PPE) available for the collection, handling and testing of specimens for SARS-CoV-2? |  |  |  |  |
| Are procedures in place to ensure safe and secure transport of samples to the laboratory for SARS-CoV-2 NAAT molecular testing? |  |  |  |  |

### Consumables & Reagents

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Does the testing site experience problems with reagent delivery such as delays, inadequate temperature, reference error, etc. (1. Never; 2. Sometimes; 3. Regularly; 4. Not applicable)? | | | |  |
| Is there a staff member responsible for consumable and reagent management at the testing site (inventory, order, etc.)? |  |  |  |  |
| Is there an inventory system for consumables and reagents? |  |  |  |  |
| Are there mechanisms for inspecting consumables and reagents upon receipt? |  |  |  |  |
| Are there protocols for accepting/rejecting consumables and reagents? |  |  |  |  |
| Are suitable storage areas (temperature, humidity, etc.) available for consumables and reagents? |  |  |  |  |
| Are mechanisms in place for new reagent (new product, new lot) testing? |  |  |  |  |
| Are mechanisms in place for recording consumable and reagent consumption rates? |  |  |  |  |
| Is there a system for accurately forecasting needs for consumables and reagents? |  |  |  |  |
| Are the necessary materials and reagents available for SARS-CoV-2 Antigen RDT sample collection and testing? |  |  |  |  |
| Are the reagents required for SARS-CoV-2 Antigen RDT testing in-date (not expired)? |  |  |  |  |

### Sample Collection

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Are specific SARS-CoV-2 sample collection procedures available to relevant personnel? |  |  |  |  |
| Are current versions of published standards and other similar documents in use for SARS-CoV-2 testing available (e.g., norms, guidelines, test kit inserts etc.)? |  |  |  |  |
| Are logbooks, worksheets, computers or other comparable systems available for recording sample details and test results? |  |  |  |  |

### Recording, Reporting & Data Management

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Are procedures in place to record all test results in a standardized logbook, worksheet or electronic database? |  |  |  |  |
| Are procedures available to report SARS-CoV-2 Antigen RDT results? |  |  |  |  |
| Are procedures available to immediately notify physicians of SARS-CoV-2 Antigen RDT results? |  |  |  |  |
| Are procedures available to immediately notify test results to the National SARS-CoV-2 Response Team? |  |  |  |  |
| Is there a mechanism for referring samples to a laboratory for SARS-CoV-2 NAAT molecular testing? |  |  |  |  |
| For samples referred to a laboratory for SARS-CoV-2 NAAT molecular testing, is there a procedure to record the results of the SARS-CoV-2 NAAT molecular testing in a standardized logbook, worksheet or electronic database? |  |  |  |  |
| Is access to sensitive information, e.g., results logbooks, etc., controlled? |  |  |  |  |

### Quality Assurance (QA)

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Are procedures available for performing corrective actions if the assessment result is poor? |  |  |  |  |
| Are quality control samples available for performing SARS-CoV-2 Antigen RDT testing? |  |  |  |  |
| Are procedures available for recording and reporting quality control results and corrective actions as appropriate? |  |  |  |  |
| Are procedures available for the testing site to collect Quality Indicators (QIs) for measuring trends in SARS-CoV-2 Antigen RDT quality? |  |  |  |  |
| Are procedures available for the testing site to report QIs to supervisory structures, such as the national body in charge of QA of RDTs, National SARS-CoV-2 Response Team or reference laboratory? |  |  |  |  |

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1. For more information on conducting a risk assessment see: [Health workers exposure risk assessment and management in the context of COVID-19 virus: interim guidance, 4 March 2020](https://apps.who.int/iris/handle/10665/331340) and [Interim U.S. guidance for risk assessment and work restrictions for healthcare personnel with potential exposure to COVID-19](https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html) [↑](#footnote-ref-1)