# SARS-CoV-2 Antigen Rapid Diagnostic Test –

# Testing Site Supervision Checklist

This tool is intended to be used by supervisors undertaking testing site supervision visits to support SARS-CoV-2 Antigen Rapid Diagnostic Test (RDT) implementation and roll-out. Supervision visits should be undertaken by trained supervisors who are responsible for supporting SARS-CoV-2 Antigen RDT implementation and roll-out activities.[[1]](#footnote-1) Supervision visits provide an opportunity to support testing at the testing site and to provide feedback for improving the testing. Supervision visits should be performed periodically (e.g., four times per year). However, more frequent visits should be arranged, particularly when a new test (e.g., SARS-CoV-2 Antigen RDT) is introduced.

Prior to the supervision visit, the supervisor should review the assessment report from the most recent visit. During the visit, the supervisor must review the actions identified during the previous visit to address areas of weakness, and check for completeness. All documents, including a copy of the supervision report, must be sent to the testing site within five working days of the supervision visit. In addition, all documents, including a copy of the supervision report, must be sent to the central or district-level authorities within seven working days of the supervision visit.

### 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 |  | |

### SARS-CoV-2 Antigen RDT Data[[2]](#footnote-2),[[3]](#footnote-3)

Obtain the Quality Indicator (QI) data since the last supervision visit from the Clinical Facility SARS-CoV-2 Antigen RDT Logbook(s). Record the data below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SARS-CoV-2 Antigen RDT Result Summary** | **Month** | | | |
| **\_\_\_\_\_\_** | **\_\_\_\_\_\_** | **\_\_\_\_\_\_** | **\_\_\_\_\_\_** |
| SARS-CoV-2 Not Detected |  |  |  |  |
| SARS-CoV-2 Detected |  |  |  |  |
| SARS-CoV-2 Invalid |  |  |  |  |
| Total number of tests performed |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SARS-CoV-2 NAAT Result Summary** | **Month** | | | |
| **\_\_\_\_\_\_** | **\_\_\_\_\_\_** | **\_\_\_\_\_\_** | **\_\_\_\_\_\_** |
| Total number of tests sent for NAAT |  |  |  |  |
| SARS-CoV-2 Not Detected |  |  |  |  |
| SARS-CoV-2 Detected |  |  |  |  |
| SARS-CoV-2 Invalid |  |  |  |  |
| Total number of tests performed |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Final Test Result Summary** | **Month** | | | |
| **\_\_\_\_\_\_** | **\_\_\_\_\_\_** | **\_\_\_\_\_\_** | **\_\_\_\_\_\_** |
| SARS-CoV-2 Not Detected |  |  |  |  |
| SARS-CoV-2 Detected |  |  |  |  |
| SARS-CoV-2 Indeterminate |  |  |  |  |
| Total number of tests performed |  |  |  |  |

### Infrastructure

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the space allocated for SARS-CoV-2 Antigen RDT testing sufficient to perform the work without compromising the quality and safety of patients and personnel? |  |  |  |  |
| Are the allocated workstations clean and well maintained? |  |  |  |  |
| Is the 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** |
| --- | --- | --- | --- | --- |
| Is appropriate personal protective equipment (PPE) available for the collection, handling and testing of specimens for SARS-CoV-2? |  |  |  |  |
| Is appropriate PPE being used during sample collection and testing? |  |  |  |  |
| Are procedures being used to ensure the safe and secure transport of samples to the laboratory for SARS-CoV-2 NAAT molecular testing? |  |  |  |  |

## Consumables & Reagents

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the testing site experiencing problems with reagent delivery, including delays, inadequate temperature, etc.  (1. Never; 2. Sometimes; 3. Regularly; 4. Not applicable)? | | | |  |
| Has the testing site experienced a stockout of consumables, reagents or ancillary items since the last supervision visit? |  |  |  |  |
| Are the necessary materials and reagents for SARS-CoV-2 Antigen RDT sample collection and testing currently available? |  |  |  |  |
| Are the reagents required for SARS-CoV-2 Antigen RDT testing in-date (not expired)? |  |  |  |  |

## Sample Collection

## Observe a tester[[4]](#footnote-4) performing sample collection for SARS-CoV-2 testing:

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Are SARS-CoV-2 specific sample collection procedures being followed? |  |  |  |  |
| Did the tester put on the appropriate PPE for sample collection? |  |  |  |  |
| Did the tester collect all the necessary supplies to perform the SARS-CoV-2 sample collection procedure? |  |  |  |  |
| Did the tester assess ventilation in the room where sample collection and testing would happen? |  |  |  |  |
| Did the tester insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx? |  |  |  |  |
| Did the tester swab over the surface of the posterior nasopharynx? |  |  |  |  |
| Did the tester withdraw the sterile swab from the nasal cavity? |  |  |  |  |
| Was the sample tested as soon as possible after collection? |  |  |  |  |

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Are logbooks, worksheets, computers or other comparable systems available for recording sample details and test results? |  |  |  |  |
| Are logbooks, worksheets, computers or other comparable systems being used to record sample details and test results? |  |  |  |  |

## SARS-CoV-2 Antigen RDT Procedure[[5]](#footnote-5)

## Observe a tester[[6]](#footnote-6) performing the SARS-CoV-2 Antigen RDT testing procedure:

| **Question** | **Yes** | **No** | **Comment** |
| --- | --- | --- | --- |
| Did the tester put on the appropriate PPE for testing? |  |  |  |
| Did the tester carefully read the instructions for using the SARS-CoV-2 Antigen RDT? |  |  |  |
| Did the tester collect all the necessary supplies to perform the SARS-CoV-2 Antigen RDT procedure? |  |  |  |
| Did the tester set up the workstation correctly? |  |  |  |
| Did the tester check the expiry date on the back of the foil pouch? |  |  |  |
| Did the tester check that the test device and the desiccant pack in the foil pouch were not damaged or invalid? |  |  |  |
| Did the tester insert the swab into an extraction buﬀer tube and, while squeezing the buﬀer tube, stir the swab for the required number of times? |  |  |  |
| Did the tester remove the swab while squeezing the sides of the buffer tube to extract the liquid from the swab? |  |  |  |
| Did the tester press the nozzle cap tightly onto the tube? |  |  |  |
| Did the tester apply the correct number of drops of extracted specimen to the specimen well of the test device? |  |  |  |
| Did the tester read the test result within the specified period? |  |  |  |
| Did the tester interpret the test result correctly? |  |  |  |
| Did the tester record the test result in the SARS-CoV-2 Antigen RDT Logbook? |  |  |  |
| Did the tester report the result to the clinician using a standardized reporting form? |  |  |  |
| Did the tester dispose of all waste (e.g., used test kit, extraction buffer tube, swab and paper stand, etc.) in the biohazard bag? |  |  |  |
| Did the tester remove their gown and gloves before leaving the workstation? |  |  |  |
| Did the tester practice proper hand hygiene after completing the SARS-CoV-2 Antigen RDT testing procedure? |  |  |  |

## Recording, Reporting & Data Management

| **Question** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| Are procedures for reporting SARS-CoV-2 test results being followed? |  |  |  |  |
| Are clinicians immediately notified of SARS-CoV-2 test results? |  |  |  |  |
| Is the relevant National COVID-19 Response Team notified of SARS-CoV-2 test results? |  |  |  |  |
| Are samples being referred to a laboratory for SARS-CoV-2 NAAT molecular testing? |  |  |  |  |
| Are the results from the laboratory that conducts SARS-CoV-2 NAAT molecular testing recorded in the SARS-CoV-2 Antigen RDT Logbook? |  |  |  |  |
| Is access to sensitive information, e.g., results logbooks, etc., controlled? |  |  |  |  |

## Quality Assurance (QA)

| **Question** | **Not Applicable** | **Yes** | **Partial** | **No** | **Comment** |
| --- | --- | --- | --- | --- | --- |
| Is the testing site performing corrective actions when the assessment result is poor? |  |  |  |  |  |
| Are quality control specimens available for performing SARS-CoV-2 Antigen RDT testing? |  |  |  |  |  |
| Are quality control specimens being used when performing SARS-CoV-2 Antigen RDT testing? |  |  |  |  |  |
| Is there evidence that patient results have not been reported in cases where quality controls have failed? |  |  |  |  |  |
| Is the testing site collecting Quality Indicators (QIs)? |  |  |  |  |  |
| Is the testing site reporting QIs to supervisory structures, such as the national body in charge of QA of RDTs, National COVID-19 Response Team or reference laboratory? |  |  |  |  |  |

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1. Supervisors should be familiar with SARS-CoV-2 Antigen RDT testing and must have completed the SARS-CoV-2 Training of Trainers Workshop. [↑](#footnote-ref-1)
2. It is highly recommended that supervisors obtain the necessary permission to review the clinical facility’s QI data. [↑](#footnote-ref-2)
3. Review the QI data and note any QIs that fall outside of the acceptable range or show unusual trends. [↑](#footnote-ref-3)
4. Depending on the time and the number of testers at the testing site, several testers may be observed performing SARS-CoV-2 Antigen RDTs. [↑](#footnote-ref-4)
5. This procedure must be adapted to the specificities of the SARS-CoV-2 Antigen RDT being performed. [↑](#footnote-ref-5)
6. Depending on the time and the number of testers at the testing site, several testers may be observed performing SARS-CoV-2 Antigen RDTs. [↑](#footnote-ref-6)