# SARS-CoV-2 Antigen Rapid Diagnostic Test –

# Competency Assessment

**Intended use**

This tool is intended to be used by the trainer to assess the success of the training and the resulting competency of laboratory or health care workers in conducting SARS-CoV-2 Antigen RDT testing. The objective of the competency assessment is to determine whether participants have understood the content of the training, can safely and accurately perform the nasopharyngeal sample collection and SARS-CoV-2 Antigen RDT(s), and can interpret and record the test result(s).

This competency assessment will be carried out after initial training. Once testers have collected two nasopharyngeal samples and processed a minimum of two SARS-CoV-2 Antigen RDTs during the training, each tester will be asked to independently perform two complete SARS-CoV-2 Antigen RDT tests in parallel using blinded samples (if possible). Testers will be able to use job aids. The moderator will observe without intervening or correcting mistakes.

To obtain a Certificate of Successful Completion, testers will be required to:

1. obtain a passing score of 80% on the practical test (Section A), in which testers will be required to collect one nasopharyngeal sample while being observed by a trainer;
2. obtain a passing score of 80% on the practical test (Section B), in which testers will be required to perform two SARS-CoV-2 Antigen RDTs on blinded samples while being observed by a trainer;
3. obtain a passing score of 80% on the written theoretical test (Section C), in which testers will be required to answer fifteen multiple-choice questions on content presented in the workshop;
4. obtain a passing score of 80% on the practical result reading test (Section D), in which testers will be required to correctly interpret different SARS-CoV-2 Antigen RDT results from photographs provided.

**Materials needed to conduct competency assessments**

See the Checklist of Training Materials. Training materials include:

* new (unopened) sterile swabs for each participant to perform three sample collections
* personal protective equipment (PPE), including gloves, gowns, eye protection or face-shields, respirators (FFP2 or N95 various sizes) and medical masks
* pens for marking or labelling
* household bleach, ethanol and paper towels to clean the workstation and hands
* soap for hand-washing
* sufficient SARS-CoV-2 Antigen RDT kits for each participant to perform three (practice) tests and two competency (proficiency) tests
* leak-proof biohazard bags for containing or moving biohazard waste and waste bins
* two spray bottles (one for bleach, the other for ethanol)
* measuring devices for making bleach and alcohol solutions
* timers
* proficiency test materials (positive and negative controls)[[1]](#footnote-2)
* SARS-CoV-2 Antigen RDT Logbook
* thermometer.
* reading glasses (to be used during the competency assessment if required by some participants)

**SARS-CoV-2 Antigen Rapid Diagnostic Test –**

**Competency Assessment**

1. **Practical Test: Nasopharyngeal sample collection**

**Instructions:**

* Don PPE.
* Prepare the workspace.
* Collect one nasopharyngeal sample.
* The tester has to perform the tasks outlined in the checklist correctly. If not, the answer should be “NO” and an explanation should be provided in the last column.
* For each correctly performed item, the tester will obtain 1 point.

**Tester’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

| **Number** | **Question** | **Yes** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| 1 | Did the tester put on the appropriate PPE for testing?  |  |  |  |
| 2 | Did the tester collect all the necessary supplies to perform nasopharyngeal sample collection?  |  |  |  |
| 3 | Did the tester insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx? |  |  |  |
| 4 | Did the tester swab over the surface of the posterior nasopharynx? |  |  |  |
| 5 | Did the tester withdraw the sterile swab from the nasal cavity? |  |  |  |
| **SECTION A: Score / Number of correct answers** | **/ 5 = %** | …………… % |

**Moderator’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

**SARS-CoV-2 Antigen Rapid Diagnostic Test –**

**Competency Assessment**

1. **Practical Test: SARS-CoV-2 Antigen RDT[[2]](#footnote-3)**

**Instructions:**

* Don PPE.
* Prepare the workspace.
* Process two samples in parallel according to the SARS-CoV-2 Antigen RDT Quick Reference Guide/Instructions for Use.
* Doff PPE.
* The tester has to perform the tasks outlined in the checklist for **BOTH** samples correctly. If not, the answer should be “NO” and an explanation should be provided in the last column.
* For each correctly performed item, the tester will obtain 1 point.

**Tester’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

| **Number** | **Question** | **Yes** | **No** | **Comment** |
| --- | --- | --- | --- | --- |
| 1 | Did the tester put on the appropriate PPE for testing?  |  |  | (See Section A:1) |
| 2 | Did the tester carefully read the instructions for using the SARS-CoV-2 Antigen RDT? |  |  |  |
| 3 | Did the tester collect all the necessary supplies to perform the SARS-CoV-2 Antigen RDT procedure? |  |  |  |
| 4 | Did the tester set up the workstation correctly? |  |  |  |
| 5 | Did the tester check the expiry date of the SARS-CoV-2 Antigen RDT? |  |  |  |
| 6 | Did the tester check that the test device and the desiccant pack in the foil pouch were not damaged or invalid? |  |  |  |
| 7 | Did the tester insert the swab into an extraction buﬀer tube and, while squeezing the buﬀer tube, stir the swab? |  |  |  |
| 8 | Did the tester remove the swab while squeezing the sides of the tube to extract the liquid from the swab? |  |  |  |
| 9 | Did the tester press the nozzle cap tightly onto the tube? |  |  |  |
| 10 | Did the tester apply the required number of drops of extracted specimen to the specimen well of the test device? |  |  |  |
| 11 | Did the tester read the SARS-CoV-2 Antigen RDT result after the required amount of time? |  |  |  |
| 12 | Did the tester interpret the SARS-CoV-2 Antigen RDT result correctly? |  |  |  |
| 13 | Did the tester record the test result in the SARS-CoV-2 Antigen RDT Logbook? |  |  |  |
| 14 | Did the tester dispose of all waste (e.g., used test kit, extraction buffer tube, swab and paper stand) in the biohazard bag? |  |  |  |
| 15 | Did the tester remove their gown and gloves before leaving the workstation? |  |  |  |
| 16 | Did the tester practice proper hand hygiene after completing the SARS-CoV-2 Antigen RDT procedure? |  |  |  |
| **SECTION B: Score / Number of correct answers** | **/ 16 = %** | …………… % |

**Moderator’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

**SARS-CoV-2 Antigen Rapid Diagnostic Test –**

**Competency Assessment**

1. **Theoretical Test**

**Instructions:**

* The moderator will provide the tester with this sheet.
* The tester will be required to answer fifteen multiple-choice questions on the content presented in the workshop.
* The tester will obtain 1 point when the whole question is answered correctly.

**Tester’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

|  |  |  |
| --- | --- | --- |
| **SARS-CoV-2 Antigen RDT Questions** | **Answered correctly** | **If NO, add comment** |
| 1. **SARS-CoV-2 diagnostic testing (using NAAT or antigen RDTs) can be used to:​**

 Confirm infection in patients who fulfil the COVID-19 clinical criteria​ Rapidly screen suspected cases Screen for infection in asymptomatic contacts of confirmed COVID-19 cases​ All of the above | YES | NO |  |
| 1. **What does an antigen RDT detect?**

 Viral antigens Viral RNA Viral DNA None of the above | YES | NO |  |
| 1. **What are the advantages of testing for SARS-CoV-2 infections with antigen RDTs?**

 Tests can be performed outside a laboratory (e.g., clinical facility) Results are rapidly available Antigen RDTs are more sensitive than NAAT None of the above | YES | NO |  |
| 1. **In which of the following cases does WHO currently recommend NOT using SARS-CoV-2 Antigen RDTs?**

 When testing individuals without symptoms (unless the person is a contact of a confirmed case)When testing individuals with symptoms in areas where SARS-CoV-2 transmission is very highWhere appropriate biosafety and infection prevention and control measures are lackingFor airport or border screening at points of entry | YES | NO |  |
| 1. **When can testing errors occur?**

 Before testing During testing After testing All of the above | YES | NO |  |
| 1. **Which of the following are not good practice and could lead to testing errors?**

Testing according to the manufacturer’s Instructions for Use (IFU) Testing several days after specimen collection Using kits past their expiry date Systematically cross-checking the labels of the sample request form and the sample container  | YES | NO |  |
| 1. **Which of the following is key to minimizing risk when performing SARS-CoV-2 testing with RDTs?**

Ensuring good ventilationUsing PPEFollowing procedures and good practicesAll of the above | YES | NO |  |
| 1. **Which PPE should personnel be wearing when performing RDTs?**

GlovesLong-sleeved gownEye protectionRespiratory protection, adapted to procedure (specimen collection and/or testing)All of the above | YES | NO |  |
| 1. **Which of the following statements is NOT correct?**

Currently, only nasopharyngeal swabs should be tested using RDTs If collecting a specimen for NAAT confirmation, this should be done immediately after collecting the specimen for antigen RDT testingSpecimens should be triple packaged for shippingIt is not necessary to wear a respirator (e.g., N95 or FFP2) when collecting a nasopharyngeal specimen | YES | NO |  |
| 1. **Which of the following are good practices for supply management?**

Performing regular stock counts (e.g., weekly)Identifying personnel in charge of stock counts and record management Checking the integrity of supplies when they are delivered to the facilityPlacing new kit orders based on kit usage before running out of tests, accounting for the time it may take to receive the order All of the above | YES | NO |  |
| 1. **Which of the following statements are NOT correct?**

A SARS-CoV-2 Antigen RDT that is negative can be re-used for another test/patientIf the pouch or seal of the test is damaged, that test should not be usedIt is fine to use the extraction buffer tube from another kit if a tube is missingTest results can be read several hours after the specified period of time | YES | NO |  |
| 1. **What type(s) of records should be kept at the testing site?**

Test requisition formsSpecimen transfer logsSARS-CoV-2 Antigen RDT LogbookTemperature logs (e.g., monitoring of storage fridge)Inventory recordsAll of the above | YES | NO |  |
| 1. **Which of the following are examples of Quality Indicators (QIs) that must be collected to monitor SARS-CoV-2 Antigen RDT testing?**

Temperature of the storage fridge Number and proportion of specimens tested, by specimen type, by batch/lot, by testerNumber of days where testing services were interruptedNumber and proportion of spoilt testsAverage turnaround time | YES | NO |  |
| 1. **Which of the following are components of quality assurance?**

Quality control testingSupervisory visitsNew lot testingProficiency testingAll of the above | YES | NO |  |
| 1. **Which of the following statements about quality control (QC) are correct?**

Quality controls are materials with known positive and negative resultsIf QC results differ from what is expected, patient test results cannot be releasedNew lot testing can be conducted with QC materialsAll of the above | YES | NO |  |
| **SECTION C: Score / Number of correct answers** |  **/ 15** | …………… %  |

**Moderator’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

**SARS-CoV-2 Antigen Rapid Diagnostic Test –**

**Competency Assessment**

1. **Practical Result Reading Test**

**Instructions:**

* The tester has to select the option (positive, negative, invalid) for each of the result examples.
* The tester must describe the patient management based on the result.
* For each correct item, the tester will obtain 1 point.

Note: reading test results requires normal or corrected near vision. If any difficulty in reading the test lines, please alert the trainer.

**Tester’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Test result example** | **Result interpretation** | **Comment** |
| 1. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| 2. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| 3. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| 4. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| 5. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Test result example** | **Result interpretation** | **Comment** |
| 6. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| 7. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| 8. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| 9. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| 10. | A close up of a door  Description automatically generated | Positive | Negative | Invalid |  |
| **SECTION D: Score / Number of correct answers** |  **/ 10** | …………… %  |

**Moderator’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

**SARS-CoV-2 Antigen Rapid Diagnostic Test –**

**Competency Assessment**

1. **Conclusion**

**Tester’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

|  |  |  |  |
| --- | --- | --- | --- |
| **Performance targets met?** |  |  | **If NO, add comment** |
| Score Part A: ≥80%?  | YES | NO |  |
| Score Part B: ≥80%?  | YES | NO |  |
| Score Part C: ≥80%?  | YES | NO |  |
| Score Part D: ≥80%?  | YES | NO |  |
| **Conclusion: Tester passed competency assessment** | **YES**# | **NO** |  |

#Tester can only pass the competency test if the scores for individual Parts A, B, C and D are ALL met.

**Moderator’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (dd/mm/yy): \_\_ \_\_/\_\_ \_\_/\_\_ \_\_**

**Theoretical test answers**

|  |
| --- |
| **SARS-CoV-2 Antigen RDT Questions** |
| 1. **SARS-CoV-2 diagnostic testing (using NAAT or antigen RDTs) can be used to:​**

 Confirm infection in patients who fulfil the COVID-19 clinical criteria​ Rapidly screen suspected cases Screen for infection in asymptomatic contacts of confirmed COVID-19 cases​◼︎ All of the above |
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◼︎ Tests can be performed outside a laboratory (e.g., clinical facility)◼︎ Results are rapidly available Antigen RDTs are more sensitive than NAAT None of the above |
| 1. **In which of the following cases does WHO currently recommend NOT using SARS-CoV-2 Antigen RDTs?**

◼︎ When testing individuals without symptoms (unless the person is a contact of a confirmed case)When testing individuals with symptoms in areas where SARS-CoV-2 transmission is very high◼︎ Where appropriate biosafety and infection prevention and control measures are lacking◼︎ For airport or border screening at points of entry |
| 1. **When can testing errors occur?**

 Before testing During testing After testing◼︎ All of the above |
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| 1. **Which of the following statements are NOT correct?**

◼︎A SARS-CoV-2 Antigen RDT that is negative can be re-used for another test/patientIf the pouch or seal of the test is damaged, that test should not be used◼︎It is fine to use the extraction buffer tube from another kit if a tube is missing◼︎Test results can be read several hours after the specified period of time |
| 1. **What type(s) of records should be kept at the testing site?**

Test requisition formsSpecimen transfer logsSARS-CoV-2 Antigen RDT LogbookTemperature logs (e.g., monitoring of storage fridge)Inventory records◼︎All of the above |
| 1. **Which of the following are examples of Quality Indicators (QIs) that must be collected to monitor SARS-CoV-2 Antigen RDT testing?**

 Temperature of the storage fridge ◼︎ Number and proportion of specimens tested, by specimen type, by batch/lot, by tester◼︎ Number of days where testing services were interrupted◼︎ Number and proportion of spoilt tests◼︎ Average turnaround time |
| 1. **Which of the following are components of quality assurance?**

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**Reading sheet answers**

|  |  |
| --- | --- |
| 1. | Positive |
| 2. | Negative |
| 3. | Invalid |
| 4. | Negative |
| 5. | Positive |
| 6. | Negative |
| 7. | Invalid |
| 8. | Positive |
| 9. | Positive |
| 10. | Negative |

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1. See Module 10: Assuring quality results for instructions on how to prepare the quality control material. If no positive and negative controls are available, collect nasopharyngeal swabs for demonstrating the SARS-CoV-2 Antigen RDT testing and conducting the competency assessments. [↑](#footnote-ref-2)
2. This procedure must be adapted to the specificities of the SARS-CoV-2 Antigen RDT being performed. [↑](#footnote-ref-3)