# 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 healthcare 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 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
* three spray bottles (two for bleach working solutions of 0.1% and 1%, one 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

**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[[2]](#footnote-3).
* 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[[3]](#footnote-4)**

**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. **What does an antigen RDT detect?**

 Viral antigens Viral RNA Viral DNA None of the above | YES | NO |  |
| 1. **One disadvantage of testing for SARS-CoV-2 infections with antigen RDTs is that**

❑ Tests can be performed outside a laboratory (e.g., clinical facility)❑ Results are rapidly available❑ Antigen RDTs are less sensitive than NAAT (Nucleic Acid Amplification Test)❑ Antigen RDTs are simple to perform |  |  |  |
| 1. **In which of the following scenarios does WHO currently recommend 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. **Select one practice from the list below that could lead to testing errors.**

❑ Testing according to the manufacturer’s Instructions for Use (IFU)❑ Testing several days after specimen collection❑ Using test kits that have not expired❑ Systematically cross-checking the labels of the sample request form and the sample container | YES | NO |  |
| 1. **Which one of the following practises might increase the risk of disease transmission when performing SARS-CoV-2 testing with antigen RDTs?**

❑ Ensuring good ventilation❑ Using Personal Protective Equipment (PPE)❑ Having inappropriate waste management❑ Following procedures and good practices | YES | NO |  |
| 1. **Which PPE should personnel be wearing when performing SARS-COV-2 antigen RDTs? (select all that apply)**

❑ Gloves❑ Long-sleeved gown❑ Coveralls❑ Eye and respiratory protection | YES | NO |  |
| 1. **Which of the following should be performed when managing supplies? (select all that apply)**

❑ 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❑ Allowing kits to expire before ordering more  | YES | NO |  |
| 1. **Select one correct statement from the list below**

❑ 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. **Which of the following are components of quality assurance?**

Quality control testingSupervisory visitsProficiency testingAll of the above | YES | NO |  |
| 1. **Among the following statements, which one is incorrect?**

❑ Record keeping allows the testing site to monitor the quality of testing using quality indicators (QIs)❑ Records such as test requisition forms, results logbooks and temperature logs should be kept onsite❑ All records can be accessed by anyone as they do not contain confidential information❑ When QIs fall outside of an acceptable range, the cause should be identified, and corrective actions taken | YES | NO |  |
| 1. **How would you interpret this SARS-CoV-2 antigen RDT result, based on the photograph?**

A close up of a door  Description automatically generated❑ Positive❑ Negative❑ Invalid |  |  |  |
| 1. **How would you interpret this SARS-CoV-2 antigen RDT result, based on the photograph?**

A close up of a door  Description automatically generated❑ Positive❑ Negative❑ Invalid |  |  |  |
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| 1. **How would you interpret this SARS-CoV-2 antigen RDT result, based on the photograph?**

A close up of a door  Description automatically generated❑ Positive❑ Negative❑ Invalid |  |  |  |
| 1. **You run a SARS-CoV-2 antigen RDT on a sample from a patient with respiratory symptoms. According to the instructions for use of the test kit, the maximum reading time is 15 min. You were distracted by your boss who came to ask you a question and you only read the result at 20 min. What would be your action if when reading the RDT result you see a faint line in front of ‘T’ (test line) and a line in front of ‘C’ (control)?**

A close up of a door  Description automatically generated❑ Record the test as positive❑ Record the test as negative❑ Repeat testing❑ None of the above |  |  |  |
| **SECTION C: Score / Number of correct answers** |  **/ 15** | …………… %  |

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

If the optional self-testing module (S1- Use of SARS-CoV-2 Ag-RDTs for COVID-19 self-testing) is included in the training, select one question on self-testing, and replace one of the theoretical questions with it.

|  |
| --- |
| **SARS-CoV-2 Antigen RDT self-testing** |
| 1. **What priority population should be targeted for self-testing?**

qAsymptomatic individuals with no known exposureq Essential workersq Individuals at risk of hospitalization or severe diseaseq Individuals with challenges in accessing existing services |
| 1. **Select all correct statements from the list below.**

q A positive self-test result likely indicates active SARS-CoV-2 infectionq A positive self-test result is likely false if the individual has no known exposure and live in an area of low prevalence for COVID-19 A negative self-test must be confirmed by a NAAT (Nucleic Acid Amplification Test)q A negative self-test indicates a lower likelihood of current SARS-CoV2 infection |

**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.

**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. **What does an antigen RDT detect?**

◼︎Viral antigens Viral RNA Viral DNA None of the above |
| 1. **One disadvantage of testing for SARS-CoV-2 infections with antigen RDTs is that**

❑ Tests can be performed outside a laboratory (e.g., clinical facility)❑ Results are rapidly available◼︎Antigen RDTs are less sensitive than NAAT (Nucleic Acid Amplification Test)❑ Antigen RDTs are simple to perform |
| 1. **In which of the following scenarios does WHO currently recommend using SARS-CoV-2 antigen RDTs?**

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| 1. **Select one practice from the list below that could lead to testing errors.**

❑ Testing according to the manufacturer’s Instructions for Use (IFU)◼︎Testing several days after specimen collection❑ Using test kits that have not expired❑ Systematically cross-checking the labels of the sample request form and the sample container |
| 1. **Which one of the following practices might increase the risk of disease transmission when performing SARS-CoV-2 testing with antigen RDTs?**

❑ Ensuring good ventilation❑ Using Personal Protective Equipment (PPE)◼︎Having inappropriate waste management❑ Following procedures and good practices |
| 1. **Which PPE should personnel be wearing when performing SARS-COV-2 antigen RDTs? (select all that apply)**

◼︎Gloves◼︎ Long-sleeved gown❑ Coveralls◼︎Eye and respiratory protection |
| 1. **Which of the following should be performed when managing supplies? (select all that apply)**

◼︎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❑ Allowing kits to expire before ordering more  |
| 1. **Select one correct statement from the list below**

❑ 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. **Which of the following are components of quality assurance?**

Quality control testingSupervisory visitsProficiency testing◼︎All of the above |
| 1. **Among the following statements, which one is incorrect?**

❑ Record keeping allows the testing site to monitor the quality of testing using quality indicators (QIs)❑ Records such as test requisition forms, results logbooks and temperature logs should be kept onsite◼︎All records can be accessed by anyone as they do not contain confidential information❑ When QIs fall outside of an acceptable range, the cause should be identified, and corrective actions taken |
| 1. **How would you interpret this SARS-CoV-2 antigen RDT result, based on the photograph?**

A close up of a door  Description automatically generated◼︎Positive❑ Negative❑ Invalid |
| 1. **How would you interpret this SARS-CoV-2 antigen RDT result, based on the photograph?**

A close up of a door  Description automatically generated❑ Positive◼︎ Negative❑ Invalid |
| 1. **How would you interpret this SARS-CoV-2 antigen RDT result, based on the photograph?**

A close up of a door  Description automatically generated❑ Positive❑ Negative◼︎Invalid |
| 1. **How would you interpret this SARS-CoV-2 antigen RDT result, based on the photograph?**

A close up of a door  Description automatically generated❑ Positive◼︎Negative❑ Invalid |
| 1. **You run a SARS-CoV-2 antigen RDT on a sample from a patient with respiratory symptoms. According to the instructions for use of the test kit, the maximum reading time is 15 min. You were distracted by your boss who came to ask you a question and you only read the result at 20 min. What would be your action if when reading the RDT result you see a faint line in front of ‘T’ (test line) and a line in front of ‘C’ (control)?**

A close up of a door  Description automatically generated❑ Record the test as positive❑ Record the test as negative◼︎Repeat testing❑ None of the above |

**Self-testing theoretical test answers**

|  |
| --- |
| **SARS-CoV-2 Antigen RDT self-testing** |
| 1. **What priority population should be targeted for self-testing?**

qAsymptomatic individuals with no known exposure◼︎Essential workers◼︎Individuals at risk of hospitalization or severe disease◼︎Individuals with challenges in accessing existing services |
| 1. **Select all correct statements from the list below**

◼︎ A positive self-test result likely indicates active SARS-CoV-2 infection◼︎A positive self-test result is likely false if the individual has no known exposure and live in an area of low prevalence for COVID-19 A negative self-test must be confirmed by a NAAT (Nucleic Acid Amplification Test)◼︎A negative self-test indicates a lower likelihood of current SARS-CoV-2 infection |

**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. Nasopharyngeal swabs are the often preferred sample for testing using SARS-CoV-2 Antigen RDTs. As new tests become available, other sample types are being used, such as nasal swabs. Always refer to the kit's IFU which will specify the type of samples to use [↑](#footnote-ref-3)
3. This procedure must be adapted to the specificities of the SARS-CoV-2 Antigen RDT being performed. [↑](#footnote-ref-4)