



COVID-19: ANTIGEN DIAGNOSTIC TEST COMPETENCY ASSESSMENT

Version 1.0

Publication Date: 29th January 2021

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SARS-CoV-2 Antigen Diagnostic Test Competency Assessment – v1.0

Version	Date Approved	Changes	Author
1.0	29.01.21	First draft	ADT Validation Scientific Lead ADT Implementation Project Manager

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 Diagnostic Testing (ADT). 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 or nasal sample collection and SARS-CoV-2 ADT(s), and can interpret and record the test result(s).

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

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

1. Obtain a passing score of 80% on the practical test (Section A), in which operators will be required to perform two SARS-CoV-2 ADTs on blinded samples while being observed by a trainer;
2. Obtain a passing score of 80% on the written theoretical test (Section B), in which operators will be required to answer ten multiple-choice questions on content presented in the workshop;
3. Obtain a passing score of 80% on the practical result reading test (Section C), in which operators will be required to correctly interpret different SARS-CoV-2 ADT results from photographs provided.

Materials needed to conduct competency assessments

See the Checklist of Training Materials. Training materials include:

- 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 ADT kits for each participant to perform three (practice) tests and two competency (proficiency) tests
- leak-proof biohazard bins for containing or moving biohazard waste
- 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)
- SARS-CoV-2 ADT Logbook

A. Practical Test: SARS-CoV-2 ADT

Instructions:

- ✓ Don PPE.
- ✓ Prepare the workspace.
- ✓ Process two samples in parallel according to the SARS-CoV-2 ADT Quick Reference Guide/Instructions for Use.
- ✓ Doff PPE.
- ✓ The operator 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 operator will obtain 1 point.

Operator’s name: _____

Date (dd/mm/yy): ___/___/___

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

Moderator’s name: _____

Date (dd/mm/yy): ___/___/___

B. Theoretical Test

Instructions:

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

Operator's name: _____

Date (dd/mm/yy): __ __ / __ __ / __ __

SARS-CoV-2 ADT Questions	Answered correctly		If NO, add comment
<p>1) SARS-CoV-2 diagnostic testing (using PCR or ADTs) can be used to:</p> <p><input type="checkbox"/> Confirm infection in patients who fulfil the COVID-19 clinical criteria</p> <p><input type="checkbox"/> Rapidly screen suspected cases</p> <p><input type="checkbox"/> Both of the above</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<p>2) What does an ADT detect?</p> <p><input type="checkbox"/> Viral antigens</p> <p><input type="checkbox"/> Viral RNA</p> <p><input type="checkbox"/> Viral DNA</p> <p><input type="checkbox"/> None of the above</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<p>3) What are the advantages of testing for SARS-CoV-2 infections with ADTs?</p> <p><input type="checkbox"/> Tests can be performed outside a laboratory (e.g. clinical facility)</p> <p><input type="checkbox"/> Results are rapidly available</p> <p><input type="checkbox"/> ADTs are more sensitive than PCR</p> <p><input type="checkbox"/> None of the above</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<p>4) Which of the following are NOT good practice and could lead to testing errors?</p> <p><input type="checkbox"/> Testing according to the manufacturer's Instructions for Use (IFU)</p> <p><input type="checkbox"/> Testing several days after specimen collection</p> <p><input type="checkbox"/> Using kits past their expiry date</p> <p><input type="checkbox"/> Systematically cross-checking the labels of the sample request form and the sample container</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<p>5) Which of the following is key to minimizing risk when performing SARS-CoV-2 testing with ADTs?</p> <p><input type="checkbox"/> Ensuring good ventilation</p> <p><input type="checkbox"/> Using PPE</p> <p><input type="checkbox"/> Following procedures and good practices</p> <p><input type="checkbox"/> All of the above</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO	

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<p>6) Which PPE should personnel be wearing when performing ADTs?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Gloves <input type="checkbox"/> Long-sleeved gown <input type="checkbox"/> Eye protection <input type="checkbox"/> Respiratory protection, adapted to procedure (specimen collection and/or testing) <input type="checkbox"/> All of the above 	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<p>7) Which of the following statements are NOT correct?</p> <ul style="list-style-type: none"> <input type="checkbox"/> A SARS-CoV-2 ADT that is negative can be re-used for another test/patient <input type="checkbox"/> If the pouch or seal of the test is damaged, that test should not be used <input type="checkbox"/> It is fine to use the extraction buffer tube from another kit if a tube is missing <input type="checkbox"/> Test results can be read several hours after the specified period of time 	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<p>8) Which of the following are examples of Quality Indicators (QIs) that must be collected to monitor SARS-CoV-2 ADT testing?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Temperature of the storage fridge <input type="checkbox"/> Number and proportion of specimens tested, by specimen type, by batch / lot, by operator <input type="checkbox"/> Concordance of SARS-CoV-2 ADT result with PCR result where both tests are performed <input type="checkbox"/> Number and proportion of spoilt tests 	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<p>9) Which of the following are components of quality assurance?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Training and ongoing competency assessment of the operator. <input type="checkbox"/> Correct patient identification. <input type="checkbox"/> Performance of the test in accordance with the manufacturer's instruction. <input type="checkbox"/> Recording of non-conformances, and corrective and preventive actions. <input type="checkbox"/> All of the above 	<input type="checkbox"/> YES	<input type="checkbox"/> NO	

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<p>10) Which of the following statements about quality control (QC) are correct?</p> <p><input type="checkbox"/> Quality controls are materials with known positive and negative results</p> <p><input type="checkbox"/> If QC results differ from what is expected, patient test results cannot be released</p> <p><input type="checkbox"/> A quality management system (for point of care/near-patient testing) should be implemented in line with national guidelines.</p> <p><input type="checkbox"/> All of the above</p>	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<p>SECTION C: Score / Number of correct answers</p>	<p align="center">/ 10</p>		<p align="center">..... %</p>

Moderator's name: _____

Date (dd/mm/yy): __/__/__

C. Practical Result Reading Test





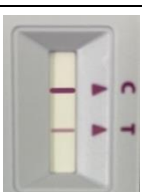
Instructions:

- ✓ The operator has to select the option (detected, not-detected, invalid) for each of the result examples.
- ✓ The operator must describe the patient management based on the result.
- ✓ For each correct item, the operator 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.

Operator's name: _____

Date (dd/mm/yy): ____/____/____

	Test result example	Result interpretation			Comment
		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
1.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
2.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
3.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
4.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
5.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	

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	Test result example	Result interpretation			Comment
6.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
7.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
8.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
9.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
10.		<input type="checkbox"/> DETECTED	<input type="checkbox"/> NOT DETECTED	<input type="checkbox"/> Invalid	
SECTION D: Score / Number of correct answers			/ 10	 %

Moderator’s name: _____

Date (dd/mm/yy): ___ / ___ / ___

D. Conclusion

Operator's name: _____

Date (dd/mm/yy): __ __ / __ __ / __ __

Performance targets met?			If NO, add comment
Score Part A: ≥80%?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
Score Part B: ≥80%?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
Score Part C: ≥80%?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
Conclusion: Operator passed competency assessment	<input type="checkbox"/> YES [#]	<input type="checkbox"/> NO	

[#]Operator can only pass the competency test if the scores for individual Parts A, B, C are ALL met.

Moderator's name: _____

Date (dd/mm/yy): __ __ / __ __ / __ __

Theoretical test answers

SARS-CoV-2 ADT Questions

1. SARS-CoV-2 diagnostic testing (using PCR or ADTs) can be used to:

- Confirm infection in patients who fulfil the COVID-19 clinical criteria
- Rapidly screen suspected cases
- Both of the above

2. What does an ADT detect?

- Viral antigens
- Viral RNA
- Viral DNA
- None of the above

3. What are the advantages of testing for SARS-CoV-2 infections with ADTs?

- Tests can be performed outside a laboratory (e.g. clinical facility)
- Results are rapidly available
- ADTs are more sensitive than PCR
- None of the above

4. 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

5. Which of the following is key to minimizing risk when performing SARS-CoV-2 testing with ADTs?

- Ensuring good ventilation
- Using PPE
- Following procedures and good practices
- All of the above

6. Which PPE should personnel be wearing when performing ADTs?

- Gloves
- Long-sleeved gown
- Eye protection
- Respiratory protection, adapted to procedure (specimen collection and/or testing)
- All of the above

7. Which of the following statements are NOT correct?

- A SARS-CoV-2 ADT 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

8. Which of the following are examples of Quality Indicators (QIs) that must be collected to monitor SARS-CoV-2 ADT testing?

- Temperature of the storage fridge
- Number and proportion of specimens tested, by specimen type, by batch/lot, by operator
- Concordance of SARS-CoV-2 ADT result with PCR result where both tests are performed
- Number and proportion of spoilt tests

9. Which of the following are components of quality assurance?

- Training and ongoing competency assessment of the operator.
- Correct patient identification.
- Performance of the test in accordance with the manufacturer's instruction.
- Recording of non-conformances, and corrective and preventive actions.
- All of the above

10. 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
- A quality management system (for point of care/near patient testing) should be implemented in line with national guidelines.
- All of the above

Reading sheet answers

1.	Detected
2.	Not Detected
3.	Invalid
4.	Not Detected
5.	Detected
6.	Not Detected
7.	Invalid
8.	Detected
9.	Detected
10.	Not Detected

Disclaimer

These training materials have been adopted from WHO guidance and have been modified in line with local guidelines for the HSE.