SARS-CoV-2 Antigen detecting rapid diagnostic test implementation projects

* Required

Project coordinator

1. First Name

   

2. Last name *

   

3. Contact email *

   

4. Phone number *

   

5. Affiliation

   

11/26/2020
6. Role/Responsibility *

7. Address *

8. City *

9. Country *
Collaborating institutions

Please provide details for all institutions collaborating on this project. These groups may be providing technical support to the main implementing institution and/or they may themselves be an implementing partner in the same or different country.

10. How many countries will the project be conducted in? *

- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ Other

11. List the countries the project will be conducted in. *

12. Collaborating institution 1 - Name of institution

13. Collaborating institution 1 - Country
14. Collaborating institution 1 - Address of institution

15. Collaborating institution 1 - Focal person full name and title

16. Collaborating institution 1 - Role/responsability of focal person

17. Collaborating institution 1 - Contact email for focal person

18. Do you want to add another collaborating institution?
   - Yes
   - No

19. Collaborating institution 2 - Name of institution

20. Collaborating institution 2 - Country

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21. Collaborating institution 2 - Address of institution

22. Collaborating institution 2 - Focal person full name and title

23. Collaborating institution 2 - Role/responsability of focal person

24. Collaborating institution 2 - Contact email for focal person

25. Do you want to add another collaborating institution?
   - Yes
   - No

26. Collaborating institution 3 - Name of institution

27. Collaborating institution 3 - Country

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28. Collaborating institution 3 - Address of institution

29. Collaborating institution 3 - Focal person full name and title

30. Collaborating institution 3 - Role/responsability of focal person

31. Collaborating institution 3 - Contact email for focal person

32. Do you want to add another collaborating institution?

○ Yes

○ No

33. Collaborating institution 4 - Name of institution

34. Collaborating institution 4 - Country
35. Collaborating institution 4 - Address of institution

36. Collaborating institution 4 - Focal person full name and title

37. Collaborating institution 4 - Role/responsibility of focal person

38. Collaborating institution 4 - Contact email for focal person

39. Do you want to add another collaborating institution?
   □ Yes
   □ No

40. Collaborating institution 5 - Name of institution

41. Collaborating institution 5 - Country

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42. Collaborating institution 5 - Address of institution

43. Collaborating institution 5 - Focal person full name and title

44. Collaborating institution 5 - Role/responsability of focal person

45. Collaborating institution 5 - Contact email for focal person
Project Objectives

Using the WHO Master Protocol for Monitored Implementation of SARS-CoV-2 Ag RDTs as a template, answer the following questions:

46. What are the primary objectives you want to assess during this project?

47. What, if any, secondary objectives do you want to assess during this project?

48. Do you have any additional research objectives you want to assess during this project?

  ○ Yes
  ○ No
Eligibility Criteria

49. For the following criteria, please state whether you fulfil or partially fulfil the criteria.

1. SARS-CoV-2 Ag-RDTs are included in the national testing strategy/policy and use cases are aligned with those outlined in this protocol and in the WHO interim guidance;
2. At least one WHO EUL approval SARS-CoV-2 Ag-RDT registered according to national requirements in effect at the time of the application; *

☐ Fulfil criteria
☐ Partially fulfil criteria

50. For the following criteria, you stated that you fulfil the criteria. Please explain how you fulfil the criteria, giving examples.

1. SARS-CoV-2 Ag-RDTs are included in the national testing strategy/policy and use cases are aligned with those outlined in this protocol and in the WHO interim guidance;
2. At least one WHO EUL approval SARS-CoV-2 Ag-RDT registered according to national requirements in effect at the time of the application;
51. For the following criteria, you stated that you partially fulfil the criteria. Please explain how you fulfil the criteria, giving examples, and ways that you will compensate for those criteria that you don’t fulfil.

1. SARS-CoV-2 Ag-RDTs are included in the national testing strategy/policy and use cases are aligned with those outlined in this protocol and in the WHO interim guidance;
2. At least one WHO EUL approval SARS-CoV-2 Ag-RDT registered according to national requirements in effect at the time of the application;

52. For the following criteria, please state whether you fulfil or partially fulfil the criteria.

3. Capacity to train and supervise health workers and/or lay persons in safe and accurate performance and reporting of SARS-CoV-2 Ag-RDT; *
   - Fulfil criteria
   - Partially fulfil criteria
53. For the following criteria, you stated that you fulfil the criteria. Please explain how you fulfil the criteria, giving examples.

3. Capacity to train and supervise health workers and/or lay persons in safe and accurate performance and reporting of SARS-CoV-2 Ag-RDT;

54. For the following criteria, you stated that you partially fulfil the criteria. Please explain how you fulfil the criteria, giving examples, and ways that you will compensate for those criteria that you don’t fulfil.

3. Capacity to train and supervise health workers and/or lay persons in safe and accurate performance and reporting of SARS-CoV-2 Ag-RDT;
55. For the following criteria, please state whether you fulfil or partially fulfil the criteria.

4. The capacity to perform data entry into a database developed by WHO and to keep personal data confidential, noting that:
   a. One or more members of staff will be needed to dedicate time to project implementation and data quality management;
   b. Experience using DHIS-2 is highly desirable;
5. Expertise in implementation research and informing evidence-based policy development at national and/or global level;
6. Previous experience with enhanced program monitoring and evaluation is an asset, particularly with the implementation and scale-up of new technologies.

- [ ] Fulfil criteria
- [ ] Partially fulfil criteria

56. For the following criteria, you stated that you fulfil the criteria. Please explain how you fulfil the criteria, giving examples.

4. The capacity to perform data entry into a database developed by WHO and to keep personal data confidential, noting that:
   a. One or more members of staff will be needed to dedicate time to project implementation and data quality management;
   b. Experience using DHIS-2 is highly desirable;
5. Expertise in implementation research and informing evidence-based policy development at national and/or global level;
6. Previous experience with enhanced program monitoring and evaluation is an asset, particularly with the implementation and scale-up of new technologies.
57. For the following criteria, you stated that you partially fulfil the criteria. Please explain how you fulfil the criteria, giving examples, and ways that you will compensate for those criteria that you don’t fulfil.

4. The capacity to perform data entry into a database developed by WHO and to keep personal data confidential, noting that:
   a. One or more members of staff will be needed to dedicate time to project implementation and data quality management;
   b. Experience using DHIS-2 is highly desirable;
5. Expertise in implementation research and informing evidence-based policy development at national and/or global level;
6. Previous experience with enhanced program monitoring and evaluation is an asset, particularly with the implementation and scale-up of new technologies.

58. For the following criteria, please state whether you fulfil or partially fulfil the criteria.

8. For sites with access to NAAT, the following will also be required:
   a. Staff competent in specimen packaging, transport (for example, cold chain logistics) and storage;
   b. Access to a laboratory with the following:
      i. Adequate infrastructure and trained personnel for performing NAAT for SARS-CoV-2 infection (for example, using real-time reverse transcription polymerase chain reaction (rRT-PCR));
      ii. Demonstrated quality system;
      iii. Participation in proficiency testing scheme for SARS-CoV2 is desirable.

- [ ] Fulfil criteria
- [ ] Partially fulfil criteria
8. For sites with access to NAAT, the following will also be required:
   a. Staff competent in specimen packaging, transport (for example, cold chain logistics) and storage;
   b. Access to a laboratory with the following:
      i. Adequate infrastructure and trained personnel for performing NAAT for SARS-CoV-2 infection (for example, using real-time reverse transcription polymerase chain reaction (rRT-PCR));
      ii. Demonstrated quality system;
      iii. Participation in proficiency testing scheme for SARS-CoV2 is desirable.
60. For the following criteria, you stated that you partially fulfil the criteria. Please explain how you fulfil the criteria, giving examples, and ways that you will make up for those criteria that you don’t fulfil.

8. For sites with access to NAAT, the following will also be required:
   a. Staff competent in specimen packaging, transport (for example, cold chain logistics) and storage;
   b. Access to a laboratory with the following:
      i. Adequate infrastructure and trained personnel for performing NAAT for SARS-CoV-2 infection (for example, using real-time reverse transcription polymerase chain reaction (rRT-PCR));
      ii. Demonstrated quality system ;
      iii. Participation in proficiency testing scheme for SARS-CoV2 is desirable.

61. For the following criteria, please state whether you do or do not fulfil the criteria.

9. Permission to export samples to international reference laboratories is an advantage;

   - Fulfil criteria
   - Do not fulfil criteria
62. Is there currently community transmission in any of the planned project sites? *

- Yes
- No

63. If known, what is the current range of positivity rates amongst SARS-CoV-2 suspects in the country(s) where you are planning to implement Ag-RDTs?

- <1%
- 1-3%
- 4-9%
- 10-15%
- 16-20%
- >30%
- Don't know
- Other

64. Are there any SARS-CoV-2 Ag-RDTs currently registered in the planned project country(s)? *

- Yes
- No
- In process
- Don't know
65. Which Ag-RDT(s) is/are registered in your country? Select all that apply. *

- STANDARD Q COVID-19 Ag Test (SD Biosensor)
- Panbio COVID-19 Ag Rapid Test Device (Abbott)
- Other

66. What are the policies for use of SARS-CoV-2 Ag-RDTs? Where do they fit in the overall national testing strategy?
Please attach any official policy/statement or declaration from the Ministry of Health or alternative authority for use in the country(s) where project implementation is planned. Please combine into one file and upload into the link below file uploads after completing this application.


67. In what scenario, described in the Master Protocol, would the antigen detecting SARS-CoV-2 rapid diagnostic tests (Ag-RDTs) be used in your country/setting? *

- Point of care Ag-RDT use for case management in settings with access to delayed confirmatory NAAT testing
- Point of care Ag-RDT use for case management in settings with no access to confirmatory NAAT testing
- Point of care Ag-RDT use for surveillance or primary investigation of outbreaks or clusters in settings with access to delayed confirmatory NAAT testing
- Multiple settings

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68. In what health facilities or settings would these tests be used? Select all that apply.

- Hospitals
- Clinics
- Community-level settings
- Private providers
- All levels
- Other
Target population

As stated in the Master Protocol, the target population includes 'Individuals meeting a COVID-19 suspected case definition, asymptomatic contacts of confirmed COVID-19 cases and health workers involved in the use of Ag-RDTs.'

69. What is the COVID-19 case-definition that you will be using for the project?

70. Explain any inclusion and exclusion criteria for people being enrolled into the project.
Materials and Methods

Use the Master Protocol to answer the questions.

71. How will you conduct the sampling for your project? e.g. in what areas/regions will you conduct the project and how will you select these?

72. How will you select the health facilities/sites to be included in the project?

73. How many health facilities/settings do you plan to include in this project? How many health workers will participate in each health facility?
74. Who will be responsible for supervising and overseeing the project in each site? How will this be managed?

75. What, if any, specific research questions do you plan to address through this project? Describe briefly the study population, enrolment and study procedures, inclusion/exclusion criteria, data collection and how confidentiality will be maintained.

Describe the procedures and time required to obtain local and/or national ethical clearance, if required.
Endpoints

Table 1 in the Master Protocol lays out a menu of possible project endpoints, from this list, select the endpoints you aim to assess and are within the capacity of the team to fulfil in a 6-9 month period.

76. Epidemiology.
Select all that apply.

☐ Percentage of suspected COVID-19 cases and contacts of cases positive by Ag-RDT

☐ Percentage of suspected COVID-19 cases and contacts of cases positive by both Ag-RDT and by NAAT

☐ Percentage of negative Ag-RDTs that are positive on repeat testing by Ag-RDT

☐ Other

77. Field performance: Sensitivity and Specificity.
Select all that apply.

☐ Number of Ag-RDT positive tests

☐ Number of Ag-RDT negative tests

☐ Number of true positives according to reference NAAT assay

☐ Number of true negatives according to reference NAAT assay

☐ Viral load (Ct threshold value or copies/mL)

☐ Sample type (nasopharyngeal, nasal etc)

☐ Days since onset of symptoms

☐ Days since known contact with positive case

☐ Symptomatic vs pre or asymptomatic suspects (contacts)

☐ Other
78. Field performance: positive and negative predictive value. Select all that apply.

☐ Number of true positives
☐ Number of false positives
☐ Number of true negatives
☐ Number of false negatives

79. Field performance: Test line characteristics. Select all that apply.

☐ Band strength (0 to 4) of test line based on provided standard colour charts
☐ Inter-reader variability by test band strength and positive/negative result
☐ Number of invalid tests
☐ Stability of test lines over time
☐ Number of anomalies according to standard chart (ghost lines, failure to migrate, etc.)
☐ Other
80. Feasibility: Supplies, storage conditions, testing capacity and quality control. Select all that apply.

☐ Number of days with temperature recordings that exceed manufacturers storage conditions

☐ Number of days tests stored onsite

☐ Number of days of stock-outs of tests

☐ Number of days of stock outs of essential test kit components e.g. swabs or personal

☐ Number of days reader instrument out of service

☐ Maintenance and customer support needs

☐ Number of failed quality control checks

☐ Frequency quality controls checks performed

☐ Other

81. Feasibility: Competency. Select all that apply.

☐ Health worker competency after e.g. 0.5-1 days training based on standard checklist

☐ Maximum number of test (RDT and/or NAAT) that can be performed per day per person

☐ Health worker competency based on standard checklist after 3 months (paired results).

☐ Other
82. Acceptability: Adherence.  
Select all that apply.

☐ Proportion of negative test results for which health workers followed the recommended protocol for case management

☐ Proportion of tests done on patients or surveillance participants that meet recommended suspect case definitions or other criteria defined by the MOH

☐ Proportion of positive test results for which health workers followed the recommended protocol for case management

☐ Proportion of tests done on patients or surveillance participants that do not meet recommended suspect case definitions or other criteria defined by the MOH

☐ Other

Select all that apply.

☐ Turnaround time for results of Ag-RDT (hrs)

☐ Turnaround time for NAAT as first line and second line test (hrs)

☐ Number of NAAT for SARS-CoV-2 requested per day

☐ Number of contacts with virologic confirmed (RDT or NAAT) disease

☐ Days since symptom onset prior to testing

☐ Number of Ag-RDT for SARS-CoV-2 performed per day

☐ Number of contacts screened

☐ Number of patients or surveillance participants tested

☐ Number of suspected cases (meeting MOH definition) seen per day

☐ Number of cases detected by NAAT per day

☐ Number of cases detected by Ag-RDT per day

☐ Other

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84. Impact: Impact on quarantine procedures. 
Select all that apply.

- [ ] Days close contacts of suspects spent in unnecessary quarantine
- [ ] Days suspects spent out of isolation potentially transmitting while waiting for a positive PCR result
- [ ] Days suspects spent in unrequired isolation waiting for a negative PCR result
- [ ] Time to return to work or school compared to routine for contacts of cases
- [ ] Time to return to work or school compared to routine for suspects
- [ ] Other

Select all that apply.

- [ ] Time from alert received by response team to detection
- [ ] Time to implementation of targeted countermeasures
- [ ] Other

86. Cost-effectiveness 
Select all that apply.

- [ ] Cost per test result
- [ ] Cost per patient compared to routine – can include both direct and indirect costs
- [ ] Cost per day of quarantine
- [ ] Other

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87. Ease of use.
   Select all that apply.

☐ Assess user appraisal through standard ease of use assessment

☐ Other

88. Please list any other endpoints you wish to assess and link them back to specific objectives of the master protocol or described under specific research objectives (Question 53).
Data management and statistical analysis

89. Based on information provided in the Master Protocol and any additional analysis, what is the estimated sample size required for your project?


90. Will your project use the DHIS-2 template provided by the WHO for data collection?

○ Yes

○ No

91. If you will not use DHIS-2, what data management package will you use?


92. Describe your statistical analysis plan (eg. program used, who will conduct the analysis etc). A statistical plan will be shared by WHO.


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93. Describe the steps you will take to ensure the quality of the work and of the outcomes. For example, you may refer to adherence to standards, norms, procedures, control and review mechanisms, supervisory responsibilities, etc.
Results uptake and use; sustainability

94. Describe how you plan to communicate the results of this project to contribute to optimized uptake of Ag-RDTs.
Terms of the agreement including publications

95. Does your institution accept the terms set you WHO Agreement for Performance of Work including the Addendum?

- [ ] Acceptable
- [ ] Partially acceptable
- [ ] Not acceptable

96. If partially or not acceptable, provide additional information in sufficient detail to inform a revised terms of agreement.
97. Provide information on how you plan to ensure adequate protection of the human subjects’ rights and well-being. Provide additional information in sufficient detail to inform a revised terms of agreement.

98. Describe measures that will be in place to reduce the project’s potential impact on environment (for example disposal of chemicals, biosafety measures, environmental pollution, CO2 emissions etc.).
File uploads

In the separate link provided below, please upload four files listed below.


1. SARS-CoV-2 Ag-RDT policies. What are the policies for use of SARS-CoV-2 Ag-RDTs? Where do they fit in the overall national testing strategy? Please attach any official policy/statement or declaration from the Ministry of Health or alternative authority for use in the country(s) where project implementation is planned. Please combine into one file.

2. Patient consent. For any aspects of the project that require patient consent, please upload consent forms based on WHO master protocol templates.

3. Budget and Deliverables. Please fill in and upload the budget template and deliverables. A template project budget and table of deliverables and milestones has been provided.

4. Project timeline. Please create and upload a Gantt chart of your proposed project.