



STANDARD Q COVID-19 Ag Test SD BIOSENSOR

Introduction

This procedure is the qualitative detection of specific antigens to SARS-CoV-2 by a rapid chromatographic immunoassay using STANDARD Q COVID-19 Ag test kit.

Procedure

1. Preparation of the kit prior testing

1 Carefully read instructions for using the STANDARD Q COVID-19 Ag Test.



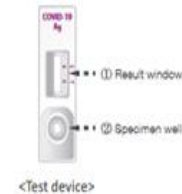
2 Check the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.



3 Check the test device and the desiccant pack in the foil pouch.



<Foil pouch>



<Test device>



<Desiccant>

2. Specimen collection and sample preparation

For specimen collection, please follow the nasopharyngeal swab sampling method.

Precautions

- Wear personal protective equipment during nasopharyngeal swab collection.
- Prior sample preparation, nasopharyngeal swab can be transported in a viral transport media from point of collection to testing area.

Sample preparation from direct nasopharyngeal swab,

1 Insert a sterile swab into the nostril of the patient, swab over the surface of the posterior nasopharynx. Withdraw the sterile swab from the nasal cavity.



2 Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.



3 Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



4 Press the nozzle cap tightly onto the tube.



Sample preparation from nasopharyngeal swab in transport media

1 Using a micropipette, collect the 350µl of specimen from the collection cup or VTM. Mix the specimen with an extraction buffer.

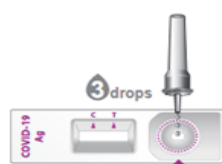


2 Press the nozzle cap tightly onto the tube.



3. Sample analysis

1 Apply 3 drops of extracted specimen to the specimen well of the test device.



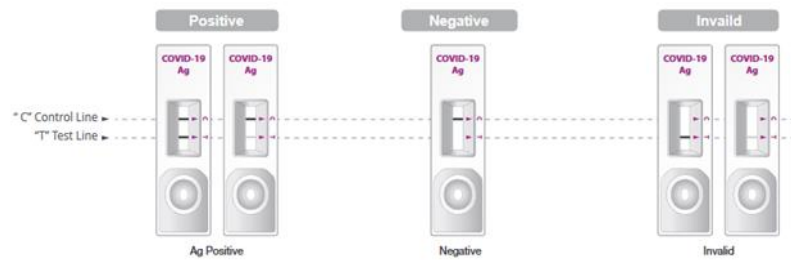
2 Read the test result in 15-30 minutes.



CAUTION
Do not read test results after 30 minutes. It may give false results.



4. Result interpretation



- A colored band will appear in the top section of the result window and this band is control line (C).
- A colored band will appear in the lower section of the result window and this band is the test line of SARS-CoV-2 Ag (T) and can be interpreted as Ag Positive.

5. Limitation of the test

- The test procedure, precautions, and interpretation of results for this test must be followed strictly when testing and failure to follow may adversely affect test performance and/or produce invalid results.
- Neither the quantitative value nor the rate of SARS-CoV-2 antigen concentration can be determined by this qualitative test.
- A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
- For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
- The test result must always be evaluated with other data available to the physician.
- A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by viral culture or a molecular assay or ELISA.
- Positive test results do not rule out co-infections with other pathogens or negative test results are not intended to rule in other coronavirus infection except the SARS-CoV.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
- When using VTM, sensitivity can be reduced due to dilution and only Copan UTM, BD UTM and STANDARD™ Transport Medium have been validated with the assay.

References

- SD Biosensor (standard Q COVID-19 Ag Test) pamphlet instruction 07/2020