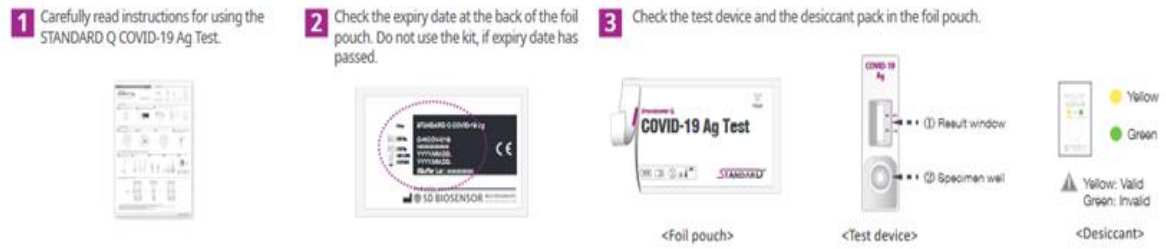
STANDARD Q COVID-19 Ag Test
SD BIOSENSOR

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



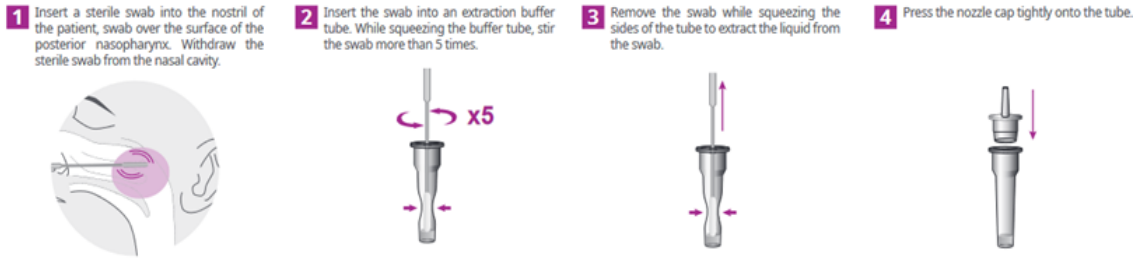
2. Specimen collection and sample preparation

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.

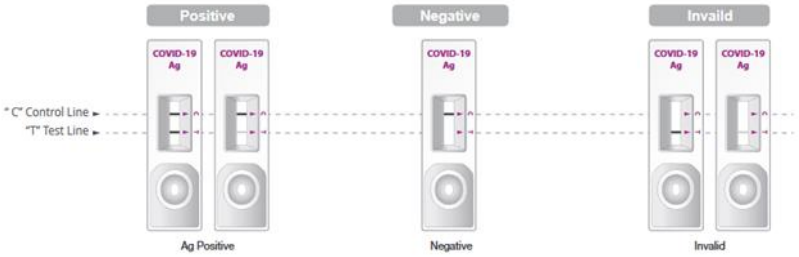
Sample preparation from direct nasopharyngeal swab,



Sample preparation from nasopharyngeal swab in transport media

3. Sample analysis

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-Co-V2 Ag (T) and can be interpret 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