

Saliva Antigen Test

LIMITATIONS

1. This reagent is only for detecting respiratory secretions and saliva samples.
2. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, stale sample or repeated freezing and thawing of samples will affect the test results.
3. The test card only provides qualitative detection of the COVID-19 antigen in the sample. If you need to test the specific content of a certain index, please use relevant professional instruments.
4. The test results of this reagent are for clinical reference and are not used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in conjunction with their symptoms/signs, medical history, other laboratory tests and treatment responses.
1. Due to the methodological limitations of antigen-based test reagents, its analytical sensitivity is generally lower than that of nucleic acid-based reagents. Therefore, experimenters should pay more attention to negative results and need to combine other test results for comprehensive diagnosis. It is recommended that negative results in doubt use nucleic acid testing for review.
6. Analysis of the possibility of false negative results:
 - ⊖ Unreasonable sample collection, operation and processing, and low virus titers in the sample may lead to false negative results.
 - ⊖ Various gene mutations may cause changes in antigenic determinants, resulting in false negative results. This type of situation is more likely to occur with monoclonal antibody reagents.
 - ⊗ The optimal sample type and the optimal sampling time after infection (peak virus titer) have not been verified. Therefore, collecting samples from multiple sites in the same patient may avoid false negatives.

PRECAUTIONS

1. The kit is for in vitro diagnostic use only.
2. The test card, sample extraction tube and dripper are all disposable and cannot be reused.
3. Please check the integrity and expiry date of the kit packaging before use, and then open the package. When storing at low temperature, it should be restored to room temperature before opening the package for use. Reagents whose single package is damaged and expired cannot be used.
4. The components in the kits of different batch numbers cannot be exchanged.
5. After the test card is taken out of the aluminum foil bag, the experiment should be carried out as soon as possible to avoid leaving it in the air for too long, which may cause moisture.
6. Pay attention to safety measures during operation, such as wearing protective clothing and gloves.
7. The detection temperature is 15°C ~ 30°C, and the relative humidity is 40% ~ 60%.
8. There is a desiccant in the aluminum foil bag and it is not allowed to be taken orally.
9. There is no ribbon on the quality control line and the inspection line, indicating that an error detection has occurred and the inspection should be repeated.
10. All specimens, reagents and potential contaminants should be disinfected and processed in accordance with relevant local regulations

For a reliable result, the rapid test must be performed by (care) emergency services.