

Precautions for antigen rapid test kit evaluation – JOYSBIO Biotechnology CO., LTD

This document is intended to help you for the evaluation of JOYSBIO's SARS-COV-2 Antigen Rapid Test Kit.

1. Samples for evaluation:

- Double nostril swab samples of COVID-19 patients should be used. The samples must be fresh collected;
- Live virus culture medium diluted by virus preservation solution can also be used for the evaluation. The virus inactivation process will lyse the virus and cause protein degradation, which cannot accurately reflect the virus lysis process in antigen test kit clinical study. The live virus culture medium can better simulate clinical patient samples comparing to the inactivated virus culture medium. JOYSBIO has developed a high-performance extraction buffer which provides better lysis for live virus.

2. Sampling:

- Evaluate against RT-PCR:

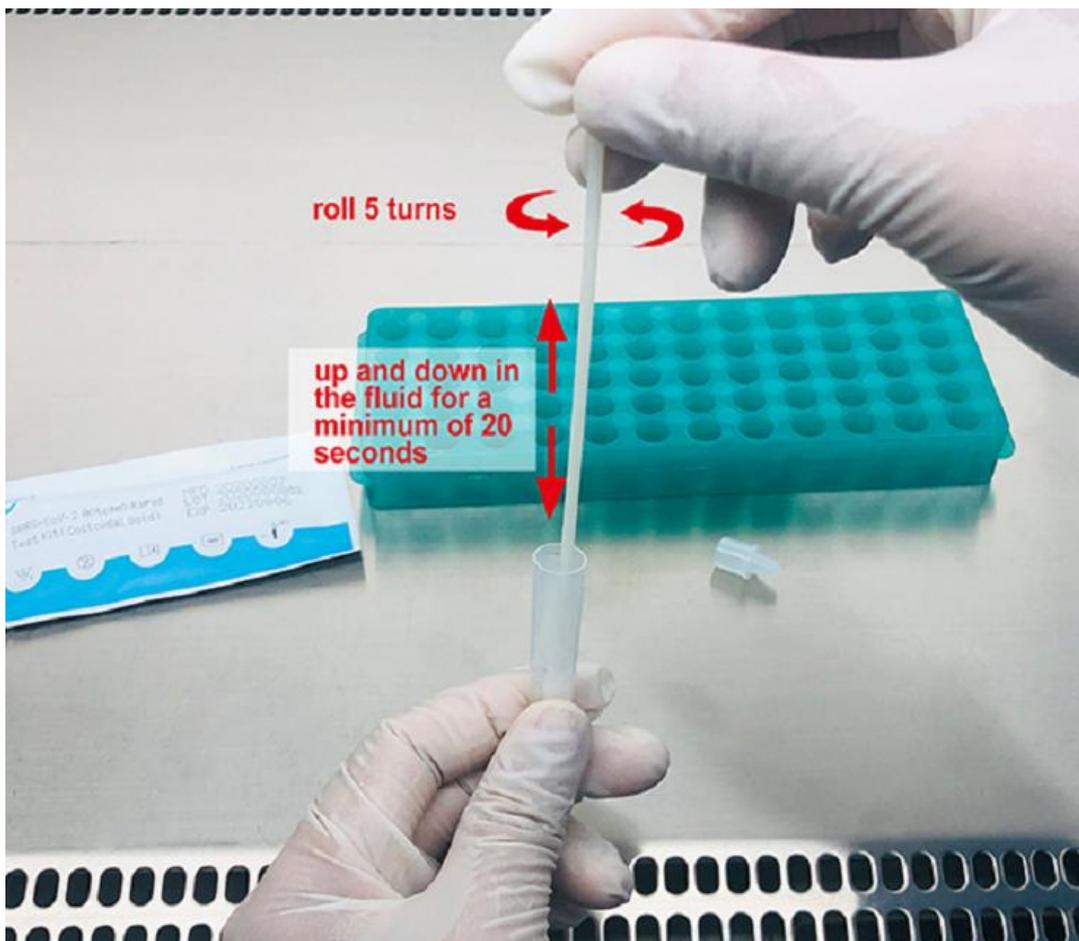
Since the nasal swab comes with JOYSBIO's SARS-COV-2 Antigen Rapid Test Kit goes ~2.5cm into nostril, it will not affect the sampling results of nasopharyngeal swab used in molecular test. Therefore, when evaluating against RT-PCR, the double nostril swab for antigen rapid test should be sampled first, then followed by the nasopharyngeal swab for RT-PCR.

- Evaluate with live virus culture medium:

Add 50 µl diluted live virus culture medium into the extraction tube, and mix it with the buffer provided with antigen test kits.

3. Swab sample processing:

Hold the bottom of the extraction tube, keep the swab pressed (horizontally) with two fingers as shown in the figure below.



- The treated sample solution should be used within 5 minutes and should not be stored.

5. Number of test samples:

More samples should be tested to reduce the errors and make the evaluation results better reflect the clinical performance of the antigen rapid test kit. It is recommended to test at least 100 positive samples and 400 negative samples.