

SARS-CoV-2 Antigen Rapid Test

Clinical report summary

- Comparative analysis of clinical diagnosis results with test reagent results.

The detection results of test reagent and clinical diagnostic results are shown in the following table:

| | | clinical diagnosis results | | Total |
|----------------------|--------------|----------------------------|-----------|-------|
| | | confirmed diagnosis | exclusion | |
| Test reagent results | Positive (+) | 45 | 0 | 45 |
| | Negative (-) | 3 | 240 | 243 |
| Total number | | 48 | 240 | 288 |

Sensitivity: 93.75%; (95% CI: 83.16%~97.85%)

Specificity:100 %; (95% CI: 98.42%~100%)

Total clinical coincidence rate: 98.96%. (95% CI: 96.98%~99.65%)

- Comparative analysis of test reagent results with PCR test results

The detection results of test reagent and the PCR test results were shown in the following table:

| | | PCR test results | | Total |
|----------------------|--------------|------------------|--------------|-------|
| | | Positive (+) | Negative (-) | |
| Test reagent results | Positive (+) | 112 | 3 | 115 |
| | Negative (-) | 5 | 360 | 365 |
| Total number | | 117 | 363 | 480 |

Sensitivity: : 95,7% (95%CI*:90,3%-98,6%)

Specificity:: 99,2% (95%CI*:97,6%-99,8%)

Total clinical coincidence rate: 98,3% (95%CI*:96,7%-99,3%)

The above results showed that there was no statistically significant difference between the detection reagent and the PCR results.