Comparison of SARS-CoV-2 Omicron nucleic acid test for COVID-19 infection with real-time RT-PCR using different nasopharyngeal swabs

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Abstract

Background: A new one SARS-CoV-2 Variant of Concern (VoC), Omicron, was born in a world weary of COVID-19, which anger and frustration with the pandemic was widespread, with wide-ranging negative impacts on health, social and economic well-being. The Omicron variant, which main types was BA5.2and BF.7 in China, in December 2022 to January 2023 leaded to off-target of the S and N genes, and the kits used were not adequately and independently evaluated when these agents are studied and developed. To ensure the accuracy of coronavirus test results, performance verification of commercial Real-Time quantitative PCR (RT-qPCR) was required. **Objective:** We performed a clinical evaluation for two Real Time SARS-CoV-2 assay, and to verify them based on different detection reagents and different clinical specimens. **Methods:** We performed clinical evaluations of two existing Chinese SARS-CoV-2 RT-qPCR kits COVID-19 nucleic acid detection kits (e-Diagnostic Biomedical, Wuhan, China) and 2019-nCoV nucleic acid diagnostic kits (Fosun Biotechnology, Shanghai, China) using BSD (Bondson) (Guangzhou Bondson Biotechnology Co. Ltd.;batch number 2022101), quality controls provided by the inspection center and a large number of clinically confirmed specimens. Overall, through the BDS performance verification reference product kit, It was best used to verify the performance of the reagent through a large number of clinical specimens for further verification. **Results:** The coincidence rate for Fosun and e-Diagnostic kits were individually 95% and 100%. Verified that the detection limit for Fosun and e-Diagnostic kits was 300copies/mL. All were below the detection limit for Fosun reagent was 300copies/mL. e-Diagnostic was 500copies/mL. Fosun had the largest CV for ORF1ab and N gene at the the detection limit concentration(4.80%,3.49%), while e-Diagnostic had the smaller (0.93%,1.10%). Negative results were tested in cross-reactivity. During the verification of clinical samples, sequencing analyses had shown that Fosun single gene miss rate was relatively high, especially ORF1ab, followed by N gene miss rate. we survey that all N genes were detected in clinical specimens, ,ORFab dropout (i.e., a negative/low result) occurred in (10.8%) of 225 Omicron variant. **Conclusions:** Our results endorse the use of these two commercial kits for the diagnosis of SARS-CoV-2 in China, as their clinical performance has been fully validated by a large number of clinically confirmed cases.

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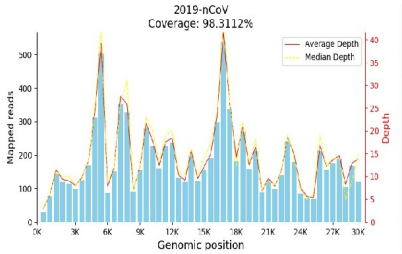
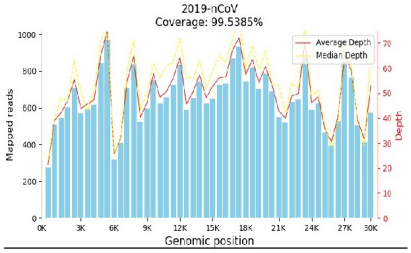
A



The data volume of specimens was 10M, the number of species sequence was 19,066, and the relative abundance (%) of species was 100

Sequence of BA.5.2 virus strain detection

B



The data volume of specimens was 9M, the number of species sequence was 74750, and the relative abundance (%) of species was 100

Sequence of BF.7 virus strain detection

A

Reference method(Fosun)

	POS	Neg
POS	7	0
Neg	1	12

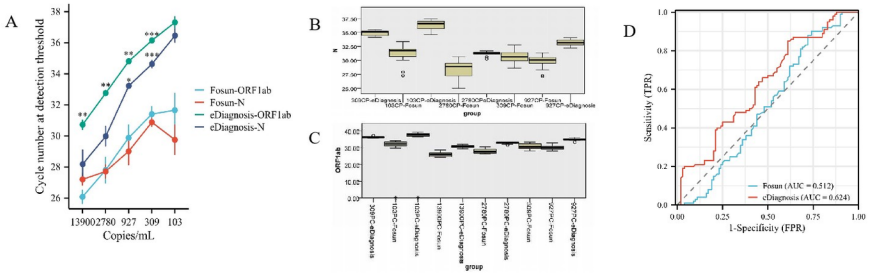
Coincidence rate=95%

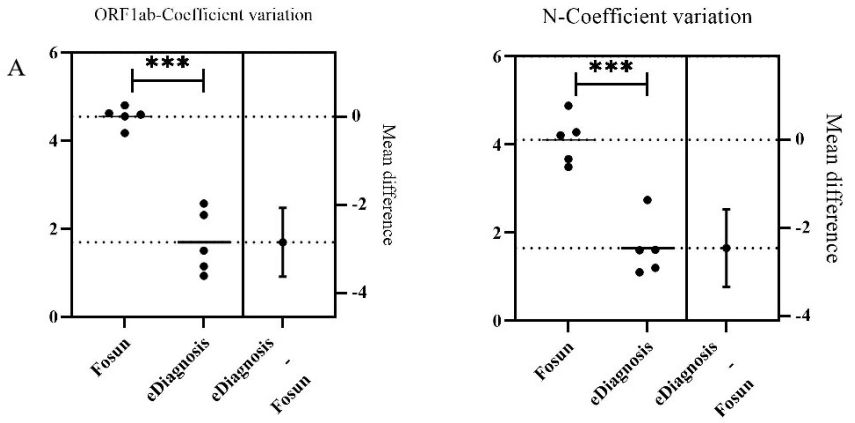
B

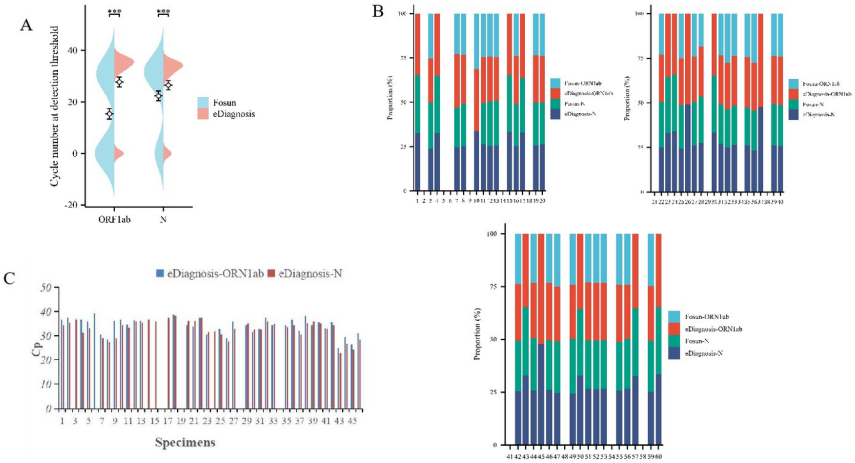
Reference method(eDiagnosis)

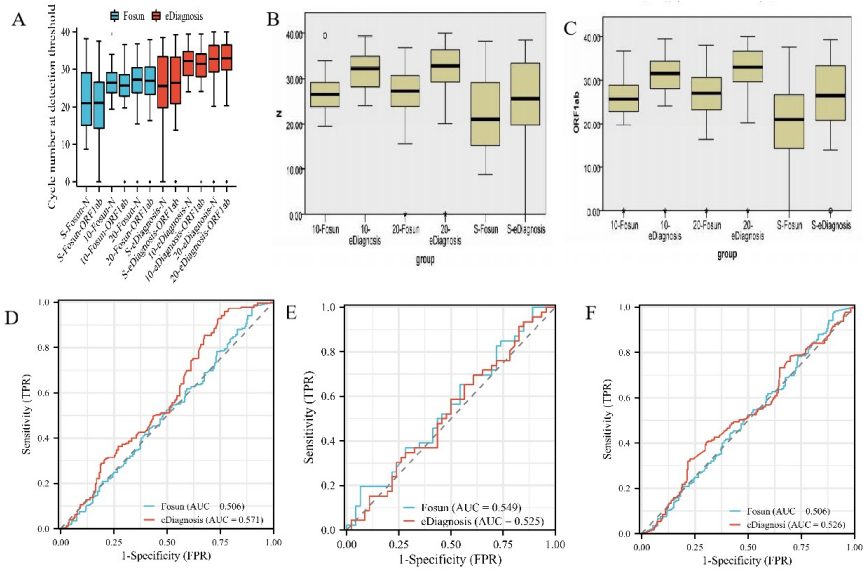
	POS	Neg
POS	8	0
Neg	0	12

Coincidence rate=100%









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