投稿 ▶原著

共通ウイルスゲノムRNAを用いたCOVID-19診断用核酸増幅検査薬の一斉性能評価試験

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Performance Evaluation of COVID-19 Diagnostic Nucleic Acid Amplification Tests Using SARS-CoV-2 Genomic RNA

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Summary

At the beginning of the coronavirus disease 2019 (COVID-19) pandemic in early 2020, nucleic acid amplification test (NAT) kits to identify severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection were urgently developed, and within a short period of time (2-6 months), dozens of NAT kits were permitted for clinical diagnostic use in Japan. These urgently developed NAT kits were subjected to an emergent review process based on performance evaluation using a limited number of clinical specimens. To verify the performance of these NAT kits, we conducted a performance evaluation study in September 2020. For this purpose, genomic RNA isolated from the SARS-CoV-2 Wuhan strain with a defined copy number was used as a standard material to evaluate nine NAT kits permitted for emergency use by the end of May 2020. A series of diluted solutions of viral RNA (5 to 500 copies per reaction) were used, and the positive detection rate at each concentration was calculated based on the criteria for each NAT kit. The results showed that eight of the nine NAT kits were capable of detecting samples containing more than 50 copies/reaction with a probability of 100%. The“50 copies/reaction” is a reference value used by the National Institute of Infectious Diseases in the pathogen detection manual 2019-nCoV in 2020. These eight NAT kits also correctly judged samples containing no viral RNA as“negative”. Thus, eight of the nine NAT kits were considered to be reliable in terms of sensitivity and specificity. On the other hand, one NAT kit judged samples containing no viral RNA as“positive” with a probability of 33%. Based on this result, the company that developed this NAT conducted additional experiments and found that these false-positive results occur when a specific combination of measurement plates and nucleic acid amplification devices was used. In addition, our study showed that there were differences in the positive detection rate and nucleic acid amplification efficiency even between NAT kits with the same primers, probably due to differences in the composition and reaction conditions of the reagents used. Also, the positive detection rate and the efficiency of nucleic acid amplification differed among the primer sets, which are constituents of the NAT kits.

Key words

COVID-19, SARS-CoV-2, Nucleic acid amplification test, PCR