投稿 ▶原著

早期に使用許可を受けたCOVID-19診断用核酸増幅検査薬の構成に関する調査と考察

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（受付：令和4年9月21日，受理：令和4年12月23日）

Survey and Consideration of the Composition of COVID-19 Diagnostic Nucleic Acid Amplification Tests Approved for Use in the Early Stage of COVID-19 Pandemic

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Summary

With the spread of a novel coronavirus disease COVID-19 in early 2020, dozens of nucleic acid amplification test (NAT) kits were developed in Japan and used for the diagnosis of COVID-19. Because of the urgent need to supply the kits to testing facilities, they were developed over a short time period and had to be urgently approved for use. In this study, we investigated the composition and specifications of COVID-19 diagnostic NAT kits that were approved for emergency use in Japan and the USA to see if there are any distinctive features that might be related to the urgency of development. With regard to primer design, we found that several NAT kits had adopted primers designed by public organizations such as the National Institute of Infectious Diseases in Japan and the USA Centers for Disease Control and Prevention (CDC), without designating manufacturer's original primers. In addition, some of the NAT kits had been developed to detect a single region of the viral genome, rather than multiple regions. A comparison between the NAT kits approved in Japan and the USA, showed that a higher percentage of NAT kits had adopted newer methods for specimen processing and nucleic acid amplification in Japan than in the USA. In addition, some NAT kits developed in Japan did not use an internal standard, which is a positive control nucleotide sequence to ensure valid amplification reaction and/or RNA extraction, whereas all kits in the USA used an internal standard. Based on the results of this survey, we discuss how NAT kits should be developed for a future pandemic, as well as the points to be considered in order to ensure the reliability of NAT kits.

Key words

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