Uji Teknis BioCore 2019-nCoV Real Time PCR Kit untuk Mendeteksi SARS-CoV-2 Menggunakan Protokol Pemantapan Mutu Eksternal Kementerian Kesehatan Republik Indonesia = BioCore 2019-nCoV Real Time PCR Kit Technical Test for SARS-CoV-2 Detection Using Ministry of Health of Republic of Indonesia External Quality Assurance Protocol

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Abstrak

Pandemi Coronavirus Disease 2019 (COVID-19) merupakan pandemi disebabkan oleh virus SARS-CoV-2. Indonesia diketahui sebagai salah satu negara dengan tingkat infeksi COVID-19 paling tinggi di dunia. Deteksi cepat secara Real Time Reverse Transcription Polymerase Chain Reaction (rRT-PCR) merupakan salah satu langkah yang diperlukan untuk menekan laju penyebaran COVID-19. Kit deteksi BioCore 2019-nCoV Real Time PCR Kit adalah salah satu kit dignosis COVID-19 produksi BioCore. Ltd., Korea Selatan. Kit diagnosis BioCore telah beredar di Indonesia dan perlu diuji keakuratan diagnosis yang dihasilkan untuk menghindari hasil negatif palsu. Pengujian dilakukan menggunakan protokol Penjaminan Mutu Eksternal (PME) Kementerian Kesehatan Indonesia dengan melibatkan 30 sampel uji dan membandingkan hasil uji terhadap kit gold standard CDC dengan gen target N1, N2, dan HRP. Alur kerja penelitian dimulai dari proses pengambilan sampel, ekstraksi RNA, persiapan mastermix, adisi template RNA, dan amplifikasi template dengan metode rRT-PCR. Hasil penelitian menunjukkan adanya amplifikasi pada kontrol yang digunakan, sehingga proses diagnosis dapat dilakukan. Nilai Ct IC kit Biocore dan IC CDC menunjukkan perbedaan signifikan (P 0,05; CI=95%). Gen target SARS-CoV-2 tidak terdeteksi pada kit Biocore dengan nilai Ct>35, serta didapatkan nilai sensitivitas dan spesifisitas analitik kit Biocore berturut-turut sebesar 75% dan 100%. Hasil uji Kit Biocore terhadap pasien terinfeksi COVID-19 di Indonesia tidak memenuhi standar kit diagnosis yang ditetapkan oleh WHO, yaitu memiliki sensitivitas analitik sebesar 95%. Peninjauan ulang primer pada kit Biocore perlu dilakukan untuk memperbaiki mutu kit dalam deteksi awal virus SARS-CoV-2 di Indonesia.

..... The Coronavirus Disease 2019 (COVID-19) pandemic is a pandemic caused by the SARS-CoV-2 virus. Indonesia is known as one of the countries with the highest COVID-19 infection rate in the world. Real Time Reverse Transcription Polymerase Chain Reaction (rRT-PCR) detection is one of the steps needed to accelerate the spread of COVID-19. The BioCore 2019-nCoV Real Time PCR Kit is one of the COVID-19 diagnosis kits produced by BioCore. Ltd., South Korea. The BioCore diagnostic kit has been circulating in Indonesia and needs to be tested for the accuracy of the resulting diagnosis to avoid false negative results. The test was carried out using the External Quality Assurance (PME) protocol of the Indonesian Ministry of Health involving 30 test samples and test results against the CDC gold standard kit with target genes N1, N2, and HRP. The research workflow starts from the sampling process, RNA extraction, mastermix preparation, RNA template addition, and template amplification using the rRT-PCR method. The results showed that there was amplification of the controls used, so that the diagnosis process could be carried out. The Ct values of the Biocore IC kit and the CDC IC showed a significant difference (P 0.05; CI=95%). The SARS-CoV-2 target gene was not detected in the Biocore kit with a Ct value>35, and the sensitivity and

analytical specificity of the Biocore kit were 75% and 100%, respectively. The results of the Biocore Kit test on patients infected with COVID-19 in Indonesia do not meet the diagnostic kit standard set by WHO, which has an analytical sensitivity of 95%. Primary review on the Biocore kit needs to be done to improve the quality of the kit in early detection of the SARS-CoV-2 virus in Indonesia.