Uji Diagnostik Kit BioCoV-19 RT-PCR dengan N1N2 CDC RT-PCR Untuk Mendeteksi SARS-CoV-2 = Diagnostic Test of BioCov-19 RT-PCR Kit With N1N2 CDC For Detecting SARS-CoV-2

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Abstrak

Pada bulan Desember, 2019, serangkaian kasus pneumonia dengan penyebab yang tidak diketahui muncul di China. Analisis data menunjukkan adanya coronavirus baru, yang diberi nama SARS-CoV-2. Beradasarkan WHO dan CDC pemeriksaan yang digunakan untuk mendeteksi SARS-CoV-2 adalah metode molekular RT-PCR, salah satu kit yang digunakan adalah BioCoV-19 RT-PCR. Penelitian ini bertujuan membandingkan uji RT-PCR kit BioCoV-19 RT-PCR dengan N1N2 CDC sebagai standar dalam mendeteksi SARS-CoV-2, serta melakukan uji deteksi minimal untuk mengetahui sensitivitas analitik dari kit BioCoV-19 RT-PCR, menguji reaksi silang terhadap mikroba saluran nafas lain, dan menilai secara deskriptif karakteristik subjek penelitian. Perbandingan uji kit BioCoV-19 RT-PCR dengan N1N2 CDC mendapatkan nilai sensitivitas, spesifisitas, nilai duga positif (NDP) dan nilai duga negative (NDN). Hasil pada penelitian ini menunjukkan bahwa sensitivitas dan spesifisitas BioCoV-19 RT-PCR Kit secara umum adalah 97,50% dan 100%, dengan Nilai Duga Positif (NDP) 100% dan Nilai Duga Negatif (NDN) 96,49%. Hasil uji minimal deteksi untuk primer-probe N1N2 CDC dan BioCoV-19 RT-PCR Kit setelah dilakukan dilusi bertingat sebanyak enam kali pengenceran yakni 3,5 kopi/reaksi (rerata nilai Ct 35,21). Uji reaksi silang tidak terdeteksi adanya reaksi silang dari 12 bakteri, tujuh virus dan tiga jamur. Karakteristik subjek penelitian lebih banyak pada laki-laki sebanyak (61,5%), untuk usia lebih banyak pada usia berkisar 20-40 tahun (56,29%), gejala klinis pasien saat datang lebih banyak gejala ringan.

.....In December, 2019, a series of pneumonia cases of unknown cause appeared in China. Analysis of the data indicated the presence of a new coronavirus, which was named SARS-CoV-2. Based on WHO and the CDC, the tests used to detect SARS-CoV-2 are the molecular RT-PCR method, one of the kits used is BioCoV-19 RT-PCR. This study aims to compare the RT-PCR test of the BioCoV-19 RT-PCR kit with the CDC's N1N2 as a standard in detecting SARS-CoV-2, as well as to conduct a minimal detection test to determine the analytical sensitivity of the BioCoV-19 RT-PCR kit, to test cross reactions against other respiratory tract microbes, and descriptively assessed the characteristics of the research subjects. Comparison of the BioCoV-19 RT-PCR test kit with N1N2 CDC obtained sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). The results of this study showed that the sensitivity and specificity of the BioCoV-19 RT-PCR Kit in general were 97.50% and 100%, with a positive predictive value (PPV) of 100% and a negative predictive value (NPV) of 96.49%. The minimum test results for detection of the N1N2 CDC primer-probe and the BioCoV-19 RT-PCR Kit were carried out after six dilutions of 3.5 copies/reaction (mean Ct value 35.21). The cross-reaction test did not detect any positives of 12 bacteria, seven viruses and three fungi. The characteristics of the study subjects were more male (61.5%), for ages ranging from 20-40 years (56.29%), the clinical symptoms of the patients when they arrived were more mild symptoms.