Uji kesesuaian real-time reverse transcriptase loop-mediated isothermal amplification iDetectTM SARS-CoV-2 detection kit dengan real-time reverse transcriptase polymerase chain reaction dalam mendeteksi SARS-CoV-2 = Comparison of real-time reverse transcriptase loop-mediated isothermal amplification iDetectTM SARS-CoV-2 detection kit and real-time reverse transcriptase polymerase chain reaction in detecting SARS-CoV-2

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Abstrak

Latar Belakang. Penyakit COVID-19 yang disebabkan oleh SARS-CoV-2 dengan cepat menyebar dan menjadi Pandemi serta menimbukan kerugian yang sangat besar pada masyarakat di seluruh dunia. Deteksi virus yang cepat dan akurat memegang peranan penting untuk mengendalikan penyebaran di masyarakat dan membantu pasien untuk menghindari perkembangan penyakit lebih lanjut. Saat ini real-time Reverse Transcriptase Polymerase Chain Reaction (real-time RT-PCR) merupakan reference standard diagnostic test dalam mendeteksi SARS-CoV-2 di seluruh dunia. Real-time Reverse Transcriptase Loop Mediated Isothermal Amplification (RT-LAMP) merupakan metode amplifikasi asam nukleat isotermal yang memiliki sensitivitas dan spesifisitas tinggi dan waktu pengerjaan yang jauh lebih cepat dibandingkan real-time RT-PCR. Tujuan. Penelitian bertujuan untuk
iDetectTM SARS-CoV-2 Detection Kit
SARS-CoV-2.
Metode. Penelitian ini merupakan uji kesesuaian dengan studi potong lintang dan menggunakan metode pengumpulan sampel secara consecutive sampling. Subjek penelitian yaitu spesimen swab nasofaring dan orofaring dalam VTM (N=80) yang dianalisis di Laboratorium Mikrobiologi Klinik Fakultas Kedokteran Universitas Indonesia. iDetectTM SARS-CoV-2 Detection Kit menggunakan uji kesesuaian Kappa aplikasi SPSS versi 25.
Hasil. Dari 72 sampel valid yang diperiksa dengan real-time RT-LAMP iDetectTM SARS- CoV-2 Detection Kit dan real-time RT-PCR, 24 sampel terdeteksi positif oleh real-time RT-PCR dan hanya tiga sampel yang terdeteksi positif oleh real-time RT-LAMP. Tiga sampel yang terdeteksi positif oleh real-time RT-LAMP termasuk ke dalam sampel - sampel yang terdeteksi positif oleh real-time RT-PCR. Secara statistik, uji reliabilitas / uji kesesuaian dari penelitian kedua alat diagnostik ini menunjukkan nilai Kappa yang sangat rendah, yaitu 0,16. Uji kesesuaian Kappa kedua alat ini menunjukkan bahwa hasil pemeriksaan alat real-time RT-LAMP iDetectTM SARS-CoV-2 Detection Kit tidak sesuai dengan alat real-time RT-PCR dalam mendeteksi SARS-CoV-2. Kesimpulan. Real-time RT-LAMP iDetectTM SARS-CoV-2 Detection Kit tidak sesuai dengan alat real-time RT-PCR dan tidak dapat digunakan sebagai alat diagnostik dalam mendeteksi SARS-CoV-2.
.....Introduction. COVID-19 caused by SARS-CoV-2 quickly spread and became Global Pandemic and caused enormous losses to people around the world. Rapid and accurate virus detection plays an important role in controlling spread in the community and helping patients to avoid further disease progression. Currently, real-time Reverse Transcriptase Polymerase Chain Reaction (real-time RT-PCR) is determined as

the reference standard diagnostic test for detecting SARS-CoV-2 worldwide. Real-time Reverse Transcriptase Loop Mediated Isothermal Amplification (RT-LAMP) is an isothermal nucleic acid amplification method that has high sensitivity and specificity and provide faster result than real-time RT-PCR. Aim. The research aims to compare real-time RT-LAMP iDetectTM SARS-CoV-2 Detection Kit and real-time RT-PCR in detecting SARS-CoV-2. Method. This research is a comparison test with a cross-sectional study and uses a consecutive sampling method to collect samples. The research subjects were nasopharyngeal and oropharynx swab specimens in VTM (N=80) which were analyzed at the Clinical Microbiology Laboratory, Faculty of Medicine, Universitas Indonesia. The data obtained from the real-time RT-LAMP iDetectTM SARS-CoV-2 Detection Kit and real-time RT-PCR test results were analyzed using Kappa test SPSS version 25.
Results. Of the 72 valid samples examined by the real-time RT-LAMP iDetectTM SARS- CoV-2 Detection Kit and real-time RT-PCR, 24 samples were detected positive by real- time RT-PCR and only three samples were detected positive by real-time RT-LAMP. Three samples that were detected positive by the real-time RT-LAMP were included in the samples that were detected positive by the real-time RT-PCR. Statistically, the comparison test of the research of these two diagnostic tools showed a very low Kappa value, which was 0.16. The Kappa suitability test of these two tools showed that the real- time RT-LAMP iDetectTM SARS-CoV-2 Detection Kit were not compatible with the real- time RT-PCR in detecting SARS-CoV-2. Summary. Real-time RT-LAMP iDetectTM SARS-CoV-2 Detection Kit is not compatible with real-time RT-PCR and cannot be used as a diagnostic tool in detecting SARS-CoV-2.