

Uji Teknis Season U-TOPTM COVID-19 Kit untuk Mendeteksi SARS-CoV-2 Menggunakan Protokol Pemantapan Mutu Eksternal Kementerian Kesehatan Republik Indonesia = Technical Test of Season U-TOPTM COVID-19 Kit to Detect SARS-CoV-2 Using External Quality Assurance Protocol Ministry of Health Republic of Indonesia

Aditya Hendrika, author

Deskripsi Lengkap: <https://lib.ui.ac.id/detail?id=20516506&lokasi=lokal>

Abstrak

Penyakit Coronavirus Disease 2019 (COVID-19) merupakan penyakit infeksi saluran pernafasan akut yang ditandai dengan batuk kering, sesak nafas, demam, dan Acute Respiratory Distress Syndrome (ARDS). Penyakit COVID-19 disebabkan oleh infeksi virus SARS-CoV-2 di saluran pernafasan manusia. Menurut Satuan Tugas COVID-19, kasus terkonfirmasi COVID-19 di Indonesia sampai tanggal 28 Juli 2021 sebanyak 3.287.727 pasien dengan penambahan kasus 47.791 pasien baru per hari. Salah satu langkah memperlambat penyebaran tersebut adalah dengan meningkatkan laju deteksi keberadaan virus SARS-CoV-2 berbasis pendeteksian asam nukleat virus SARS-CoV-2. Satuan tugas COVID-19 Indonesia telah merilis daftar kit komersial yang diizinkan beredar untuk deteksi materi genetik virus SARS-CoV-2 salah satunya adalah kit Season U-TOPTM COVID-19 pabrikan dari Season Biomaterials. Korea Selatan. Penelitian ini bertujuan untuk mengetahui baku mutu kit Season dalam mendeteksi virus SARS-CoV-2 di Indonesia. Pengujian baku mutu kit Season dilakukan dengan membandingkan nilai Cycle threshold (Ct) kit Season terhadap kit golden standard US CDC serta uji diagnosis kit Season menggunakan 20 sampel pasien positif COVID-19 dan 10 sampel pasien negatif COVID-19 berdasarkan protokol Pemantapan Mutu Eksternal (PME) Laboratorium COVID-19 Kementerian Kesehatan Republik Indonesia. Hasil analisis nilai Ct menunjukkan bahwa nilai Ct gen HRP dan gen N dari kit Season tidak berbeda signifikan dengan gen N1, gen N2, dan gen HRP dari golden standard US CDC berdasarkan uji ANOVA satu arah ($p > 0,05$; CI = 95%). Uji diagnosis menunjukkan kit Season terdapat hasil negatif palsu pada sampel N00212. Kit Season memiliki tingkat sensitivitas analitik sebesar 95% dan spesifisitas analitik sebesar 100%. Kit Season memiliki nilai baku mutu berada pada rentang nilai yang disetujui dan direkomendasikan oleh WHO serta dapat digunakan untuk kit deteksi SARS-CoV-2 di Indonesia

.....Coronavirus Disease 2019 (COVID-19) is an acute respiratory infectious disease characterized by dry cough, shortness of breath, fever, and Acute Respiratory Distress Syndrome (ARDS). COVID-19 is caused by infection with the SARS-CoV-2 in the human respiratory tract. There were 3.287.727 confirmed cases of COVID-19 in Indonesia on July 28, 2021, with 47.791 new cases per day. The steps to slow the spread is to increase the detection rate of SARS-CoV-2 based on detection of the nucleic acid of the SARS-CoV-2. The Indonesian COVID-19 task force (Satgas COVID-19) has released a list of commercial kits allowed to detect genetic material for the SARS-CoV-2, one of them is the Season U-TOPTM COVID-19 kit. This study aims to determine the quality standard of the Season kit in detecting SARS-CoV-2 in Indonesia. The Season kit quality standard test was carried out by comparing the Cycle threshold (Ct) value of Season kit against the United States CDC golden standard kit and the Season kit diagnostic test using 20 samples of positive and 10 samples of negative COVID-19 patients based on the External Quality Assurance COVID-19 Laboratory protocol of the Ministry of Health of Republic of Indonesia. The results showed that the Ct

values of the HRP gene and the N gene from the Seasun kit were not significantly different from the N1 gene, N2 gene, and the HRP gene from the CDC golden standard based on ANOVA one-way ($p > 0,05$; CI = 95%). The diagnostic test showed that the Seasun kit had false-negative results in sample N00212 so that the Seasun kit had analytical sensitivity of 95% and analytical specificity of 100%. Seasun kit approved and recommended by WHO to become a SARS-CoV-2 detection kit in Indonesia.