Uji banding kit antigen “genbody COVID-19 test Ag®” dengan rRT-PCR untuk deteksi COVID-19 dari spesimen swab nasofaring dan orofaring pada pasien contact tracing COVID-19 = Comparison test of the antigen kit genbody COVID-19 test AgÂ®â with rRT-PCR for COVID-19 detection from nasopharing and oropharing swab specimens in COVID-19 contact tracing patients

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Abstrak

Latar Belakang. Saat ini sedang terjadi pandemi COVID-19 di seluruh dunia, pandemi ini dimulai dari Wuhan, Cina. Virus SARS-CoV-2 penyebab COVID-19 sangat menular dan penyebarannya sangat cepat, sehingga memerlukan penanganan khusus seperti isolasi atau karantina. Gejala penyakit COVID-19 menyerupai gejala infeksi saluran pernapasan akut yang disebabkan oleh patogen lain seperti SARS, influenza, rhinovirus, dll. Diagnosis penyakit COVID-19 perlu ditentukan untuk membedakan dari ISPA yang diakibatkan oleh patogen lain. Beberapa uji diagnostik telah di kembangkan untuk deteksi cepat penyebab COVID-19.
Tujuan. Tujuan penelitian ini adalah membandingkan alat diagnostik kit antigen ”Genbody COVID-19 Test Ag®” dengan rRT-PCR yang menjadi refensi test, untuk mendapatkan alat diagnostik yang murah, cepat dan akurat serta memiliki kemampuan yang setara dengan rRT-PCR.
Metode. Penelitian ini merupakan uji banding dengan desain penelitian potong lintang dan metode pengumpulan spesimen secara consecutive sampling pada pasien contact tracing COVID-19. Penelitian dilakukan di Fasilitas Pelayanan Kesehatan (FASYANKES) Puskesmas Kecamatan Tanah Abang, Sawah Besar, Senen dan Laboratorium Mikrobiologi Klinik (LMK) FKUI pada bulan Oktober 2020-Desember 2020. Sampel penelitian merupakan swab Nasofaring dan oropharing dari pasien contact tracing COVID-19 yang dilakukan pemeriksaan rRT-PCR menggunakan reagen LiliF COVID-19 Real Time PCR kit dan pemeriksaan antigen menggunakan “Genbody COVID-19 Test Ag®”. Analisis penelitian ini menggunakan tabel 2x2.
Hasil. Dari 233 sampel sebanyak 80 (34,33%) sampel positif rRT-PCR dan 53 (22,74%) sampel yang positif pada kit antigen. Kit antigen yang digunakan pada penelitian ini mempunyai sensitivitas 66,25% (55,89-76,61), spesifisitas 100% (100-100), Nilai Duga Positif (NDP) 100% (100-100), Nilai Duga Negatif (NDN) 85% (79,78-90,22) dan akurasi 88,41%. Pada hasil rRT-PCR dengan CT < 20, kit test antigen mempunyai sensitivitas 97,14% (91,62-102,66), spesifisitas 100% (100-100) dan pada CT 21- 30 sensitivitas kit antigen terus menurun.
Kesimpulan. Pemeriksaan COVID-19 menggunakan kit test antigen “Genbody COVID-19 Test Ag®” mempunyai sensitivitas rendah yang tidak sesuai dengan rekomendasi WHO. Kit antigen ini mempunya sensitivitas yang tinggi pada sampel dengan hasil rRT-PCR pada CT rendah (CT <20).
.....Introduction. Currently, the COVID-19 pandemic is happening over the world, this pandemic started in Wuhan, China. The SARS-CoV-2 virus that causes COVID-19 is highly contagious, spreads very quickly and requiring special handling such as isolation or quarantine. The symptoms of COVID-19 resemble an acute respiratory infection caused by other pathogens such as SARS, influenza, rhinovirus, etc. The

diagnosis of COVID-19 disease needs to be determined to distinguish it from acute respiratory infection caused by other pathogens. Several diagnostic tests have been developed for rapid detection of the cause of COVID-19.
Aim. The research aims to compare the antigen kit "Genbody COVID-19 Test Ag®" with rRT-PCR as a reference test to obtain an affordable, fast and accurate diagnostic tool and have equivalent capabilities as rRT-PCR.
Method. The research is a comparative testing with a cross-sectional design and consecutive sampling method for collecting specimens in COVID-19 contact tracing patients. The research was conducted at the Health Service Facility (FASYANKES) Puskesmas Kecamatan Tanah Abang, Sawah Besar, Senen and Laboratorium Mikrobiologi Klinik (LMK) FKUI in October 2020-December 2020. The research samples were nasopharyngeal and oropharyngeal swabs from COVID-19 contact tracing patients who were carried out rRT-PCR test using LiliF COVID-19 Real Time PCR kit and antigen test using “Genbody COVID-19 Test Ag®”. The research analysis used a 2x2 table.
Results. Of the 233 samples, 80 (34.33%) were positive for rRT-PCR and only 53 (22.74%) were positive for the antigen kit. The antigen kit used in this research had a sensitivity of 66.25% (55.89-76.61), specificity 100% (100-100), Positive Prediction Value (NDP) 100% (100-100), Negative Suggestion Value (NDN) 85% (79.78-90.22) and accuracy 88.41%. On the results of rRT-PCR with CT < 20, the antigen test kit had a sensitivity of 97.14% (91.62-102.66), specificity 100% (100-100) and at CT 21-30 the sensitivity of the antigen kit continued to decrease.
Summary. The COVID-19 examination using the “Genbody COVID-19 Test Ag®” antigen test kit has a low sensitivity which is not in accordance with WHO recommendations. This antigen kit has high sensitivity in rRT-PCR results at CT (CT < 20).