

# Evaluasi bio-rad NS1 AG strip sebagai alat diagnostik infeksi dengue akutdenv -2, denv-4 dan campuran di Indonesia = Evaluation of bio-rad NS1 AG strip AS diagnostic kit for denv -2, denv -4 and mixed acute dengue infection in Indonesia

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## Abstrak

Protein Non Struktural-1 (NS-1) dari virus dengue terbukti menjadi penanda untuk diagnosis awal infeksi dengue. Bio-Rad NS1 Ag adalah salah satu alat diagnostik di Indonesia yang menggunakan NS1. Tujuan dari penelitian ini adalah untuk mengukur sensitivitas dan spesifisitas kit pada virus dengue serotype-2 (DENV-2), virus dengue serotype-4 (DENV-4) dan infeksi campuran Uji diagnostik dilakukan selama 36 bulan (Maret 2010 - Februari 2013). Sebanyak 102 pasien dengan demam kurang dari 48 jam memenuhi kriteria inklusi dalam studi ini. Reverse Transcription-Polymerase Chain Reaction (RT-PCR) atau isolasi virus di cell line C6/36 atau kenaikan titer antibody dijadikan sebagai standar baku penentu infeksi dengue. RT-PCR juga digunakan untuk menentukan serotipe virus. Analisis statistik dilakukan dengan menggunakan SPSS versi 17.0. Variabel data binomial disajikan dalam interval kepercayaan 95%. Sensitivitas dan spesifisitas kit diagnostik disajikan dalam tabel 2x2 dan area di bawah kurva (AUC) dari Receiver Operating Characteristics Curve. Dari 102 pasien secara berurutan didapatkan DENV-1, DENV-2, DENV-3 dan DENV-4, adalah 17 (16.7%), 21 (20.5%), 16 (15.7%) dan 4 (3.9%). Pada penelitian ini juga ditemukan infeksi campuran yaitu campuran (i) DENV-1 dan DENV-2, (ii) DENV-1 dan DENV-3, (iii) DENV-1 dan DENV-4, (iv) DENV-1, DENV-3, dan DENV-4, (v) DENV-2 dan DENV-4 dan (vi) serotipe yang tidak diketahui secara berurutan adalah 2 (2.0%), 3 (2.9%), 1 (1.0%), 1 (1.0%), 1 (1.0%), dan 2 (2.0%). Sensitivitas dan spesifisitas masing Bio-Rad NS1 Ag Strip untuk mendeteksi infeksi DENV-2 adalah 76,2% dan 100% (95% CI, 76.8% to 99.3%). Sementara itu, sensitivitas dan spesifisitas strip untuk mendeteksi infeksi DENV-4 adalah 50% dan 100% (95% CI, 50% to 100%). Sensitivitas dan spesifisitas Bio-Rad NS1 Ag Strip pada infeksi campuran adalah 100% (95% CI, 95% to 100%). Bio-Rad NS1 Ag memiliki sensitivitas tinggi dan spesifisitas untuk menentukan infeksi akut DENV-2 dan infeksi campuran. Namun, Bio-Rad NS1 Ag memiliki sensitivitas yang terbatas, namun spesifisitas tinggi untuk diagnosis infeksi akut DENV-4.; Non Structural-1 (NS1) protein of dengue virus is proven to be a marker for early diagnosis of dengue infection. Bio-Rad NS1 Ag Strip is one of the available diagnostic kit in Indonesia that comprised of NS1. The aim of this study was to measure the sensitivity and specificity of the kit within DENV-2, DENV-4 and mixed dengue virus serotypes. This study was done in 36 months (March 2010-

February 2013). There were 102 dengue suspected patients with fever less than 48 hours was fulfilling inclusion criteria. Reverse Transcription- Polymerase Chain Reaction (RT-PCR) or virus isolation in C6/36 cell line or increase titer antibody by ELISA was used as gold standard. RT-PCR was also used to determine serotype of the dengue virus. SPSS version 17.0 was the main statistical tool that we used. Data binominal variables was presented as incidence rates with 95% confidence intervals. Sensitivity and specificity of diagnostic kit was presented in 2x2 tables and area under the curve (AUC) of the Receiver Operating Characteristics Curve. From 102 patients, 68 (68.3%) patients were confirmed positive dengue infection. Within confirmed dengue infection patients by RT-PCR we found DENV-1, DENV-2, DENV-3, DENV-4 17 (16.7%), 21 (20.5%), 16 (15.7%), 4 (3.9%), respectively. It was also found some mixed infection cases, which were (i) DENV-1 and DENV-2, (ii) DENV-1 and DENV-3, (iii) DENV-1 and DENV-4, (iv) DENV-1, DENV-3 and DENV-4, (v) DENV-2 and DENV-4 and (vi) unknown were of 2 (2.0%), 3 (2.9%), 1 (1.0%), 1 (1.0%), 1 (1.0%) and 2 (2.0%), respectively. The sensitivity and specificity of Bio-Rad NS1 Ag Strip for DENV-2 sera collected were 76.2% and 100% (95% CI, 76.8% to 99.3%), respectively. The sensitivity and specificity of Bio-Rad NS1 Ag Strip for DENV-4 were 50% and 100% (95% CI, 50% to 100%), respectively. The sensitivity and specificity of Bio-Rad NS1 Ag Strip for mixed infection were both 100% (95% CI, 95% to 100%). Bio-Rad NS1 Ag Strip has high sensitivity and specificity to determine DENV-2 and mixed infection. On the other hand, Bio-Rad NS1 Ag Strip has limited sensitivity, but high specificity for diagnosis of DENV-4 acute infection; Non Structural-1 (NS1) protein of dengue virus is proven to be a marker for early diagnosis of dengue infection. Bio-Rad NS1 Ag Strip is one of the available diagnostic kit in Indonesia that comprised of NS1. The aim of this study was to measure the sensitivity and specificity of the kit within DENV-2, DENV-4 and mixed dengue virus serotypes. This study was done in 36 months (March 2010-February 2013). There were 102 dengue suspected patients with fever less than 48 hours was fulfilling inclusion criteria. Reverse Transcription- Polymerase Chain Reaction (RT-PCR) or virus isolation in C6/36 cell line or increase titer antibody by ELISA was used as gold standard. RT-PCR was also used to determine serotype of the dengue virus. SPSS version 17.0 was the main statistical tool that we used. Data binominal variables was presented as incidence rates with 95% confidence intervals. Sensitivity and specificity of diagnostic kit was presented in 2x2 tables and area under the curve (AUC) of the Receiver Operating Characteristics Curve. From 102 patients, 68 (68.3%) patients were confirmed positive dengue infection. Within confirmed dengue infection patients by RT-PCR we found DENV-1, DENV-2, DENV-3, DENV-4 17 (16.7%), 21 (20.5%), 16 (15.7%), 4 (3.9%), respectively. It was also found some mixed infection cases, which were (i) DENV-1 and DENV-2, (ii) DENV-1 and DENV-3, (iii) DENV-1 and DENV-4, (iv) DENV-1, DENV-3 and DENV-4, (v) DENV-2 and DENV-4 and

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