ABSTRAK

Latar Belakang : Persyaratan reagen HIV dengan metode Imunokromatografi *Rapid Test* harus memenuhi standar lulus uji prekualifikasi WHO dan evaluasi Badan Evaluator Nasional untuk menjamin kualitas dan keamanannya, sehingga diuji sensitivitas dan spesifiitasnya terhadap metode ECLIA sebagai *Gold Standard.*

Tujuan : Untuk mengetahui sensitivitas dan spesifiitas pemeriksaan HIV metode Imunokromatografi *Rapid Test* terhadap ECLIA di UDD PMI Kota Yogyakarta.

Metode : Analitik observasional dengan pendekatan *cross-sectional* yang dilakukan untuk mengevaluasi hubungan antara Rapid Test dengan metode ECLIA sebagai *gold standard.*, serta menghitung sensitivitas, spesifisitas, PPV, dan NPV secara akurat.

Hasil : Total sampel yang diperiksa sebanyak 30 sampel darah donor. Berdasarkan hasil ECLIA, terdapat 4 sampel darah donor yang teridentifikasi reaktif HIV dan 26 sampel darah donor non reaktif. Dalam penelitian ini, metode Imunokromatografi *Rapid Test* hanya mampu mendeteksi 2 dari 4 kasus yang dikonfirmasi reaktif oleh ECLIA, Imunokromatografi *Rapid Test* diperoleh nilai spesifisitas yang tinggi, yaitu 100%, tetapi nilai sensitivitasnya relatif rendah, yaitu hanya 50%.

Kesimpulan : Nilai sensitivitas pemeriksaan HIV metode Imunokromatografi *Rapid Test* terhadap ECLIA sebesar 50%, sedangkan nilai spesifisitas sebesar 100% sehingga belum memenuhi syarat menurut petunjuk CPOB 2018 khususnya dalam hal spesifisitas, yaitu untuk Imunokromatografi *Rapid Test* harus memiliki spesifisitas lebih dari 98%.

Kata Kunci : HIV, Imunokromatografi *Rapid Test,* ECLIA

ABSTRACT

Background : HIV reagent requirements with the Immunochromatography Rapid Test method must meet the WHO prequalification test pass standards and National Evaluator Agency evaluation to ensure its quality and safety, so that its sensitivity and specificity are tested against the ECLIA method as the Gold Standard.

Objective : To determine the sensitivity and specificity of HIV examination using the Immunochromatography Rapid Test method against ECLIA at the PMI UDD in Yogyakarta City.

Method : Observational analytic with a cross-sectional approach was carried out to evaluate the relationship between the Rapid Test and the ECLIA method as the gold standard, and to calculate sensitivity, specificity, PPV, and NPV accurately.

Results : A total of 30 donor blood samples were examined. Based on the ECLIA results, there were 4 donor blood samples identified as HIV reactive and 26 non-reactive donor blood samples. In this study, the Immunochromatography Rapid Test method was only able to detect 2 out of 4 cases confirmed reactive by ECLIA, the Immunochromatography Rapid Test obtained a high specificity value, which was 100%, but the sensitivity value was relatively low, which was only 50%.

Conclusion : The sensitivity value of the HIV examination using the Immunochromatography Rapid Test method against ECLIA was 50%, while the specificity value was 100% so that it did not meet the requirements according to the 2018 CPOB instructions, especially in terms of specificity, namely for the Immunochromatography Rapid Test must have a specificity of more than 98%.

Keywords : HIV, Immunochromatography Rapid Test, ECLA