

ABSTRACT

Background: Clinical laboratories played an important role in supporting patient diagnosis and monitoring through high-quality biological sample examinations. Budget efficiency regulations encouraged laboratories to modify examination procedures, one of which was the implementation of half-volume reagents and samples in uric acid testing using the TBHBA (2,4,6-tribromo-3-hydroxybenzoic acid) method. However, validation of this modified method had never been conducted, even though ISO 17025 required revalidation for every change in a standard method.

Objective: This study aimed to determine the linearity, precision, Limit of Detection (LoD), and Limit of Quantitation (LoQ) values of the TBHBA (2,4,6-tribromo-3-hydroxybenzoic acid) method in uric acid examination with modified half-volume reagents and samples to ensure its feasibility as a validated method in clinical laboratories.

Methods: This study used a descriptive analytical method with control serum diluted into five concentration levels for the linearity test, low- and high-level control sera for the precision test, and blank samples for the LoD and LoQ tests. All data were processed using Microsoft Excel.

Results: The linearity test results showed an R^2 value of 0.9987, which met the acceptance criteria. The CV value for the low-concentration control serum was 4.35%, which did not meet the TEa limit ($\leq 3.3\%$), whereas the CV value for the high-concentration control serum was 3.04%, which met the criteria. The LoD and LoQ values obtained were 0,26 mg/dL and 0,78 mg/dL, respectively.

Conclusion: The TBHBA (2,4,6-tribromo-3-hydroxybenzoic acid) method for uric acid analysis, with a modification involving half the volume of reagent and sample, exhibits excellent linearity; however, the precision of this method is not yet fully optimal because the CV value for the low-concentration control serum does not meet the acceptance limit.

Keywords: Linearity, Precision, LoD, LoQ, Uric acid.

ABSTRAK

Latar Belakang: Laboratorium klinik berperan penting dalam mendukung diagnosis dan pemantauan pasien melalui pemeriksaan sampel biologis yang bermutu. Regulasi efisiensi anggaran mendorong laboratorium memodifikasi prosedur pemeriksaan, salah satunya dengan menerapkan setengah volume reagen dan sampel pada pemeriksaan asam urat metode TBHBA (*2,4,6-tribromo-3-hydroxybenzoic acid*). Namun, validasi terhadap metode modifikasi ini belum pernah dilakukan, padahal ISO 17025 mewajibkan revalidasi pada setiap perubahan metode standar.

Tujuan Penelitian: Mengetahui linieritas, presisi, nilai *Limit of Detection* (LoD), dan nilai *Limit of Quantitation* (LoQ) metode TBHBA (*2,4,6-tribromo-3-hydroxybenzoic acid*) pada pemeriksaan asam urat dengan modifikasi setengah volume reagen dan sampel untuk memastikan kelayakannya sebagai metode tervalidasi di laboratorium klinik.

Metode Penelitian: Penelitian ini menggunakan metode deskriptif analitik dengan objek berupa serum kontrol yang diencerkan pada lima tingkat konsentrasi untuk uji linieritas, serum kontrol kadar rendah dan tinggi untuk uji presisi, serta sampel blank untuk uji LoD dan LoQ, yang seluruh datanya diolah menggunakan Microsoft Excel.

Hasil Penelitian: Hasil uji linieritas menunjukkan nilai R^2 sebesar 0,9987 yang memenuhi syarat keberterimaan. Nilai CV serum kontrol kadar rendah sebesar 4,35% belum memenuhi batas keberterimaan presisi ($\leq 3,3\%$), sedangkan serum kadar kontrol tinggi sebesar 3,04% telah memenuhi kriteria tersebut. Nilai LoD dan LoQ yang diperoleh masing-masing sebesar 0,26 mg/dL dan 0,78 mg/dL.

Kesimpulan: Metode TBHBA (*2,4,6-tribromo-3-hydroxybenzoic acid*) pada pemeriksaan asam urat dengan modifikasi setengah volume reagen dan sampel memiliki linieritas yang sangat baik, namun presisi metode ini belum sepenuhnya optimal karena nilai CV pada serum kontrol kadar rendah belum memenuhi batas keberterimaan.

Kata Kunci: Linieritas, Presisi, LoD, LoQ, Asam urat.