

ABSTRAK

Latar Belakang: Pemantapan mutu internal (PMI) merupakan upaya penting dalam menjamin keakuratan dan ketelitian hasil pemeriksaan laboratorium. Keterbatasan bahan kontrol komersial mendorong penggunaan alternatif seperti *pooled* serum. Namun, *pooled* serum dalam bentuk cair memiliki stabilitas yang terbatas sehingga perlu diproses dengan metode kering beku (liofilisasi) untuk meningkatkan daya simpannya.

Tujuan Penelitian: Mengetahui pemanfaatan *pooled* serum yang diproses kering beku dan disimpan selama 2 bulan pada suhu 2–8°C sebagai bahan kontrol kualitas laboratorium pada parameter *Aspartate Aminotransferase (AST)*.

Metode Penelitian: Penelitian ini merupakan *pre-eksperimental* dengan desain *one group pretest-posttest without control*. Uji homogenitas dilakukan sebelum penyimpanan menggunakan 10 sampel secara duplo, sedangkan uji stabilitas dilakukan setelah penyimpanan selama 2 bulan menggunakan 5 sampel secara duplo. Analisis data dilakukan secara deskriptif dan berdasarkan standar ISO 13528:2015.

Hasil Penelitian: Rerata kadar *AST* sebelum penyimpanan sebesar 25,15 U/L dan setelah penyimpanan sebesar 25,40 U/L. Uji homogenitas menunjukkan nilai S_s sebesar 0,000000 yang memenuhi kriteria ($S_s \leq 0,3\sigma_{pt}$). Uji stabilitas menunjukkan nilai $|X_r - Y_r| \leq 0,3\sigma_{pt}$ yaitu $0,25 \leq 2.088932$, sehingga memenuhi kriteria stabilitas.

Kesimpulan: *Pooled* serum yang diproses kering beku dan disimpan selama 2 bulan pada suhu 2–8°C bersifat homogen dan stabil, sehingga layak digunakan sebagai bahan kontrol kualitas laboratorium pada parameter *AST*.

Kata kunci: *pooled* serum, liofilisasi, stabilitas, homogenitas, pemantapan mutu internal

ABSTRACT

Background: Internal quality control (IQC) is an essential effort to ensure the accuracy and precision of laboratory test results. The limited availability of commercial control materials has encouraged the use of alternative materials such as pooled serum. However, liquid pooled serum has limited stability, thus requiring processing using a freeze-drying (lyophilization) method to improve its shelf life.

Objective: To evaluate the utilization of freeze-dried pooled serum stored for 2 months at 2–8°C as a laboratory quality control material for the Aspartate Aminotransferase (AST) parameter.

Methods: This study was a pre-experimental design using a one group pretest-posttest without control approach. Homogeneity testing was conducted prior to storage using 10 samples in duplicate, while stability testing was performed after 2 months of storage using 5 samples in duplicate. Data were analyzed descriptively based on the ISO 13528:2015 standard.

Results: The mean AST level before storage was 25.15 U/L and after storage was 25.40 U/L. The homogeneity test showed a between-sample standard deviation (Ss) of 0.000000, which met the acceptance criteria ($Ss \leq 0.3\sigma_{pt}$). The stability test showed that the difference value $|X_r - Y_r| \leq 0.3\sigma_{pt}$, specifically $0.25 \leq 2.088932$, indicating that the stability criteria were fulfilled.

Conclusion: Freeze-dried pooled serum stored for 2 months at 2–8°C is homogeneous and stable, thus suitable for use as a laboratory quality control material for the AST parameter.

Keywords: pooled serum, lyophilization, stability, homogeneity, internal quality control