

ABSTRACT

Background: Clinical laboratories require daily Quality Control (QC) to maintain the accuracy of laboratory examinations, however, commercially available control materials are relatively expensive and often inconsistently available. As an alternative control material, lyophilized pooled serum derived from patients' residual samples can be used because it is more stable than liquid pooled serum, which is susceptible to contamination and analyte degradation during storage.

Objective: This study aimed to determine the homogeneity and stability of lyophilized pooled serum after 3 months of storage at 2-8°C.

Method: The research design used was pre-experimental with a One-Group Pretest-Posttest Without Control design. The data obtained were primary data and analyzed based on ISO 13528:2015, where homogeneity was assessed using the between-sample standard deviation value ($S_s \leq 0.3 \sigma$), and stability was assessed using the difference between the mean values before and after storage ($|X_r - Y_r| \leq 0.3 \sigma$).

Result: The sample was declared homogeneous as it met the criteria of $S_s \leq 0,3 \sigma$, with a value of $0,903450 \leq 1,894898$. Conversely, the sample was declared unstable after 3 months of storage at 2-8°C because it did not meet the criteria of $|X_r - Y_r| \leq 0,3 \sigma$, resulting in $4,605000 \not\leq 1,894898$.

Conclusion: Urea levels in the lyophilized pooled serum were found to be homogeneous but unstable after 3 months of storage at 2-8°C.

Keyword: Homogeneity, Stability, Pooled Serum, Lyophilized, Urea Levels

ABSTRAK

Latar Belakang: Laboratorium klinik memerlukan *Quality Control* (QC) harian untuk menjaga akurasi pemeriksaan, namun bahan kontrol komersial yang umum digunakan relatif mahal dan ketersediaannya sering kali tidak konsisten. Sebagai alternatif bahan kontrol, dapat digunakan *pooled serum* liofilisat dari sisa sampel pasien, karena lebih stabil dibandingkan *pooled serum* cair yang rentan terhadap kontaminasi dan penurunan kadar analit selama penyimpanan.

Tujuan: Penelitian ini bertujuan untuk mengetahui homogenitas dan stabilitas *pooled serum* liofilisat setelah disimpan selama 3 bulan pada suhu 2-8°C.

Metode: Jenis penelitian yang digunakan adalah *pre-experimental* dengan desain penelitian *One Group Pretest-Posttest Without Control*. Data yang diperoleh merupakan data primer dan dianalisis berdasarkan ISO 13528:2015, dimana homogenitas dinilai dari nilai simpangan baku antar sampel ($S_s \leq 0,3 \sigma_{pt}$), dan stabilitas dinilai dari selisih rata-rata sebelum dan sesudah penyimpanan ($|X_r - Y_r| \leq 0,3 \sigma_{pt}$).

Hasil: Sampel dinyatakan homogen karena memenuhi kriteria $S_s \leq 0,3 \sigma_{pt}$ yaitu $0,903450 \leq 1,894898$. Sampel dinyatakan tidak stabil setelah disimpan selama 3 bulan pada suhu 2-8°C karena tidak memenuhi kriteria $|X_r - Y_r| \leq 0,3 \sigma_{pt}$ yaitu $4,605000 \not\leq 1,894898$.

Kesimpulan: Kadar Ureum pada *pooled serum* liofilisat dinyatakan homogen namun tidak stabil setelah disimpan selama 3 bulan pada suhu 2-8°C.

Kata Kunci: Homogenitas, Stabilitas, *Pooled Serum*, Liofilisat, Kadar Ureum