

ABSTRACT

Background: Clinical laboratories require quality assurance of test results through quality control using control materials. However, commercial control materials are relatively expensive and limited in availability. Pooled serum is an alternative because its composition is similar to human specimens. The addition of 0.1% Sodium Azide (NaN_3) is expected to inhibit the growth of microorganisms to maintain stability during storage.

Objective: To determine the homogeneity and stability of freeze-dried processed pooled serum so that it can be used for medical laboratory quality control in glucose examination for 2 months (8 weeks).

Methods: This research is a pre-experimental type with a one-group pretest-posttest design. Data analysis used homogeneity and stability test calculations according to ISO 13528:2015 standards. The material is declared homogeneous if $S_s \leq 0,3\sigma$ and stable if the value $|X_r - Y_r| \leq 0,3 \sigma_{pt}$. The σ value is determined based on the CVHorwitz calculation.

Results: The homogeneity test of pooled serum showed a general average value (X_r) of 119.85 mg/dL with a between-sample standard deviation (S_s) of 0.36515, which met the requirement of $S_s \leq 0,3\sigma$ (1.16774). In the stability test after 2 months of storage, an average value (Y_r) of 119.33 mg/dL was obtained with a difference $|X_r - Y_r|$ of 0.52 mg/dL. This value is smaller than the tolerance limit of $0,3\sigma$ (1.16774).

Conclusion: Pooled serum with the addition of 0.1% NaN_3 was declared homogeneous and stable for glucose level examination after being stored for 2 months, so it can be used as a laboratory quality control material.

Keywords: pooled serum, homogeneity, stability, control serum, NaN_3 , glucose

ABSTRAK

Latar Belakang: Laboratorium klinik memerlukan jaminan mutu hasil pemeriksaan melalui *quality control* menggunakan bahan kontrol. Namun, bahan kontrol komersial relatif mahal dan ketersediaannya terbatas. *Pooled serum* menjadi alternatif karena komposisinya yang mirip dengan spesimen manusia. Penambahan Natrium Azida (NaN_3) 0,1% diharapkan dapat menghambat pertumbuhan mikroorganisme guna menjaga stabilitas selama masa penyimpanan.

Tujuan: Mengetahui homogenitas dan stabilitas *pooled serum* yang diproses kering beku sehingga dapat digunakan untuk kontrol kualitas laboratorium medis pada pemeriksaan glukosa selama 2 bulan (8 minggu).

Metode: Jenis penelitian ini adalah *pre-eksperimental* dengan desain *one group pretest-posttest*. Analisis data menggunakan perhitungan uji homogenitas dan stabilitas sesuai standar ISO 13528:2015. Bahan dinyatakan homogen apabila $S_s \leq 0,3\sigma$ dan stabil apabila nilai $|X_r - Y_r| \leq 0,3 \sigma_{pt}$. Nilai σ ditentukan berdasarkan perhitungan CV_{Horwitz} .

Hasil: Uji homogenitas *pooled serum* menunjukkan nilai rata-rata umum (X_r) 119,85 mg/dL dengan standar deviasi *between sample* (S_s) sebesar 0,36515, yang memenuhi syarat $S_s \leq 0,3\sigma$ (1,16774). Pada uji stabilitas setelah penyimpanan 2 bulan, diperoleh nilai rata-rata (Y_r) 119,33 mg/dL dengan selisih $|X_r - Y_r|$ sebesar 0,52 mg/dL. Nilai tersebut lebih kecil dari batas toleransi $0,3\sigma$ (1,16774).

Kesimpulan: *Pooled serum* dengan penambahan NaN_3 0,1% dinyatakan homogen dan stabil terhadap pemeriksaan kadar glukosa setelah disimpan selama 2 bulan, sehingga dapat digunakan sebagai bahan kontrol kualitas laboratorium.

Kata Kunci: *pooled serum*, homogenitas, stabilitas, serum kontrol, NaN_3 , glukosa