

PEMANFAATAN *POOLED* SERUM YANG DI PROSES KERING BEKU
UNTUK BAHAN KONTROL KUALITAS LABORATORIUM MEDIS
PARAMETER ALT

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ABSTRAK

Latar Belakang: Laboratorium klinik memiliki peran penting dalam menunjang diagnosis dan pemantauan penyakit melalui hasil pemeriksaan yang akurat dan presisi. Bahan kontrol komersial memiliki keterbatasan berupa biaya yang relatif mahal, sehingga diperlukan alternatif yang lebih ekonomis. Pooled serum yang diproses dengan metode kering beku (liofilisasi) berpotensi menjadi bahan kontrol alternatif karena berasal dari serum manusia dan memiliki karakteristik yang mendekati spesimen pasien pada pemeriksaan Alanine Aminotransferase (ALT).

Tujuan Penelitian: Untuk mengetahui homogenitas dan stabilitas *pooled* serum yang diproses kering beku sebagai bahan kontrol kualitas laboratorium medis pada parameter ALT.

Metode Penelitian: Penelitian ini merupakan penelitian pre-eksperimental dengan desain one group pretest-posttest. Sampel berupa pooled serum yang diproses menggunakan metode kering beku (liofilisasi) dan disimpan pada suhu 2–8°C selama 2 bulan. Pemeriksaan kadar *Alanine Aminotransferase* (ALT) dilakukan sebelum penyimpanan untuk uji homogenitas dan setelah penyimpanan untuk uji stabilitas. Data dianalisis secara deskriptif berdasarkan standar ISO 13528:2015. Sampel dinyatakan homogen dan stabil apabila memenuhi kriteria penerimaan ISO 13528:2015.

Hasil Penelitian: Rerata kadar ALT sebelum penyimpanan sebesar 14,05 U/L dan setelah penyimpanan sebesar 13,50 U/L dengan selisih 0,55. Hasil uji homogenitas menunjukkan nilai standar deviasi antar sampel (Ss) sebesar 0,60 lebih kecil dari batas penerimaan ($0,3\sigma = 0,81$), sehingga dinyatakan homogen. Hasil uji stabilitas menunjukkan nilai $|X_r - Y_r|$ sebesar 0,42 lebih kecil dari batas penerimaan 0,81, sehingga dinyatakan stabil.

Kesimpulan : *Pooled* serum yang diproses dengan metode kering beku (*liofilisasi*) memenuhi kriteria homogenitas dan stabilitas berdasarkan ISO 13528:2015, sehingga dapat digunakan sebagai bahan kontrol kualitas alternatif pada pemeriksaan ALT di laboratorium medis.

Kata kunci : *Pooled serum, Liofilisasi, ALT, Homogenitas, Stabilitas, Quality Control*

UTILIZATION OF *POOLED* SERUM PROCESSED BY FREEZE DRYING FOR MEDICAL LABORATORY QUALITY CONTROL MATERIAL ALT PARAMETER

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ABSTRACT

Introduction : Clinical laboratories play a crucial role in supporting disease diagnosis and monitoring through accurate and precise test results. Commercial control materials are limited by their relatively high cost, necessitating more economical alternatives. Pooled serum processed by freeze-drying (lyophilization) has the potential to be an alternative control material because it is derived from human serum and has characteristics similar to those of patient specimens used in alanine aminotransferase (ALT) testing.

Purpose: To determine the homogeneity and stability of freeze-dried pooled serum as a quality control material in medical laboratories for the ALT parameter.

Methods: This study was a pre-experimental study with a one-group pretest-posttest design. The samples were pooled serum processed using the freeze-drying method (lyophilization) and stored at 2–8°C for 2 months. Alanine Aminotransferase (ALT) levels were measured before storage for homogeneity testing and after storage for stability testing. Data were analyzed descriptively based on the ISO 13528:2015 standard. Samples were considered homogeneous and stable if they met the ISO 13528:2015 acceptance criteria.

Result: The mean ALT level before storage was 14,05 U/L and after storage was 13.50 U/L, with a difference of 0,55. The homogeneity test showed that the between-sample standard deviation (Ss) was 0,60 which was lower than the acceptance limit ($0,3\sigma = 0.801$), indicating that the samples were homogeneous. The stability test showed that the value of $|X_r - Y_r|$ was 0,42, which was lower than the acceptance limit (0.81), indicating that the samples were stable.

Conclusion: Freeze-dried *pooled* serum meets the homogeneity and stability criteria based on ISO 13528:2015 and has the potential to be used as an alternative quality control material for ALT testing in medical laboratories.

Keywords: *Pooled serum, Lyophilization, ALT, Homogeneity, Stability, Quality Control*