

# **HOMOGENEITY AND STABILITY TEST OF POOLED PLASMA ETHYLENEDIAMINETETRAACETIC ACID (EDTA) AS A REQUIREMENT FOR CONTROL MATERIAL IN ALANINE AMINOTRANSFERASE (ALT) ACTIVITY EXAMINATION**

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## **ABSTRACT**

**Background:** Internal quality control in clinical laboratories is essential to ensure accurate and precise test results. Pooled plasma EDTA is an innovative and economical material that utilizes leftover patient plasma, thereby reducing waste and potentially serving as an alternative control material.

**Objective:** This study aims to determine the homogeneity and stability of pooled plasma EDTA as a control material for alanine aminotransferase (ALT) enzyme activity.

**Method:** This descriptive study used pooled EDTA plasma from healthy university students. Homogeneity test was performed on 10 samples randomly and duplo. The stability test was conducted for four weeks at  $-16^{\circ}\text{C}$  to  $-20^{\circ}\text{C}$  with 3 samples per week which were also examined in duplicate. Data were analyzed using the ISO 13528:2015 standard formula.

**Results:** The samples were declared homogeneous with  $S_s \leq 0.3\sigma$  ( $S_s = 0.612762$ ;  $0.3\sigma = 0.7888$ ). Pooled EDTA plasma stored for one and two weeks was stable with  $|X_r - Y_r| \leq 0.3\sigma$ . However, samples stored for three and four weeks exceeded the  $0.3\sigma$  threshold, which was declared unstable. The final homogeneity test after 4 weeks showed  $S_s \leq 0.3\sigma$  ( $S_s = 1.304641 \leq 0.3\sigma = 0.758656521$ ), which was declared inhomogeneous.

**Conclusion:** Pooled plasma EDTA does not qualify as a control material because it is only homogeneous and stable up to two weeks of storage at  $-16^{\circ}\text{C}$  to  $-20^{\circ}\text{C}$ .

**Key words:** Homogeneity, stability, EDTA pooled plasma, ALT, control material.

**UJI HOMOGENITAS DAN STABILITAS *POOLED PLASMA*  
*Ethylenediaminetetraacetic Acid* (EDTA) SEBAGAI SYARAT BAHAN  
KONTROL TERHADAP AKTIVITAS *Alanine Aminotransferase* (ALT)**

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**ABSTRAK**

**Latar Belakang:** Pengendalian mutu internal di laboratorium klinik sangat penting untuk memastikan hasil pemeriksaan yang akurat dan presisi. Pooled plasma EDTA merupakan bahan inovatif dan ekonomis yang memanfaatkan sisa plasma pasien, sehingga mengurangi limbah dan berpotensi sebagai bahan kontrol alternatif.

**Tujuan:** Penelitian ini bertujuan untuk mengetahui homogenitas dan stabilitas pooled plasma EDTA sebagai syarat bahan kontrol terhadap aktivitas enzim alanine aminotransferase (ALT).

**Metode:** Penelitian deskriptif ini menggunakan pooled plasma EDTA dari mahasiswa yang sehat. Uji homogenitas dilakukan pada 10 sampel secara acak dan duplo. Uji stabilitas dilakukan selama empat minggu pada suhu  $-16^{\circ}\text{C}$  hingga  $-20^{\circ}\text{C}$  dengan 3 sampel per minggu yang juga diperiksa secara duplo. Data dianalisis menggunakan rumus standar ISO 13528:2015.

**Hasil:** Sampel dinyatakan homogen dengan hasil  $S_s \leq 0,3\sigma$  ( $S_s = 0,612762$ ;  $0,3\sigma = 0,7888$ ). Pooled plasma EDTA yang disimpan selama satu dan dua minggu dinyatakan stabil dengan  $|X_r - Y_r| \leq 0,3\sigma$ . Namun, sampel yang disimpan selama tiga dan empat minggu melebihi ambang batas  $0,3\sigma$ , yang dinyatakan tidak stabil. Pengujian homogenitas akhir setelah 4 minggu menunjukkan  $S_s \leq 0,3\sigma$  ( $S_s = 1,304641 \leq 0,3\sigma = 0,758656521$ ) yang dinyatakan tidak homogen.

**Kesimpulan:** Pooled plasma EDTA tidak memenuhi syarat sebagai bahan kontrol karena hanya homogen dan stabil hingga penyimpanan dua minggu pada suhu  $-16^{\circ}\text{C}$  hingga  $-20^{\circ}\text{C}$ ,

**Kata Kunci:** Homogenitas, stabilitas, pooled plasma EDTA, ALT, bahan kontrol