

ABSTRACT

Background : One aspect of strengthening laboratory quality is the use of control materials as monitoring of inspection performance. The use of control materials can support the improvement of laboratory quality because it is directly involved in the implementation of internal quality control of a laboratory. In this study using normal control materials then made into abnormal. The abnormal control material in its manufacture is dissolved using distilled water according to the calculation concentration obtained. to determine the tolerance of an examination.

Objective : The purpose of this study was to determine the homogeneity and stability of the abnormal control made with the normal control in the examination of total cholesterol stored for 4 weeks and 8 weeks.

Methods : In this study, descriptive research was used with the object of research, namely normal control serum samples. Data analysis used the calculation of homogeneity and stability tests according to ISO 13528: 2015.

Result : Based on ISO 13528: 2015, the control serum is declared homogeneous if it meets the requirements of $S_s \leq 0.3\sigma$. The homogeneity test calculation obtained results of $0.296461 \leq 0.627302556$ (low), $0.45375 \leq 0.571342256$ (normal) and $2.515154 > 0.566597995$ (high). The results are declared homogeneous at low and normal levels and not homogeneous at high levels. In the stability test, the results are declared stable if they meet the conditions $|X_r - Y_r| \leq 0.3 \sigma$. The results of the normal level stability test are $0.4375 \leq 0.571342256$ (4 weeks) and $0.5125 \leq 0.571342256$ (8 weeks), at the low level obtained $0.2675 \leq 0.627302556$ (4 weeks) and $0.305 \leq 0.627302556$ (8 weeks), at the high level $5.7975 > 0.566597995$ (4 weeks) and $6.1975 > 0.566597995$ (8 weeks). Results were stable at low and normal levels and unstable at high levels.

Conclusion : Normal and low level control serum in total cholesterol examination were homogeneous and stable at 4 and 8 weeks of storage at -20°C . Results were not homogeneous and unstable in high level control serum.

Keywords: Control material, homogeneity, stability, total cholesterol, abnormal

ABSTRAK

Latar Belakang: Salah satu aspek pemantapan kualitas laboratorium yaitu penggunaan bahan kontrol sebagai pemantauan kinerja pemeriksaan. Penggunaan bahan kontrol dapat menunjang peningkatan kualitas laboratorium karena terlibat langsung dalam penyelenggaraan kendali mutu internal suatu laboratorium. Pada penelitian ini menggunakan bahan kontrol normal kemudian dibuat menjadi abnormal. Bahan kontrol abnormal dalam pembuatannya dilarutkan menggunakan aquadest sesuai konsentrasi perhitungan yang didapat. Untuk mengetahui toleransi suatu pemeriksaan.

Tujuan: Tujuan penelitian ini untuk mengetahui homogenitas dan stabilitas kontrol abnormal yang dibuat dengan kontrol normal pada pemeriksaan kolesterol total yang disimpan selama 4 minggu dan 8 minggu.

Metode: Dalam penelitian ini digunakan jenis penelitian deskriptif dengan objek penelitian yaitu sampel serum kontrol normal. Analisis data menggunakan perhitungan uji homogenitas dan stabilitas menurut ISO 13528:2015.

Hasil: Berdasarkan ISO 13528:2015 serum kontrol dinyatakan homogen jika memenuhi syarat $S_s \leq 0,3\sigma$. Perhitungan uji homogenitas didapatkan hasil $0,296461 \leq 0,627302556$ (*low*), $0,45375 \leq 0,571342256$ (*normal*) dan $2,515154 > 0,566597995$ (*high*). Hasil dinyatakan homogen pada level *low* dan *normal* serta tidak homogen pada level *high*. Pada uji stabilitas hasil dinyatakan stabil jika memenuhi syarat $|X_r - Y_r| \leq 0,3\sigma$. Hasil uji stabilitas level *normal* yaitu $0,4375 \leq 0,571342256$ (4 minggu) dan $0,5125 \leq 0,571342256$ (8 minggu), pada level *low* didapatkan $0,2675 \leq 0,627302556$ (4 minggu) dan $0,305 \leq 0,627302556$ (8 minggu), pada level *high* $5,7975 > 0,566597995$ (4 minggu) dan $6,1975 > 0,566597995$ (8 minggu). Hasil dinyatakan stabil pada level *low* dan *normal* serta tidak stabil pada level *high*.

Kesimpulan: Serum kontrol level *normal* dan *low* pada pemeriksaan kolesterol total hasilnya homogen dan stabil pada penyimpanan 4 dan 8 minggu suhu -20°C . Hasil tidak homogen dan tidak stabil pada serum kontrol level *high*.

Kata Kunci: Bahan kontrol, homogenitas, stabilitas, kolesterol total, abnormal