

ABSTRAK

Bahan kontrol digunakan sebagai indikator pemantauan kinerja pemeriksaan laboratorium agar hasil yang dikeluarkan valid. Metode penilaian pelaksanaan Pemantapan Mutu Eksternal (PME) menggunakan *Variance Index Score* (VIS). Mahalnya bahan kontrol membuat laboratorium terkendala dalam pengadaanya. Penelitian ini bertujuan untuk mengetahui perbedaan *pooled sera*, liofilisat buatan sendiri dan komersial pada parameter AST dan ALT berdasarkan VIS. Jenis penelitian menggunakan deskriptif komparatif dengan pendekatan kuantitatif. Penelitian dilaksanakan pada Desember 2023-Mei 2024. Pembuatan liofilisat buatan sendiri dilakukan di laboratorium teknobiologi UBAYA, penentuan *true value* dilakukan di 2 laboratorium reference dan laboratorium kimia klinik Poltekkes Surabaya serta penentuan VIS dilakukan di 10 laboratorium klinik tingkat pertama wilayah Surabaya Raya yang ditentukan secara *purposive sampling*. Kriteria berdasarkan VIS terhadap *true value* pada *pooled sera* parameter AST didapatkan 100% baik, ALT didapatkan 60% baik, 30% cukup, 10% kurang. Pada liofilisat buatan sendiri parameter AST diperoleh 80% baik, 20% cukup, ALT didapatkan 50% baik, 50% cukup. Pada liofilisat komersial parameter AST didapatkan 70% baik, 30% cukup, ALT diperoleh 90% baik, 10% cukup. Kriteria berdasarkan VIS terhadap seluruh peserta pada *pooled sera* parameter AST dan ALT didapatkan 100% baik. Pada liofilisat buatan sendiri parameter AST diperoleh 80% baik, 20% cukup dan ALT didapatkan 70% baik, 30% cukup. Pada liofilisat komersial parameter AST didapatkan 80% baik, 20% cukup dan ALT diperoleh 90% baik, 10% cukup. Hasil analisis statistik menunjukkan tidak terdapat perbedaan antara bahan kontrol buatan sendiri dan komersial berdasarkan VIS terhadap *true value* maupun seluruh laboratorium peserta sehingga disimpulkan bahan kontrol buatan sendiri dapat dijadikan pengganti dalam implementasi PME.

Kata Kunci: *pooled sera*, liofilisat buatan sendiri, liofilisat komersial, AST, ALT, VIS

ABSTRACT

Control materials are used as indicators of monitoring the performance of laboratory examinations so that the results issued are valid. Method of assessing the implementation of External Quality Assurance (EQAS) used Variance Index Score (VIS). The high cost of control materials makes the laboratory constrained in its procurement. This study aims to determine difference between pooled sera, homemade and commercial lyophilizates on AST and ALT parameter based on VIS. This research used comparative descriptive with quantitative approach. Reasearch conducted in December 2023-May 2024. Homemade lyophilizates performed at UBAYA technobiology laboratory, determination of true value performed at 2 reference laboratories and clinical chemistry laboratory Poltekkes Surabaya, and determination of VIS performed at 10 primary level clinical laboratories in Surabaya raya which determined by purposive sampling. Criteria based on VIS to true value in pooled sera AST parameters obtained 100% good, ALT obtained 60% good, 30% sufficient, 10% less. In homemade lyophilizate, AST parameters obtained 80% good, 20% sufficient, ALT obtained 50% good, 50% sufficient. In commercial lyophilizate, AST parameters were 70% good, 30% fair, ALT was 90% good, 10% fair. Criteria based on VIS of all participants in pooled sera AST and ALT parameters obtained 100% good. In homemade lyophilizate, AST parameters were 80% good, 20% fair and ALT parameters were 70% good, 30% fair. In commercial lyophilizate, the AST parameter was 80% good, 20% fair and ALT was 90% good, 10% fair. The results of statistical analysis showed there was no difference between homemade and commercial control materials based on VIS to the true value and all participating laboratories, so it was concluded that homemade control materials could be used as a substitute in implementing EQAS.

Keywords: *pooled sera, homemade lyophilizate, commercial lyophilizate, AST, ALT, VIS*