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Assessment of Dilutional Linearity of Six Common Serum Tumour Markers Using Commercial Diluents and Pooled Serum on Automated Immunoassay Platforms

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Background: Tumour markers are produced in the body on cancers and quantified in laboratories for diagnosis of malignancies. If concentrations of markers lie beyond the analytical ranges, dilutions are performed. The dilutional linearity, the deviation of concentrations by dilutions, indicates the accuracy and it should be excellent to obtain readings of dilutions as analyte concentrations. The dilutions are performed in small dilution factors instead of maximum dilution factors (MDFs) which give high accuracy by diluting interfering substances. But the use of MDFs requires a high volume of diluents. Therefore, the determination of MDFs and cost-effective alternative diluents are important for routine laboratory settings**.**

Objectives: To assess dilutional linearities and define MDFs for selected six tumour markers using commercial diluents and pooled human serum on automated platforms

Methods: The requests received to Teaching Hospital-Karapitiya within 3 months (October-December, 2019) were counted to find the number of dilution-required samples. Retained samples (n = 7 per marker) with high concentrations of analyte [Carbohydrate Antigen 125 (CA-125), Prostate-Specific Antigen (PSA), Ferritin, Thyroglobulin (TG), Alpha-fetoprotein (AFP) and β-Human Chorionic Gonadotropin (β-HCG)] were diluted as 1:10,1:20,1:50,1:100 and 1:200 using commercial diluents and in-house prepared serum pool and analyzed in automated analyzers (Snibe Maglumi 1000 and Vitros 3600 analyzers). Non-parametric and recovery studies were performed.

Results: The 5-15% of received samples were required dilutions within 3 months. The Kendall's coefficients were nearby 1 (0.921-0.995), illustrating satisfied dilutional linearities of assays. There were no significant differences (p >0.05) among results generated by diluents and pooled serum. The acceptable MDFs were defined by considering "mean recovery percentages" and "*p*-values". The acceptable MDFs for β-HCG, AFP, TG, ferritin and CA-125 were 1:50, 1:20, 1:50, 1:20 and 1:20 respectively in commercial diluents. The acceptable MDFs for β-HCG, AFP, PSA, TG, ferritin and CA-125 were 1:50, 1:200, 1:200, 1:50, 1:100 and 1:100 respectively in pooled serum.

Conclusions: The pooled serum can be used with high MDFs as 1:200 for assays of serum AFP and PSA and 1:100 for serum ferritin and CA-125. The pooled serum is more preferable for maximum dilutions due to cost-effectiveness.

***Keywords:** Dilution, Dilutional linearity, Maximum dilution factor, Tumor marker*

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