



VALIDATION OF SODIUM SULPHITE PRECIPITATION METHOD FOR FIBRINOGEN DETERMINATION

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ABSTRACT

Among many complex, expensive, lengthy, antigenic methods for fibrinogen antigen quantification, sodium sulphite precipitation method is an easy, inexpensive, and a rapid method. Therefore validation of this method became important. This experimental study was carried out using 45 plasma samples obtained from the patients attending the thrombolytic clinic, National Hospital Sri Lanka (NHSL). Validation parameters were measured according to Clinical Laboratory Improvement Amendments' (CLIA) guidelines at the haematology laboratory, University of Sri Jayewardenepura (USJP). Results obtained from validated method were compared with results of existing method and clauss method. Statistical analysis was done using SPSS16. Currently this method uses an albumin standard to plot the standard curve. So an attempt was taken to validate the method using a fibrinogen standard which is more reliable to plot the standard curve. Reaction mixture gave peak absorbance at 412 nm. Suitable time duration to obtain results was 6-10 minutes. Limit of detection (LOD), limit of quantitation (LOQ) and analytical sensitivity were 0.5066 g L⁻¹, 0.802 g L⁻¹ and 0.086 respectively. Both existing method (p=0.002) and clauss method (p=0.001) have positive high correlation and significant association with the validated method. Positive high correlation (Pearson correlation coefficient: >0.8) and significant association was yielded between values that obtained in different laboratory setups (labs in NHSL and USJP) in validated method. It was concluded that fibrinogen concentrations within 0.802 g L⁻¹-5.5 g L⁻¹ can be measured by validated method with accepted precision and accuracy. Validated method is more reliable and precise than existing method. Both validated method and existing method were less precise to measure low fibrinogen concentrations. 12.5% sodium sulphite reagent can be used only for three days after preparation.

Keywords: Fibrinogen, Dysfibrinogenemia, Antigen, Sodium Sulphite Precipitation method and Method Validation