

Abstract Submission No.: A-0736**Rapid Detection and Surveillance of Chronic Kidney Disease: Protein-Bound Uremic Toxin ELISA Kit**

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Objectives : Indoxyl sulfate (IS) is a protein-bound uremic toxin (PBUT) produced by intestinal flora during the decomposition of tryptophan in food. Normally, it is excreted through the kidneys. However, in patients with chronic kidney disease (CKD), impaired renal function (characterized by decreased glomerular filtration rate, GFR) leads to IS accumulation, resulting in elevated concentrations in vivo. Accumulation further damages renal and cardiovascular systems. Traditional methods for detecting PBUTs require sophisticated equipment and skilled technicians. Leadgene develops monoclonal antibodies against small molecules bringing out LEADGENE® Indoxyl Sulfate (IS) ELISA Kit. This kit is registered with CE-IVD (DE/CA09/0760/L05/IVD/001) and has received IVD certification (MOHW-MD-No. 007625) from the Taiwan Food and Drug Administration (TFDA).

Methods : This ELISA kit quantitatively measures IS levels in human serum directly by employing the competitive ELISA method. In this process, IS in the serum competes with microplate-conjugated IS for binding to the anti-IS monoclonal antibody. The anti-IS antibodies bound to the solid phase are detected by anti-IgG antibodies conjugated with peroxidase.

Results : The clinical performance showed that the area under the ROC curve (AUC) was 0.96. The optimal cutoff was determined to be 2.233 µg/mL, with a sensitivity of 0.872 (95% CI: 0.816 - 0.912), and a specificity of 0.940 (95% CI: 0.856 - 0.977). Precision was assessed using Nested-ANOVA analysis, with an acceptance criterion of 10% (Total %CV). Compared to LC-MS analysis, the Pearson product-moment correlation coefficient (Pearson's r) was 0.971.

Conclusions : The LEADGENE® IS ELISA Kit, which utilizes patented antibodies (US Patent No. US 10,723,791 B2 & US 11,560,423 B2; Taiwan Patent No. I710577; Japan Patent No.7366353; China Patent No. CN 111741974 B), employs the competitive ELISA method for the quantitative detection of indoxyl sulfate (IS) in human serum. It offers a rapid, highly sensitive, cost-effective, and user-friendly solution for monitoring IS levels.

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Cut-off: 2.233 ($\mu\text{g/ml}$)
ROC Curve (AUC = 0.96)



