Development and Validation of Multiplexed Human Kidney Biomarker Assay Panels

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Abstract

Purpose: Measurement of protein biomarkers in human urine and serum has promise in improving drug safety and efficacy. However, the use of multiple assays, especially when using multiple analytes, is challenging due to the potential for matrix effects and the need for accurate quantification in clinical settings.

Methods: Meso Scale Discovery® (MSD) developed three panels of multiplexed assays according to fit-for-purpose assay development. Theiddleware panels consisted of 17 assays, each of which measured a different biomarker of kidney damage. The assay development process included calibration curves, dilution linearity, and spike recovery studies.

Results: The panels were assembled based on the abundance of the biomarkers in human urine: low abundance—GST, RBP4, and Bak; intermediate abundance—Calbindin, Clusterin, and KIM-1; and high abundance—Cystatin C, Cystatin B, and Albumin. The dilution linearity of all assays was within 1:100–1:200, and the spike recovery in matrix results were between 80% and 120% for all assays with the exception of osteopontin, which is known to have a lower recovery in urine samples.

Conclusions: These panels provide a comprehensive approach to the simultaneous measurement of multiple kidney biomarkers, enabling the identification of complex biomarker profiles.

1 Standard Curves for Kidney Injury Panels

2 Matrix Tolerance

3 Sample Testing for Kidney Injury Panels

4 Conclusion