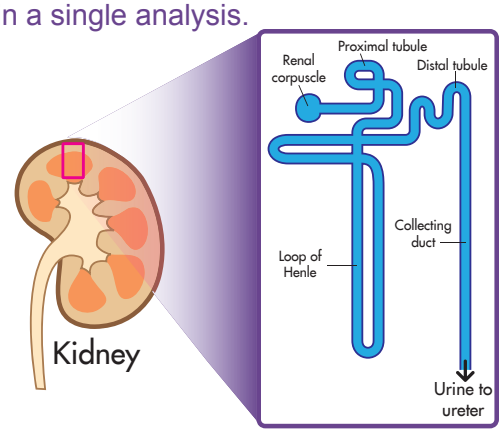
Kidney Biomarkers for Drug Safety

Kidney Injury Protein Biomarker Assays for Non-clinical (Rat, Monkey) and Clinical studies (GLP and non-GLP)

Sensitive urinary biomarkers are needed to detect kidney injury at the earliest stages. Nextcea simultaneously measures multiple proteins in urine samples to monitor the onset and time-course of toxicity. Nextcea has developed/validated a proprietary UPLC-MS/MS assay to quantitate up to seven protein biomarkers in a single analysis.

Nextcea measures kidney injury protein biomarkers, suggested by FDA/EMEA, via UPLC/MS/MS

- KIM-1
- Clusterin
- Trefoil Factor 3
- Cystatin C
- β2-microglobulin
- NGAL/Lipocalin-2
- Albumin

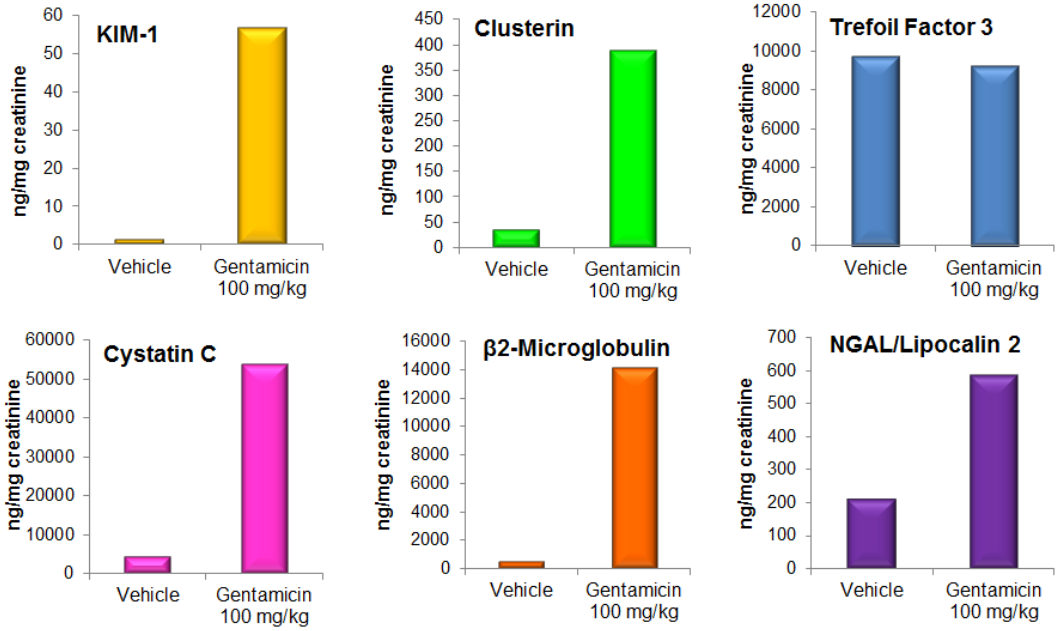


Safety Assessment by UPLC/MS/MS Analysis

These renal injury protein biomarkers have been shown to provide higher sensitivity than traditional biomarkers BUN, NAG, and serum creatinine. The GLP validated UPLC-MS/MS method can be applied in non regulated and regulated (GLP) nonclinical studies as well as the analysis of human urine from clinical trials (GCP).

The multiplex LC-MS/MS format enables robust and reproducible measurement over ELISA. Concentrations of protein biomarkers are determined based on representative signature peptides which are absolutely quantitated. No antigen-antibody labeling is required.

Example: A 2-Week Study of Gentamicin in Rats



500 W. Cummings Park, #4550
Woburn, MA 01801
781-457-4010
English
inform@nextcea.com
日本語
Hirohide Mimura (三村博英): hiro.mimura@nextcea.com

About Nextcea, Inc.

Nextcea, Inc. is a drug development service company dedicated to optimizing efficacy and minimizing toxicity in all phases of drug development. Nextcea integrates cross-species biomarker studies with traditional PK/PD and TK/TD. In-house platforms include HPLC/UPLC coupled to mass spectrometry LC-MS and LC-MS/MS (API-6500s and TripleTOF 6600).