

# Resource Summary Report

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## ILSI HESI Drug-induced Nephrotoxicity Biomarkers

RRID:SCR\_003716

Type: Tool

### Proper Citation

ILSI HESI Drug-induced Nephrotoxicity Biomarkers (RRID:SCR\_003716)

### Resource Information

**URL:**

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualification>

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**Description:** Urinary kidney biomarkers, Clusterin and Renal Papillary Antigen-1 (RPA-1), that sponsors may use to determine more conservative NOAELs for estimating starting doses in the initial human clinical trial of a drug that displays nonclinical nephrotoxicity as determined by histopathology. When tested with a limited number of nephrotoxic compounds, the Receiver Operating Characteristic (ROC) analyses showed that urinary clusterin and renal papillary antigen-1 (RPA-1) have better sensitivity and specificity than BUN and creatinine for the detection of specific kidney pathologies in male rats. Clusterin and RPA-1 provide additional and complementary information to BUN, serum creatinine (sCr), and histopathology for the detection of acute drug-induced nephrotoxicity in safety assessment studies.

**Abbreviations:** HESI Nephrotoxicity Biomarkers

**Synonyms:** HESI Drug-induced Nephrotoxicity Biomarkers, ILSI / HESI Nephrotoxicity Working Group Drug-induced Nephrotoxicity Biomarkers, International Life Sciences Institute / Health and Environmental Sciences Institute Nephrotoxicity Working Group Drug-induced Nephrotoxicity Biomarkers

**Resource Type:** data or information resource, narrative resource, standard specification

**Keywords:** biomarker, drug development, drug, urinary, urinary biomarker, gold standard, clusterin, renal papillary antigen, kidney, gold standard

**Related Condition:** Nephrotoxicity, Drug-induced nephrotoxicity

**Availability:** Public

**Resource Name:** ILSI HESI Drug-induced Nephrotoxicity Biomarkers

**Resource ID:** SCR\_003716

**Alternate IDs:** nlx\_157892

**Record Creation Time:** 20220129T080220+0000

**Record Last Update:** 20260821T193717+0000

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## Ratings and Alerts

No rating or validation information has been found for ILSI HESI Drug-induced Nephrotoxicity Biomarkers.

No alerts have been found for ILSI HESI Drug-induced Nephrotoxicity Biomarkers.

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## Data and Source Information

**Source:** [SciCrunch Registry](#)

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## Usage and Citation Metrics

We have not found any literature mentions for this resource.