

OVERVIEW

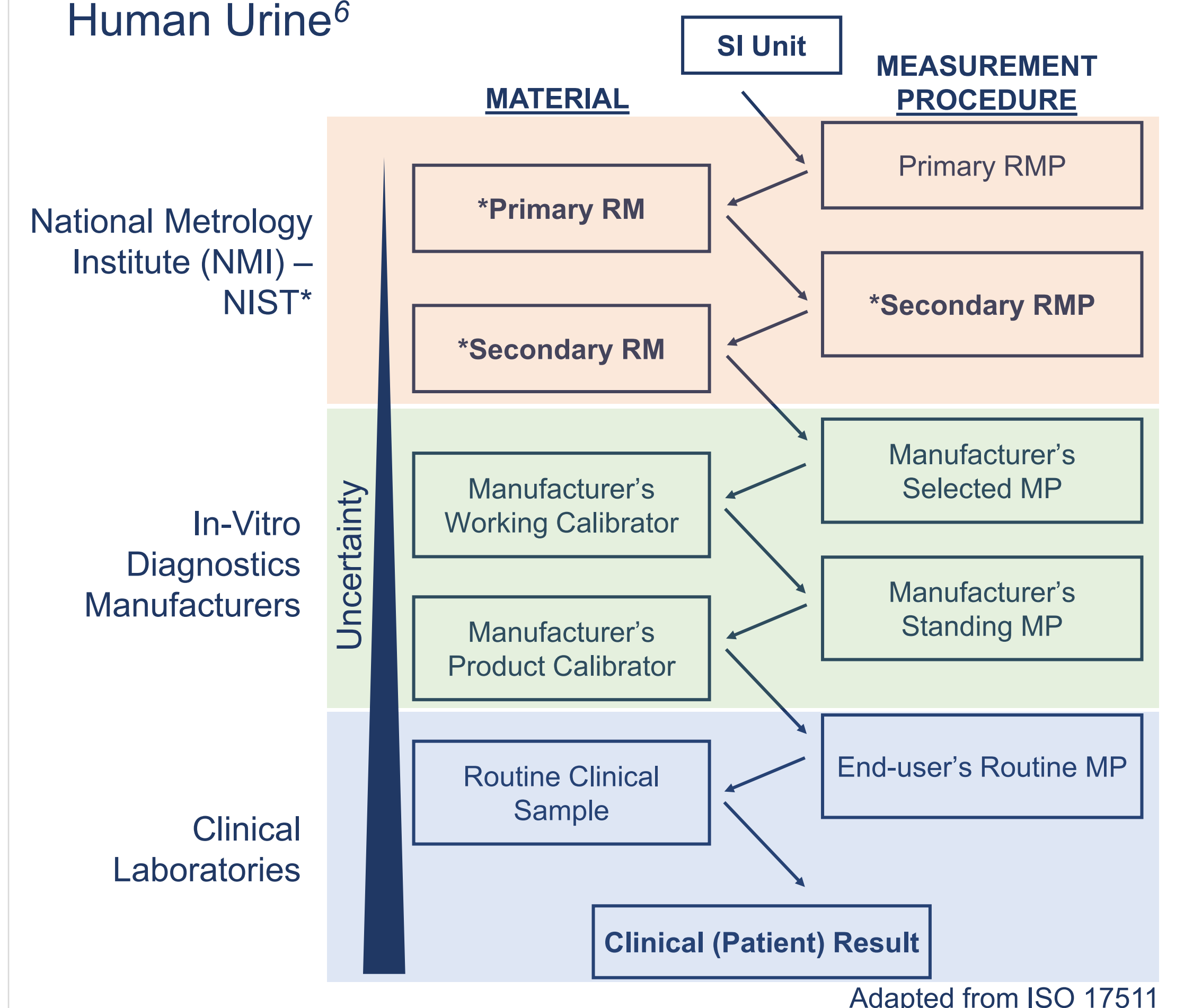
- ✓ Establish a Reference Measurement System (RMS) for urine albumin to enhance the quality of routine clinical results for kidney disease.
- ✓ Develop the higher-order reference materials (RMs) and reference measurement procedure (RMP) for albumin in human urine.

BACKGROUND

- ✓ Urine albumin is a key clinical biomarker for the diagnosis and management of kidney disease. Therefore, it is crucial for healthcare practitioners to have access to accurate and consistent clinical urine albumin results, as these results are fundamental to making informed clinical decisions regarding kidney health.
- ✓ The primary objective of this study is to establish an RMS for urine albumin. This system will provide a traceability framework that links clinical urine albumin results to the International System of Units (SI) through an unbroken chain of reference materials and reference measurement procedures.
- ✓ NIST has developed the foundational components of the urine albumin RMS, including a primary RM, a secondary RM, and a secondary RMP. This initiative aims to enhance the accuracy and global comparability of routine clinical urine albumin results to improve the quality of clinical decisions for kidney disease.

URINE ALBUMIN RMS

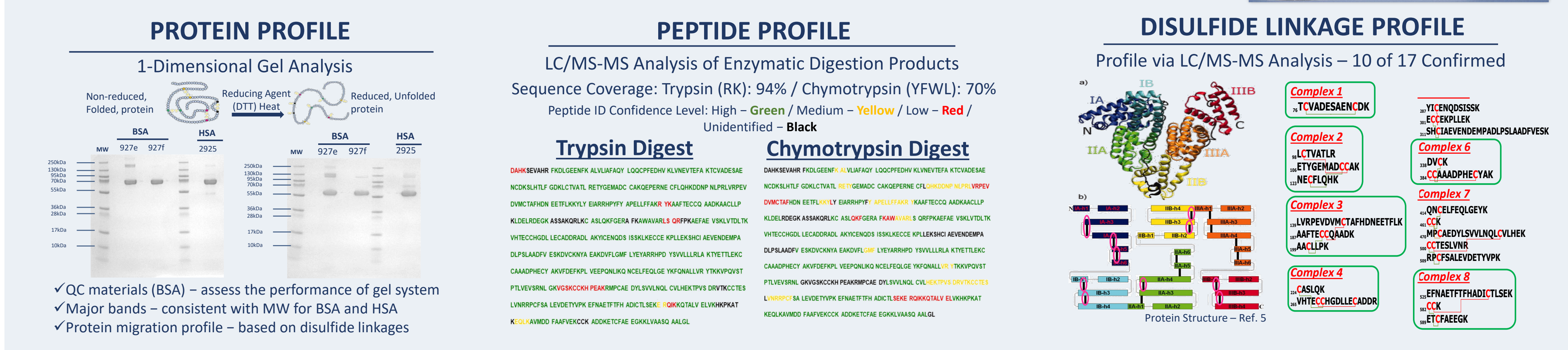
- ✓ **Primary Reference Material**
NIST SRM 2925 Recombinant Human Serum Albumin Solution (Primary Reference Calibrator for Urine Albumin)¹
- ✓ **Secondary Reference Measurement Procedure**
NIST RMP for Albumin in Human Urine²⁻⁵
- ✓ **Secondary Reference Material**
NIST SRM 3666 Albumin and Creatinine in Frozen Human Urine⁶



RESULTS

Primary RM – NIST SRM 2925 Recombinant Human Serum Albumin Solution¹

Purpose: Use in the calibration of LC-MS/MS procedures for the determination of albumin in urine; Listed in Joint Committee for Traceability in Laboratory Medicine (JCTLM) Database for Reference Materials (C18RM1) as an internationally recognized higher-order RM for clinical measurements of urine albumin



Secondary RMP – NIST RMP for the Determination of Albumin in Human Urine²⁻⁵

Purpose: Multiplexed ID-LC-MS/MS RMP for the quantitative and qualitative determination of albumin in urine; Developed a framework to estimate measurement uncertainty (MU) of an MS-based protein procedure (GUM⁷)

