

**[F-FC142] Expressing the MDRD Study Equation for Estimating GFR with IDMS Traceable (Gold Standard) Serum Creatinine Values.**

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GFR estimation equations require standardized methods for serum creatinine ( $P_{cr}$ ) assays. The College of American Pathologists (CAP) prepared fresh-frozen  $P_{cr}$  reference materials, traceable to a gold standard material at the National Institute of Standards and Technology (NIST), for the purpose of standardizing reference materials for method calibration. Assigned values were based on isotope dilution mass spectrometry (IDMS). We report calibrated MDRD Study laboratory  $P_{cr}$  assay and re-express the four-variable MDRD Study equation with IDMS traceable  $P_{cr}$ .

The Cleveland Clinic Laboratory (CCL) used Beckman modified kinetic rate Jaffe reaction (Beckman Synchron CX3) method during the MDRD Study and at present. The CX3 method was calibrated to the Roche enzymatic method which was accurate across the range of  $P_{cr}$  using CAP 2003 C-02 (0.902 mg/dl) and CAP 2004 LN-24 accuracy-based samples (0.5008 to 4.0150 mg/dl). Re-analysis of 253 frozen MDRD Study samples in 2004 revealed a +4.56% drift from the time of original measurement. MDRD Study calibrated  $P_{cr}$  was derived by calibrating original MDRD Study samples to 2004 data and then to IDMS-traceable values (Equation 1). The four-variable MDRD Study equation (Equation 2, GFR in ml/min/1.73 m<sup>2</sup>,  $P_{cr}$  in mg/dl, and age in years) is re-expressed with IDMS traceable  $P_{cr}$  in Equation 3.

The availability of standard reference materials and accurate assays, such as the Roche enzymatic method, will enable instrument manufacturers and clinical laboratories to calibrate  $P_{cr}$  assays to IDMS-traceable values. The MDRD Study equation and future equations should be expressed in terms of IDMS-traceable  $P_{cr}$  values.

**Equation 1: Calibration of CCL to IDMS**

MDRD Study calibrated  $P_{cr}$  = 0.95 x original MDRD Study  $P_{cr}$

**Equation 2: Published MDRD Study equation before calibration of CCL**

GFR = 186 x  $P_{cr}^{-1.154}$  x age<sup>-0.203</sup> x 1.212 (if black) x 0.742 (if female)

**Equation 3: Re-expression of MDRD Study equation after calibration of CCL to IDMS**

GFR = 186 x ( $P_{cr}/0.95$ )<sup>-1.154</sup> x age<sup>-0.203</sup> x 1.212 (if black) x 0.742 (if female)

= 175 x  $P_{cr}^{-1.154}$  x age<sup>-0.203</sup> x 1.212 (if black) x 0.742 (if female)

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