Dear **[insert manufacturer's name]** Customer:

We are writing on behalf of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC); the National Kidney Disease Education Program (NKDEP), an initiative of the National Institutes of Health (USA); and the European Communities Confederation of Clinical Chemistry (EC4) to introduce you to our Creatinine Standardization Program and highlight its implications for clinical laboratories. The effort is part of a larger worldwide initiative to help health care providers better identify and treat chronic kidney disease (CKD) in order to prevent or delay kidney failure and improve patient outcomes.

Reliable serum creatinine measurements are critical to increasing the diagnosis and treatment of CKD. Until now, inter-laboratory variability in serum creatinine measurement rendered all equations for estimating glomerular filtration rate (GFR), including the Modification of Diet in Renal Disease (MDRD) Study equation, less accurate in the slightly elevated range of serum creatinine concentrations [<133 µmol/L (1.5 mg/dl)]—the relevant range for detecting CKD (<60 mL/min/1.73 m^2). The Creatinine Standardization Program is intended to reduce inter-laboratory variation in creatinine assay calibration and provide more accurate estimates of GFR.

To that end, the Creatinine Standardization Program encourages IVD manufacturers to adjust the calibration of routine serum creatinine methods to be traceable to the internationally accepted reference system (reference materials, methods, and laboratories) described in ISO 17511 and CLSI X5R and approved by the JCTLM (www.bipm.org). The Program also encourages manufacturers to work with clinical laboratories to coordinate this calibration adjustment with the introduction of a revised GFR estimating equation appropriate for use with standardized creatinine methods.

[insert specific IVD manufacturer] and other concerned IVD manufacturers are responding to the need for standardization, while recognizing the challenge to and patience required of its customers when implementing the new calibration. **[insert specific IVD manufacturer]** will be communicating with you regarding their timeline for full implementation. Once completed, the clinical laboratory community's efforts will dramatically help to improve CKD detection.

Please visit the laboratory professionals section of the NKDEP website http://www.nkdep.nih.gov/labprofessionals to learn more about the Creatinine Standardization Program, find useful materials and resources, and sign up to receive free email updates so we can help you stay abreast of creatinine standardization activities.

We wish to thank **[insert specific IVD manufacturer]** and their customers for their efforts and patience during this transition period. Please do not hesitate to send us your questions or comments at csp@info.niddk.nih.gov.

Regards,

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Chair, IFCC Scientific Division

Greg Miller, Ph.D.
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