STANDARDIZED (IDMS) CREATININE TESTING

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the National Institute of Health’s National Kidney Disease Education Program (NKDEP) have introduced an initiative for a Creatinine Standardization Program through the National Institutes of Health (USA) and the European Communities Confederation of Clinical Chemistry (EC4). The standardization of creatinine testing worldwide will assist health care providers better identify and treat chronic kidney disease (CKD), enabling the prevention or delay of kidney failure, thus improving patient outcomes. By standardizing serum creatinine measurements, there is an expected improvement in the detection, diagnosis and treatment of chronic kidney disease by reducing inter-laboratory bias and yielding more accurate estimates GFR using the updated Modification of Diet in Renal Disease (MDRD) equation.

On December 1, 2008, Lakeland Laboratory will change the creatinine method used for testing and move to a method of creatinine testing which is calibrated to a traceable reference method (Isotope Dilution Mass Spectrophotometry or IDMS), resulting in more accurate and standardized creatinine results. The impact of this change will be:

• Serum and urine creatinine reference intervals will change:

<table>
<thead>
<tr>
<th>Serum</th>
<th>Creatinine Reference Range</th>
<th>Urine (<strong>)24 hour collections</strong>)</th>
<th>Creatinine Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>0.7 - 1.3 mg/dl</td>
<td>Male</td>
<td>1.0 - 2.0 g / day</td>
</tr>
<tr>
<td>Female</td>
<td>0.5 - 1.0 mg/dl</td>
<td>Female</td>
<td>0.8 - 1.8 g / day</td>
</tr>
</tbody>
</table>

• This change in creatinine calibration will affect interpretive criteria and drug dosage adjustments based on estimates of kidney function. It is very important to recognize that the Cockcroft-Gault equation for calculating creatinine clearance has not been adjusted or standardized to account for the accuracy shift in IDMS traceable serum creatinine values, as compared to conventional (non-IDMS traceable) creatinine values. Therefore, serum creatinine values obtained with IDMS-traceable creatinine methods may impact the dosage estimates obtained based on the use of drug dosing algorithms published by pharmaceutical manufacturers, as part of the product labeling for certain drugs. In some instances, the use of creatinine values obtained with IDMS-traceable creatinine methods may result in calculated doses for a given drug that are higher than doses calculated using non-IDMS-traceable creatinine results. The equations to allow conversion from IDMS-traceable Creatinine to non-IDMS (traditional) Creatinine is as follows for both urine and serum:

For Serum Creatinine in the range of 0.50 to 2.50 mg/dl:

\[
\text{Non-IDMS CREA (mg/dL)} = \text{IDMS CREA (mg/dL)} \times 1.065 + 0.067
\]

For more information regarding NKDEP’s recommendations for pharmacists and authorized drug prescribers, please visit: [tp://www.nkdep.nih.gov/labprofessionals/Pharmacists_and_Authorized_Drug_Prescribers.htm](tp://www.nkdep.nih.gov/labprofessionals/Pharmacists_and_Authorized_Drug_Prescribers.htm)

For questions or additional information contact:
Deborah Fuke, Chemistry Technical Specialist at 982-4889 or
Roger Gregorski, Supervisor of Technical Services at 982-4303.