Ortho-Clinical Diagnostics
a Johnson & Johnson company

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IMPORTANT NOTIFICATION

Updated Information for IDMS Traceable VITROS® Chemistry Products CREA Slides

Dear Customer,

Ortho Clinical Diagnostics (OCD) recognizes that some laboratories are experiencing issues related to pharmaceutical dosing calculations when transitioning from a non-IDMS traceable serum creatinine method to one that is traceable to the internationally accepted reference method, isotope dilution mass spectrometry (IDMS). The purpose of this notification is to provide you with updated information and conversion equations that may facilitate your laboratory's transition to IDMS traceable VITROS Chemistry Products CREA Slides.

The National Kidney Disease Education Program (NKDEP) acknowledges the need for laboratories to support pharmaceutical dosing calculations for a number of pharmaceuticals, especially for patients with impaired kidney function. Certain drug dosage schedules are typically calculated by the pharmacy based on the patient's renal function test results, which may be estimated from a calculated creatinine clearance using the Cockcroft-Gault equation and the patient's serum creatinine value. In these circumstances, it is very important for the laboratory and the pharmacy to recognize that the Cockcroft-Gault equation for calculated creatinine clearance **has not been adjusted or standardized** to account for the accuracy shift in IDMS traceable serum creatinine values 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.[1] We recommend that you work closely with your pharmacy and your clinical staff in specific instances, to evaluate the clinical implications for your institution when converting to IDMS-traceable serum creatinine measurements.

OCD is committed to support the global effort to standardize serum creatinine measurements, which is expected to improve the detection, diagnosis and treatment of chronic kidney disease by reducing inter-laboratory bias and yielding more accurate estimates of glomerular filtration rate (GFR) using the updated Modification of Diet in Renal Disease (MDRD) equation. Please refer to our previous notifications for information regarding the availability of IDMS traceable VITROS CREA Slides and the subsequent adjustment of the calibrator values for serum/plasma creatinine to improve alignment with our reference method (Ref. CM07-001, CM07-177 and CM07-257).

[1]Recommendations for Pharmacists and Authorized Drug Prescribers and Recommendations for IVD Manufacturers (National Kidney Disease Education Program, July 2006); available from http://nkdep.nih.gov/labprofessionals/index.htm; Internet.

In order to assist your laboratory and pharmacy during the transition to IDMS traceable VITROS CREA Slides, we are pleased to announce the availability of updated equations that may be used to convert ***serum*** *IDMS traceable* VITROS CREA results to *non-IDMS traceable* VITROS CREA results. We are now providing equations that apply across the full reportable range that can be used with the Cockcroft-Gault equation, for calculating creatinine clearance.

Reportable Range for VITROS CREA Slides	
Conventional Units (mg/dL)	**SI Units (µmol/L)**
0.05 - 14.00	4 - 1238

The equations for converting ***serum*** *IDMS traceable* VITROS CREA results to *non-IDMS traceable* VITROS CREA results are as follows.

- *Non-IDMS* CREA (mg/dL) = IDMS CREA (mg/dL) x 1.065 + 0.067
- *Non-IDMS* CREA (µmol/L) = IDMS CREA (µmol/L) x 1.065 + 5.92

We previously communicated that these equations were intended for serum creatinine results in the range of 0.50 to 2.50 mg/dL (44.2 to 221.0 µmol/L), as recommended by the NKDEP. Acceptable performance has been demonstrated using these equations to estimate non-IDMS traceable creatinine results across the entire reportable (dynamic) range for VITROS CREA Slides, in order to calculate an estimated creatinine clearance using the Cockcroft-Gault equation.

We continually strive to focus on the needs of our customers, and in order to allow additional time for the conversion to the new IDMS-traceable VITROS CREA Slides, OCD will extend the availability of non-IDMS traceable VITROS CREA Slides (CAT No. 814 1947). We will continue to monitor the conversion rate and reevaluate the feasibility of discontinuing the non-IDMS traceable VITROS CREA Slides in another six months. We strongly encourage you to begin planning for your laboratory's conversion, if you have not already done so.

Ordering Information for IDMS Traceable VITROS CREA Slides

VITROS Chemistry Products CREA Slides	**Quantity**	**CAT No.**
GEN 80 and Above (IDMS Traceable)	300 slides/pack	680 2584

Thank you for your continued support of VITROS Chemistry Systems. If you have any questions regarding this notification or need further assistance, please contact Customer Technical Services at 1-800-421-3311.

Sincerely,

Suzanne Carrillo

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