

# CLIA BITS



North Dakota Department of Health  
Division of Health Facilities

Spring 2006

## ! FDA Alert !

### Avoiding Glucose Monitoring Errors in Patients Receiving Other Sugars

FDA issued a reminder regarding the potential for falsely elevated glucose readings in patients who also are receiving products that contain other sugars. These products include oral xylose, parenterals that contain maltose or galactose, and peritoneal dialysis solutions that contain icodextrin.

All glucose meters don't suffer from this problem. There are four types of enzymatic glucose

monitoring methods, and this problem occurs only with the method that uses an enzyme called GDH-PQQ.



The test method used in glucose meters is identified in the package insert that comes with the glucose test strips. The most important thing to remember is not to use the GDH-PQQ method if the

patient recently received other sugars.

Additional information: FDA MedWatch Safety Alert 2005 - Parenteral Maltose/Parenteral Galactose/Oral Xylose-Containing Products

<http://www.fda.gov/medwatch/safety/2005/safety05.htm#maltose>



### Equivalent Quality Control Reminders



EQC pertains to non-waived testing. For waived testing, follow the manufacturer's instructions.

The laboratory director must be involved in the EQC process.

All EQC activities must be documented and retained.

After EQC has been implemented, external controls must be performed with each new lot number or shipment of reagents.

After EQC has been implemented, external controls must be performed at the frequency required with the option chosen, regardless if patients are tested in that time frame or not.



### Announced CLIA Surveys

CLIA is still conducting routine recertification, initial certification, and validation surveys as announced. Complaint and follow-up surveys are conducted unannounced. CMS has not indicated that this will be changing any time soon.

### Roche Diagnostics Voluntary Recall

On Jan. 16, 2006, Roche Diagnostics initiated a voluntary recall of certain Accu-Chek Aviva meters due to the potential for an electronic malfunction that can cause the meter to report an erroneous result or shut down and not be useable. Meters affected in the U.S. include serial numbers 52500000000 through 52510999999. For more information, visit the website at [www.acu-check.com](http://www.acu-check.com) or call 800.858.8072.



## Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Jan. 1, 2005, through Dec. 31, 2005.

**D5805 – Test Report.** The test report must include the test result and, if applicable, the units of measurement or interpretation, or both.

**D2015 – Enrollment and Testing of Samples.** The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the proficiency testing program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

**D5217 – Evaluation of proficiency testing performance.** The laboratory must verify the accuracy of any nonregulated analyte at least twice a year.

**D5407 – Procedure manual.** Procedures and changes in procedures must be approved, signed and dated by the current laboratory director before use.

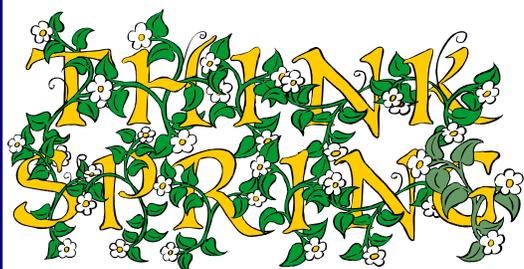
**D5447 – Control Procedures.** For each quantitative procedure, include two control materials of different concentrations.

Take a close look at your laboratory and identify if it is deficient in these areas. If so, take the corrective actions necessary to fix these areas prior to your next survey. If you have any questions about the deficiencies or the requirements, please contact the North Dakota Department of Health, Division of Health Facilities, at 701.328.2352.



## Plan To Attend

The North Dakota Department of Health's Division of Health Facilities CLIA staff will be presenting "CLIA and Quality Control" at the 2006 Annual Spring Meeting of the American Society of Clinical Laboratory Scientists – North Dakota. The meeting will be held April 24<sup>th</sup>-26<sup>th</sup> in Fargo. For registration information, contact Kathy Jones at [kathy.jones@meritcare.com](mailto:kathy.jones@meritcare.com).



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