NEW YORK STATE DEPARTMENT OF HEALTH
Clinical Laboratory Evaluation Program

Off Label use of Glucose Meters
February 18, 2014

The New York State Department of Health’s (the Department) Clinical Laboratory Evaluation Program (CLEP) distributed a letter to laboratories located in NY on January 13, 2014 regarding the off-label use of glucose meters. This letter is available on our website at http://www.wadsworth.org/labcert/clep/inthenews/inthenews.htm. It is not the intent of the Department to prohibit the off-label use of glucose meters but to inform facilities on the policies and requirements surrounding the off-label use of these devices. These policies and requirements for off-label use of a FDA cleared/approved device have not changed. The Department is providing this guidance in the form of frequently asked questions (FAQs).

FAQ1: What is the problem identified with off-label use of the glucose meters?
ANS1: Glucose meters are being used for purposes other than those cleared by the FDA. The FDA and others have also raised concerns that these devices may not be accurate or reliable for use on critically ill patients. Laboratories that perform waived testing, e.g. using a point-of-care glucose meter, are required to follow the manufacturer’s instructions for the device. Such instructions specify the patient population and conditions in which the testing has been proven to perform well. The device is FDA cleared for such patients and conditions only. When an FDA cleared device is being used for a purpose other than that for which it is cleared to be used, this is referred to as off-label use. When an FDA cleared device is used off-label, additional New York State requirements for testing need to be met.

FAQ2: The Department’s letter stated that use of glucose meters on critically ill patients is considered to be an off-label use of the device. If there is a known diabetic patient that is critically ill, why can’t a glucose meter be used to monitor glucose levels?
ANS2: The FDA and others have stated that patients in critical care settings can be acutely ill and medically fragile, and are more likely to present with physiological, pathological and pre-analytical factors that could interfere with glucose measurements as compared to other diabetic patients. For critically ill patients, any inaccuracies in the meters could further increase the risk to patients. It is very important for anyone performing testing to be familiar with all specifications and limitations as described by the manufacturer of these devices.

FAQ3: Hospitals and other healthcare facilities are currently using glucose meters off-label and do not meet appropriate requirements for high complexity testing. What do facilities need to do at this time?
ANS3: As previously stated, it is not the intent of the Department to prohibit the off-label use of glucose meters but to inform facilities on the policies and requirements surrounding the off-label use of these devices. As a regulatory agency, it is the Department’s responsibility to ensure that if glucose meters are used for off-label purposes, that the laboratory has established the performance specifications for use in the facility’s patient population to ensure an accurate and reliable test result. If an on-site survey shows that the facility is not meeting the requirements for the off-label use of glucose meters, a deficiency will be cited. The plan of
correction will provide the opportunity for the facility to describe steps being taken to correct the deficiency and a timeline for implementation.

**FAQ4**: Glucose meters are used to monitor glycemic control of non-diabetic patients and to screen people for diabetes at health fairs. Why can’t glucose meters be used in these ways?

**ANS4**: Many glucose meters are currently cleared by the FDA for the quantitative measurement of whole blood glucose for use by healthcare professionals or lay users as an aid in monitoring the effectiveness of a diabetes control program. The meters are not intended to be used for the diagnosis of, or screening for, diabetes. If a glucose meter that has not been approved for diagnosis of diabetes is being used to screen patients for diabetes or to measure glucose levels on a patient who has not been diagnosed with diabetes, then the device is being used off-label.

**FAQ5**: Why are hospitals and other healthcare facilities receiving this guidance now?

**ANS5**: The Department decided to send out letters and provide this additional guidance based on information provided to us by the FDA and CMS.

**FAQ6**: What are our options for monitoring glucose in patients?

**ANS6**: Glucose monitoring can be carried out using glucose meters off label provided performance specifications and other requirements have been met (see FAQ7, FAQ8 and FAQ9). Alternatively, blood glucose in critically ill patients or other patients requiring serial glucose testing can be performed in the clinical chemistry laboratory. A third option is to use a device (such as a non-strip-based point of care instrument) that does not have the same limitations against use in the critically ill as glucose meters. A very brief review of package inserts indicates, for example, that the Alere Cholestech LDX is cleared by the FDA for quantitative determination of glucose in whole blood. The package insert, in the intended use section, describes that glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and pancreatic islet cell carcinoma. Therefore, in accordance with the intended use in the package insert, this device could be used for diagnosis and treatment. The Intended Use according to the package insert for glucose, as part of the Abbott i-STAT system, describes that this device is intended for use in the in vitro quantification of glucose in arterial, venous or capillary blood. The glucose measurements are used in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma. A review of the Intended Use for the HemoCue Glucose 201 Analyzer describes similar language to the i-STAT. There may be additional devices that are appropriate for monitoring glucose in such patients. Facilities should clarify with individual manufacturers to determine if this is indeed the case. Please note that the mention of any specific manufacturer or equipment does not constitute an endorsement by the Department.

**FAQ7**: What requirements need to be met for a healthcare facility to use a glucose meter off-label?

**ANS7**: The laboratory would need to design and perform appropriate studies to demonstrate analytic and clinical performance specifications for the glucose meter that would be used for the intended patient population. When a glucose meter is used off-label, the glucose meter defaults to high complexity testing and the laboratory must meet New York State requirements for high complexity testing. Performance of high complexity testing requires a laboratory to hold a New York State clinical laboratory permit in the category of Clinical Chemistry or Clinical Chemistry - Restricted. Results of the validations studies do not need to be submitted for review; review will take place during the on-site survey of the facility. Please refer to FAQ9 for information regarding personnel requirements for high complexity testing.

**FAQ8**: What steps need to be taken to perform validation studies on glucose meters being used off-label?

**ANS8**: The Department’s original letter referred to a January 7, 2014 draft guidance document from the FDA that describes steps that can be taken to perform validation studies by manufacturers. For validation in some
patient settings the CLSI guidance document POCT12-A3 may provide helpful guidance that is more appropriate for a laboratory.

**FAQ9:** What educational requirements must be met for staff performing high complexity testing?

**ANS9:** To perform high complexity testing, personnel must hold an Associate Degree or have documented coursework totaling 60 semester hours that includes 24 hours of science with 6 hours of chemistry, 6 hours of biology and 12 hours of chemistry, biology or medical laboratory technology in any combination. Additionally, in New York State, only personnel licensed by the New York State Education Department are eligible to perform the testing. Licensed RNs would qualify to perform high complexity testing. LPNs may not qualify unless they can document that coursework has been obtained for an Associate Degree.

**FAQ10:** Are there specific training requirements for nursing staff performing high complexity testing?

**ANS10:** It is the responsibility of the laboratory director in collaboration with the nursing director to develop a training program for staff performing glucose testing, including regularly scheduled competency assessments. There are no defined requirements for the number of hours that staff need to be trained. Timeframes for training will be dependent upon the content that is included to ensure that individuals have received an adequate amount of training to obtain an accurate and reliable test result.

**FAQ11:** What if a facility uses one of the devices described in ANS6 for its FDA cleared intended uses? Is this considered high complexity testing and does our staff need to meet specific educational requirements?

**ANS11:** No, if the laboratory is performing testing using one of the devices described in ANS6 in accordance with the device’s Intended Use as cleared by the FDA, this is not considered high complexity testing due to off-label use and appropriately trained staff can continue to carry out the testing.