STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

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To: Participants of the Michigan Regional Laboratory System
Topic: Changes in Quality Control requirements
Date: March 15, 2011

The Michigan Regional Laboratory System (MRLS) has established specific Quality Standards that all participating laboratories are expected to comply with. These standards specify the frequency that Quality Control (QC) testing must be performed. In some instances, these requirements exceed the minimal requirements established by the manufacturer of the test system. We have evaluated the impact of these more stringent QC requirements on ensuring the quality of testing within the MRLS. Careful review of manufacturer requirements and review of QC records indicate that quality of testing will not be impacted if less stringent QC requirements are adopted. The MRLS therefore announces the adoption of minimal requirements for Quality Control based upon the requirements of the test manufacturer.

It is important to note that these are minimal requirements for ensuring quality in laboratory testing. Each site has the option of maintaining the QC requirements currently in effect. Each laboratory must make a determination whether to utilize the minimal requirements or retain the more stringent requirements currently in use. If any changes are made, your Quality Assurance Manual must be modified to specify the frequency that QC testing is performed.

The attachment specifies the minimal requirements for all waived testing performed in the MRLS. These changes are summarized as follows:

1. Hemoglobin by HemoCue: Quality Control is no longer required when opening a new bottle of the same lot number received in a shipment that has already been QC'd.
2. Whole Blood Glucose: QC is only required when a new kit lot number or a new test kit is received. Weekly QC is no longer required.
3. Urine Pregnancy: QC is only required when a new kit lot number or a new test kit is received. Monthly QC is no longer required.
4. Manual Urine Chemistry: No changes, monthly QC is still required.
5. Automated Urine Chemistry: Daily QC is required.

Your agency must first determine whether to adopt these minimal requirements or retain the more stringent requirements currently in place. Your agency must then modify your Quality Assurance Manual to reflect these changes. A Word document containing these modifications has been posted at the MDCH website (www.michigan.gov/mdchlab). Please contact myself (517-335-8074), your laboratory director or your technical consultant if you have further questions.

Respectfully,

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Attachment: Table – Frequency of Quality Control for Waived Tests