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Date: May 21, 2010

DQA Memo 10-011

To: Clinical Lab Improvement Amendments

CLIA 03

From: Crenear Mims, Director  
Bureau of Health Services

Via: Otis Woods, Administrator  
Division of Quality Assurance

**CLIA requirements for manufacturer's recommendations and instructions**

The purpose of this memo is to inform Certificate of Compliance laboratories about non-waived testing requirements.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for non-waived testing found in Title 42 of the Code of Federal Regulations (CFR) Part 482 to End, 2009 edition, at § 493.1252(a) states "Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under § 493.1253."

The CFR § 493.1256(e)(5) states "Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results."

To follow instructions means that the laboratory complies with the recommendations, suggestions and requirements in package inserts and/or instrument operator manuals.

Therefore, CLIA surveyors are to cite deficiencies whenever it is determined that the laboratory is not following all manufacturer's recommendations, suggestions and requirements for non-waived test system.

These recommendations and suggestions include, but are not limited to:

- Instrument differential flags on hematology analyzers with peripheral smear evaluation recommendations;
- Protime/INR methods with hematocrit recommendations;
- Rapid Strep methods with culture confirmation recommendations.

If you have any questions about this memo, please contact the CLIA Section at (608) 261.0653 or [barbara.saar@wi.gov](mailto:barbara.saar@wi.gov)