DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

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DATE: **November 13, 2003**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Guidance On Test Systems That Are Categorized as Either Waived or Moderate Complexity Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

The purpose of this memorandum is to provide clarification and guidance regarding test systems that may be categorized as either waived or moderate complexity, and their use in laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures.

Under CLIA, Food and Drug Administration (FDA)-approved laboratory test systems are categorized as high complexity, moderate complexity, or waived. Usually, each test system is assigned to only one of these categories. However, there are a small number of test systems that may be categorized as either moderate complexity or waived, depending on certain criteria that will be described in this memo. The manufacturer's package insert provides guidance for users when choosing the correct category to apply in their laboratories. Laboratories and surveyors have requested additional guidance to ensure that the correct category is always applied. Questions usually arise in applying the correct test system categorization in laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures. The only CLIA requirement for testing performed at laboratories with a CLIA Certificate of Waiver is to follow the manufacturer's instructions.

Laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures must always follow manufacturers' instructions for waived testing. These laboratories may only use the specimen types approved for waived testing, and they must follow the manufacturers' Quality Control (QC) and test performance requirements for waived testing. Any of these laboratories that are found to be using manufacturers' instructions for moderate complexity testing should be advised that they must use the manufacturers' instructions for

waived testing. If the situation remains uncorrected, the laboratory may be cited for performing tests beyond the scope of the certificate held by the laboratory, as well as failing to follow manufacturers' instructions. Laboratories holding a Certificate of Compliance or a Certificate of Accreditation may perform both waived and moderate complexity tests, but must still meet applicable CLIA requirements and follow manufacturers' instructions.

There are three ways in which test systems may be categorized in multiple categories, and may be based on the specimen type, the QC requirements, or the test instrument. They are more fully described below.

1. **Test Systems That Are Categorized As Waived or Moderate Complexity Depending on the Specimen Type**
   Certain test systems may be categorized as waived or moderate complexity depending on the specimen type used for the test system. Laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures that utilize these test systems may only use the specimen types approved for waived testing. For example, a number of pregnancy test kits are waived when the specimen type is urine, but are moderate complexity when the specimen type is serum. Other test systems are categorized as waived or moderate complexity depending on whether the sample type is whole blood or serum. Additional examples of test systems that may be waived or moderate complexity depending on the specimen type used for the test include tests for mononucleosis, Helicobacter pylori, Borrelia burgdorferi and Streptococcus Group A. Note that this list is not intended to be all-inclusive. The manufacturers' instructions should be consulted to determine the impact of specimen type on test categorization for any particular test system.

2. **Test Systems With Different QC Requirements for Waived or Moderate Complexity Testing**
   We have encountered one test that fits this description, Roche CoaguChek™. The package insert correctly states that it is a waived test. The test is categorized as waived regardless of the number of test strips in the kit (30 or 48).

   The manufacturer's instructions for this test system, however, contain QC requirements that vary in frequency depending on whether it is used for waived testing or moderate complexity testing.

   For waived testing, the manufacturer has supplied daily, weekly, and additional QC requirements. These QC requirements for waived testing apply to all laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures.

   The manufacturer has also provided for less stringent QC frequency for moderate complexity testing (non-waived). Only laboratories holding a Certificate of Compliance or a Certificate of Accreditation may use these QC requirements for moderate complexity testing. Although the package insert QC requirements are less stringent for moderate complexity testing, it should be noted that these laboratories are also subject to additional CLIA QC, personnel, and proficiency testing requirements that do not apply to waived testing.

3. **Test Instruments That May Be Categorized as Waived Or Moderate Complexity Depending On The Analyte Tested**
   We have encountered one instrument that fits this description, the Bayer DCA 2000+ Analyzer. This instrument performs quantitative measurement of HgbA1C, which is categorized as a waived test. However, it can also be used to measure urine creatinine and urine microalbumin, which are categorized as moderate complexity tests. Laboratories holding a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures may use the Bayer DCA 2000+ Analyzer to perform HgbA1C testing, but they may not use it to perform urine creatinine or urine microalbumin testing.

For additional information on the category of any test system, consult the FDA web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm, which contains a database of test systems, searchable by manufacturer or analyte.

If you have questions or would like further clarification, please contact Judy Yost at 410-786-3407 or Virginia Wanamaker at 410-786-7304. We appreciate your ongoing dedication to effective administration of the CLIA program.

Effective Date: Immediately

Training: The information contained in this announcement should be shared with all CLIA survey and certification staff, their managers and the state/RO training coordinator.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)