

CLIA Update

A memorandum was sent out in November 2003 from CMS as a clarification regarding tests categorized as either waived or moderate complexity under CLIA. Under CLIA, the FDA approved laboratory test systems are categorized as either waived, moderate, or high complexity tests. There are a small number of tests that may be categorized as either a moderate complexity test or a waived test, depending on certain criteria. The manufacturer's package insert provides guidance for users when choosing the correct category to apply to their laboratories.

Laboratories holding a Certificate of Waiver or a Provider Performed Microscopy Certificate must always follow manufacturer's instructions for waived testing. These labs must follow the manufacturer's Quality Control and test performance requirements for waived testing. Any of these laboratories that are found to be using manufacturer's instructions for moderate complexity testing should be advised that they must use the manufacturer's instructions for waived testing. If the situation is uncorrected, the laboratory may be cited for performing tests beyond the scope of the certificate.

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

1. Test Systems that are categorized as Waived or Moderate complexity depending on specimen type

An example would be a number of pregnancy test kits are waived when the specimen is urine, but are moderate complexity when the specimen is serum. Manufacturer's instructions should be consulted to determine impact of specimen type on test categorization.

2. Test Systems with Different QC Requirements for Waived or Moderate Complexity Testing

An example of this would be the Roche CoaguChek. The package insert correctly states it is a waived test. The test is categorized as waived regardless of the number of test strips in the kit. The manufacturer's instructions for this test system, however, contain QC requirements that vary in frequency depending on whether it is waived or moderate complexity. The QC requirements for waived are more stringent than are the requirements for moderate complexity (nonwaived).

3. Test Instruments Categorized as Waived or Moderate Complexity based on Analyte Tested

An example would be the Bayer DCA 2000+ Analyzer. This instrument performs quantitative measurement of Hemoglobin A1C, 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.

For additional information refer to links below.

• **Information on category of any test system**

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm

• **List of CLIA waived tests including manufacturer**
<http://www.cms.hhs.gov/clia/waivetbl.pdf>

• **List of CLIA Approved Proficiency Testing Programs**

<http://cms.hhs.gov/clia/ptlist.pdf> ◆

FDA Recommends Caution When Using Rapid Flu Diagnostic Tests

7 rapid influenza diagnostic tests have been cleared by the Food and Drug Administration (FDA) for marketing. These 7 rapid tests can produce results within 30 minutes. These tests directly detect influenza A or B virus associated antigens or enzyme in throat swabs, nasal swabs, or nasal washes.

Binax's NOW Flu A, Binax's NOW Flu B, and Becton Dickinson's Directogen Flu A+B can detect and distinguish between influenza A and B virus antigens.

Becton Dickinson's Directogen Flu A test can detect only antigens associated with influenza A virus.

Quidel's QuickVue Influenza and Thermo BioStar FLU OIA can detect but do not distinguish between influenza A and B antigens.

ZymeTx's ZstatFlu test can detect neuraminidase, the presence of which denotes a high probability that infectious virions are present; it also does not distinguish between influenza A and B.

The Quidel QuickVue and ZymeTx's ZstatFlu influenza tests are considered low complexity and may be used in physicians' offices. The other five tests mentioned above are considered moderately complex and are for use in a hospital or clinical reference laboratories. ◆

Labline Dec 2003

CMS Releases CLIA Interpretive Guidelines

The Centers for Medicare and Medicaid Services released on January 12, 2004, the 300+ page CLIA '88 Interpretive Guideline, a web source that both clinical laboratories and CLIA surveyors can use to ensure that labs are in compliance with the CLIA law. New in the guidelines are several "equivalent quality control" (EQC) options labs may use to comply with CLIA '88's new quality control requirements.

One notable change in the guidelines is what CMS has done in the point-of-care blood gas and coagulation area. Initially, labs were excluded from using the EQC options for these instruments, and CMS was looking into developing a specific EQC option for this purpose, but instead has decided to lift the exclusion. This means that labs using instruments like the i-STAT can use the same EQC options that are available for other types of testing.

The guidelines are now available for anyone to read free of charge on the CMS Web site—just go to:
<http://www.cms.gov/clia/appendc.asp> ◆

STRATEGIES MANAGEMENT ALERT Jan 12 2004

Firm Guidance Finally Available to Clinical Laboratories Regarding Date of Service Rule

Previous regulations left it up to individual contractors to decide how long a specimen must be stored before being considered "archived." Requests from regional laboratories poured into the Centers for Medicare & Medicaid Services asking for a uniform standard. The problem for labs with multiple contractors was that in one jurisdiction the date of service would be the collection date, while in another it would be the day the specimen was retrieved from storage creating a major roadblock when it came to programming automated electronic billing software

A notice published in the Dec 24 Federal Register offers much needed clarification:

- To be considered "archived" a specimen must be stored for more than 30 calendar days.
- The date of service for archived specimens is the date obtained from storage.
- The date of service for specimens stored 30 days or less is the date it was collected.
- The date of service for tests when the collection spanned more than 24 hours, such as with fecal occult blood tests and urine collections for hormone analysis in pregnant women, is the date collection began. To see the rule, go to: http://www.access.gpo.gov/su_docs/fedreg/a031224c.html

MEDICAL NEWSWIRE JAN 15 2004 ◆

New Staff at Avera McKennan's Client Services Dept.



Kim Heim has been at McKennan for 6 years. She joined AMRL as a Client Service representative one month ago. She grew up in Wessington Springs, and now lives in Egan, SD. She graduated from Mitchell Vo-Tech in 1992 in the Laboratory Technician program. She is also a graduate of the Avera McKennan Paramedic Program - 1998.

She and her spouse Bob have two children, Tanner (4) and Logan (3). She and her family spend time camping and attending sporting events.

Kim enjoys all the people she works with, and she thrives on the different challenges that come with each day.



Pam Stroud has been at McKennan for 2 1/2 years. She recently joined the client service department for Avera McKennan Regional Laboratory. She has an Associates Degree from Southeast Vo Tech in the medical laboratory field. She hails from Salem, SD., has one son, Aaron who is 25 years old, 2 dogs, 5 cats and 2 turtles. She spends her spare time reading, crocheting and enjoying time with her pets. She loves people, and interacting and working with AMRL clients every day is truly enjoyable.