

NEW WAIVED TESTS

On October 20, 2003, the Food and Drug Administration (FDA) approved the **EKF Diagnostic Hemo_Control Measurement and Hemo_Control Microcuvettes**, K031898, for waived status for the analyte hemoglobin. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On October 21, 2003, the FDA approved the **Genosis Fertell Female Fertility Test**, K02002, for waived status for the analyte follicle stimulating hormone (FSH).

On November 25, 2003, the FDA approved the **Biosys Laboratories Optima Urine Analyzer**, K980047/A005 for the analytes urine qualitative dipstick ketone, blood, bilirubin, glucose, leukocytes, nitrate, pH, protein, specific gravity and urobilinogen. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On February 2, 2004, FDA approved the **SA Scientific SAS Strep A (Direct From Throat Swab)**, K023270/A006, for waived status for the analyte Streptococcus Group A. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On February 6, 2004, the FDA approved the **Quidel Quickvue Influenza A+B Test**, K031899/A004, for waived status for the analyte Influenza A/B. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On February 24, 2004, the FDA approved the **Advantage Diagnostics Corporation ADC Multiple Drug Test Card**, K023712/A001, for waived status for the analytes cocaine metabolites, cannabinoids, methamphetamines, opiates and PCP. The waived test status is applicable to the professional use test system and their instructions cleared by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

On February 23, 2004, the FDA approved the **Synova Healthcare Menocheck Menopause Indicator Test**, K023408/A003, for waived status for the analyte FSH. The waived test status is applicable to the test system and their instructions approved by the FDA. The FDA recommended that the test system instructions include a statement that the test system is waived under CLIA.

OSCAR RELEASE 2004.1

On February 26, 2004, the Division of Laboratory Services (DLS) in Survey and Certification Group (SCG) of the Centers for Medicare and Medicaid Services (CMS) sent a note to all CLIA Regional Office (RO) staff and OSCAR Coordinators informing them about the upcoming Oscar release 2004.1. This release was completed on February 27, 2004.

The contents of the OSCAR 2004.1 release were the following:

1. CLIA Revised D Tags

- On March 3, 2004, the Oscar system was converted to accommodate the new deficiency tags (D tags). Previous D tags were not kept but were converted to the comparable requirement in the final regulations. In many cases, this is a one-to-one conversion. For a number of tags the conversion is not so straightforward. Some tags convert to multiple tags.
- The crosswalk provided with the January 8 memorandum was revised and was attached to this note.
- The ASPEN Survey Explorer has been updated to include the current CLIA regulations, published in the Federal Register on January 24, 2003 and their associated interpretive guidelines. The Laboratory Regulation Sets are posted on the QTSO website to be downloaded for use during laboratory surveys.

2. CLIA Enforcement Edits

The following three additional enforcement edits were added:

- The date the state and/or RO propose the sanction cannot be less than the survey date or the first revisit date, if present;
- The date the appeal is filed to the Department Appeal Board must be greater than or equal to ALJ decision date; and
- The rescind date, if present, must be equal to the imposed date.

3. CLIA Leap Year Conversion

The programming has been changed to correct a problem with dates generated based on the preceding leap year. We requested that States be encouraged not to use the February 29 date so that we can keep the certificate periods consistent.

4. CLIA /ODIE Test Volume

The online program was modified to ensure the proper storage of test volume for both compliance and accredited laboratories.

5. ODIE Ambulatory Surgical Centers (non-CLIA)

The value of American Osteopathic Association (AOA) to accreditation indicator was added for ASCs on the C&T form. The user can only select 'AOA' if survey date (L34) is on or after January 30, 2003.

LIST OF PROFICIENCY TESTING (PT) PROGRAMS APPROVED FOR THE CALENDAR YEAR 2004 UNDER CLIA

On February 27, 2004, DLS/SCG in CMS sent a memorandum to all Survey and Certification Regional Office Management that provided a list of PT programs that have been approved under CLIA for certain specialties, subspecialties, analytes/tests for the calendar year 2004. These include:

Accutest, Inc
American Academy of Family Physicians (AAFP)
American Association of Bioanalysts (AAB)
American Proficiency Institute (API)
California Thoracic Society (CTS)
The College of American Pathologists (CAP)
External Comparative Evaluation for Laboratories (Excel)
Medical Laboratory Evaluation (MLE)
New Jersey Department of Health and Senior Services
Commonwealth of Pennsylvania
Puerto Rico Department of Health
Wisconsin State Laboratory of Hygiene
Maryland Department of Health and Mental Hygiene
New York State Department of Health

For a complete list of analytes, please access the CLIA website at:
www.cms.hhs.gov/clia/ptlist.pdf

UPDATE TO NCCLS SUSCEPTIBILITY TABLES

On March 4, 2004, DLS/SCG in CMS issued a memorandum stating that we recently received the NCCLS documents entitled "Performance Standards for Antimicrobial Susceptibility Testing; Fourteenth Informational Supplement" (M100-S14). This NCCLS document contains the following updated NCCLS susceptibility limit tables:

M100-S14: (For Use With M2-A8 - Disk Diffusion), Table 3. Acceptable Limits for Quality Control Strains Used to Monitor Accuracy of Disk Diffusion Testing of Nonfastidious Organisms (Using Mueller-Hinton Medium Without Blood or Other Supplements);

M100-S14: (For Use With M2-A8 – Disk Diffusion), Table 3A. Acceptable Limits for Quality Control Strains Used to Monitor Accuracy of Disk Diffusion Testing of Fastidious Organisms;

M100-S14: (For Use With M7-A6 - MIC Testing), Table 3. Acceptable Limits for Quality Control Strains Used to Monitor Accuracy of Minimal Inhibitory Concentrations (MICs) (μ g/mL) of Nonfastidious Organisms (Using Cation-Adjusted Mueller-Hinton Medium Without Blood or Other Nutritional Supplements); and

M100-S14: (For Use With M7-A6 - MIC Testing), Table 3A. Acceptable Limits for Quality Control Strains Used to Monitor Accuracy of Minimal Inhibitory Concentrations (MICs) (μ g/mL) of Fastidious Organisms.

These updated tables included the following changes:

- MIC quality control (QC) criteria for oritavancin was added for *Staphylococcus aureus* ATCC® 29213 and *Enterococcus faecalis* ATCC® 29212 in Table 3 (M7-A6; Table 3) and for *Streptococcus pneumoniae* ATCC® 49619 in Table 3A (M7-A6; Table 3A);
- A footnote was added to the MIC table (M7-A6; Table 3) that includes the QC range for ticarcillin-clavulanic acid and *Escherichia coli* ATCC® 35218;
- A footnote was added to both the disk diffusion Table 3A (M2-A8; Table 3A) and the MIC Table 3A (M7-A6; Table 3A) that specifies the QC ranges for amoxicillin-clavulanic acid and *Escherichia coli* ATCC® 35218 when using *Haemophilus* Test Medium (HTM); and
- A footnote was added to the MIC table (M7-A6; Table 3A) that indicates testing of amoxicillin and *Escherichia coli* ATCC® 35218 on HTM may help to determine if the isolate has maintained its ability to produce β -lactamase.

These updated tables replace Table 3 and Table 3A from M2-A8 Disk Diffusion, and Table 3 and Table 3A from M7-A6 MIC Testing that were published in the past and should be used according to previous instructions for NCCLS tables provided in Appendix C of the SOM.