NEW WAIVED TESTS

On June 4, 2004, the Food and Drug Administration (FDA) approved the **Polymedco Poly Stat Strep A Liquid Test**, K021375/A004, 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 June 9, 2004, the FDA approved the **Stanbio Hemoglobin Analyzer**, K032482, 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 June 23, 2004, the FDA approved the **Trinity Biotech Uni-Gold HIV**, BP030025, for waived status for the analyte HIV antibodies. 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 June 25, 2004, the Food and Drug Administration (FDA) approved the **Orasure Oraquick Advance Rapid HIV-1/2 Antibody Test (Oral Fluid, Fingerstick Whole Blood and Venipuncture Whole Blood)**, BP010047/S016, for waived status for the analytes HIV-1 and HIV-2 antibodies. 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 June 28, 2004, the FDA approved the **Immunostics Detector Strep A Direct**, K023766/A010, 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 June 30, 2004, the FDA approved the **Hemocue HB 201+System (Capillary, Venous, Arterial Whole Blood)**, K032203/A001, for waived status for the analyte hemoglobin, single analyte inst. w/self-cont... 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 August 18, 2004, the Food and Drug Administration (FDA) approved the **ThyroTec, Inc. ThryoTest Whole Blood TSH Test**, K030912/A002, for waived status for the analyte TSH. 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 August 19, 2004, the FDA approved the A**ccu-Stat Drugs of Abuse Home Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates and Phencyclidine**, K041221, for waived status for the analytes cannabinoids, cocaine

metabolites, amphetamines, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates and phencyclidine. 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 August 24, 2004, the FDA approved the **Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC)** and the **Accu-Stat Drugs of Abuse Home Test for Marijuana (THC)**, K040327/A003, for waived status . 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 August 26, 2004, the FDA approved the **Bristol-Myers Squibb Co. Choice DM**, K033847/A001, for waived status for the analyte glycated hemoglobin, total. 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 September 16, 2004, the Food and Drug Administration (FDA) approved the **PEP Performance Enhanced Products Strep A Cassette Test**, K023766/A011, 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 September 16, 2004, the FDA approved the **PEP Performance Enhanced Products Strep A Dipstick**, K010582/A015, 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 October 15, 2004, the FDA approved the **Applied Biotech Truview Mono Test**, K973559/A007, for waived status for the analyte infectious mononucleosis antibodies. 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.

FDA LETTER TO MANUFACTURERS OF ANTIMICROBIAL SUSCEPTIBILITY TESTS

On June 23, 2004, the FDA sent a letter to manufacturers of antimicrobial susceptibility tests. This letter informed manufacturers that the FDA and the Centers of Disease Control and Prevention (CDC) have become aware of a third documented clinical isolate of vancomycin-resistant Staphylococcus aureus (VRSA) from a patient in the U.S. (MMWR- April 23, 2004/ 53(15);322-323 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5315a6.htm); and that follow-up investigations with this isolate showed inconsistent detection of vancomycin resistance by commercial automated susceptibility systems and raised the concern that additional

VRSA infections may occur and be missed when these systems are used for reporting S.aureus resistance and susceptibility profiles.

This letter said the following:
“Until automated and other commercial systems can be evaluated for reliability with relevant organisms, clinical laboratories performing such testing should be aware of this potential shortcoming of these systems and should use methods that have been shown to reliably detect the strains that have been described. At present, non-automated MIC methods (e.g., broth microdilution or agar dilution) with a full 24-hours incubation before reading results are recommended. The CDC previously reported that BHI agar supplemented with 6ug/mL vancomycin is useful for detecting staphylococci with reduced susceptibilities to vancomycin (JCM 1998; 36:1020-7) and that this method is also reliable with the three recognized VRSA isolates.”