

OIG REPORTS RELATING TO CLIA

OIG FINAL REPORT: CLIA REGULATION OF UNESTABLISHED LABORATORY TESTS

On July 1, 2001, the Office of the Inspector General (OIG) released the final report entitled "CLIA Regulation of Unestablished Laboratory Tests." This report examined the regulation of unestablished laboratory tests--i.e., tests that are not generally accepted by those involved in traditional laboratory practice and oversight. An example of such a test is "live blood cell analysis." The OIG found that this test has not been able to meet requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Furthermore, some laboratories performing unestablished tests may have improperly obtained CLIA certification. This report may be viewed at:

<http://oig.hhs.gov/oei/reports/oei-05-00-00250.pdf>

OIG FINAL REPORT: ENROLLMENT AND CERTIFICATION PROCESSES IN THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS PROGRAM

On August 27, 2001, the Office of the Inspector General (OIG) released their final report, "Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program (CLIA)." The report identifies vulnerabilities in CLIA enrollment and certification processes and recommends specific actions to address these, but notes that additional funding may be required for their implementation because of limited resources. The report may be viewed at:

<http://oig.hhs.gov/oei/reports/oei-05-00-00251.pdf>.