SURVEY AND CERTIFICATION MEMORANDUM

The following memorandum was released on October 3, 2008:

S&C-09-02 - Approval of Deeming Authority of Det Norske Veritas Healthcare, Inc. for Hospitals

This memorandum summarized the new approval of Det Norske Veritas Healthcare, Inc. (DNV Healthcare) for recognition as a national accreditation program for hospitals seeking to participate in the Medicare program as announced in the Federal Register released on Monday, September 29, 2008. The organization is approved through September 26, 2012.

While this action does not directly involve laboratories, clarification was sought regarding the organization's acceptance of CLIA certification for laboratories serving hospitals under their accreditation. This organization will acknowledge either a CLIA certificate of compliance or a CLIA certificate of accreditation as acceptable for compliance with their standards. There is no requirement that the laboratories be exclusively under a CLIA certificate of accreditation.

For additional information, logon to the following CMS website:
http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

NEW WAIVED TESTS

On October 31, 2008, the Food and Drug Administration (FDA) approved the **Wako APOLOWAKO Analyzer {Whole blood},** K080125, for the analytes cholesterol and triglyceride. Waived 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 is waived under CLIA.

On October 31, 2008, the FDA approved the **Wako APOLOWAKO Analyzer {Whole blood},** K080123, for the analytes glucose and glycosylated hemoglobin (Hgb A1c). Waived 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 is waived under CLIA.

On October 31, 2008, the FDA approved the **Siemens DCA 2000 analyzer** and th**e Siemens DCA 2000+ analyzer,** K951361, for the analyte glycated hemoglobin, total. Waived 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 is waived under CLIA.

On November 4, 2008, the FDA approved the **Mossman Associates, Inc. NicCheck I Test Strip,** K963733 for the analyte nicotine and/or metabolites. Waived 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 is waived under CLIA.

On November 4, 2008, the FDA approved the **Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test,** X070057, for the analyte pH, urine. Waived 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 is waived under CLIA.

On November 13, 2008, the FDA approved the following under K053110:

- **Abbott i-STAT Crea Cartridge {Whole blood}** for creatinine;
- **Abbott i-STAT G Cartridge {Whole blood}** for glucose;
- **Abbott i-STAT 6+ Cartridge {Whole blood}** for glucose, hematocrit, hemoglobin, sodium, urea, chloride, and potassium;
- **Abbott i-STAT EC4+ Cartridge {Whole blood}** for glucose, hematocrit, hemoglobin, sodium, and potassium; and
- **Abbott i-STAT E3+ Cartridge {Whole blood}** for hematocrit, hemoglobin, sodium, and potassium.

Waived 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 is waived under CLIA.