MEASUREMENTS AND STANDARDS FOR CLINICAL DIAGNOSTICS

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Abstract

The recently enacted European Directive 98/79/EC on in vitro diagnostic medical devices (IVDs) requires that products be traceable to "standards of the highest order", e.g., nationally/internationally recognized certified reference materials (CRMs). At present, reference methods and/or CRMs are available for only a limited number of the several hundred analytes that are measured in medical laboratories on a daily basis using IVDs. Since approximately 60% of the IVD products on the European market ($5.6 billion in 1998) are imported from the USA, this becomes an important trade issue.

NIST has developed and maintains high accuracy reference methods for 12 important health status markers (calcium, chloride, cholesterol, creatinine, glucose, lithium, magnesium, potassium, sodium, triglycerides, urea and uric acid) to support the national reference system for clinical chemistry. These definitive methods and our Standard Reference Materials (SRMs) have helped the Centers for Disease Control and the College of American Pathologists in proficiency testing of more than 20,000 U.S. clinical laboratories. Laboratories, doctors, and their patients have gained accuracy and confidence in test results due to NIST efforts. They also have saved time and money by getting it right the first time.

New challenges are on the horizon as medical research is identifying new health care markers for which they need measurement methods and standards. Many of these markers are proteins, peptides or other large biological molecules, usually present in low concentrations. The US IVD industry needs help to assure a level-playing field. NIST is working on new analytical tools and reference materials to meet these challenges.