



Source: A2LA

Website: <http://www.a2la.org>

Contact: Ray Minnick at 301-644-3215

E-Mail: rminnick@a2la.org

Spectra Laboratories – Rockleigh, NJ earns ISO 15189

FREDERICK, Maryland (June 3, 2010)—The American Association for Laboratory Accreditation (A2LA) announced today that its first U.S. based medical testing laboratory has earned accreditation in accordance with stringent international requirements of ISO 15189:2007 *Medical Laboratories - Particular requirements for quality and competence*. The accredited laboratory, [Spectra Laboratories](#) of Rockleigh, New Jersey, demonstrated technical competence for a defined scope of rigorous tests and operation of a quality management system. Spectra Laboratories is a unit of Fresenius Medical Care North America (NYSE:FMS).

A2LA's ISO 15189:2007 accreditation is recognized by all 65 of the signatories to the International Laboratory Accreditation Cooperation mutual recognition agreement and 32 signatories to the Asia-Pacific Laboratory Accreditation Cooperation mutual recognition agreement. This means that Spectra Laboratories' accreditation will be recognized in all of the signatories' economies. A2LA is a nonprofit, non-governmental, public service, membership society, whose stated mission is "to provide comprehensive accreditation services for laboratories, inspection bodies, proficiency testing providers, and reference material producers." Services are available to any type of laboratory or inspection body, product certification body, reference material provider, and proficiency testing provider, whether governmental or private. It is the largest multi-discipline accreditation body in the United States.

"Obtaining A2LA accreditation was the result of the collective efforts undertaken by the staff and personnel of the laboratory during the past four years. Considerable energy and focus were devoted to labor and training that ultimately led to this accreditation. This achievement represents Spectra Laboratories' continued leadership in addressing the domestic and global needs of the clinical laboratory arena" stated Roxanne Robinson, A2LA vice president and chief operating officer.

Nicholas Brownlee, president, Spectra Laboratories commented, "We are very pleased to be awarded the A2LA ISO 15189 accreditation. Over the years, Spectra has demonstrated its adherence to rigorous regulatory standards through the voluntary pursuit of accreditations. We believe that the ISO 15189 accreditation through A2LA enhances and strengthens our market leadership position as a clinical laboratory service provider."

"It is a credit to our great team of employees, whose unstinting commitment to quality, day in and day out, that Spectra earned this designation," added Chinu M. Jani, general manager and vice president, Spectra Laboratories (Rockleigh, NJ). "The unique accreditation further validates our service to the medical providers and to the patients for whom they care," Jani continued.

Established in 1982, Spectra Laboratories, Inc. is the leading provider of renal-specific laboratory testing services in the United States. The company's state-of-the-art analytical equipment, automated specimen processing, and reporting applications provide more than 57 million rapid and reliable test results annually, reaching over 168,000 renal patients and 2,300 free-standing and hospital-based dialysis facilities across the United States. Spectra also supplies laboratory services to the clinical research and correctional healthcare communities through its Spectra Clinical Research and Spectra Diagnostics divisions. Fresenius Medical Care North America is the world's leading provider of services and products for individuals undergoing dialysis because of chronic kidney failure, a condition that affects about 1.9 million people worldwide.