



ATCC Adds ISO 13485:2003 Certification to its Quality Management Program to Further Strengthen the Organization's Commitment to the Production of Quality Products

The most cited resource for biomaterials globally strengthens its ability to produce standards, controls, reagents, and infectious disease surveillance kits

FOR IMMEDIATE RELEASE – Manassas, VA, August 7, 2014 – ATCC, the premier global biological materials resource and standards organization, announced today that it has received [ISO 13485:2003](#) certification for the development, manufacture, and distribution of standards, controls, reagents and *in vitro* diagnostic test kits.

Every day researchers in life science, medical diagnostics, applied sciences, and clinical drug development leverage ATCC's expansive collection of cell lines, microorganisms, cellular and microbial panels, genomic and synthetic nucleic acids, biological products, and associated derivatives to generate quality research and reproducible results. ISO 13485 enhances ATCC's existing Quality Management Program as an ISO 9001:2008 certified and ISO 17025:2005 and ISO Guide 34:2009 accredited organization.

"ISO accreditations have bolstered ATCC to evolve from a traditional culture collection to a trusted partner and resource for biomaterials and custom solutions globally," stated Kristina Peterman, ATCC Senior Director, Compliance, Quality Assurance and Laboratory Testing Services/Chief Compliance Officer. "Our rigorous quality management systems and infrastructure coupled with this certification provide our international customers with greater traceability of our raw materials and products."

ATCC products produced under ISO 13485 certification can be used as controls in molecular diagnostic research, including the development and validation of assays; the detection, evaluation, and analysis of disease status; and the surveillance of infectious agents affecting public health. Examples of products covered under this certification include the [ATCC® HIV-1 Drug Resistance Genotyping Kit](#) used for surveillance purposes and the ATCC Synthetic Dengue virus RNA standards, representing serotypes 1-4 ([ATCC® VR-3228SD™](#), [ATCC® VR-3229SD™](#), [ATCC® VR-3230SD™](#), and [ATCC® VR-3231SD™](#)). Each quantified Synthetic Dengue RNA standard contains short fragments from the capsid, membrane, and envelope genes of the Dengue virus genome. They exhibit minimal variability, eliminate the need to culture viruses, and can be used under BSL-1 conditions for validation and verification studies.

ATCC will further develop and manufacture a pipeline of new products under ISO 13485.

About ATCC

ATCC collaborates with and supports the scientific community with industry-standard products and innovative solutions. With the world's largest and most diverse collection of human, animal, and plant cell lines, as well as molecular genomic tools, microorganisms, and biological products, ATCC is a trusted biological resource for the worldwide research community. Together, the people of ATCC share in its mission to acquire, authenticate, preserve, develop, and distribute biological materials and information for the advancement of scientific knowledge. Founded in 1925, ATCC is a non-profit organization with headquarters in Manassas, VA. Discover more at www.atcc.org.

Company contact

Renée Randall
ATCC
Tel: (703) 365-2773
Email: rrandall@atcc.org