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VOLUME 30 NUMBER 1

# ATCC CONNECTION™



## What is in your Vial? The Requirement for Polyphasic Microbial Identification and Strain Characterization of *Escherichia coli* (*E. coli*) ATCC® 8739™

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In the pharmaceutical, personal care, and food industries, quality control testing is used to monitor and address potential microbial contamination of products, processes and environments. Microbial strains with confirmed identity, viability and purity—produced by meticulous laboratory procedures that minimize subculturing—are important components of quality control testing programs. The testing procedures and the associated use of reference QC organisms are often conducted under United States, European, and Japanese compendia guidelines.

For the pharmaceutical industry, recent regulatory guidelines issued to address current good manufacturing practice (cGMP)<sup>1</sup> have stressed a need for genetic-based techniques for the identification of microorganisms. These techniques have been proposed because of the advantages they can bring to understanding and investigating potential physical and temporal sources of microbial contamination recovered in the course of pharmaceutical manufacturing. In response to industry demands for rapid microbiological testing, instrumentation and associated databases have been developed to allow for the standardized testing of both

phenotypic and genotypic traits across a wide array of microorganisms.

A polyphasic approach to identification and strain characterization provides a more definitive confirmation and avoids the pitfalls of misidentification resulting from the limitations of various commercial phenotypic and genotypic microbial ID systems and their associated databases. In the current study, Molecular Epidemiology Inc. (MEI) examined a polyphasic identification approach which combined genetic-based microbial ID (16S rRNA sequencing) with a broad spectrum of phenotypic and biochemical analysis to accurately identify a very common microorganism used in QC compendial testing, *Escherichia coli* ATCC® 8739™. This species also forms the platform for both industrial fermentation bioprocesses in the pharmaceutical industry and can represent an environmental contaminant in various production processes (e.g. food) with a potential for pathogenicity. The current study was further complemented by DNA fingerprinting using pulsed field gel electrophoresis (PFGE) with three restriction

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## Introducing Certified Reference Materials from ATCC

The inherent variability of biological materials brings unique challenges to establishing reference materials for *in vitro* model systems. ATCC® Certified Reference Materials (CRMs) were developed to meet these challenges. ATCC is ISO Guide 34 and ISO/IEC 17025:2005 accredited. For biological material production and testing processes, ATCC is accredited to ISO Guide, an international multi-industry standard specifically designed for producers of reference materials. ISO Guide 34 provides the highest level of quality assurance; providing objective third-party recognition that ATCC is a qualified reference material producer. ATCC CRMs are produced using an ISO 34 accredited process and tested in an ISO 17025 accredited laboratory. Certification to ISO 17025:2005 attests that ATCC is consistently proficient in testing the quality of CRMs. ISO 17025:2005 provides assurance that the characterization and purity testing (QC testing) protocols used in the manufacture of ATCC CRMs are precise, accurate and repeatable. ATCC Certified Reference Materials produced under an ISO Guide 34 accredited process have confirmed identity, viability, purity, well-defined characteristics and an established chain of custody—all qualities essential to their effectiveness as biological standards. Count on ATCC CRMs to provide consistent, reliable results.

ATCC Certified Reference Materials are homogeneous and stable with respect to one or more specified properties and for which traceability and values of uncertainty at a stated level of confidence are established, where applicable. ATCC CRMs have:

- Confirmed identity, verified using polyphasic characterization testing (genotypic and phenotypic)
- An established chain of custody using serialized vials
- Proven integrity at a stated level of confidence

Each CRM vial is accompanied by a detailed certificate of analysis (according to ISO Guide 31) stating lot specific property values, expiration date, and proper use; confirming that the necessary procedures have been carried out to ensure their validity and traceability.



Intended uses of ATCC Certified Reference Materials are to:

- Challenge assay performance
- Validate or compare test methods
- Facilitate inter-laboratory studies
- Establish sensitivity, linearity and specificity during assay validation or implementation
- Benchmark critical assay performance during development/validation for regulatory submissions and production lot release
- Use in testing and calibration of ISO 17025 accredited laboratories
- Produce laboratory reference materials
- Use in Pharmacopeia compendial tests
- Produce ATCC® Proficiency Standard® Program proficiency panels

For more information regarding new ATCC CRMs, please visit [www.atcc.org](http://www.atcc.org) and click on 'ATCC Certified Reference Materials' in the Standards drop down menu. Please contact us regarding custom Certified Reference Materials.

### Ordering Information

The following CRMs are now available:

ATCC® No.	Item Description	Designation
<b>CELL LINES</b>		
CRM-CCL-2™	HeLa	
CRM-CRL-1550™	Ca Ski	
<b>BACTERIA</b>		
CRM-6633™	<i>Bacillus subtilis</i> subsp. <i>spizizenii</i>	NRS 231
CRM-11437™	<i>Clostridium sporogenes</i>	L.S. McClung 2006
CRM-8739™	<i>Escherichia coli</i>	Crooks
CRM-11229™	<i>Escherichia coli</i>	AMC 198
CRM-9341™	<i>Kocuria rhizophila</i>	FDA strain PCI 1001
CRM-9027™	<i>Pseudomonas aeruginosa</i>	R. Hugh 813
CRM-6538™	<i>Staphylococcus aureus</i>	FDA 209
CRM-12228™	<i>Staphylococcus epidermidis</i>	FDA strain PCI 1200
<b>FUNGI AND YEAST</b>		
CRM-16404™	<i>Aspergillus brasiliensis</i>	WLRI 034 (120)
CRM-10231™	<i>Candida albicans</i>	3147
CRM-9763™	<i>Saccharomyces cerevisiae</i>	NRRL Y-567