

## FACILITY OVERVIEW

# Newark, Delaware

Charles River's Accugenix® laboratory in Newark, Delaware provides cGMP-compliant, ISO 17025 accredited contract testing services for rapid and accurate identification of environmental isolates. We utilize DNA sequencing and MALDI-TOF technologies, including tracking and trending solutions for secure data management.

### Background

- Founded as AccuLab in 1990 performing microbial identifications by fatty acid analysis.
- Started performing DNA Sequencing identifications in 1999 under the name Accugenix, Inc. Discontinued fatty acid analysis in 2005.
- Expanded testing portfolio to include MALDI-TOF mass spectrometer identification services in 2010.
- Acquired by Charles River Laboratories in 2012 as a wholly owned subsidiary, but retained legal name of Accugenix, Inc.
- Developed strain typing services in 2013 and an in-house MALDI-TOF identification solution with Axxcess® in 2014.

### Laboratories and Facilities

- 22,000 ft<sup>2</sup>, approximately two-thirds of which is laboratory space, including dedicated DNA sequencing and MALDI-TOF testing laboratories, and an R&D laboratory.

### Staff

- Approximately 76 employees, including 20 with Masters & higher degrees.

### Service Areas/Study Types

Specialize in microbial identification and strain typing services utilizing Charles River's proprietary test methods and libraries.

- DNA sequencing
- MALDI-TOF mass spectrometry
- Strain typing

There are currently 8 Accugenix® laboratories worldwide in the US, France, Ireland, Singapore, India, Korea, Australia, and China.

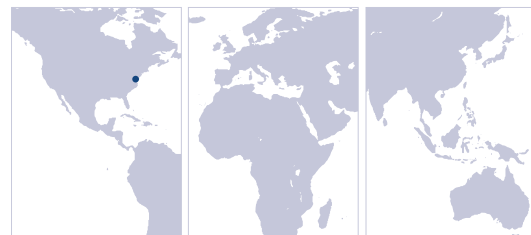
### Compliance, Certifications, Accreditations, and Professional Affiliations

Charles River's Newark, Delaware facility operates in compliance with the requirements of the following regulatory agencies or accredited organizations:

- Meets US FDA cGMP requirements; registered with the US FDA.
- ISO 17025 accredited by A2LA for AccuGENX-ID® and AccuPRO-ID®.

### Quality and Process Initiatives

- Origination, development, and validation of all Accugenix® test methods, microbial reference libraries, and software.
- Development and validation of the Accugenix® Laboratory Information Management Systems (LIMS) and Customer Web Portal used by customers to submit test requests, access results, and perform tracking and trending of their results.
- Excellent track record of regulatory compliance with ISO assessments, FDA inspections, and Client Audits.
- The Newark facility has held ISO 17025 accreditation since 2016.



EVERY STEP OF THE WAY