



COLLEGE of AMERICAN
PATHOLOGISTS

CERTIFICATE OF ACCREDITATION

AZENTA US INC
Laboratory
South Plainfield, New Jersey
Jeffrey M. Otto, PhD, MBA

CAP Number: 8015683
AU-ID: 1625854
CLIA Number: 31D2038673

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to **September 9, 2025** to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Kathleen G. Beavis, MD, Accreditation Committee Chair

Emily Volk, MD, FCAP, President, College of American Pathologists





COLLEGE of AMERICAN
PATHOLOGISTS

CAP#: 8015683
AU-ID: 1625854
September 15, 2023

Jeffrey M. Otto, PhD, MBA
AZENTA US INC
Laboratory
Clinical NGS Services
111 Corporate Blvd
South Plainfield, New Jersey 07080-2480

Dear Dr. Otto:

The College of American Pathologists (CAP) is pleased to inform you that the medical laboratory you direct, AZENTA US INC Laboratory, in South Plainfield, New Jersey, has successfully met the Laboratory Accreditation Program Standards for Accreditation in the area(s) listed on the attached sheet.

The Accreditation Committee congratulates you and your entire staff on this achievement as together you provide excellence in laboratory medicine services. This is a significant accomplishment and I encourage you to share the inspection results with your organization's leadership.

Your Certificate of Accreditation is enclosed. Accreditation is maintained through continuous compliance with the Terms of Accreditation contained in the attached document. **Please retain this letter and list of accredited services in your records, as this is your official notification of accreditation.**

Thank you for your laboratory's commitment to continuous quality improvement. As your trusted partner, we look forward to working with you in the future to help you achieve the highest quality service and standard of care for the patients you serve.

Sincerely,

Kathleen G. Beavis, MD, Accreditation Committee Chair

cc: Richard Scanlan, MD, Council on Accreditation Chair

Terms of Accreditation

Accreditation by the College of American Pathologists' (CAP) Accreditation Program is contingent on compliance with the terms and obligations listed below.

A laboratory that is accredited by CAP or that has applied for accreditation must:

- Cooperate in any CAP investigation or inspection and promptly notify the CAP if the laboratory becomes:
 - The subject of an investigation by a government entity (including federal, state, local, or foreign),
 - The subject of a validation inspection, or
 - The subject of adverse media attention.
- Promptly notify the CAP if the laboratory discovers actions by laboratory personnel that appear to violate federal, state, or local laws that regulate laboratories.
- Have a written procedure for employees to communicate concerns about quality and safety to management and for management to investigate employee complaints.
- Incorporate corrective or preventive actions into the laboratory Quality Management Plan
- Provide a trained inspection team comparable in size and scope to that required for its own inspection, if requested by the regional and/or state commissioner at least once during the two-year accreditation period.
- Participate annually in a CAP-accepted proficiency testing program, if applicable.
- Promptly notify the CAP and, if subject to US CLIA regulations, the Centers for Medicare and Medicaid Services (CMS), in writing 30 days prior to any changes in the following: directorship, location, ownership, name, insolvency or bankruptcy.
- Promptly notify the CAP when there is a change in the laboratory's test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing.
- Authorize the CAP to release its inspection and proficiency testing data and other information required by law to the appropriate regulatory or oversight agencies such as CMS, Department of Veterans Affairs, Department of Defense, Joint Commission, HFAP(AOA), UNOS, or state/provincial agencies.
- If the laboratory is subject to US CLIA regulations:
 - Make available on a reasonable basis the laboratory's annual PT results upon request of any person.
 - Allow CMS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operation and permit CMS to monitor the correction of any deficiencies found through such an inspection.
 - Obtain a CLIA Certificate of Accreditation and pay all applicable fees as a CLIA-certified laboratory if it will use CAP accreditation to meet CLIA certification requirements.
- Submit a completed Self-Inspection Verification Form in the interim year.
- Accept and adhere to the Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design, if the laboratory is/ or will use the CAP Certification Mark of accreditation. The Agreement may be downloaded and printed from the CAP web site.
- Submit only documentation and other materials to CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, unless the laboratory must submit PHI to CAP in order to respond to a deficiency or patient complaint.
- Refrain from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.

- Laboratories participating in the Laboratory Accreditation Program are required to pay for CAP Annual Accreditation Fees based on the applicable Discipline/Sub-Discipline of the lab. Those fees are set based on complexity points, test volume points, base fee and specialty fees that apply at the time of the billing month for the site. Find further information about specific fees by emailing accred@cap.org.
- Laboratories participating in any CAP Specialty Programs, including Reproductive Laboratory Accreditation, Forensic Drug Testing Accreditation, Biorepository Accreditation, System Inspection Option, are required to pay for these Annual Accreditation Fees that apply at the time of the billing month for the site.
- International Laboratories are subject to pay business class airfare for any United States-based inspector that inspects on-site.