COLLEGE of AMERICAN PATHOLOGISTS

CERTIFICATE OF ACCREDITATION

Quest Diagnostics Venture LLC
Clinical Laboratories
Pittsburgh, Pennsylvania
Kambiz Merati, MD

CAP Number: 1285102
AU-ID: 1178140
CLIA Number: 39D0938116

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 **July 6, 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#: 1285102
AU-ID: 1178140
September 27, 2023

Kambiz Merati, MD
Quest Diagnostics Venture LLC
Clinical Laboratories
875 Greentree Rd, 4 Parkway Ctr
Pittsburgh, Pennsylvania 15220-3610

Dear Dr. Merati:

The College of American Pathologists (CAP) is pleased to inform you that the medical laboratory you direct, Quest Diagnostics Venture LLC Clinical Laboratories, in Pittsburgh, Pennsylvania, 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.

COLLEGE of AMERICAN PATHOLOGISTS

Quest Diagnostics Venture LLC
Clinical Laboratories

LAP Number: 1285102
AU ID: 1178140

The above Laboratory is accredited by the College of American Pathologists Laboratory Accreditation Program for the following services:

All Common
Bacteriology
Body Fluid Analysis
Chemistry
Coagulation
Director Assessment
Hematology
Immunology
Laboratory General
Molecular Microbiology
Molecular-based COVID-19 Testing
Mycology
Parasitology
Special Chemistry
Toxicology
Urinalysis
Virology

This accreditation is valid for the period ending July 6, 2025.

PLEASE RETAIN THIS DOCUMENT IN YOUR RECORDS.

Quest Diagnostics Venture LLC
Clinical Laboratories

LAP Number: 1285102
AU ID: 1178140
Reference Number: 39D0938116

The Laboratory Accreditation Program currently has the subspecialty information listed below on file for your laboratory. This information is used for reporting to regulatory agencies.

ABO Group/Rh Type
Antibody Detection (Non-Transfusion)
Bacteriology
Endocrinology
General Immunology
Hematology
Mycology
Parasitology
Routine Chemistry
Syphilis Serology
Toxicology
Urinalysis
Virology

PLEASE RETAIN THIS DOCUMENT IN YOUR RECORDS.

Laboratory Accreditation Programs
List of Deficiencies

LAP Number: 1285102

Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

Address: 875 Greentree Rd, 4 Parkway Ctr
Pittsburgh, PA 15220-3610

Director: Merati, Kambiz, MD

AU Inspection Date: 06/12/2023

Inspection Type: Routine

Team Leader: Speakman, Eric D., MD

Number of Deficiencies: 8

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1289704
Section Unit (SU): Chemistry & Toxicology
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement

There were no deficiencies from the inspection of this section.

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1289702
Section Unit (SU): Chemistry, Special Chemistry
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement

There were no deficiencies from the inspection of this section.

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1289708
Section Unit (SU): Endocrinology (Special Chemistry)
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement
Chemistry and Toxicology	CHM.13750	II	For qualitative tests that use a quantitative cut-off value to distinguish positive from negative results, the analytic performance around the cut-off value is verified or established initially, and reverified at least every six months thereafter.
All Common	COM.01800	II	There is no interlaboratory communication about proficiency testing specimens and results until after the deadline for submission of data to the proficiency testing provider.
	COM.30600	II	The laboratory performs and records appropriate maintenance and function checks for all instruments (eg, analyzers) and equipment (eg, centrifuges) following a defined schedule, at least as frequent as specified by the manufacturer.

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1289701
Section Unit (SU): Hematology, Immunology
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement
All Common	COM.40250	II	The laboratory follows manufacturer's instructions for all test systems or provides validation records if the test has been modified.

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1432981
Section Unit (SU): Immunology, Special Chemistry
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement

There were no deficiencies from the inspection of this section.

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1178141
Section Unit (SU): Lab General
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement
Laboratory General	GEN.20375	II	The laboratory has a document control system to manage policies, procedures, and forms that are subject to CAP accreditation.
	GEN.20450	II	The laboratory makes corrections to laboratory records (eg, quality control data, temperature logs, and intermediate test results or worksheets) using appropriate techniques.
	GEN.76200	II	Precautionary labels are present on the containers of all hazardous chemicals, indicating type of hazard and what to do if accidental contact occurs.
	GEN.77500	II	Adequate policies, procedures, and practices are in place for the use of liquid nitrogen (LN2) and dry ice

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1289706
Section Unit (SU): Microbiology
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement

There were no deficiencies from the inspection of this section.

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1815575
Section Unit (SU): Molecular/Virology
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement

There were no deficiencies from the inspection of this section.

Laboratory Accreditation Programs
List of Deficiencies

AU ID: 1178140
Accreditation Unit (AU): Quest Diagnostics Venture LLC-Clinical Laboratories

SU ID: 1882906
Section Unit (SU): Urinalysis
SU Inspection Date: 06/12/2023

Checklist	Requirement ID	Phase	Requirement

There were no deficiencies from the inspection of this section.