COLLEGE of AMERICAN PATHOLOGISTS

CERTIFICATE OF ACCREDITATION

Quest Diagnostics Massachusetts LLC
Laboratory
Marlborough, Massachusetts
Salim E. Kabawat, MD

CAP Number: 8698344
AU-ID: 1669399
CLIA Number: 22D2051942

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 **May 1, 2024** to maintain accreditation.

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

Michael Bradley Datto, MD, PhD, FCAP
Chair, Accreditation Committee

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

COLLEGE of AMERICAN PATHOLOGISTS

CAP#: 8698344
AU-ID: 1669399
August 14, 2021

Salim E. Kabawat, MD
Quest Diagnostics Massachusetts LLC
Laboratory
200 Forest St Fl 3
Marlborough, Massachusetts 01752-3023

Dear Dr. Kabawat:

The College of American Pathologists (CAP) is pleased to advise you that the medical laboratory you direct, Quest Diagnostics Massachusetts LLC Laboratory, in Marlborough, Massachusetts, has successfully met the Laboratory Accreditation Program Standards for Accreditation in the area(s) listed on the attached sheet. **Please retain this letter and list of accredited services in your records, as this is your official notification of accreditation.**

Your Certificate of Accreditation is enclosed. Accreditation is valid for two years and is maintained through continuous compliance with the Terms of Accreditation contained in the attached document.

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.

Please remember CAP accreditation is not a substitute for the laboratory personnel's continuous in-depth monitoring and maintenance of a safe and properly functioning laboratory. We look forward to working with you in the future and commend your commitment to the highest level of laboratory accreditation for the patients you serve.

Sincerely,

Michael B. Datto, MD, PhD, Accreditation Committee Chair

cc: Walter H. Henricks, MD, Chair, Commission on Laboratory Accreditation

COLLEGE of AMERICAN PATHOLOGISTS

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.

325 Waukegan Rd.
Northfield, IL 60093
cap.org

Quest Diagnostics Massachusetts LLC
Laboratory

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AU ID: 1669399

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

All Common
Anatomic Pathology Processing
Bacteriology
Body Fluid Analysis
Chemistry
Coagulation
Conventional Cytogenetics
Cytology Processing
Cytology Screening
Director Assessment
Flow Cytometry
Genomic Copy Number - Microarray
Gynecologic Cytopathology
Hematology
Immunohematology
Immunology
In Situ Hybridization
Laboratory General
Molecular Microbiology
Molecular-based COVID-19 Testing
Mycobacteriology
Mycology
Non-Gynecologic Cytopathology
Parasitology
Special Chemistry
Surgical Pathology
Toxicology
Urinalysis
Virology

This accreditation is valid for the period ending May 1, 2022.

PLEASE RETAIN THIS DOCUMENT IN YOUR RECORDS.

Quest Diagnostics Massachusetts LLC
Laboratory

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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)
Antibody Detection (Transfusion)
Antibody Identification
Bacteriology
Clinical Cytogenetics
Cytology
Endocrinology
General Immunology
Hematology
Histopathology
Mycobacteriology
Mycology
Parasitology
Routine Chemistry
Syphilis Serology
Toxicology
Urinalysis
Virology

PLEASE RETAIN THIS DOCUMENT IN YOUR RECORDS.