CAP #: 1147901 AU ID: 1176738 Apr 03, 2024

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

Dear Dr. Kabawat:

Quest Diagnostics LLC-Laboratory, in Marlborough, MA under the direction of Salim Kabawat, MD is accredited by the CAP's Laboratory Accreditation Program.

Accreditation is a continual process. A laboratory will **remain accredited** until otherwise notified. Accreditation does not terminate on the reinspection due date of the CAP Accreditation certificate.

If you have any questions regarding this matter, please call 800-323-4040.

Sincerely,

Ashley Blair
Inspection Assignments Team
CAP Accreditation Programs
College of American Pathologists

Phone: 1-800-323-4040 x7510

Email: ablair@cap.org



## CERTIFICATE OF ACCREDITATION

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

CAP Number: 1147901

AU-ID: 1176738

CLIA Number: 22D0076229

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





CAP#: 1147901 AU-ID: 1176738 August 14, 2021

Salim E. Kabawat, MD Quest Diagnostics LLC Laboratory 200 Forest St FI 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 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 indepth 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

## **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 twoyear 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.

## Quest Diagnostics LLC Laboratory

**LAP Number:** 1147901 **AU ID:** 1176738

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.

Quest Diagnostics LLC Laboratory

**LAP Number:** 

1147901

AU ID:

1176738

**Reference Number:** 

22D0076229

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