

NEW JERSEY DEPARTMENT OF HEALTH DIVISION OF PUBLIC HEALTH & ENVIRONMENTAL LABORATORIES

CLINICAL LABORATORY IMPROVEMENT SERVICES

CLINICAL LABORATORY LICENSE

ESOTERIX GENETIC LABORATORIES, LLC

3 FOREST PARKWAY SHELTON, CT 06484

The above, pursuant to Chapter 166, P.L. of 1975, is hereby authorized to perform the below indicated services:

DIAGNOSTIC IMMUNOLOGY

GENETICS AND/OR TISSUE TYPING



CLIS ID #:

45826

S/N #:

10002436

EFFECTIVE DATE: 12/09/2024

EXPIRATION DATE: 12/31/2025

The laboratory is only authorized to perform the individual tests within the above specialties as registered with the Department as of the effective date of this license. This license must be conspicuously displayed in the laboratory. License is not transferable.



State of New Jersey DEPARTMENT OF HEALTH

PHILIP D. MURPHY Governor

TAHESHA L. WAY

PO BOX 361 TRENTON, N.J. 08625-0361

www.nj.gov/health

KAITLAN BASTON, MD, MSc, DFASAM Commissioner

December 9, 2024

Jonathan Klein, MD Laboratory Director Esoterix Genetic Laboratories, LLC 3 Forest Parkway Shelton, Connecticut 06484

Dear Dr. Klein:

The Clinical Laboratory Improvement Services (CLIS) is pleased to inform you that Esoterix Genetic Laboratories, LLC (CLIS ID# 45826) has been granted approval to perform those tests within the following Specialties for which validation studies and satisfactory proficiency testing data have been submitted for review, effective **December 9, 2024**:

Diagnostic Immunology: Flow Cytometry

Genetics and/or Tissue Typing: Cytogenetic Chromosome Analysis

Please be advised that if you wish to expand the test menu to include tests other than those tests listed in your initial application package, you must request such approval in writing to this office and document satisfactory performance in an approved proficiency program prior to patient testing.

Please retain this letter as documentation of approval to test. Enrollment in a CMS approved proficiency program is required to maintain licensure. If you have any questions or if we can be of any further assistance, you may contact me at 609-718-8081.

Sincerely,
Tom Mikita/TZ

Joan Mikita, MS

Manager, Clinical Laboratory Licensing Program Clinical Laboratory Improvement Services Public Health and Environmental Laboratories

Enclosure: State License