



Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Acting Executive Deputy Commissioner

Single Use Laboratory Permit

January 12, 2024

NYS PFI #: 9938

CLIA # 99D2146167

Diana Valbuena Perilla

Igenomix S.L.U.

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Paterna, Spain 46980

This is in response to requests received by the Clinical Laboratory Evaluation Program (Program) to submit clinical specimens obtained in New York State for testing at your laboratory. You are advised that New York State Public Health Law and regulations require that all specimens collected within the state be tested by laboratories that hold a New York State clinical laboratory permit from the Program. Laboratories holding such permit are required to hold explicit approval from the Program for laboratory-developed tests.

Your laboratory has applied for, but does not currently hold, a New York State clinical laboratory permit and has submitted for review the required method validation materials to support the analytic and clinical validity of the test indicated below. We are therefore granting this Single Use Permit, specific to the test indicated below, which shall be valid for the dates indicated. This Single Use Permit may be rescinded at any time at the Program's discretion. The laboratory's continued compliance and cooperation with Program requirements are mandatory, and noncompliance is grounds for revocation of this Single Use Permit.

Your laboratory must maintain a copy of this document, as well as all records associated with the testing of New York specimens. The laboratory must provide such documentation upon request by the Department.

Test: preimplantation genetic testing for monogenic disorders (PGT-M)
Specimen Type: embryo biopsy cells, blastomere or trophectoderm biopsy
Start date: January 12, 2024
End date: December 31, 2024 or until a determination is made on the laboratory's application

Igenomix S.L.U. is responsible for notifying its clients that a Single Use Permit has been granted for the test indicated above. The Clinical Laboratory Evaluation Program will not accept individual patient-specific requests for this test, and such requests will be returned to the requestor.

Please contact us if you have additional questions: by mail at The Clinical Laboratory Evaluation Program, Wadsworth Center, New York State Department of Health, Empire State Plaza, Albany, NY 12237-0012; by email at CLEPNPL@health.ny.gov.

Sincerely,

Beverly Rauch

Director
Clinical Laboratory Evaluation Program

DOH Accession G71172