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**NY STATE NON-PERMITTED
 LABORATORY TEST REQUEST
 APPROVAL FORM**

**NEW YORK STATE DEPARTMENT OF HEALTH
 CLINICAL LABORATORY EVALUATION PROGRAM**

NON-PERMITTED LABORATORY TEST REQUEST APPROVAL INSTRUCTIONS:

The New York State Law and Public Health Department Regulations require that all specimens collected within the state be tested by laboratories that hold New York State clinical laboratory permits, including specific test approval when required. However, diagnostic testing for all clinical conditions may not be available from NYS approved laboratories, or there may be adequate justification for use of a specific laboratory. In these cases, the Department’s approval must be obtained prior to submitting a specimen collected within the State for testing by a non-approved laboratory.

Approval to submit specimens to laboratories which do not hold NY State permits will be granted if the required test is not provided by a NY State approved (permit holding) laboratory or if adequate justification for use of a non-approved laboratory is provided.

It is the responsibility of the physician or laboratory ordering the test to document that the patient or legal guardian has been informed that the laboratory performing the diagnostic testing does not hold a New York State laboratory permit or that the test is not approved by the Department. Department approval to refer a specimen to a non-permitted laboratory should not be considered as an endorsement of the laboratory’s competence or a guarantee that the laboratory has complied with all relevant federal and/or State regulations.

Requests for approval to submit a specimen for testing to a laboratory which does not hold a State permit should be submitted, in writing, using the enclosed form and to the addresses listed below.

The program will respond, in writing, to each request to use a non-permitted laboratory. If the request is rejected, the reasons for denial will be explained in the Department’s response.

If you have any questions, please contact the Clinical Laboratory Evaluation Program at (518) 485-5378.

For Genetic Tests:

Michele Caggana, Sc.D.,FACMG
 Genetic Testing Quality Assurance Program
 Wadsworth Center
 New York State Department of Health
 PO Box 509
 Albany, NY 12201-0509
 Phone: (518) 474-6271 Fax: (518) 486-2693

For all other tests:

Deirdre Astin/Beth Johansen/Michael Neal
 Certification Unit
 Clinical Laboratory Evaluation Program Wadsworth
 Center
 New York State Department of Health
 PO Box 509
 Albany, NY 12201-0509
 Phone: (518) 485-5378 Fax: (518) 485-5414

**NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER CLINICAL LABORATORY
EVALUATION PROGRAM EMPIRE STATE PLAZA,
PO BOX 509 ALBANY, NEW YORK 12201-0509.**

**NON-PERMITTED
LABORATORY TEST
REQUEST APPROVAL
FORM**

(Please type or print neatly.)

Please provide justification for requesting use of a facility without a NYS Laboratory Permit or test approval below:

PATIENT INFORMATION

Request Date: _____
Patient Name: _____
Patient Medical Record Number: _____
Disease: _____
Gene Name: _____
OMIM#: _____
Test Requested: _____
Specimen Type: _____

REQUESTOR INFORMATION (PHYSICIAN OR FACILITY SUBMITTING REQUEST)

Ordering Physician: _____
Contact Person: _____
Phone Number: _____
Fax Number: _____
Office/Laboratory/Institution Name: _____
Address: _____
City/State/Zip: _____
PFI#: _____

TESTING LABORATORY INFORMATION

Director: John Shoffner, MD
Laboratory/Institution Name: Medical Neurogenetics, LLC
Address: One Dunwoody Park, Suite 250
City/State/Zip: Atlanta, GA 30338
Phone Number: 678.225.0222
Fax Number: 678.225.0212
Web: www.medicalneurogenetics.com
Email: testing@medicalneurogenetics.com
CLIA #: 11D0703390
PFI#: 8159