



STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center

The Governor Nelson A. Rockefeller Empire State Plaza

P.O. Box 509

Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr.Ph.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

Clinical Laboratory Evaluation Program Testing by Non-Permitted/Non-Approved Laboratories

Background:

The New York State Public Health Law and Department regulations require that all specimens obtained within New York State be tested by laboratories that hold a New York State clinical laboratory permit, including test-specific approval when required. Test-specific approval is offered for all molecular genetic tests, and for in-house developed or non-FDA cleared assays. Due to the rarity of many diseases, it is anticipated that testing for all potential conditions may not be available from permit-holding 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 New York State for testing by a non-permitted or non-approved laboratory.

Administration:

The Clinical Laboratory Evaluation Program (CLEP) administers this process and monitors the volume and frequency of requests. Formal letters of approval (or denial) are issued to the requesting physician or laboratory, and a "Restricted Permit" granting a one-time approval to perform the test is issued to the testing laboratory. With each issuance of a Restricted Permit, laboratories are reminded of the permit and test-specific approval requirements.

Approval Rationale:

Approval to submit specimens to laboratories that do not hold New York State permits or test-specific Department approval will be granted if the requests to conduct the test are limited in number and if a New York State approved laboratory does not provide the requested test. Approval to use a non-approved laboratory, while there exists an approved laboratory, may be granted in the following circumstances:

- Continuity of care: If the patient (or in the case of a genetic mutation, a member of the patient's family) was previously tested at a non-approved laboratory and additional testing must be performed at the same laboratory to ensure consistent test results.
- Specimen integrity: If referring a specimen to an approved laboratory would compromise specimen integrity, e.g., due to the need to split a sample or due to specimen or shipping requirements.

Each test request justification is evaluated specifically in light of current patient circumstances and status of approved laboratories. Requests will not be approved based on cost, reimbursement, or customer service considerations.

Practitioner/Submitter Responsibility:

The physician or laboratory requesting the test must document that the patient or legal guardian was informed that the laboratory performing the 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 or non-approved 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. For genetic tests, clinicians and laboratorians must comply with the New York Civil Rights Law Section 79-l provisions for informed consent.

Instructions for Providers and Laboratories

Written requests for authorization to use a non-permitted or non-approved laboratory must include the following information. A standardized form is available for your convenience.

1. Patient name and medical record number or laboratory identification number;
2. Disease(s) involved;
3. Specimen type (e.g. blood, plasma, urine, etc)
4. Test requested;
5. Full explanation of reason/justification for request;
6. Name, address, telephone number, fax number and PFI number (for laboratories holding a NYS permit) of the facility submitting the request; and,
7. Name, address, telephone number and CLIA number of the non-permitted or non-approved laboratory to which the specimen is being submitted for testing.
8. When requesting permission to refer *in vitro* fertilization (IVF) samples (blastomeres) for preimplantation genetic diagnosis (PGD) to a laboratory that does not hold New York State clinical laboratory permit or to a permitted laboratory that lacks test-specific approval for the intended PGD testing, please provide the following additional information. This information will assist the Program in tracking the chromosomes and diseases being studied, the reagents and methods used for PGD and in notifying clinicians when approved laboratories become available.
 - The anticipated date of the IVF cycle when PGD will be performed.
 - For chromosome abnormalities (cytogenetic testing) by fluorescence *in situ* hybridization (FISH), provide the type of chromosome abnormality being considered, e.g., numerical (aneuploidy) or structural. For familial structural chromosome aberrations, provide the cytogenetic diagnosis of the carrier parent and the FISH probes to be used in the PGD study.
 - For genetic conditions, provide the disease being considered, the gene/mutation to be detected, and the testing methodology used.

How to Submit Requests

Requests for permission to use an unapproved laboratory may be submitted to the individuals below by fax.

For genetic tests:

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

For all other tests:

Ellis Jacobs, Ph.D., DABCC
Director, Clinical Laboratory Evaluation Program
Wadsworth Center, PO Box 509
New York State Department of Health
Albany, New York 12201-0509
Telephone: (518) 485-5378
Fax: (518) 485-5414

The program will respond, in writing, to each request to use a non-permitted laboratory. If the request is rejected, the reason 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.

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

NEW YORK STATE NON-PERMITTED LABORATORY REQUEST FORM

Request Date: _____
Patient Name: _____
Patient Number: _____
Disease:

Justification for Test:

Gene Name:
OMIM#
Test Requested:

Specimen Type: Blood

REQUESTOR INFORMATION

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

TESTING LABORATORY INFORMATION

Director: Timothy Vo, PhD
Laboratory/Institution Name: Ambry Genetics
Address: 100 Columbia #200
City: Aliso Viejo State: CA Zip code: 92656
Phone Number: 949-900-5500 Fax Number: 949-900-5501
CLIA #: 05D0981414 PFI#: 8160

Genetic Tests To:

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

All Others To:

Clinical Laboratory Evaluation Program
Wadsworth Center
New York State Department of Health
Phone: (518) 485-5378 Fax: (518) 485-5414