

NEW YORK STATE NON-PERMITTED LABORATORY TEST REQUEST FORM INSTRUCTIONS

Background:

New York State Public Health Law (Article 5, Title V, Section 574) and regulations (Part 58-1.10 (g) of 10NYCRR) require that all specimens obtained within New York State be tested by a laboratory that holds a New York State clinical laboratory permit, including test-specific approval when required. Test-specific approval is not required for tests designated as FDA-cleared, approved or exempt. Notification to add such tests to the laboratory's test menu is still required.

Due to the rarity of many diseases, 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 that does not hold a permit. In these cases, the department's approval must be received prior to submitting a specimen collected in New York State for testing by a non-permitted laboratory or a permitted laboratory that does not hold approval for that particular test. All laboratories performing testing, however, must hold a valid CLIA number.

Administration:

The Clinical Laboratory Evaluation Program (CLEP) administers this process and monitors the volume and frequency of requests. Approval (a ***Restricted Laboratory Permit***) is issued to the requesting physician or laboratory and to the laboratory requested to perform the test. ***Restricted Laboratory Permits*** are one-time approvals to perform the test is issued to the testing laboratory. With each issuance of a ***Restricted Laboratory 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, when 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 subsequent testing must be performed at the same laboratory and on the same instrumentation to allow relevant comparisons of test results over time. The necessity for continuity must be well-established and justified for the test requested.
- **Specimen integrity:** If referring a specimen to an approved laboratory would compromise specimen integrity as in the following situations:
 - the sample would have to be split to allow testing at another facility that is approved to perform the test and such splitting would put the specimen at risk of compromise.
 - the sample must be tested within a defined timeframe to provide accurate results and shipping of the specimen to another facility approved to perform the test would delay the receipt of the sample beyond this timeframe. Laboratories should be cognizant of the specimen integrity requirements prior to sending the specimen to a laboratory that does not hold approval to perform the test. **Please note: Reference laboratories must have mechanisms in place to avoid unnecessary delays that would affect specimen integrity when seeking approval for a restricted permit.**

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. Denials for request to send specimens to a non-permitted laboratory are issued when there exist New York State permitted/approved laboratory(ies) or when there is a documented lack of analytical and/or clinical validity for the test requested.

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

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 Completing Request Form

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 unique patient identifier (for example, a medical record number);
2. Symptoms, Diagnosis or Gene Name (as applicable);
3. Test requested;
4. Specimen type (e.g. blood, plasma, urine, etc);
5. Full justification for request;
6. Name, address, telephone number, contact person, fax number and PFI number or CLIA number of the facility making request /sending specimen; and,
7. Name, address, telephone number and CLIA number of the non-permitted or non-approved laboratory performing the test;
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 as indicated below by fax using the form available here: www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval

Genetic Tests to:

Genetic Testing Quality
Assurance Program
Wadsworth Center, NYSDOH
Ph: (518) 474-6271
Fax: (518) 486-2693

Cytogenetic Tests to:

Cytogenetics Quality
Assurance Program
Wadsworth Center, NYSDOH
Ph: (518) 474-6796
Fax: (518) 486-4921

All others to:

Clinical Laboratory Evaluation
Program
Wadsworth Center, NYSDOH
Ph: (518) 485-5378
Fax: (518) 449-6917

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.