

Clinical Specimens from New York Practitioners

RealTime laboratories does not currently hold a New York State clinical laboratory permit, although, we do have an application pending. There are two circumstances under which New York licensed healthcare providers may order clinical tests from our lab. There is no limitation on ordering environmental tests.

1. Specimens collected outside the state and sent directly to the lab fall outside the purview of Clinical Laboratory Evaluation Program (CLEP).

New York State Public Health Law (Article 5, Title V, Section 574) and regulations (Subsection 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. Explicit 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.

2. A provider may request approval from CLEP. Approval must be obtained in advance of submitting the specimen. Additionally, approval must be obtained for each specimen. As a courtesy, we have provided the form with our information prefilled.

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. The Clinical Laboratory Evaluation Program (CLEP) administers this process and monitors the volume and frequency of requests.

We will provide this information to any new or existing New York practice which orders from us. As RealTime laboratories does not currently fall under the purview of CLEP, it is the responsibility of the practitioner to comply with the state's requirements. As such, we will not inquire where the specimen was collected, nor if an approval was received by the state. And, the practitioner has no burden to share that information with us.