

August 12, 2010



Dear Client:

IGeneX has been offering "high complexity tests" since 1992. It is certified by Centers for Medicare and Medicaid Services (CMS), formally known as CLIA and bills Medicare in U.S. In addition, it holds California, New York, Maryland, Pennsylvania and Florida licensure since these States require a separate license to perform testing for patients.

To ensure that it maintains the standards of a High Complexity Testing Laboratory, IGeneX is inspected by the California Department of Public Health (CDPH), CMS and New York State Department of Health (NYDH) on a regular basis prior to renewal of licenses. IGeneX was last inspected by both CDPH and NYDH in 2009. It passed both inspections and the licenses were renewed.

Proficiency Testing (PT)

In order to monitor the testing quality, PT must be performed on every test offered by a clinical laboratory at least twice a year. We have an overall score greater than 98% for all PTs for last 8 years. (More details on PT performance can be obtained on request.)

Validation Protocol

Before IGeneX offers any 'home-brew' test, for clinical use, extensive validation is carried out as described in our validation protocol (part of the QC-QA procedure). This process has been reviewed and accepted by CDPH, CMS and NYDH. Before a new test can be offered in New York State, NYPH has to review and accept the new test validation.

The following tests are currently not offered in New York State - the recombinant antigen test for 31kDa band on the Western blots, the Lyme Dot-Blot assay (LDA), Lyme IFA, Rickettsia IFA, Bartonella FISH, CD57 and B. duncani IFA.

Bartonella FISH and CD57 tests are recent additions. We shall be sending validation packages for these tests to NYDH for review.

A handwritten signature in black ink that reads "Nick S. Harris".

Nick S. Harris, Ph.D., ABMLI
President/CEO
IGeneX Inc.