

January 2013

Dear Client;

As you are aware, the NY State Department of Health (DOH; hereafter NYS or NYS DOH) Clinical Laboratory Evaluation Program (CLEP) has specific clinical laboratory regulatory requirements limiting the testing of NYS clinical patient samples, and samples originating from a NYS based laboratory, to methods first approved by them. This letter is intended as a reminder of these requirements and to clarify NMS Labs' position within the framework of these regulations.

NMS Labs (hereafter, NMS) has been licensed by NYS DOH in all categories that cover the testing we perform since the 1990's, however, with the implementation of the NYS Method Approval process in 2003, changes occurred to the approval status of NMS tests that were previously considered acceptable by NYS for residents and laboratories of the State. **NMS is currently approved to perform testing on all matrices in the category of Toxicology and select designated tests in the category of Endocrinology. NMS is also approved to perform testing on all standard matrices (blood, serum, plasma, urine, oral fluids) in the category of Metals testing as well as limited RBC metals tests. NMS is NOT approved for the majority of non-standard matrix Metals tests (RBC, hair, nails, tissues, fluids).** To highlight this information, we have marked, on our website Directory of Services, those tests that are NOT approved by NYS. This information can be found in the "Purpose" field for each test. As we continue to submit select non-standard matrix Metals validations to NYS, we will update the status of the respective test on our website. To our knowledge, there are no laboratories in the United States approved by NY State to perform tests in this latter category that NMS has not already received permission to perform.

Should you have a need to order a test marked as not approved by NYS, we refer you to the NYS Non-Permitted Laboratory Test Request process. The NYS DOH can assist you in determining if any given laboratory is permitted to perform such testing. Forms are located on the NYS website at:

<http://www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm>.

Rest assured that relevant testing offered by NMS is validated and characterized to generate accurate, quality results, and **the limitation regarding non-standard matrix testing is a regulatory restriction only applicable to NYS patients and NYS laboratories.** NMS continues to perform the same quality testing on a large variety of matrices for all clients who do not need to be compliant with NYS regulations. NMS continues to work with NYS on method validation requirements for approval of non-standard matrix analysis for all relevant tests in the Metals category, and will provide updates on our website Directory of Services at www.nmslabs.com when there are approval decisions.

Should you have any questions regarding the information in this letter, please contact our Clinical Customer Support Team at 866-522-2206. They can also assist you with determining the NYS approval status of any test offered by NMS Labs.

Respectfully,



Robert A. Middleberg, Ph.D., DABFT, DABCC
Laboratory Director