National Jewish Health

Advanced Diagnostic Laboratories

IMPORTANT NOTICE UPDATE: RE Test Report Disclaimer Language Changes

Dear Valued Client,

Effective February 22, 2024, the disclaimer language present on reports for multiple tests performed by the ADx Complement laboratory was updated to resolve potential client confusion regarding the nature of the lab developed tests (LDT) in question.

Prior to February 22, 2024, the affected test reports contained the following disclaimer language:

This test uses a kit/reagent designated by the manufacturer as "for research use, not for clinical use." The performance characteristics for this test have been validated by National Jewish Health. It has not been cleared or approved by the US Food and Drug Administration. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical laboratory testing.

The updated language removes the first line, resulting in the following updated disclaimer language:

The performance characteristics for this test have been validated by National Jewish Health. It has not been cleared or approved by the US Food and Drug Administration. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical laboratory testing.

Though these tests use research use only (RUO) materials as defined by the kit or reagent manufacturer, they are validated internally as LDTs according to CAP/CLIA standards and are offered to providers to aid in diagnosis and/or treatment in a clinical capacity. The RUO language was therefore removed from the disclaimer that appears on test reports so as to mitigate any confusion on the part of clients and providers that would stem from misinterpreting the results as "not for clinical use."

Patient results are not affected due to the update to the disclaimer language. Appendix A on page 2 of this memorandum includes a table of the tests affected by this change.

We apologize for any inconvenience or issues this update may have caused. If you have any questions, please contact our Client Service Team at 800-550-6227 or via email at ClinRefLabs@NJHealth.org.

Sincerely,

Steve Groshong, MD, PhD
Medical Director, Advanced Diagnostic Laboratories
National Jewish Health

Appendix A: List of tests affected by updates to test report disclaimer language made effective February 22, 2024:

Test Name
Bb Level, Plasma
C3a Level by RIA, Plasma
C4a Level by RIA, Plasma
C5a Level by RIA, Plasma
IL-2 By Luminex, Plasma
IL-4 By Luminex, Plasma
IL-5 By Luminex, Plasma
IL-6 By Luminex, Plasma
IL-10 By Luminex, Plasma
IL-12 (P70) By Luminex, Plasma
INF-g By Luminex, Plasma
TNFA By Luminex, Plasma
TH1 Cytokine 4 Plex Panel by Luminex
Th2 Cytokine 4 Plex Panel By Luminex
Th1/Th2 Panel A
TH1/TH2 Panel B
C1 Esterase Inhibitor Function Chromogenic, Serum
SC5b-9 Level, Plasma