Compliance Statements

AION Laboratories is a division of PAML, LLC (Pathology Associates Medical Laboratories)

Compliance Statement A

ASR Compliance Statement

Analyte specific reagents (ASR) are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration (FDA) approval or clearance. This test was developed and its performance characteristics determined by PAML. The U.S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This test should not be regarded as investigational or for research use.

Compliance Statement B

This test was developed and its performance characteristics determined by PAML. For method details see the AION test directory. The U.S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

Compliance Statement C

Genetic Compliance Statement

The performance characteristics of this test were validated by PAML. The U.S. Food and Drug Administration (FDA) has not approved or cleared this test; however, FDA approval or clearance is currently not required for clinical use of this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. PAML is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.