

COMPLIANCE STATEMENTS

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 approval. This test was developed and its performance characteristics determined by ARUP Laboratories, Inc. It has not been approved by the U.S. Food and Drug Administration. This test should not be regarded as investigational or for research use.

COMPLIANCE STATEMENT B

Non-FDA Approve Compliance Statement

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

COMPLIANCE STATEMENT C

Genetic Compliance Statement

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

COMPLIANCE STATEMENT D

Commercial “Research Use” Kit Compliance Statement

This test uses a kit designated by the manufacturer as “for research use, not for clinical use”. The performance characteristics of this test were validated by ARUP Laboratories, Inc. The U.S. Food and Drug Administration (FDA) has not approved this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.