

AMS Diagnostics - Corporate Compliance

STATEMENT OF PURPOSE

AMS Diagnostics is the manufacturer and supplier of clinical chemistry analyzers, reagents, assays and supplies regulated by the U.S. Food and Drug Administration. All AMS Diagnostics operations are subject to federal and state and local laws.

The U.S. Food and Drug Administration (FDA) and Clinical Laboratory Improvement Amendment (CLIA) laws and regulations governing Class II devices regulate our operation and we are committed to obtain all required permits, registrations and to be in full compliance with all such applicable regulations.

AMS Diagnostics' management and employees are dedicated to the highest business ethical standards and are committed to comply with all applicable guidance and quality standards.

AMS Diagnostics, LLC

FDA Owner / Operator Number: 10035849

FDA Establishment Registration Number: 3009128555
