

## **Survey Summary**

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### **Part One: Compliance with Fundamental Standards of Practice**

**Quality Management System Fundamental Standard**-The laboratory director and owner are jointly and separately responsible for laboratory operations and shall exercise authority for the design, implementation, maintenance and improvement of a quality management system for the delivery of services that meet the needs of patients and all clinical personnel responsible for patient care.

The laboratory meets minimum requirements for this Fundamental Standard; however, deficiencies have been cited that require correction.

**Human Resources Fundamental Standard**-The laboratory shall have effective leadership and personnel with education, training and experience commensurate with the complexity of services provided and as necessary for the design, validation and delivery of clinically useful laboratory services.

The laboratory does not meet minimum requirements for this Fundamental Standard; deficiencies have been cited that require immediate correction.

**Facility Design and Resource Management Fundamental Standard**-The facility design and resource management, applicable to general facilities, laboratory equipment, laboratory information systems, reagents and laboratory safety, must meet specifications established by the laboratory's quality management system, shall be in substantial compliance with the requirements of this part, and identified non-conformance does not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to patient care.

The laboratory meets minimum requirements for this Fundamental Standard except for the following categories: Bacteriology, Mycobacteriology

**Operating Procedures and Compliance Fundamental Standard**-The laboratory shall have a standard operating procedure manual (SOPM) that describes completely and accurately all procedures that have been validated and approved for use in the pre-examination, examination, and post-examination phases of laboratory services, and be in substantial compliance with requirements provided in Operating Procedures Sustaining Standards of Practice, SOPM SSP1 through SSP7.

The laboratory exceeds minimum requirements for this Fundamental Standard.

**Pre-Examination Procedures Fundamental Standard of Practice**-The laboratory shall be in substantial compliance with *Examination Requisition* and *Specimen Processing* Sustaining Standards of Practice as required for establishing and maintaining: integrity of patient and specimen identification; stability of specimens; and, completeness and accuracy of information essential to the interpretation and reporting of examination results.

This Fundamental Standard Practice has not been evaluated during this survey.

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### Part Two: Compliance with Specialty Standards of Practice

The following categories meet minimum requirements, deficiencies were cited that require correction:

**Hematology-Cellular  
Chemistry  
Endocrinology**

The following categories do not meet minimum requirements, deficiencies were cited that require immediate correction:

**Bacteriology  
Mycobacteriology-Smears Only**

**The following categories were not surveyed during this evaluation:**

Urinalysis  
Urine Pregnancy