

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0966877	(X3) Date Survey Completed 03/28/2023
Name of Provider or Supplier Ochsner Clinic Foundation Infectious Disease	Street Address, City, State Benson Cancer Center Rm 1n103, New Orleans, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification Survey was conducted on March 28, 2023 at Ochsner Clinic Foundation/Infectious Disease Research Lab-CLIA ID # 19D0966877. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to maintain a complete policy for proficiency testing. Findings: 1. Review of the laboratory's "Quality Control" policy under the section "Proficiency testing program" revealed the laboratory did not include review of scores from the proficiency testing provider to include but not limited to scores that are ungraded and/or educational, as well as, documentation of review. 2. Review of proficiency testing events from the College of American Pathologists revealed no documentation of review for educational and/or not graded results for the following: D-B 2021 D-C 2021 D-A 2022 D-B 2022 D-C 2022 3. In interview on March 28, 2023 at 10:12 AM, Testing Personnel 1 stated that for ungraded/educational results, they read the report but do not document anything.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are</p>

established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5291.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to provide written job responsibilities for all laboratory personnel. Findings: 1. Review of the laboratory's documents and personnel records revealed the laboratory did not have written job responsibilities/descriptions for the following: Laboratory Director Clinical Consultant 2. In interview on March 28, 2023 at 11:58 am, Testing Personnel 1 confirmed the laboratory did not have written job descriptions that included the Laboratory Director and Clinical Consultant.