

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0718550	(X3) Date Survey Completed 03/13/2026
Name of Provider or Supplier Ochsner St Anne General Hospital Cardiopulmonary	Street Address, City, State 4608 La Highway 1, Raceland, 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 Validation survey was performed at Ochsner St. Anne General Hospital Cardiopulmonary, CLIA ID 19D0718550, on March 13, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, CMS-209 (Laboratory Personnel Report) form, and personnel records; as well as interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a policy for competency assessment of the Technical Consultant to include frequency of performance. 2. Review of the laboratory's CMS-209 form revealed Personnel 2 served as Technical Consultant. 3. In interview on March 13, 2026 at 10:37 a.m., the Technical Consultant confirmed the laboratory did not have a policy for competency assessment of the Technical Consultant.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform</p>

test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and personnel records and interview with personnel, the Laboratory Director failed to define written job responsibilities for the Clinical Consultant. Findings: 1. Review of the laboratory's policies and personnel records revealed the laboratory did not include written job responsibilities for personnel serving as Clinical Consultant. 2. In interview on March 13, 2026 at 10:35 a. m., the Regional Cardiopulmonary Director confirmed the laboratory did not have a policy for job responsibilities for Clinical Consultant.