Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2158638	05/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Louisiana Organ Procurement Agency	68190 Highway 190 Service Road, Covington, 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 performed on May 1, 2023 at Louisiana Procurement Organ Agency, CLIA ID # 19D2158638. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) 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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on observation, review of patient test records, the laboratory's policies and procedure manual, and quality assurance records, as well as interview with laboratory personnel, the laboratory failed to monitor and correct specimen stability for blood gas testing. Findings: 1. On May 1, 2023 at 10:18 a.m. during the lab tour, the surveyor observed the laboratory utilized the Gem 5000 analyzer for blood gas testing. 2. Review of the laboratory's "Monthly Review" document revealed the laboratory failed to have a quality assurance monitor to identify problems with sample stability. 3. Review of the laboratory's policy and procedure manual revealed the optimal sample stability for blood gas testing was fifteen (15) minutes. 4. Review of patient test records revealed one (1) of three (3) patient samples tested greater than fifteen (15) minutes from the time of collection. 5. In interview on May 1, 2023 at 1: 30 p.m., the Technical Consultant said she does not review sample stability of blood gases.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained 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 identify failures in the quality of laboratory services provided. Refer to D5391.