Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2158638	07/29/2019
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 Certification Survey was performed on July 29, 2019 at Louisiana Organ Procurement Agency, CLIA ID # 19D2158638. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written polices and procedures that included: a) Complete Blood Counts (CBC) flagging issues that occur on the Sysmex XN-430 instrument, to include what alternate actions are taken. 2. In interview on July 29, 2019, the Technical Consultant confirmed the laboratory's policies and procedures did not include CBC flags.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify complete performance specifications for Hematology testing. Findings: 1. Observation on July 29, 2019 revealed the laboratory utilized a Sysmex XN430 for Complete Blood Counts (CBCs). 2. Review of the installation and validation records revealed the laboratory did not address reference or normal ranges prior to patient testing. Further review revealed the instrument was approved for use on June 25, 2019. 3. Interview with Personnel 2 and 3 on July 29, 2019 at 1:15 pm revealed the laboratory uses the CBC results to monitor for any changes in the patient, not for direct treament. Personnel 2 confirmed the data provided did not specifically address cerification of the reference ranges.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for Complete Blood Count (CBC) testing. Findings: 1. Observation by surveyors during laboratory tour on July 29, 2019 revealed the laboratory utilizes the Sysmex XN-430 for CBC testing with XN-L CHECK controls. 2. In interview on July 29, 2019 at 2:18 pm, the Technical Consultant stated the laboratory utilizes the manufacturer's QC ranges for CBC controls. 3. Review of the manufacturer's package insert under the "Performance characteristics and limitations" section revealed "The expected ranges listed on the assay sheet represent estimates of inter-laboratory variation for each parameter. These expected ranges should not be used as QC file limits." 4. Review of the laboratory's quality control records revealed the laboratory utilized XN-L CHECK control lot numbers 9074 and 8355.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5469.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.