Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464339	07/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Steven Unkel Md	811 James Ave, Farmerville, 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	An Offsite revisit survey was conducted at Steven Unkel MD - CLIA ID # 19D0464339 on August 2 laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories. No deficiencies A Recertification survey was conducted at Steven Unkel MD - CLIA ID # 19D0464339 on July 23, 2 laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standa 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 and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's wr 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 have a complete policy manual. Findings: 1. Review of the laboratory's policy and procedure manuals revealed the laboratory detailed policies for the following: Performance specifications: detailed policy of how the laboratory accuracy, complete precision, reportable range and reference range of new instrumentation prior to us criteria of each. 2. In interview on July 23, 2019 at 11:07 am, Personnel 1 stated she was unaware of t required. Personnel 1 confirmed the above areas were not included in the current policies.
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 foll reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications compara established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1

	(1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's refe (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to have comp performance specification verification studies for the Sysmex XP-300 Hematology analyzer. Findings by surveyor during the laboratory tour on July 23, 2019 revealed the laboratory utilizes the Sysmex X hematology analyzer for Complete Blood Counts (CBC) testing. 2. Review of the laboratory's records laboratory did not have a policy for performance verification studies for new instruments. 3. Review laboratory's performance verification studies revealed the laboratory did have studies to include accu (run-to-run, within run, and operator variance), reportable range, and reference range;however, the lal include the day-to-day precision studies and the raw data to support these studies. 4. In interview on J 11:07 am, Testing Personnel 1 confirmed the installation studies did not include the day-to-day data f precision.
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, i employment of personnel who are competent to perform test procedures, and record and report test re accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laborat must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accur and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to complete verification procedures were performed. Refer to D5421.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, i employment of personnel who are competent to perform test procedures, and record and report test re accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laborat must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to en approved procedure manual was available to all personnel responsible for any aspect of the testing pr D5401.