Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0721046	(X3) Date Survey Completed 07/26/2019
Name of Provider or Supplier Thomas A Pressly Iii Md Apmc	**Street Address, City, State** 2751 Albert L Bicknell Drive Ste 2e, Shreveport, 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 at Thomas Pressly III, APMC - CLIA ID # 19D0721046 on July 26, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy and procedure for addressing internal complaints and problems reported to the laboratory. 2. In interview on July 26, 2019 at 11:07 am, Personnel 4 confirmed the laboratory did not have a policy for internal complaints.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed

	to have a system in place to ensure that it documents communication problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not have written policies and procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. In in interview on July 26, 2019 at 11:07 am, Personnel 4 confirmed the laboratory failed to have a complete policy and procedure manual.
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 laboratory policy and procedure manual. Findings: 1. Review of the laboratory's documents and records revealed the laboratory did not have written polices and procedures that included: a) Performance specification: detailed procedures for performing accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria b) Proficiency Testing including requirements for handling, testing, reporting, and actions for failures 2. In interview on July 26, 2019 at 12:00 pm, Personnel 4 confirmed the above policies were not included in the laboratory policy and procedure manual.
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 observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for the Sysmex XN-330 instrument. Findings: 1. Observation by surveyor during the laboratory tour on July 26, 2019 revealed the laboratory utilizes the Sysmex XN-330 Hematology instrument for patient testing of Complete Blood Counts (CBC). 2. Review of the laboratory's data revealed the following studies performed: a) simple precision b) Method Verification for accuracy c) Reportable Range d) Reference Range 3. Review of the laboratory's data revealed the following information was not included: a) Complete Precision: day-to-day and operator variance including the raw data to support these studies 4. In interview on July 26, 2019 at 12:00 pm, Personnel 4 stated

	the Sysmex XN-330 was installed in December 2018 and patient testing started in January 2019. 5. In further interview on July 26, 2019 at 12:00 pm, Personnel 4 stated she was unaware that the documentation needed for complete studies was not included in the installation binder. Personnel 4 confirmed the performance studies were not complete. 6. Review of the Task 1 & 3 test list provided by the laboratory revealed the laboratory performs the following tests annually on the Sysmex XN-330 Hematology instrument: CBC - 4,079
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 observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that 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, 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 observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that it documents communication problems reported to the laboratory. Refer to D5207. 3. The laboratory failed to establish a laboratory policy and procedure manual. Refer to D5401.