Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0460740	07/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ronald J Daigle, Md, Apmc	155 Hospital Drive Suite 404, Lafayette, 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 31, 2019 at Ronald J. Daigle, MD, APMC, CLIA ID # 19D0460740. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of the performance of Histopathology testing at least twice annually. Findings: 1. Review of the laboratory's test menu revealed the laboratory reads Hematoxylin ad Eosin (H&E) stained Histopathology slides. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a written policy for verification of the accuracy of performance of Histopathology testing. 3. Review of the laboratory's documents revealed the laboratory did not have documentation of the verification of the accuracy of Histopathology testing for 2017 and 2018. 4. In interview on July 31, 2019 at 1:30 pm, the Laboratory Director stated he did not perform verification of the accuracy of Histopathology testing. The Laboratory Director confirmed no performance at least twice annually in 2017 and 2018.
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: I. 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 policies and procedures revealed it did not include the following: a) Twice a year verification of the accuracy of histopathology test performance to include frequency, acceptability criteria, and corrective action plan. 2. In interview on July 29, 2019 at 1:30 pm, the Laboratory Director confirmed the laboratory did not have a written policy for verification of the accuracy of histopathology test performance. II. Based on record review and interview with personnel, the laboratory failed to follow their established microscope maintenance policy. Findings: 1. Review of the laboratory's "Equipment Maintenance" policy revealed the following: "Microscope stage and ocular eye pieces are to be cleaned weekly; the stage is to be cleaned with alcohol or similar cleaner and ocular pieces are to be cleaned with tissue paper. Grounding check is monitored every 6 months. Actions will be documented on the maintenance record." 2. Review of the laboratory's "Maintenance Record-Microscope" log revealed the last documented date of stage and ocular cleaning and grounding was "9/5/15." 3. In interview on July 31, 2019, the Laboratory Director confirmed the microscope maintenance was not documented since September 5, 2015.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure patient final test reports included two (2) patient identifiers. Findings: 1. Review of random selection of patient final reports from the following dates revealed the laboratory did not include two (2) patient identifiers. The laboratory included the patient's name: July 30, 2018 May 21, 2019 2. In interview on July 31, 2019 at 2:05 pm, the Laboratory Director stated the patient's name is used as the identifier on final reports. The Laboratory Director confirmed an identification number was not included. 3. Review of the laboratory's test volume reveals the laboratory performs one hundred fifty (150) Histopathology tests annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel were performing the test methods as required for accurate and reliable results. Findings: 1. The laboratory failed to verify the accuracy of the performance of Histopathology testing at least twice annually. Refer to D5217. 2. The laboratory failed to follow their established microscope maintenance policy. Refer to D5401 II.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the patient test reports included pertinent information required for interpretation. Refer to D5805.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 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. Refer to D5401 I.