

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0692192	(X3) Date Survey Completed 04/08/2019
Name of Provider or Supplier I Ricardo Martinez, Md, Phd, Llc	Street Address, City, State 4224 Houma Boulevard, Suite 360, Metairie, 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 April 8, 2019 at I. Ricardo Martinez, MD, PhD, LLC, CLIA ID # 19D0692192. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>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 Task 1 and 3 form 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. In interview on April 8 , 2019, Personnel 1 stated he performs diagnosis comparisons on some Histopathology cases. 4. Review of the laboratory's documents revealed the laboratory did not have documentation of the verification of the accuracy of Histopathology testing at least twice annually for the following two (2) years: 2017: laboratory did not have documentation of performance after April 2017 2018 5. In interview on April 8, 2019 at 1:48 pm, Personnel 1 stated he performed diagnosis comparisons in 2018. Personnel 1 further stated all cases performed in 2018 would have to be reviewed to find documentation. Personnel 1 confirmed he did not have documentation of verification of the accuracy of Histopathology testing at least twice annually for the identified years at the time of the survey.</p>
D5401	PROCEDURE MANUAL

	<p>CFR(s): 493.1251(a)</p> <p>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.</p> <p>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 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 April 8, 2019, Personnel 1 confirmed the laboratory did not have a written policy for verification of the accuracy of histopathology test performance.</p>
<p>D6087</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer D5217.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>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.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p>

This STANDARD is not met as evidenced by:

*** Repeat deficiency from survey conducted on April 24, 2017*** Based on record review and interview with personnel, the Laboratory Director failed to specify in writing the duties and responsibilities of personnel involved in all phases of testing. Findings: 1. Review of the laboratory's policies and procedures revealed job descriptions related to the duties of the Laboratory Director were not included. 2. Review of the laboratory's documents and personnel records revealed the laboratory did not have a written job description for the Laboratory Director (who also serves as the Technical Supervisor, Clinical Consultant, General Supervisor, and Testing Personnel). 3. In interview on April 8, 2019 at 1:20 pm, Personnel 1 stated he thought the "Dermatopathology Procedure," outlined his responsibilities.