

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2164782	(X3) Date Survey Completed 04/19/2022
Name of Provider or Supplier Luis E Alvarez, Md, Apmc	Street Address, City, State 1100 Andre Street, Suite 301, New Iberia, 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 Initial survey was performed on April 19, 2022 at Luis E. Alvarez, MD, APMC, CLIA ID # 19D2164782. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of the laboratory's policies, temperature and humidity logs, and interview with personnel, the laboratory failed to monitor the room temperature and humidity of the laboratory for one (1) of twelve (12) months reviewed in 2021. Findings: 1. Review of the laboratory's "Temperature and Humidity Limits" policy revealed "Ambient temperature of the laboratory shall be recorded daily. Ambient humidity levels will be recorded daily." 2. Review of the laboratory's room temperature and humidity logs for 2021 revealed the laboratory did not document the room temperature and humidity for January 2021. 3. In interview on April 19, 2022 at 12:56 pm, the Testing Personnel stated she could not find the room temperature and humidity log for January 2021. II. Based on review of the laboratory's policies, temperature and humidity logs, and interview with personnel, the laboratory failed to define the room humidity limits. Findings: 1. Review of the laboratory's "Temperature and Humidity Limits" policy revealed "Ambient humidity levels will be recorded daily. Humidity range shall be within 25-80%." The current Laboratory Director</p>

	<p>approved the policy on October 29, 2021. 2. Review of the laboratory's temperature and humidity logs for 2020 revealed the laboratory's acceptable humidity range was 25-80%; however, beginning in March 2021, the laboratory's acceptable humidity range was listed as 10-80%. The laboratory's policy was not updated to reflect the change that was made to the humidity logs. 3. In interview on April 19, 2022 at 11:39 am, the Testing Personnel confirmed the laboratory's temperature and humidity policy did not include the change to the laboratory's humidity limits.</p>
<p>D5785</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for humidity readings outside of acceptable limits for sixteen (16) of sixteen (16) days in June 2020. Findings: 1. Review of the laboratory's "Temperature and Humidity Limits" policy revealed "Ambient humidity levels will be recorded daily. Humidity range shall be within 25-80%. If the humidity is out of range, adjust thermostat and retake humidity reading after 2 hours. If humidity remains out of range, STOP testing and contact Medical Director. Humidifiers, fans, and other equipment may be installed if humidity cannot be maintained within range. Testing shall resume when humidity is within range." 2. Review of the "Room Temp & Humidity Log" for June 2020 revealed the laboratory documented humidity readings outside of acceptable limits without documented corrective actions for the following sixteen (16) of sixteen (16) test dates: June 1, 2022: documented humidity 16% June 2, 2022: documented humidity 16% June 3, 2022: documented humidity 16% June 4, 2022: documented humidity 16% June 9, 2022: documented humidity 16% June 10, 2022: documented humidity 16% June 11, 2022: documented humidity 16% June 12, 2022: documented humidity 16% June 15, 2022: documented humidity 16% June 16, 2022: documented humidity 16% June 17, 2022: documented humidity 16% June 22, 2022: documented humidity 16% June 24, 2022: documented humidity 16% June 25, 2022: documented humidity 16% June 27, 2022: documented humidity 16% June 30, 2022: documented humidity 16% 3. In interview on April 19, 2022 at 11:39 am, the Testing Personnel confirmed the laboratory did not perform corrective actions for the identified dates in June 2020.</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. Refer to D5413 I and D5413 II.</p>
<p>D6096</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1445(e)(7)

The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5785.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6128.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the Technical Supervisor failed to retain documentation of annual competency assessments for one (1) of two (2) testing personnel reviewed. Findings: 1. In interview on April 19, 2022 at 12:03 pm, the current Testing Personnel stated Testing Personnel 2 was no longer employed at the laboratory since March 3, 2021. 2. Review of personnel records for Testing Personnel 2 revealed the laboratory did not have documentation of an annual competency assessment for 2020. 3. In interview on April 19, 2022 at 12:08 pm, the current Testing Personnel stated the laboratory did not have documentation of the 2020 annual competency assessment for Testing Personnel 2.