

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2016974	<b>(X3) Date Survey Completed</b>  02/22/2022
<b>Name of Provider or Supplier</b>  Lamar Family Medicine	<b>Street Address, City, State</b>  45020 Hwy 17, Vernon, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to locate 2020 2nd Event Hematology attestation. This was noted on one out of seven PT events reviewed by the surveyor. The findings include: 1. A review of the API PT records revealed no attestation statement for the 2020 2nd Event Hematology survey. 2. During an interview on 02/22/2022 at 11:20 AM, Testing Personnel #1 confirmed the above noted findings, and was unable to locate the attestation statement during the survey.</p>
<b>D3000</b>	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State</p>

Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:  
Based on record review and an interview with Testing Personnel #1, the laboratory failed to report SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) test results for positive and negative Coronavirus Disease 2019 (COVID-19) performed on the QuickVue SARS Antigen test kit and the LumiraDx SARS-CoV-2 Antigen test kit from 09/01/2021 to date of survey 02/22/2022. Findings include: 1. A review of SARS-CoV-2 test results revealed patients were tested for SARS-CoV-2 using the QuickVue Sars Antigen test kit, starting 09/01/2021 to 01/25/2022. The LumiraDx SARS-CoV-2 Antigen test was put into use 01/26/2022 through date of survey 02/22/2022. A total of 676 test were performed (Positive 188 and Negative 488) during this time period. 2. During an interview on 02/22/2022 at 09:45 AM, Testing Personnel #1 confirmed positive and negative results for SARS-CoV-2 test were not reported to Alabama Department of Public Health.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on a review of American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to review and evaluate the PT results. This was noted on one out of seven Hematology surveys reviewed for 2019 (3rd Event), 2020 (all three events), and 2021 (all three events). The findings include: 1. A review of Proficiency Testing records revealed the 2021 1st Event results obtained on proficiency testing were not reviewed and evaluated by the laboratory or the Laboratory Director. This event scored 80% each for MCHC (Mean Corpuscular Hemoglobin Concentration), MCV (Mean Corpuscular Volume), MPV (Mean Platelet Volume), and RDW (Red Cell Distribution Width). 2. During an interview on 02/22/2022 at 11:20 AM, Testing Personnel #1 confirmed the above event was not reviewed and evaluated.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or

she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory Personnel Report (Form CMS-209), personnel records, and an interview with the Laboratory Director, the Laboratory Director failed to employ an individual who qualified as technical consultant for Hematology for approximately six months from August 28, 2021 (when the previous Technical Consultant retired) to the date of the survey (02-22-2022). The findings include: 1. A review of the Laboratory Personnel Report (Form CMS-209) revealed no Technical Consultant listed. 2. A review of personnel records revealed a letter from the previous Technical Consultant stating she would retire as of August 28, 2021. 3. During an interview on 02/22/2022 at 9:45 AM, the Laboratory Director confirmed the previous Technical Consultant had retired in August 2021, and had not been replaced. The laboratory failed to have an individual providing technical oversight and supervision for approximately six months from August 2021 to 02/22/2022 (the date of the survey).

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the Laboratory Personnel Report (Form CMS-209), personnel records, and an interview with the Laboratory Director and Testing Personnel #1, the laboratory failed to employ an individual who qualified as Technical Consultant (TC) for Hematology and fulfill the TC's responsibilities. This was noted from August 2021 to date of survey for filling the TC position and for 2020 - 2021 for fulfilling the TC responsibilities. The findings include: 1. Refer to D6034. 2. Refer to D6054.

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory Personnel Report (Form CMS-209), personnel records, and an interview with the Laboratory Director, the laboratory failed to employ an individual who qualified as technical consultant for Hematology for approximately six months from August 28, 2021 (when the previous Technical Consultant retired) to the date of the survey (02-22-2022). The findings include: 1. A review of the Laboratory Personnel Report (Form CMS-209) revealed no Technical Consultant listed. 2. A review of personnel records revealed a letter from the previous

Technical Consultant stating she would retire as of August 28, 2021. 3. During an interview on 02/22/2022 at 9:45 AM, the Laboratory Director confirmed the previous Technical Consultant had retired in August 2021, and had not been replaced. The laboratory failed to have an individual providing technical oversight and supervision for approximately six months from August 2021 to 02/22/2022 (the date of the survey).

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on a review of the Laboratory Personnel Report (Form CMS-209), personnel records, and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate and document the performance of each Testing Personnel responsible for Hematology [Complete Blood Count (CBC)] testing. This was noted for 2020 and 2021. The findings include: 1. A review of the CMS-209 revealed Testing Personnel #1 was qualified during the previous survey on 11/27/2019. Testing Personnel #2 was not listed as a testing personnel during the previous survey. 2. A review of the personnel records revealed Testing Personnel #1's last documented evaluation was on 11/19/2019. Testing Personnel #2 had no training or evaluations documented. 3. During an interview on 02/22/2022 at 10:45 AM, Testing Personnel #1 confirmed she had no evaluations since November 2019. Also, she confirmed Testing Personnel #2 has been employed for 4 years and she performs CBCs occasionally, but had no training or evaluations documented.