

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0931056	(X3) Date Survey Completed 10/05/2018
Name of Provider or Supplier Family Medicine Center Alexandria	Street Address, City, State 3335 Prescott Rd, Alexandria, 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 PT Desk Review SURVEY was performed on October 5, 2018. Family Medicine Center- 19D0931056 was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing results from the CMS-153, CMS-155D and American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing as evidence by: 1. The laboratory failed to attain a score of at</p>

	<p>least 80% for all Hematology analytes. Please refer to D2121. 2. The laboratory failed to attain an overall satisfactory score of at least 80% for Hematology in Event 2 of 2018. Refer to D2122. 3. The laboratory failed to achieve satisfactory performance for White Blood Cell Differential in two of three consecutive events resulting in initial unsuccessful participation. See D2130</p>
<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS 155D Report and American Proficiency Institute (API), the laboratory failed to attain a score of at least 80% for all Hematology analytes. Findings: 1. Review of API Proficiency Testing Records revealed that the laboratory failed to achieve a score of at least 80% for analytes in the specialty of Hematology for the following events: a) For the 2nd Event in 2018 the laboratory received a score of 0% for Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), Platelets (PLT) and White Blood Cell Differential (WBC Diff). b) For the 1st Event in 2018 the laboratory received a score of 33% for White Blood Cell Differential (WBC Diff)</p>
<p>D2122</p>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing results, the laboratory failed to attain a satisfactory score of at least 80% for Hematology in Event 2 of 2018. Findings are: 1. Review of CASPER Reports 0155D and 0153D along with API Proficiency Testing Records revealed the laboratory received an overall score of 0 % for Hematology in the second event of 2018.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results from the CMS-155D and American Proficiency Institute (API), the laboratory failed to achieve a score of at least 80% for White Blood Cell Differential in two of three consecutive events. Findings: 1. Review of proficiency testing records and the CMS 155D Report revealed the following proficiency testing scores for White Blood Cell Differential (WBC Diff) resulting in initial unsuccessful performance: a. 2018 Event 2: Score of 0% b. 2018 Event 1: Score of 33%</p>

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

The laboratory director failed to ensure that proficiency testing samples are satisfactory as required. Findings: 1. The laboratory failed to attain a score of at least 80% for all Hematology analytes. Please refer to D2121. 2. The laboratory failed to attain an overall satisfactory score of at least 80% for Hematology in Event 2 of 2018. Refer to D2122. 3. The laboratory failed to achieve satisfactory performance for White Blood Cell Differential in two of three consecutive events resulting in initial unsuccessful participation. See D2130