

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0235470	(X3) Date Survey Completed 02/05/2018
Name of Provider or Supplier Allen Family Practice	Street Address, City, State 658 Main Street Suite A, Rainelle, WV	
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
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 the American Association of Bioanalysts (AAB) proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile, David P. Allen, DO, located in Rainelle, WV, failed to successfully participate in a program approved by CMS for the analyte of WBC Differential (3rd Event 2016, 2nd Event 2017, and 3rd Event 2017). The findings include: 1. This is a repeat deficiency. 2. WBC Differential Event 3 (2016) - 0%-No data received Event 2 (2017) - 60% Event 3 (2017) - 0%-No data received</p>
D2123	HEMATOLOGY

CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile, David P. Allen, DO, located in Rainelle, WV, failed to participate in a program approved by CMS for the analytes of WBC Differential (3rd Event 2016, and 3rd Event 2017). The findings include: 1. This is a repeat deficiency. 2. WBC Differential Event 3 (2016) - 0%-no data received Event 2 (2017) - 60% Event 3 (2017) - 0%-no data received

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 review of American Association of Bioanalysts proficiency testing (PT) records and the CLIA 155 Individual Laboratory Profile, the laboratory director failed to ensure successful participation in a program approved by CMS for the analyte of WBC differential (3rd event 2016, 2nd event 2017 and 3rd event 2017). The findings include: 1. This a repeat deficiency. 2. WBC Differential Event 3 (2016) - 0%-No data received Event 2 (2017) - 60% Event 3 (2017) - 0%-No data received

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 reapportions 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 review of American Association of Bioanalysts proficiency testing (PT)

records and the CLIA 155 Individual Laboratory Profile, the laboratory director failed to assure compliance with the regulation requiring successful participation in PT testing (see D2016) for the analyte of WBC Differential (3rd Event 2016, 2nd Event 2017, 3rd Event 2017). The findings include: 1. This a repeat deficiency. 2. WBC Differential Event 3 (2016) - 0%-No data received Event 2 (2017) - 60% Event 3 (2017) - 0%-No data received