

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0879841	(X3) Date Survey Completed 08/10/2023
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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 a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT reports and PT records from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte Hematocrit (Hct). The following scores were assigned: Hct 2023 first event = 60% 2023 second event = 0% (failure to participate) This is considered unsuccessful PT performance. Refer to D2130</p>

<p>D2123</p>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT reports and PT records from the AAB-MLE PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the speciality Hematology and the test analyte's Red Blood Cell Count (RBC), White Blood Cell Count (WBC), Hemoglobin (Hgb), Cell Identification (Cell I.D.) and Platelet. The following scores were assigned: 2023 second event = 0% (failure to participate) This is considered unsatisfactory PT performance.</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 PT desk review of the CMS PT reports and PT records from the AAB-MLE PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte Hematocrit (Hct). The following scores were assigned: Hct 2023 first event = 60% 2023 second event = 0% (failure to participate) This is considered unsuccessful PT performance.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on PT desk review of the CMS PT and AAB-MLE PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the speciality Hematology and the test analyte's Hct, RBC, WBC, Hgb, Cell I.D. and Platelet. Refer to D6016</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

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:

Based on PT desk review of the CMS PT and AAB-MLE PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the speciality Hematology and the test analyte's Hct, RBC, WBC, Hgb, Cell I.D. and Platelet. The following scores were assigned: Hct 2023 first event = 60% 2023 second event = 0% (failure to participate) This is considered unsuccessful PT performance. Hematology and RBC, WBC, Hgb, Cell I. D. and Platelet. 2023 second event = 0% (failure to participate) This is considered unsatisfactory PT performance.