

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0306320	(X3) Date Survey Completed 01/31/2022
Name of Provider or Supplier Pediatric Associates Of Auburn	Street Address, City, State 2901 Corporate Park Drive, Opelika, AL	
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 review of the CMS CASPER Reports (#153 and #155) for Proficiency Testing (PT) and API (American Proficiency Institute) PT evaluations, the surveyor determined the laboratory failed to successfully participate in Hematology [Complete Blood Count (CBC)] for three out of three consecutive events Event #1 2021, Event #2 2021, and Event #3 2021. The failures of Hematology for these three out of three consecutive events resulted in a noninitial unsuccessful participation. The findings include: 1. Refer to D2130. 2. Refer to D2131.</p>
D2130	HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on the CMS CASPER reports (#153 and #155) and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the laboratory failed to successfully participate in Hematology [Complete Blood Count (CBC)] testing for three of three consecutive events (Event #1, Event #2, and Event #3 of 2021). The failures resulted in a noninitial unsuccessful participation for the laboratory. The findings include: 1. A review of the CASPER reports revealed the following: a) the laboratory failed to participate in 2021 Events #1, resulting in zero scores for Hematology (CBC) b) the laboratory failed to participate in 2021 Events #2, resulting in zero scores for Hematology (CBC) c) the laboratory failed to successfully participate in 2021 Event #3, resulting in an overall score of seventy-one percent (71%) for Hematology (CBC). 2. A review of the API proficiency testing records revealed the laboratory failed to participate in the first and second testing events of 2021 resulting in 0% scores. The laboratory also failed to achieve satisfactory scores in the third event of 2021. The result of 3 of 3 testing event failures in 2021 is non-initial unsuccessful performance. See below: Testing Event Test Score 2021-1 Hematology 0% 2021-1 WBC Diff 0% 2021-1 RBC 0% 2021-1 Hematocrit 0% 2021-1 Platelets 0% 2021-2 Hematology 0% 2021-2 WBC Diff 0% 2021-2 RBC 0% 2021-2 Hematocrit 0% 2021-2 Platelets 0% 2021-3 Hematology 71% 2021-3 WBC Diff 67% 2021-3 RBC 60% 2021-3 Hematocrit 60% 2021-3 Platelets 60%

D2131

HEMATOLOGY

CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on the CMS CASPER reports (#153 and #155) and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the laboratory failed to successfully participate in Hematology [Complete Blood Count (CBC)] testing for three of three consecutive events (Event #1, Event #2, and Event #3 of 2021). The failures resulted in a noninitial unsuccessful participation for the laboratory. The findings include: 1. A review of the CASPER reports revealed the following: a) the laboratory failed to participate in 2021 Events #1, resulting in zero scores for Hematology (CBC) b) the laboratory failed to participate in 2021 Events #2, resulting in zero scores for Hematology (CBC) c) the laboratory failed to successfully participate in 2021 Event #3, resulting in an overall score of seventy-one percent (71%) for Hematology (CBC). 2. A review of the API proficiency testing records revealed the laboratory failed to participate in the first and second testing events of 2021 resulting in 0% scores. The laboratory also failed to achieve satisfactory scores in the third event of 2021. The result of 3 of 3 testing event failures in 2021 is non-initial unsuccessful performance. See below: Testing Event Test Score 2021-1 Hematology 0% 2021-1 WBC Diff 0% 2021-1 RBC 0% 2021-1 Hematocrit 0% 2021-1 Platelets 0% 2021-2 Hematology 0% 2021-2 WBC Diff 0% 2021-2 RBC

	<p>0% 2021-2 Hematocrit 0% 2021-2 Platelets 0% 2021-3 Hematology 71% 2021-3 WBC Diff 67% 2021-3 RBC 60% 2021-3 Hematocrit 60% 2021-3 Platelets 60%</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 the CMS CASPER reports and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the Laboratory Director failed to fulfill the Laboratory Director's responsibilities. The failures of Hematology for these three out of three consecutive events resulted in a noninitial unsuccessful participation. The findings include: 1. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on the CMS CASPER reports and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the Laboratory Director failed to fulfill the Laboratory Director's responsibilities. The failures of Hematology for these three out of three consecutive events resulted in a noninitial unsuccessful participation. The findings include: 1. Refer to D2130. 2. Refer to D2131.</p>