

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0857774	(X3) Date Survey Completed 09/21/2018
Name of Provider or Supplier Pediatric Associates Of Davidson County	Street Address, City, State 2201 Murphy Avenue Suite 201, Nashville, TN	
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: Hematology: Based on the review of the CASPER 153 and CASPER 155 reports, the laboratory failed to maintain satisfactory participation in two out of three events for the specialty Hematology leading to a first unsuccessful performance for Hematocrit (HCT) in 2015. Also, the laboratory failed to maintain satisfactory participation in the third event 2016 and two out of three events for automated hematocrit (HCT), resulting in the non-initial (subsequent) unsuccessful proficiency testing (PT) occurrence for the specialty Hematology for 2018. (Refer to D2130)</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 a desk review of the Casper Report 153 and Casper 155 reports and telephonic interview with the laboratory director, the laboratory failed to maintain satisfactory performance for the specialty Hematology for the first unsuccessful PT performance for Hematocrit (HCT) in the first and third events 2015. Also, the laboratory failed to maintain satisfactory participation in the third event 2016 and two out of three events for automated hematocrit (HCT), resulting in the non-initial (subsequent) unsuccessful occurrence. The findings include: 1) Review of the Casper 153 and 155 reports revealed the specialty Hematology revealed first unsuccessful PT performance for Hematocrit (HCT) in the first (20%) and third (60%) events 2015. 2) Review of the Casper 153 and 155 reports revealed the specialty Hematology revealed an unsatisfactory PT performance for Hematocrit (HCT) in the third event 2015 (40%). 3) Review of Casper 153 and 155 reports revealed the specialty Hematology revealed a non-initial (subsequent) unsuccessful occurrence performance for Hematocrit (HCT) in the first (0%) and third (0%) events 2018. 4) During a telephonic interview with the laboratory director on July 18, 2018, at 9:07am, revealed the laboratory failed to submit the specialty Hematology PT results for first and second events 2018 in a timely manner resulting in a score of 0% for Hematocrit (HCT) for the first and second events 2018, resulting in the non-initial (subsequent) unsuccessful occurrence.

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 a review of the laboratory's unsatisfactory performance of proficiency testing (PT) unsuccessful performance in the specialty Hematology for Hematocrit (HCT) in the first and third events 2015 and subsequent non-initial PT unsuccessful performance in the specialty Hematology for Hematocrit (HCT) in first and second events 2018, the laboratory director failed to ensure director responsibilities were met in PT for Hematocrit (HCT) for 2015 and 2018. (See D6004)

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 a review of the CASPER 153 and 155 reports for 2015-2018 and telephonic interview with the laboratory director, the laboratory director failed to ensure compliance with successful participation in proficiency testing (PT) for Hematocrit (HCT) in the first and third events 2015 and subsequent non-initial PT unsuccessful performance in the specialty Hematology for Hematocrit (HCT) in first and second events 2018. Findings include: 1. Review of the CASPER 153 and 155 reports for 2015-2018 revealed the specialty Hematology for Hematocrit (HCT) in the first (20%) and third (60%) events 2015 and subsequent non-initial PT unsuccessful performance in the specialty Hematology for Hematocrit (HCT) in first (0%) and second (0%) events 2018 2. During a telephonic interview with the laboratory director on July 18, 2018, at 9:07am, revealed the laboratory failed to submit the PT results for Hematocrit (HCT) for the first and second events 2018 in a timely manner (0%) resulting in the non-initial (subsequent) unsuccessful performance.