

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0986736	(X3) Date Survey Completed 08/24/2022
Name of Provider or Supplier Pediatric Partners Of Memphis	Street Address, City, State 6063 Mt Moriah Ext Suite 13, Memphis, 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: The laboratory failed to maintain satisfactory proficiency testing performance for the hematocrit analyte for three of three testing events, resulting in non-initial unsuccessful PT performance. (Refer to D2130)</p>
D2130	<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>

This STANDARD is not met as evidenced by:
 Based on a desk review survey of the Center for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2021 and 2022 proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance in three of three PT events for the hematocrit analyte, resulting in non-initial unsuccessful PT occurrence. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory PT scores for the hematocrit analyte: 2021 Event three=60% 2022 Event one=60% 2022 event two=0% 2. Review of the laboratory's American Academy of Family Physicians (AAFP) PT performance evaluation records revealed the following: 2021 event three: sample numbers HD-14 and HD-15 scored as unacceptable for hematocrit analyte resulting in an overall event score of 60%. 2022 event one: sample numbers HD-2 and HD-5 scored as unacceptable for the hematocrit analyte, resulting in an overall event score of 60%. 2022 event two: sample numbers HD-6, HD-7, HD-8, HD-9 and HD-10 scored as "Fail-No results received", resulting in an overall event score of 0%. 3. Phone interview with the laboratory lead and laboratory director on 08/24/2022 at 12:10 pm confirmed the survey findings.

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:
 The laboratory director failed to ensure the laboratory performed proficiency testing in such a manner as to achieve and maintain satisfactory performance with successful proficiency testing for the hematocrit analyte, resulting in non-initial unsuccessful proficiency testing occurrence. (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:
 Based on a desk review of the Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2021 and 2022 proficiency testing (PT) evaluation reports, the laboratory director failed to ensure the laboratory performed proficiency testing in such a manner as to achieve and maintain satisfactory performance, resulting in unsatisfactory performance for three of three consecutive proficiency testing events for the hematocrit analyte, resulting in non-initial unsuccessful proficiency testing occurrence. The findings include: 1. Review of the CMS 155 and the laboratory's American Academy of Family Physicians (AAFP)

proficiency testing evaluation reports revealed the following unsatisfactory scores for the hematocrit analyte: 2021 Event three=60% 2022 Event one=60% 2022 event two=0% 2. Phone interview with the laboratory lead and laboratory director on 08/24 /2022 at 12:15 pm confirmed the survey findings. The laboratory director further stated that testing for complete blood count was ceased approximately June 2022 when the first proficiency testing failure citations were issued.