

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0986736	<b>(X3) Date Survey Completed</b>  10/30/2018
<b>Name of Provider or Supplier</b>  Pediatric Partners Of Memphis	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 (PT) performance for the hematocrit analyte in 2017 event two, 2017 event three, and 2018 event two, resulting in the second unsuccessful PT occurrence for the hematocrit analyte. (Refer to D2130)</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>

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 Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and the laboratory's 2017 and 2018 proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory performance for three out of four proficiency testing events for the hematocrit analyte resulting in the second unsuccessful PT occurrence for hematocrit. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory hematocrit scores: 2017 event two 60%, 2017 event three 0%, 2018 event two 40%. 2. Review of the 2017 PT event two evaluation report revealed unacceptable scores for hematocrit for sample numbers HD-6, HD-7. 3. Review of the 2017 PT event three evaluation report revealed unacceptable scores for hematocrit for sample numbers HD-11, HD-12, HD-13, HD-14, HD-15. 4. Review of the 2018 PT event two evaluation report revealed unacceptable scores for hematocrit for sample numbers HD-6, HD-7, HD-8; resulting in the second unsuccessful PT occurrence for the hematocrit analyte.

**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 maintain compliance with successful hematocrit analyte proficiency testing (PT) for three out of four events and failed to follow the approved allegation of compliance (AOC) for the hematocrit analyte, resulting in the second unsuccessful PT occurrence for the hematocrit analyte. (Refer to 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 reappoints 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 desk review of the Centers for Medicare and Medicare Services Casper report 155 (CMS 155), the laboratory's 2017 event two, 2017 event three, and 2018 event two proficiency testing (PT) evaluation reports and the laboratory's December 20, 2017 Allegation of Compliance (AOC), the laboratory director failed to follow the approved AOC for the hematocrit analyte, resulting in the second unsuccessful PT occurrence for the hematocrit analyte. The findings include: 1. Review of the CMS

155 report and the laboratory's 2017 events two and three, and 2018 event two PT evaluation reports revealed the hematocrit scores as follows: 2017 event two = 60%, 2017 event three = 0%, 2018 event two = 40%. 2. Review of the laboratory's AOC dated December 20, 2017, in reference to a previous failure to maintain compliance with successful PT, signed by the laboratory director on January 18, 2018 revealed the following statements: "Beckman Coulter has been notified and are look at Q&A of control/start ups to determine the problem." "All staff will be inserviced again on Hematology." "Service on instrument."