

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315886	(X3) Date Survey Completed 04/14/2020
Name of Provider or Supplier Columbia Pediatric Clinic	Street Address, City, State 1600 Nashville Hwy, Columbia, 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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for the hemoglobin analyte in 2019 event two and 2020 event one, resulting in the first unsuccessful PT occurrence for the hemoglobin analyte. (Refer to D2130)
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 Centers for Medicare and Medicaid Services Casper report 155 (CMS 155) and the laboratory's 2019 and 2020 proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance for the hemoglobin analyte in two out of three PT events, resulting in the first unsuccessful PT occurrence for the hemoglobin analyte. The findings include: 1) Review of the CMS 155 revealed the following unsatisfactory PT scores for the hemoglobin analyte: 2019 event two: 0% 2020 event one: 0% 2) Review of the laboratory's proficiency testing records revealed the following: 2019 event two: Sample numbers FH2-06, FH2-07, FH2-08, FH2-09 and FH2-10 scored as unacceptable, resulting in an overall score of 0% for the hemoglobin analyte. 2020 event one: Sample numbers FH2-01, FH2-02, FH2-03, FH2-04, and FH2-05 scored as unacceptable, resulting in an overall score of 0% for the hemoglobin analyte, and the first unsuccessful PT occurrence for the hemoglobin analyte.