

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0995453	(X3) Date Survey Completed 12/17/2021
Name of Provider or Supplier Gi For Kids, Pllc	Street Address, City, State 1975 Town Center Blvd, Knoxville, 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: The laboratory failed to maintain satisfactory participation in two out of three events for the Cell Identification (Cell I.D.), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), and Platelet (PLT) analytes resulting in the initial unsuccessful proficiency testing (PT) occurrence for Cell I.D., RBC, HCT, HGB, WBC, and PLT (Refer to D2130) =====</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</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.

This STANDARD is not met as evidenced by:

===== Based on a desk review of the CMS CASPER Report 0155D and the laboratory's 2021 Proficiency Testing (PT) performance summary records from the College of American Pathologists (CAP) Proficiency Testing program, the laboratory failed to maintain satisfactory performance for the Cell I.D., RBC, HCT, HGB, WBC, and PLT analytes in the 1st event 2021 and 3rd event 2021, resulting in the initial unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed unsatisfactory Cell I.D., RBC, HCT, HGB, WBC, and PLT analyte scores of 0% for the 1st event of 2021 and the 3rd event of 2021. 2. A review of the laboratory's CAP Proficiency Testing records revealed unsatisfactory Cell I.D., RBC, HCT, HGB, WBC, and PLT analyte scores of 0% for the 1st event of 2021 and the 3rd event of 2021, resulting in the initial unsuccessful PT occurrence.

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