

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0995453	(X3) Date Survey Completed 05/05/2022
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: ===== The laboratory failed to maintain satisfactory participation in three out of four events for the following analytes: Cell ID or WBC Diff, hemoglobin (HGB), hematocrit (HCT), white blood cells (WBC), red blood cells (RBC) and platelets (PLT), resulting in non-initial unsuccessful participation in proficiency testing. (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 proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 155 (CMS 0155D) and College of American Pathologists (CAP) performance summary, the laboratory failed to maintain satisfactory performance in Cell ID or WBC Diff, Hemoglobin (HGB), Hematocrit (HCT), White Blood Cell (WBC), Red Blood Cell (RBC) and platelets (PLT) for the 1st and 3rd events 2021 and 1st event 2022, resulting in non-initial unsuccessful performance in proficiency testing. The findings include: 1. A review of the CMS 0155D report for 2021 revealed the Cell ID or WBC Diff, HGB, HCT, WBC, RBC and PLT scores for event one and event three= 0%. 2. A review of the CMS 0155D report for 2022 revealed the Cell ID or WBC Diff, HGB, HCT, WBC, RBC and PLT scores for event one=0%. 3. A review of the 2021 CAP PT Performance Summary for event one and event three revealed the Cell ID or WBC Diff, HGB, HCT, WBC, RBC and PLT analytes were graded as unsatisfactory with scores of 0%. 4. A review of the 2022 CAP PT Performance Summary for event one revealed the Cell ID or WBC Diff, HGB, HCT, WBC, RBC and PLT analytes were graded as unsatisfactory with scores of 0%, resulting in non-initial unsuccessful performance in proficiency testing performance.

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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 provide direction for successful Proficiency Testing (PT) Participation in three out of four events for Hematology in 2021 and 2022 resulting in non-initial unsuccessful proficiency testing participation. (Reference D6016).

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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 review of the CMS 0155D

Report and the College of American Pathologists (CAP) PT Program Evaluation Report of the Unsatisfactory Scores for Hematology for three of four events for 2021 and 2022, determined the Laboratory Director failed to provide effective direction over Proficiency Testing for Cell ID or WBC Diff, Hemoglobin (HGB), Hematocrit (HCT), White Blood Cell (WBC), Red Blood Cell (RBC) and platelets (PLT) for the 1st and 3rd events 2021 and 1st event 2022, resulting in the non-initial unsuccessful participation in proficiency testing (PT) performance. (Refer to D2130)