Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D0995453	**(X3) Date Survey Completed** 11/29/2022
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	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: Based on a desk review of the Center for Medicare and Medicaid Services CASPER Report 0155D (CMS 155) and the laboratory's College of American Pathologists (CAP) proficiency testing records, the laboratory failed to successfully participate in the specialty of Immunology for the Immunoglobulin E (IgE) and Immunoglobulin M (IgM) analytes for two out of three consecutive testing events, resulting in the initial unsuccessful proficiency testing (PT) occurrence. (Refer to D2084 and D2085).
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing 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 survey of the CMS 155 and the laboratory's 2021 and 2022 CAP PT records, the laboratory failed to maintain satisfactory performance for the Immunoglobulin E (IgE) and Immunoglobulin M (IgM) analytes in the 2nd event of 2021 and 1st event of 2022, resulting in the initial unsuccessful PT occurrence. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory PT scores for the IgE and IgM analytes: 2021 Event two: IgE: 0% IgM: 60% 2022 Event one: IgE: 0% IgM: 0% 2. Review of the Laboratory's CAP PT performance evaluation records revealed the following unsatisfactory scores for the IgE and IgM analytes: 2021 Event two: IgE: 0% IgM: 60% 2022 Event one: IgE: 0% IgM: 0%
D2085	GENERAL IMMUNOLOGY CFR(s): 493.837(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing 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 survey of the CMS 155 and the laboratory's 2021 and 2022 CAP PT records, the laboratory failed to achieve satisfactory performance for the overall specialty of Immunology in two out of three PT events in 2021 (event 2) and 2022 (event 1). The findings include: 1. Review of the CASPER CMS 155 report, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Immunology in two of three events: 2021 Event two: 65% 2022 Event one: 0% 2. Review of the Laboratory's College of American Pathologists (CAP) performance evaluation records revealed the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Immunology in two of three events: 2021 Event two: 65% 2022 Event one: 0%