

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2086917	<b>(X3) Date Survey Completed</b>  09/13/2023
<b>Name of Provider or Supplier</b>  Kids First Pediatric Specialists Georgetown	<b>Street Address, City, State</b>  5300 Sr 64, Ste 105, Georgetown, IN	
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>D0000</b>	A proficiency testing desk review survey was completed on 9/13/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.803(a)(b)(c) Successful Participation
<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: Based on record review and interview, the laboratory failed to successfully participate in the American Proficiency Institute (API) proficiency testing (PT) program for one (White Blood Cell Differential (WBC Diff)) of six regulated tests in the specialty of Hematology. The laboratory received 73% percent for two consecutive testing events (event 1, 2023 and event 2, 2023) for WBC Diff. (Refer to D2130)</p>

**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 record review and interview, the laboratory failed to achieve a satisfactory performance (80% or greater) for one (White Blood Cell Differential (WBC Diff)) of six regulated tests for two consecutive testing events (event 1, 2023 and event 2, 2023) in the specialty of Hematology. Findings include: 1) Review of "Casper Report 0155D, Individual Laboratory Profile" indicated a score of 73% for event 1 and event 2 in 2023 for White Blood Cell Differential (WBC Diff). 2) Upon request for copies of the Proficiency testing scores from their proficiency testing provider via email on 9/13/2023 at 8:50 am, SP-1 (Office Manager) provided the scores from the American Proficiency Institute (API) confirming the scores of 73% for event 1 and event 2 in 2023 for White Blood Cell Differential (WBC Diff). 3) Review of API "Performance Summary 2023 Hematology / Coagulation - 2nd Event", not dated, indicated the following scores: a) White Blood Cell Differential 2023 1st = 73% b) White Blood Cell Differential 2023 2nd = 73% c) Lymphocytes 2023 1st = 60% d) Lymphocytes 2023 2nd = 60% e) Monocytes 2023 1st = 60% f) Monocytes 2023 2nd = 60%