

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0359210	<b>(X3) Date Survey Completed</b>  05/20/2021
<b>Name of Provider or Supplier</b>  Kids First Pediatric Specialists	<b>Street Address, City, State</b>  1263 Hospital Drive, Nw, Ste 180, Corydon, 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>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 document review and interview, the laboratory failed to successfully participate in the American Proficiency Institute (API) proficiency testing (PT) program for the analyte cell identification (ID) during PT testing event 3 in 2020 and testing event 1 in 2021. (Refer to D2128).</p>
<b>D2128</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons</p>

other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on document review and interview (email confirmation), the laboratory failed to achieve a proficiency test (PT) score of 80% or higher for cell identification (ID) during two consecutive PT events (Events 3, 2020 and Event 1, 2021), resulting in unsatisfactory performance. Findings include: 1. Review of "CASPER Report 0155D" indicated the laboratory received unsatisfactory scores for cell ID: a) Event 3, 2020 = 67% b) Event 1, 2021 = 0% 2. Review of proficiency testing scores from American Proficiency Institute (API), indicated the above failing scores for event three in 2020 and event one in 2021. 3. In interview on 5/20/21 at 10:15 a.m. SP-1 (Laboratory Technician), confirmed (via email), the unsatisfactory scores from API (Proficiency Testing Provider) for the above listed analyte, cell ID.