

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0359210	<b>(X3) Date Survey Completed</b>  07/19/2023
<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>D0000</b>	A recertification survey was completed on 7/19/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.1409 Technical Consultant - Moderate Complexity
<b>D6033</b>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on document review, the laboratory failed ensure one (SP-7) of three personnel performing responsibilities of a Technical Consultant (TC) was qualified from January 27, 2023 to the date of the survey (refer to D6035).</p>
<b>D6035</b>	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or</p>

subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on record review, the laboratory failed ensure one ( SP-7) of three personnel performing responsibilities of a Technical Consultant (TC) was qualified from January 27, 2023, to the date of the survey. Findings Include: 1. Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 7/07 /2023, indicated the following: a) SP-4 is a testing person b) SP-5 is a testing person. c) SP-6 is a testing person. d) SP-7 is a testing person. 2. Review of "Competency Assessment Checklists" for SP-4, SP-5, and SP-6 performed on dates: 1/27/23, 2/02 /23, and 2/07/23 revealed SP-7 (testing person) signed off as the "observer" for competency involving "CBC direct observation ...in specimen handling, processing, and testing" on analyzer Cell Dyn Emerald, SN: 250322-001698. 3. Review of personnel files for SP-7 indicated the highest education achieved was high school. 4. Review of "Quality Assessment Statement of Fact" for 2023 Quality Assurance Minutes signed by the laboratory director on 6/15/23, under number 7. 493.1239: G: General Lab System Assessment: letter r, states "100% of all personnel have been assessed for competency within 12 months" but did not specify who was responsible for competency evaluation. 5. Review of SP-7's job description/ responsibilities signed on 8/09/21 did not specify performance or observation of competency as one of the duties of a testing person. 6. Annual Test Volume for Hematology is approximately 345.