

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0667880	(X3) Date Survey Completed 07/13/2018
Name of Provider or Supplier Pediatric Health Care	Street Address, City, State 3275 N Arlington Heights Rd, Ste 410, Arlington Heights, IL	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the proficiency testing (PT) records, manual, and an interview with the technical consultant (TC); the laboratory failed to test PT samples the same number of times that it routinely tests patient samples during Event #3 of 2017 in the specialty of Hematology. Findings: 1. The PT data sheets, test result sheets, and PT attestation statement, revealed the following: a). The laboratory received 5 PT samples, which were numbered FH2-11, FH2-12, FH2-13, FH2-14, and FH2-15, on 10/02/2017 to test for Event #3 of 2017. b). The PT file for Event #3 of 2017 contained 2 sets of CELL BLOOD COUNT (CBC) analysis results. Both PT samples were tested on 10/02/2017 and both were tested between the hours of 11:15-11:30 AM. c). The attestation sheet documents 2 testing personnel (TP) performing the PT samples' tests during this event. d). No documented evidence was presented to explain the reason the TP tested these 5 PT samples in duplicate. 2. The laboratory manual states that all PT samples are to be treated the same as patients. 3. On a Recertification survey conducted on 07/13/2018 at 2:15 PM, the TC confirmed the above findings and state that all patients are tested once unless directed by a physician.</p>
D6033	<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</p>

accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), the laboratory personnel files, manual, records, and an interview with the technical consultant (TC); the technical consultant (TC) failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings: 1. The TC failed to identify training needs and assure that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed in the specialty of Hematology. See D6045.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), personnel files, manual, records, and an interview with the technical consultant (TC); the TC failed to identify the training needs and assure that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed in the specialty of Hematology, affecting 4 out of 5 testing personnel (TP). Findings: 1. The CMS 209 lists 5 TP, who had been hired within the years of 2016 and 2018 (listed on lines 7 thru 11), performing Cellular Blood Count (CBC) analysis in the laboratory. 2. The personnel files revealed that 4 out of 5 TP received no training in CBC analysis prior to testing patients. No documentation was provided as evidence that the above 4 TP had been trained to perform CBC analysis and then assessed as competent, prior to testing patients. 3. The laboratory's patients' test logs, quality control sheets and patients' result reports revealed that the 4 untrained TP were performing patient testing during the period of 2016 through to 2018. 4. On a Recertification survey conducted on 07/13 /2018 at 2:00 PM, the TC confirmed the above findings.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files and an interview with the technical consultant (TC); the laboratory failed to employ individuals who meet the qualification requirements of 493.1423 for testing personnel (TP). Finding: 1. The laboratory failed to ensure laboratory personnel meet the education qualification requirements for performing moderately complex testing in the specialty of Hematology. See D6065.

D6065**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, and an interview with the technical consultant (TC), the laboratory failed to ensure laboratory employees meet the education requirements for performing moderately complex testing in the specialty Hematology. Findings: 1. The CMS 209 lists 7 testing personnel (TP) performing Cellular Blood Count (CBC) analysis in the laboratory. 2. The employee files of the TP listed on line 11 (TP-H86), contained no education credentials. No documented evidence was provided to show that TP-H86 met the required education criteria to perform moderately complex testing, prior to testing patients. 3. On a Recertification survey conducted on 07/13/2018 at 2:00 PM, the TC confirmed the above findings.