

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D2059207	<b>(X3) Date Survey Completed</b> 06/19/2019
<b>Name of Provider or Supplier</b> Pediatric Specialists Of Tulsa	<b>Street Address, City, State</b> 7412 S Yale, Tulsa, OK	
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>	The Recertification survey was performed on 06/19/19. The findings were reviewed with the laboratory director, office manager/testing person #3, testing person #1 and testing person #2 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with office manager/testing person #3 and testing person #2, the laboratory failed to ensure the manufacturer's instructions were followed for waived testing. Findings include: (1) At the beginning of the survey, testing person #2 stated the laboratory performed Mononucleosis testing using the Henry Schein One Step+ test kit; (2) The surveyor reviewed the package insert for the test kit, which stated "This assay has not been established for patients under 18 years of age. A heterophile antibody response is observed in approximately 80-90% of adults and children with EBV-caused IM"; (3) The surveyor requested testing records for Mononucleosis testing from August 2017 through May 2019. The office manager obtained records for 27 patients that had Mononucleosis testing performed using the Henry Schein One Step+ test kit. It was determined that for 27 of 27 patients, all were less than 18 years old. The testing for 29 patients occurred as follows: (a) Patient #1 (age 13) - testing performed on 08/11/2017 (b) Patient #2 (age 5) - testing performed on 11/27/17 (c) Patient #3 (age 8) - testing performed on 12/19/17 (d) Patient #4 (age 15) - testing performed on 01/09/18 (e) Patient #5 (age 6) - testing performed on 01/19/18 (f) Patient #6 (age 9) - testing performed on 02/09/18 (g) Patient #7 (age 12) - testing performed on 02/09/18 (h)</p>

Patient #8 (age 11) - testing performed on 03/08/18 (i) Patient #9 (age 8) - testing performed on 03/13/18 (j) Patient #10 (age 6) - testing performed on 07/17/18 (k) Patient #11 (age 8) - testing performed on 08/03/18 (l) Patient #12 (age 15) - testing performed on 08/21/18 (m) Patient #13 (age 14) - testing performed on 09/10/18 (n) Patient #14 (age 14) - testing performed on 09/14/18 (o) Patient #15 (age 12) - testing performed on 09/20/18 (p) Patient #16 (age 12) - testing performed on 11/14/18 (q) Patient #17 (age 15) - testing performed on 11/14/18 (r) Patient #18 (age 16) - testing performed on 12/04/18 (s) Patient #19 (age 15) - testing performed on 12/21/18 (t) Patient #20 (age 7) - testing performed on 12/27/18 (u) Patient #21 (age 16) - testing performed on 01/10/19 (v) Patient #22 (age 15) - testing performed on 01/29/19 (w) Patient #23 (age 5) - testing performed on 02/11/19 (x) Patient #24 (age 16) - testing performed on 02/12/19 (y) Patient #25 (age 16) - testing performed on 04/05/19 (z) Patient #26 (age 14) - testing performed on 04/22/19 (aa) Patient #27 (age 13) - testing performed on 04/24/19 (3) The surveyor explained to office manager/testing person #3 and testing person #2 that specimens could only be tested on patients over the age of 18.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:  
Based on a review of records, written policy and interview with the office manager /testing person #3, the laboratory failed to have a written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017, 2018 and 2019. There was no evidence competencies had been performed for the technical consultant, based on their job responsibilities; (2) The surveyor asked the office manager/testing person #3 if a written policy to evaluate the technical consultant based on job responsibilities was available. The office manager/testing person #3 stated a policy to evaluate the technical consultant based on job responsibilities had not been written; and competencies had not been performed.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on a review of records and interview with the office manager/testing person #3, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2017 Hematology Event (i) RDW (Red Cell Distribution Width) - 3 of 5 results exhibited a positive bias (aa) HEM-11 - SDI of 2.2

(bb) HEM-12 - SDI of 2.1 (cc) HEM-15 - SDI of 2.2 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the office manager/testing person #3, and asked if the biases had been addressed. The office manager/testing person #3 stated the biases had not been addressed.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on a review of records and interview with the office manager/testing person #3, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for 4 persons who performed moderate complexity testing during 2017 and 2018. For 2 of the 4 persons (testing person #3 and testing person #4), there was no evidence annual evaluations had been performed in 2018; (2) The surveyor reviewed the findings with the office manager /testing person #3. The office manager/testing person #3 stated the annual evaluations had not been performed as indicated above in 2018 for the testing persons.