

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0124054	(X3) Date Survey Completed 04/04/2019
Name of Provider or Supplier Tiefenbrunn & Fortin Pediatrics	Street Address, City, State 503 Cranbury Road, East Brunswick, NJ	
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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to evaluate results when the laboratory received an unacceptable score in PT for Urine Colony Count Combo performed with the College of American Pathologists (CAP) in 2018. The finding includes: 1. There was no review or evaluation documented when the laboratory received an unacceptable result for MC-02 in the MC4-A, and MC-10 in the MC4-B 2018 events. 2. The TP#2 listed on CMS form 209 confirmed on 4/4/19 at 1:20 pm that the laboratory did not perform and document an evaluation of unacceptable PT performance.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by:</p>

a. Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to have appropriate education records for all Testing Personnel (TP) on file from 5/10/17 to the date of the survey. The finding includes: 1. 7 out of 8 TP did not have education records. 2. The TP#2 listed on CMS form 209 confirmed on 4/4/19 at 12:00 pm education records were not in the PF. b. Based on surveyor review of the PF and interview with the TP, the LD failed to have training documentation for Throat Culture tests for TP #8 from February 2019 to the date of the survey. The TP #2 listed on CMS form 209 confirmed on 4/4/19 at 12:20 pm training records were not in the PF for TP #8.