

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0955681	<b>(X3) Date Survey Completed</b>  08/03/2021
<b>Name of Provider or Supplier</b>  Norman Indich Pediatrics	<b>Street Address, City, State</b>  603 West County Line Road, Lakewood, NJ	
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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Hematology events performed in 2019 and 2020. The finding includes: 1. There was no evidence of evaluation documented. The Performance Review and Corrective action was not signed and dated for API 2019 Hematology/ Coagulation- 3rd Event. 2. There was no evidence of evaluation documented. The Performance Review and Corrective action was not signed and dated for API 2020 Hematology/ Coagulation- 1st Event. 3. The TP # 6 as listed on CMS form 209 confirmed on 8/3/21 at 9:45 am that the laboratory did not review and evaluate all PT results.</p>
<b>D5781</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:  
Based on surveyor review of the temperature logs and interview with the Testing Personnel (TP), the laboratory did not document Corrective Action (CA) taken when the Strep Fridge Temp log was out of range from 2019 to the date of the survey. The findings include: 1. A review of the Strep Fridge Temp log revealed that the temperature was outside the established range as below: a. 2019: 16 out of 365 days b. 2020: 24 out of 365 days c. 2021: 11 out of 145 days 2. There was no documented evidence of Corrective Action (CA) taken. 3. The TP # 6 as listed on CMS form 209 confirmed on 8/3/21 at 10:00 am the laboratory did not document CA when the Strep Fridge Temp was out of range.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD), failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology performed with the American Proficiency Institute (API) for the third event in the calendar year 2019 and the first event of 2020. The TP # 6 as listed on CMS form 209 confirmed on 8/3/21 at 9:45 am that the PT results were not reviewed.