

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2070721	<b>(X3) Date Survey Completed</b>  09/20/2022
<b>Name of Provider or Supplier</b>  Coyle S Connolly, Do Pa	<b>Street Address, City, State</b>  2099 New Albany Road, Cinnaminson, 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>D5028</b>	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of Procedure Manual (PM) the lack for Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to ensure that quality systems for the analytic phase of Histopathology testing were monitored from 12/12/19 to the date of survey. 1. The laboratory the laboratory failed to verify the accuracy and reliability of Histopathology. Cross Refer to D5217.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar years 2020 2021 and 2022. The findings include: 1. The form used for BA was entitled Quality Assurance, proficiency testing. 2. There was no acknowledgment that the reviewing physicians diagnosis agreed or disagreed with the referring physicians diagnosis. 3. The names of reviewing physician and the referring physician were not on the form. 4. The BA was not signed by the reviewing physician or the referring physician. 5. The last BA was</p>

performed 12/12/19. 6. The OM confirmed on 9/21/22 at 11:00 am that BA was not performed. Note: This was previously cited 2/24/20.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on a interview with the Office Manager (OM), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 12/12/19 to the date of the survey. 1. The LD failed to ensure BA was performed to evaluate the laboratory's performance accurately. Cross refer D6091

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure 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 the lack of the Biannual Assessment (BA) records and interview with the Office Manager (OM), the Laboratory Director failed to ensure BA was performed to evaluate the laboratory's performance accurately from 12/12/19 to the date of survey. The OM confirmed on 9/20/22 at 11:00 am the BA was not performed to evaluate the laboratory's performance accurately.