

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2100926	<b>(X3) Date Survey Completed</b>  07/24/2023
<b>Name of Provider or Supplier</b>  Beacon Medical Group Ireland Rd	<b>Street Address, City, State</b>  1815 E Ireland Rd, South Bend, IN	
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>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 record review, lack of documentation and interview, the laboratory failed to perform twice annual verification of accuracy in one of one subspeciality Histopathology for Mohs Surgery (Mohs) and for two (PT1 and PT2) of seven patients reviewed in 2022. Findings include: 1. Review of the "Enclosure I Methodology Testing List", signed by the laboratory director on 7/13/23, indicated the "Proficiency Program" for histopathology/Mohs slides as "Sample Exchange". 2. Review of proficiency testing (PT) documents indicated one verification of accuracy was successfully performed for the first half of 2022 for Histopathology (Mohs). 3. On 7/24/2023 at 1:45pm, upon request for the "sample exchange" documents for the second half of 2022, SP2 (Histology Technician) verified that the facility is unable to locate documentation of a second slide exchange in 2022. SP2 further indicated a second slide exchange was performed, but the documentation was misplaced. 5. Review of patient files indicated the following patients had slides reviewed without twice annual verification being performed in 2022: Patient Date of Testing PT1 8/1/22 PT2 10/6/22 6. The laboratory was unable to provide the second slide exchange for 2022 within seven days of the survey with additional communication with the laboratory via email 7/28/2023 and phone call 8/3/2023. 7. Total histopathology annual test volume is 1424.</p>