

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2100926	<b>(X3) Date Survey Completed</b>  04/22/2025
<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>D3043</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(7)</p> <p>(a)(7) Slide, block, and tissue retention-- (a)(7)(i) Slides. (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). (a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination. (a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain Mohs micrographic surgery (Mohs) quality control (QC) slides for eight (PT#1 through PT #8) of ten patients reviewed from January 2024 to January 2025. Findings include: 1. Mohs QC slides were not retained for eight of ten patient records (PT#1 through PT #8) for the following: a. PT #1 had no QC slide. Mohs procedure completed on 1-11-2024. b. PT #2 had no QC slide. Mohs procedure completed on 2-12-2024. c. PT #3 had no QC slide. Mohs procedure completed on 3-07-2024. d. PT #4 had no QC slide. Mohs procedure completed on 4-11-2024. e. PT #5 had no QC slide. Mohs procedure completed on 9-16-2024. f. PT #6 had no QC slide. Mohs procedure completed on 11-06-2024. g. PT #7 had no QC slide. Mohs procedure completed on 12-03-2024. h. PT #8 had no QC slide. Mohs procedure completed on 1-09-2025. 2. During an interview on 4-22-2025 at 2:46 pm, SP-01(Laboratory Director) confirmed the slide quality was not documented." 3. Review of document titled, "Mohs/Dermatology Quality Control Procedure" signed but not dated by the laboratory director under procedure #6, "Storage of Materials" stated, "slides must be maintained for 10 years. Slides are kept for a minimum of 1year on site." 4. The annual test volume for histopathology is 1500.</p>

**D5609****HISTOPATHOLOGY**

CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document staining quality acceptability for microscopic surgery (Mohs) in the specialty of histopathology for eight of (PT #1 through PT#8) ten patients reviewed from January 2024 to January 2025. Findings include: 1. Patient record review indicated the following patients had Mohs slides read by the laboratory director without quality control documentation. Patients Slide Examination Date PT # 1 1-11-2024 PT #2 2-12-2024 PT# 3 3-07-2024 PT#4 4-11-2024 PT#5 9-16-2024 PT#6 11-06-2024 PT#7 12-03-2024 PT#8 1-09-2025 2. Review of document titled, "Mohs/Dermatology Quality Control Procedure" signed but not dated by the laboratory director under procedure #1, states, "On a daily basis the quality of staining will be documented on the Mohs maintenance checklist." 3. In an interview on 4-22-2025 at 2:46pm, SP-01(Laboratory Director) confirmed the slide quality was not documented. 4. The annual test volume for Histopathology is 1500.