

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0987079	<b>(X3) Date Survey Completed</b>  07/31/2023
<b>Name of Provider or Supplier</b>  Cytology Pathology Services	<b>Street Address, City, State</b>  8244 E Us 36 Ste 1220 Bldg #2, Avon, 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 and interview, the laboratory failed verify the accuracy of histopathology frozen section slides twice annually in 2021, and 2022. Findings Include: 1. Review of policy "QA Histology", no date of laboratory director signature, read, "Requirements to assess proficiency: Proficiency testing is performed by correlating frozen section diagnosis with frozen section control diagnosis." The policy did not require slides to be reviewed by a different pathologist. 2. Review of documents "Frozen Section Interlab Proficiency Test" for 2021 (July-December), 2022 (Jan-June), 2022 (July-December), and 2023 (Jan -June) identified five frozen section cases per year (Total of 20 cases) were compared to the frozen section control of the same sample. The documents did not show who performed the reviews. 3. Review of documents "Competency and Proficiency" evaluation for 2021 frozen section cases, signed by the laboratory director on 7/01/2021, revealed SP-1 (laboratory director) reviewed five section cases that resulted in "No discrepancies". Review of document titled, " Pathologist Review" also indicated SP-1 (laboratory director) signed off on proficiency test for dates: 7/11/21 and 7/14/22. No other pathologist reviewed these cases. 4. During an interview on 7/31/2023 at 12:00 pm, SP-1 (laboratory director) indicated frozen section slides were not sent out for peer review due to possible loss of original slides, instead a correlation between the slides and the control slides were assessed for "discrepancies" by the laboratory director (SP-1). SP-1 confirmed that the slides were not reviewed by another pathologist. The same pathologist (SP-1) who read the frozen section slides, also read the control slide. Then reviewed the results of the two readings. 5. Patients' records for three of ten patients reviewed (PT1, PT2, and PT7) were used in the 2021 and 2022 correlation and were</p>

reviewed by the laboratory director (SP-1) for proficiency testing. No other pathologist reviewed these cases. Patient Collection Date Frozen Section Case# PT1 12/28/21 21-F395 PT2 1/06/22 22-F002A PT7 10/20/22 22-F281 6. Annual Test Volume for Histopathology is approximately 400.