

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2026907	(X3) Date Survey Completed 03/18/2024
Name of Provider or Supplier Digestive Disease Specialist	Street Address, City, State 1627 E Windmill Lane, Ste 300, Las Vegas, NV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	<p>This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility on March 18, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
D5217	<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 a review of the laboratory proficiency testing procedure, a review of the laboratory College of American Pathologists (CAP) Performance Improvement Program (PIP) records, and an interview with the laboratory director conducted on March 18, 2024 at approximately 1:00 PM, the laboratory failed to ensure that twice per year verification of accuracy for gross tissue examination that is not included in Subpart I was performed and documented during 2023. Findings include: 1. A review of the laboratory procedure entitled, "External Assessment - Histology" stated, "Proficiency testing must be performed for all patient tests designated by CAP (College of American Pathologists). If CAP does not require participation, an alternative performance assessment system will be implemented to determine the reliability of analytic testing. At this time, all tests performed have an associated CAP proficiency test as listed below." 2. The laboratory participated in the CAP Performance Improvement Program (PIP) for histology. The Performance Improvement Program does not include gross tissue examination as part of the</p>

enrollment. 3. The director confirmed the findings during an interview conducted on March 18, 2024 at approximately 1:00 PM. The laboratory performs approximately 16,000 histopathology tests annually.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a random patient audit tested between the dates of February 15, 2023 and January 9, 2024, and an interview conducted on March 18, 2024 at approximately 2:30 PM with the laboratory director, the laboratory failed to ensure that the final patient report specified the name and address of the laboratory where the technical component and gross tissue examination was performed, and the final patient report failed to specify the name and address of the laboratory where the microscopic examination of slides was performed. Findings include: 1. A random patient audit of five patients tested between the dates of February 15, 2023 and January 9, 2024 revealed that the final reports for five of five patients did not specify that the gross tissue examination and technical component was performed at the Digestive Disease Specialist laboratory. 2. A random patient audit of five patients tested between the dates of February 15, 2023 and January 9, 2024 revealed that the final reports for five of five patients did not specify that the microscopic examination of the slides was performed at the laboratory director's laboratory located in California (CLIA number 052047227). 3. The findings were confirmed during an interview with the laboratory director conducted on March 18, 2024 at approximately 2:30 PM The laboratory performs approximately 16,000 histopathology tests annually.