Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0711013	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dayton Gastroenterology Llc	75 Sylvania Drive, Dayton, OH	

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	An announced CLIA validation survey was conducted at Dayton Gastroenterology LLC on June 10, 2025, by a federal surveyor from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be compliance with condition-level CLIA requirements. The following standard-level deficiencies were found during the CLIA validation survey completed on June 10, 2025.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory procedures and an interview with the clinic operations manager, the laboratory failed to include the performance of negative stain quality control in the Helicobacter pylori Immunohistochemistry (IHC) stain procedure for 2 of 2 years. Findings Included: 1. Review of the Helicobacter pylori IHC stain procedure June 10, 2025, at 11: 45 am, revealed the procedure only included the performance of positive stain QC. 2. The laboratory could not provide stain QC records that included the performance and documentation of negative stain QC. 3. In an interview on June 10, 2025, at 12:00 pm, the manager of clinic operations confirmed the above findings.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must

	be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on a review of stain evaluation records and an interview with the manager of clinic operations, the laboratory failed to document quality control (QC) for Hematoxylin and Eosin (H&E) stain each day of microscopic histology slide examinations for three out of 118 days from December 12, 2024, to April 9, 2025. Findings Included: 1. Review of the H&E stain evaluation records on June 10, 2025, at 11:00 am, revealed the following three out of 118 days from December 12, 2024, to April 9, 2025, QC was not documented: a. December 12, 2024. b. December 31, 2024. c. April 9, 2025. 2. The following number of patients slides microscopic histology examinations were analyzed on the below days QC was not documented: a. December 12, 2024 - 71 slides. b. December 31, 2024 - 62 slides. c. April 9, 2025 - 76 slides. 3. In an interview on June 10, 2025, at 11:30 a.m., the manager of clinic operations confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory personnel competency assessment records and an interview with the manager of clinic operations, the laboratory failed to perform competency assessments at least semiannually during the first year for five out of eight medical doctors who examined microscopic histology slides from 2024 to 2025. Findings Included: 1. Laboratory personnel report (CLIA) Form CMS 209 listed eight medical doctors who perform histology slide examinations, which was signed by the laboratory director on June 2, 2025. 2. On June 10, 2025, the laboratory could not provide competency assessment documentation for the five medical doctors contracted in August 2024 to perform microscopic histology slide examinations. 3. In an interview on June 10, 2025, at 10:40 a.m., the manager of clinic operations confirmed that the contracted personnel were not assessed semiannually for competency for histology slide examinations from 2024 to 2025.