

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1093630	(X3) Date Survey Completed 08/25/2026
Name of Provider or Supplier Bryn Mawr Med Spec Asso Dpt Of Gastro	Street Address, City, State 825 Old Lancaster Road, Suite 340, Bryn Mawr, PA	
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, and interview with the Laboratory Director (LD), the laboratory failed to provide a complete procedural manual for 1 of 1 Hematoxylin and Eosin (H&E) Quality control (QC) procedure for histopathology microscopic examinations performed from 03/06/2025 to 08/25/2026. 1. On the day of the survey, 08/25/2026, review of the laboratory's histopathology procedure manual revealed the laboratory failed to provide 1 of 1 H&E policy that includes QC requirements for histopathology examinations performed from 03/06

/2025 to 08/25/2026. 2. The laboratory performed 3,000 microscopic histopathology examinations in 2025 (CMS 116, estimated annual volume dated 08/24/2026). 3. The LD confirmed the findings on 08/25/2026 at 10:30 am.

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 review of quality control (QC) records, lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to document positive and negative reactivity each time of use for 782 out of 782 immunohistochemical (IHC) stains slides used for microscopic histopathology examinations performed from 03/06 /2025 to 08/25/2026. Findings include: 1. On the day of survey, 08/25/2026 at 10:00 am, review of QC records revealed the laboratory failed to document positive and negative reactivity each time of use for 782 of 782 IHC stain slides used for microscopic histopathology examinations performed from 03/06/2025 to 08/25/2026. 2. The LD confirmed the above findings in email communications on 09/02/2026 at 1: 01 pm.