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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0220589 | (X3) Date Survey Completed 03/04/2021 |
| Name of Provider or Supplier Frederick Gastroenterology Assoc | Street Address, City, State 7109 Guilford Drive #300, Frederick, MD | |
| 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 |
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| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on remote review of the procedure manual and phone interview with the histotechnologist (HTL) on 03/04/2021 at 9:00 AM, the laboratory's procedure manual failed to contain updated protocols for slide preparation and timer calibration. Findings: 1. The laboratory procedure "LAB-SOP-05" titled "Warthin-Starry Stain" contains a note stating to use "chemically cleaned coplin jars rinsed in distilled water." The HTL confirmed that this was no longer a requirement and the procedure needed to be updated. 2. The laboratory procedure "LAB-SOP-19" titled "Masson's Trichrome Stain" does not contain information on what should be used as a control</p> |

slide for the stain. The HTL confirmed that the procedure needed to be updated with the material used for the stain control slide. 3. The laboratory procedure "LAB-SOP-24" titled "Immunohistochemistry [IHC] Validation of New Antibodies" states for "each new antibody brought in house to be used for patient testing, a protocol needs to be developed to ensure accurate and consistent results" and provides instructions for validating a new IHC antibody stain. The reviewed procedures did not include the staining protocol to follow and the control slides to be used for each individual IHC antibody stain used in the laboratory. The HTL confirmed that all the individual IHC antibody stain records and protocols are maintained in a separate binder that is not part of the laboratory's approved procedure manual. 4. The laboratory procedure "LAB-SOP-17" titled "Timer Calibration" instructs to calibrate the laboratory timer against the National Institute of Standards and Technology (NIST) traceable website for 1 hour. The procedure includes a "Timer Calibration Log Sheet" template that states "Timer Acceptability Criteria: The timer being calibrated should read one hour +/- 2 seconds." The "Timer Calibration Log Sheet" completed for 2019 and 2020 show that the laboratory timers being calibrated were compared to the NIST website for 1 minute and 3 minutes, respectively. The HTL stated that the laboratory timers should be calibrated for 1 minute and the procedure needed to be updated.