Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2083634	01/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
Premier Gastroenterology At Quiet Cove	1880 Quiet Cove, Second Floor, Fayetteville, NC	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 laboratory records, interview with laboratory director (LD) 1/22/20 and phone interview with laboratory manager (LM) 1/23/20, the laboratory failed to verify the accuracy of the histopathology testing performed at least twice annually. Findings: The laboratory performs Hematoloxylin Eosin (H&E) and Alcian Blue/Periodic acid-Schiff (AB/PAS) histopathology testing. Review of 2018 and 2019 laboratory records revealed a policy "Laboratory Performance Improvement Plan" and monthly reviews performed by the laboratory director which are then compiled into a yearly review. The policy includes various aspects of the laboratory testing process and states "proposed performance aspects/processes for assessment include, but are not limited to: Completeness and accuracy of pathologic studies, Discrepancies in specimen interpretation..., review of stain quality...review of histological technique, consistency of readability and clarity of pathologic reports...". Review of the documentation for the 2018 and 2019 monthly and yearly reviews performed by the laboratory director revealed the reviews failed to demonstrate a verification of the accuracy of the H&E and AB/PAS testing performed. The reviews did not assess the accuracy of the final test results obtained by the testing personnel performing the slide interpretations at least twice annually as required. During interview with LD 1/22/20, at approximately 9:30 a.m., the LD stated verification of accuracy was all there, and referred the surveyor to the laboratory's performance improvement plan monthly and yearly reviews. Phone interview with the LM at the main facility the following day, 1/23/20, confirmed the laboratory had not

	demonstrated a twice annual verification of accuracy for the testing performed. She stated they were unaware the verification was not being performed at this facility, she stated they do perform it at their other sites.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of random patient test report, review of laboratory procedure manual, and interview with histology technician (HT) 1/22/20, the laboratory procedure manual failed to include a referral process procedure for slides that are sent to the main laboratory for additional testing. Findings: Review of random patient test report, Pathology Number: HS2019-003628, which included the pulling of histology slides for the test report, revealed the laboratory did not have the slides on site and could not, at time of survey, determine if the slides were at the referral site or if the slides had been sent back to the laboratory and possibly misfiled. Review of laboratory procedure manual revealed no procedure for the transportation, processing, tracking and referral of specimens (slides) sent out for additional testing. Interview with HT at approximately 1:00 p.m. confirmed the laboratory did not have a procedure for specimen (slide) referral when additional testing is requested. She stated she was not involved in the sending out of the slides. She also stated the pathologists do not sign out the slides when they are sent out and the laboratory does not have a tracking system for ensuring that the slides are returned for storage when additional testing is complete.