

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2277803	(X3) Date Survey Completed 03/18/2026
Name of Provider or Supplier Bay Area Advance Gastroenterology Care Inc	Street Address, City, State 1130 Kyle Wood Lane, Brandon, FL	
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 recertification survey was conducted at Bay Area Advanced Gastroenterology Care Inc on 3/18/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;</p> <p>This STANDARD is not met as evidenced by: Based on record reviews and interview, the Laboratory Director failed to ensure that prior to testing patients' specimens, two of two Testing Personnel (TP-A and TP-B) received the appropriate training and had demonstrated that they could perform all testing operations for Histopathology. Findings included: 1. The CMS-209 Laboratory Personnel Report (CLIA) signed and dated by the Laboratory Director on 3/16/26 listed two Testing Personnel (TP-A and TP--B) who currently perform Histology testing at the laboratory. The The CMS-209 Laboratory Personnel Report (CLIA) signed and dated by the Laboratory Director on 2/12/24 for the prior survey did not list TP-A or TP-B. 2. The date of hire (DOH) for this laboratory, training records, and evaluation of competencies for TP-A and TP-B were requested for review. The Quality Assurance (QA) Coordinator stated on 3/18/26 at 12:05 p.m., both had worked for the parent company for a long time and could not provide a definite date from 2/12/24 to 3/18/26 for the DOHs and there were no training records or evaluation of competencies for this laboratory prior to performing patient testing at this laboratory. 3. The policy for Medical Director (Laboratory Director) Qualifications and Duties last approved by the Laboratory Director on 5/5/25 listed one of the duties as ensuring staff could demonstrate competencies and receive</p>

appropriate training. 4. The procedure for Pathologist Professional Competency (Testing Personnel) signed and dated by the Laboratory Director on 5/5/25 listed the frequency of evaluation as six months and annually there after. There was no indication there was an approved policy that required training and evaluation of competencies prior to performing patient testing. 5. The Laboratory Director confirmed via phone on 3/18/26 at 12:35 p.m. both TP-A and TP-B had worked for the parent company for a long time and could not provide a definite date from 2/12/24 to 3/18/26 for the DOHs and there were no training records or evaluation of competencies for this laboratory prior to performing patient testing at this laboratory.