Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1102955	(X3) Date Survey Completed 03/12/2025
Name of Provider or Supplier Gastroenterology Medical Clinic	**Street Address, City, State** 1580 Creekside Dr Ste 200, Folsom, CA	

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
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the document review of the laboratory director's delegation of responsibilities to the testing personnel and the cumulative nature of the deficiencies identified, the laboratory director is herein cited at the standard level for failure to provide an overall operation and administration of the laboratory. See D6171.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) (e)(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(5); This STANDARD is not met as evidenced by: Based on review of laboratory personnel report (CMS-209, dated 2/11/2025) form, delegation of duties documentation, policy/procedure, and an interview with histology

	technologist (HT), the laboratory director (LD) is herein cited for deficient practice in failing to ensure that a general supervisor provides on-site supervision for grossing, a high complexity test. See D6144.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's policy/procedure, delegation of duties documentation, and an interview with the testing personnel (TP), the general supervisor (GS) is herein cited for the deficient practice in failure to provide general oversight of the laboratory and personnel. The findings include: 1. The TP is the histology technologist performing grossing, a high complexity test, without supervision. 2. The delegation of responsibility signed by the laboratory director stated that all responsibility that he/she is not able to personally and practically perform were delegated to the TP. 3. The TP stated in an interview on March 12, 2025, at approximately 2:00 p.m., that the GS does not visit the laboratory area to provide oversight in the absence of the laboratory director. 4. According to the laboratory's testing declaration submitted at the time of the survey, 9,000 Histopathology samples were processed and reported without supervision. Thus, the accuracy and reliability of reports released could not be assured.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered

	qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on the interview with the histology technologist (HT), review of laboratory documentation, policy/procedures, submitted survey forms, and twelve (12) pre-selected patient reports, it was determined that the laboratory failed to ensure that the testing personnel performing high complexity testing met the qualification requirements. The findings include: 1.The laboratory performed Histopathology testing, not limited to grossing and slide interpretation. Grossing, a high complexity test, was performed by the HT who was an unqualified personnel under Code of Federal Regulations (CFR) 493.1489. 2. The review of the document entitled "Delegation of Duties by Laboratory Director", signed by the laboratory medical director on March 15, 2022 stated that the HT was delegated of the duties of the laboratory director. 3.The HT was declared in CMS-209 survey form as a testing personnel due to grossing performed. Assessment of records revealed that the HT possessed an ASCP certification for histology technologist. However, no other licenses under personnel qualification requirements were found. 4. Review of the HT's resume mentioned affiliation with the laboratory since March 2022. 5. All 12 patient reports were pre-selected by the laboratory. Included in the reports are statements mentioning grossing was performed at the location in California, while, the interpretation of pathology slides was performed at another laboratory in Texas. 6.The HT stated in an interview on March 12, 2025, at approximately 2:00 p.m. as follows: a. Grossing was performed under no supervision from either a general supervisor or laboratory director. b. The general supervisor stated in the CMS-209 form does not visit the laboratory area. c. As stated in the document entitled, "Delegation of Duties by Laboratory Director", all responsibilities that the laboratory director cannot personally and practically perform were delegated to the HT including grossing. d. The HT earned her bachelor of science in healthcare administration with an associates of medical histology technician, which were not in chemical, physical, biological, clinical laboratory science, or medical technology under testing personnel qualifications. 6. According to the laboratory's declaration form (Lab-144) submitted at the time of survey, 9,000 Histopathology samples were processed and reported during the time an unqualified personnel performed a high complexity testing. Thus, the accuracy and reliability of results reported cannot be assured.