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|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D1101377 | <b>(X3) Date Survey Completed</b><br><br>07/14/2026 |
| <b>Name of Provider or Supplier</b><br><br>San Jose Gastroenterology                                                       | <b>Street Address, City, State</b><br><br>231 O'Connor Dr, San Jose, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
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| D6101              | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1445(e)(11)</p> <p>(e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor's review of laboratory personnel qualifications, the pathology processing log, a review of ten (10) Histopathology patient test records, and interview with laboratory director on July 14, 2026, at approximately 11:30 am it was determined that the laboratory director failed to ensure that testing personnel who routinely performed specimen grossing, including specimen measurement and description, were qualified to perform high complexity testing under 493.1489. The findings included: Laboratory director failed to ensure that testing personnel satisfied the education requirement necessary for high complexity testing in accordance with regulation 493.1489(b). See D6171</p> |
| D6171              | <p>TESTING PERSONNEL QUALIFICATIONS<br/>CFR(s): 493.1489(b)</p> <p>(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</p>                                                                                                                                                                                                                                                                                                                                                                                    |

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 surveyor's review of laboratory personnel qualifications, the pathology processing log, a review of ten (10) Histopathology patient test records, and interviews with laboratory director (LD) and laboratory testing personnel (TP) on July 14, 2026, at approximately 11:30 am, it was determined that two (2) of three (3) testing personnel who regularly performed specimen grossing were not qualified to perform high complexity testing under regulation 493.1489(b). The findings included: 1. The laboratory conducted high-complexity histopathology test of gross (macroscopic) examination. Gross examination consisted of tasks such as weighing, measuring, describing color, ensuring proper orientation for diagnostic purposes, and other tissue characteristics, as well as mechanical procedures like inking and marking; these are all considered high-complexity tests. Three testing personnel were responsible for performing gross examinations in the laboratory. 2. On July 14, 2026, at approximately 11:30 a.m. laboratory director and testing personnel #1 confirmed that TP#2 and TP#3 did not meet the education requirements to perform high complexity macroscopic examinations. 3. The laboratory's testing declaration form, signed by the laboratory director on July 2, 2026, indicated that approximately 20,000 histopathology tests were performed annually.