

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1074973	(X3) Date Survey Completed 06/03/2025
Name of Provider or Supplier Prithipal S Sethi, Md, Inc	Street Address, City, State 3133 W March Lane Ste 1040, Stockton, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of eight (8) Histopathology patient records, lack of personnel competency documentation, and interviews with the office manager (OM) and histology technologist (HT); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessments for the HT in the years 2022, 2023, 2024 and 2025. The findings include: 1. Surveyor's review of 8 Histopathology records showed that competency assessment for HT was missed to be performed for the years 2022, 2023, 2024, and 2025 2. The OM and HT affirmed by interviews on June 3, 2025, at approximately 10:28 a.m. that no competency records were available for review from 2022 to 2025. Thus, the quality and reliability of patient reports could not be assured. 3. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory reported and performed approximately 2.160 tests for Histopathology for which competency assessments of HT were not performed.</p>
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>

This STANDARD is not met as evidenced by:
Based on the lack of personnel competency assessment records, review of personnel qualifications, eight patient records for Histopathology, and interviews with the office manager and histology technician, it was determined that the laboratory director is herein cited for failure to ensure that prior to testing patient specimens, all personnel have the appropriate education and experience. 1. No competency records. See D5209. 2. Testing personnel qualifications. See D6171.

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 review of eight (8) Histopathology patient records, lack of personnel competency documentation, and interviews with the office manager (OM) and histology technologist (HT); it was determined that the laboratory failed to meet personnel requirements as specified in subpart M. The findings include: 1. The laboratory performed Histopathology testing, not limited to gross examination and

technical preparation of all specimens received. Grossing, a high complexity test, was performed without supervision by the HT who was an unqualified personnel under Code of Federal Regulations (CFR) 493.1489. 2. The OM and HT affirmed by interviews on June 3, 2025, at approximately 10:28 a.m. that gross examination is performed without supervision of a qualified personnel. 3. According to the testing declaration submitted at the time of survey, the laboratory performed and reported 2,160 Histopathology cases including the period when the HT was missing competency documentation.