

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2234618	(X3) Date Survey Completed 09/04/2024
Name of Provider or Supplier Kaiser Permanente Largo Orthopedics Laboratory	Street Address, City, State 1221 Merchantile Lane, Upper Marlboro, MD	
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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical consultant (TC), the laboratory director failed to ensure that there was an approved quality assessment (QA) program to assure the quality of the laboratory services. Findings: During the survey on 09/04/24 at 1:15 PM, the TC confirmed that the procedure manual did not include a written QA program designed to monitor the activities of the laboratory. Please note: The QA program defines the oversight of the laboratory testing to ensure a total assessment. The QA plan must include, but is not limited to the following: patient test management, testing methods, quality control, proficiency testing, comparison of test results, relationship of patient information to patient test results, personnel assessment, communication, complaint investigation and quality assessment reviews.</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology</p>

from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the documentation of personnel credentials and interview with the technical consultant (TC), the laboratory failed to ensure that all testing personnel (TP) were qualified to perform moderate complexity patient testing. Findings: 1. The surveyor reviewed the qualifications for the TP listed on the Laboratory Personnel Report (CLIA) (CMS-209) signed and dated on 09/03/2024 by the Laboratory Director. 2. The credentials for the one of the four TP listed on the CMS-209 were missing and could not be provided within 10 days of the survey. 3. An email received on 09/13/2024 at 12:32 PM from the TC verified that one of four TP was not qualified to perform moderate complexity testing since the minimum requirements for performing moderate complexity testing, e.g., have earned a high school diploma or equivalent were not available.