Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2234618	04/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente Largo Orthopedics Laboratory	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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on observation of the written procedures and interview with the technical consultant, the laboratory did not have a written procedure to check the accuracy of the alpha defensin test at least two times each year by performing proficiency testing or split sampling of test samples or using controls as unknown samples for staff to test and then evaluate the laboratory's performance. Findings: 1. The laboratory did not have a written procedure stating that proficiency checks would be performed at least two times each year and did not state how many unknown samples would be tested. 2. The laboratory did not have procedures for staff to test these proficiency check samples and did not have procedures to evaluate results for accuracy and provide corrective actions if needed. 3. The laboratory did not have procedures to rotate the accuracy checks among staff. 4. This was confirmed during interview with the technical consultant at noon on the day of survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on record review and interview with the technical consultant, the laboratory did not document the quality control reagent lot number and expiration date for one of three test records reviewed. Findings: 1. The laboratory performs a test for the presence or absence of alpha defensin in synovial fluid. 2. The written test record for patients tested December 21, 2022 and January 12, 2023 was missing the lot and expiration dates of both the positive and negative quality control reagents. 3. This was confirmed during interview with the technical consultant at noon on the day of survey.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of patient test records for the peptide alpha defensin and interview with the technical consultant, the laboratory did not record that the results of the internal patient control was acceptable for nine of nine patients tested from November 29, 2022 to April 4. 2023. 1. The alpha defensin test is a cartridge that a sample of patient synovial fluid is applied to in order to determine the presence of alpha defensin, presence of the peptide may indicate infection. Each patient test has an internal quality control check to show that an adequate amount of specimen was applied to the test cartridge. 2. The appearance of the internal quality control line means that the test is acceptable and on the patient written log is a box that the testing person marks to show that the test was acceptable. But, testing staff did not mark that the internal quality control check was acceptable on the patient test records. 3. This was confirmed during interview with the technical consultant at noon on the day of survey. B. Based on record review and interview with the technical consultant, the laboratory did not follow the laboratory written procedure to perform positive and negative external quality control checks each day of testing for the peptide alpha defensin. Findings: 1. The laboratory written procedure stated to perform an external quality control check each day a patient is tested for the presence or absence of alpha defensin in the sybovial fluid. 2. The laboratory tested each different kit lot number or shipment of test kits with a positive and negative control, but not each day of patient testing 3. The laboratory did not have an individualized quality control plan including manufacturer references showing that testing each kit lot number or shipment met the manufacturer's and laboratory's quality control requirements. 4. This was confirmed during interview with the technical consultant at noon on the day of survey.