Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2234619	04/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente Gaithersburg Orthopedics Lab	655 Watkins Mill Rd, Gaithersburg, 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.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer instructions for immunology testing (alpha defensin peptide in synovial fluid), the manufacturer states that testing must be conducted between 12 - 25 degrees Centigrade. The laboratory did not document the room temperature each day of testing to ensure this requirement was met. This was confirmed during interview with the technical consultant on the morning of 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 6, 2022 was missing the lot and expiration date of the positive quality control reagent. 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: 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.