Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0668653	08/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente Skyline Medical Office Lab	5125 Skyline Rd S, Salem, OR	

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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the Quality and Compliance Specialist, the laboratory failed to ensure that all providers (4 listed on CMS form 209) performing vaginal wet mounts and fern testing completed bi-annual competency assessments for each assay as outlined in the laboratory's policy for competency assessment. Findings include: 1. Review of the facility's Competency Assessment policy for this site revealed that the requirement for competency assessment for providers performing vaginal wet mounts and fern testing is twice yearly, using the MTS training site. 2. The CMS 209 form submited during survey listed four (4) providers, performing vaginal wet mounts and fern testing. Review of testing records from the MTS training site revealed one (1) of four (4) providers (TP #2) had not completed one (1) of two (2) bi-annual competency assessments for each of these assays in 2022, 2023, and 2024 to date, equaling a 50% compliance with Competency Assessment for this facility. 3. Interview with the Quality and Compliance Specialist at 2:00 pm confirmed that TP#2 had not completed the required competency assessments as stated in the facility's policy for Competency Assessment for providers performing vaginal wet mounts and fern testing in 2022, 2023 and 2024 to datte. 4. The annual count of these assays was not available during survey. The previous survey in 2022 reflects a count of thirty (30) for both assays.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel competency records during survey and interview with the Quality and Compliance Specialist, the Laboratory Director (LD) failed to ensure that the Technical Consultants (TC) had current competency assessments and their duties were designated in writing. Findings include: 1. Review of the CMS 209 form submitted by the laboratory during survey, listed two (2) TC"s. 2. Request for TC competency records for these two (2) personnel revealed one (1) of two (2) TC's had no current comptency assessment on record. 3. Upon request for a procedure for competency assessment of TC's during survey, none could be produced. 4. Upon request for a current signed and approved delegation of duties by the LD, for these two (2) TC's, none could be produced. 5. Interview with the Quality and Compliance Specialist at 2:00 pm confirmed that TC #2 had no current assessment of competency as a TC for the whole blood testing for human chorionic gonadotropin (HcG). . 6. The laboratory reports performing 632 whole blood pregnancy tests annually using the Adexus whole blood HcG cassette assay.