Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0064851	11/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
University Health Services Laboratory	1590 E 13th Ave, Eugene, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the proficiency testing testing records from the American Proficiency Institute (API) for 2025 and interview with the Technical Supervisor (TS #1), the laboratory failed to ensure that the Laboratory Director (LD) reviewed, signed and dated the attestation declaration for eight (8) PT events completed in 2025. Findings include: 1. Upon review of the records for API PT for 2025, it was revealed that the LD failed to review sign and date the following API PT events: a. Immunology 2025 events #1 & #2 b. Hematology 2025 events #1 & #2 c. Microbiology 2025 events #1 & #2 d. Chemistry 2025 events #2 & #3 2. Interview with the LD and TS #1 on 11/04/2025 at 3:20 pm confirmed the lack of review and signature by the LD. 3. The laboratory attests to performing 45630 moderate and high complexity tests annually.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) results for 2024 and 2025 and interview with the Technical Supervisor (TS #1), the laboratory failed to ensure corrective action (CA) was performed on each single unacceptable PT analyte. Findings include: 1. Review of the API PT results from the following years and events failed to note any written CA or follow up with the testing personnel (TP) who performed these unacceptable assays. a. Chemistry 2024 event #2 ALT(SGPT) score 1 out of 5 missed = 80% b. Chemistry 2024 event #3 Chloride score 1 out of 5 missed = 80% c. Chemistry 2025 event #1 Cholest. HDL's score 1 out of 5 missed = 80% d. Chemistry 2025 event #1 Creatine kinase score 1 out of 5 missed = 80% e. Chemistry 2025 event #2 Creatine kinase score 1 out of 5 missed = 80% 2. Interview with the TS #1 at 2:00 pm confirmed that no written CA or follow up with TP responsible for the above missed PT had occurred. 3. The laboratory reports performing 45,630 moderate and high complexity assays annually.
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 personnel training and competency assessment records and interview with the Laboratory Director (LD), the laboratory failed to establish and follow written procedures for evaluating the competency of those personnel fulfilling the federal duties of Technical Consultant (TC), Technical Supervisor (TS) and General Supervisor (GS). Findings include: 1. Upon review of the laboratory personnel training and competency assessment records, including the competency assessments by the LD for the positions listed on the CMS form 209 for TC, TS or GS, none could be produced. 2. Interview with the LD at 3:15 pm confirmed that there was no policy or competancy assessments for personnel listed on the CMS 209 form as TC, TS, and/or GS. 3. The laboratory reports performing 45,630 assays annually.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (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 the laboratory's policy and procedure manual and interview with the Technical Supervisor (TS #1), the Laboratory Director (LD) failed to ensure a current signed, dated and approved designation of duties was in place. Findings include: 1. During review of the personnel records presented during survey, a current

	copy of the designation of duties by the LD was requested. None could be produced. 2. Interview with the TS #1 at 2:00 pm confirmed that there was no current approved designation of duties for review. 3. The laboratory reports performing 45,630 assays annually.