Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 33D2049859	**(X3) Date Survey Completed** 12/10/2024
Name of Provider or Supplier Ur Medicine Labs- Red Creek	**Street Address, City, State** 125 Red Creek Dr Suite 104, Rochester, NY	
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**
D0000	An announced CLIA exempt-state validation survey was conducted at UR MEDICINE LABS - RED CREEK on December 10, 2024, by a federal surveyor from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be compliance with condition-level CLIA requirements but not standard-level CLIA requirements. The following standard-level deficiency was found during the CLIA exempt-state validation survey performed on December 10, 2024.
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 the review of the Employee Competency Program and Documentation Requirements policy, and interviews with Technical Supervisor (TS) #3 and General Supervisor (GS) #1, the laboratory failed to establish a procedure for assessing the competency of non-technical supervisors who conducted supervisory competency assessments for three of three technical supervisors. Findings Include: 1. On the day of survey, December 10, 2024 at 1:00 pm, review of the supervisory competency assessment records revealed, three of three TS competency assessment were not signed by laboratory personnel listed on the Laboratory Personnel Report (Form CMS 209). 2. The laboratory was unable to provide a supervisory competency assessment for the individuals not listed on Form CMS 209 who conducted the competency assessment for the three technical supervisors. 3. TS #3 confirmed the findings above on December 10, 2024, at 4:00 pm.