Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 50D2116270	(X3) Date Survey Completed 01/31/2024
Name of Provider or Supplier Overlake Medical Clinic Lake Hills Urgent Care	**Street Address, City, State** 619 156th Ave Se, Bellevue, WA	
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
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on the laboratory's lack of policy or procedures, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to perform a comparison between the iSTAT analyzer and the Sysmex XN 300 for the analytes Hemoglobin (HGB) and Hematocrit (HCT) to define the relationship between the two methodologies. Findings include: 1. The laboratory performs and reports patient results for HGB and HCT on the Abbot iSTAT point of care testing (POCT) chemistry whole blood analyzer and the Sysmex XN 300 hematology analyzer, 2. The laboratory failed to perform twice-annual comparison evaluations of the relationship between the test methodologies for 2021, 2022, and 2023. 3. The laboratory TC confirmed, by interview on 01/31/2024 at 10:50 a.m., the failure to perform twice-annual comparisons between the two methodologies for the analytes HGB and HCT. 4. The laboratory reports performing 791 HGB/HCT patient samples annually.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory Form CMS - 209, the laboratory personnel records, and interview with the Technical Consultant (TC), the laboratory Director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education. Findings Include: 1. The laboratory Form CMS - 209 submitted by the laboratory Director on 01/29/2024, identified three new testing personnel (NTP) since 2021. One of three NTP had an international high School diploma written in a foreign language, See D6065. 2. The laboratory reports performing 4039 moderate complexity patient tests, and 3,161 waived tests annually.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory Form CMS-209, the laboratory personnel records, and interview with the Technical Consultant (TC), the laboratory failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratories Form CMS-209, review of new testing personnel educational records, and an interview with the laboratory Technical Consultant (TC), the laboratory failed to ensure that all testing personnel had the educational requirements to qualify as testing personnel prior to performing patient testing. Findings include: 1. The laboratory's submitted Form CMS-209 identified three new testing personnl (NTP) since 2021. 2. One of the three NTP (NTP-#2. see Form CMS

	209) had an international high school diploma written in a foreign language. 3. The laboratory lacked documnntation of an HHS-approved International Equivalency Agency assessment being performed for NTP-#2. 4. The laboratory reports performing a total of 4039 Complete Blood Cell (CBC) counts and Chemistry tests annually. The NTP-#2 performed six (6) patient tests performed from January 1, 2024 to January 31, 2024. Patient # Date Test H000707638 02/01/2024 Chem8 H002393136 01/06/2024 Troponin H000368601 01/08/2024 Chem8 H000368601 01 /08/2024 CBC H002553319 01/09/2024 Chem8 H002553319 01/09/2024 CBC 5. The laboratory TC confirmed by interview on 01/31/2024 at 09:00 a.m., the lack of an educational equivelancy assessment being performed for NTP-#2.