

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D0965601	<b>(X3) Date Survey Completed</b>  05/21/2024
<b>Name of Provider or Supplier</b>  Ohsu-Cho Tualatin	<b>Street Address, City, State</b>  19260 Sw 65th Suite 435, Tualatin, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	OHSU CHO Tualatin located at 19260 SW 65th Avenue Suite 435, Tualatin, OR 97062 submitted an allegation of compliance (AoC) and evidence of correction (EoC) on 06/09/2024 in response to the deficiencies cited on 05/21/2024 during a recertification survey. The AoC is credible and the EoC is acceptable for each deficiency cited. All deficiencies cited have been corrected or have a credible/ acceptable EoC. The Laboratory is now in substantial compliance with the CLIA regulations (42 CFR, Part 493 effective April 24, 2003).
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: D2000 Based on a review of proficiency testing (PT) records and an interview with the section coordinator, the laboratory failed to enroll in an approved HHS PT program for the analyte Prothrombin Time/International Normalized Ratio (PT/INR). Findings include: 1. The laboratory performs PT/INR using the CoaguCheck Pro moderate complexity test system. A review of the PT records shows no enrollment record for the regulated analyte PT/INR for 2024. 2. An interview with the section coordinator on 05/21/2024 at 10:00 AM confirmed these findings. 3. The laboratory reports performing 12 PT/INR tests annually.</p>

<p><b>D2123</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: D2123 Based on the Casper Report 0096D review and an interview with the section coordinator, the laboratory failed to participate in the proficiency testing (PT) event for the regulated analyte Prothrombin Time/ International Normalized Ratio (PT /INR). Findings include: 1. A review of Casper Report 0096 shows zero % for the 3rd event of 2023 for PT/INR. 2. The laboratory discontinued participating in the third event of 2023 because it intended to use the waived PT/INR CoaguCheck plus test system. However, the laboratory still used the moderately complex CoaguCheck Pro test system during the survey. 3. An interview with the section coordinator on 05/21 /2024 at 10:00 AM confirmed these findings. 4. The laboratory reports performing 12 PT/INR tests annually.</p>
<p><b>D5801</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: D5801 Based on a review of urinalysis analysis (UA) manual results and an interview with the section coordinator, the laboratory failed to ensure that manually entered results were accurately entered and reliably sent from the point of data entry to the final report destination in a timely manner. Findings include: 1. The laboratory failed to document that manually entered UA results were accurate and sent to the authorized individuals in a timely manner. 2. An interview with the section coordinator on 05/21/2024 at 11:00 AM confirmed these findings. 3. The laboratory reports performing 533 UA tests annually.</p>
<p><b>D6088</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-</p>

approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

D6088 Based on a review of proficiency testing (PT) records and an interview with the section coordinator, the laboratory director (LD) failed to ensure the laboratory was enrolled in an approved HHS PT program for the analyte Prothrombin Time /International Normalized Ratio (PT/INR). Findings include: 1. The laboratory performs PT/INR using the CoaguCheck Pro moderate complexity test system. A review of the PT records shows no enrollment record for the regulated analyte PT /INR for 2024. 2. An interview with the section coordinator on 05/21/2024 at 10:00 AM confirmed these findings. 3. The laboratory reports performing 12 PT/INR tests annually.