

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0626643	(X3) Date Survey Completed 03/15/2021
Name of Provider or Supplier Wvci Eugene	Street Address, City, State 520 Country Club Rd, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES 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: Review of Proficiency Testing (PT) records and discussion with laboratory staff revealed the laboratory is NOT enrolled in HHS approved PT Provider for the regulated analytes IgA, IgG, and IgM. Finding includes: 1. Review of Proficiency Testing records revealed that the laboratory was testing IgA, IgG, and IgM in Diagnostic Immunology. 2. The laboratory had records of participation of PT through a PT provider called "Improve Quality Assurance Scheme Binding Site"(IQASBS) which was received 03/03/2021, performed 03/11/2021 and results submitted 03/11/2021. 3. Further investigation revealed that the PT Provider IQASBS was NOT approved by HHS. This was confirmed by phone conversation between the PT provider's Technical Representative and the General Supervisor on 03/15/2021 at 12:30PM. 3. Discussion with the General Supervisor on 03/15/2021 @ 12:30 PM concurred with these findings.</p>