

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2033373	(X3) Date Survey Completed 11/22/2021
Name of Provider or Supplier Synergy Women's Health Care	Street Address, City, State 2525 Nw Lovejoy, Suite 300, Portland, 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records for 2020 and 2021 and interview with the Office Manager, the laboratory failed to ensure the testing personnel (TP) and the Laboratory Director (LD) both signed the Attestation form. Findings include: 1. For event #2 Hematology, 2020, the attestation form was not signed by the TP or the LD. 2. For event #3 Hematology, 2020, the attestation form was not signed by the TP or the LD. 3. For event #1 Microbiology, Hematology and Chemistry 2021, the attestation form was not signed by the TP or the LD. 4. For event #2 Microbiology and Chemistry, 2021, the attestation form was not signed by the TP or the LD.</p>
D2026	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(1) For any unsatisfactory 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) 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (TP) results for 2020 and 2021 and discussion</p>

with the Office Manager, the laboratory failed to ensure that corrective action (CA) was performed and documented for unsatisfactory performance on any analyte. Findings include: 1. For PT event #2, there was no evidence of CA or the Laboratory Director's signature or review for three (3) analytes : MCH, MCHC and Gardenerella vaginalis.