

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2033373	(X3) Date Survey Completed 11/29/2023
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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the lead testing personnel, the laboratory failed to monitor and document quality assessments as outlined in the Quality Assurance (QA) plan procedure. Findings include: 1. Review of the QA plan procedure states the laboratory will perform biannual quality assessment. 2. The laboratory have identified 5 performance indicators to include pre-analytical, analytical , and post analytical phases of the testing process. No quality assessment documentations for the year 2022 and 2023. The last quality assessment documentation was 07/25/2021. 3. Interview with the lead testing personnel on 11/29/2023 at 11:30 AM confirmed these findings. 4. The laboratory performed 2,648 bacteriological specimens annually.</p>