

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1105840	(X3) Date Survey Completed 06/24/2019
Name of Provider or Supplier Premier Diagnostics	Street Address, City, State 1349 S Rochester Road Suite 210, Rochester Hills, MI	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review, lack of documentation, and interview with the office manager, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified in 493.1231 through 493.1236 in the general laboratory systems for 15 (April 2018 to June 2019) of 24 months. Findings include: 1. "General Systems Quality Checks" procedure section D, "Records Review", "random audits will be made of all records to ensure daily compliance". 2. "Patient Chart Audit" review logs state to perform monthly. No documentation was found to show the monthly patient chart audits were performed from April 2018 to the date of the survey. 3. During the interview on June 24, 2019 at approximately 12:15 pm, the office manager confirmed the patient chart audits were not performed and documented.</p>