

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2096521	(X3) Date Survey Completed 01/17/2024
Name of Provider or Supplier Exclusive Physicians, PLLC	Street Address, City, State 911 E 9 Mile Rd Suite 100, Ferndale, 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
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interviews, the laboratory failed to perform its open-system polymerase chain reaction (PCR) panel testing in a uni-directional workflow and have separate areas for specimen and reagent preparation for 17 (July 2022 to January 2024) of 17 months. Findings include: 1. The surveyor observed the PCR testing laboratory on 1/17/24 at 9:07 am and noticed mechanical pipettes had been in only one area of the laboratory and the biohazardous waste was housed in front of the area with the mechanical pipettes. 2. A verbal walkthrough of the laboratory's PCR panel testing process on 1/17/24 at 9:26 am Testing Personnel #1 revealed the laboratory prepares reagents in the same area specimens are prepared. The post-amplification PCR plates are discarded in the reagent preparation and specimen testing area. 3. An interview on 1/17/24 at 9:26 am with Technical Consultant #2 confirmed the laboratory had not used a uni-directional workflow and did not have separate areas for specimen and reagent preparation.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:
. Based on observation and interview with the Technical Consultant, the laboratory failed to ensure stool specimen collection containers had not exceeded expiration dates for 5 of 5 stool collection containers observed. Findings include: 1. The surveyor observed five formaldehyde stool collection containers with the expiration date of "8/23" during a tour of the laboratory on 1/17/24 at 9:26 am. 2. An interview on 1/17/24 at 1:56 pm with the Technical Consultant confirmed the stool collection containers identified had exceeded the expiration date.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
. Based on record review and interview with Technical Consultant #2, the laboratory failed to verify manufacturer's reference intervals were appropriate for the laboratory's patient population for 7 (Apolipoprotein A1, Gamma-glutamyl transferase, Apolipoprotein B, Insulin, Transferrin, C-Reactive Protein, and Lipoprotein A) of 38 routine chemistry analytes on the laboratory's test menu. Findings include: 1. A review of the laboratory's verification of performance data for its routine chemistry analytes revealed the following lacked verification of reference interval appropriateness for its patient population for the following analytes: a. Apolipoprotein A1 b. Gamma-glutamyl transferase c. Apolipoprotein B d. Insulin e. Transferrin f. C-Reactive Protein g. Lipoprotein A 2. An interview on 1/17/24 at 10:50 am with Technical Consultant #2 confirmed the laboratory had not verified the manufacturer's reference intervals were appropriate for its patient population.