

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2096521	(X3) Date Survey Completed 12/03/2020
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
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: . Based on record review and a interview with office liaison (OL) and the Office Manager (OM) , the laboratory failed to enroll in a proficiency testing program for 10 (March to December) of 10 months of operation for the urinary tract infection (UTI) and the respiratory pathogens panel (RPP) polymerase chain reaction (PCR) testing in 2020. Findings include: 1. A record review revealed there was no documentation of proficiency testing for 10 (March to December) of 10 months of operation in 2020. 2. On 12/04/2020 when requested per email to OL and the OM, the OM responded via a phone call on 12/09/2020 at 12:27 PM. 3. A phone interview on 12/09/2020 at 12:27 PM the OM stated the PCR testing was not enrolled in a proficiency testing program at the present time.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)</p>

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

. Based on observation and interview with Testing Personnel #2 (TP2), the laboratory failed to label the reagents on the processing table used for the polymerase chain reaction (PCR) testing with the preparation dates when the reagents were put into use for 10 (March to December) of 10 months in use. Findings include: 1. An observation by the surveyor on 12/03/2020 at 9:09 AM during a tour of the PCR lab, the following reagents were noted to be in use with no open dates recorded on the bottles for the 10 (march to December) of 10 months in use. a. Invitrogen Ultra distilled water lot 2186750 b. Gibco pH 7.4 lot 2120787 c. Applied Biosystems MagMax Viral /Pathogens Wash Buffer lot 2004016 d. Applied Binding Solution lot 1910006 e. Applied Biosystems MagMax Proteinase K lot 2008036 f. Applied Biosystems MagMax Viral/Pathogen Elution lot 2003012 g. Applied Biosystems MVP II Binding Beads lot 00951034 h. Ethanol for Molecular Biology i. Applied Biosystems MagMax Viral/Pathogens Wash lot 2007087 2. An interview on 12/03/2020 at 9:09 AM with TP2 confirmed the open dates had not been recorded on the bottles or a log when put into use.

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on observation and interview with Testing Personnel #2 (TP2), the laboratory failed to perform and document the function checks as required by the manufacturer for the ThermoScientific and Genex Beta pipettes for 10 (March to December) of 10 months of use. Findings include: 1. During a tour of the laboratory on 12/03/2020 at 9:09 AM, the surveyor noticed a pipette stand with 5 ThermoScientific pipettes and 1 Genex Beta pipette. 2. A review of the "Standard Operating Procedure" manual revealed a lack of documentation for the pipette calibration from the manufacturer and a policy or procedure for the pipette calibrations. 3. On 12/03/2020 at 1:46 PM when queried, TP2 stated that the manufacturer package inserts were discarded when the pipettes were unpacked for use. 4. During the interview on 12/03/2020 at 1:46 PM, TP2 confirmed there was no documentation of pipette calibrations from the manufacturer or an outside source and no policy or procedure for pipette calibration and function checks.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to provide reference intervals on the complete blood cell count (CBC) test reports for 2 (#1 and #3) of 10 patient charts audited for 2 years. Findings include; 1. A record review for 2 (#1 and #3) of 10 patient charts audited revealed the test reports did not have a reference range listed on the final report in the electronic medical record (EMR) system for the following hematology parameters: a. red blood cell distribution width - SD b. mean platelet volume c. neutrophil % d. lymphocyte % e. mixed cell % f. eosinophil % g. basophil % 2. During an interview on 12/03/2020 at approximately 12:00 PM, TC2 confirmed the final CBC report in the EMR system did not contain all of the parameter reference ranges.