Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2096521	03/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Exclusive Physicians, Pllc	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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain 1) the maintenance records for the chemistry Abbott Architect Plus ci 4100 analyzer for 12 (April 1, 2017 to March 6, 2018) of 18 months reviewed and 2) the daily hematology Sysmex XS-1000i analyzer background counts for 11 (September 2016 to July 2017) of 19 months reviewed in 2016, 2017, and 2018. Findings include: 1. On March 6, 2018 at 1:05 p.m. and 1:45 p.m., review of maintenance records revealed a lack of documentation for the chemistry analyzer and hematology analyzer as follows: a. chemistry Abbott Architect Plus ci 4100 - no monthly maintenance records for 12 of 18 months reviewed in 2016, 2017, and 2018 b. hematology Sysmex XS-1000i - no daily background counts for 11 of 19 months reviewed in 2016, 2017 and 2018 2. During the interview on March 6, at 1:05 and 1:45 p.m., technical consultant #2 as listed on the CMS-209 confirmed the records were not available on the day of the survey for the surveyor.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	. Based on record review and interview, the laboratory failed to verify the accuracy of testing for the endocrinology testing at least twice annually for two (2016 and 2017) of two years reviewed. Findings include: 1. On March 6, 2018 at 11:24 a.m., record review of the at least twice annual verification of accuracy for the endocrinology folate, ferritin, prostate-specific antigen (PSA) and the vitamin B12 testing revealed there was no documentation for: a. second verification in 2016 b. twice annual verification in 2017 2. During the interview on March 6, 2018 at 11:24 a.m., technical consultant #2 as listed on the CMS-209 confirmed the endocrinology testing was not verified for accuracy at least twice annually in 2016 and 2017.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and document the hematology Sysmex XS-1000i monthly maintenance for three (June and November 2017 and February 2018) of 18 months reviewed. Findings include: 1. On March 6, 2018 at 12:40 p.m., record review of the monthly "Maintenance Log Sysmex XS-1000i" log revealed there was no documentation to show the laboratory had performed the monthly maintenance for three of 18 months reviewed in 2016, 2017, and 2018. 2. During the interview on March 6, 2018 at 12:40 p.m., technical consultant #2 as listed on the CMS-209 confirmed the monthly maintenance tasks were not completed and documented as required for 2016, 2017, and 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and evaluate one (first calibration in 2017) of three Abbott Architect Plus ci 4100 chemistry analyzer calibration verifications at least once every six months as required. Findings include: 1. When requested on March 6, 2018 at 11:24 a.m., the technical consultant #2 as listed on the CMS-209 was not able to provide documentation showing the calibration verification was completed for one (first calibration in 2017) of three every six month calibrations in 2016 and 2017. 2. During the interview on March 6, 2018 at 11:24 a.m., the technical consultant confirmed the calibration verification was not completed at least every six months in 2017.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to establish a system to ensure the Abbott Architect ci 4100 instrument chemistry tests values that were reported using calculations were accurately sent from point of entry to the final report for accuracy during the 18 (September to December 2016, 2017 and January to present date 2018) of 18 months of patient testing. Findings include: 1. On March 6, 2018 at 1:58 p.m., document review for the Abbott Architect Plus ci 4100 chemistry instrument identified five [estimated glomerular filtration rate (EGFR), urea nitrogen (BUN)/creatinine ratio, albumin/globulin (A/G) ratio, globulin, and the low density lipoprotein (LDL)] tests that require an instrument calculation. 2. On March 6, 2018 at 1:58 p.m. when queried, technical consultant #2 as listed on the CMS-209 was not able to provide the surveyor documentation that the calculations were checked for accuracy. 3. During the interview on March 6, 2018 at 1:58 p.m., technical consultant #2 confirmed the calculations were not checked for accuracy.