Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0962469	09/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Macomb Physicians Group Pllc	8244 Metro Parkway Suite C, Sterling Heights, 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 with the Technical Supervisor, the laboratory failed to retain its documentation of quality control manufacturer instructions for 1 (Lot #40383) of 2 lots reviewed. Findings include: 1. A review of the laboratory's handwritten "Quality Control Chart" for its Prostate Specific Antigen testing revealed the high-end control range for lot #40383 revealed a range of 15.2 to >25.0 for testing dates between 12/4/20 and 5/5/23. 2. The surveyor requested the manufacturer's instructions for lot #40383 on 9/13/23 at 1:03 pm and they were not made available. 3. An interview on 9/13/23 at 1:03 pm with the Technical Supervisor confirmed documentation of quality control manufacturer instructions for lot #40383 was not available.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to ensure positive patient identification during the testing process for 2 patient results with no identifiers

	documented in the NanoEnTek Frend analyzer (refer to D5203), failed to perform control procedures according to policy for its Prostate Specific Antigen (PSA) and Vitamin D patient testing (refer to D5445 B), and failed to ensure the results of control materials for Prostate Specific Antigen (PSA) testing had met manufacturer's criteria for acceptability before reporting patients (refer to D5481).
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to verify performance specifications of its Free Thyroxine (Free T4) testing (refer to D5421) and failed to perform control procedures each date of Free Thyroxine (Free T4) patient testing (refer to D5445 A).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to ensure positive patient identification during the testing process for 2 patient results with no identifiers documented in the NanoEnTek Frend analyzer between June 2023 and August 2023. Findings include: 1. A review of the laboratory's NanoEnTek Frend analyzer's stored data revealed the following Prostate Specific Antigen (PSA) test results lacking any patient identifiers: a. Date: 6/29/23, Time: 22: 32:27, PSA: 2.46 ng/mL. b. Date: 8/25/23, Time: 02:21:46, PSA: 0.86 ng/mL. 2. A review of the laboratory's patient testing logs revealed Patient 3262 performed on 8/25 /23 had a PSA result of 0.86 and Patient 3035 performed on 6/30/23 had a PSA result of 2.46. 3. An interview on 9/13/23 at 1:10 pm with the Technical Supervisor confirmed the patients listed above did not have positive identification on the NanoEnTek Frend analyzer performing their testing.
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 the Technical Supervisor, the laboratory failed to verify performance specifications of its Free Thyroxine (Free T4) testing for 7 (March 2023 to September 2023) of 7 months since the test system was put into use. Findings include: 1. A review of the laboratory's quality control tapes revealed the laboratory started testing for Free T4 using the Frend analyzer on 3/3/23. 2. An interview on 9/13/23 at 12:55 pm with the Technical Supervisor revealed the laboratory had not verified the performance specifications of the Frend analyzer's Free T4 assay prior to testing patients. 3. A review of patient testing logs revealed a total of 120 patients were tested for Free T4 between March 2023 and September 2023.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Technical Supervisor, the laboratory failed to perform control procedures each date of Free Thyroxine (Free T4) patient testing for 19 of 25 testing dates since testing began using the NanoEnTek began on 3/3/23. Findings include: 1. A review of the laboratory's patient and quality control testing logs revealed a lack of Free T4 quality control performance at least once each day patient specimens were assayed for the following dates: a. 9/8/23 b. 8/25/23 c. 8/18/23 d. 8/11/23 e. 7/22/23 f. 7/14/23 g. 7/7/23 h. 6/30/23 i. 6/24/23 j. 6/16/23 k. 6/9/23 l. 5/29/23 m. 5/24/23 n. 5/19/23 o. 5/12/23 p. 4/28/23 q. 4/21/23 r. 3/31/23 s. 3/25/23 2. The surveyor requested an established Individual Quality Control Plan (IQCP) for its NanoEnTek Free T4 testing on 9/13/23 at 12:43 pm and it was not made available. 3. An interview on 9/13/23 at 2:03 pm with the Technical Supervisor confirmed the laboratory had not performed quality control testing at least each day of patient testing for the dates listed above. B. Based on record review and interview with the Technical Supervisor, the laboratory failed to perform control procedures according to policy for its Prostate Specific Antigen (PSA) and Vitamin D patient testing for 1 (July 2023) of 7 months reviewed. Findings include: 1. A review of the laboratory's Individual Quality Control Plan (IQCP) for PSA and Vitamin D revealed a section stating, "Testing with the CLINIQA Liquid Control Material is performed on two levels of external QC monthly, with each new lot of reagents, with each new shipment of reagents, when training new operators, whenever the lab conditions have changed significantly, or any time the accuracy of patient results is in question." 2. A review of the laboratory's quality control stored data on the NanoEnTek revealed a lack of quality control performed for PSA and Vitamin D assays between 6/2/23 and 8/4/23. 3. A review of patient testing logs revealed five patients were tested for PSA

	and one patient was tested for Vitamin D in July 2023. 4. An interview on 9/13/23 at 12:05 pm with the Technical Supervisor confirmed the laboratory had not established an IQCP and failed to perform PSA and Vitamin D controls in July 2023.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to ensure the results of control materials for Prostate Specific Antigen (PSA) testing had met manufacturer's criteria for acceptability before reporting patients for 8 of 8 patients tested in January 2023. Findings include: 1. A review of the laboratory's Individual Quality Control Plan (IQCP) for PSA testing revealed a section stating, "Testing with the CLINIQA Liquid Control Material is performed on two levels of external QC monthly, with each new lot of reagents, with each new shipment of reagents, when training new operators, whenever the lab conditions have changed significantly, or any time the accuracy of patient results is in question." 2. A review of the laboratory's "Liquid QC Immunoassay Control" documentation showed the reference ranges for the NanoEnTek Frend analyzer PSA assay were as follows: a. Level 1- 0.98 to 2.42 ng/mL b. Level 2- 9.55- 20.35 ng/mL 2. A review of the laboratory's NanoEnTek Frend Analyzer quality control documentation revealed the quality control level 2 performed on 1/3/23 had a result of 2.50 ng/mL. 3. A total of eight patients were tested for PSA in January 2023 when quality control results were not acceptable. 4. An interview on 9/13/23 at 2:03 pm with the Technical Supervisor confirmed the laboratory had reported patient PSA testing when controls had not been acceptable.
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 record review and interview with the Technical Supervisor, the laboratory failed to accurately document patient test results on the test report for 1 (Patient 3262) of 12 patient test record reviewed. Findings include: 1. A review of the laboratory's NanoEnTek Frend analyzer stored data revealed Patient 3262 had a Vitamin D result of 50.8 ng/mL on 8/25/23. 2. A review of the laboratory's handwritten patient testing logs revealed Patient 3262 had a Vitamin D result of 51.0 ng/mL on 8/25/23. 3. A review of Patient 3262's test report revealed a Vitamin D result of 51.0 ng/mL on 8/25

	/23. 4. An interview on 9/13/23 at 1:10 pm with the Technical Supervisor confirmed the patient's test result had not been accurately entered in the test report.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interviews, the Laboratory Director the failed to ensure verification of performance specifications for its Free Thyroxine (Free T4) testing were performed prior to patient testing (refer to D6085), failed to ensure control procedures were established for the laboratory's Free Thyroxine (Free T4) testing (refer to D6093 A), failed to ensure control procedures were maintained for the laboratory's Prostate Specific Antigen (PSA) and Vitamin D patient testing (refer to D6093 B), and failed to ensure corrective actions were taken when results of control materials for Prostate Specific Antigen (PSA) testing had failed to meet manufacturer's criteria for acceptability and patients had been reported (refer to D6096).
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director the failed to ensure verification of performance specifications for its Free Thyroxine (Free T4) testing were performed prior to patient testing. Refer to D5421.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: . A. Based on record review and interview, the Laboratory Director failed to ensure control procedures were established for the laboratory's Free Thyroxine (Free T4) testing. Refer to D5445 A. B. Based on record review and interview, the Laboratory Director failed to ensure control procedures were maintained for the laboratory's Prostate Specific Antigen (PSA) and Vitamin D patient testing. Refer to D5445 B.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)

	The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure corrective actions were taken when the results of control materials for Prostate Specific Antigen (PSA) testing had failed to meet manufacturer's criteria for acceptability and patients had been reported. Refer to D5481.