Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0962469	12/04/2019
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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor #1 (TS1) and the Assistant Office Manager (AOM), the laboratory failed to retain the manual patient chemistry test requisition for 7 (#1-#6, #8, and #10 - #11) of 14 patient charts audited for 2 years. Findings include: 1. Record review of patient test results in the electronic medical record (EMR) revealed for 7 (#1-#6, #8, and #10 - #11) of 14 patient charts audited the manual patient chemistry test requisition with testing results was not scanned into or a part of the EMR system. 2. During the interview on 12/4/19 at approximately 2:20 pm, TS1 and the AOM acknowledged the manual chemistry test requisition was not consistently scanned into the EMR system or retained for 2 years.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by:

	. Based on record review and interview with Technical Supervisor #1 (TS1), the laboratory failed to maintain a record system that included the identity of the testing personnel (TP) performing the complete blood cell (CBC) count for 3 (#3, #7, and #13) of 14 patient charts audited. Findings include: 1. Record review for 3 (#3, #7, and #13) of 14 patient charts audited revealed the laboratory did not have a record system in place that included the identity of the testing personnel who performed and documented the CBC test results on the instrument printout. 2. During the interview on 12/4/19 at approximately 2:20 pm, the TS1 acknowledged that the TP inconsistently recorded their initials on the CBC instrument printouts.
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: . A. Based on record review and interview with Technical Supervisor #1 (TS1) and the Assistant Office Manager (AOM), the laboratory failed to 1) provide accurate and reliable patient test reports for 6 (#1-#4, #6, and #11) of 14 patient charts reviewed and 2) provide accurate and reliable manually resulted complete blood cell (CBC) counts for 6 (#2, #7, #9, and #12 - #14) of 14 patient charts audited. Findings include: 1. Record review of patient final test reports revealed the laboratory had reported CBC, hemoglobin A1C (A1C), glucose (Glu), cholesterol (Chol), triglycerides (Trig), high density lipoprotein (HDL), low density lipoprotein (LDL), thyroid stimulating hormones (TSH), bile acid (BA), thyroxine (FT4), vitamin B12, vitamin D, iron, % saturation, and total iron binding capacity (TIBC) with multiple results for the same test for the same patient on the same day of testing as follows: a. Patient #1 - collection date 12/20/17 1. Vitamin B12 - resulted 8 times 2. TSH, Trig, HDL, and LDL - resulted 6 times 3. A1C - resulted 5 times 4. Glu and FT4 - resulted 4 times 5. CBC - resulted 2 times b. Patient #2 - collection date 2/7/18 1. CBC, Trig, HDL, and LDL - resulted 4 times 2. TSH - resulted 3 times 3. Chol, FT4, and BA - resulted 2 times c. Patient #3 - collection date 4/18/18 1. Chol, Trig, HDL, and LDL - resulted 2 times d. Patient #4 - collection date 06/6/18 1. Chol and HDL - resulted 6 times 2. A1C and Trig - resulted 4 times 3. LDL - resulted 2 times e. Patient #6 - collection date 10/12/18 1. TSH - resulted 6 times 2. HDL - resulted 5 times 3. Iron, % saturation, TIBC, Chol, and Trig - resulted 4 times 4. LDL, Vitamin B12, and Vitamin D - resulted 2 times f. Patient #11 - collection date 7/23/19 1. Glu, iron, and % saturation - resulted 4 times 2. AIC and TIBC - resulted 2 times 2. Record review for 6 (#2, #8 #9, and #12 - #14) of 14 patient charts audited revealed the manually entered CBC test results in the EMR system were entered in duplicate. 3. During the interview on 12/4/19 at approximately 2:20 pm, TS1 and the AOM acknowledged multiple test results were available in the electronic medical record system for the same patient on the same day of testing. B. . Based on record review and interview with the Technical Supervisor #1 (TS1), the laboratory failed to provide accurate patient test results for 2 (#4 and #6) of 14 patient charts audited. Findings include: 1. Record review for 2 of

	14 patient charts audited revealed inaccurate patient test results entered into the electron medical record (EMR) system as follows: a. Patient #4 - Hemoglobin A1C entered incorrectly as 58%, should be 5.8% b. Patient #6 - Vitamin B12 entered incorrectly as 2000, should be >2000. 2. During the interview on 12/4/19 at approximately 2:20 pm, TS1 acknowledged the results were entered into the EMR system incorrectly.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor #1 (TS1) and the Assistant Office Manager (AOM), the laboratory failed to maintain the patient's final test report as part of the patients' electronic medical record (EMR) for 4 (#5, #7, #8, and #10) of 14 patient charts audited. Findings include: 1. Record review revealed for 4 of 14 patient charts audited the following final patient test reports were not available in the EMR system for the surveyor on the day of the survey when requested as follows: a. Patient #5 - prostate specific antigen (PSA), written on patient log, no results in the EMR. b. Patient #7 - no manual complete blood cell (CBC) results in the patient's EMR system. c. Patient #8 - no thyroxine (FT4), Vitamin D, Vitamin B12, and folate results, written on the patient log no results in the EMR. d. Patient #10 - no PSA, iron, and total iron binding capacity results, written on the patient log no results in the EMR. 2. During the interview on 12/4/19 at approximately 2:20 pm, TS1 acknowledged results were not in the patient's EMR system for the 4 patient's listed above.